Transferring the Aviation Risk Management Model (ARMM) into an Ambulatory Healthcare Organization

Proefschrift

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door

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Acknowledgments

This work is dedicated to the very special people we met on our professional road, some of them flying airplanes and some of them curing people. We met highly professional and dedicated people willing to fulfill their mission perfectly but without compromising safety.

Among these many wonderful people we will just mention a few: Colonel S. from the IAF, Prof. Aviram, Dr. Willff-Meron and Dr. Gindi from Maccabi.

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To our families, for being patient and empathetic, when in a sudden we became students again, this time absolutely committed.

Writing this thesis, stressed our personal and professional partnership and companionship. We express hereby gratitude for this rare opportunity to join personalities, attitudes and abilities that are evident in this work.

Preface

Risk management, from our point of view, has to do with the very core of human existence and beliefs. Being able to manage risks, means that we are not victims of some unknown forces, but rather in control of our lives, reality and fate. A world governed by belief and means to manage risks, is a more optimistic, safe and satisfactory one.

In our professional experience, we have witnessed people and organizations, acting in a total disbelief, that things may be controlled and changed for better. We believe, that Risk Management, can serve as a positive organizational drive, based on a deep inquiry of past events, thorough learning of the present and visionary consideration of the future.

In most of the cases, Risk Management is approached after all the conventional tools of management bankrupt and the organization is in deep distress. Meeting a successful organization, willing to start Risk Management activity, although rare, is a wonderful opportunity to make real progress in quite a short time.

Risk management is a dynamic discipline, which has to adopt itself to the ever changing reality. Practicing the risk management concepts and methodologies of yesterday, poses a serious risk today.

Being dogmatic and rigid in analyzing reality is a risk by itself, because of the very dynamic nature of risks. Risks may be considered as a negative potential energy, that has the power to destroy, harm and cause losses. Thus, risks will forever be existent and striving to crystallize themselves in adverse events.

We believe, we have proved in this work, that there is a great value of sharing knowledge and adopting knowledge, even when it doesn't seem feasible, like in the case of such remote domains as Aviation and Medicine.

While writing this work, we have undergone many professionally maturating changes and have by doing it, actually discovered the Aviation Risk Management Model. This is to say, that whenever you are involved, as a professional, the intervention changes you, your tools and thinking forever.

Risk Management in Healthcare, although originated from the first days of medicine, has still a long way to go, to become a fully mature professional discipline. We hope to share our experience and to contribute to its development, from our deepest motivation to save human lives.

Yossi Tal and Itzik Lichtenfeld

Tel-Aviv, Israel May 2010

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Chapter 1

The Purpose and Goal of this Work

"Whosoever saves a single soul of Israel,
Scripture ascribes it to him as though
He had saved a whole world"

(Sanhedrin, Collection of Tales)

Why are we writing this book?

One Friday morning about two years ago (2005), one of those Fridays, in our offices, on which we usually review the past week and plan the week ahead, we discussed this question – why are we writing this book and why did we choose this particular subject?

The discussion started with the instant, with our motivation to deal with risk management in the present, and in the end, we came to our personal roots and to the national, Jewish roots.

The psychological journey, on which we went that morning, made it clear to us why we are dealing with risk management, and why we are writing this book, but not only that – it made it also clearer to us who we are as persons.

This chapter aims to explain to the readers and no less to us, why we have been dealing for so many years with risk management, in spite of the personal and organizational frustrations and struggles associated with dealing with this professional field.

The field of risk management is a difficult field, abounding in challenges, but also in frustrations. There certainly are easier ways to make a living. In our opinion, it is something like a calling, not just an occupation.

Professionals active in the field of risk management may be divided into two groups: those for whom risk management activity is a stage in their professional career. Persons belonging to that group will, after a term as risk managers, return

to the occupational position they originally came from. On the other hand, there are those who are attracted by the fascination of the profession and consider it their calling. No doubt, we belong to the second group.
How did it happen that we are dealing with risk management?

- **Yossi Tal**

In 1977, I graduated from the Bar-Ilan University with a B.A. in Psychology. Simultaneously with starting my studies towards the second degree, I was looking for a job to earn a living during my university studies. When perusing the vacancies advertised in the weekend edition of a newspaper, I noticed an ad saying "Research Officer wanted" for the Ministry of Defense, with an education in behavioral sciences.

During the job interview I was informed that it concerned an Air Force research team, investigating the human factor in flight safety, in the framework of the Aviation Safety and Quality Directorate (ASQD - MAVKA).

The ASQD, was established after the Yom-Kippur-War, 1973, as a result of lessons learned from that war. MAVKA is directly subordinated to the Air Force Commander and has two central objectives: To integrate and guide flight safety activities and to carry out quality control in the domains of operations, maintenance and management.

The research team, to which I presented my candidacy, had the task to investigate the human factor in flight accidents and incidents, in order to provide insights to the commanders for limiting the extent of involvement of air crew members in aircraft accidents.

It is important to emphasize that, according to various estimates, both of the Israeli Air Force (IAF) and of the Air Forces worldwide, which existed at that time, approximately 80 per cent of the accidents, were attributed to the human factor. On this background, the team was founded, which I joined and managed in the years 1979-1990.

Here is not the place to outline the activities carried out by the team, which involved ever growing circles of commanders on various levels, from Air Force Commanders to Squadron Leader, but I will only mention that in the course of those years the rate of accidents went down by hundreds of percents.

From the time I joined that team until now, with short interruptions, I am dealing with Risk Management and in 1997, I began to be active also in medical risk management, through the "Maccabi Project", on which this work focuses.

In the perspective of time, I know that only few of those who became exposed to risk management in the framework of the Safety and Quality Control Administration, actually turned their job into their calling.

Despite its power, the Israeli Air Force is a relatively small corps. At that time, almost everybody knew each other, so that each time somebody was involved in an accident or was killed, the personal and organizational trauma was very deep and affected everyone who was part of the Air Force. I believe, that particularly one occurrence shocked me and also many others.

In 1978, I was involved in a study on the subject of *"Collisions and close "near misses" during air combat exercises"*. The objective of that study was to understand the underlying human mechanism of collisions and near misses and suggest recommendations aiming to reduce the rate of these events. Not being a pilot myself, I required help from a combat pilot team, who would help me to analyze the events.

The team included Captain G., who was considered to be an excellent and analytic pilot. We, two young Captains, spent many hours together, coming from different worlds, and joined forces in a common task: to understand how and why combat aircraft collide during air combat exercises.

G. lived in a Kibbutz, was good looking and had a promising future in the Air Force. I was a young psychologist, lived in a city, and had immigrated to Israel from Russia.

We became close friends. Our talks were not only about air combats, but about subjects, which interested young men in Israel at that time.

Meanwhile, we finished our joint work; it was published and widely and seriously discussed and considered in the Air Force.

In the course of the years, the rate of collisions during air combats decreased. Probably, G. and I have contributed to it in a way.

At 29 September 1979, G. was killed in an aircraft accident, on the date, on which exactly a year later my son Tommy was born.

From then on and still today, G. accompanies me on my professional career and perhaps it is because of him, or maybe thanks to him and on behalf of him, that I never left the risk management domain.

What does risk management mean to me? I am frequently asked this question and as frequently I am asking it myself. Apparently, the deepest answer, as far as I understand, is related to my background, which led me to attach the greatest value to human life and to the fight for saving it. In my view, risk management is a constant fight for saving human life.

- **Itzik Lichtenfeld**

In 1969, the day I was drafted into the Israeli Army, the I.D.F., a significant day in the life of every Israeli, both for himself and for his family, and certainly so for the son of parents, who survived the Holocaust. In all the hustle and bustle, excitement, fears, in the queue for inoculations, examinations, receiving the regimentals, I accidentally met Yossi Tal and spent some hours with him.

We came from different backgrounds and had different characters. In those few hours we became united in a common destiny and later on developed a rare friendship. At the end of the day of our recruitment our ways parted.

During our military service, we happened to meet hurriedly for a few minutes.

Four years later, by the hand of fate, we met again at the Bar Ilan University. We studied together with our wives towards the first degree in psychology and together continued our studies towards the second degree at the faculty of psychology, in the department of clinical research.

During my studies, I worked in the publishing house of my family. The world of business in general, and the occupation with other, unique, new and unusual matters attracted my attention.

In the course of approximately 20 years I implemented my practice in psychology, partly as reserve duty psychologist in an elite unit of the army.

Indirectly, and from a totally different angle, I implemented my knowledge and understanding in psychology to comprehend the political motivations as a partner

to the Studio of Political Illustrations, which took part in numerous occurrences all over the world.

This activity required the ability to analyze political events, the acquaintance, appreciation, understanding and reading of characters and leaders, media stars, artists and tycoons, who received exceptional treatment by the Studio.
During those years I heard and knew about Yossi's work. I was fascinated by the subject and I used to say that the day would come when we would do something together in the business world to give expression to our experiences.

In 1987, we, Yossi and I, decided to examine possibilities to implement the know-how and experience of experts in safety, who acquired unique and exceptional experience in the I.A.F., in order to implement it in civil and other military fields.

In the same year, an article was published in the American *Fortune*, which foretold which fields would be key fields in the next decade, fields worthy of investment and development; prominent among these fields was the field of risk management and safety.

In those years, Yossi continued with his military career and I ventured my first steps into the world of risk management and safety. I recruited into the company professionals, who had served in the I.A.F. and were specialists in the field.

During the first years, we studied, developed models and implemented risk management in military institutions, including the I.A.F., as well as in civil institutions, in various fields – aviation, banking and industry.

After approximately 10 years of joint activity, we were looking for a new content world, offering opportunities for pioneering and implementing the vast know-how acquired, a content world comprising components and characteristics similar to the aviation world.

And again it was the hand of fate, which brought me together with an organization consultant, who worked for a large factory. He told me about his work and the difficulties encountered with the customer and his occupation. After this meeting, it became clear to me that our future would lie in the field of medical risk management.

In the beginning, the road was paved with quandaries and misgivings. We presented our view to a medical forum at the "Rambam"-Hospital in Haifa, and the reactions were encouraging.

Dr. Daddy Sharim, a Lawyer and Physician, who had been acting in this field on behalf of the largest medical insurer in Israel, attended our presentation at the "Rambam"-Hospital. He was impressed and introduced us to people of the "Maccabi" Healthcare Fund, which, in those days, was in the first stages of establishing a risk management department.

The unusual frankness of the Medical Director at that time, Prof. Aviram, and of the Manager of the newly established department – Dr. Rachel Wilf Miron, enabled our entering "Maccabi". Both were aware of our potential and our ability and were ready to take the risk to implement the aviation model in the risk management activity of their organization.

Lots of differences, lots of similarities

We have known each other for 40 years, since we queued up in the recruiting center and until this very day. We spent together the major part of our life, we studied together, enjoyed together, satisfaction and frustration together.

Despite all these years together, on that Friday morning, when we tried to understand why we are writing this book, we revealed new things about each other.

Both of us belong to the second generation of Holocaust survivors. The parents of Itzik survived the Holocaust in concentration camp in Czechoslovakia and immediately thereafter immigrated to Israel. Yossi's father was the only survivor of his family in Poland, after having fled from the Ghetto of Lodz and joined the Red Army. His heart's desire was to immigrate to Israel, which he made true in 1963.

Itzik grew up in Tel Aviv, in an urban center full of life, whereas Yossi grew up in an immigrant neighborhood in Rishon-LeZion. However, when the two of them met in the recruiting center in October 1969, in spite of the many differences between them, they became attached to each other almost immediately.

Although their ways parted on the day of their recruitment, as they were recruited into different army units, their ways crossed again and again until they finally met at the Bar Ilan University, when queuing up for registration to first year courses in Psychology. From that day on, they became friends and after several years they became business partners.

Trying to understand the reason why the two of us are active in risk management, brought us back to the past of our families, to the values on which we were brought up and which we adopted and which became our own life values.

Although, both of us had various opportunities and despite the frustration involved in Risk Management, we were persistent in being active in this field.

Without giving any thought to it, we both choose the same attitude of saving human life, whenever possible.

We chose to ignore the difficulties involved in risk management activity, to bear the frustration of engaging in pioneering, being glad with small successes and saw therein a breakthrough, and for some reason, although we sometimes pondered about it, we never seriously considered turning to some other activities.

The deep rationale we found in the risk management concept, is associated to its underlying meaning, which in our view, is an attempt to refer to risk as something which can be controlled and managed, as opposed to the attitude of waiting passively, until risk becomes reality and takes the lives and precious resources of human beings. It concerns an attempt to control something, which is mostly considered as being beyond control and as an inevitable outcome of reality.

With all the differences between us, we agree on the deep meaning of risk management for us and on the strong will to bring about a deep change in the medical system, its target being to save the lives of human beings, not only by medical cure, but also by limiting the increased occurrence of errors and the harm caused thereby.

The need to share and impact

Yossi, who, in the Israel Air Force, had been dealing with the human factor in flight safety, witnessed in the years of his activity the far-reaching changes which occurred in the I.A.F., and which found expression in the drastic reduction in the rate of accidents.

The Israel Air Force fought against accidents with the same measure of determination as it fought against his other enemies.

Once the Air Force commanders understood that they are losing more air crew members and planes in accidents than in combat, they decided to undertake

determined action in order to change the professional flight culture, including the basic definition of what was considered to be a "good pilot".

As from the middle of the 70's until the middle of the 90's, the I.A.F. underwent many changes, among them a deep cultural change in respect to flight safety. Flight safety became the permanent companion of professionalism and operational activity, which found expression in a most significant reduction in the rates of severe and fatal accidents. Moreover, as a result of the cultural change process, the Israel Air Force not only became safer, but also more professional. The argument voiced by I.A.F. veterans, that a basic clash exists between the aspiration for operational achievements and the aspiration for safety, was fundamentally refuted. It was proven that there is no need to pay dearly by loss of life and aircraft in order to develop and reach a high professional level, but that rather the opposite is true: adopting a policy and culture which emphasizes safety, improves the professional and operational level.

We sometimes discussed this significant experience of being part of and contributing to far-reaching changes in a system, as large and mission oriented as the Israel Air Force.

The need to share and impact in the professional vacillations, achievements and frustrations was extremely powerful.

Once the I.A.F. completed the deep cultural change and stabilized on the lowest rates of accidents it had ever known, we looked together for other high risk fields, where it would be possible to arouse the need and the fervor to undergo a similar process as we had witnessed in the I.A.F.

The need to share the experience accumulated in the domain of aviation safety, constituted the profound reason for our entering the domain of medicine.

We felt like having experienced a revelation, we saw how psychological knowledge succeeds in stimulating a fundamental change in a large system in order to improve the organization and to save human life and costly resources.

This right to take part in a process as significant as this, gave rise to the duty to continue further on this way in an attempt to repeat the success in other fields.

During the discussion we had, it became clear to us that our commitment to risk management, over many years stemmed from the deepest meanings, which we attribute to risk management. The need to share the experience we accumulated

in aviation is related to the need to influence and change matters, which would make it possible for errors to manifest themselves.
Doubtlessly, encouraged by the experience of the I.A.F., which succeeded in a period of about twenty years to change completely in its approach to flight safety, we fully believed that it would be possible to repeat the success also in other content worlds. The world of medicine fascinated us in particular, as we were exposed in many cases to errors by physicians, errors, which from our point of view, were not appropriately exploited in order to serve as levers for preventing a recurrence of similar cases. We felt a strong urge to make a change in the domain of medicine.

We presume that this feeling was similar to the feeling experienced by missionaries - a strong urge to share their truth with others. Only that here it was not a matter of religious fervor, of miracles we had witnessed, but a methodical long-term process, which had succeeded in saving human life.

It was said about William Carey, who is regarded by many as the missionary, who laid the infrastructure for the modernization of India:

> *"He believed in understanding and controlling nature instead of fearing, appeasing or worshipping it; in developing one's intellect instead of killing it…"*
>
> Vishal and Ruth Mangawaldi, 1999

This book meets the need to share, out of the belief that the project described here, will stimulate the feeling of ability and belief among the managers of the healthcare systems to introduce the changes required in the organizational and professional culture in healthcare systems in order to prevent unnecessary loss of human life, harm to patients and traumatic experiences on behalf of the medical staff.

Challenges and obstacles

Those engaged in risk management as their main career, are encountered with the opportunity to learn a chapter in understanding what challenges and obstacles are. The field of risk management, with all its growing importance, is not yet the main focus of most of the business organizations. This holds particularly true in systems and organizations, where the subject of risk management does not take a prominent place on the agenda. The ability to absorb a wide scale of frustrations, without despairing and giving up, is a vital characteristic trait of the risk manager. It goes without saying that we

experienced and are experiencing these frustrations also in the present. Following, is a partial list of frustration sources, which might be encountered by risk managers and which he will have to face:

- **Considering risk management as a marginal field:** In not a few cases, we have been told that the significance of risk management is ultimately a financial one, and as long as it is possible to purchase an insurance, which will cover the damages, there is no need for any special preventive activity. As the costs of healthcare, as well as the cost of insurance, are debited to the patients, this approach might have discouraged us. In cases, where these matters had been expressed openly, a dialogue could have been held and the benefits of risk management could have been pointed out, as described in chapter 6.13. The problem was in those cases, in which, on a rhetorical level, there was agreement with us that risk management activity is of value for the organization, but on a practical level, it should be considered of no value. Frequently, we were led astray by rhetoric, because it was pleasant to the ear, while on the other hand, we shunned those who spoke their truth openly, according to which, in their view, risk management is of no value to them . In the course of the years we learned that it is more correct to regard those who honestly are against the risk management concept, for reasons of their own, as potential partners, than those who, for political reasons, provide us with lulling rhetoric.

- **Cynic consideration of human life**: As we expressed above, engaging in risk management, means for us a matter of life and death, particularly so, as the extent of errors and the harm caused by them, may be reduced by appropriate treatment. At times, we encountered cynic understanding of the eventuality of loss of human life as a result of improper consideration of risk management. Needless to say that, considerations of this kind, could have discouraged us, as without committed partners, from within the organization, no effective risk management activity is possible.

- **Disbelief in the possibility that a model, which had been successful in one content world, would be successful also in another content world**: In chapter 6.5, we are referring to the countless doubts we encountered, when we offered to implement our experience in the field of risk management in aviation also in other fields, among others the field of medicine. However, to give justice to the real facts, we must confess there was a strong desire to try to implement the aviation experience also in

medicine. For some reason, it suited the physicians to learn from the pilots.

- **Lack of belief in us as being able to bring about a process of change in the attitude to risk management, and later on to a decrease in the rate of errors:** The major argument, which we had to deal with, was that we lacked the required understanding of the content world, so as to be able to promote the subject of risk management in respect thereof. The point of view, according to which the domain of risk management represents a professional discipline in itself, unrelated to specific technical know-how, was prevalent at that time. In this context, it is interesting to mention an episode, in which Yossi had been involved in the I.A.F. in 1977. When he was recruited by the Safety and Quality Control Administration to investigate the human factor, he expressed his doubts to his commander, Colonel S., a very experienced fighter pilot, about being able to carry out this task, without any background of flying. S. told him: "You will be the best pilot among the psychologists, and the best psychologist among the pilots". The truth is, in the perspective of time, S. was right. The know-how required to understand a certain content world may be acquired as necessary, so this would not pose any serious barrier to achievements in the field of risk management.

- **Our own doubts about our ability to realize concrete achievements:** The expectation of our clients was mostly that, within a relatively short time, we would succeed in bringing about changes, which would generate concrete achievements in the rate of errors and in the extent of losses to the organization. Although, we always attributed value to coordinating expectations and were careful not to promise something we were not sure we would be able to provide, it was clear to us that we must achieve results and to do so promptly. Quite often we had doubts about our ability to do it. We discussed above the background and atmosphere in organizations towards risk management concepts, which could give ground to this kind of doubts.

From all the aforesaid, a frustrating picture may arise. However, wherever we started working, we found many positive aspects, which were related to particularly dedicated people, to committed managers with a visionary attitude, to successes in domains, which, at first, appeared to be particularly complex, and to the genuine desire of most of our partners to fight the unnecessary loss of life.

Beyond business, the origins of our motivations

Risk management is our source of income, although both of us have additional occupations. Quite often, we both thought about dedicating ourselves completely to our other fields of interest and to put risk management aside, due to the frustrations we described above.

There is one frustration we did not mention in the preceding paragraph which is related to the economic aspects of dealing with risk management. Due to the fact that in all cases we had to convince our clients to enter into this domain, while they had never even considered this possibility in their work plans, we had to make significant concessions, among them financial concessions, at the stage of drafting the contracts. Thus, we found ourselves supplying substantial volumes of work, which exceeded by far the remuneration we received. Unrelated to the remuneration received, we did what we considered to be right to do, without any appropriate economic thought, as the life of human beings was concerned.

It is interesting to point out that most of the people dealing with risk management, who regard their work as a calling, are providing to the system, in which they are working, larger volumes of work hours than their employment conditions demand.

In certain cases, when negotiating with particularly difficult clients, we would make an exceptional offer, according to which we were ready to take responsibility for the risk of starting the project and to benefit, when the time came, from a certain percentage of the financial savings the system made as a result of a decrease in the rate of accidents. Much to our surprise, in no such case did the clients accept this offer.

Is there a pay for saving the life of human beings? As we consider our activity as an activity aiming to save human life, the question is, whether it is possible, at all, to state a price for our services?

Our sages said: *"Whosoever saves a single soul of Israel, Scripture ascribes it to him as though he had saved a whole world" (Sanhedrin).*

This saying summarizes to a major extent the value of human life. This conflict between an activity aiming at saving a whole world and the economic aspect is a conflict inherent in the world of risk management.
The real pay is saving human life and sometimes this will serve as a hidden argument for taking advantage of those who are dealing with risk management.

In summary, we are writing this book out of the belief and hope that our experience, which we are sharing here in a direct and honest manner, will be able to save human life, as a natural continuation of the deep-rooted motivations, which induced us to deal with risk management and to persist in doing so, despite all the many frustrations.

Chapter 2

The rationale for non empiric, experience based research, as a methodology for leading and assessing organizational change

"..The Great tragedy of Science - the slaying of a beautiful hypothesis by an ugly fact..."

Thomas Huxley, Biogenesis and Abiogenesis, 1870

The Non empiric experience based research methodology - A personal view

In 1973 when we were studying psychology at Bar Ilan University (Israel), the prevailing attitude, and the only one per se, at the psychology department was that empirical research was the only acceptable option for advancing the science of Psychology.

The qualitative approach was marginally mentioned, particularly pertaining to case studies, but in the same breath it was dismissed as irrelevant and an excuse for sloppy research.

In those days the Psychology department at Bar Ilan, had hired many new faculty, some of them were well known internationally. They had started out their careers in the US and due to their Zionist attitudes; they wished to immigrate to Israel and impact the local arena with their vast research experience. Amongst those, were Prof. Babkoff, Prof. Lobov, Prof. Weisenberg, Prof. Milgram, and some others as well. They were all trained in the positivistic approach and were its foremost advocates. In the 70s of the last century, the Psychology department at Bar Ilan achieved excellent status as a respected research facility, particularly in psychophysiology and cognition.

As young students, we respected this approach but did not necessarily feel comfortable with it. It was clear to us that Psychology in its desire to be a recognized and well established science field was mandated to function according to all the prevailing assumptions, rules and paradigms of Science. This is how it was explained to us. However, even then we were most uncomfortable within an environment in which only strict experimental structures and paradigms were an unquestionable condition for the acceptability of any premise making it impossible to express the great wealth of experiences, which occur, in the encounter of Psychology and reality.

In retrospect, the fact that we were trained in positivism, prevented us from describing the dramatic turn of events in the Israeli Air Force in the area of Risk Management, during the 70's & 80's of the previous century, since this turn of events did not strike us as fitting the positivistic requirements. We notice this regretfully, as it was in those days that the Aviation Model for Risk Management was developed, with all its insights and principles.

In Chapter 1, we detailed our great interest in pursuing this topic.
Yossi served in MAVKA (Safety and Quality Control Administration) in the Israeli Air Force for nearly 15 years and was one of the major contributors to defining concepts and procedures of IAF Risk Management model. This long-term association was the prime asset that enabled us to initiate defining our aviation risk management model, and then transfer it to Macabi within the context described in this work.

It is reasonable to assume that in another set of circumstances and particularly in the organizational reality of the Israeli Air Force, in which officers are reassigned every 2 years, all the acquired knowledge would be lost, at least partially.

The History of Qualitative Research

Tzabar Bar – Yosef (2001), states that in Israel the recognition in the legitimacy of qualitative research arised years after it was recognized in the West. This could be due to the lack of publications in Hebrew on this topic. This is in spite of the fact that this recognition and its contribution to social sciences has been growing in the west, over the past twenty years.

Applying qualitative methodology, requires a change of the research paradigm to a post –positivist paradigm, whose principles, assumptions, terminology and applications are in many ways contrary to the positivist approach, upon which we were raised along with the rest of our professional generation.

Every reality perception is based on working assumptions, which define the characteristics of reality, the options for exploring it and knowing it, the relationship between the researcher and his subject, and criteria for defining the validity, reliability and integrity of the study.

In the positivistic paradigm, reality is total, ontological, external, independent of time and context, and can be described using basic components, which are statistically related. The researcher's task in this paradigm is to separate the components of this reality, investigate them with objective tools and thus create an ever-growing mosaic body of knowledge.

In the constructivist paradigm, reality is a subjective construction, created by the cultural and personal characteristics of the subject and the researcher and thus has no existence without them. Reality is given meaning both by the researcher and subject's interpretation of it.

Therefore, the goal of qualitative research is not to discover reality, as there is no one objective reality, but rather to examine and experience it, with the goal to understand it's the various meanings. Qualitative researchers, use a variety of research methods, and cross-reference all sorts of information and sources. This approach enables them to understand the many facets of reality. According to the constructivist approach, it is impossible to isolate variables, but rather one must view reality holistically.

Denizen & Lincoln, (2000), recognize six periods in the development of Qualitative research:

1. **The Traditional Period: 1900 up to WW2 –** During this period, researchers wrote reports, meant to provide supposedly objective information about life in the colonies and dealt mostly with the odd and unusual. These reports described the “natives” and their habits from an outsider’s position. The classical example of this period was represented by Melinovsky’s work as described by Geertz (1988).

2. **The Modern Period: 1950- 1970 –** This period is defined as the Golden Age of Qualitative research, and it was during this period that attempts were made to formalize Qualitative research and create working assumptions which do not fall short of the positivist paradigm. Field data was analyzed with statistical tools using the accepted norms of positivism. Many Qualitative researchers also brought their social views, some subscribed to a Neo-Marxist view, whose proponents are the founders of the critical theory.

   Actually, we are looking at various mergers of two paradigms, which is also acceptable today. Examples of classical work in this field are (Becker et al 1961), on the socialization of medical students, as well as (Wolcott, 1973), describing the life of a manager.

3. **Blurred Genres – 1970-1986 –** Qualitative research was at its peak and many theories abounded, some of these were symbolic interaction, constructivism, phenomenology, ethno-methodology, social theory, neo-Marxism, feminism, sexual preference, and others. In 1973, Geertz published his book “A Commentary on Cultures”, and coined the phrase "Thick description", which speaks about the scope and details of events, traditions and rituals.
   The borders between social sciences and the arts were blurred. Social Scientists turned to the arts to find theories for test analysis, and Arts scholars turned to the social sciences in a search for methodologies to study cultures. The era of pure Social science passed. Literary, style replaced the scientific research style of writing. The researcher was perceived as an eclectic entity making use of many disciplines and bodies of knowledge in order to express his views and observations. Alongside these developments, doubts arose regarding the validity and integrity of these findings, since the researcher was not bound by rules or requirements in his writing, to

define his own involvement and criteria for evaluating his research. The dominant paradigm of this period was constructivism, whose founding fathers include Piaget. This style is apparent in works from that period such as Lincoln & Guba (1985), Woods (1979), Erickson (1975), as well as many others.

4. **Crisis of Representation – 1986-1990 –** This period is represented by a significant split between the various methodologies, as described by different authors primarily Marcus & Fisher (1986), who discussed the main issue of the split: Is it at all possible to represent reality, which by its very nature is subjective? What does this body of research represent? Is it the researcher, his background and his political views? Researchers are most often, white males, western, middle or upper middle class, and are these aspects represented in the research? These texts have raised significant doubts within the profession, regarding the conducting of these studies, their reporting methods, and the impact of gender, sexual and racial orientation on these studies.

5. **Post –Modernism – 1990-1995 –** Typical to this period were new & experimental ethnographies, which attempted to respond to the "Crisis of Representation" which exemplified the previous period. The trend was aimed to replace general theories with theories and narratives that apply to specific situations and problems where it is possible to give voice to "the other". Creation of new ethnographies was enabled due to the refusal to give an advantage to any of the prevailing research methodologies. Many scholars learned to express their own feelings in conjunction with their positions and conclusions and place themselves within the texts.

6. **Post Experimental 1995-2000 and the Futuristic 2000 -** These two current periods, continue in the moral narrative regarding qualitative research. The post experimental period gets its appellation as it arrives after a long period of trial and error in finding a solution for the issue of representation. In this period, the qualitative researcher poses questions of moral and ethical nature, while relating to literary ethnographies, poetry, multi – media, blogs etc. as relevant sources of information. Research deals with the issues of gender, race, regimes, the Information Revolution, community and globalization.

With the current insights of qualitative research, it is clear that scholars are investigating reality from their own perspective of gender, status, culture and personal opinions. All these, actually define the scholar's system of ideas (Theory & Ontology); this in turn defines the research questions (Epistemology), which the researcher is trying to asses, using a variety of research methods (Methodology).

In spite of the developments in qualitative research methods and its basic assumptions, over the past few years, its many shaded varieties, continue to live side by side with each other and any new structure that may appear, does not cancel out the existence of the previously existing structures.

It is worth mentioning, that in our perception, the field of Risk Management is controlled by the qualitative paradigm, from its very roots, despite many attempts, made by scientists to define algorithms and methods to formalize this discipline.

Although, there are some models implemented to understand errors (Reason, 1990), adverse events and accidents, and even though these are clearly defined models, it is common knowledge, that two risk managers, investigating the same event, will most likely arrive at different conclusions and different recommendations.

In courses, we took on the basics of Aviation Risk Management at the University of Southern California, in the 1980s, instructed by leaders in the field such as Prof. R. Woods, Prof. C. Mason, attempted to teach us models for developing an unified approach and methods, to ensure that regardless of the investigating team, investigation results would be similar.

In reality, in cases where the same event was investigated by different teams, time after time, we witnessed the variety and difference, even when the basic facts and case information were quite similar, the background and makeup of the investigation teams made a difference.

These days, as we write this chapter, we are also coordinators and lecturers of an advanced risk management course, as part of the Continuous Medical Education (CME) program at Tel Aviv University Medical School. As part of the course, we teach the basics of adverse event investigation and end the course run a hand on exercise. During this exercise, the class splits into 3-4 groups.

Each group investigates an event with identical facts. The results were as always, surprising. Differences were observed throughout each stage of the investigation:

- Definition stage – Answering the question: What is the event we are investigating?
- Defining the event's boundaries - What was the initiating factor which started the chain of events and what was its final event?
- Defining the event's outcomes.
- Defining the chain of events which led to the event itself.
- Defining the risks, which contributed to the events occurrence.
- Defining the conclusions and recommendations aimed to reduce the probability of a recurrence.

In some cases, the observed differences were radical; one team did not even perceive the event as being adverse, claiming that these types of events occur often in their workplace, therefore, there is no reason to handle them as adverse events, but rather treat them as normative. Another team discovered a number of adverse events in the report, whereas another team found the administering physician as being solely responsible for the error, whilst another team found the system to be at fault.

The obvious conclusion is that in spite of our attempts to provide these students with identical tools and formal procedures for conducting the investigation, their backgrounds, professional culture & training, status, basic attitude towards human error and the special circumstances in which these errors occur, are contributing factors towards the many versions, procedures and outcomes of the same event. Each person constructs the adverse event according to his or her personal perspective and organizational context.

The modern perception of the phenomenon of errors is that it is a systemic phenomenon, enabled and influenced by many factors. One of the prevailing models is 5M, Man, Machine, Mission, Management and Medium, encourages a systemic approach and a possibility of a multi factor contribution causing the error. Despite this, many risk managers, both senior and new to the field, tend to favor certain factors over others. For example, some risk managers tend to explain that errors are a result of overload and fatigue, whereas others focus primarily on negligence or malpractice. Some stress a lack of managerial involvement and improper supervision; others see the ergonomic interface between the operator and the machine (MMI – Man Machine Interface) as a prime factor etc. One of our main roles as risk management trainers is to enable

the novices to see a wide spectrum of possibilities and factors, in order to understand the errors, not only based on their personal experience and preferences.

Shkedi (2003), analyzes the influence of the positivistic school on the research of educational systems. He argues that concepts such as “the average student”, or the “average teacher”, are abstract models that do injustice to truly understanding the world of teachers and students. His premise, suggests that after conducting “statistical acrobatics”, we are eventually able to explain only a small percentage of variation in the studied phenomenon. He goes on to say, that the quantitative approach has in all effect neutralized all educational research for years, since the questions asked, were only those, for which objective measurement tools could be provided.

Types of Qualitative Research

Qualitative research, by its nature, allows for many possible structures. Under the definition of “Qualitative Research” come many different research paradigms whose broadest common denominator is that they are definitely not positivistic.

As there are many types of qualitative research, it is impossible to favor one over the rest, but rather one should choose the approach suitable to the task.

There are several classifications of qualitative research such as (Strauss & Corbin, 1990), which differentiate between these types of qualitative research: Grounded Theory, Phenomenology, Life Histories and Conversation Analysis. Moss (2004), uses the term tradition in order to separate the different types of qualitative research and has observed five main traditions: Ethnography, Harmonious, Phenomenology, Critical –Theoretical and Post Modernism. Creswell (1998) also suggests five types of qualitative research, although his are somewhat different: Biographical, Phenomenological, Grounded Theory, Ethnography and Case Studies. Tesch (1990), presented a very detailed list of types of qualitative research and her list includes over 40 different types.
Denizen & Lincoln (2000) suggested an all-encompassing definition for Qualitative Research, as they found the term Qualitative Research has different meanings in different situations:

“Qualitative Research is context related , offering an observation point on the world… the meaning of which is that qualitative scholars examine the objects in their natural setting , trying to uncover meaning or interpret the phenomenon in a language common to the laymen" (Translated from the Hebrew version).

Guba & Lincoln (1998), suggest differentiating between using the term qualitative to describe different methodologies of research and the concept of "Qualitative" to denote different research paradigms.

In this context, a research paradigm describes the basic assumptions of a specific research method. Accordingly, in Guba & Lincoln's opinion, both quantitative and qualitative methods may be applicable in any research paradigm.

Based on this argument, they offer differentiating between four research paradigms of qualitative research, Positivistic, Post – Positivistic, Theoretical – Critical and constructivist. In each of these paradigms, there could be both qualitative and quantitative methods in accordance with the specific requirements of the research.

The authors stress, that they prefer the constructivist paradigm as the most appropriate paradigm for qualitative research. We could reduce this to two extreme paradigms, Positivistic – Quantitative and Constructionist – Qualitative.

Clearly, adopting one paradigm or another, involves the use of specific research methodologies. Thus, adopting the Positivistic – Quantitative approach, would involve using formal mathematical methods providing generalized results lacking any specific context. Adopting the Constructivist – Qualitative paradigm on the other hand, involves the use of narrative analysis, which is context specific.

We can therefore continue to claim that the assumptions stemming from one paradigm cannot be examined with methodologies based on a different paradigm (Guba & Lincoln, 1998). The question of whether we can even discuss the validity of qualitative research with quantitative research tools has been discussed at length and qualitative researchers, such as Kvale (1989), have questioned the validity of the initial query. He stated, that in our ignorance we have attempted to adjust the characteristics of action research to the eternal debate, regarding the validity of quantitative research, which hardly address qualitative research.

In reference to the problem emerging from a lack of uniform terminology, Shkedi (2003), suggests sorting the currently prevailing terminology of qualitative research into four groups. Each term can belong to more than one group and change its meaning according to the group it is referred to:

1. **Terms related to the Research Approach –** In this group we find the following terms: Qualitative research, Ethnography, Narrative based research, Naturalistic research, Constructivist research, Descriptive research, field research, and Interpretive research. When used in reference to the research paradigm, these terms speak of the same paradigm, which Guba & Lincoln (1998), named The Constructivist Paradigm.

2. **Terms related to the Research Strategy –** this group is often called the Research tradition, type of study, or genre. This group of terms refers to the research from an operational standpoint. The prevailing terms in this case are case study, multi case study, action based research, ethnography, anthropology, biography, phenomenology, life histories, life stories, and field-based theory, quality evaluation etc. Despite the fact that all these strategies are typical of the constructivist - qualitative paradigm, several, such as, case studies or quality evaluation, can also be included in the quantitative – positivistic paradigm.

3. **Terms related to the Research Methodology -** this group refers to the research method, particularly data gathering techniques. There are research methods more applicable to the constructivist – qualitative paradigm that is participatory observation, in-depth interviews, focus groups and different ways of analyzing observations, interviews and written materials. Qualitative researchers may use some methods associated with the Positivistic- quantitative paradigm, which would be pure observation, structured interview, closed questionnaire and processing and analyzing of content.

4. **Terms related to the Final Research Report -** this group of terms refers to the character of the research written report, among which are: ethnographic description, biography, case study description, multi- case study description, phenomenological description, etc. All reports in the Qualitative – Constructivist paradigm have similar characteristics: they are descriptive, include background and cross-referencing, and are all very different form the report style based on the quantitative – positivistic paradigm, based heavily on statistical analysis.

Assumptions of the Qualitative - Constructivist Research

Kuhn (1962) was the first to coin the term "Paradigm" in reference to the history and sociology of science. He differentiated between two stages in scientific development, the normative and the revolutionary. The normative stage is exemplified by trying to piece a jigsaw puzzle by using acceptable, preconceived scientific working assumptions. However, the more pieces to the puzzle, the more chances that some pieces may not fit, the more pieces we find that do not fit the puzzle, and the harder it becomes to support the current theory.

Each research paradigm is supported by basic assumptions, these cannot be proven or refuted and they reflect series of beliefs held by a group of researchers. Basic assumptions form the infrastructure upon which scientists build their puzzle of accumulated knowledge in any given domain.

The positivistic paradigm also termed as quantitative, conventional and scientific, is the prevailing paradigm for the past few hundred years. The Constructivist Paradigm also known as qualitative, phenomenological, naturalistic, harmonious and interpretive has also been around for hundreds of years but was unpopular with researchers who preferred the former.

According to Lincoln & Guba (1985), Denzin & Lincoln (2000), as well as others, a paradigm is defined as capable of answering three central questions:

1. What is the nature of reality?
2. What is the relationship between “the knower” and the object of his knowledge?
3. In what ways is this knowledge acquired?

Accordingly the qualitative - constructivist paradigm, is inherently different from the quantitative – positivistic, in the manner it addresses these three questions.

1. The 1st basic question: What is the nature of reality?

This question has the air of an ontological question (a branch of philosophy dealing in meta-physics, which tries to understand existence). Any answer to this question influences the manner in which we investigate reality; thus, when we conduct research we view our role and ourselves in relation to the subject of our research (Maykut & Morehouse, 1994).

The term Positivism, was coined by Auguste Comte in the 30's of the 19th century, as a synonym to “Science”, meaning concrete facts which can be observed (Maykut & Morehouse, 1994). On the other hand, the qualitative-constructivist paradigm considers reality as a whole, and therefore its attitude towards reality is holistic (Stake, 1995). Therefore, constructivist researchers try to study and understand occurrences and events, as whole entities in their natural context (Lincoln & Guba, 2000).

As an outcome of these arguments, the constructivist school claims that understanding the context of the observed phenomenon is critical to understanding its reality. There is great importance as well to the historical reality in which this phenomenon takes place, its uniqueness, the state in which it takes place, the background for its occurrence, and its associations to other events and conditions.

It is noteworthy to mention that when we investigated errors, which led to accidents, an error could have been disastrous many cases, whereas in other instances it was only a “near miss”. In such cases, we raise the question: what factors create the extreme difference in the error’s ramifications. We found that close study of this difference, which in most cases is closely connected to the interaction of “the error maker”, with himself, his physical and social environment, proved of great value in the prevention of future errors, rather than a uniform definition of the error. For example, a similar error, when made by a senior pilot or by a rookie, received a completely different meaning, and following that, led often to different recommendations.

In the positivistic paradigm, the relationship between bits and chunks of information is defined in a hierarchal system, drawn up in a flow chart, therefore there will always be higher level and lower level of information. In comparison, in the constructivist school, the relationship between the bits of information is complex and varies according to each situation. One can see the manner in which the information is organized by this school as a multi dimensional hologram (Maykut & Morehouse, 1994).

The explanation given to the conclusions in the positivistic paradigm is usually linear and causal: A causes B and B causes C. On the other hand, in the constructivist paradigm cause is reciprocal: An affects B, B affects A, A & B affect C and are affected by it as well. (Maykut & Morehouse, 1994).

2. The 2nd Basic Question - What is the relationship between "the knower" and the object of his knowledge?

It is possible to rephrase this question to: *How can we be certain that we know what we know?* Usually this question is regarded as an epistemological question*. Supporters of the positivistic paradigm claim that the researcher can and should maintain an objective position towards his the study. Whereas, those supporting the constructivist paradigm claim that it is impossible to separate between the researcher and his study, (Guba & Lincoln, 1989, Lincoln & Guba, 2000).

It may be assumed, that in the constructivist school, man has no existence outside reality, and reality has no existence outside man (Maykut & Morehouse, 1994).

According to the constructivist viewpoint, the reality in which we live, is created through structure, meaning that it is not there in advance, but is constructed gradually based on the meaning , which we bestow to all that we experience (Bruner, 1996).

According to the constructivist school, the researcher cannot understand human behavior from a position of an outside observer, taking up only the physical space in which he stands. More so, the researcher must comprehend what the "actors" mean by their behavior, from their point of view. (Sciarra, 1999, p. 43):
"*Constructivist Scholars are on the inside, assimilating themselves in the social setting and minds of the participants…..*" (Translated from Hebrew)

Accordingly, if reality is the result of construction and there is no separation between the" knower" and the object of his knowledge, then the values if all participants in the study, are relevant to understanding the studied phenomenon (Moss, 1996). Nevertheless, if reality can be broken into components, and if the researcher can place himself outside his object, as the positivistic school claims, then the research can be wholly free of any values (Maykut & Morehouse, 1994).

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* Epistemology- the science of knowledge, a branch of philosophy dealing with nature and the boundaries of human knowledge, (Guba & Lincoln, 1989).

3. The 3rd Basic question - In what ways is knowledge acquired?

This question is actually a methodological one, as it deals with methods and means for obtaining knowledge about reality. According to Guba & Lincoln (1989, p. 83), methodology is a practical field in philosophy of science, dealing with methods, systems and rules for conducting research.

If we adopt scientific ontology and objective epistemology, it is reasonable to assume that we will tend towards a Quantitative - Positivistic methodology. However, if we believe in relative ontology, interactive epistemology, it is possible that we would tend towards qualitative – constructivist methodology.

Guba & Lincoln (1989, p. 88), described it best: "*Just as the response to an epistemological question depends on the response to ontological question, thus does the response to a methodology question depend on the other two".*

The qualitative – constructivist researcher, believes that he himself and other people as well, are the primary means for data collection. The most effective way to gather relevant data on reality is to observe it, talk about it, listen to what others have to say, and take an active part in all its activities. Contrary to the quantitative- positivistic school, the qualitative – constructivist researcher is not attempting to manipulate and control variables isolated from reality, but rather he accepts the complexity and the holistic nature of reality as a given.

Contrary to studying behavior and interactions under artificial laboratory conditions, in which the positivistic researcher attempts to control and manipulate, what he believes are the relevant variables, the constructivist researcher strives to learn about the people in their own environment, inner world, and routine daily activities (Reason & Rowan, 1982):

"...Research doesn't have to be another brick in the wall. It is obscene to take young researchers who actually wants to know more about people, and to divert them into manipulating "variables", counting "behaviors", observing "responses" and all the rest of the ways in which people are falsified and fragmented. If we want to know about people, we have to encourage them to be who they are, and to resist all attempts to make them - or ourselves - into something we are not, but which is more easily observable, or countable, or manipulable..."

While writing these lines, we feel a need to share an experience, from our early days as psychologists in the Air Force, entrusted to understand the meaning of human error in flight accidents.

In 1977, about a year after Yossi, started to work for IAF's ASQD (MAVKA), a fatal accident occurred in southern Israel, in which Lieutenant G. was killed. Lieutenant G., was a young pilot, who graduated from the flight school, about a year before. G. was considered to be an excellent fighter pilot, with a non-conformist fiery personality .His basic attitude was that Procedures were meant for others, not for him.

The Air Force formed a committee to investigate the accident which was comprised of senior pilots and technical staff, to eliminate any possibility of a technical failure.

The accident occurred during an air to air combat training manoeuvre, during which Lt. G. lost control of the aircraft and consequently crashed. At the time I asked the head of MAVKA, Col. S. why isn't the human factor being investigated and only the technical and operational facets are on focus? He gave me a long hard look with his deep blue eyes, (I was at the time a young Lieutenant), making me almost regret that I had even asked, and then he replied; "*Because what happened is absolutely clear, it was a typical pilot error..."* I continued my probe, "*But why did he committed that error*? *It was well known that he was an excellent pilot*. Col. S. gave me another long gaze and asked me in a semi joking manner, *"Young man, do you believe that you can teach us something new?"* I smiled in embarrassment and answered, *"I am not sure, but I would really like to know what happened there... why he was killed…"* He responded softly, stressing each word pronounced, *"You know, in our Air Force, we do not ask such questions, he erred and he paid for it and we must move on".* I thought about what he meant for a few minutes and turned back to him: *"But if we don't understand what happened there…how can you be sure it won't happen to another young lieutenant tomorrow morning"?*
He asked for some time to think about it and promised me to discuss the issue with the Air Force Commander in Chief.

A few days later, Col. S., showed up in my office, sat in the chair facing mine and said: *"I cannot believe that he would approve it…. But he did…perhaps he knows something I don't".*

The IAF, for the first time since its inception and after sustaining quite a few critical accidents, gave a green light to conduct an in-depth investigation into the human factor contribution in Lt. G. accident. It is important to note that there were no precedents from which I could learn how to do this. Not in Israel and not in any of the Western air –forces with whom we were in contact.

The mandate I was granted was to *“Ask any question, interview any person of any rank, review every document, visit any flight squadron, and observe all activities, all in order to bring us closer to understanding why Lt. G. was killed".*

Over the course of about three months I have interviewed all G. commanders, his friends both in the squadron and outside of it, and studied every scrap of paper that documented his entire Air Force service: from his first flights at flight school and up to the briefing he attended just before the fatal flight. I studied the G.'s selection file including a great deal of information about his personality and skills. I studied the record of similar flight accidents in the Air Force and abroad. I studied the technical specs of the aircraft type, and the maintenance record of the aircraft that crashed. I went into the specifics of air combat training, during which the accident occured. I reconstructed all Lt.. G’s steps and behaviour for the week preceding the accident, and in even greater detail. The 24 hours preceding the fateful flight.

My report was unprecedented, both in its scope and detail. Over 60 typed pages in which I described every detail I thought was relevant to understanding the underlying roots of G's errors. The report addressed also the general ambience of the squadron, the relationships between Lt. G. and the squadron commander as well as other pilots. I covered the common norms in the squadron for monitoring and supervising young pilots, and compared these norms with those of other squadrons. In addition I detailed Lt. G's achievements, professional development and other relevant information.

Towards the end of the report I felt that the expression “pilot error”, showed some sort of disparagement and misrepresentation of the complex system, in which the accident occurred and which had many contributors, other than the pilot who paid with his life.

When I presented the report to Col. S, he smiled and asked *“So, do you think psychologists need 60 typed pages in order to have their say, while we pilots can say it in 2 words?”*

After reading the report, he invited me to his office and stated: *"We cannot publish the report, as it would be too dangerous"*. I asked him to hand the report as is, to Air Force Commander in Chief, which he did.

The Air Force Commander in Chief, read the report carefully, made a number of meaningful corrections, trimmed it down and asked me to accept the changes.

I corrected the report accordingly and gave it back for approval. He called me in to his office along with. Col. S. and asked us: *"Is this how you intend to investigate Air Force accidents from now on?"* I responded that I thought it would be appropriate, as we have many pilots in the Air Force, whose lives we might save by learning what really causes the accidents. He was a bit aghast when he asked, *"So you think it was not his fault, but all of ours?"* And immediately added, *"I don't think you are wrong, I just think it is too early to come out with these ideas… we'll start the revolution slowly but sure enough and we will make it happen".* He suggested that the report remain confidential, albeit added to the official accident report, in a sealed envelope, with the highest security code. However, he approved this type of investigations for all future accidents involving human factors.

From close examination of Lt. G's accident and its aftermath, I can safely say that although my report was basically shelved, all its recommendations and conclusions were fully applied.

Later, many more accidents were investigated by this method, which provided the Air Force with new opportunities to understand the phenomenon of flight accidents and reduce their rates significantly.

We shared this experience to illustrate that without realizing it, and without even being aware of the constructivist paradigm, we acted according to its basic principles. We did so, as we have not found any other way to describe the wealth and complexity of the conditions, factors and background that contributed to G.'s error and its fatal outcome.

Action Research

Reason & Bradbury, (2006), describe action research as follows:
"Action research is participatory, democratic process concerned with developing practical knowledge in the pursuit of worthwhile human purposes, grounded in a participatory worldview which we believe is emerging in this historical moment. It seeks to bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people, and more generally the flourishing of individual persons and communities.."

Action researchers plan their research much like qualitative researchers when dealing with engaged and longitudinal field research. They utilize several

methods which include: interviews, focus groups and data collection through social networks.

One of the main differences between action research and other qualitative research paradigms is the fact that in action research the differentiation between the researcher and his object is often blurred, in the course of long term cooperation. Action research is mostly exemplified as a working “with” rather than working “on”. Research subjects, become over the course of time research partners (Reason & Bradbury, 2006).

In order to put some order into the broad range of action research Reason and Tobert (2001), suggested three broad tracks for application of action research:

1. **First person action research –** Relates to the researchers ability to espouse an investigative method for observing his own life, to be constantly aware, and to choose to evaluate the effects of his behaviour on the rest of the world. This type of action research may contribute too many daily activities.

2. **Second Person action research –** Deals with our ability to conduct face to face research with others on issues of mutual interest, for instance, improving our professional ability as individuals and as teams. This type of action research begins with a dialog and includes the development of research communities studying organizations and learning.

3. **Third person action research –** A type of action research geared to broaden the scope of projects and include people who have no previous acquaintance. Writing, as well as other reporting methods, describing the process and its outcomes, may provide an important standard for this type of research.

The philosophical foundation of action research is attributed to John Dewey (1933), in his book “How We Think”. Dewey encouraged his students to learn how to think and not cite facts and others ideas. He argued, that education should make greater use of team work, hereby student can generate hypotheses together, which later they should examine in reality.

Nevertheless, Dewey did not coin the phrase Action Research and according to French and Bell (1990), this phrase was attributed to two scholars who operated independently of each other, John Collier and Kurt Levin. Collier coined the phrase while working with Native American Indians and whites in attempt to

improve their relations, while working as the commissioner for Indian affairs between 1933-1945.

Levin's work was formed in the context of his Jewish German background, suffering from Anti-Semitism who eventually immigrated to the US and showed an interest in the pressing issues raised in the wake of WWII, particularly the organizational and social issues. These were the circumstances, which formed his views regarding action-research as a democratic research tool, used to take advantage of the power of science to understand and change human behavior.

Shein (2006), claims that some of the best opportunities for research are in situations that were not created by the researcher. In his opinion, data collection, structuring a concept and developing theories are the result of a research attitude, which is the desire to clarify events and communicate these clarifications to other researchers. Shein states, that the best opportunities for research are present in situations structured by others, needing assistance, and not those made by the researcher. Collection of useful data in an area defined as a "client" in need of help is the definition of a clinical research (Shein, 1987).

Shein (2006) does not oppose positivistic research, but he worries that the academic community does not prepare students in social sciences to conduct useful fieldwork using qualitative research tools. The students are not provided with basic tools for conducting an interview, observation, and developing insights, to enable them, as early as possible in their careers to get in touch with their natural tendencies: *"…We need to legitimate clinical research as a valid part of our field and start to train people in helping skills as well as research skills. And we need more insight into our cultural assumptions to determine how much they bias our perceptions and interpretations of what is going on…* "

Shein (2006), goes on to summarize by saying that he feels that the positivistic research paradigm has an imperialistic tendency, and that it presents itself to the imperator in its nudity much too often, therefore it is time to change and to innovate. This innovation is a return to good solid observation of the old-fashioned type, and clean research in situations where we try to help clients solve real problems: *"Isn't it more important to try to help them and learn in the process, than make a sacred cow of research paradigm that produces neither valid knowledge nor help? "*

Summary: Thoughts on our study and its linkage to the Qualitative – Constructivist paradigm.

As we have previously mentioned, we unknowingly conducted our Risk Management consulting work, with accordance to the Qualitative – Constructivist paradigm, as this was the paradigm, which enabled us to conduct Risk Management activities, which fit in with our views and insights, acquired through the course of our work for the Israeli Air Force.

Investigation of errors, adverse events or accidents, is a basic process in Risk Management, which serves as a constructive response of the involved parties and the system to a fault. The goal of the investigation is to try to understand: What happened? How did it happen? Why did it happen? And what can be done to prevent reoccurrence of the error? In addition, the investigation seeks to answer the following questions: What caused the accident? What were other contributing factors? What enabled it? To answer these questions, collection of a lot of data is required. The data is collected from different sources, utilizing a variety of methods, in order to understand the process of the error within its own unique context.

It is clear, that the investigation is a constructivist process; it asks many different questions, according to the particular circumstances of the error, the involved parties, the organization and the particular investigation board. The investigators, who are risk managers, bring their own backgrounds into the arena, their biases, the professional mold by which they operate, their professional and organizational culture. Risk Managers, are by no means objective, reserved observant in the error arena.

One of the main goals of Risk Management is to identify the risks proactively, asses their potential harm level, estimate the probability of occurrence and create procedures for critical risks, which provide appropriate controls and gauges, able to alert and neutralize them . This activity is called “The Risk Management Cycle”. It is far more structured than the investigative process and it utilizes many tools to help the risk manager in his work. In order to decide which risks have a higher priority than others do, the following formula is used:

RI=S*P (RI = Risk index, S = Severity, P= Probability of occurrence)

Although, this is a very useful tool, often when we try to apply it we encounter some difficulties. Our partners ask often these typical questions: How can we evaluate the severity of a risk? How can we assess the probability of a risk that has not been yet real? Since we are talking about a common methodology in Risk Management, we find that in many cases an organization is forced to play along and use it to rank the risks, when actually the targets were marked before.

Actually, first, based on prior experience, the high risks are marked and then they are evaluated accordingly on the severity and probability scales. This proves, that professional intuition will be reflected in the outcomes of the mathematical formula.

In our opinion, the situation described above, clarifies the intersection matter of the two paradigms. The positivistic paradigm receives greater credibility as it is perceived by the public as “more scientific”, more professional, more valid and reliable. The way we were brought up, forces us to believe that numbers reflect reality more precisely than our own basic instincts, knowledge and experience. We have been taught not to believe our own ability to observe and understand reality. Supposedly, the power to understand reality by examination is held by a sect privy to some unique rules enabling it to discover the essence of reality. Although, in our opinion, the more appropriate paradigm for Risk Management is the constructivist, it is forced to masquerade as positivistic, in order to gain credibility.

Reisetter et al. (2003), have conducted a qualitative study amongst postgraduate students of educational psychology and counseling, who were participating in a qualitative research methods course. They found, that some of the students showed resistance to the qualitative methods, which they believed, would not be accepted, as credible later on in their professional lives.

We noticed, that many professionals are willing to play the positivistic game, even though it is perfectly clear to them that in the professional world in which they operate, it is useless and could even be seen as a real detriment, as it cancels, distorts, and invalidates the weight of experience and knowledge of professionals.

From our experience, using quantitative models of the type we have presented here is often regarded as a sign of the Risk Manager’s professional ability and coherence. While, posing a question like, *“Which risks are you most concerned*

with in your daily operations?" is perceived as shallow and lacking in formal training in Risk Management.

While writing this work it became perfectly clear to us, that the area we are operating in is not positivistic – quantitative in its nature, but rather constructivist, as it involves people trying to get their work done, with as little error as possible, and yet occasionally err. The attempt to create a reality, in which errors are rare, can only succeed if we understand the reality in which these errors do occur. With all its complexity, we must study this reality, and glean insights on behaviors and environments to reduce the possibility of error in the future. We often found unexpected paradoxes, such as an inverse relation between the volume of error reporting and the prevalence of severe errors. We learned to explain this paradox and use it as an insight.

With the understanding that we are operating in an open field, with very few professional anchors and definitions, and with the understanding that we all have biases and tendencies, we chose to use orientation tools, in order to keep us grounded and keep us from erring to often. These orientation tools, some of which existed, and were adapted to our needs and some were developed by us. We teach new Risk Mangers to adopt not as rigid and compulsory modes, but rather wider margins for their perspectives. These may help them achieve their goals with less confusion. Amongst, these tools are models for mapping out error factors, tools for evaluating the quality of recommendations, for describing course of adverse events, tools for writing reports and tools for proactive risks management.

We chose the Qualitative – Constructivist paradigm to describe the Macabi project, we were and are still involved in, since the cooperation with Macabi has the characteristics of action research, as previously outlined.

Nevertheless, it is important to point out, that our study is different from that of action research, particularly as when we started the project we did not plan any research activity but rather set out to help Macabi build its own Risk Management practices, based on our professional experience from aviation. It was only in 2003, six years after the project's inception, that we began writing this study. We could say that this turn of events created a certain "cleanliness", which often is not possible in action research, where boundaries are often blurred between the researcher and the object of research, where in effect the researcher plays a dual role: helping the organization solve a real problem and studying the process simultaneously.

This state of affairs enabled three types of action research modes to function together side by side, according to Reason & Tobert (2001):

1. **1997-2002 – First person action research-** we focused on the consulting job for the Risk Management department in order to help them define a model and working procedures. During this period, the focus of our work was turned inwards, towards our relationship and ourselves in order to maximize our strengths to go through this process. We learned and identified each other's strengths and learned to put them to our client's best advantage by being more effective in doing our job.

2. **2003-2006 – Second person action research –** From the insights gained while writing of this work, new opportunities opened up for additional cooperation with Macabi. We developed new tools, the working model was reviewed and revised, new experience based training modules, were developed, new teaching methods for risk managers were revised and added as well.

3. **2007- To date- Third person action research –** Cooperation between the Risk Management department, at Macabi and other clients is expanding beyond the department and beyond its regular client base. New working procedures have been defined to widen the circles of Risk Management impact, interactions between Macabi and other organizations such as: MRM- the malpractice insurer, IMA - The Israeli Medical Association, Tel Aviv University- Scholl of Medicine and The Center for Medical Simulation, were established.

We are convinced that the qualitative constructivist paradigm is the right paradigm to support our practice as Risk Management consultants. It provides us with a frame of reference for the phenomena we work with, and it enables us to contemplate our performance, understand our work, our partners and ourselves and continue to expand the circles of our activity and acquired knowledge.

In this chapter, we also observed how the Hebrew language has enabled the constructivist paradigm, long before anyone even knew about paradigms, positivism or constructivism.

Hebrew morphology links the verb "to understand" (Le HAvin) and the verb "to construct" (LiVnot), this linkage makes us wonder if perhaps, Hebrew alludes to the fact that understanding means to construct reality. Meaning to say, that comprehension is an active process of building reality, form a variety of information from many sources, which is accrued about reality. This morphological linkage is similar to the one between another two verbs, "to define" (Le Hagdir) and "to fence" (LiGdor), defining therefore, means to set up fences to create meaning, what is included in the definition and what is left out.

Chapter 3

Safety, Risk Management, Quality improvement Models, Concepts and implementation.

"All stable processes we shall predict. All unstable processes we shall control. There's no sense in being precise when you don't even know what you're talking about".

John von Neumann (1903-1957)

"A life without adventure is likely to be unsatisfying, but a life in which adventure is allowed to take whatever form it will, is likely to be short".

Bertrand Russell (1872-1970)

Prologue – We are now at a different point

This chapter was written at the beginning of 2009, in the midst of the worldwide financial crisis. Presumably, if this chapter had been written several years earlier, it would have been different, have a better fit with the headlines but be less relevant to the current state in which the original Risk Management concepts were found to be insufficient.

Paradoxically, banks and other financial institutions were first to adopt the concept of Risk Management and to implement them as a mandatory protocol.

In most Western financial institutions, an organizational infrastructure was created to deal with Risk Management, and senior managers, often in Vice President Positions, were appointed to manage it. Innovative models were developed to help in analyzing risks. International Banking Associations regulated mandatory protocols such as SOX, Basel2 and COSO.

However, these tools were unable to prevent the current economic crisis, and this raises some very challenging questions with regard to the effectiveness of the current Risk Management approach. Three possible hypotheses were raised in an attempt to explain the failure of existing Risk Management models:

- The Risk Management methods which were adopted were essentially faulty.
- Current Risk Management tools are unable to track the fast changes which are part of today's business world.
- Both of the above mentioned hypotheses are correct.

Based on our experience, we believe that the 3rd hypothesis describes in a better way the current crisis of Risk Management Models.

We believe that the Risk Management arena has become too dependent on complex mathematical models and created the feeling, although unsubstantiated, that risks are being managed well.

In addition, Risk Management methodology has not provided proper response to the constantly changing reality in which so many systems are not only interrelated, but are co- dependent on each other for their performance and success.

All these, are the reasons for re-writing this chapter in order to deal with the economic crisis and its implications to the field of Risk Management.

Major approaches to Risk Management

There are two different approaches, aimed for achieving safety conditions which implies the absence of accidents and adverse events.

1. **The "Fly-Fix-Fly" approach** is a trial and error approach. Using this approach, a system or process prototype is built and tested under real conditions. Anything that goes wrong is fixed and tried again, until the desired level of reliability and safety is achieved. This approach is based on learning from errors, providing that the errors are well examined, and recommendations are implemented in updated versions of the system/process. The drawbacks of this approach are numerous and the most noted of all are; uncertainty with regard to system reliability during launching, long development time and costs.

2. **The System Safety Engineering approach** which tries to analyze and foresee the possible failures of the system/process during the design stage and to implement solutions in order to reduce possible failures already in the prototype. Once the system/process is built and operational, it is possible to use the "fly-fix-fly" method, in order to continue and improve the system and processes.

As an example, analysis of serious flight accidents shows, that often the accidents are related to failures in airplane design as well as operations and management. According to Leveson (2003), the "fly-fix-fly" approach is not sufficient since, in the best of cases, it helps in preventing the repeat of similar accidents. In systems such as nuclear reactors or civil and military aviation the fly-fix-fly approach is unacceptable because even one accident is considered catastrophic.

The system safety approach utilizes theories from the disciplines of systems and system engineering in order to prevent future failures. The concern is not only to loss of life, but also to property and environmental damages. The main target is managing risks by identifying them, analyzing them, reducing them and monitoring them proactively.

Another way to distinguish between different approaches in the field of risk management is to refer to the main methodology utilized by the approach in question. Accordingly there are three main approaches:

1. **The quantitative approach**: this approach emphasizes the use of mathematical models, based on past data, in order to evaluate the severity of risks in two dimensions: the severity of the potential damage and the probability that the risk will occur. The drawback in using this model stems from the fact that in most cases past data does not necessarily represent the phenomena, but rather gives an indication as to the level of reporting. Also, it cannot assist us in identifying and analyzing new risks which did not realize in the past.

2. **The Qualitative approach**: This approach is based on the use of soft methodologies such as interviews of managers, employees and experts, field observations, studying basic company documents, focus groups, training, and questionnaires etc, in order to identify risks and prioritize their treatment.

3. **The combined approach**: This approach makes use of soft tools, past data and mathematical models in order to evaluate the risk level while presenting the methodological problems inherent in this approach.

It goes without saying that we believe in the third approach, even though we are often asked by our clients, especially those with a background in science and engineering; to use the quantitative approach.

We have often asked ourselves the meaning of this request to use mathematical tools in a field which, we believe, is qualitative in its core. We assume that risks are associated with deep existential fears which are related to uncertainty regarding the future. Mathematical models may offer the feeling that the risks are under control, while soft models, may just amplify the fears.

Soft models are based on a process which basically asks questions while mathematical models give numerical answers which might offer a sense of security which is sometimes baseless.

Mueller (1968), described the new System Safety Engineering discipline as "organized common sense". This is a planned and systematic approach to identifying, analysis and control of risks, during the life cycle of the system, intended to reduce accidents.

Lederer (1986), describes the safety of the systems as an activity which starts in the early stages of concept definition and continues through the planning, production, tests and implementation. One of the main characteristics of this approach, which differentiates it from other approaches of Risk Management, is the emphasis on early identification and analysis of risks so that actions to reduce risks will be discussed, before final decisions regarding the system are made.

Among the main principles of system safety we may mention the following (Leveson 2003):

- Building of safe systems and not just adding safety measures to existing systems.
- Treating the system in a holistic manner, rather than a collection of sub systems and components.
- Emphasizing the value of risk management rather than investigation of failures.

- Emphasizing the system analysis over past experiences and standards.
- Emphasizing the qualitative approach versus the quantitative approach.
- Early detection of conflicts and tradeoffs of costs/ benefits decisions.
- System safety is more than just system engineering.

In writing about the history of Risk Management during the period 1900-2002, Rubin (1999), claims that risk management is one of the ideas which has, in its core, the belief that a rational systematic approach to future uncertainties, will allow us to live prudently and creatively, while preventing the unnecessary waste of resources.

The author of the book "Against the Gods: The remarkable story of Risk" (Bernstein, 1996) wrote: *"If everything is a matter of luck, risk management is a meaningless exercise. Invoking luck obscures truth, because it separates an event from its cause."*

Therefore, Risk Management is deeply imbedded in cultures, beliefs and personal approaches, which we develop as individuals, companies and organizations. As an example, the Risk Management approach is based on the belief that risks can be managed, that is, a belief that risks are not the results of random luck or lack of luck but rather results from our own doings or lack thereof.

Moreover, it is possible to perceive the reality which we create and of which we are a part, as a result of our attitudes to risks and the belief that we either can or cannot manage them. Dramatic events in human history, wars, inventions, natural disaster, and manmade disasters, have all left their mark on the way we perceive risks and believe in our ability to manage them.

At any rate, risk management, stands in complete contrast to the approach which sees everything which happens to us as a consequence of random luck and that the future is totally uncertain.

As an example, humankind's approach to risks was influenced by big disasters which were burned into our collective awareness. Such as the sinking of the Titanic, Triangle Shirtwaist Factory Fire, Minamata disease, Seveso, Bhopal, Chernobyl, Valdez, Enron,Three Mile Island, Challenger, Columbia Piper Alpha, Exxon and of course the economic crisis which the entire world plunged into in 2008 and the collapse of banks and large industrial concerns. This is in addition to large scale natural disasters, such as earthquakes, volcanoes, floods, tsunami, etc.

Holland is an excellent example of a continuous epic war against risks resulting from the North Sea. Flooding of the Dutch lowlands by the North Sea, has always presented a risk to the survival of the Dutch people. The way the Dutch chose to deal with this risk, represents their belief that this risk can be managed, otherwise they would have given up.

The Dutch have always exploited the most up to date know-how and technology in order to manage the risk of floods. Big disasters accelerated the efforts and brought about unique and creative solutions. This is what happened after the 1953 flood disaster in Zealand, in which 1850 people lost their life and many others lost their homes and property. The disaster prompted one of the most creative and effective technological solutions which included a series of projects and among them the Oosterschelde Dam*, labeled as the 8th wonder of the world and the Maaslandkering near Roterdam that was finalized in 1997.

As part of the project, a series of dynamic dams were erected. The dams protect the people against floods, while at the same time they do not hurt the environment significantly. There is a Dutch saying: "God created the world, but The Netherlands were created by the Dutch"

In her reference to the meaning of “feeling secure” Leydesdorff (2001), after interviewing several of the survivors of the great flood in Holland (1953), made the following observation: the sense of invincibility in face of disaster is a relative one. A sense of security, according to her, is defined by the culture in which we live. For example, similar disasters which affect nature and our environment these days, took place 20 years ago, however the public is more aware of them now.

According to Leydesdorff, the survivors, because of their religious background grasped their fate as God given and as a result the disaster was understood by them as a punishment by God for their sins. She also maintains that the way historical disasters are kept in our memory and re-evaluated, influences the way we perceive the probability the event will happen again

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* Following each meeting with our supervisor, Professor John Rijsman, we used to spend several days in Zealand. This was pure coincidence, while we were looking for a place to rest and talk. We chose Zealand, where we spent time in a small village called Domburg, which was also flooded during the flood disaster of 1953. Out of curiosity, we traveled in the area and saw the Oosterschelde dam. Each time, we were filled with renewed amazement and it reinforced our feeling that risks can be managed. This provided, we hold the opinion, that we are not victims of risks, but rather have the ability to manage them. As a result, we regard the project of protecting the people of Zealand, not only as a technology project of the first degree, but also as a monument to risk management concepts.

Erickson (1976), who investigated the demise of the Appalachian community as a result of a flood, found that contrary to the people of Zealand, they thought that blaming God for the disaster was an act of blasphemy. In their eyes it was forbidden to blame God for human errors.

Safety, Risk Management, Quality Assurance , Similar goals, different approaches

It is our opinion that the three terms - Safety, Risk management and Quality – represent the evolution of people's attempt to reduce the exposure to risks and to reduce the damages when risks do realize.

Safety, as a professional discipline, preceded the other two areas and its purpose was to protect, as much as possible, workers in areas which are prone to risks. Items such as safety goggles, helmets, designation of activity and rest hours, etc. are defined as safety means. These means were developed in order to perform missions in dangerous environments while protecting the operators. This is akin to the shield that knights in the middle ages wore in order to protect themselves from their enemy's weapon, but not to prevent the war itself.

At the heart of the safety concept lays an assumption that risks are an inherent part of life and so are the mission’s one has to perform in risky environments. Therefore, the only way to reduce risks is by developing and using safety equipment.

It is worth noting that high risk activities are traditionally better rewarded than low risk activities, which makes them attractive and even heroic. The interest associated with the protection of operators is often an economic one. It is cheaper to protect than to pay compensation to the families. Similarly, if damages can be reduced because of increased protection and thus decrease the risks associated with the profession, perhaps there is an option to reduce the reward. It is acceptable that some professions, such as fire fighting, diving, flying, nuclear reactors operation etc. are risky and additional "risk payment" is added to the basic salary as an appreciation for the increased risks that the operator is exposed to.

The field of Risk Management was developed when the safety field had reached its limits and could not solve the basic problem which is the existence of risks.

Risk Management discipline evolved with the development of probability models, which enabled risk evaluation, and with the spread of risk concept to other fields and not only risks to human life.

The basic concept of Risk Management received its inspiration from the insurance world as will be described later. The insurance world is coping with issues which have to do with selling insurance policies for future risks. That is, while I purchase a policy, I purchase insurance for the event that the risk will actually materialize. Then I will get a compensation which is intended to cover the amount of the damage. The question is: how does the insurance company know how to evaluate which risks will materialize and which will not, and what will be the damages in case the risks will materialize? Without this knowledge, the insurance company might lose lots of money. Therefore, in order to manage its risks, the insurance company evaluates various risks by their probability of occurring and the amount of damage they can cause, based on past experience, analysis of future trends and probability models. In light of that, it is possible to calculate the total amount of compensation that the company will pay to its insured customers. This amount, together with overhead and profit, creates the basis for the methods, policies are priced. A change in the risk projection will cause an increase in premiums.

This basic model, which includes risk identification, methodology of risk evaluation and insurance premium calculation, that maintains a positive cash flow for insurance companies, is the corner stone of traditional Risk Management. We are referring, of course to the Risk Management of the insurance companies and not of its customers.

Saying so, a question may be raised: Do insurance companies have an interest in reducing the risk level of their customers? Theoretically, if the risk level is reduced, the insurance company will need to reduce premiums and consequently its revenues and net profits might be influenced. On the other hand, one can argue, as evident with medical malpractice arena, that as the number and volume of claims rises, the premium level becomes so high, as to risk the economic viability of the insured.

The basic concept behind all Risk Management programs is the idea that future risks can be identified and analyzed. Based on past experience and proper models, suitable controls can be devised in order to reduce the probability of risks materializing and the damages caused by them. This is a proactive concept, meaning that there is no need to wait for the risk to materialize, but one can take proper steps in advance to reduce it.

An important tool in Risk Management is learning from adverse events' in which the risks were materialized, in order to improve risk assessment and the quality of controls.

The field of Quality Control, evolved as a natural evolution of the Risk Management field. It may be stated, that in many cases, successful risk controls were actually improved work processes. The basic assumption is that good and safe products are the results of good and proven work processes. Therefore, Quality Control is aiming at improving the critical work processes by measuring them standardizing them, thus lowering the risks to which individual and companies are exposed to.

The following table presents a summary comparison of the three fields: Safety, Risk Management and Quality Control

Approach	Safety	Risk Management	Quality Control
Work Assumptions	Risks are part of life, especially in certain environments. Risk protection is possible. Personal protection is preferable.	It is possible to manage risks by reducing the probability of their occurrence and the severity of the potential damages.	It is possible to improve processes and thus reduce the risks while at the same time producing better quality products at higher efficiency.
Strategy for reducing risks	Protection	Study the risk and lower the probability and/or the level of potential damage	Reduce risk by Improving work processes.
What is needed for implementation	Identifying the risky work environments. Development of effective protection means. Implementing the use of these means.	Changing the attitude from "protecting against risks" to "proactive approach". Investing resources in risk identification and reduction. Maintaining systematic and ongoing process of risk assessment and improving control systems. Commitment of top management. Encouraging learning from errors and not punishment	Defining critical processes. Studying quality control methods and implementing them intensely in the organization. Recruiting top management commitment.
Influence on Risks	No influence on risk itself	Reducing the probability of occurrence and/or level of damage if risk materializes.	Risk elimination by improving and monitoring processes. Possibility of creating other risks/

Often there is some confusion between these three terms. We can safely say that Safety, defined as a state without risks, will forever be the goal towards which we strive, whereas Risk Management and Quality Assurance, are the means at our disposal, by which we can achieve this goal.

The History of Risk Management

Vesper (2006), studied the history of Risk Management, simultaneously examining the linguistic roots of the word risk, whose origins are apparently in old French – risqué, whose meaning is " danger that holds some opportunity" (Littre, 1863). The word hazard which is often mentioned in reference to Risk Management, finds its roots in Israel, site of the Hasart Fort where the game of dice was invented while it was under siege (Oxford English Dictionary, 1989). Actually, the real name of the fort was Ain Zarba.

Bernstein (1996), in his book "Against the Gods", describes how thinking and attitude to Risk Management developed as a result of the changes in mathematical concepts, understanding probability and expanding that knowledge into gaming and the rules that govern them.

Although, gambling was prevalent even as far as in ancient Egypt, as many of their old wall paintings shows, it was only in the Renaissance era that a statistical and mathematical base for the theory of gambling began to form. This was due to the fact, that the numeric system, known to us today, whose origins are Indo – Arabian, appeared in Europe around the 10th -12th centuries. But it was only during the Renaissance, that that this numerical system replaced the old Roman numeric system.

Girolamo Cardano, a mathematician, physicist, and gambler of the 16th century, published a first of its kind essay, examining probability in the game of cards, dice and others. "Liber de Ludo Aleae – Book on Games of Chance".

According to Bernstein (1996), other prominent philosophers contributed their understanding to this field, amongst them was Galileo who wrote a short essay in 1630: "Sopra le Scoperte dei Dadi – On Playing Dice"

Additional mathematicians, especially those studying the basic organization of large data bases, such as registration of births and deaths, developed sampling methods, actuary charts, and other methods for predicting behaviors and events, which take place in large populations.

Insurance, which is a financial tool, intended to reduce the individual's risk, by creating a large group to bear the burden, has its roots as early as the 18th century BCE, when it was used to finance sea voyages of ships in ancient times.

A form of life insurance was used in ancient Rome and Greece and was supplied by the various trade guilds. In the middle Ages, as commerce spread, many new types of insurance against disasters (including floods and droughts) were developed.

Lloyd's, which is probably the world's most famous insurance brand, was established in 1687, in a café near the Tower of London. It was a popular meeting place for commercial sea captains. It was a place where they could exchange information on their recent and future voyages, the weather, dangers they had encountered, etc. Those interested in shouldering the risk of a certain voyage, could write their names on a designated board and thus accept the terms of the contract. This is the source for the term "underwriter"

The need for insurance continued to grow, out of a desire to protect individuals and groups from an ever growing list of risks.

The industrial revolution brought this issue to the foreground, as a result of the new technologies that were constantly being developed at the time, for both industry and personal use. Of these, the steam engine was probably the most influential, in changing the public's perception toward personal and public risk.

According to Burke (1997), between the years 1816-1848, there were 233 steam boats accidents in the US, which involved 2563 casualties. After years of discussions, the US Congress passed a groundbreaking bill in 1838, whose goal was to impose regulations on all aspects of steam engines. As a result of the bill "The Steamboat Inspection Service" was created. But the service was not effective enough and during 1850-1851, the accident rates continued to rise and 685 more people were killed. This prompted the congress to pass another bill, which defined higher safety standards and transferred the regulatory agency from the Justice Department to the Treasury.

Since the industrial revolution, the scope of exposure to risks continues to grow in both type and magnitude. Nuclear power plants, Giant tankers, Aviation, Space, Chemical and Biological Industries, are but a few examples of the new hazards, which were unknown prior to the industrial revolution.

Pioneering implications of Risk Management

We believe, the scope of pioneering implications of risk management is enormous. It may be assumed, that risks troubled human mind from the very beginning. There is no way to pay the right tribute to all the pioneers, most of them being anonymous. The field of risk management is still evolving, being far from its maturity. In this paragraph we will mention only few documented milestones and try to cover the issue in a more orderly manner in the next one.

As a response to the widespread proliferation of risk to individuals, society and the environment, some new approaches were adopted. One of the more extreme approaches which was implemented in the US was the “Delaney Clause”, which stipulates that the Federal Food, Drug and Cosmetics Administration, could enforce a total ban on pesticides, food coloring or additives, that were found to be carcinogenic, (in 1954, 1958, &1960 respectively).

The law was based on the premise that there is no low level point at which a material is no longer carcinogenic, it either is or isn’t. It runs on the “One hit model", which states that any contact of the material with a living cell is sufficient to cause cancer. The goal of this law was to reach 100% safety levels.

Contrary to this approach, which is most prevalent in Industrial medicine, whose intent is to protect workers exposed to hazardous materials, which could cause immediate harm or long term cumulative effects; another approach was developed called the TLV: “Threshold Limit Values”, which offers tips, recommendations, and interpretations developed by experts in the field to prevent “An unreasonable risk of disease or injury” (ACGIH, 2005).

The TLV is continuously updated and evaluated as a result of information accumulation following adverse events debriefings, involving employees in hazardous work environments.

Industrial medicine, has adopted the risk management methodology for uncovering and inspecting potential hazards. It requires companies to comply with the OSHA – Occupational Health & Safety Administration (OSHA Act). Likewise, companies are required to conduct safety inspections and ensure that hazardous work procedures are in compliance with the Code of Federal Regulations, (1992).

In 1975, the US Nuclear Regulatory Commission mandated the implementation of PRA (Probabilistic Risk Analysis), which utilizes real and empirical data, in order to assess work procedures within the system.

In 1990 the FDA (US Food & Drug Administration), began requiring food manufacturers to implement a system for Hazard Analysis and Critical Control Points (HACCP), for the purpose of identifying and monitoring risks.

The program started with manufacturers of low acid canned foods and moved on to seafood, and as of 2001 progressed to the juice manufacturers. In addition, the USDA requires meat manufacturers to use the HACCP. The goal is that all US food manufacturers will use the HACCP protocol.

Starting in 1997 the FDA requires a risk analysis under the auspices of "Design Validation" which includes updating software and a risk analysis in cases where its application is appropriate.

Major Milestones in the development of Risk Management Thinking.

In the following table, a number of significant milestones, in the development of Risk Management in the 20th century, are presented. It is important to point out, that the choice of these milestones is of a somewhat personal nature, though it is based largely on the works of Rubin (2002) and Vesper (2006).

The overview refers to events of legislation and standardization, publications, as well as establishment of institutions with important ramifications on the development of this discipline.

The overview covers over 100 years, starting at the beginning of the 20th century to date.

Year	Event	Legislation-Standardization	Publication	Institutions
1905 - 1912	Indemnity law based on a similar law from Bismarck's Germany (1881) was enacted in the U.S. Similar laws were enacted in most western countries by 1930. These laws triggered the transferring of responsibility for errors from individuals to corporations and governments.	Legislation and Insurance		

Year	Event	Legislation-Standardization	Publication	Institutions
1920	British Petroleum Corp. establishes Tanker Insurance Company one of the first “captive” Insurance companies.	Insurance		Starting “Captive” Insurance companies. As of 2002, there are 5000 such companies worldwide.
1921	Frank Knight publishes his book “Risk Uncertainty & Profit” which becomes a basic text in Risk management studies.		The book differentiates between uncertainty which cannot be quantified and risks which can be.	
1926	John Von Neumann publishes a paper on games and strategy, at Gottingen University. In 1953, Von Neumann and Oskar Morgenstern publish The Theory of Games & Economic Behavior.		The article suggests that the “don’t lose” law supersedes the “win law".	
1952	Harry Markowitz publishes in the Journal of Finance an article called “Portfolio Selection”. In 1990, Markowitz wins the Noble Prize.		The article elaborates various aspects of return on investments in a portfolio. The article becomes a cornerstone for sophisticated measures of financial risks which are applied to this day.	

Year	Event	Legislation-Standardization	Publication	Institutions
1956	Russell Gallagher, director of the Philco Insurance Company in Philadelphia, publishes in the Harvard Business Review, an article called “Risk Management: A New phase of Cost Control”.		Philadelphia becomes a center for Risk Management development, from Wayne Snider of the University of Pennsylvania, who suggested that the professional insurance manager should be a risk manager, to Herbert Denemberg also of the university of Pennsylvania, who focused on risk management research.	
1962	Douglas Barlow Insurance Risk Manager for Massey Ferguson, develops the concept of “Cost of Risk”.		The concept compares the self-financed losses, insurance premiums, the cost of losing control of the company, and administrative costs to revenues, assets and stock value. This concept separates Risk Management from Insurance.	
1966	Insurance Institute of America develops 3 tests which become a pre-requisite for appointing an Associate Risk Manager.			This is a first of its kind license for practicing Risk Management. Although in their early stages these tests were biased towards the insurance industry they were subsequently adjusted to a broader approach to Risk Management.

Year	Event	Legislation-Standardization	Publication	Institutions
1970	The OSHA act was passed by the US Congress and signed by President Nixon.	In spite of the fact that as early as 1880 the Federal Government embarked upon safety legislation to instill safety standards and awareness in the coal mining industry, it was only in 1970, after many years of discussions that the OSHA bill was approved. Its goal was to ensure the health & safety of workers.		
1974	Gustav Hamilton, Risk Manager of the Swedish company Statsforetag, describes the concept "Risk management process".		The process defines graphically the interaction between all the process' components: Starting with the risk system throughcommunications and financing.	
1980	The Society for Risk Analysis (SRA) was founded in Washington D.C.			The society was founded for representing public policy, academic and environmental risk management. That same year the publication: Risk Analysis was first published.. In 1999, the society numbered 2200 members, with activities in the USA, Europe and Japan.
1986	The Institute for Risk Management was founded in London. A few years later the institute developed a series of international tests for conferring the associate of Risk Management Degree			The institute developed the first career development program (CME) for all aspects of Risk Management.

Year	Event	Legislation-Standardization	Publication	Institutions
1990	James Reason, a psychologist from Manchester University, published his book “Human Error”.		The book became a basic text for understanding human error and unsafe behavior.	
1993	James Lam from GE Capital, first uses the term Chief Risk Officer			CRO is responsible, professionally, for all aspects of Risk Management in a company.
1995	A multinational task force, Australian/New Zealand, publishes the first standard for Risk Management; AS/NZS 4360 which was updated in 1999.	The standard was the first of its kind and was generic in his approach, meaning that it is not specific to any particular discipline. The standard defines principles and work processes in Risk Management. Canada and Japan published similar standards in 1997 and Israel in 2006.		
1996	Peter Bernstein publishes the book “Against the Gods; The Remarkable Story of Risk”, which quickly becomes a best seller, in Europe and the US and brings the subject of Risk Management to the forefront of public discussion.		The book was translated into 11 languages, and enjoyed a wide distribution. This book gave Risk Management more public exposure, than any other publication, legislation or any other single activity.	

Year	Event	Legislation-Standardization	Publication	Institutions
1997	James Reason, of Manchester University, published his book "Managing the Risks of Organizational Accidents".		This book is the turning point for understanding accidents and adverse events. The basic thesis of the book states, that an accident is an outcome of the systems structure, rather than individual errors. The book illustrates the accident process, utilizing the Swiss cheese metaphor, which became a widely acceptable explanation for how risks transform into accidents.	
1998	First Medical ISO for medical equipment – Standard 14971, was published..	This standard is meant to ensure that medical equipment is developed and manufactured according to strict safety standards for protecting the medical staff and the patients.		
2008	World economic crisis was evident and announced. The crisis has forced new ways of thinking about the way financial organizations manage their risks. This is an important matter as these organizations protected themselves via regulation and Risk Management protocols such as SOX, COSO and Basel.2.			
2009	ISO – the international Standards Organization publishes an international generic standard for Risk Management, ISO/DIS 31000, Risk Management principles and Guidelines on implementation.	The international standard was published after several countries had published their own standards following the publication of the Australian /New Zealand standard in 1995.		

Year	Event	Legislation-Standardization	Publication	Institutions
2009	Announcement regarding the need for Risk Management 2.0 following the economic crisis. Researchers at Wharton University declare the need for a new paradigm for Risk Management. Which they call Risk Management 2.0.			
2009	The Authority for Governmental Companies in Israel, publishes a circular that mandates all the Governmental Companies (more than 40, amongst them Water and Electricity supply) to establish Risk Management activities.	The circular mandates the companies to assign a Risk Manager as a part of the company's managing board, to establish procedures for reporting and analyzing adverse events and periodical risk assessment and reporting to the Directorate.		

From the historical overview outlined above, we may learn that Risk Management has developed along the following discernible steps:

- **First step**: the field developed based on the motivation of individuals to protect themselves from known risks.

- **Second Step**: An attempt was made to divide the individual risks amongst those with a vested interest, in order to lower each individual's risk; this brought about the demand for insurance.

- **Third stage**: scientists began to show an interest in RM and tried to formulate the rules of probability in statistical and mathematical terms.

- **Fourth stage**: at the onset of the industrial revolution, there was a significant increase in the number of risks and their magnitude. A need arose for government involvement in order to restrain new technologies and ensure their safety by legislation.

- **Fifth stage**: which we are currently in, attempts were made to design systems and procedures for reducing risks, procatively, as well as to improve the existing procedures by applying a quality assurance approach.

- **Sixth stage**: whose early signs we are currently witnessing, is the point at which the principles of Risk Management are completely immersed in the culture of Risk Management, which affects all areas organizational activities and not only the traditional areas marked as High Risk.

It may be observed, that the development of Risk Management is the result of an ever-growing exposure to risks on the one hand, and an ever increasing public awareness to the cumulative effects of exposure to personal and environmental risks, along with the development of philosophies and methodologies for Risk Management, all in conjunction with the belief that risks are manageable.

Current thinking on the subject vacillates between rigid rules and indications, defining each individual's place in the organization and their response to any risk, to a more flexible paradigm which relates to specific risks as well as mundane ones, problems as well as opportunities. (Coburn et. Al., 2005).

It was stated in The Economist in 2004: *"Managing risk is one of the things that bosses are paid for, yet most companies still don't have any idea what is required of risk management"*

What motivates Adopting Risk Management Attitudes and Behaviors

We cannot discuss the motivation for Risk Management without expounding on Maslow's theory (1943), which stipulates the need for safety in his article: "A theory of Human Motivation".

According to Maslow, the need for security is paramount, superseding even our physiological needs. When our physiological needs are relatively satisfied, a whole new set of needs arises which are called 'safety needs". If these needs are not met, just as in the case of physiological needs, they become the practical sole "organizers of behavior", so that our safety needs become not only our present behavior organizers but also formulate our philosophy for the future. Everything else pales in comparison to safety. Safety becomes the focus of our lives, often at the expense of our physiological needs.

Maslow concluded that in general, people prefer a safe world, with rules and a predictable order, in which nothing unexpected, which cannot be controlled ever occurs.

In our practice, we have noticed difficulties in organizations, whose safety needs have been met, (meaning, that the organization has not experienced any threat to its existence), to undertake any Risk Management action.

An organization, just like any organism, is driven toward Risk Management activity, when its safety needs are not being met, and not when it feels safe and in control of its destiny.

Following the current crisis, and until the public's faith and feeling of safety are restored, the safety needs of an organization become its "behavior organizers". In this situation, the organization is even willing to forego its basic requirements, its raison d'être, in order to restore safety.

The nature of risks is that they occur more often and cause more damage to organizations which do not feel threatened, and are less harmful to those organizations who manage their risks systematically.

According to Maslow, people clearly prefer familiar situations to over unfamiliar, the known is preferable to the unknown. The tendency to adopt religious beliefs, philosophical principles and values is driven by the need for safety.

Thus, we can also understand the motivation for the acceptance of approaches to Risk Management. Risk Management holds a promise to make the unfamiliar familiar, make the unknown – known, based on knowledge and thereby uprooting all the fear-inducing elements inherent in uncertainty.

A neurosis, in which the strive for safety receives its most extreme expression, is the "obsessive compulsive neurosis". People suffering from this disorder, attempt in the most extreme manner to exert control and stability in the world, thus ensuring that unexpected or unfamiliar events will ever occur. These neurotics protect themselves through rituals, rules and formulas for every situation, all to prevent surprises.

In our opinion, the manner in which the world economic system managed its risks is reminiscent of the symptoms of this neurosis. Over the past few years, the banking system suffered a series of giant embezzlements, which may explain the obsessive steps this system took in order to protect itself from any further embezzlements. Strict protocols, such as Basel2, COSO and SOX are examples of this strategy.

The obsessive need for safety, may explain the demand of many organizations for complex mathematical models, in which known values are entered to project results which are the predictors for future risks.

Many studies have looked at the motivation for employee safety, but few have examined the motivation for organizational safety and risk management. However, it seems reasonable to deduce to some extent from personal motivators to organizational motivators to handle risks.

Stojanovic and Zdravkovic (2002), found a strong correlation between motivations for safety as part of occupational safety, meaning, .employees who developed a strong motivation for "on the job safety", also showed motivation for Job security and vice versa. It is our opinion that this finding reinforces the general concept of safety as a behavioral organizer. Therefore, it is possible that organizations in which many accidents occur, experience a diminished sense of security, and the reverse is true as well.

Recently, studies are published, based on Andriessen's (1978), proposal which recommends not looking at safety behavior as a monolithic unit, but rather at sub groups which comprise it. For example, Ford (2008) differentiates between two types forming safe behavior:

1. **Safety Compliance** – observing safety regulations, such as wearing protective garments, working according to procedures, etc.

2. **Safety Participation** – Taking an active part in activities which enhance Safety awareness in the organization, such as voluntary safety activities.

Psychological empowerment of employees has caught the attention of a number of scholars over the past few years. Lippin et al., (2000), studied this issue in several industries and found that over half of the participants in empowerment based safety training, reported that they or a colleague had improved attitudes to health and safety as a result.

Psychological empowerment is defined from the employee's perspective. The state of empowerment is a cognitive condition characterized by a sense of control in a given situation, a feeling of competence, and internalizing the organization's goals and objectives (Manon, 1999).

The most researched area and most closely related to external safety motivation, is management's influence towards motivating the employees for sounder safety.

Management's commitment has been found to have a significant impact on the organization's safe environment, (Zohar 1980), as well as influencing the safe behavior and outcomes thereof in the organization (Clarke & Ward, 2006).

Zohar (2003), claims that a variety of aspects in the workplace environment, affect different cognitions such as, the goals and expectations, resulting from certain behaviors, which subsequently affect further behavior. This behavior is what ultimately impacts the accident rate at work.

Ford (2008), suggested a four dimensional model of safe behavior and examined which variables affect them. The premise is that it is possible to analyze safe behaviors according to a time frame: future or present, according to object which they might affect: self or others. The following chart details different safe behaviors according to the four dimensions.

	Self-Focus	**Other-Focus**
Present-Focus	• Self-protective behaviors to prevent acute injuries. • Safe performance of work tasks that do not impact others' safety.	• Helping others perform work tasks safely. • Safe performance of work tasks that impact others' Safety.
Future-Focus	• Becoming knowledgeable in work hazards and legal issues related to safety. • Behaviors that prevent cumulative injury and health decrements.	• Participating in health and safety committees. • Behaviors that contribute to the shared responsibility for a safe working environment.

(Adapted from Ford, 2008)

Ford (2008), found that psychological empowerment of employees, management commitment to safety and identification with the organization, are more closely linked with safe behaviors related to others, than those related to personal safety. Of all the examined variables, psychological empowerment had the most profound influence on behavior with far reaching ramifications, ergo relating to future and others.

In this regard, we must say, that in many interactions with medical staff, regardless of profession or seniority, we have witnessed almost universally, a lack of any sense of psychological empowerment. Oftentimes, medical staffs perceive themselves as being caught in a catch 22, between management's demands to provide high quality and safe medical services on one hand, and strict observation of time and resources devoted to each patient, on the other. This of course, in addition to pressure from patients to provide them with the most advanced medicine, and threat of litigation and legal issues as well.

Under these circumstances, it seems that medical staff has no cognition of empowerment but rather the exact opposite. It can be said, quite safely, that they have no sense of control in this situation, they do not feel capable and it is reasonable to assume that they lack a strong sense of identification with the organization, its goals and objectives.

Psychological empowerment, which has lately received a lot of attention in understanding worker motivation, particularly in light of its obvious affect on safety, requires, in our opinion, special consideration by managers of health care organizations.

The implications of the current global financial crisis on Risk Management Thinking

The world economic crisis, which came to public awareness in 2008, and which is still with us, raises fundamental questions with regard to the way large corporations and governments manage risks.

Paradoxically, financial institutions in the West were pioneers in managing risks in a systematic way. Protocols such as SOX, COSO and Basel2, defined how and what a financial institution needs to do in order to manage its risks properly. Despite their uncontested importance, these tools were unable to prevent the collapse of large financial institutions to the point of a global crisis.

In our opinion, formal bureaucratic processes of Risk Management can deal with known risks, but they are unable to deal with unknown risks. This is a major trap of the traditional RM thinking, being reactive, and based on past experiences.

We believe that risk management is a soft discipline, which functions in a constantly changing reality, both inside and outside the organization. It is constantly searching, analyzing, controlling and monitoring risks, while examining its own mechanisms and learning from adverse events. It is dangerous for Risk Management to rely too much on quantitative models while ignoring the qualitative approach and the value of common sense.

An article published in "Knowledge Wharton" (2009), presents a model of Risk Management and the current financial crisis. The article mentions that complex mathematical models that were developed in order to predict business results and probabilities, based on past performance, failed miserably to prepare companies for the current crisis.

Richard J. Herring, Professor of International Banking at the University of Pennsylvania, Wharton Management School, writes in the above mentioned article: *"I think we've learned a lot recently about the limitations of models. We've also seen that the governance of risk is not as good as it ought to be."*

The current economic crisis emphasizes two important points with regard to Risk Management, which reflects on the future of this discipline:

1. Business people, economists and academia treat risks differently than managers of companies. The most important issue for the first group with regards to risk is the diversity, whereas for company managers it is the potential damage as a result of risks materializing. If the risk for loss or damage is too high, managers, in most cases, will retreat.

2. Risk Management does not have a magic solution (Silver Bullet) for solving all risk problems all the time. As a result, companies wishing to deal with risks in a serious way need to develop a more integrated approach to the subject, rather than classifying them into groups: operational risks, market risks, credit risk, etc.

Herring, says that most managers in the area of risk management specialize in a particular type of risk, for example credit risks, and therefore do not have the expertise to think about other type of risks. He feels that without an integrated view of Risk Management activity in an organization, serious problems may occur.

Michel-Kerjan Erwann (2009), Managing Director of the Risk Management and Decision Processes at Wharton School, while referring to the current events in the global economy, says that a new risk management format is rising, which he terms Risk Management 2.0. He says that every field exhibits similar trends: changes are faster and this requires making immediate decisions based on data which is not always available. It is always better to collect all relevant data before making a decision, but in reality according to Michel-Kerjan, managers must make decisions in situations of uncertainty and sometimes in situations of no data whatsoever. In order to deal with the new reality, many companies around the world are moving beyond the traditional Risk Management model labeled as "Risk Management 1.0", which deals more with the current situation of the company and an analysis of what might go wrong. Actually, for companies to manage their risks properly, they must look outside, because companies worldwide have become depended on each other, more than ever before.

Michel-Kerjan continues and says that we have become accustomed to solving problems in which the questions are clearly stated and based on clear scientific know-how and knowledge of the historical profile of the problem. However, historical data can not predict the future in situations where the rate of change is so high. We used to study past data and draw nice diagrams, on which the severity of the damage appeared on one axis and the probability of risk occurring on the other axis. This was Risk management 1.0, which in many ways has become irrelevant.

As part of our consulting business in Israel, we also consult to Mekorot, Israel Water Company. Nine months ago, during the 2nd quarter of 2008 we were asked to perform a Risk audit for Shacham Ltd., a daughter company of Mekorot, which provides most of the infrastructure work for water network to the tune of 100 M euro per year. The Risk Audit was performed during Q III and QIV of 2008. A series of risks became evident and they were evaluated according to their severity and probability , utilizing the traditional models of risk management. Out of the critical risks, we emphasized the risk of difficulties in recruiting professional employees and the uncertainty with regard to the actualization of several large projects.

Towards the end of 2008 and beginning of 2009, when the report was presented to Shacham's management, it was evident that the world is in the midst of a deep economic crisis which will undoubtedly affect the employment market in Israel and the Israeli government’s policy with regard to the execution of large water projects. This received further emphasis when it became apparent that 2008/09 is a drought year.

The government of Israel appointed a special committee to investigate the reasons for delay in the development of Israel's water infrastructure and especially the development of desalination plants.

In less than six months, risks that were determined as significant for Shacham and Mekorot turned out to be less critical, since it is much easier to recruit high quality people among the many laid off workers and also the Government approved the start of many new projects, which had been delayed for many years. Obviously, the new reality created a favorable environment for the creation of new risks that were previously unknown.

Our conclusion, which was our position from the onset of our Risk Management activities, was that Risk Management must be as dynamic as the rate of change in the specific discipline for which the Risk Management is being conducted. Otherwise, Risk management is both unnecessary and even risky.

According to Michel-Kerjan, Risk management 2.0 will have to deal with unknown risks and the relationships between the different risks since it will no longer be possible to treat each risk separately.

Tony Blair, former British Prime Minister, was quoted in the WEF (World Economic Forum), Global Risk Report 2007: *"Interdependency is the defining element of the 21st century".*

This situation has many advantages, but it also exposes the economy of a certain country to risks, which result from its relations with other economies, and not only from risks, which are inherent in its own economy.

Philippe Hellich, Vice President of Risks at Danone, was quoted in "Knowledge Wharton" (2009) article, saying that he is implementing the new approach. He said he makes little use of mathematical models, although they are used for risks which are certain. His company relies more on interviews and benchmarking with colleagues outside the company and in sister companies around the world. The current approach is based on listening, challenging the operations managers with questions, analysis of risks based on common sense healthy judgment and good management from the top.

Peter Bernstien (1996), in the last pages of his book “Against the Gods” predicted the difficulties which many companies worldwide face today:
"Nothing is more soothing or more persuasive than the computer screen, with its imposing arrays of numbers, glowing colors and elegantly structured graphs…..As we stare at the passing show, we become so absorbed we tend to forget that the computer only answers questions; it does not ask them.... Those who live only by the numbers may find that the computer has simply replaced the oracles to whom people resorted in ancient times for guidance in risk management and decision-making."

Rosenzweig (2007), in his book "The Halo Effect and Eight Other Business Delusions That Deceive Managers" agrees with Bernstein's approach and writes:
"I would caution executives not to rely on models that are appealing for their apparent sophistication. They may delude us into thinking we've understood the underlying factors, when really we've done nothing of the kind. It's what I call the Delusion of Rigorous Research -- if the quantity of data is impressive, we forget the underlying quality may be bad.

Seems like, the field of Risk Management in large corporations is changing and with it the position of the Risk Manager.

Risk Management, after the current crisis, places the Risk Manager in a position which is different than that of just applying techniques, methodologies and models. He is now in a position of integrated strategic thinking, while observing all the various activities of his organization and the relationships between them, as well as studying the outside reality and its influence on the organization.

Risk Management 2.0 is no longer a field which is detached from the main activity of the organization, but is part of it – influenced by the activity as well as influencing the activity. Risk Management 2.0 is flexible and constantly examining existing paradigms. It challenges managers and workers in the organization with fundamental questions, without worrying about the slaughter of “sacred cows”, in order to ensure that the organization survives and prospers.

Chapter 4

Aviation and Healthcare

Give me the courage to understand my errors today, so that tomorrow I will be better able to see that which I could not see in yesterday's muted light.

Moses Maimonides: A preeminent medieval Jewish philosopher, rabbinical scholar and physician. (1135-1204).

The airplane has unveiled for us the true face of the earth.

Antoine de Saint-Exupery Aviator and Writer -(1900-1944)

Risk Management – From Aviation to Healthcare: A personal perspective

With the publication of the IOM reports (Kohn, Corrigan and Donaldson, 1999, 2001), and even back in the 1990's, as interest increased in medical errors due to increased cost to the public, Healthcare leaders started to search for solutions from other professional content worlds (chapter 6.1).

Aviation**,** following the progress displayed over years since the end of WWII, and the decrease in errors and failures causing accidents, formed a model for imitation.

The trend towards getting inspiration from Aviation, emerged during the 90's and was prevalent in every aspect, starting from papers dedicated to presenting the scope of the problem in medicine (Leape, 1994; Berwick and Leape 1999), to analyzing the unique criteria of aviation risk management in areas relevant to medical care systems (Leape 1994), and as far as President Clinton's pronouncements following the release of the IOM report (President Clinton, 1999, 2000).

As we mentioned previously (chapter 6.1), during the mid 90's, as a result of our professional development and our exposure to the medical field, we have decided, out of professional challenge and business interests, to offer the experience we had accrued in aviation risk management to healthcare organizations.

From the onset, we encountered two major reactions:

- **"It won't work"** – as there are distinct differences between aviation and healthcare, it was assumed that what works for one would not for the other. Most supporters of this approach presented a long list of contextual differences. Some of these differences were meaningful and we were compelled to address them. One of these was the, manner in which medical tasks are performed, variations which inherently increase the uncertainty in which medical practitioners perform, compared to aviation, which strives for standard and uniform performance.

- **"It sounds interesting"** - Supporters of this approach, did not immediately dismiss our proposal to learn from the aviation industry, based on two factors; firstly, there was no better option in sight and learning from a successful model was appealing. And, if there is a need to choose an industry to follow, aviation due to its image and credibility, appealed to the doctors, who felt good about aligning themselves with the pilots.

As mentioned, we dealt with these issues in depth regarding the Macabi project (Chapters 6.1-6.3) It was clear to us that unless we fully comprehend Macabi's attitude both in favor and against the aviation model, we will be unable to proceed beyond the initial enthusiasm towards a solution. Macabi's risk management team was in a state of both ideological and practical dearth, as they searched for a solution to their needs.

At this point, our familiarity with health care was minimal and did not enable us to manage the project's risks while being aware of the cultural, organizational and political nuances, which are part of risk management in healthcare.

It is reasonable to assume that were we to start this project today, we would pay greater attention to the differences and not just to the similarities, as we did at the time. It could be said, that at the onset of our work with Macabi, we choose to focus on the similarities and assume that these outnumbered the differences.

Therefore, we had a firm base to believe that the principles which worked for aviation would indeed succeed in Healthcare.

The common elements to which we attributed special importance, were those related to the high quality committed professions; the need to be capable of executing tasks with utmost concentration, the constant change and innovation of technology and procedures, the high sense self awareness particularly in the psycho professional components and less in the environmental, organizational or tasking aspects. It seemed to us at the time, that there was a common thread in the psycho professional profile of pilots and physicians and that was a promising starting point.

Macabi asked for assistance in risk management, we accepted their request and hoped to provide them with assistance, based on the experience and insights we gained in aviation. We should mention that this was our preferred mode of intervention. Our communication with Macabi was a verbal one, which included many hand signals, in order to create a cross-cultural communication mode and enable us to share our insights with them and for them to explain their needs to us.

Actually, today it is quite clear that we learned a lot about aviation and aviation risk management from the Macabi project. In addition, in order to provide a solution to this cross-cultural “transplant”, which required us to delve more deeply and refine the practice of Aviation Risk Management, as we were implementing it with Macabi.

The goal of this chapter is to examine the similarities and differences in Aviation and Medicine, pertaining to risk management.

Pilots & Doctors

We believe that pilots & doctors, share several professional characteristics. However, the more significant question is whether healthcare systems and aviation systems share anything in common? This question is most important in light of the fact that we are advocating the case for a systemic approach to risk management.; an approach, in which the system has its own significant weight, contributing to accident prevention versus the professional at the “sharp end“, (Reason, 1999).

Eric and Helmreich (2002), argue that doctors and pilots share many similarities. Both, are highly trained professionals who must go through many years of training, both operate in very complex environments, in which teams are constantly interacting with advanced technology. In both working environments, risks vary from very low to very high and the professional teams are forced to deal with varied threats from a variety of sources. Safety is a major concern in both disciplines, but financial considerations often have crucial impact on investments in risk management. When an error occurs, litigation and a demand for tougher standards present a threat in both sectors.

The similarity in tasking can be observed especially in the operating theater and intensive care units, compared to the cockpit of a passenger plane. In both situations, success hinges on communications and good teamwork involving all members of the team.

Helmreich & Merritt (1998), examined the different aspects of professional culture amongst pilots and operating theater physicians (surgeons and anesthesiologists). They have developed a questionnaire to determine the attitudes in their relation to different approaches, stances and professional performance (FMAQ – Flight Management Attitudes Questionnaire).

The questionnaire was administered to 40,000 pilots in 40 different airlines in 25 countries. A similar questionnaire, adapted for doctors, was presented to over 1000 medical staff personnel in 4 countries.

The responses to the questionnaires by both the doctors and the pilots exhibited similarities between the two groups, some could be considered as positive and others less so.

On the positive side, both groups exhibited a discernible level of pride on belonging to an elitist group which demands stringent selection and extensive training. On the negative side, both groups tend to deny personal vulnerability, claiming that their ability to make decisions is equally good in both emergency and routine situations, Both claim that they are able to leave personal considerations behind, while working, and that their skills are not diminished when working with less experienced team members.
A significant percentage of doctors deny the negative impact of fatigue on their performance.

These aspects of professional culture have an impact on flight safety as well as on the quality of medical care and thus on patient safety.. The authors continue to argue that professional pride pushes the doctors and the pilots to do their best, but the attitude of personal invulnerability potentially harms their perception of the criticality of teamwork and the need to take preventive measures needed to reduce the probability of risk.

The Pilot

Studies which attempted to present “a profile of a typical pilot” usually found a number of profiles and not a dominant one. Therefore, there is no ground to define one personality type, which could explain success as a pilot.

Christy (1975), in an excellent study describing “The outstanding fighter pilot”, found that most were first born, or some facsimile of a first born, with close relationship with the father, who strengthens the “positive male identity”. One of the interesting outcomes of this study states, that 21 out of 23 of the first astronauts were first-born sons. The outstanding pilots were described as self confident, challenge seekers, ambitious for success and not introspective. In addition, they were characterized as intelligent, mature and emotionally stable, action oriented and easy to adjust.

A follow–up study of 350 air cadets in the US Air Force over ten years, which was published by Berg et al. (2005), revealed three typical types of pilots in their sample:

- **"Typical military pilot" – 58%** of the sample was described as being competitive, dominant, easy going and stable.

- **"The right stuff" – 21%** of the sample, was found to be similar to the first type and in addition was described as being particularly aggressive, dominant, self-aggrandizing and exhibitionist.

- **“Wrong Stuff” - 21**% of the sample were described as cautious, obsessive and anti social.

A similar study conducted on experienced military pilots by Picman (1991); using the OPQ- Occupational Personality Questionnaire, found three different profiles:

- **Methodological Extroverts – 48% of the sample.** This group was characterized by a strong need to control their environment and a need for innovation and change.
- **Introverted Worriers – 36% of the sample.** This type was described a worrier, emotionally controlled introverted and not very social.

- **Competitive Individualists - 16% of the sample.** This type was described as competitive, very independent and decisive.

It seems, that there are similarities in the types as described in the two studies presented herewith, in spite of the fact that they were conducted on differing samples and at different times.

The three latter profiles were also found in a study on space pilot candidates in the final stages of assessment (Musson et al. 2004).

It should be noted that most of the studies conducted on pilot personality profiles, focused on the top percentile of outstanding fighter pilots or astronauts, primarily men. Information is missing regarding the relevancy of these studies in regard to transport pilots, helicopter pilots, civilian pilots and women.

In an attempt to find a relation between the personality traits and performance, it has been found that Conscientiousness is the best predictor of the five big personality traits; this is in comparison with neuroticism, extroversion, being open to new experiences, and agreeability. (Siem, 1994).

Boyd et al. (2005), explored the differences between personality traits of pilots flying different types of aircraft; fighter planes versus transport/fuelling planes. In the 5 big personality traits, the fighter pilots got higher marks for conscientiousness and lower on the agreeability scale. Likewise, fighter pilots ranked higher in assertiveness, activism, challenge/satisfaction seeking. Fighter pilots ranked lower on fears, self-awareness, vulnerability, warmth and gentleness as compared to transport/fuelling pilots.

Helmreich and Merritt (1998), pages 6-12, describe the world of commercial airline pilots in the following manner:
"Although separated from their company and its managers, crews don't operate in a vacuum. They are members of an airline that has formal rules governing the conduct of their jobs. Their flights are conducted as a part of a complex and regulated aviation system that has formal rules for the operation of the aircraft. The specific direction of flight is coordinated by air traffic controllers who issue commands by radio regarding navigation, speed and destination, based on formal flight plans filed by each company. During flight, crews must also coordinate their activities by radio with their company's flight operations department"

The Doctor

It is worth noting that just as most studies on pilot's personalities were conducted on fighter pilots and space pilots, thus most of the research conducted on doctor's personalities, have focused on surgeons and anesthesiologists, and very few on family practitioners.

King et al. (1975), tried to confirm or debunk the established stereotype of the surgeon versus the internist. The stereotype of surgeons versus internists, according to this study, was described as following: Surgeons are more aggressive, intransigent, insensitive, aloof, hostile, extroverted, impulsive, energetic and ambitious.

At least at the stereotypical level, these traits are reminiscent of the "Right Stuff" fighter pilots mentioned by Berg et al. (2002). The study was conducted by interns at Boston City Hospital. Most of the traits mentioned in the stereotype were not verified by the study.

Surgeons were indeed found to have impulsive tendencies, more intransigent in their approach to problem solving and demanding more information and detail, they were more realistic, tending towards formal procedure and fact based.

Shuenman et al. (1985) studied 141 surgical Residents using an array of psychological tests. It may be stated, that no correlation was found between the test results and surgical performance. There were a few predictors of surgical ability, but they seemed rather baseless. For example, "left handed women were less successful residents than their male colleagues".

It could be assumed that motor dexterity is paramount to surgical success, but several facts dispel this thought. Psychometric capabilities do not differentiate between gifted & mediocre surgeons. (Squire et al. 1989; Steel et al 1992).

Wanzel et al.(2002), conducted tests to evaluate surgeons' special vision abilities. They chose complex surgical procedures as a measure for results and proved that these tests could predict the performance of novice surgeons.

Greenburg et al. (1984), examined senior surgeons' positions regarding their views on what constitutes a "characteristic surgical personality". There was a high level of correlation between the respondents regarding the following: honesty in cases of error, discipline, ability to incorporate all available information, motivation and staying power.

Shuenman et al. (1984), found that the foremost personal trait which is the best predictor of a surgeon's ability, is "stress tolerance" as tested in the State Trait Anxiety Inventory.

Two additional studies show that surgical residents are more introverted and conscientious (Deary et al. 1992), they are more intuitive and cautious. "Intuitive" was defined as a tendency to gather information using the 6th sense and then attaching meaning to the information. "Caution" was defined as organizing and structuring of information in order to make logical and objective decisions, Fitzgerald, (1993).

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Ferguson et al. (1994), examined what were the predictors for success during the course of 5 years of medical school. They discovered that teacher's assessments did not predict achievement levels. Responses given on a Personal Statement Questionnaire were predictors of success in clinical studies, whereas an A grade was better able to predict the Para clinical success. Personal traits, such as conscientiousness was found to be the most stable predictor during school. Conscientiousness was found to be directly related to A grades and to Para clinical performance and a negative correlation to clinical grades.

Clarke et al. (1994), handed over 300 anesthesiologists a questionnaire on personality assessment (16PF), in addition to a demographic questionnaire and a job satisfaction survey. They found that the anesthesiologists' personality profile described by Howat (1977) was unfounded. Howat claimed that a typical anesthesiologist wants to be part of a team, naturally gregarious with a sharp sense of humor and seeking change. Both Clarke et al., and Reevel (1980), show that contrary to the accepted stereotype, claiming that most anesthesiologists have high job satisfaction, and are classified as highly intelligent, dominant yet sensitive, independent yet slightly lacking in confidence and somewhat tense. Likewise, they are tolerant, bashful and serious. There were some differences between differing age groups, married and unmarried doctors and between men and women.

Helmreich & Merritt (1998), pages 12-17 describe the operating theater environment:
"A milieu where a number of professionals must come together to perform multiple and complex task in a noisy and cluttered environment… A number of subgroups- surgeons anesthesiologists, nurses, technicians and orderlies, must coordinate their activities to complete the operation successfully. Other than the well-being of the patient, individuals and subgroups may have different and competing agendas and requirements. Adding to the complexity of the environment, the condition of patients is highly variable and frequently unpredictable….. Status inequalities in the OR are pervasive and readily observable. However, the authority structure in the OR is not clearly defined…"

Aviation and Healthcare: A Comparison

In the chart below, we have presented a comparison of the typical characteristics of the two professions based on Helmreich and Merritt (1998), and also insights based on our professional experience. The comparison relates to the characteristics of the environments of commercial aviation and medicine, with an emphasis on the hospital setting.

Topic	Aviation	Medicine
Professional Training	Lengthy- LLL- Life Long Learning	Very lengthy - LLL- Life Long Learning. Physicians are obliged to be continuously updated and to practice accordingly to the state of art medical knowledge.
Type of Training	Some theory , mainly practical, hands on and simulators emergency training	A lot of theory and increased practical experience as training progresses.
Performance assessment after graduation	Regular assessments, formally at least once a year. Failing to pass minimum requirements results in loss of license.	Performance is assessed regularly as part of training until receiving formal expertise degree. No further routine assessments.
Type of Tasks	In civil aviation, usually routine, very seldom requires coping with problems or emergency situations. In ,military aviation, especially fighters, many uncertain scenarios pushing the aircrew to the edges of physical and psychological performance. In some types of civil aviation e.g. flight rescue operations or air fire fighters, the task profile resembles the military one..	Non-routine. There are many differences between patients, even when conducting similar procedures. In the hospital setting, frequent emergencies and complications. In the ambulatory setting many "false alarms" requiring continuous alertness to be able to identify and treat timely the real emergency conditions.
Applying New Technologies	Many years between “generations” of evolving technologies.	High rate of change & innovation. Large amount of new findings published continuously in professional journals.
Teamwork and professional interfaces	A clearly structured hierarchy, including a clear job allocation. Teamwork is part of initial training and essential factor in success or failure.	Undefined job interfacing is common, also systems interface is blurred, relations within the team are not defined, and teamwork is not part of basic professional training. Recently, teamwork is getting more attention due to malpractice investigations that highlight the importance of sound teamwork and communication to assure patient safety.

Topic	Aviation	Medicine
Professional supervision and control	Routine checks are part of the task, including audio and video recording for debriefing at end of each flight	Hardly any. There is no recording of any routine activities and no debriefing and study- only in cases of severe adverse events and complications. The basic assumption is of "Master – Apprentice".
Commitment to the profession	According to Helmreich and Merritt (1998), who canvassed 40,000 pilots in 25 countries on job satisfaction, got an average of: 4.7 out of 5. This degree may be compared to job satisfaction of senior managers conducted in Cornell (1995), which found 54%, to be satisfied.	According to Helmreich & Merritt (1998), who asked 500 medical professionals in 3 countries, the same question, job satisfaction was ranked on the average of 4.2 out of 5.

In one of Israel's hospitals, in which we assisted the risk manager to build a risk management plan, we revealed how difficult it was to apply clinical results of any significance to patient safety. When we asked, why the new procedures were not Being implemented, we were told that it was due to a disagreement between the chief of anesthesiology and the chief of surgery, regarding who would be the one in charge to carry out the implementation. We understood that despite its importance for patient safety, a lack of designated authority and manager's egos were a hurdle in the implementation of the new findings, aimed at improving patient safety.

Following is a comparison chart between Aviation and Medicine, according to selected Risk Management parameters.

Topic	Aviation	Medicine
Frequency of Accidents	Very Low. Civil Aviation is considered to be the safest means of transportation and it becomes safer each year. Military aviation, by its nature is accident prone, but the western military aviation, is making great progress in lowering accident rates in the last decades.	High: 2.5% - 4.5% of all in-patients, according to various sources. There is a large dispute over the issue of the accident rates in medicine, mainly because its difficult to separate the iatrogenic factors from the patients condition, which in many cases is complex.

Topic	Aviation	Medicine
Public Visibility	Very High - In most of the cases an aviation accidents involves many people and becomes easily and rapidly a leading news item.	Low, except in cases of litigation, complaints or a dramatic case involving the media..
Extent of Damage	High- large scale loss of life and resources. In all of the cases the crew is exposed to similar risks as the passengers. In some cases the accident involves loss of reputation and professional credit.	Usually harm and losses are on the individual level. Nevertheless, we witness more and more considerations to the issue of "The second victim" according to which the involved medical staff, suffers psychologically from the error and in some cases even from PTSD.
Detriment to team	Crew is as vulnerable to injury/death as the passengers.	Team is not susceptible to physical injury, but rather to psychological, professional prestige & financial damages.
Post Accident activity	Usually documented in a dedicated database and in-depth investigation & enquiry ensue. Results are published as well as recommendations for risk reduction. In cases the failure was technical, worldwide fleet of similar airplanes may undergo checks.	In-depth, investigation & enquiry are rare. Publicity is mainly from a media viewpoint or in cases of litigation or patients complaints.. Insights and recommendations are published and implemented locally.
Accident management procedures	Procedures are in place for receiving, sorting, managing, investigating and documenting the adverse events as well as making them public. Separation exists between procedures aimed to compensate the victims and their relatives and between the need to learn lessons from the accident in order to prevent the next one.	No standard procedures. Each organization creates its own standards. In Israel, legislation hinders debriefing adverse events without exposing involved parties to claims. In other western countries e.g. Denmark, the system provides compensation to the harmed patient without legislation and without the need to prove malpractice. This kind of approach, similar to that of Aviation, enables separation between the need to compensate the harmed and to learn lessons from accidents.

Topic	Aviation	Medicine
Approach to Errors	Encourages reporting, including near misses, as an opportunity to learn and derive insights in order to prevent reoccurrence Resources are allocated for systematical procedures of debriefing and learning from errors in order continuously to improve the system. Culture of "No Name, No shame and No blame" is promoted and backed up by senior management.	A philosophy of no tolerance for error, forces doctors to strive to achieve error free performance.. Errors are perceived as carelessness and malpractice. Doctors and nurses are taught that perfection is attainable and that error is a result of carelessness (Jones 2002). Change is underway leading to more transparency in a "No Fault" culture.
Victims response	Morrison & Harris (1991), found that even 5 years after an accident, victims and their relatives will still be suffering emotionally and often exhibit PTSD.	Victims demand litigation and compensation, mostly for physical injury but also for "anguish". The issue of "The second victim" is recently getting more attention. There are recorded cases of doctors involved in serious errors suffering from PTSD (Bub, 2005).

Odegard (2000), compares the formal aspects of risk management in aviation and medicine and recommends adopting the aviation approach. He recommends developing organizational systems at a national level as well as multi national health organizations whose function will be risk management as currently managed by the aviation industry. Additionally, he recommends that healthcare follow the aviation industry's routine testing of health care practitioners to ensure their proficiency as well as reducing shifts and constantly learn from adverse events.

The following table shows Odegard's (2000) comparison between aviation and health care risk management.

Type of activity	Organization for work concerning safety	Regular proficiency tests	Restrictions concerning length of work shifts*	Regular risk analyses
Civil aviation	Yes	Yes	Yes	Yes
Health care sector	No	No	No	No

A variety of resources developed by the aviation industry, serve both for immediate response as well as crisis management of adverse events as they unfold. They also serve as investigative and learning tools, both during and after an event and aid in outlining large-scale action plans capable of revealing substantial risks.

Over time, the aviation industry has placed safety as a primary focus of air transportation safety and has developed a series of methodologies and data gathering systems geared to enhance aviation safety.

Healthcare attempts to adopt these methodologies, understanding that lacking quality, systematic and current information about errors, risks and adverse events, the industry will be unable to make any substantial steps to improve patient safety.

The following table exhibits information sources for risk management used by the aviation industry and the manner in which it implements each of these methods for improving its safety practice, as compared to those utilized in medicine.

Source	Aviation	Medicine
Reporting of Adverse Events	Lots of available systems exist for reporting adverse events and "near misses' on international, national and organizational levels. All of the systems are characterized by a "No-Fault" policy being non-punitive and anonymous. Of note: ASRS – (Aviation Safety Reporting System), (Reynard 1986). FAA- (Federal Aviation Administration). ASRS) which receives over 30,000 reports annually. ASAP – (Aviation Safety Action Partnership), which enables pilots to report adverse events to their companies under the same anonymity conditions as ASRS. Since all this reporting is on a voluntary basis this information cannot be used to assess the actual level of potential risks. (March, Sproul & Tamuz, 1991).	There are numerous systems for reporting errors and & adverse events. In most of the cases the systems are on a organizational level. Most common is the report to the malpractice insurer, for whom a comprehensive report is a precondition for insurance coverage. Compared to aviation, there are hardly any national level reporting systems and most of the existing systems are organizational. According to (Barach & Small 2000), there are more reporting systems for anesthesiology events, cytology, trauma, occupational medicine, heart surgery, pharmacology and nursing. From our experience it is more commonplace to encounter reporting systems on nursing errors, and medication and rare to find such

		systems for doctor errors. In 2000, the VA- Veterans Administration, announced the establishment of a national database for medical "near misses", in cooperation with NASA (VA Plans No Penalty Medical error reporting, 2000). Also, the JCAHO (Joint Commission on Accreditation of Healthcare Organizations), requires hospitals to establish reporting systems and investigate Root Causes (RCA), which are part of the reported events. (Kohn et al 2000). The main impediment for reporting is and has been the fear of litigation (Brenan, 2000).
Error and Accident Investigation.	Investigation boards are assigned in cases of events with severe consequences or serious “near misses”. There is a methodology in place as well as specific investigation training. These investigations are often conducted by outside risk management specialists. Routine events are handled and debriefed by in-house investigators.	Investigations are rarely conducted, except high profile cases of public interest. Occasionally the government (Ministry of Health) investigates when it receives complaints. The connotation of these investigations is often disciplinary and they are published long after the event. There is no standardized methodology for investigation of adverse events in Healthcare and formal training is still rare. In the 2010 academic year, a risk management certificate program will start at the University of Beer-Sheba Medical School, sponsored by IMA (Israel Medical Association), aimed to qualify professional risk managers for the Israeli Healthcare system. .

Source	Aviation	Medicine
Data collection while performing the mission	Widespread use of data collection tools, as part of operations protocol and ongoing as tasks are executed, (i.e. FOQA – Flight Operations Quality Assurance), data for each task is constantly recorded, and investigated in cases of deviation from required procedures	We do not know of any such system in place for Health Care. Clinical records for medical purposes, may serve as data source for debriefing adverse events.. The quality of the records may be a finding by itself in the debriefing.
Assessment observation during operations	A methodology called LOSA (Line Operation Safety Audit), developed by Texas University over 15 years (Helmreich, Klinect, Wilhelm & Sexton 2002) is utilized by some airlines. This procedure conducts a well-structured observation during routine flights and records flight risks, errors & error management. LOSA was carried out in 40,000 flights and revealed, at least two errors and two flight risks in every flight. In 2006, the FAA (Federal Aviation Administration) approved the LOSA procedure as a means of enhancing flight safety, which is not mandated by regulation, but enables aviation companies to apply it voluntarily. (Ballough 2006).	According to Helmreich & Eric (2002), operating theaters are the primary medical entity; it is in that context that flight risk management was applied to healthcare. Andrews et al (1997), observed surgical teams in a Chicago academic hospital and found that 17.7% of surgical patients suffered at least one adverse event during the surgical procedure. Similar studies of this type found that problems in surgical teamwork and poor communications were serious impediments to surgery safety. However, it must be noted, that this was not part of an ongoing routine observation of operating theaters, but rather a sporadic episodic observation, as part of a study. . Tal, Segal, Lichtenfeld et al. (2007), presented an experience-based approach to the study of risk management in health care. Which One of its components is PRMC (Personal Risk Management Coaching). In this component, risk management professionals observe the behavior of medical staff at work and provide them with feedback directly related to behavior with high-risk potential to patient safety.

Source	Aviation	Medicine
Simulation	Simulation is widely used as part of training and certification process. Simulation is a primary source of information regarding flight safety risks. Emergency procedures are mainly instructed in simulation facilities.	Use of simulators is on the rise for training of medical personnel; Particularly procedural simulations and most specifically in anesthesiology (Kapur & Steadman 1998). In Israel's Sheba Medical Center, operates a medical simulation facility which conducts a wide range of activities; starting with selection of medical school candidates, preparation courses for interns, and topic specific programs for advanced medical teams. .

Since we believe in the organizational approach, as a hotbed for error and as this is the main playing field of risk management, we will address a common problem in patient safety namely the "continuity of care" problem or Transient Patients.

We will compare how the aviation industry copes, as an organization, with a challenge that resembles the risks involved in "Continuity of Care".

The problem is both well known and one of the most crucial in Healthcare and as such, can be a risk factor for patient safety (Coleman and Berenson, Haggerty 2003, 2004).

The problem consists of several variants:

- Interface between the hospital and the community; moving patients to and from the hospital. The inherent risk factors are: lack of knowledge on the patients' medical background and the difficulty in ensuring continuing care in the community.
- Hospital care – Lack of integrative and updated information of the patients care program, what needs to be done and what has already been done. The inherent risk factors are over- treatment or lack of critical treatment.
- Community Care – Moving between many caregivers. The inherent risks are: insufficient communication between the various caregivers, depending on the patient as the conduit for information between caregivers, lack of a single integrated and updated clinical record so all caregivers can see what has been done and what needs to be followed through, and who needs to do it.

- Post discharge information –results of tests conducted while hospitalized, which are received post discharge. In some cases, these results may be pathological and may require immediate attention and treatment.
- Transfer between different departments – while moving the patient between different departments in the same facility, information may often not be transferred along with the patient, which may be necessary for ensuring quality and safe care.

It is possible to conclude that the information available to the caregivers in each interaction with a patient is at best partial and by and large is based on what the patient is able to report on his condition. It is important to note that there are healthcare systems which have existing protocols meant to minimize the risks inherent in patient transfer. Recently, some medical organizations, e.g. Maccabi, introduce a centralized EMR (Electronic Medical Record), which enables, each physician to review patients entire medical background. Still even this centralized EMR doesn't solve the problem of interfaces between different medical organizations treating a particular patient.

The phenomenon of “transfer” between "caregivers" is common in aviation as well. Each aircraft is supervised by the control tower at each airport, and while on route he passes through a number of control units on the way to its destination. . At any given moment, during the flight from taxi and take off at airport A to landing and switching off at airport B, every step of the flight is monitored and supervised. There are clear international standards for passing between checkpoints. The minute contact with an aircraft is lost, one of two things have definitely occurred; failure in the aircraft’s communication systems (highly unlikely in today’s advanced technology), or that the craft is in some kind of distress. The time lapse from loss of contact to discovering that the plane is in distress is usually miniscule. Control and Supervision provide the plane’s crew with data and constant updates, for ensuring flight safety; including distance from other aircraft, and weather forecasts. In emergencies, all these assist the pilot for optimal emergency management.

Control and monitoring systems for patients actions, while in treatment process, are practically non-existent in health care. Continuity of care depends mainly on the attitude and mind set of the doctors and other caregivers at the various points of treatment.

Errors such as misdiagnosis or delayed diagnosis, lack of vital medical treatment, over- treatment, losing track of the patient for follow up, non-administration of urgent care, etc. are typical of the problem. The problem also exists in the administration of preventive medicine, such as in screening of high-risk populations for serious illness

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It may be stated, that the above example is a clear expression of one of the paramount differences between aviation and health care. Aviation operates as an integrative system, both locally and globally, it incorporates monitoring and controls, as a primary value at each and every step of its operations. Whereas Healthcare still operates on a “point of service” approach in which each station provides the best possible service but does not function as an integrative system. The patient can easily get lost between the different points of service as we often observe in adverse events. This issue becomes even more explicit in countries with minorities, immigrants, language barriers etc, which complicate straightforward communication between caregivers and patients.

We suggest the establishment of a new position among the healthcare professions, a supervisor/monitor to oversee all patients’ transitions and thus ensure “continuity of care”.

In all fairness, we must add that many Health Management Organizations (HMO) worldwide, are doing their best to find solutions to these issues, not in the least Macabi, which has taken a series of steps in order to reduce risks involved in patient transfer. Amongst these are the following: developing a central electronic medical record, designating the primary care provider as the “personal doctor” to coordinate all treatments and procedures of each patient, appointing nurses as communication facilitators and as monitors in leading hospitals as well as training physicians to develop better communication skills amongst themselves.

Summary

When we started the Macabi project, between the years 1997-1999, we were fascinated by the similarity between aviation and healthcare, particularly the similarities we discovered between doctors and pilots. However, it is reasonable to assume that in our enthusiasm with this insight and willingness to assist Macabi, may have caused us to overlook the differences between the disciplines, on the organizational and individual levels

As we mentioned in this chapter, in any professional group, doctors and pilots included, there is a significant heterogeneous profiles. The studies conducted on this matter were based on elite groups of fighter pilots and astronauts in aviation and surgeons and anesthesiologists in health care. There may be some doubt as to how much these two groups actually represent their respective professions. The majority of pilots are neither fighters nor astronauts, but rather commercial pilots and most doctors are not surgeons or anesthetists, but rather family practitioners, pediatricians, gynecologists, etc. In spite of this, both these professions share many similarities, particularly in their professionalism, mission orientation, and professional pride in belonging to an elite group.

The two main differences between the two groups and the most relevant to establishing a risk management model are not their personality differences but rather the differences between their tasks and the systems in which they operate.

Commercial airline pilots' tasks are mostly structured and standard, they operate under strict international guidelines and it definitely comes under the definition of a system. This was exhibited in the examples provided under "continuity of care" and how the aviation industry copes with this issue. On the other hand, healthcare has yet to complete the switch from a decentralized, individualized and fragmented system to a comprehensive integrated one, in which patient care is closely monitored and supervised. Additionally, HMO's, due to financial restraints, function as reactive systems rather than pro-active. Rather than treat illness, they should spearhead preventive health care. As in aviation, where the system does not wait for something to break in order to fix it, or for a pilot to fail his mission due to poor vision or health problem, it preempts it by providing protocols for constant aircraft care and maintenance, and by requiring pilots to undergo annual health checks.

The three parameters we used to compare aviation and healthcare were: professional characteristics, risk management, and resources for risk management applications. We pointed out the similar characteristics, especially the individual's perception of the profession; however here too, there exist several significant differences. These are mainly related to the lower level of awareness that doctors have regarding their limitations and the inherent probability to err.

Unfortunately, there is very little published reference comparing aviation and healthcare as systems. Since early attempts at applying aviation risk management methodology were attempted in the operating theater, clearly reminiscent of an airplane's cockpit, in which each designated person has a clear assignment and role in the procedure. The comparisons conducted in this chapter between aviation and healthcare, are an attempt to compare systems while focusing on the parameters relevant to risk management.

From our standpoint, it is important to understand how the aviation system functions in order to ensure flight safety and not only how they manage errors. That is, how the aviation industry constructs its organization and working procedures in order to achieve maximum flight safety.

We believe that there is room for a comprehensive comparative study of aviation and healthcare from both an organizational and cultural stance as a basis for a successful conceptual exchange between the two disciplines, primarily the risk management model.

Chapter 5

Transferring a model from one content world to another

Verum esse factum (truth itself is constructed)

Giovanni Batista Vico (1688-1744)

Introduction

The basis of modern medicine is empirical evidence regarding the efficacy of drugs and treatments. This approach is known as EBM. (Evidence Based Medicine), is in fact representative of the positivistic school of research, according to which there is an "objective truth", and science is obligated to reveal this truth, while conducting rigorously controlled scientific observations .

On the other hand, most approaches to Safety and Risk Management are usually the result of" expert experience", of field operators, who provide effective solutions to urgent issues ,by incorporating changes in a variety of work environment. While working, those experts, gain insight as to what works and what doesn't .

This was our modus operandi, applying the insights we had gained in our Psychology studies and our Risk Management experience in the varied environments of aviation ,medicine, military, insurance, banking, industry and infrastructure . The aviation model for safety and risk management was developed along similar lines .

Accordingly, we may assume that the aviation model for safety and risk management, represents the Constructivist approach .

The attempt to assimilate the ARMM in medicine, took an interesting turn of events, since we are not only transferring a model from one content world to another, but rather transporting an entire philosophy, which is contrary to the basic tenets of the receiving (medicine) content world. Actually, we are transferring a constructivist approach into a content world which is mostly positivistic. This situation is somewhat like, forcing a cat and a dog to live peacefully together .

In this chapter, we will differentiate between an “imparting” content world, the one in which the model was originally developed and a “recipient” content domain, considers to assimilate an “alien” model .

The rationale for transferring models

The question of why we should transfer models, methods and insights, is a valid one. Although, the answer is practically intuitive; in order to start from the point that others have already reached. It is inefficient and ineffective to reinvent the wheel, and to dismiss the experience of others, gained over time at great effort, as irrelevant .

The human race develops and advances by gaining knowledge, passing it on to others and incorporating it to new situations. According to Piaget’s learning theory (1983), we generalize information and thereby develop our cognitive skills. We create schemes, called "constructs” of generalized knowledge, and apply these “constructs” to new situations .

Actually, the process of cognitive development exists in the tension between assimilation and adaptation. Assimilation occurs when a construct (previously developed scheme), can be applied to a new situation, and it changes as a result.of the new application. Adaptation occurs when the existing scheme is irrelevant to the new situation and there is a need to adjust the scheme or develop a new one.

Therefore, the rationale for transferring a scheme or construct or model from one setting to another is aimed for resources conservation, which means, attaining maximum effectiveness with minimal waste of energy .

The main question is how do we define the problem field, regarding the tension between assimilation and adaptation, meaning, will the characteristics of risk management in healthcare enable assimilation of the existing model of aviation risk management, or are the differences between these two environments so vast, that they require adaptation; development of a new scheme, unique to healthcare .

Even if adaptation is needed, since we are in a complex field, it may be advisable to learn from the aviation risk management model, in order to create one unique to healthcare, based on lessons learned, gleaned while implementing the aviation model .

Choosing the right model, choosing the right organization

As previously mentioned, it is not a question of principle, whether it is appropriate to transfer a working model from one content world to another, but rather a practical one of choosing the right model for transfer and the right organization for the model's application .

Within this context, we will discuss the criteria for a "correct model" as well as criteria for choosing the "right" organization for its application. We will explore both questions from the perspective of the project described in this work.

The "right" model, in our opinion should answer the following criteria. Although Macabi's management did not specify these, we felt however, that they were present anyway:

- **A proven model** – a model whose application, under a variety of circumstances, achieved the goals for which it was designed; significantly and consistently reducing risks. We can witness, that the aviation model, is indeed such a model, as observed by the results yielded in civil aviation, which has been quoted in many studies, including this one. We may add, that from our own experience in the Israeli Air Force, the Aviation Risk Management model proved itself as a working one.

- **A model with clearly defined principles** – we have already mentioned in this work, that the aviation model is more of an idea than a clear set of principles, well defined procedures and tools. The aviation model stresses aspects of the professional culture and not defined methods of one kind or another. Therefore ,it is not the "right" model according to this criterion. But, this attribute turns it into a generic model versus specific models, thus easing its transition into another content world. For example principles such as transparency, teamwork, placing a premium on safety and equaling it to performance, investigation, a pro-active approach, and others. These principles, although successfully applied in the aviation industry, are not necessarily unique to this industry .

- **A flexible model** which can be adjusted to changing circumstances -A narrow model designated for one specific context or use, is not easily transferable to other areas of activity. Flexibility may in fact be one of the model's principles or an outcome of the model's features and the experience accrued while applying it in other areas .

- **A model which serves the needs of an entire organization**, for both management and employees -This criterion reflects the motivational aspect of the employees. If workers perceive that the model is designed to only serve organizational goals, important as they may be, and will not contribute anything to them, directly or indirectly, its chances of being adopted are very slim. If the workers are not committed to the successful assimilation process, its chances of success are very slim. It is therefore imperative that the right model will be one which the workers perceive, as in some way, improving their position, their status, their value and contribution .

- **A model with an ideological appeal and not just a functional one** –Assimilation of a new model within an organization is a large-scale change. In organizational culture as well as in work procedures, an investment in resources and worker motivation is required for successful application of the model .Therefore, if the model is meant to solve a specific problem and has no value driven context, it is fair to assume that it will be hard to harness the workers to make the extra effort needed to assimilate it into the organization. The workers must sense that they are partners in a large and meaningful process .

- **A model already applied successfully in several contexts** – it is reasonable to assume that if a model has already been applied successfully in different contexts; it can be successfully applied to healthcare. The aviation risk management model has been applied in several variants in parts of the Western hemisphere, in both civil and military aviation. This fact makes it a flexible model which can be applied in different cultural, social and political settings. However ,this being said, we do not know of any recorded transfer of the aviation model to a content world so different such as the worlds of aviation and healthcare .

- **A Model originating in a content world, which the recipient employees perceive as prestigious as their own** – as we discussed in previous chapters, aviation answers this criterion in the eyes of medical professionals.

The second question, concerns the characteristics of the recipient organization. It is important to assess the recipient organization's ability and willingness to receive a model from another content world, according to the following criteria :

- **Presence of a real problem within the model's context** – The motivation for applying the model, by an organization, which at face value seems totally unsuitable, is more probable in case that a real and chronic problem exists, which pertains to the organization's main activity. This is indeed the perception of healthcare risk management since the publication of the IOM reports in 1999 and 2001 .

- **Lack of a similar existing model in the content world of the organization-** If there is specific model within the context of the recipient organization, adapting a model from a different discipline will be nearly impossible. The naysayers for assimilating the aviation model for risk management in healthcare claim that they have accumulated sufficient experience and expertise in risk management to develop their own model specifically for healthcare. This attitude would certainly be more adamant had there been a healthcare specific model in existence .

- **Awareness to essential differences between imparting and recipient organizations** – Denying the differences between content worlds and organizational differences, may bring about total rejection of the model . Healthcare's context is in many ways different from that of aviation. Any attempt at minimizing or denying these differences, could create antagonism from management and medical staff.. Alternately, presenting the differences and analyzing them, can promote trust in the process making it seem in –depth and not ad-hoc. These considerations may prevent it as being seen as a "default" decision due to little choice, but rather one in which all the parameters were taken into account .

- **Attention to the differences in the assimilation process** – By attention we mean defining action plans from a deep understanding of the differences in context between the two environments, e.g., making adaptations in the model to adjust it to the recipient organization, investing resources for training and implementation, as well as handling resistance .

- **Clear definition of the recipient organization's goals by adopting the "alien" model** – Any large-scale change, arouses resistance and expectations. It is advisable to identify expectations, primarily in order to manage them, and to prevent straying from them. The success of such a large-scale process is not certain. This is especially true when assimilating an "alien" model whose chances of success are not clear .

- **Management commitment to assimilating the model** -Since we are talking about a process whose prospects of success are not clear, management must commit to support this process. Not only must they provide encouragement and a safety net to all those whose positions may be threatened should it fail, these organizational pioneers must not be made to feel that they will be blamed, abandoned or fired in case something should go away. In addition, management must be committed and available to respond at very short notice to changes in strategy and tactics, which are a natural outcome of specific and generic problems that can be encountered during the assimilation process .

The following table presents our assessment of the "right" model and the "right" recipient organization. On a scale of 1-5, we evaluated the ARMM and Macabi healthcare services as the recipient Organization. The assessment was made during the writing of this chapter, but it relates to the early stages of our engagement with Macabi for assimilation of the model .

The Suitability of the ARMM		Macabi's Suitability	
Topic	**Score***	**Topic**	**Score***
Proven model	5	Existence of a real problem	5
Defined Principles	2	Lack of a specific Model	5
Flexibility of the Model	4	Awareness to differences	3
Serves the entire Organization	5	Attention to differences in the assimilation process	3
Ideological Model	5	Clear definition of Goals	4
Applied in a variety of contexts	3	Management Commitment	5
Prestige of the imparting party	5		
Total 83%	**29**	**Total 83%**	**25**

*1= low, 5= high

In spite of our awareness to the bias in the above table, still, in our opinion it reflects closely enough, the actual state of affairs in 1997-8, when Macabi adopted the aviation risk management model. The above assessment clearly shows that "Model suitability" was assessed at 83%, as was the Maccabi's suitability to receive the model.

In 2001, AHRQ (Agency for Healthcare Research and Quality), published a comprehensive report dealing with risk management and healthcare safety. The report addresses, amongst others, the issue of transferring risk management models and insights from other industries, in order to advance the issue in medicine. According to the authors, in medicine, only empirically proven practices are adopted, and that it owes its development to this scientific approach. Therefore, medical practitioners will wonder at the lack of scientific proof in safety procedures and risk management taken from other disciplines. Also, one could argue, that adopting unproven methods, from other contexts, could more likely than not, bring harm to healthcare safety. However, the report continues, in spite of the scientific criticism, it is undeniable that the achievements of other industries in this matter and civil aviation in particular, are by any standard higher than those of healthcare .

The report proceeds to introduce the method used by Reason (2002), which recommends adopting general organizational models, which are able to advance the field of risk management in high-risk organizations, rather than adopt specific methods from other industries .

As we further mention in chapter 6 of this work, upon recommending the aviation risk management model to Macabi, we too were challenged to find any publications describing the model and empirical evidence regarding its effectiveness. Likewise, Kirwan (1998) ,(Hollinagel (1999), and others, claim that even precise engineering methods, used in applying risk management procedures, may be relevant for healthcare safety, were lacking empirical evidence. For example, many methods promise that they can detect "human error", predict human error and profess to have developed monitoring tools to reduce these errors. A small number of these methods have been documented and fewer yet were empirically tested for their claims. Additionally, even if we ignore the demand for hard evidence, we will find that there are very few cases in which assessment of the capabilities of these various techniques was actually conducted .

In another case, when Healthcare attempted to incorporate TQM (Total Quality Management), an approach which had impressive success in industry, but there was little empirical evidence to support its success in healthcare .Gerovitz, Blumenthal and Kilo (1998) , Shortell et. Al (1998), Shortell ET. al. (2000)(

It seems that when discussing complex procedures of change, such as assimilation of a risk management model in a large organization, it is impossible to assume that an empirically proven model under certain circumstances, would be any more successful than a model developed on the basis of extensive field experience.

We suggest that the "right model" and the "right organization" assessment techniques, described in this subchapter, as well as proper and well planned deployment, are most critical towards successful assimilation of an "alien" model.

Establishing the organizational infrastructure for the adaptation of the model – Professionals and Consultants .

What is required of the recipient organization in order to successfully assimilate a model developed in a completely different discipline? We will address the question from a perspective of the experience we acquired in several organizations where the aviation ,risk management model was adopted .

In chapter 6, we described in detail the process which Macabi followed in order to assimilate the aviation risk management model. It is important to mention that during1997-8 , when we embarked on this project with Macabi, they were the first

organization with whom we assimilated the aviation model. A significant number of our current insights were not mature at the time .

We assume that part of the insights brought forth in this paper, are pertinent to any major change in a large organization .It is our opinion that assimilation of an "alien" model must include the necessary components from 3 major categories :

1. **Management participation** – as previously mentioned, assimilation of the risk management model is a major change, engaging the entire organization. Unless management is explicit, involved and committed, the chances of success are nil. Many of the reasons for this lack of success are mentioned throughout the paper . Following we have detailed the requirements for management participation :

    - **Top management commitment and participation** -This was always our first demand from the start, with each organization. One reason for this is the organizational structure required for risk management. In most organizations which have a risk management tradition, the person in charge of Risk Management reports directly to the General Manager . Therefore, it is imperative that all managers are aware of this from the start. This is particularly important when the assimilation of a new model is at stake. The level of commitment is not just a theoretical one in support of the project but a daily routine involvement. Management needs to be available to discuss issues, make decisions and understand that this is a critical component of the project's progress. More so, we might add that in most cases the risk management officer has no managerial responsibilities, but rather serves the organization in a consulting and facilitating capacity. In this situation, the risk management function draws its authority from top management, who base their decisions on the formers recommendations .

    - **Policy** – This means a clear and explicit statement by the General Manager and the board of directors regarding the following issues: the meaning of Risk Management for the organization, areas of responsibility, interfaces and the core principles of risk management in the organization and major risk management procedures. Macabi issued a policy statement three years after the Risk Management Department was established. It dealt with the issue of managerial immunity, which was necessary in order to encourage medical staff to report errors in patient care. The caregiver's reluctance to report their

own errors ,from fear of repercussions, without a clear-cut policy, created a modicum of confusion in the interfaces between the Risk Management Department and other organizational organs, both in the headquarters and field. . With this insight in mind, upon starting to work with MEKOROT (Israel National Water Company), to implement the Risk Management model, we recommended that a policy statement be issued and approved (after lengthy discussion), and made public, in the first few months of our activity in that company. They did so and the policy statement was in effect long before a risk manager was appointed.

- **Steering Committee** – The purpose of a Risk Management steering committee is to gather periodically all those with a vested interest around a table, in order to discuss all aspects of the assimilation process. The Steering Committee chair should be the General Manager and all other top managers should be a part of this group as well. Each manager should report on his contribution to promote Risk Management in the organization, and receive new tasks to be completed before the next meeting. The committee should also address failures and successes in the process and learn from them. The minutes of the committee meetings should be disseminated to all lower level managers .

- **Assimilation Program** -despite the uncertainty of such a project, and perhaps because of it, it is most important that a yearly schedule and operative plan be followed for the model assimilation. This program should include action items, those responsible for each task, checkpoints ,overall supervision, etc .

2. **Resources and Infrastructure** -In order to assimilate the model under the special circumstances previously delineated, a significant investment of resources is required. More so, there should be willingness to a continuing and growing investment in the process, since the scope of Risk Management activities is continually expanding. This issue is discussed in chapter 6, where we described the process of establishing employee standards and job descriptions for the Risk Management Department of Macabi. Once the department's contribution to the organization is apparent, a growing number of managers join in and willingly begin to apply the process. This ongoing development demands a constant availability of training supervision and follow-up personnel in conjunction with the ongoing project assimilation. By resources we mean :

- **Professional Manpower** -In chapter 6.6, we discussed the recruiting process of employees for the Risk Management Department in Macabi. Clearly, selecting and assigning the manager, is the most critical act with the most ramifications for the long run, including the department's progress, and its success in assimilating the "alien" model. We can safely say that the basic attributes of the first manager in Macabi outlined in chapter 6.6, are the ones required for this job . This holds true at the outset of the project, but at any rate, recruitment of new staff, must be stringent and uncompromised by hiring readily available candidates .

- **External Consultants** – After 12 years of working with Macabi ,we are still assisting the department, both in ongoing activities and in development of new ideas and projects. Consultancy has an important part to play in the assimilation of a new model and therefore it is a basic ingredient of the process. The external consultants are supposed to be the ones who have already successfully assimilated a similar model in the original setting. In a situation which is not an empirically controlled environment, in which each any action affects its surroundings and interacts with it, the actions and their outcomes continue to affect more people and more events down the line. It is of cardinal importance to have consultants on hand who have already experienced this complex process. They are then able to provide explanation to the events and assist in overcoming obstacles. The consultants perform several functions, e.g. they pass on information, using several different methods they train the Risk Management staff internally, conduct various activities with the department staff .Prepare the staff for activities outside the department assist in crisis managing, support the department staff individually and as group .In fact, through this modus operandi they develop a professional partnership with the Risk Management Department's staff.

- **Organizational Structure** – The department must be established under the direct responsibility of the General Manager. The department should be placed in the second managerial tier, just below senior management. It is important for the department to be budgeted and functional from its inception .Throughout the first year, recruiting of new personnel should take place according to topics handled and scope of activity .

- **Information System** – An information system for handling adverse events and risks is an absolute must. From the moment ,the department begins to receive reports, the information system is a tool for assimilating working procedures of the unit and standardizing them to a uniform format. In chapter 6.9 we described the process of establishing the computerized system for risk management in Macabi. The system serves the Risk Management department in Macabi to this day. Even though it is about to be replaced by a newer more technologically advanced system, it will maintain its original principles of operation. Macabi's system was based on the principles of the Israeli Air Force Risk Management system from the early 80's of the 20th century. It is important to mention that there are many off the shelf software packages for organizational risk management. However, it is most effective if the system is specifically geared to the needs and parameters of the organization and the model which it is planning to implement. One could compare the information system to the genetic code of Risk Management activities. Since it retains the memory traces of all adverse events, the risks involved decisions and recommendations by the Risk Management Department. Since Macabi's system was based on the insights gained by the Air Force , we could claim that the Air Force "genes" were thereby transmitted through the model to Macabi. We could also add that the information system is the hard-core base for assimilation of an alien model .

3. **Working Procedures** – Work procedures in Risk Management, must be based on the assimilated model, be supported by policy, and executed via the computerized system .

    - **Defining the working procedures in Risk Management** – By working procedures we mean to define the following functions: reporting of adverse events, managing and handling those events, development and execution of a pro-active annual Risk Management program. The working procedures, must be based on the principles of the assimilated model, clearly defined from the very beginning and updated according to developing needs. It should be noted that since we are "importing" a model from an "alien" world, the expectation of management and employees is that they are not getting a "cat in a bag", or an unknown commodity, but rather a tried and tested well proven model. Therefore, the working policies and procedures, which are in the immediate interface with organization, must be properly defined from the earliest stages .

- **Applying Risk Management into the assimilation process** – The assimilation process, originating in a totally alien content world, is in and of itself a risky undertaking. It is therefore advisable to conduct the assimilation process in a pro-active Risk Management mode. The goal of this approach is to uncover the risks, evaluate them, define checkpoints for the cardinal risks and monitor these checkpoints and their efficacy. This stage is of utmost importance, most of all in order to instill the Risk Management staff with the understanding that their own work is fraught with risks which must be dealt with and handled pro actively .

- **Training** – This is one of the most crucial components of the assimilation process and especially when dealing with a new model whose origins are from extraneous sources. Training must encompass a broad spectrum as possible of manager, and employees and to impart as much information as possible about the model, work procedures, and expectation thereof. Training must well planned as an integral part of a model assimilation .

We will discuss our own strategy for assimilating the model with Macabi, according to the parameters brought herewith. We will mention that the above strategy was developed with the writing of this chapter in 2008, and not upon embarking on the Macabi project in 1997-8. The assumptions are subjective on a scale of 1-5, and is based on insights gained over the years of working with Macabi and other organizations. The following table presents our assumptions and scoring for the first year of the assimilation process:

Management's Involvement	**Score***	**Tools and Infrastructure**	**Score***	**Working Procedures**	**Score***
Commitment and Involvement of senior management	5	Professional staff : Quality and quantity	4	Defined work procedures for Risk Management	2
Written Risk Management policy	4	External consultants	5	Risk Management for the assimilation process	3
Steering committee	3	Organizational structure	3	Training program	2
Annual assimilation program	2	Dedicated Information system	4		
Total 70%	**14**	**Total 80%**	**16**	**Total 47%**	**7**

*1=low, 5= high

According to the assumptions above, management involvement received 70%. Tools Infrastructure 80%, and working procedures 47%. Today, we can clearly say that had we been aware of the importance of preparedness for model assimilation, according to these parameters, we would have invested more time and effort in preparing for assimilation of the model, and most particularly we would focus on working procedures .

The following table illustrates our current viewpoint regarding the appropriate timing for each of the stages and segments of model assimilation. In the first year, we are able to observe that Q1 is the busiest and requires large investment of resources in order to get it off the ground. This is also the reason that the first stage holds the greatest risk factors for the entire project. Lacking proper resources, compromises are made; these are not always the optimal choice for a successful assimilation process .

Activity	Q1	Q2	Q3	Q3
Management 's Involvement				
1. Commitment and Involvement of senior management	V	V	V	V
2. Written Risk Management policy	V			
3. Steering committee	V	V	V	V
4. Annual assimilation program	V			
Tools and Infrastructure				
5. Professional staff : Quality and quantity	V	V		
6. External consultants	V	V	V	V
7. Organizational structure	V			
8. Dedicated Information system	V	V		
Working Procedures				
9. Defined work procedures for Risk Management	V	V		
10. Risk Management for the assimilation process	V	V	V	V
11. Training program			V	V

Resistance to Change and practices from other content worlds

Initial theoretical ideas about the resistance to change were attributed to Kurt Lewin (1947) , in an article published in Human Relations, he argued that organizations just like biological creatures, strive for homeostasis. This being the tendency to maintain stability by resisting change and/or retuning to an original state in case homeostasis is subverted .

Accordingly, the success of any change is dependent on melting away the balance, by altering the dynamics between those championing change and those resisting it .

Coch and French (1948), also published in Human Relations, an article dealing with overcoming the resistance to change .

Lewin's model (1947-1952), was adopted and further developed by Shein, (1969-1980) . The model presents a three phase cognitive process of change: unfreezing, displacement , and refreezing .

These works were the foundation for many studies thereafter on change and resistance to it. As well as changing attitudes and the relation between changing attitudes and behavior, (Fishbein and Ajzen, 1975). According to these assumptions, there is a consistent relation between attitudes, intentions and behaviors. Also, there is sufficient evidence to assume that beliefs and attitudes will have bearing on management and employees ability to accept a planned change .

Zaltman and Duncan (1977), defined change as; *"Any behavior which serves to maintain homeostasis in response to stress to change it"*

Piderit (2000), states that "*People seldom develop a resistant behavior, act out this resistance, without the source of this resistance stemming from their fear of negative personal repercussions from this change*". Meaning, people resist change when they perceive it as a threat on their homeostasis, their status in the organization, loss of control and loss of income .

We have already mentioned that the assimilation of the Risk Management model carries many large scale organizational changes. Following is a list of some of these changes, which are outcomes of the Risk Management model assimilation. Adapted from aviation to healthcare:

- Changing the basic paradigm of positivism, common in Western Medicine as a sole method of adopting new practices and attitudes. In our case, the suggested model is the result of a constructivist approach .

- A change in the traditional work habits whereby patient care is the main task ,developing a greater awareness of the inherent risks of healthcare and making patient safety central in healthcare .

- Changing the professional culture, which until a few years ago, was intolerant of medical errors towards a culture which understands and accepts that “to err is human".

- A change in attitude from blame and ostracism of erring healthcare practitioners to one of support and understanding accompanied by a frank effort to learn from each mistake in order to minimize future reoccurrence .

- A change in the doctor/patient relationship from a lofty attitude to one in which the doctor may err and when he does, he discloses this to the patient .

- A change in the attitude wherein the error was blamed on those involved, versus the current concept in which failures are attributed to chronic systemic shortcomings, which enable physician's error .

- A change from an attitude in which medical errors should be secreted to an attitude of partnership with the patient, aimed to manage the error and minimize current and future harm.

- A change in interfaces with external parties such as suppliers , malpractice insurance companies, medical malpractice litigators, labor unions, government agencies etc .

- A change in the basic tenet of medicine as being professionally conservative, to a new openness enabling the assimilation of an "alien" model

These changes are only the tip of the iceberg of the many changes occurring as result of adopting the Aviation model for Risk Management in healthcare. Some, are perceptions and some are very practical, as they address and challenge every aspect of the entire system, as well as affect every doctor- patient interaction .

In chapter 6.4, we describe some of the resistant behaviors, which we encountered in the Macabi project. .

Odegard (2000) compares the formal aspects of Risk Management in Aviation and Medicine and recommends using the aviation methods as well as developing standards at the national and the international level of health organizations, similar to those of Aviation. He goes on to say that healthcare should follow aviation, in this matter, such as doctors annual proficiency testing and drawing conclusions from adverse events. Although this is a very thorough study, it does not address the possible resistance to all these suggestions, which may reduce the chances of accomplishing these suggestions and working along these suggestions .

Thomas and Helmreich (2002), analyze the similarities and differences between medicine and aviation, referring to studies, which compared the operating theatre and emergency room to airline crews operating in the cockpit. . Although they found several common components, there were differences in routine activities as well as in emergencies. One of the most apparent differences was the complexity of medical tasks: *"Patients are far more complex than aircrafts*". However, that being said, they point out that these differences do not necessarily hinder the adoption of the aviation model. They foresee a risk as resulting from the stress on the healthcare system to improve care practices, which could bring them to adopt the aviation model, without actually examining it sufficiently. This work too, does not take into account the profound implications of adopting an "alien" model and the resistance it could arouse .

Lacking relevant professional literature in this immediate matter under discussion, we turned to two disciplines which had been studied in greater depth; one was doctor's resistance to insertion of information systems into healthcare , and the other was business based – Mergers and Acquisitions. We assume, that the greater body of literature on these issues is closely related to financial arguments and greater popularity of these topics compared to risk management

Freudenheim (2004), mentions a case from 2003, where doctors in the prestigious Cedars Sinai Medical Center of Los Angeles, rebelled at the installation of CPOE (Computerized Physician Order Entry), which was supposed to improve their work efficiency. The physicians perceived it as an impediment to their caretaking work. The system was removed, after it had already been installed in 2/3 of this large hospital (870 beds) .

Mergers and Acquisitions of companies has been thoroughly studied due to the enormous financial impact to large corporations and the scope of their activities. Between 1998-2000, Mergers and Acquisitions generated a total of 2,851 billion dollars, 1,526 in the USA alone (Thomson 2001). According to the consulting firm of A.T. Kearney, failures in Mergers and Acquisitions range from around 58% (Habech 2000), to 83% according to KPMG consultants (KPMG 2001.

According to Bertoncelli and Kovac (2007), the main causes for these failures are managers focusing only on the "hard" parameters of the transaction, such financial statements, markets, production capacity, etc. while ignoring the "soft" parameters such as cross cultural differences and employee expectations . There is a tendency to marginalize the human factor in Mergers and Acquisitions so that in effect it is often overlooked (Huang and Kleiner ,2004).

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Majidi (2007), also analyses the many failures of Mergers and Acquisitions, particularly international transactions. He claims that one of the main reasons for failures in this area ,especially in multinational mergers, is lack of attention to cross cultural differences between the different nationalities involved in the merger. He recommends using a reference called "cultural distance" (Kogut and Sing 1988), to assess the scope of the problem and define appropriate solutions based on it .

In spite of dealing with two very different processes, Risk Management model assimilation and Mergers and Acquisitions, it is our opinion that that we can draw important insights from comparison of the two. Thus, we learn that failure in attempts to merge large organizational systems is quite frequent and their results affect large numbers of people and can cause management and employees severe financial harm. These failures are mainly attributed to lack of attention at all stages of the transaction, to the "soft" differences between the merging companies, these include cultural, national, and organizational differences, employee expectations etc .

In our opinion the assimilation of an "alien" model like in Macabi, it is imperative to pay significant attention, far more than we did, to the cultural differences between aviation and healthcare, between the Israeli Air Force and Macabi, and to plan and implement activities to reduce resistance which developed due to a lack of awareness and sensitivity to these" soft "differences .

The issue of managing change in organizations is one of the most popular in management . Close to 2000, books on the subject are published yearly, and a significant number of those deal with organizational change. In a search in Current Content (2002), 1300 articles were found, since 1994, all dealing with the topic .

Kotter (1995), of the Harvard Business School, in his reference to Organizational Change said the following :"A *few… corporate change efforts have been very successful. A few have been utter failures. Most fall somewhere in between, with a distinct tilt toward the lower end of the scale ".*

According to Strebel, (1996) also of Harvard *:"Change management isn't working as it should. In a telling statistic, leading practitioners of radical corporate reengineering report that success rates in Fortune's 1000 companies are well below 50%, some say they are as low as 20%.*

Champagne (2002), In reference to non-implementation of necessary changes in Canada's healthcare system over the past 15 years, states :"Recommendations to reform Canada's health systems made over the last fifteen years, have rarely been given effect, although often commanding a broad consensus ."

Champagne claims that the overall conclusion from analysis of professional literature dealing with failures in Organizational Change, is that they are all about changes themselves which are all highly complex processes, unexpected, ad carrying an array of risk factor, whose role and intervention changes over time. Likewise, she raises the hypothesis that successful implementation could be related to preparation for change, paying attention to the social and emotional implications, organizational structure and political dynamics.

Berwick (2005), president of the IHI, Institute for Healthcare Improvement, and one if the foremost leaders in the field of patient safety in the USA, compares the reactions of the medical community, to the IOM reports of 1999 and 2001, which he helped to write , to mourner's reaction to death, as described by Kubler – Ross (1969)

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The mourner is the medical community, mourning the demise of the traditional image of medicine, as a caregiver and savior, who suddenly realizes the harm and to patients and its scope. . The medical establishment in general and medical staff as individuals in particular, are going through a complex grieving composed of six stages :

1. **Denial** – the data is incorrect and there's no actual problem

2. **Anger** – If there is a problem it has nothing to do with me and *"Who are you to judge my practices ?"*

3. **Bargaining** – *"My patient's condition is more critical, therefore these methods are not applicable for me …"*

4. **Depression** – general drop in morale, as manifested in the following statement*: "I consider leaving the profession ."*

5. **Acceptance** – *"Whether I like it or not, we need to sit down and be capable of playing by the new rules".*

6. **Leadership** – *"Let's actually participate in putting together the new playing rules and lead in this direction*".

This insight, which Berwick turned towards the medical profession, illustrated that although its intention is to cure, it causes also harm. This reflection helped physicians to make the mental switch, needed to realize the call for a change in the system and reframing the rules of the game as, highlighted in stages 5 and 6, above.

We often use this reflection in lectures and workshops which we conduct for risk management professionals and medical staff, in order to assist them in evaluating their current stage. It is not rare to find out, that many physicians are fixated in the early stages, challenging us to assist them to proceed to the more constructive stages of the mourning process. From these encounters we have learned, that many care providers, are well aware of the of the grim statistics and that many of them are stuck somewhere between stages 1-4, most of them in stages 1-2. . Without the Kubler –Ross reflections, their chances of participating in the Risk Management model assimilation from an "alien" world are very low .

Denham (2005), argues that one of the biggest myths about medicine, is that it readily adopts innovations. It is true that that medicine leads in developing new products and processes . However, if there is no significant financial remuneration in the short term for practitioners or hospitals, it takes 17 years for clinical studies to be implemented in standard medical practice. (Balas, Austin, Ewigman et al. 1995)

Denham adds that, regarding safety in healthcare, the time required for adoption of new procedures, could be even longer. Unfortunately, the strongest catalysts for changes are the new codes of remuneration for caregivers in computerized systems, which in most cases are not closely related to patient safety .

Chapter 6.1

In search of a model with proven results

"Give me a fruitful error any time, full of seeds, bursting with its own correction. You can keep your sterile truth for yourself"

(Vilfredo Pareto, Comment on Kepler, 1870)

In the United States of the late 1990's, the administration of President Bill Clinton launched an unique initiative to tackle the subject of risk management. The work of the Institute of Medicine (IOM), which published two reports that shed light on the phenomenon of medical errors, was the principal trigger for the initiative. The reports staggered the professional medical community, the Clinton administration and American public opinion. The two reports – "To Err is Human: Building a Safer Health System" (1999) and "Crossing the Quality Chasm: A New Health System for the 21st Century" (2001) – impelled the administration, headed by President Clinton, to take very clear positions and set in motion processes that within five years would reduce deaths due to medical errors by 50 percent, estimated at the time at about 100,000 each year.

From a speech by President Clinton on December 7, 1999: *"….Last week the Institute of Medicine released a disturbing report about patient safety and medical errors in our nation's health system (refers to the 1st report by IOM). According to the study, as many as 98,000 Americans lose their lives each year as a result of preventable medical errors…."*

With this speech, President Clinton set in motion actions by the administration to define operative work plans that would reduce the scope of medical errors.

In another speech two months later, on February 21, 2000, given in front of the committee, he had appointed to submit the operative work plans that would reduce the extent of medical errors, President Clinton said:
"…..Have we given all of our care-givers adequate training? Do they adequately coordinate with, and communicate with, one another? Do all settings have the right kinds of teams and systems in place to minimize mistakes? These were the kinds of questions that were asked and answered in our landmark efforts as Americans to improve Aviation Safety and workplace safety. And if these questions are properly asked and answered in the context of the health care system, they will dramatically reduce errors there as well…."

The president's clear and resolute positions set in motion a large number of processes within the American medical system that led to the adoption of risk-management models borrowed from the aviation system.

In 1996, about three years before President Clinton's milestone speech, when Maccabi Healthcare Services (in Israel) decided to establish its risk-management department, the field of risk management still represented virtually untouched ground.

After making the organizational decision to enter into the field of risk management, in the expectation that engagement in the subject at the institutional level would improve the quality of the medical care provided by Maccabi and perhaps also reduce the number of claims against it, it was realized that a model to guide the risk-management department in its nascent steps, and perhaps at the later stages too, had to be immediately found. It was clear to the policymakers at Maccabi as well as to the founders of the department that it would be impossible to invent a new model, test and validate it in the narrow time frame at their disposal. They realized that they had to make every effort to minimize the possibility of error on the part of the department. As paradoxical as it may sound, the department, one of whose principal goals was to legitimize errors on the part of physicians, felt that it had no right to make any mistakes in its work, because the organizational tolerance for such mistakes appeared minimal.

The department was given the authority to begin its work on risk management at Maccabi Healthcare Services with the expectation of rapid results, "clean" work that would be free of errors, with a minimum of organizational "noise" on its way to success. It was clear that the window of opportunity given to the department in its early days was small. The immediate and urgent goal that faced the department was to define itself, its goals and its work methods.

The feeling among the founders of the department was that the mandate that they had been given would not last forever. They would have to very quickly prove that there was justification for the establishment of the RMD and attain legitimization for its work within a period no longer than a year. The sense of urgency stemmed from a number of factors:

1. In the mid 1990's, in the State of Israel as well as in the Western world, the subject of risk management in health services was still in its infancy. A number of initial projects had been carried out, especially in medical organizations that had inpatient services, but these projects involved processes related to nursing-care staff rather than to the clinical processes (Mills and von Bolschwing, 1995). Because the principal motivation for approaching the subject of risk management was to reduce number of malpractice claims against medical staff and institutions and because it was easier to sue hospitals for cases of nursing-staff malpractice than physicians malpractice, until recent years, medical risk management focused principally on non-clinical malpractice, e.g. falls by patients, surgical staff leaving sponges or surgical instruments inside patients, mistaken identity of patients, etc. It was discovered, for example, that simply introducing a defined procedure into the third equipment count before closing off the surgical area was sufficient to prevent most cases of sponges and surgical instruments being left inside patients. Nonetheless, no medical organization having a significant scope of activity was known to have taken upon itself the subject of risk management in a systematic and consistent fashion (Wilf-Miron and Levenhoff, 2001; Wilf-Miron et al., 2003).
2. Risk management in general and particularly in medicine is perceived as a double-edged sword, because it awakens the hope that real improvement in the quality of health care can be achieved as a result, while on the other hand, the very discussion and occupation with the subject, stimulates awareness of problems, that require action, because they may have inter/ extra-organizational repercussions. This involves shedding light on problems traditionally viewed as an inherent part of medical activity, the result of the constraints within which the medical organizations work and bringing them to public awareness. The involvement in risk management often requires the breaching of existing paradigms, a process of slaughtering sacred cows, as it were, which is often perceived as undermining the very foundation of the organization. An organization that decides to move in this direction must make sure that certain guarantees exist to ensure that if the process does not succeed, it will at least not cause damage. This in fact involves managing the risks that are part of the assimilation of risk management within an organization. In their book, *Leadership on the Line: Staying Alive through the Dangers of Leading* (Linsky and Heifitz, 2002), the authors note that

managers who decide to introduce changes into their organization, are taking considerable risk upon themselves, which is the result of the tendency of organizations to resist change. This is because every organizational change comes at a cost the organization must pay and which the organization resists to pay. In 1996, the decision to implement risk management in a medical organization was a dangerous one for those who conceived it.

3. The Israeli Medical Association (IMA), which represents physicians vis-à-vis their various employers and protects their rights was liable to view the treatment of risk management as potentially harming doctors' rights. It was important to take quick action that would focus on dealing with the elements of risk management that support and aid doctors in distress, following their involvement in adverse events in the wake of which they are sued for malpractice.

   IMA defines its activities in the area of quality improvement as follows:

   "The IMA focuses its activities on the medical community in the area of quality assurance and risk management: informed consent forms, scientific activity in the area of clinical instructions and following up surveys and tests. It also periodically takes all the steps necessary to advance the goals of quality assurance in medicine." (From the Internet site of the IMA: http://www.ima.org.il/)

   It seemed self-evident, that the IMA viewed itself as a player in the area of quality assurance and risk management and that the formation of an internal department within Maccabi to deal with these subjects would be compatible with the activities of the IMA.

4. The major medical malpractice insurer in Israel is MCI (Medical Consultants International) and the overwhelming majority of medical personnel in Israel are insured by it. MCI conducts activities in the area of risk management, particularly from a legal standpoint. The insurance agency publishes a periodical in which it discusses medical errors from various aspects, but especially legal ones. MCI has not taken proactive steps in the area of risk management. It was feared, that the insurer would not to view Maccabi's internal risk management activities favorably. In retrospect, this fear turned out to have no basis in reality because the insurance company and Maccabi focused on completely different areas of activity in the context of risk management and in the later stage even acted conjointly to promote RM. But this was viewed as a factor that could work against independent risk-management activity within Maccabi.

It was clear to the founders of the risk-management department that the clock had begun to tick the moment the organizational decision to enter into the area of risk management had been made, that the window of opportunity was small and that there were certain expectations among certain parts of the organization and beyond that the project would fail so that they could declare the situation "business as usual." There was without doubt a sense of urgency, pressure and mission.

Already at the earliest stages in the establishment of the risk-management department, it became clear that it was necessary to find a model and organizations implementing risk-management methods that could serve as possible prototypes and role models for the activities of Maccabi's department. Due to the shortage of time and the danger the department faced, it was necessary to come up with clear, proven steps that had maximum chances of success. To find a proven model that had been assimilated well into a medical community, and which had proven positive results, both from the point of view of its assimilation, as well as the results that it attainted, was the goal of the search.

The initial definition of the required model was very specific. In order to optimally address Maccabi's needs, it would have to be:

1. A risk-management model, rather than a model dealing with safety or quality A comprehensive, complete model applied over time on a broad scale within an organization and which integrated well with the medical organizational culture.
2. A model that had already been applied in an Ambulatory health care organization on the scale of Maccabi (about 3,000 physicians and 1.5 million members) that successfully implemented risk-management activity.
3. A proactive model that underscored two main goals:
    a. The drawing of systemic conclusions and actions from adverse events reported by caregivers.
    b. Personal and professional support for reporting caregivers based on empathy with the emotional and professional distress they are subject to in the wake of their involvement in an adverse event, and especially in cases in which a malpractice claim may be pending against them.

The model defined for the search was an optimal model that if found, needed only to be adopted and implemented.

Already at the initial stages of defining the model, three central problems, working against the chances of finding an optimal model were identified:

1. Maccabi Healthcare Services as a community health organization was the youngest of the organizations providing services of this type in Israel. Progress and quality were its watchwords and it made every effort to position itself apart from the competing health caregivers from the day of its inception. It was obvious that there was no Israeli organization that could provide a suitable model. Additionally, the structure of the medical system in Israel, in which the insurance carrier and the provider of healthcare services in the community with government subsidization are one and the same, was unique. Organizations of this type are almost nonexistent in the Western world.

   In other words, the unique characteristics of the Israeli health care system and the distinctive nature of Maccabi as an organization that provides community health care in Israel were incompatible with the expectation of finding an optimal risk-management model.

2. The subject of risk management in medicine was still in its infancy in the mid-1990s and there was no medical organization in Israel that dealt with the subject on a systemic level.

3. In the mid-1990's, the United States health care system was occupied with the accreditation of medical organizations in the belief that standardization of medical treatment, inspired by the principles of TQM as applied in the fields of industry and services, would improve the quality of medical treatment. A model implementing proactive risk management was unknown.

The picture that emerged following intense efforts to locate an optimal model was both disappointing for the founders of the department. They learned that no optimal medical risk-management model that could be implemented in Maccabi existed. Moreover, it emerged that involvement in risk management in the field of medicine was extremely limited for the reasons outlined in Chapter 4, which deals, above others, with the characteristics of the medical world.

The working assumption of the medical world today, that a doctor as an individual and a medical organization as a system are doing their best to provide the finest medical treatment to patients, hinders reflective thought, the factor that enables individuals and organizations to learn from adverse events. Systemic reflective thought is one of the most central elements upon which risk-management activities are based. However, if you believe that you are already doing the best you can and that you are working under unremitting systemic constraints, there is nothing you can do to improve, what you are doing, because you are already doing the best you can.

Most doctors and medical systems do not view themselves as likely to benefit from the results of risk management since they believe that they are already extracting optimum output from themselves within the system in which they are working.

The efforts to locate a suitable model focused on conversations with colleagues, a study of existing risk management activities in closely related fields: safety and quality in Israel and the rest of the Western world, participation in professional conferences and attempts to find information over the Internet.

Neither an optimal model nor one even close to it was found. The results of the search were frustrating, but on the other hand, it was clear to the founders of the Maccabi risk-management department, that they would be pioneers and trailblazers in a new field and this filled them with a sense of mission.

The decision that was finally made, established the need to form an interdisciplinary team that would include doctors, nurses, psychologists and aviation experts with experience in the field of risk management in the Israeli air force, so that principles used in the aviation risk-management model could be adopted (Wilf-Miron et.al.,2003).

Chapter 6.2

The role of pioneering: What to do without a benchmark in the HealthCare industry?

"As soon as questions of will or decision or reason or choice action arise, human science is at loss"

Noam Chomsky (1928 >) Linguist and Philosopher

Redefining the needed model: Proactive RM with proven results.

After failing to find a working model for risk management in medicine, there was place to ask what is the meaning of the absence of a model to follow in the healthcare risk management realm?

How is it possible that in 1996 one couldn't allocates even a single healthcare organization, implementing fully and as a primary effort, risks management with proven results?

As we have already mentioned, there was some activity in hospitals for specific and focused purposes, for example, preventing errors of leaving sponges and surgery tools inside the operated patient, but there were no explicit signs of risk management in ambulatory healthcare systems.

The insight that risk management is taking its first steps in the medicine realm was very surprising. Being an entrepreneur, alongside the excitement of creating "Something from the scratch" you ask yourself why no one has done it before you, doubts begin to rise for it is possible that many did try but fail and this is the real reason why the issue have not come into fruition yet.

The feeling of entering a new domain, without the alternative to learn from others and utilizing their experience to avoid unnecessary mistakes, made the establishing process of the risk management department more rational and controlled.

The first step was, to redefine the specified model: ***"A proactive risk management model with proven results".***

Since there is no documentation of these first phases of searching for the model and various parties participated in it, such as the departments' founders, Head of the Medical Department, Head of the Procurement Department and us as consultants, there are different views, regarding the events, procedures, considerations and decision-making in these initial phases. It is important to note that the point of view represented here is primarily ours, despite the attempt to support it by other partners' points of view.
One of the issues on which there are diverse theses, is the one related to the definitions of the compromised model, after the failure to find the optimal model. Was the term "proactive" defined as an important parameter of the specified model, or only in retrospect, after a couple years of activity, when it was already obvious that Maccabi's model, based on the Air Force's model, is very much characterized by its proactively, this aspect was added. In any case, we will refer to the thesis according to which the search was after a proactive model.

What is a proactive model? Proactive models have two major characteristics:

- The existence of procedures aiming to identify potential risks before coming into realization, by using various tools and methodologies.

- An attempt to handle the risks revealed in a particular event, beyond the specific circumstances aiming, to generalize and eliminate the entire phenomenon.

Proactive models reflect a more advanced development level of risk management than the conventional reactive models, since they oblige planning and investment of resources before the potential risks realize. In most cases, when an organization starts risk management activities, it adopts a reactive approach, meaning, when an adverse event occurs; actions are taken in order to understand the causes leading to the event and to prevent its recurrence.

The organizational motives for adopting the reactive models are usually related to legislation, social pressure, the organization's public image, and the will to minimize the extent of claims and premiums paid to the insurance companies.

One can identify a tendency of moving from reactive to proactive models in organizations that are active in the safety and risk management domains. The reactive models are associated more with external focus of control, while the proactive models are more internally motivated. In other words, organizations that adopt organizational culture of risk management and ascribe great value to that issue, seek means to manage risks and not only to follow the letter of the law, or succumb to public pressure.

The second characteristic of the specified model, a model with proven results, relates to two significant sub-characteristics:

- A model that has proved its success in large scale organizations. Success in this context has many meanings: The management's commitment to the model's implementation, establishing cooperation on behalf of the management and achieving positive results – reducing the risks.

- The model does not have to stem from the healthcare realm; there is a place for learning from other realms, sharing common characteristics. This insight formed a revolution of thought. The healthcare world perceives itself as very professional and committed, thus the idea that it can learn from other professional sectors, was a significant breakthrough that shattered this set of thought.

It can be claimed, that in a second thought, after it was clear that a successful risk management model couldn't be found within the medical realm's boundaries, Macabbi's Risk Management department founders have come to the following insights that guided them up the road:

- The risk management sector in medicine is relatively new.

- A lack of healthcare organizations, implementing risk management in a systemic and integrative approach, raised the need for cautious, deliberated and controlled moves.

- Maccabi does not go in a well-known way but takes the role of pioneering.

- It is too early to abandon the search for a model, but it is necessary to expand its definitions without waiving the basic principles of the specified model: a proactive attitude and proven results.

In case there is no model, is it wise to define one based on personal experience and organizational goals ?

The redefinition of the need, after failing to allocate a model that is congruent with Maccabi's specific needs and the insight that it is a new domain taking its first steps, gave rise to the thought that it may not be possible to find a model, even in its redefined and alleviated definition.

The dilemma of what is the better way rose - to search for a model that will congruent partly with the specifications or maybe to develop a new model that will congruent with Maccabi's specific needs perfectly.

The insight that the healthcare risk management sector is underdeveloped was the decisive factor in setting the goal of searching for a new model, even if it is not the ideal model that will guide Maccabi in its first steps in the risk management realm.

Looking back at the events, it became clear that this was a right decision since it allowed relying on a relevant model from another realm on the one hand, and focusing on routine risk management procedures, that have gradually expanded during the years on the other hand.

The idea of developing a model in the department's first days, would have kept it busy for a long time, not allowing the establishment of work interfaces with its customers, the caregivers, and the establishment of working patterns with the managers in the center and the districts, thus causing its failure.

Many buzzwords, lots of papers, lot of ideas, but no benchmarks, neither model that can exhibit proven results.

The organizational need, to learn lessons from its own activities, motivated vast organizational activities in order to utilize knowledge resources accumulated during activity. Terms such as "Knowledge Management", debriefing and lessons learning, have become very trendy during the nineties.

Along with the traditional organizational structure, a new position of Chief Knowledge Officer (CKO), was instituted for the purpose of managing the creating processes, collecting and implementing the organization's knowledge.

The evolved concept stated that along with the organization's work procedures which aim to achieve its defined goals, great deal of knowledge, regarding the implementation methods of diverse procedures, have been accumulated which is not necessarily utilized in order to improve the quality of procedures and products.

A wise utilization of this knowledge, can improve the competitiveness of the organizations by improving their work procedures.

In Aviation and especially in combat/operational aviation, it is customary to debrief every sortie in order to learn lessons in the individual level and impart it to the whole system. The emphasis is on debriefing every flight rather then flights in which adverse events took place. There is no doubt that aviation owes its low accidents rate and qualities of performance to the debriefing procedures.

The basic concept of all of the attempts to have a benefit from the knowledge accumulated in organization, is expressed in the term "reflective thought", which is , the thought about the activity and decision procedures as an integral part of the organizational culture.

Sullivan and Harper, in their book "Hope is not a Method (1996), present a new approach that has significantly advanced the US Army to be capable of dealing with the new characteristics of the modern battle-field. Among other, Sullivan served also as the Chief of Staff in the US Army. Gordon and Harper believe that the most significant progress was a result of implementing the AAR – After Action Review concept, that is basically a reflective thought aiming to derive insights from activities and decision making processes, in order to implement them in the next mission in a better way.

What about other industries that share some common specifications?

In retrospect, in the mid nineties first thinking of association between medicine and aviation have become apparent, demonstrating the relation between medicine and aviation in the aspect of risk management. It is interesting to notice, that the striving towards the meeting between the two sectors was born almost simultaneously from three directions:

- By national factors, such as the American presidents Clinton and Bush, following the IOM's studies (1999, 2001) were published and after it became clear to the Federal Government that it is not possible to ignore these thought-inspiring works.

- By healthcare factors, feeling that they have to move fast in order to present activity and results in relatively short time periods.

- By aviation risk management factors, willing to contribute from their successful experience in aviation.

We assume that these authorities' motives were complex and included the following elements:

- The awareness to the extent of errors and their criticalness has permeated the consciousness of the aviation risk management professionals and they felt they have the knowledge and experience through it is possible to assist the healthcare realm to manage its risks. Thus for example, in the 11th Aviation Psychology Symposium, was sponsored by the Ohio State University (OSU) in 2001, Uhlig, Haan, Nason et al. presented an article titled: "Improving patient care by the application of theory and practice from the aviation safety community". It is important to mention that the conference has been dealing for more than 20 years with the diverse aspects of the human factors in aviation and flight safety, and is intended to a professional community of aircrew members, psychologists, managers and aviation risk management professionals.

- We all need healthcare services in one time or another. Those are relatively frequent interfaces of ours, of our family members and of friends. Each one of us has heard "stories" of dissatisfaction due to the care given and is some cases of negligence. Aviation risk management professionals have noticed the risks prominently, due to their professional experience and identified the need to improve the healthcare system.

- Some of the risk management professionals, after many years in the aviation, looked for other professional and business sectors. The healthcare sector has the needed characteristics: It is a highly professional sector with a vast extent of activity, that is becoming aware of the risk management issue, that pays an enormous price for errors, in human life, growing budgets and lose of public image . The healthcare sector was definitely perceived as a professional and business opportunity to the aviation risk management professionals.

This was the situation with Maccabi's as well. Maccabi was looking for a risk management model and Eilat – Consulting and Accidents Prevention Means ltd. that dealt with risk management in aviation and other sectors, has come to the conclusion that the healthcare sector might need the risk management experience accumulated in aviation.

In retrospect, it seems that what appealed to the healthcare sector in the Aviation was the explicit and prominent characteristic of risk management in aviation: The reporting system. The hope that physicians will report adverse events in which they were involved and also " near miss" events, was perceived in the healthcare sector as a significant breakthrough, even before the question of "what should be done with the reports? " was discussed. Liang and Storti (2000), believe that the healthcare realm will adopt the successful reporting model from the aviation sector in which the reports are received, processed and stored by a third and uninvolved party.

In many occasions, the issue of taking inspiration and adopting processes from aviation, regarding risk management, was raised and discussed, after the publication of the IOM reports (1999, 2001). Here are some illustrative examples:

Selecky, (2000), the secretary of Health, stated, following the publication of the 1st IOM report, to err is human" (1999):
"There is no "magic bullet" to solve the problem of medical errors. A comprehensive approach to improving patient safety is needed. Such a large and complex problem needs a thoughtful and multifaceted response. A combined response is suggested to both compel health care organizations and providers to take action and to enhance knowledge and tools to improve safety and break down legal and cultural barriers. The authors urge healthcare providers to adopt strategies, processes and technology that other high-risk industries (e.g., aviation) have implemented to reduce error…"

At AMIA, Annual Symposium (2000), it was stated by a panel dealing with slips, mistakes and faulty reasoning:
"Several industries (e.g., aviation and nuclear power plants) have been very successful in preventing human errors and there is much that health-industry can learn. As an interdisciplinary field for the study of information processing in humans and machine, cognitive science can make a significant contribution to human error studies and the panelists will take this challenge."

The will to adopt the aviation approach to risk management, in which one of the basic principles is "Blame free Culture", had to challenge the traditional professional healthcare culture of caregivers personal responsibility for errors. This cultural discrepancy was stressed by Renhard (2001):
"Most of the evidence and argument about the effectiveness of punitive approaches comes from the health sector; however, the experiences of other industries like the aviation industry in the USA suggest that the basic findings about punitive approaches are transferable. There is the question of the transferability of evidence from high risk (where people die or are injured directly as a result of mistakes) to low risk industries. However, if the problem is understood from a behavioral perspective, the appeal of the argument that punitive approaches suppress problem-solving information is apparent".

At the beginning of 21th century, the awareness that healthcare systems are high risk systems, spread widely amongst healthcare leaders, public and politicians. It also became evident, that healthcare may benefit by learning from other high risk industries, like aviation and nuclear power plants, rather than trying to invent specific tailored made approaches.

Enhancing Patient Safety and Reducing Errors in Health Care

In a conference that took place in Annenberg in November 1998, which was defined as a multidisciplinary conference and in which some of the leading organizations from the healthcare, science, government and medical accreditation sectors participated, a reference was made to the first conference in 1996, stating:
"….. More than 300 participants from around the world discussed case histories of human injury during patient care, reviewed research findings on patient safety and medical error, and studied parallels between health care and other endeavors-including aviation and high-technology industries-in which safety and human error are of concern….".

In the setup of the 11th Aviation Psychology Symposium, Wood presented the adverse events reporting cycle, the debriefing, analysis and feedback, as principles of the accustomed reporting procedure in the US Aviation and its potential contribution to medicine by adopting it.

According to Reason (1994), in the mid eighties several multidisciplinary studies were initiated with the purpose of understanding the human err phenomenon in medicine. In his opinion, one of the most significant conclusions of these initiatives was that causative models of accidents, that were developed in a

specific content world, such as aviation or nuclear power stations, are congruent with most of the medical environments. Moreover, this conclusion is also valid for many recommendations and remedies that were developed in other realms.

In retrospect, after Maccabi adopted the aviation model, it became evident that the insight that the healthcare sector can learn from other high risk sectors such as aviation and nuclear power sites , when it comes to understanding the diverse factors causing human error and implementing organizational activity, aiming to reduce the extent of the phenomena, has validity. The principle of reporting of adverse events in an atmosphere that encourages reporting and learning rather then punishment was especially stressed.

From the point of view of the departments founders and mangers, it was elementary that the issue of errors during medical care, is a complex and sensitive issue and that it will be helpful to allocate a sector that shares common characteristics and handles it successfully.

Chapter 6.3

Good things happen by accident- Maccabi is introduced to Aviation

Eilat's - Experience and practical "know how" in search of opportunities for implementation.

In 1996, the Eilat Company, which we established in 1987, provided consulting services focusing on safety consulting and tool development (especially computerized tools), for the Israeli Defense Forces, Air Force, El-Al and other large organizations. These clients were characterized by their high awareness of safety issues due to the high price they had to pay when safety was compromised, and had a long history of dealing with this subject. It can be said, that our clients hired our services, since we had many years of expertise in dealing with safety issues in the Israeli Air Force, which serves as a model of excellence in the human, technological and organizational aspects in Israel.

Aviation has a proven model for accident prevention - Can it be implemented in other areas that share the criticality of errors outcomes - Healthcare?

Since Eilat's marketplace was small and limited and since it had no interest in safety training, which is the main occupation of safety experts, we began to think of new markets: content worlds that traditionally have not dealt with safety issues and Risk Management.

We thought of three new optional domains:

1. **Large insurance companies** - The concept we established for them was based on risk management work with their larger clients. The target was to minimize the risks the companies are exposed to, and thus lower their claims. However, after several intensive attempts and expressions of interest by them, we realized we were still unable to get a full scale project. After several years, and accomplishing several limited projects in the insurance arena, we realized that in the set up of insurance companies, the claims department and

the underwriting departments were separated, so that actually there were two organizations in each company, each organization having its own agenda, sometimes contradictory. So we decided to give up insurance and to look for another marketplace.

2. **Banks** – Israeli Banks, lost hundreds of millions of dollars every year due to irrecoverable client debts. The concept we developed for the banks was to treat each case of lost debt as an accident and a debt, that was eventually redeemed as "near miss". Our suggestions , generated much interest among the senior management of the Israeli banks, but at that period, we did not receive any requests for projects from them. . Several years later, we ran a risk management project for one of the leading banks in Israel. In the crucial discussions on whether to address the subject and start the project or not, the dominant argument was that there are already guidelines and policies covering the risks of giving credit to clients, and all there is to be done is to enforce them, and therefore, there is no need for risk management activities. We learned, that the banks are conservative organizations, that as long as they make profit, despite the lost debts, they are not going to get involved in any proactive risk management action.

3. **The Healthcare domain –** There, we discovered an almost "virgin land" with only minimal and local activity of few devoted professionals, but with no significant methodology and infrastructure. The need to manage risks in healthcare, seemed valid, appropriate and timely. We chose to apply our expertise in risk management in the aviation area to the medical field. In addition, to the business considerations, we felt that we might be able to contribute significantly to the improvement of healthcare quality in Israel and maybe even worldwide.

The Rambam hospital encounter.

In the middle of 1996, in social circumstances, an introduction was made between an organizational consultant, who worked on organizational development at the Rambam Hospital in Haifa at the time, and us. During that social encounter, we told the consultant about our expertise and our ideas of expanding our knowledge and applying it to the medical risk management field.

He thought it was a great idea and it was decided that we would make a presentation in a conference on legal aspects of Risk Management, that was

conducted on June 4, 1996. Our presentation was titled “The human factors in risk management in aviation and medicine”. Tens of physicians and nurses participated in the conference and the presentation received much applause as an “eye opener”. In the same conference, other prominent speakers were: Prof. Moshe Revah, the hospital director, Prof. Shimon Polak, director of quality control, Dr. Ran Lin, director of the risk management unit, IMA representatives, legal advisors and Dr. David Shram, then a risk manager with MRM, a subsidiary of an malpractice insurance company, specializing in medical risk management.

During the conference, a professional association was made with Dr. Shram, who was deeply impressed with our unique perception and expertise in the area of risk management in aviation and its potential applications in medicine. Following the conference, it was decided to conduct a one-day workshop on safety in medicine, based on the Air Force model, to the nursing staff at the hospital, as part of the “management skills” course they participated in.

The workshop took place on September 9th, 1996, in which and seventeen people of the nursing personnel participated. The workshop included, among others, the following topics: basic concepts (accident, risk, near miss), human factors in safety, analysis of risks and risk situations, models, incident analysis and application of the principles in the hospital set up and more.

The feedback for the workshop was positive - on a scale of 1-7, the scores on the different items were between 5.5 and 6.7. In the open section of the questionnaire, we received comments such as:

- *“I think the subject is very important and should be given two days of study, since there was a lot of material and time pressure…”*
- *“Training in the area, might prevent tragedies and exposure of the erring person to harmful situations.…”*
- *“A very important subject. There should be a training program for the subject for all nurses in the hospital”.*

Despite the workshop’s success, there was no continuation of the project at Rambam. At that period of time in 1996 it was very discouraging, since there was no obvious reason to stop the activity, especially with such a positive feedback . The activity subsided.

Looking at it after some time, with a different perspective, we understood that it was not enough to be right: we also had to be smart, and that the relations we made at Rambam were not with the decision makers but with practitioners, whose ability to change attitudes and work patterns was very limited, as was shown retrospectively.

Eilat is introduced to Maccabi.

During our activity at Rambam hospital, a cooperative relationship was built with Dr. Sharm, who presented himself as a “risk management expert” and had both medical and legal education. Dr. Shram was the one who made the initial introduction between Maccabi and us. Dr. Shram was aware of Maccabi’s attempts to find a working model and experts in the area of risk management to assist them in their first steps.

In the beginning of 1997, we had a professional relationship with Dr. Shram, which was aimed at preparing a presentation to decision makers of Maccabi that would focus on our experience and perceptions regarding risk management, based on the aviation experience.

Dr. Shram's approach was based on a combination of medical and legal issues aimed at providing a legal umbrella for all the activities in a medical organization, especially with regard to risk management, since work processes in risk management create a relatively wide exposure to legal risks. .As opposed to Dr, Shram's approach, we had the “clean” approach of aviation risk management, in which legal aspects of human errors and accidents were irrelevant to risk management experts, whose efforts are directed at understanding the causes of errors and generating organizational processes to prevent their recurrence. This separation between risk management and legal aspects is a unique feature of the aviation attitude, but in the medical field, the inherent conflict between the need to reveal and investigate errors and the need to provide legal protection to the medical staff as individuals and as an organization, still remains unsolved.

Maccabi: This is what we are looking for, finally.

Our presentation to Maccabi was given on April 15, 1997, and following it, we offered Maccabi our services for conducting an initial assessment in order to be able to establish an operative working plan.

A month later, in May 13, 1997, the medical director of Maccabi, Prof. Aviram, approved our proposal for the assessment, and conditioned it with our signature on a confidentiality agreement.

Dr. Racheli Wilf-Miron, director of the risk management department, participated in November 1997 in the 19th annual conference of the American Society for Healthcare Risk Management (ASHRM) in health care systems which have taken place in Atlanta, USA.

In her report, Dr. Miron wrote that the opening lecture in the conference was given by John Nance, a pilot, legal expert and specialist in the area of aviation safety. This lecture focused on the common characteristics between the cockpit and the operating room, and what can be learned from crew resource management, which was applied in aviation, to the improvement of the work of the surgical team in the operating room. Dr. Miron remarks that the audience's response to the lecture was very favorable as if saying, *"How come we did not think of it before…?"*

It seems that the initial work done at Rambam hospital, though did not continue, generated the opportunity for the relationship with Maccabi. The approach of studying the organization and its current work in the area of risk management in order to establish a working plan was the right one, since it allowed for the expression of expectations and fears of the interim directors in the area of risk management.

The assessment work itself allowed for a mutual exposure between the organization and us and for the creation of a basis of trust between us. The participation of Dr. Racheli Miron in the 19th annual conference of risk management, in which the resemblance between the worlds of aviation and medicine was shown, gave the final legitimacy to the way Maccabi chose to assimilate the subject of risk management.

Retrospectively, it seems that the process was led by chance or even incidental, but we believe that it was a meeting of real needs, in the right timing, with encouragement, given by the professional community in the US.

Chapter 6.4

The initial stages of establishing the dialog with Maccabi

"Discovery consists of what everybody has seen and thinking what nobody has thought"

Albert von Szent-Gyorgyi – 1937 Nobel Prize Laureate in Medicine

After the initial enthusiasm and the feeling of Eureka, proof is needed.

Eilat's capabilities met Maccabi's needs for risk management with perfect timing, with the USA professional community opening a dialog between medicine and Aviation, aimed at learning from the successful experience of the latter, in order to apply it to the world of medicine.

The initial feeling was one of enthusiasm, both on the part of Eilat, with the possibilities for entering a new domain and the approval for it's professional approach, stating that the aviation risk management model can be transferred to the world of medicine, and on the part of Maccabi that an entity exists in Israel, rich in experience in the world of aviation, with an approach similar to that presented in the USA, willing to transfer the aviation experience in the world of risk management to the realm of medicine.

The risk management staff and the Head of the Medical Department were enthusiastic. The administrators were much more hesitant and skeptical, regarding the association between Eilat and Maccabi.

With hindsight, and from the perspective of time, we realized that two forces with differing agendas and interests operate in medical organizations: professionals versus the administrators, some of whom have a medical background.

In most medical organizations in Israel, the authority for taking decisions is held by the administrators, due, amongst other reasons, to the claim that the doctors should focus on providing the patients with optimal treatment and need to be free of any foreign considerations in their decision-making. The administrators,

however, represent the general systemic view that includes budgetary constraints, procedures and regulations of the Ministry of Health, familiarity with the health market and so on.

Accordingly, following the enthusiastic reaction of the professionals in Maccabi, we conjointly with them had to persuade the administration of:

- The need for external consultants to develop and promote the case of risk management in Maccabi
- The justification for choosing the firm that specialized in aviation and lacked any real experience in the medical arena.
- The justification of the specific choice of Eilat, a small consultancy firm, with a narrow field of specialization: Risk management, focusing on aviation.

Some of the administration's attitudes towards medical professionals, came to light in meetings with them, primarily with the Head of the Procurement and Logistics who noted, amongst other things that:
"I didn't think about risk management. I don't like this concept. There should be quality control for doctors. They have complete academic freedom, they don't want to be computerized since this might inundate them with information and endanger them. The correct approach is: information, procedures and control."

In 1989, Eilat was involved in a CRM (Cockpit Resource Management) project in El-Al (Israeli Airlines).

While considering this attitude of the administrators in Maccabi, we had a kind of de ja vue as to the initial stages of the El-Al project. Prior to the approval of the project, we had to convince the administrative managers there, that the project is of high importance, while they claimed that:*"…Pilot's should act according to the regulations and everything will be fine…"*

Another representative on behalf of the administrators wondered: *"What will you provide us with ? What has been ordered from you?"*

On February 26th 1997, the IMA (Israeli Medical Association) and the Ministry of Health signed a treaty on "Advancing the Quality of the Health Services". This was brought to the attention of all the members of the IMA in a special letter sent

to each of them. The first subject to which the treaty related was Risk Management:

"A joint risk management administrative forum will be established that will include a representative of the Ministry of Health, the Clalit HMO, representatives of the IMA, a representative of the public hospitals and of MCI (The medical malpractice insurer). Once in a while, and in the beginning, once a month, this forum will discuss adverse events that will be selected for it, after removing any identifying details from them, and will draw and distribute conclusions on the national healthcare level. The forum will be entitled to recommend on establishing clinical and administrative procedures in order to maintain quality healthcare".

A flow chart was also attached to the treaty outlining the adverse events reporting process in hospitals and community up to the point of drawing and disseminating conclusions on a national level.

The treaty was signed by the Minister of Health, Mr.Yehoshua Matza, the Director General of MOH, Prof. Barabash and the chairman of IMA, Dr. Balashar.

In clarifying the treaty, Dr. Udi Kantor, Head of the Healthcare Policy Department in the IMA states, amongst others:

"The hasty demand to receive a report of an individual event before the Committee for Quality Control was appointed and met, contradicts the declaration of intentions, as formulated in the treaty. In our opinion, a national view of risk management of the present style that necessitates immunity on the one hand and cooperation on the other, will demand transferring assembled lists on a periodic basis. The reporting procedure, the events to be reported, the method of reporting and so on will be drawn up by the committee to be established."

Thus it happened, that a step of a national character, totally ignored Israel's other health funds, apart from the Clalit HMO, and from the beginning there were splits over differing perspectives, as can be noted in Dr. Kantor's comments.

The above is cited, in order to complete the general background, creating a feeling that the authorities, as well as the professional medical organizations, view risk management as an extremely important issue. Moreover, Maccabi was apparently not included in the "Forum" that was supposed to be the engine behind risk management in Israeli medicine.

Trying to define the relationship: Professionalism and business

In order to overcome the doubts of the administrative elements in Maccabi, following several presentations to them, and in order to commence the project, we offered them to perform a preliminary assessment of the existing risk management activities in Maccabi at our expense. The basic idea behind such a proposal was a gesture of good will that would enable us to start working. We, assumed that the joint work and the product of the assessment, would create the trust necessary to launch the full scale project.

In previous cases in which we proposed and performed assessments of the type offered to Maccabi the rates of success were not high. In other words, we invested considerable amounts of work, and when the diagnostic report was submitted to the organization's managers, they usually recoiled from its meaning and the need to establish risk management activities, preferring to deny the existence of such problems. In retrospective, considering some of this experiences sharing these common characteristics, one can wonder why these organizations were willing to do the assessment process without being ready to act upon it's findings ?

This entailed an additional business risk, since we received no compensation and nevertheless had to invest about 45 man-days , It would have been possible, due to overload and pressure of other activities, to devote less time than necessary to the assessment process, which was liable to fail us. In order to avoid this attitude risk, we submitted a detailed diagnostic program, including a Gant chart, to Maccabi, so that the planning would protect us from the possibility of inadequate attitudes to the work done for free, and which, in some of the previous cases, did not lead to prosperity.

On May 13th. 1997, we received permission from the Head of the Maccabi Medical Division to perform the assessment according to the proposal and the program submitted, and on the condition that we sign confidentiality documents.
This was the first formal step in a long term relationship, with many ups and downs and with a continuous watchful eye from the administrators to check whether we provide what we aimed to.

Chapter 6.5

The criticality of initial stages: about organizational politics versus enthusiasm of pioneers.

Managing the possible risks of establishing a Risk Management Department.

The decision to establish the Risk Management Department preceded by a year and half our acquaintance with Macabbi.

The main reasons for the Risk Management Department establishment, are reflected in an interview with Professor Aviram, (Head of the Medical Department in Maccabi, during the establishment period in 1996) ,which we conducted in November 2003.

From Professor Aviram's considerations it is evident that the establishment of the department was the result of several external and internal factors:

- As we have already mentioned IMA, Israeli Medical Association (1996) has come to an understanding with the Ministry of Healthcare to act conjointly in order to improve the Quality of Healthcare in Israel.

- A reporting procedure for adverse events was defined. According to these understandings. Healthcare organizations in Israel, particularly, the Klalit HMO (the largest Healthcare fund in Israel) and the hospitals, should report adverse events to a special committee, comprised of representatives from the Ministry of Healthcare, IMA and Klalit HMO.

- The first foundation of Maccabi's Risk Management Department, was materialized by a half-time employed nurse, financed equally by IMA and Macabbi, whose major role was to transfer the reports, received from Macabbi's caregivers, to the quality committee.

- MCI, Macabbi's malpractice insurer, demanded to get adverse events reports, as part of the insurance agreement, in order to enable them to asses the extent of claims they may face. This requirement was based on the insurers need to maintain financial stability. This requirement obliged the existence of an internal mechanism that gets the reports, processes them and passes them in an agreed format to the insurer. Even though, theoretically, there were two other ways to perform this task: by the legislation department and the ombudsman.

Anyhow, Maccabi's senior management has decided to separate the legislative and ombudsman activities from adverse events processing, and by this decision, actually, paved the road towards the establishment of Risk Management Department.

After studying the reported adverse events, the Head of the Medical Department, came to the conclusion that Macabbi does not utilize efficiently the reported events in order to prevent their reoccurrence. This insight led to decisions and actions that aimed for a better utilization of the risk management potential found in adverse events, in addition to Macabbi's external commitments in respect of adverse events: reporting to the Quality Committee and MCI (the insurer).

In the mid ninetie's, new voices that challenged the traditional ones, became evident, especially in the US, claiming that physician errors are not an inevitable result of the medical doing. These voices demanded to relate to the healthcare system as a system in which errors are the result of systemic failures, rather than merely the result of the individual physician's malpractice. Additionally, those voices suggested approaching other industries, such as aviation, in order to learn from their successful experience in minimizing the extent of errors and losses

Macabbi's management was not indifferent to those voices, while taking into account other above-mentioned-factors, decided to establish the Risk Management Department, based of the half-time nurse that was already working, and the assignment of the department manager – Dr. Rachely Wilff-Meron.

The initiative was pioneering and daring in Israel. Risk Management units were already operating partially in Israeli hospitals, based on an approach that focused mainly on nursing aspects and not in physicians' decision making and performance .

In the state of low awareness for Risk Management issues in Israel of the mid nineties, this move had several clear inherent risks:

- It was unclear to what level the caregivers will cooperate and will be willing to report adverse events, in which they were involved, and might expose them to criticism from their managers.

- It was unclear how to protect legally a caregiver that has reported an adverse event for which he might be held responsible. In such cases, the court of law might use the report as a confession for being guilty in case of a claim.

- It was unclear how to prove the contribution of the Risk Management Department to Maccabi, when taking into account its relatively high operating cost.

- It was unclear, based on what concept or model the Risk Management Department should operate.

Our partners in Macabbi, professionals from the healthcare sector that were appointed to lead the task of establishing the risk management infrastructure in Macabbi, needed our support in order to convince the administrators, that the adoption the aviation model, is the right and necessary step.

In practice, a professional coalition between us and the department's managers was created, having one declared goal: to convince the administrative people that the department's managers made their homework well in searching after a proper model in Israel and abroad, and that their choice of us is right both in the professional and business aspects.

The department managers' statement: *"We have checked well and this is what we want"* is a statement that administration people found hard to accept. Administrative people in healthcare organizations, earn their organizational accreditation by assisting the professionals, by finding the optimal administrative and procurement solutions for them, while the physicians have to focus on care giving only.

The mutual need to convince the administrative people, has actually created the first base for a professional cooperation between us and the department's managers.

The first shared goal was defined and a team work was established, aimed to the right marketing of the general idea of cooperation between Maccabi and us, and the operative plans to adopt the risk management aviation model in Macabbi.

From reflections we have conducted in the framework of this work, we have realized that the mode of birth of the department into the reality described here, influenced its first steps. We do not know, to what extent this reality was clear to the decision makers in Macabbi, before and during the department's establishment.

By analyzing the state of things in the in Israeli healthcare system in the timing of Risk Management Department establishment, it is evident that the department was not born into a supporting, mature, and encouraging reality, but into a reality in which the main players such as the Ministry of health , IMA, the insurer, and internal factors such as the legislation department, procurement and the ombudsman, had different apprehensions, sometimes contradictory, to the road map by which risk management, should be implemented in a healthcare organization according to our experience.

Nevertheless, we have found in 1996-1997, at the time of the department's establishment, three crucial national events took place in Israel and assumedly influenced the department's first steps:

- Publishing the patients rights law - 1996
- Publishing the Quality promotion treaty in Healthcare in Israel, by the MOH and IMA – 1997.
- Publishing the report of the committee assigned to examine the issue of responsibility for harm in the care giving process - 1999

In retrospect, it is possible to explain many of the attitudes towards the department's establishment, by the difficulties it faced setting its agenda and defining the further steps, by understanding the public atmosphere, that could no longer accept the lack of activity aimed to handle the physician's errors and trying to prevent them.

Among the other factors that influenced the establishment of the department, we may refer to the attitudes of the major players in the sector, among them the MOH, IMA and the insurer, who stressed the reactive approach that focuses on minimizing the losses after the adverse event has already occurred and internal Maccabi factors, that perceived the department as a threat, who may criticize their operation on one hand, and expose the physicians to claims, instead of protecting them on the other hand.

We realized that despite its pioneering, Maccabi's risk management department didn't born into a welcoming reality, but rather into a complex and ambivalent setup.

Who is responsible for managing the risks?

Basically, three alternatives were considered:

- The Physicians
- The "Center" - Risk Management Department (RMD)
- Risk Management Department will define the policy and guidelines and support physicians whenever they err and the physicians will be responsible for the patient safety.

The issue of responsibility for Risk Management is complex. First, it is necessary to distinguish between different kinds of responsibilities:

- **Legal responsibility** – The law system perceives the caregiver and the organization in which he practices as responsible for the malpractice in a case a patient decides to submit a claim.

- **Professional responsibility** – The perception of professional responsibility is directly related to the character of relationship between the individual physician and the organization in which he works. Thus, for example, a physician working in a solo practice is fully responsible for the professional level of the care giving he provides his patients. Macabbi employs physicians in two different ways: full time and part time freelancers, so it is fully responsible for the full time physicians' professional level and partly responsible for the freelancers. Macabbi's professional and administrative system is responsible for the professional level of its

fully employed physicians by guidelines, selection, training, professional supervision and quality control.

- **Moral responsibility** – an individual physician or a healthcare organization are morally responsible to provide a patient with the best available care, avoid harm during the medical care and take responsibility in case harm was done. The moral responsibility is a result of the values on which the profession of medicine is based and a kind of an unwritten agreement between the physicians and their patients that creates the basic trust, which is a necessary condition for achieving treatment success.

Therefore, in regard to risk management in medicine, it is more appropriate to consider it as a mixture of professional responsibility with moral responsibility. Even though, the legal responsibility is occasionally part of the overall responsibility for a medical error, it is not the direct interest of this work. For this reason we will relate to the notion of responsibility as professional responsibility solely.

The issue of who is responsible for the physicians' professional level is not solved since a substantial part of the physicians work in several organizations simultaneously: Hospital, Private clinic, Academy and HMO's. In addition, many of the physicians are employed in different work formats: Salaried, freelancers, consultants per hour etc.

Under these conditions, it is difficult for the employer to develop and control physicians professionally, and in the same time to act in order to promote risk management. On the other hand, relying on the alternative, that the individual physician will take responsibility for his own professional level and manage his risk, is not always reasonable.

Therefore, It seems that the optimal solution to the issue of responsibility for risk management, is one that is based on a risk management entity that functions at the headquarters level and is in charge of : developing and bequeath the risk management methodology, collects adverse events reports, investigates them and derives recommendations to prevent reoccurrence, provides feedback to the reporting physician along with professional guidelines aimed to reduce the probability of future involvement in adverse events, herein improve patients' safety.

The Management has to be committed

We refer to the process of risk management concepts transfer, first and foremost as an organizational cultural change. From our experience, two major reflections may be concluded:

- A process of organizational culture change is a marathon run and not a sprint. It took more than 10 years in the Israeli Air Force, till the organization, as organization, begun to adopt and internalize the culture of safety and risk management.

- Since it is a long term process, which entails every individual in the organization to change, the management's commitment to the process, which requires investment of substantial resources at the beginning of the process, without seeing any results, and later on consistency despite difficulties, is absolutely necessary. Not many managers are willing to sow today in order to make it possible for someone else to harvest tomorrow. It is a process with inherent risks and various obstacles, substantial resources must be invested, different organizational priorities must be set, so it is understandable why many managers withdraw from initiating risk management activities.

In any case, the persistence of Macabbi, who deals with risk management for the second decade by now and ascribes great value to the subject, indicates management's strong commitment to the process and understanding that it involves a cultural change and not a short term process.

In the preface to the booklet "Preventing the Next Error", published by Macabbi's Risk Management Department on May 2001, Maccabi's CEO at that time, Mr. Shabtai Shavit *, mentions, among others:
"From the standpoint of public commitment to take care of the patient's safety and the quality of care, Macabbi Healthcare fund has made a strategic decision to develop the risk management domain as a part of the Quality Assurance System. Accordingly, we have decided to do any effort in order to treat the factors for healthcare errors in a professional and long term approach, based on cooperation between the medical and managerial teams in Macabbi".

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*Mr. Shabtai Shavit was Macabbi's CEO when the risk management department's activity was initiated.

The booklet was distributed to all of the 3,500 Physicians in Macabbi, an action that reflects by itself the value ascribed by the organization to the risk management issue.

Mr. Shavit was quoted as saying more than once, that he is willing to pay one million dollars for a claim that is the result of a physician's reporting, if the adverse event is investigated in order to prevent its reoccurrence. He stated this uncompromising statement, when opponents to the establishment of Risk Management Department, tried to convince him that this might be a risky step because of the exposure of physicians to claims due to their voluntary reporting.

One of the most significant expressions of the management's commitment to an issue, is allocation of resources to certain activity. It is even more prominent in times of financial difficulties that require re-organization. Most of the healthcare organizations in Israel are in a budgetary deficit for years and work under continuous government pressure to re-organize and cut off expenses. This state of events is even more evident in the last three(2001-2003) years due to the economic decline in Israel.

The expansion of the department's manpower, from its foundation day till the beginning of 2003, is presented in the following table:

Year	1996	1997	1998	1999	2000	2001	2002	2003
Staffing of the RMD	0.5	2	4	4	5	6.5	7	7.5

It is evident, that during its first eight years of activity, the department has impressively grown from 0.5 employee to 7.5 employees, a growth of 1500%. This indicator is especially impressive, when considering the restrictions to expansion of other headquarter units in Macabbi. Risk Management Department's growth over the years is a result of appreciation of its contribution and potential to decrease the volume of physician's errors and to improve patient's safety.

The position of IMA (Israeli Medical Association)

We do not know about an explicit position taken by IMA towards the risk management activity in Macabbi. IMA joined the Ministry of Health and the leading malpractice insurer in Israel - MCI, in order to lead an national initiative aimed to improve the quality of healthcare in Israel. This intention was demonstrated in the treaty mentioned previously in chapter 6.4.

Actually, as we have already mentioned, the first active risk manager in Macabbi was financed by IMA and Macabbi conjointly. We know that IMA didn't support the initiative to establish a sovereign Risk Management Department with no relation to IMA, but we have no evidence to support this notion. IMA's concerns had to do with the argument that Macabbi's adverse events investigations, might be used as evidences in the court of law against physicians who reported adverse events.

IMA perceives itself as a major player in the risk management arena in Israel, but its position towards independent risk management activity in the healthcare organization in Israel, was not clear enough, in days RMD was established.

The position of MCI (The Israeli leading Malpractice insurer)

In the initial stages of the Risk Management Department's activity, the insurer objected Macabbi's independent risk management activity, claiming he already has a risk management activity which is based, among others, on Macabbi's reports. MCI deals with risk management activity as part of the secondary insurer's requirements to conduct such an activity. The activity is operated by MCI's subsidiary named MRM – Medical Risk Management.

The main insurer's argument for the objection is related to the approach according to which the relationship between the insurer and the physicians is similar to a lawyer-client relationship. This kind of relationship provides confidentiality to the reporting physician, whereas there is a possibility of exposing the reporter to claims and a usage of investigation findings as crucial evidence in the court of law, in case an internal risk management department is investigating the adverse events.

The insurer's preferred model, according to which the Risk Management Department serves as a relay for transferring field reports, was implemented in Klalit HMO. According to this model, all the reports are transmitted to MCI and processed in a triple mode:

- A reactive risk management, in order to learn lessons from adverse events and utilize them to control and minimize its losses.

- Estimation of the financial obligations extant (Quantum), it is expected to face as a result of claims following the adverse events and conducting the legislative procedure.

- Conducting Risk Management activities conjointly with the insured in order to prevent adverse events reoccurrence.

The commitment Macabbi, was ready to take upon itself towards the insurer, was to report to MCI on the occurrence of an adverse event in order to supply legislative protection to the physician and to make it possible for MCI to asses the quantum. No investigation findings or conclusions are transmitted to MCI by Maccabi.

The position of Israeli Ministry of Health

In 1999, the Israeli Ministry of Health has published a special report of the committee appointed by the government to handle the issue: "*The report of the committee for examining the responsibility for harm during medical care"*. In the committee's report it is mentioned that the government's motives to appoint it are unclear and documentation regarding the possible motives was unavailable.

The presumption is that the government's motives were related to the increasing number of claims due to malpractice, following the "Patient Rights Law" published in May 1996 which made the medical record accessible to the patient, and the attempts to prepare accordingly to deal with this issue.

Physicians and jurists were appointed to the committee and Judge Dr. Gavriel Klinger was appointed as Chairman.

The committee's report presents actually the approach of the Ministry of Health, regarding the issue of risk management in Israel.

Chapter 9 of the committee's report: "Insurance and Risk Management" clarifies the Ministry of Health attitude towards risk management in Israel, at the time of the report publishing. As a matter of fact, the chapter's title clarifies the attitude in an undisputable manner - risk management is considered as a mean of the insurer to control and minimize losses of adverse events in medical practice. A citation from the Chapter 9 makes the point even clearer:

"Risk management is intended to document every adverse event in a healthcare institution, in real-time. The documentation is independent and not related to the complaint or financial claims. The documentation is intended to assure the ability to asses potential claims and the existence of documentation in case a claim for compensations will be submitted in the future".

A reference to risk management, aimed to improve patient's safety and quality of care appears after the previous statement:
"Risk Management is also of great importance for another purpose that has public significance and eventually will also decrease costs. Risk Management may help in allocating problems related to caregivers or circumstances that might lead to malpractice. A truthful reporting at real time, to a system, experienced in learning lessons and deriving conclusions, might lead to a significant improvement in the quality of care in a relatively short time".

As we have already stated, in February 1997, a treaty was signed between the Ministry of Health and IMA aiming to structure the issue of "Promoting the Quality in the Healthcare Services". According to this treaty, a Risk Management Forum will be established including representatives from the Ministry of Health, IMA, Klalit HMO, hospital managers and MRM on the behalf of the insurer,.

From the above said, one can conclude that the Ministry of Health did not take a clear position regarding the establishment of internal risk management organs in Israeli healthcare organizations.

Moreover, according to the committee's report, addressing the issue of responsibility for harm during care giving and the treaty for promoting the quality in the healthcare services, the Ministry perceived risk management as a reactive function, aimed mainly to reduce costs, rather than a proactive one .

Establishing interfaces with the Legislation department and the Ombudsman.

Allegedly, there is a contradiction between the Legislation department's activity and the Risk Management Department that pushes both sides to be in the opposite trenches.

The Legislation department is expected to supply legal consulting and deface to the healthcare organization and its employees, in order to set the appropriate working conditions enabling them doing their job.

The RMD gets the adverse events reports, investigates them and provides personal feedback to the involved caregivers and to the organization in order to reduce the exposure to risks.

From the Legislation department's point of view Risk Management Department's activities create an exposure of both, organization and caregivers to claims.

The "Patient Rights Law" published in 1996, provides immunity to a healthcare organization regarding information created by its Control and Quality Committee. The act doesn't formulate the immunity conditions for information generated by internal Risk Management Department activities.

In this state of affairs, it was understandable why the legislation department tended to adopt one of three following solutions:

- The caregivers will report adverse events to the Legislation department, which will allow defining these reports as a part of lawyer-client relationship, thus immune.

- The caregivers will report to the insurer and he will be in charge for risk management activities, which will allow a similar lawyer- client definition of the relationship.

- Establishment of organizational and functional relationship between Legislative department and Risk Management Department, which will enable the possibility to interpret Risk Management Department and reporting caregiver's relationship as lawyer-client relationship, thus immune against claims.

This position was expressed dramatically when one of Legislative department lawyers, in a presentation to physicians, recommended to stop reporting adverse events, in order to avoid exposure to claims.

In retrospect, the Legislation department's considerations were not verified even once - there was no a single instance in which a caregiver was sued as a result of reporting to Risk Management Department or as a result of an investigation conducted by it.

From time to time, the tension between Risk Management Department and the Legislative department arises again, as if refusing to quit, especially when malpractice is discussed by the media or when new lawyers join the Legislative department of Maccabi.

There are two systems in Macabbi receiving reports, which may serve as quality indicators: Claims regarding the Quality of service, reported by patients to the Ombudsman, and adverse events reported to Risk Management Department by the caregivers. In many cases patients claims, reported to the Ombudsman include an adverse event too. This issue was studied in 2002 by the Risk Management Department and it was found that about 60% of patient claims are actually adverse events that should be reported by the physicians to Risk Management Department.

Facing the reality of a small percentage of adverse events being reported (about 5%, according to several references in the USA and Great Britain), adverse events being reported as patient claims, is a valuable resource for Risk Management activities.

Working interfaces with the Ombudsman had to be established at the very initial stages of Risk Management Department activities, in order to feed the Risk Management processes with adverse events from this source.

Documented, Initial organizational decisions regarding the RMD

Due to the criticality of the unsolved issue of confidentiality, regarding information associated with adverse events reporting by physicians, few documents were compiled dealing with Risk Management decisions.

In many cases, although decisions were made regarding general approach questions and specific issues, they were not documented.

In this section we will present and reflect on two documents, from the first months of Risk Management Department activities:

- **Risk Management reason de etre'** – a presentation by Dr. Willf – Meron to the CEO and the secretariat of Maccabi ion March 1997.

- A Summary of the first decade of operation: 21.11.1996-12.6.1997 and the first working plan for the year 1998 published in July 1997 and sent for the approval of Maccabi's CEO Mr. Shavit.

The mission statement that opened the presentation was:
"Decreasing redundant expenses and improving the public image of the organization by identification and improvement of procedures being risky to healthcare services"

The mission statement, presented to the secretariat, which serves as the board of directors, stressed the financial benefits of Risk Management activities.

In retrospective, this was a marketing argument, aimed to convince that Risk Management will be of value to Maccabi, in terms of cost-effectiveness, although nor we nor Risk Management Department managers knew how to measure the financial benefits, at that time.

The argument was based on the Aviation experience in which the financial benefits, proved as valid, by saving many lives and resources.

The presentation to the secretariat focused on the following issues:

- **Risk Management's History and current trends**– Changes in the litigation atmosphere towards recognizing patients rights and physicians responsibility for errors, insurers demand to establish Risk Management activities as a condition for insurance renewal and financial aspects considering Risk Management as means to decrease the entire healthcare expense per capita.

- **Current approaches to Risk Management** – Integration of Quality and Risk Management activities, utilization of statistical methods, characterization of behavior and patterns that lead to harming patients and claims and development of programs aimed to improve clinical procedures.

- **Problems encountered by Risk Management** – Unclear policy regarding the issue of information confidentiality, the psychological barries to reporting and avoiding reporting due to fears of being punished, threat to the physicians autonomy due to managements involvement, geographically dispersed clinics and the character of working agreements Maccabi has with the physicians.

- **Suggested solutions** - Senior management commitment, establishing a Quality improvement forum headed by clinical leaders, wide dissemination of adverse events lessons learned, Risk Management participation in physicians professional meetings, frequent presence in the "field" and stressing the benefits for the physician from early reporting of adverse events.

- **Maccabi's Risk Management Department goals** –Reducing the expense per capita due to malpractice, Risk Management as a countermeasure to malpractice and improving accountability – the manner the public perceives the Healthcare services approach to physician's errors.

- **The suggested work plan** consisted of five major activities:
    1. Identification and mapping of risks.
    2. Improving the Quality of care
    3. Claims management
    4. Participating in Maccabi's strategically thinking and planning.
    5. Establishing a Risk Management forum with representatives from: Risk Management Department, Legislative Department and Head of Medical Division to discuss and decide periodically upon Risk Management activities and its organizational implications.

Following this presentation, Maccabi's secretariat, approved the initial work plan suggested by Risk Management Department's managers.

The presentation served actually as the Risk Management Department's first work plan and although being general, addressed the major issues anticipated to be opportunities and threats.

While analyzing the work plans in the following years, as presented in chapter 6.11, we realized that Risk Management Department's focus has changed from financial benefits to preventing errors reoccurrence, as the major goal. After convincing the secretariat with financial arguments, Risk Management Department managers realized that the real and immediate challenge is in preventing physician's errors reoccurrence, by deriving lessons learned from actual adverse events.

The summary of the first decade of operation, sent to Maccabi's CEO for approval, published four months after the presentation to the secretariat, was held, had some significant modifications as compared to the presentation.

Two major conceptual modifications are evident:

- The first was recognizing the urgent need for: *"Developing means for quantitative and qualitative assessment of the goals mentioned above".* RMD managers felt as if they have still to prove their case. Being able to monitor the progress in fulfilling the goals and to report this progress to senior management, was crucial for building trust and breaking the opposition to Risk Management Department establishment and its activities. It became evident that to conduct Risk Management activities isn't enough, being able to prove its contribution to the organization isn't less important.

- The second modification had to do with proactive rather reactive approach to Risk Management, following our promotion of the basic ideas of the Aviation Risk Management model : *"The philosophy behind the proactive approach, states that it is more cost-effective to prevent the harm, than trying to control the damage afterwards…"*

Three additional differences may be found, that share common characteristics of being operational issues to be addressed at the initial stages of Risk Management Department's activities:

1. Formalization of the relationships with the insurer – the summary states, that discussions were conducted with the insurer and the flow of information between Risk Management Department and the insurer was defined.

2. Allocation of a dedicated Risk Management computer system, able to support the evolving methodology of handling reported adverse events. The summary states, that the only available systems, are with inpatient orientation, supporting retrospective handling of adverse events and lacking the proactive approach adopted by Risk Management Department, following the Aviation model.

3. Promoting the Risk Management approach – a goal was set to meet with additional 1,750 physicians, in order to present them with the goals and activities of Risk Management Department. In addition, a half day workshop was intended to be developed and delivered to various professional sectors, in order to establish and maintain the relationships with Maccabi's physicians.

Summary

In this chapter, we tried to describe and reflect on the initial operational steps, taken by the Risk Management Department and modifications they underwent while being held.

As we have already mentioned, the establishment of the RMD in Maccabi, was revolutionary and visionary, thus evoking many ambivalent reactions inside Maccabi and its external interfaces.

Thus, the first Risk Management challenge of the recently established Risk Management Department had more to do with establishing and maintaining its case, rather than immediate handling of physician's errors.

The environment in which the RMD was established was quite hostile and not welcoming.

We believe that hiring us, was one of the decisions that served as countermeasure and protection means against this hostile and sometimes cynical setup, as if saying:
"It can be done; these guys have already done it in the Aviation, so give us together a fair chance".

Chapter 6.6*

Recruiting the right staff

"Many people dream of success. To me success can only be achieved throug repeated failure and introspection. In fact success represents 1% of your work whic results from 99% that is called failure "

Soichiro Honda – Founder, Honda Corporation

First Assignments – the criticality of assigning the right people to lead the change.

It may be stated that the department's character, goals and ways of action were highly influenced by the personal and professional characteristics of the "Founders Generation." The two department founders were outsiders to Maccabi, before their assignments in the Risk Management Department. It may have been coincidental, but maybe an intuitive decision that could have stemmed from several reasons:

- The department's establishment, was accompanied with oppositions from various sources in Maccabi, as we have outlined in the previous chapters. Assigning a department manager and deputy from outside Maccabi, could partly neutralize, at least in the beginning, biased attitudes towards the subject as a result of acquaintance with the leading functionary.

- The department's chances of succeeding were unclear at that time. Macabii's employees, were not keen to man a position with vague future and certainly a difficult one.

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* It is important to mention that this chapter, more than other parts in this work, is based mostly on our impressions, since literature on this subject is unavailable, and documentation of staffing the department in Maccabi is almost unavailable as well. It is of course, an important question on itself: why are not there works that deal with the professional profiles of risk managers?

- Due to the virginity of Risk Management domain in medicine, there was a shortage of people, with medical background and experience in risk management. In this state of affairs, the professional background and personality's characteristics had crucial weight in choosing the candidates.

More than once, when meeting people who are involved in safety or risk management in various domains, we have asked ourselves: *"Do they share any common characteristics?*", and if the answer is "Yes", what is the meaning of it?

Whenever, we met new risk managers in the framework of our work, these questions raised again and again. For some unknown reasons, we had the feeling we "know" them, their attitude, their way of thinking, their ambitions and determination.

Although it is not based on evidence, from our experience, we can draw several common lines of risk managers, whoever they are. It is important to mention that we refer to full-time risk managers who have been operating in this function for a long period, and not with risk managers, who function in risk management additionally to their defined duties and for a short period of time. Most of the risk managers we have met and worked with shared the following characteristics:

- **High level of morality**- Risk Managers, are people with definite values and high morality, which is expressed in many areas, including outside their job such as social involvement and activity in various association for the benefit of other humans.

- **Ascribing a great value to human life** and high sensitivity to cases in which this value is offense. People who practice risk management, have the feeling that they can save life's by their work, a feeling that gives high validity to what they are doing and a strong motive to make every possible effort and utilize any given opportunity to save human life.

- **A belief that a change is possible** - The domains we practiced in, mainly Aviation and Medicine are characterized by traditions and conservatism. We view the basic aims of risk management to be focused on conditions and processes modification, which allow the making of errors. We found, that most of the risk managers, preserve a positive attitude regarding the possibility of change.

- **A total commitment to the mission -** . Even though, most of the risk managers are employed as wage earners, they invest more effort and time, than is required by their position. This extra effort is aimed to produce a greater and a more significant impact. More than once, we found ourself telling a risk manager, in late evening hours*: "Maybe it would be better to call it a day; you will not be able to solve all the problems today, leave something for tomorrow..."*

- **A Personal Trauma** – Even though, this issue was seldom raised, especially in cases where a personal relationship was established between us and risk managers, we had the impression, that most of the risk managers have a personal motive in preventing errors that might harm severely humans. In some cases it was a personal involvement in a severe error or a serious harm to someone close, as a result of a preventable medical error.

- I**ntrinsic motivation** - Internal Locus of Control. In most of the cases, risk managers are motivated by the will to reduce the extent of errors, believing that their work truly promotes the achievement of this goal. Unlike other employees that need, from time to time, to be motivated by their managers, it may be stated that most of the risk managers are motivated by a feeling of a "mission."

- **Assertiveness** – In the first years of the department's activity, the managers experienced a professional dilemma - on the one hand, they lacked knowledge in risk management, but where assured they know how things should work on the other hand. It may be stated, that risk managers are assertive.

- **The courage to challenge the system** and to express personal points of view, even if it is not a normative and popular attitude. In many cases, managers prefer not to confront problems, that are brought up to agenda by risk managers. Managers are busy with promoting their business, providing service to their clients and keeping an eye on their competitors, and usually they are not willing to spend management attention to risk management issues.

Every time the department indented to recruit new risk-managers, it encountered difficulties in defining their profile. The department managers, had the feeling they have to look out for someone with some kind of uniqueness, someone that does not fit to a specific profile, since they valued more the personality characteristics than the professional background. In retrospect, two of the important criteria's were “glittering eyes” and a strong will to deal with the subject.

In retrospect, we may say, that all the risk managers that were recruited by the RMD, shared the above mentioned characteristics, to some degree.

Assigning the Head of Risk Management Department and her Deputy

When professor Aviram, Head of the Health Division in Maccabi, was looking for candidates for the departments managerial positions (manager and deputy), he did not find them among Maccabi's employees.

In an interview we had with professor Aviram on this matter, on December 5th 2003, when referring to the issue of allocating the department manager, he mentioned: *"It was obvious that he or she should be a physician with a lot of clinical experience, with a dynamic character, someone who will adopt the mission as his/her “baby” and together we will learn... We did not know what risk management is...good instincts are necessary as well, someone who managed something in an intermediate level, made decision and is familiar with organizational politics and practice".*

Dr. R.Willf Meron was about to finish her obligations at Tel-Hashomer hospital as a deputy manager of the pediatric department, and approached Maccabi to check whether there is a position for her. She was not familiar with the topic of risk management and did not necessarily look for a position in this domain.

The position was offered to Dr. Meron by Professor Aviram, after he considered her as an appropriate candidate for founding and managing the department. Trying to understand what RM is about, Dr. Meron has done for two weeks a thorough “homework” and eventually accepted the challenge.

When referring to Risk Management, Prof. Aviram stated: *"…Regarding risk managers it was even harder to characterize them, but it was clear they should not be lawyers."* The possibility of nominating lawyers as Risk Managers, was raised because a part of Risk Management duties had to do with interactions with the insurer and the legislation department and because it was crucial to provide the reporting physician an administrative immunity.

When examining the participant's composition, at ASHRM (American Society for HealthCare Risk Management) conventions, it becomes evident that most of the people who deal with Risk Management are nurses, few are physicians and few are lawyers. We have analyzed the background of the presenters in the ASHRM conventions in 1997 and compared it to this of 2003. The following table presents the results:

	1997		**2003**	
Papers Presentors	*Number*	*%*	*Number*	*%*
MD	2	*2.9*	2	*5.7*
Lawyer	13	*18.8*	6	*17.1*
MD-Lawyer	1	*1.4*	3	*8.6*
Nurse	**13**	***18.8***	**14**	***40.0***
CP	5	*7.2*	2	*5.7*
Manager: Judical, Insurance,Consulting, Medical firms	**35**	***50.7***	**8**	***22.9***
Total	**69**	***100***	**35**	***100.0***

When examining the table, we came to the following conclusions:

- Physicians are rarely active participants or presenters in the conventions, and this state of things did not change during the years.

- Nurses are the ones who deal with the professional aspect of risk management, almost solely, and there was no change in this setup during the years.

- The convention's character has changed: In the 1997 convention, more than half of the presenters belonged to the second professional circle of people who deal with Risk Management: lawyers, insurers, managers and consultants, while in the 2003 convention they comprised less then a quarter. Opposed to that, the share of nurses in the convention was doubled.

- The total number of presentations in 2003 convention has decreased to 50% of the 1997 convention.

Since the ASHRM convention is a major event, for those who deal with risk management, based on the assemble of presenters in it, it may be stated that the risk management profession was in those days perceived as a nurses profession.

It became apparent, that Risk Managers should be nurses with sound clinical background and with experience in clinical and administrative decision making. The rest of the skills were summarized by Prof. Aviram: *"They should be good inspectors..."*

The department's deputy, Mrs. Irena Levinhoff, was previously to arriving to Macabbi, a department's chief nurse at Ichilov hospital. "*Irena was a wonderful nurse professionally speaking, but nonconformist in her attitude..."* (Prof. Aviram).

The deeds of the pioneers as the model for the followers.

The impact of Dr. Meron and Mrs. Levinhoff, the first head of Risk Management Department and her deputy, was so crucial, that only with the nomination of Dr. Gindi, in 2002, the basic questions regarding the RMD operation, were raised again. These questions addressed issues like: What are the criterions for investigating an adverse event? What is the proper methodology to debrief an adverse event?, What is the right approach to implementing recommendations?

Most probably, if Dr. Gindi, a senior radiologist would have been different in her approach, the previous basic perceptions would be still dominant.

Dr. Gindi's basic approach was to test and challenge basic assumptions. It may be stated that Dr. Gindi doesn't take anything for granted and doubts any given set of assumptions. In this aspect she represents the classical risk manager's profile.

It is important to mention, that close to the nomination of Dr. Gindi as Head of Risk Management Department, the Risk Management Department was defined as and independent department in the Quality Directorate. This closeness of events made it easier for Dr. Gindi to revise Risk Management Department's basic work assumptions.

The issue of challenging the basic assumptions of the founders generation and the proper timing for it is an important topic in organizational development (OD).

Edgar, H. Schein, in his book "*Organizational Culture and Leadership"* (1997), dedicates a whole chapter to the way in which founders embed and bequeath a culture. Schein, distinguishes between Primary Embedding Mechanisms, which is the basic mechanisms by which an organizational culture is rooted, among them: issues to which the managers pay attention, measure and control regularly, the way in which managers react to critical events and crisis etc, and between Secondary Articulation and Reinforcement Mechanism, by which managers guarantee the continuation and transformation of culture, among them: The organization's structure, organizational system and work procedures, the organizational physical structure, ceremonies etc.

In our opinion, it is indeed possible to say, that after years of activity the department has developed a unique culture. One, who joins the department, senses almost immediately the existence of this unique culture and its power. This culture had numerous unique characteristics; some of them were discussed in the previous chapters. Among the main characteristics of the developed culture, we may refer to the following:

- Maintaining the reporters and reports immunity as a central value, and providing it with a confidential framework.

- Supporting physicians involved in adverse events as the department's core activity.

- Emotional involvement in the department's activities.

- Very close and direct relationships among the Risk Management Department staff, beyond the formal relationships imposed by the common goals.

- Total commitment of the staff to handle adverse events in order to allocate the right means to prevent its reoccurrence.

- A feeling of *"They and Us"* when promoting risk management issues was considered. It should be noted, that this feeling was prevalent at the early stages of the departments' establishment and in the last years it almost diminished and gave place to a cooperative approach between the center and districts.

- Managing the external affairs solely by the department's managers and only rarely by risk managers.

As already mentioned, with the nomination of Dr. Gindi, as head of Risk Management Department, all of the cultural characteristics listed above, were subject to a review and revision process.

Defining the right mixture of professions - Physicians and Nurses.

As we have already mentioned, it was clear to the Head of Healthcare Division, as well as to the new Risk Management Department managers, that most of the department's operations will be based on nurses that will be recruited and qualified for the job based on OJT (On the Job Training).

In their qualifying process, nurses are accustomed to work according to defined procedures, whereas physicians focus mainly on decisions making.

Since most of the department's activities, especially in the first years, were based on processing advese events, and since most of the risk managers worldwide are nurses, it was necessary to base the department's activity on nurses.

At the same time, in order to provide validity to the department's activity, especially when evaluating adverse events against the criterions of best practice medicine, it was important to integrate in the process a valued physician. The role of this physician was to represent the physician's standpoint and level of practice.

Dr. Meir Liron, a senior internist, previously a division manager at Ichilov Medical Center, who retired lately, was recruited for this position.

Even though, during the years, the department has constantly changed its face and grew in order to address the challenges of increase in reporting rate and starting new activities. It may be stated that the professional mixture didn't change: about 70% of the resources were based on nurses and 30% on physicians.

The ideal risk manager

It is important to mention, that despite the department's excessive efforts to allocate, screen and recruit risk managers, a profile of an ideal risk manager that will serve as a yardstick for candidates, was never defined.

The department's managers preferred to screen the candidates one to one, using their experience, intuition and personal preferences.

Nonetheless, there were several characteristics of the ideal risk manager that were discussed, whenever new candidate compatibility was assessed. These characteristics were raised in the case of their absence or weakness. In some of these screening processes, we took part and observed that three characteristics were especially dominant:

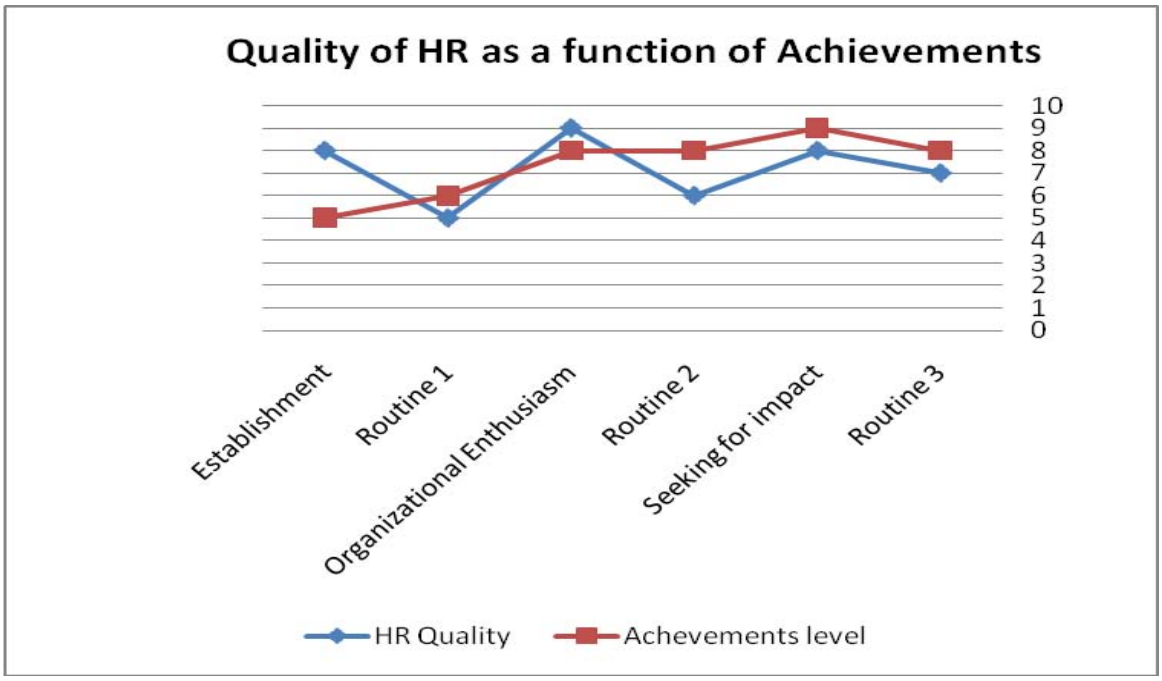
- **Relevant professional background -** a nurse with administrative and managerial background as a mandatory condition.

- **Enthusiasm** to deal with Risk Management issues and the ability to express and communicate it.

- **Unfitness of personality** that exhibits itself in attitudes, professional approach, values and career.

It appeared as if the RMD, managers looked for candidates similar to their self perception.

Based on our experience in aviation, especially in the IAF, we can state that the quality of human resources assigned to deal with safety and Risk Management issues, over time, behaves according to the following illustration:



It is important to make several remarks regarding the above illustration:

- It is based merely on our impression, which obviously, cannot be supported and validated by documentation.
- The illustrated milestones, are the result of our retrospective on flight safety activities, over a period of 20 years in the IAF.
- The suggested milestones, may endure different periods of time, according to the organizational setup.
- It seems as if the suggested milestones may be generalized to activities of new organizational entities, with a defined mission, not of the core organizational activities.

The illustration describes ASQAD, 20 years of activity, since it was established in 1974.

The illustration consists of six principal stages:

1. **The establishment stage** – in order to raise the issue into the organizational attention and define appropriate directives, an initial core staff of high quality is assigned. The achievements in this stage are basic, since it's a new entity, characterized by sporadic making, neither planned nor coordinated.

2. **The 1st routine stage** – After positioning the issue on the organizational agenda, the organization returns to its original attitude regarding that issue and prefers to appoint quality manpower to positions that are in the core of the organizational making. The accomplishments improve, thanks to the activities of the founding nucleus.

3. **The organizational enthusiasm stage** – Together with improvement in accomplishments in risk management, the organization's managers show more interest in this activity. They consider risk management as means to reduce expenditure, to improve the organization's public image and ascribe the compliments to them. This stage provides a good opportunity to get resources for the activity as well as manpower of higher quality. Accomplishments keep improving, even though the improvement rate is low as a result of the first routine period.

4. **The 2nd routine stage** – After the enthusiasm's stage, the organization starts to consider risk management activity as a well-based one, with proven results, and assigns quality manpower to other areas - core areas and new activities. There is a consistent improvement in accomplishments, as a result of continuity, standard procedures, and perseverance and positive changes in the organization's attitude towards risk management.

5. **The "Search for the impact" stage**- The second routine period creates in the entire organization and among the Risk Management Department staff an atmosphere of stagnation. It looks as if nothing of real significance is happening. Overcoming this situation is, of course, dependent on the organization's and risks management managers. The second routine stage, might last until, a severe adverse event will occur and stir the organization to conduct a revision of its basic concepts regarding the risk management issue. The very existence of this stage is contingent.

The accomplishments during the second routine stage, are usually satisfactory and there is no reason to change the situation. Realizing this stage requires quality manning, which the organization is willing to provide if the conditions to enter this stage have been created.

6. **The 3rd routine stage** - We consider this stage as a stage of maturity and stability, with good accomplishments and above moderate level of staffing.

No need to advertise - candidates are willing to join the RMD

We may state, that the Risk Management Department was in a continuous process of looking for personnel in order be able to cope with the increasing amount of reports and compensate for abandonment of staff- two risk managers and one physician in charge of departments R&D activities. Abandonment of staff from the Risk Management Department was a rare occurrence, due to strict recruiting procedures, which succeeded to allocate the right people for the right job. The few cases of abandonment were attributed to personal problems and not due to incompatibility.

The RMD's working procedures involved wider and wider professional circles - nurses and physicians in debriefings and defining recommendations. These encounters eventually produced interest in the department's activities and from time to time willingness to become a part of it. Actually, there was no need to advertise in order to recruit quality manpower for the Risk Management Department. In most of the cases there were several good candidates from which the most appropriate were chosen.

The screening process – a family like decision making.

Even after becoming larger, the department was still a relatively small organizational entity, characterized by high degree of involvement of the employees in each others life, professionally and personally. It is unclear, when and how it was decided that all of the department’s employees, should participate in the screening process of new candidates to join the department.

The decision who will be accepted was eventually always taken by the department's managers, but the department's employees had the opportunity to get to know the candidate by an interview, and express their opinion on the nominee's fitness for the position.

Some of the nominees, those who passed successfully the initial interviews, were sent to a screening institute to take psychometric tests that focused on cognitive and interpersonal capabilities

In some cases, the diagnosis results from the institute were controversial, that is, they didn't meet the expectations from the nominee. In at least one case, we are familiar with, the diagnosis results were less than expected in the personality aspects, nevertheless, the department accepted the nominee, since during the interviews, they have got the impression he/she can function well and has the "*right personality*".

To conclude, the selection process consisted of the following phases:

- The initial classification of the candidates, according to curriculum vitae and an initial interview, conducted by the department's managers.
- Personal interviews by each and all members of the Risk Management Department.
- Passing an aptitude battery in an external psychometric institute.
- Risk Management Department's summary meeting, integrating all the impressions and information.
- A decision made by the department's managers.

The training process – OJT (On the Job Training)

The training process of new risk managers was a mix of formal training with OJT and hands on and consisted of the following elements:

- **The risk management principles:** theories, terms and models
- **Risk management in medicine**: historical aspects and future trends

- **The RMD's working processes** - among them: receiving a report, managing and handling adverse events differentially, according to their classification, working with the risk management computerized information system, formulating and implementing recommendations.

- **Receiving calls via the "Hot-Line"** and giving support and feedback to physicians involved in adverse events.

- **Representing the subject of risk management** in different frameworks in the Maccabi's headquarters and districts.

The department's deputy had the global responsibility for the qualifying process. Theoretical "lessons" were given by us and practical ones by experienced risk managers.

Instructor's team's meetings took place from time to time, in order to evaluate the progress rate and identify specific problems that demanded a focused training or a different approach.

The qualifying process that had characteristics of OJT (On the Job Training), lasted a year averagely. The criterion to finish the formal qualification was: being able to manage all classes of adverse events and the ability to manage an independent investigation of level 3 (including a field investigation).

It is important to mention that even after the formal qualification has finished, the qualification process actually continues with professional supervision of the department's managers, medical and Risk Management consultants.

To compare, the qualifying process of an Air Accident Investigator in the US Air-Force was conducted in a framework of a formal course, which lasted three-four intensive months and consisted of about 500 class and hands on hours.

Sharing the experience - supervision, department meetings

Over the years of its existence, the RMD, has accumulated unique experience, in handling adverse events from a risk management point of view, with the sole purpose of preventing reoccurrence. To our best knowledge, this experience is rare and unique.

This unique experience focuses on understanding the factors and processes that enabled the occurrence of errors and adverse events, by methodical investigation of the events, as well as defining and implementing recommendations that stem from those investigations. The basic assumption of these activities wasn't aimed to defend the involved parties in case of claims, but rather to minimize the probability of error reoccurrence and thus harm to patients.

That kind of attitude towards adverse events characterizes the Aviation's Risk Management model, which despite its fashionability in medicine, is not implemented methodically and continuously by any organization we know, except Maccabi. VA (Veteran Affairs) in the States has established procedures for adverse events handling, without blaming the involved medical staff (PSRS, Patient Safety Reporting System).. VA's solution is based on the principles of the ASRS, Aviation Safety Reporting System. VA's medical staff reports the events to a third party (NASA), preserving this way the reporters anonymity and immunity. This approach seems to be a good solution for encouraging medical staff to report their errors, but, in our opinion, is of less value in formulating and implementing valid recommendations, aimed to decrease chances of error reoccurrence. Saying this, we believe that Maccabi's approach, is unique in preserving reporters' immunity, against claims on one hand, and debriefing adverse events, internally on the other hand.

Since the Risk Management Department's experience was unique, in the first years of its operations, it was almost impossible to inspire and enrich it by external resources. Therefore, the department's development was driven by three major factors:

- Experience accumulated among the department's staff, while handling adverse events.
- Our professional supervision and guidance, based on the Aviation experience.
- Transferring knowledge and experience between department's members.

Sharing personal experience is of great value in RMD's professional processes and culture, which was expressed in shared work-processes, in which a risk-manager involves the medical consultant, the department's manager, the deputy manager and us in his routine work. It is possible to say, that even though the responsibility to handle a certain event is of a specific risk-manager, it is actually a team work, which in its framework the professional and personal experience of each individual in the department is expressed and shared.

Additionally, a “cases review meeting” took place once a month, which in its framework, exemplary adverse events were reviewed and discussed. In the meeting, risk managers presented cases that were chosen for review by Risk Management Department's managers, and got feedback from all the participants, addressing the investigation’s process, its findings, conclusions and recommendations.

Nevertheless, in our opinion the internal lessons’ learning process, regarding the errors made by the department’s staff, while handling adverse events, despite improvement in the last years, still needs an upgrade, in order to enable the department to learn from its own errors on the one hand, and assimilate the meaning of being involved in an error on the other hand.

Chapter 6.7

Establishing the Adverse Events Reporting System

"Admitting an error was made, is taking the most significant step in preventing i reoccurrence"

Tal. Y. 2003

Motivating physicians to report their own errors

Studies conducted in the USA have shown that immediate reporting of adverse events by the involved clinicians, can serve as a forewarning in the identification of future claims regarding medical negligence and creation of a knowledge base for improving the quality of medical care (Lindgren, Christensen and Mills, 1991).

The researchers conducted an empirical study aimed to test the hypothesis that immediate reporting of adverse events may improve claim management and its results. The research confirmed the hypothesis that indeed, immediate reporting reduces the time needed for handling claims and their costs. According to Lindgren and Secker-Walker (1995), estimates regarding the scope of reporting by clinicians prior to claims, show a rate of 5-30% in the US and 0-2% in the UK. They claim that there are three alternatives for the establishment of reporting structure for adverse events in the health care systems:

1. Systematic survey of medical records in order to screen out adverse events in advance. According to this approach, there is no need to wait for the physician's reports of his own error, but to review patients files actively and manage them professionally. The disadvantage of this method is its inapplicability. At Macabbi, more than 12 million physician-patient encounters take place and about 3.5 million encounters with other health care professionals, yearly (data as of 2000). There is no practical way to conduct professional quality control over such an amount of information. In addition, even if it was possible, this effort would be intended at minimizing the damages from claims (the reactive approach) and not preventing them. This method proved beneficial for research purposes, but not for practical implication (Brennan et al., 1990).

2. Active risk survey in the medical environment in order to screen in advance for risks before they were expressed in an adverse event. This alternative is especially common in quality control activity, but is usually unacceptable for minimizing damages or risk management.

3. A reporting system in which physicians and other professionals report adverse events immediately after they occur. The reports are classified and investigated by one central entity. This alternative is the one adopted by Macabbi, with changes and modifications and it is also the most common alternative in health care systems taking risk-management actions.

The blame-free approach is presented in works regarding error reporting by physicians, as an essential condition for the establishment of physician error-reporting systems. Frankel (2001), remarked in a symposium dedicated to patient safety, the golden rules of the reporting system in aviation ASRS (Aviation Safety Reporting System), as rules the medical field should adopt as well:

- *Limited immunity*
- *Time limitation for disciplinary action*
- *Analysis of reports: two analysts read each report*
- *Involves everyone*
- *Ensures protection: prohibits the use of any reports submitted (on any disciplinary action, except for information concerning criminal offenses)*
- *De-identification*

Cohen (2000) and others, list a number of error reporting system characteristics in medicine. In the following table***.** Those characteristics are presented, together with our evaluation of Macabbi's standing with regard to each one of them.

Characteristic		Explanation	Evaluation of Maccabi's Reporting System**
1	No punitive	Reporters are free of fear of punishment	**7**
2	Confidential	The identity of the patient, reporter, and institution are never revealed to a third party.	**5**
3	Independent	The program is independent of any authority with power to punish the reporter or organization.	**5**
4	Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize the underlying system factors.	**7**
5	Timely	Reports are analyzed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.	**4**
6	System-oriented	Recommendations focus on changes in systems, processes, or products rather than on individual performance.	**6**
7	Responsive	The agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implement recommendations when possible.	**5**

* The basic table (Characteristics and Explanation) was adopted from Leape, 2002

** 1=Very low, 3=Moderate, 7=Very high

As a matter of fact, the table above can be used as a tool for evaluating existing reporting systems on adverse events in medicine. The picture that emerges regarding Maccabi's reporting system is rather positive, among other reasons, since it is based on the Aviation reporting model. Characteristics 2 and 3 are linked to Maccabi's organizational structure and to its obligation to report to its insurance company, and therefore cannot be modified.

Nevertheless, in our opinion there are two characteristics that still require improvement:

- **Timely** – the time span between the event occurrence and the reporting should be reduced, as well as the time between reporting and finalizing the investigations and the time between finishing the investigation and releasing recommendations. In most cases, the whole process, from the time of occurrence to the time of releasing recommendations lasts no longer than six months.

- **Responsive** – the working interfaces with the patients in charge for implementing the recommendations should be improved. We suggest considering the process of making the managers understand their responsibility for implementing the recommendations as a long term assimilation process and a cultural change.

In general, it can be said that the reporting system at Maccabi is a very good one, regarding the above criteria and that it is indeed based on the aviation model principles.

Organizational decisions to provide administrative immunity

The risk management department began to work as an organizational unit in Macabbi in the beginning of 1997. Still, the organizational decisions as of mandatory reporting at Macabbi and providing administrative immunity to the physicians, reporting their own errors, were accepted only in August 2000, when the board of Maccabi approved the “Adverse event reporting protocol”.

The protocol defined the term “adverse event” as an “*Unexpected occurrence during medical intervention that caused, or may have caused, physical or mental damage to the patient”.*

The objectives of the protocol, as listed in the protocol itself, were:

1. Establishing a uniform system for reporting adverse events in order to identify areas of malfunction and prevent risks with commitment to patient safety.

2. Defining a reporting process for adverse events to the risk-management department, that is in charge of investigating the events and reaching conclusions and recommendations.

3. Establishing adverse event reporting procedure to the Ministry of Health.

The protocol states that clinicians, as defined in the Patient Rights Law (1996), must report every adverse event to the risk management department.

In order to eliminate the clinicians' reluctance to reporting of adverse events, because it might expose them to claims, the medical director of Maccabi then, Prof. Alexander Aviram, sent a written assurance to all Maccabi's physicians stating that *"No disciplinary actions will be taken against a clinician reporting an adverse event".*

This was an extraordinary and a pioneering step in the Israeli health care system, and was intended to assure that the risk management activity at Maccabi will have a decent chance to succeed. Without this commitment, it is reasonable to think that it would have taken much longer to achieve the reporting rate seen today, if at all. This statement was termed "administrative immunity" and was implemented by the assigning the risk management activity as an operational subdivision of the "Committee of Control and Quality", according to its functional definition in the Patient Rights Law (1996).

The commitment of the head of the medical division raised several questions:

- Should it be applied to all types of events? If not what should be the exceptions and under what conditions? Will the legal structure adopted by Maccabi withstands the court test?

- To what extent will the doctors trust this commitment? And will it encourage them to report more of their errors?

Why should a physician report? The direct and indirect benefits.

Coles et al. (2001), conducted a study in the UK regarding clinicians' attitudes toward reporting adverse events. They have interviewed clinicians as well as risk management experts. A citation from one of those interviews shows the complexity of the problem:
"I think you have to address the fears and say why people don't do these things. I am sure some people don't do it for fear that they might lose their jobs, or being pilloried in the press. There could be a chief executive who says anyone in my Trust who instead of employee of the month is risk taker of the month and his or her names will be put around the Trust. They wouldn't lose their jobs, but they would lose the respect of their colleagues. I think you have to address those issues and give someone security – say we all make errors, no one is perfect."

The code of ethics of 2000 (E8, 12) of the American Medical Association, states that:
"…. Situations occasionally occur in which patient suffer significant medical complications, that may have resulted from physicians error or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred"

Understanding, what might motivate and what might prevent a physician from reporting an error is a major issue in each risk management activity. A risk management system cannot exist without physicians reporting their errors, since it is the basis for every reactive and proactive activity of risk management, both in the short and long term.

The motivation to report adverse events can be intrinsic or extrinsic. In most cases, where a risk management operation exists, issues regarding nursing were taken care of first (Mills and Bolshwing, 1995), while physician's adverse events were taken care of at later stages, if at all. The question why, traditionally, risk managers agenda was determined by nursing events and not physician events, is another question, which should be addressed in order to understand doctor's motivation to report their errors.

Physician's main role is perceived as decision-making (Badihi, 1993, among many others). The doctor-patient encounter, conducted in the form of SOAP (Subjective, Objective, and Assessment Plan) is a classical example of decision-making process. The doctor listens to the patient's complaints (subjective), checks the patient and his medical record (objective), analyses the data and makes an assessment, according to which he makes decisions regarding the care plan. Since it is a decision-making process, the alternatives are numerous and in most cases there isn't a clear cut solution.

The determination of adequateness of the decision, is in terms of reasonable or unreasonable. Thus, in most cases in which an error has been made, the physician has not always been aware of it, except in cases in which the decision had actual harming consequences to patient's health. Even in this case, a causative relationship between the available information the physician had at the time of making the decision, the decision made and the negative consequences is very difficult, if not impossible, to establish.

The meaning is that in a large portion of the cases, in which there was an error made by a physician, he was not aware of it, whether because the error didn't result in significant or obvious harm, or because of the difficulty in establishing an association between the physician's decisions and the patients deteriorating health.

Unlike physicians, the nurses' duty is to carry out doctors' orders, or the "plan", and provide the doctors with feedback regarding the treatment results and the patient's condition. Therefore, in the nurses work, there is a reference point to which it is possible to compare the nurse's actions. For example, if the doctors order was to inject the patient with a certain drug, in a certain dosage, it can be relatively easy to find out whether the nurse had performed the order accurately and according to certain standards or not.

From our observations, we can conclude that doctor's errors, are in the majority of instances, the result of faulty doctor-patient communication and decision-making, while nurse's errors are performance errors. In addition, nurse's errors are more easily pinpointed than physician's errors, since the nurses have to document their work in the patients chart. This documentation, makes it difficult to disguise errors and to move on with the routine. These maybe some of the reasons that it was so much easier for risk management systems to start with nurses errors.

We believe that all doctors, wish not to err and that if they have already made an error, they should be used to learn from and prevent their reoccurrence.

Still, a very high portion of doctors refrains from reporting adverse events. As we have already noted, estimates regarding reporting rates prior to claims, range from 5-30% in the US and 0-2% in the UK (Lindgren and Seckler-Walker, 1995). The data refers to reporting events, that ended up with legal claims. Thus, the reporting rates of events that have not ended up with claims are even lower, probably significantly lower.

It is important to note, that events that ended up with harm to patients do not fit into the intrinsic motivation to report, since the physician has a good reason to believe that his error, would lead to a complaint, and therefore it is better in his perception to report it beforehand.

We can summarize and say that doctors' reporting rates of their errors in cases of "near misses" and no harm to patient, are very low and amount to few percentages only.

Studies of physicians reporting of clinical errors, present many barriers to reporting, including fear, shame, lack of trust in the system, lack of time, arrogance and individualism (Anderson et al., 2001; Coles et al., 2001 and others).

It seems that doctors have a strong dilemma, regarding the reporting of adverse events. On one hand, they acknowledge the value of reporting as a basis for improving the quality of medical care, but on the other hand, they refrain from reporting due to the following reasons:

- **Fear of damage to their medical reputation** – the medical community is a relatively small and intimate community in which intense professional relationships take place. The doctor's reputation is a significant asset for him, both with regard to his patients and with regard to his colleagues. Doctors fear, that reporting events might damage their reputation. Since the organizational culture of most health organizations don't stress the distinction between blaming and learning from errors, the reporting physician might be pictured as a Don Quixote, fighting the windmills of the medical institution, that have not adopted the learning from errors culture.

- **Fear of claims** – the issue of legal immunity for doctors reporting their errors, which we discussed in the beginning of this chapter, still remains unsolved and doctors do not feel fully secure that they will not be sued after they report an adverse event. There are some creative solutions to this problem, such as reporting to an insurer, whose relationships with the doctor can be considered as lawyer-client relationships, or activity as the operating subdivision of the Quality and Control Committee, which is the solution adopted by Maccabi, and more. These are intermediate and not full solutions of the problem.

- **Fear of being "the village fool"** – since physicians are expected to perform with no errors, and the senior physicians tolerance of younger doctors is low, physicians make every effort to acquire all the knowledge that might prevent them from erring. Doctors image of a good doctor is still that of one that does not make errors and not of one that learns from errors. This might be the reason why the title of the first report of the Institute of Medicine is "To Err is Human" (1999). The authors claim that there is a need to break the cultural and perceptive paradigm according to which doctors do not err and those who do err could not be "good doctors". Breaking this paradigm is a necessary condition for creating the adequate foundation for improving the quality of care and patient safety. In current healthcare systems, a doctor reporting his errors by his own will,, with no legal action standing against him, might see himself as the "village fool".

Currently, when the concept of medical error is not clear enough, due to the roles of the doctor as the decision maker, to the professional culture that does not allow for making errors and to the high personal and professional prices a doctor might pay for reporting his errors, it is clear that without significant changes in the organizational and professional culture, reporting of errors can't be expected to increase.

It was clear to the department managers, from the beginning, that without due reference to this central issue, it will not be possible to create and establish a valid foundation for the risk management activity at Maccabi.

Statistics – How did the reporting statistics develop ?

On June 1997, in an interim report of the risk management department at Maccabi: "Department activity – underlying principles", the desirable situation regarding reporting, was defined as follows:
"Increasing the amount of self reporting by doctors. It is impossible to define the desirable or optimal amount at this stage".

This objective was defined as the first among other objectives, that will be described in more detail later. The emphasis in defining the objective was on "self reporting", meaning reporting initiated by doctors themselves, with the intrinsic motive to prevent reoccurrence of errors. This in contrast to the reporting, due to fear of legal claims, actual claim or complaint by a patient. The value of self-reporting to the risk management is great, for two aspects:

- It points to a potential risk, before it was fully actualized and as such, it has much value for a proactive risk management activity.

- It points to the depth of cultural change taking place in the organization, regarding identification with and commitment to risk management objectives. The self-reporting portions of the total reporting rates can be used as a measure of the assimilation of risk management culture in the organization.

In the interim report, a comparison between reporting rates at two time periods was presented:

- **Time period A – 1.9.95-20.11.96**, in which there was only a basic activity of risk management, based on the half time position of a nurse, whose main role was to transmit reports to the insurer.

- **Time period B – 21.11.96-12.6.97,** in which the department was established, with a physician in a full position as the director of the unit.

The analysis of the data shows that in the second time period, the rate of reporting increased by 320% and the scope of self-reporting increased by 200%.

The increase in the total reporting rate and especially in the self-reporting rate was attributed to the following factors:

- The strategic decision to establish the department and assign a physician as its director.

- Presenting the issue of reporting and its significance to all administrative doctors, by the department director.

- Field work in branches, institutes and administrative units aimed to raise the awareness to the activities of the risk management department and the importance of adverse events reporting.

- Promoting the subject in the doctors' quarterly newsletter.

Analyzing the data on adverse events, reported during 1995-2003, in the following figure, leads to identification of three typical periods:

- **1995-1997** – characterized by a steep increase in reporting rates.
- **1997-2001** – characterized by relative stability.
- **2001-2003** – characterized by an increase in reporting rates of adverse events and starting handling "near misses".

It seems, that the reporting of adverse events, which includes mainly events that were followed by complaints, claims or in which there was a reasonable chance of a claim, was reaching close to saturation by 1997. The doctors understood that the department's activity in this area might be beneficial to them and that it would be better for them to report than deny the complaint, claim or a potential for a claim.

"Near misses" were reported to the department prior to 2000, but only toward the end of 2001, the department began recording them into the computerized risk management system.

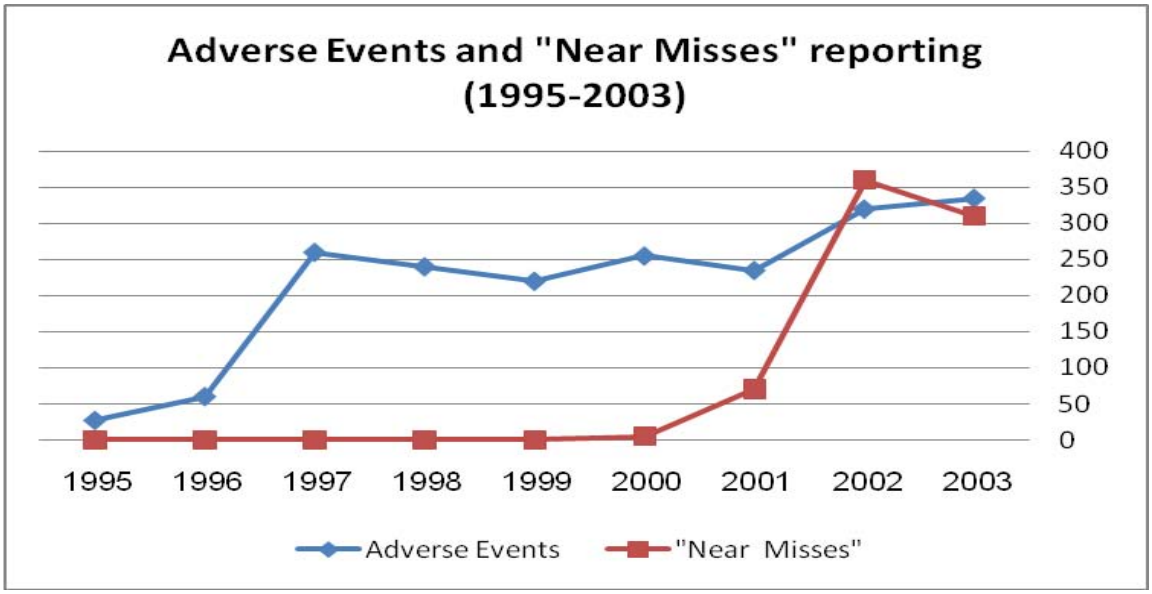
Two major hypotheses can be formulated, regarding the causes for the second increase in reporting rate of adverse events starting 2001:

1. It may be, that due to the activity of the risk-management department in previous years, the self-reporting rate increased, and that this was the reason for the observed increase in the total reporting rate starting 2001.

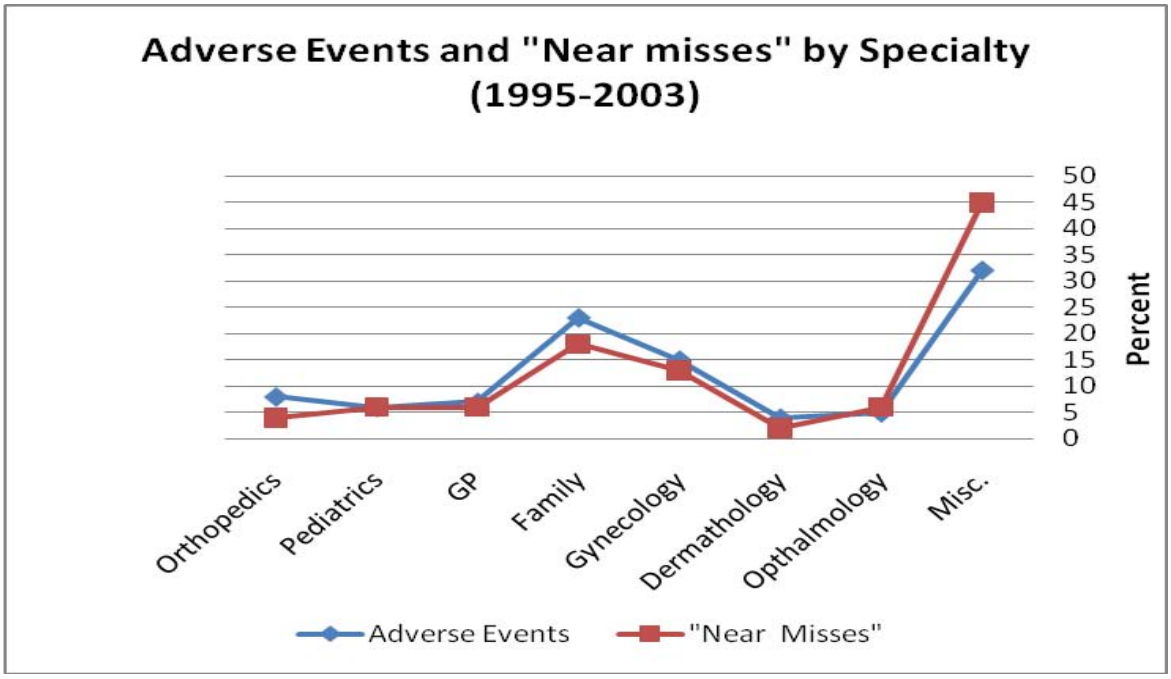
2. Another possibility, that can't be tested, is that the handling of the near misses, led to the second wave increase in reporting adverse events.

It is also possible that a combination of the above two factors operated conjointly.

We will try to test these hypotheses based on data accumulated in the risk management department between 1995 and 2003.



In the following figure, data regarding "near misses" and adverse events is presented according to the medical specialty categories. Categories, in which the portion of events was less than 2%, were combined under the "miscellaneous" category.



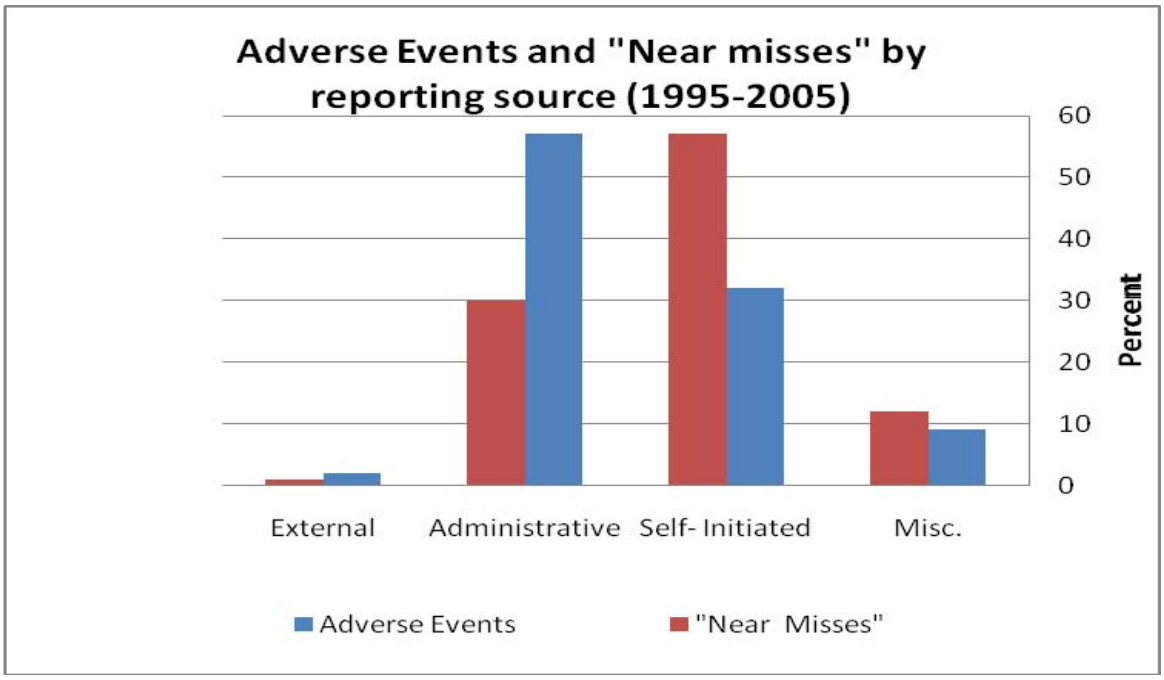
* Due to lack of data regarding the number of medical encounters in each specialty (exposure index), it was impossible to calculate reporting rates per specialty

In order to analyze the reporting rates, by reporting sources, four categories of reporting sources were comprised:

- **External sources** – the report was received from sources outside Macabbi, such as the media, Ombudsmen or Ministry of Health. This category refers to cases in which the initial report, arriving at the department, was from a newspaper article or from the Ministry of Health or from any other external source. This scenario happens, when from unclear reasons, the event was reported to the Ministry of Health and then to Macabbi, instead of being reported directly to Macabbi or when a patient choose to tell his story to a reporter or to submit a complaint to the Ombudsmen. It should be mentioned, that it isn't rare for the medical staff to be unaware of an error, in the ambulatory setting, due to the fact that the treatment is inherently fragmented and many instances may be involved in such a process.
    - **Administrative source** – when the event was reported by an administrative physician or manager in the center or in the districts and was not reported directly by the physician to the RMD. Most events in this category were preceded by a patient's complaint, claim or indication of possible claim.

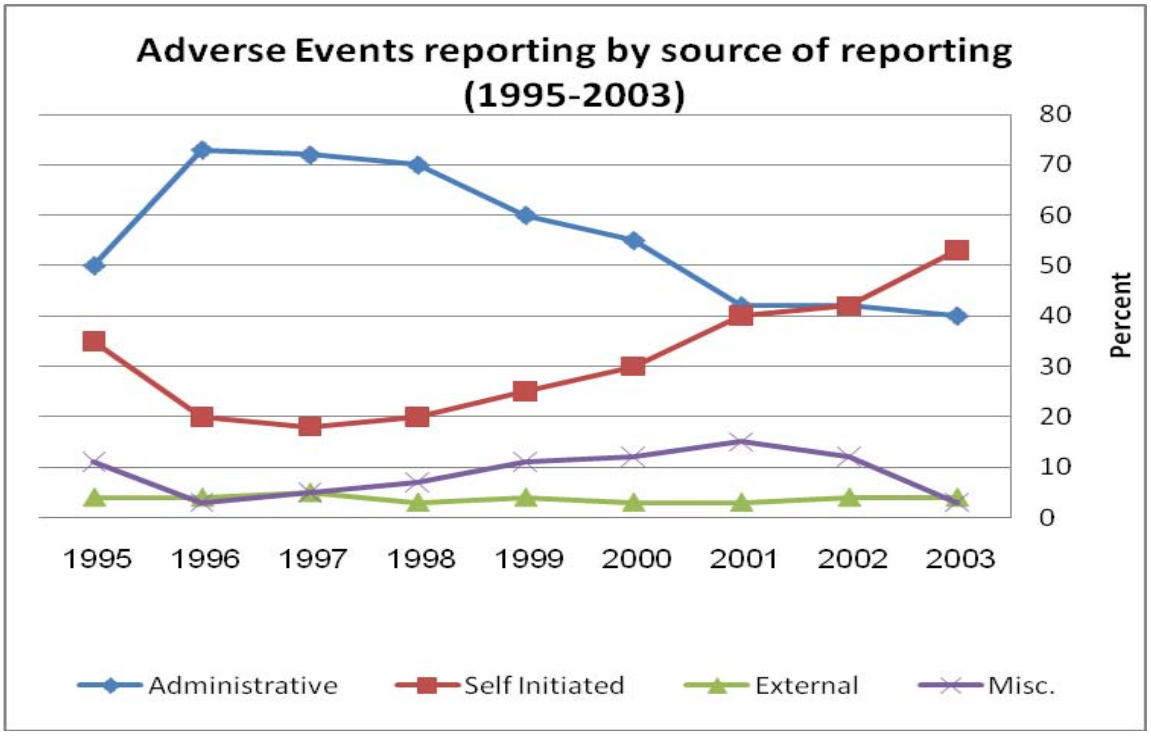
- **Self initiated reporting**– in case the event was reported directly by a physician or another health care professional, based on their awareness that an error has occurred, that should be reported to the RMD. Cases in which a complaint was received, but it was preceded by a medical staff member report, are considered as being self initiated reports.
- **Miscellaneous** - all those reports, that could not be related to any of the above categories.

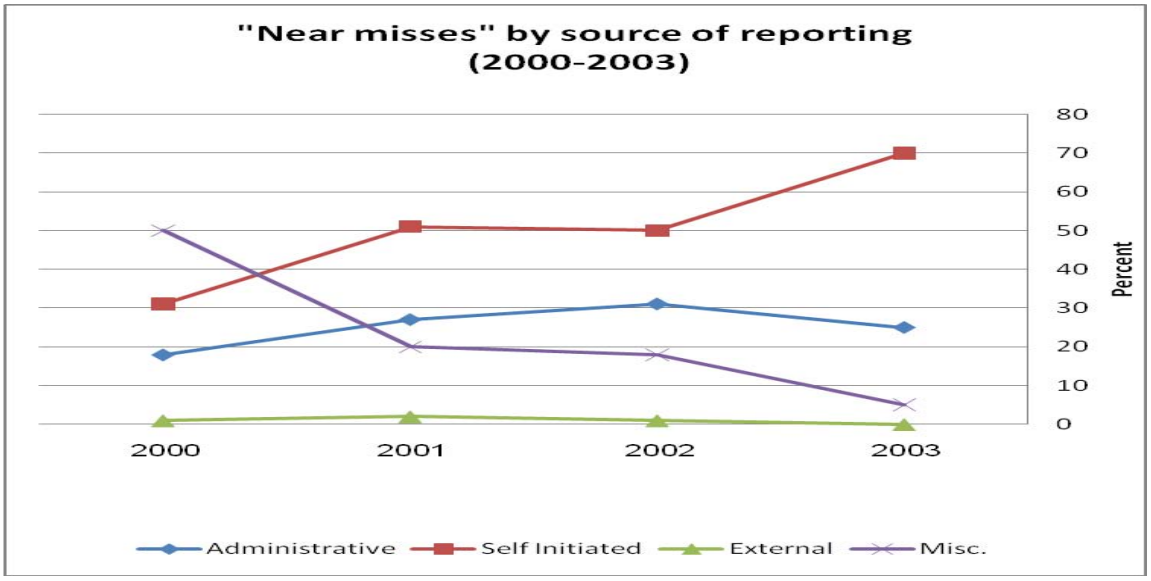
In the following figure, adverse events and near misses are presented: according to the four categories of reporting sources.



By analyzing the data, it can be observed that almost 60% of the adverse events were reported by administrative sources and only 30% by clinicians self initiated reporting. When considering near misses, the ratio is the exact opposite, meaning that most of the reports were self initiated by the medical staff.

In order to analyze the development of self initiated reporting trends, compared to administrative reporting, we examined the data according to the annual distributions by the sources of reporting (see the two following figures).





It can be observed, that the increase in reporting between 1995 and 1997 resulted from an increase in the reports from administrative sources. From 1997 on, there is a clear and consistent increase in self initiated reports vs. administrative sources.

In 2002, a transformation occurred: the relative portion of self initiated reporting was, for the first time, higher than the reporting from administrative sources. This stable trend of increase in the portion of self initiated reporting from 1997 can be considered as a success of the activities of the risk management department at Macabbi. While the relative portion of the administrative reporting, which is the result of claims, complaints, or potential for legal action decreased from 70% to 40% over the years, the relative portion of self-reporting increased from 20% to 50%.*

Despite the limited scope of the data, it can be stated that with regard to adverse events reporting, as for "near misses" reporting, there was a change in the relative portions of reporting sources: the portion of self initiated reporting increased, while the portion of administrative reporting decreased over the years.

It seems that the change in relative proportions of self and administrative reporting supports the hypothesis that it was the activity of the risk management department that brought the second increase in reporting from 2001 on. The meaning is that the combination of two trends: The second wave of increase in reporting from 2001on, after four years of asymptote consistent change in proportion of reporting sources, since 1997, the timing of establishment of the risk management department, from dominance of administrative reporting to dominance of self initiated reporting, was the significant factor in the increase in reporting rates since 2001.

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*In the years 2004-2009, this trend was stable and the portion of self –initiated reporting reached the level of about 70%.

What is reported and various origins and routes of reporting

The risk management department at Macabbi considers the adverse event reports as a major input for the reactive and proactive risk management activities. The information reaching the department can be classified according to three dimensions: type of event, reporting channel and the reporting source:

- **Type of event** – even though the department focuses on adverse events, as we have already outlined, which serve as the major input for the department's activities in recent years, there are two more types of events the department handles:
  - **Malpractice claims** – reports of cases in which a patient or his attorney, submitted to the court of law a malpractice claim, following medical treatment received at Macabbi. Reporting of legal claims, might reach the department in several ways: from the legal department, by an administrative physician, by the insurer or by the involved physician. In most cases, despite the value of legal claims for preventing error reoccurrence, it is difficult to benefit from those reports, since in most cases they reach the risk management department a long time after the event took place. Thus the handling of a legal claim is aimed less at lesson learning and more at supporting the involved personnel and analyzing the event together with them, so they could learn personal lessons.
  - **Complaints** – the direct managers handle the complaint from a local point of view and the Ombudsman is trying to generalize from them, meaning for the entire organization. In the year 2000, 3,115 complaints were submitted, about 23 per 10,000 patients. It is important to emphasize, that since there were submissions of different types, such as gratitude letters and refund requests, the number of submissions regarding the quality of medical care, was much lower. In the sixth report of the ombudsman (for 2001), it is noted that of all submissions, 514 dealt with the medical service, and only 102 of them, dealt with the quality of care aspects. About one-third of complaints seemed justified. According to this data, only about 35 complaints a year are in the direct interest of the RMD. The department's reference to this source of reporting have been undergoing changes over the years, from no response at all due to the small number of relevant reports, through assistance in answering complaints following the request of administrative district physicians, to a periodic survey, usually quarterly, of the complaints received, in order to pick out the

relevant events. In the 4/2001 quarter, the department conducted a study of the subject, in which the complaints received at the department were analyzed. The results of this analysis were the following*: "Out of the total number of 35 complaints studied, 8 (23%) were considered as adverse events and 6 (17%) had the characteristics of near misses. It means that the risk management department might be interested in about 40% of the total number of complaints. Two of the cases were reported as adverse events, in addition to being processed as complaints".*

In recent years*, the department has been receiving about 170 reports per quarter (about 80 adverse events and 90 near misses), complaints add about 10% to events reported by other channels. Since the department's resources do not allow investigation of all events reported, it becomes clear that this channel should also be tested continuously in terms of costs and benefit, especially that in certain cases there is duality of reports: the same event was reported as an adverse event and was then received as a complaint.

By analyzing the complaints data (see the following table) an interesting phenomenon can be observed, which may be associated with the activity of the risk management department. Despite the increase in complaints rate during 1999-2001, from 16.5 in 1999 to 21.3 complaints per 10,000 members in 2001 (a 29% increase), there was a 21% decline in the rate of complaints due to quality of medical care. Even though, this achievement should be attributed to all of Macabbi's medical staff and managers, it can be assumed that the activity of the risk management department was an important contributing factor.

year	**1999**	**2000**	**2001**
Number of complaints.	2241	2787	3222
Rate per 10,000 members	***16.5***	***19.3***	***21.3***
Number of complaints due to quality of care problem.	196	192	165
Rate per 10,000 members	***1.4***	***1.3***	***1.1***

*This chapter was originally written at 2003. Since then the reporting rate has increased significantly. At the beginning of the year 2009, the estimated number of reports reaches the level of 400 reports on adverse events and near misses, per quarter.

- **The reporting channel** – reports might be received via different channels, though the most common is the “hot line” channel, which serves as a major link for information interchange regarding adverse events.
  - **The “hot line”** – is a dedicated telephone line, by which every Macabbi's clinician can call a risk manager directly and report an event in which he or she was involved in. The department’s risk managers divide between themselves the shifts for answering phone calls via the hotline. A typical report via the hotline includes the following components:
    - Reception of the report, in the phrasing of the involved clinician, and clarification of significant details.
    - Giving support to the reporter, who might feel uneasy or be in a state of stress as the result of being involved in an adverse event. Giving practical advice to the reporter on how to continue handling the case: with the patient, insurer, legal representatives if needed, etc.
    - Giving initial feedback, professional and non-judgmental, if the type of event and available information, allows it.

    If the line is busy, or the call was made after the working hours, a message can be left and one of the risk managers returns to the reporter as soon as possible.

    The hotline serves for a two-sided communication, which means that the risk manager in charge of the case can use the line to get more information or to give feedback and the reporter can call the risk manager in order to discuss various issues regarding the event he was involved in.
- **Mail/Fax** – a clinician can report an adverse event by mail/fax, using a special form and fill in the necessary information needed for handling the event by the department.
- **E-mail** – following the distribution of case analysis with clear lessons learned, to all the physicians at Macabbi, the use of e-mail become more frequent. This channel has the advantages of simplicity, immediacy and security, assuring that the report reaches the intended addressee only.

- **Reporting agent** – there is a clear relationship between the type of event and reporting agent. Thus, for example, reports received by the ombudsman, are reported mostly by administrative physicians, nursing events by a district nurse or senior nurse, malpractice claims by the insurer etc.

To summarize, it can be said that in the last two years, the department's main reporting agents are the physicians themselves, via the "hotline". The other channels provide between 20% and 25% of the reports received by the department.

How to classify reports and what is the importance of the classification?

The classification system of reported events has several goals, which it should address:

- Creating a distinction between events for the purpose of differential handling. The risk management department receives about 170 reports per quarter, from which 80 are defined as adverse events and 90 as near misses. The department's limited resources do not allow for the identical treatment of all cases, so they have to be classified according to preferences for investigation and depth of investigation.
- Allowing for the retrieval of information according to report category, representing the severity of events for statistical and research purposes.
- Creating a uniform and clear organizational language, allowing for the inter-unit communication in the organization, both in the headquarters and in the field, with relation to the different classes of reports.

It is important to note that in our experience at Macabbi, we found that there is an actual need, not just a theoretical one, for classification of events in order to solve practical problems as we have presented above.

It is commonly accepted to classify accidents according to the severity of outcomes. Accepting this approach raises the question: what does the severity refer to - the results or the causes? In some cases the error is marginal, but the results are disastrous, or the opposite – a severe error with no consequent damages.

From an organizational point of view, it is important that events with grave results receive the maximal treatment, while non-damaging events receive minimal care. On the other hand, from a risk-management point of view, especially in the proactive approach, it is important to give most attention to events with the highest potential for damage, even if it was not actualized.

Until the middle of 2002, the risk-management department acted according to two classification categories: adverse event, an event that was being investigated, and near miss– an event that was handled mainly administratively. In the middle of 2002, the department adopted a unique classification system combining the severity of results with potential risk existing in each report. The new classification system allows for the department a successful control of resources and prioritizing the handling of reports according to a combination of risk potential and actual damage.

The new classification system distinguishes between the type of an event (three categories, according to the severity of damage) and the definition of type of handling of event (3 treatment categories). In this method, each event is actually classified twice: once by its results and once by its potential risk. The classification categories according to consequences are as follows:

- **Type A** – An adverse event with potential for damage, which ended with minor or no damages at all. These events are termed “near misses”.
- **Type B** – An adverse event that resulted in moderate damage to a patient, reversible or with estimated damage claims up to $250K. The event is classified by the severest of damages: to the patient or to Macabbi.
- **Type C** – An adverse event that resulted in severe or irreversible damage to a patient, or an estimated malpractice claim of over $250K. Death of a patient is included automatically in this category. The event is classified according to the more severe of damages: to the patient or to Macabbi.

The classification categories by type of treatment are as follows:

- **Treatment type 1** – Registering the event in the computer system for administrative and statistical needs.
- **Treatment type 2** – Investigating the causes of the event in a way, which allows for the definition of findings and conclusions and in some cases recommendations as well. The resources allocated by a risk manager will not exceed 8 working hours.

- **Treatment type 3** –, Detailed analysis of the causation process and the sequence of events proceeding the adverse event, including field investigation if needed, reviewing of medical records and protocols, investigating the human factor issues , etc. For an event handled at this level there has to be at least one recommendation. The resources invested for this type of investigation would not exceed the average of 25 working hours.

In the following table, classification data is presented for the events reported during 11 months since the new classification system was integrated. The data shows that many events, type A, were classified at treatment level 2, while not all events type C were investigated in depth, level 3.

We calculated the correlation ($r=0.44$, $p<0.01$) between the type of event and the level of handling in 342 events that took place over 6 months (November 2002-april 2003). The correlation is statistically significant but relatively low and points to the fact that event type classification explains only 20% of the variance in the handling of it. The conclusion is that the risk management department applies the new classification system, which means that in addition to the severity dimension, the event is also classified according to its potential risk.

Treatment Type	Event Type (Level of Harm)			Total
	A	B	C	
1	179	40	17	**236**
2	68	120	97	**285**
3	3	3	1	**7**
Total	**250**	**163**	**115**	**528**

Efforts to enhance reporting

We believe that the value of reporting adverse events and the professional handling of them, is well acknowledged and widely accepted in Macabbi and in most healthcare organizations worldwide. Despite the small number of studies showing the linkage between reporting systems and positive outcomes for patient safety, it is acceptable to think that the advantages overrule the disadvantages.

From our experience in Aviation, we have learned that there is a significant negative correlation between reporting of near misses and actual accident rates. In other words, the higher the reporting rate, the lower the accident rate. This finding was also established at the level of secondary units. It can be explained by the accountability process, which means, that a system reporting adverse events takes the responsibility and the needed steps for preventing their reoccurrence.

It is also clear that the current reporting rate at Macabbi is lower than the actual number of errors.

Treating the adverse event reporting as fuel for improving the quality of medical care and patient safety, is an acceptable process, thus the willingness to increase the report rates. In this regard, it is important to mention two reservations:

- Leape (2002), in an article regarding reporting adverse events at the national level , notes that despite the advantages of developing the system, it can also confront a serious problem of lack of resources for handling the increasing number of reports. According to some estimates, the number of severe adverse events in the US reaches about a million a year, and if adding the near misses the number may reach up to 5 million a year. If only 10% of the events were reported and handled, it would be 15 times more than the number of events handled by the Aviation Safety Reporting System (ASRS) in the US. According to ASRS' estimates the average cost of handling an event is $70, so if to assume a similar cost and a reporting rate of 10%, the costs of a national healthcare reporting system in the US could reach 35 million dollars a year. This is in addition to the need to recruit and train a very large number of experts in the field. According to Leape, a more practical approach is to encourage local reporting systems focusing on specific areas such as labor and delivery, neonatal units and adult intensive care units. In the terms of Macabbi, assuming that the current reporting rate stands at 10% of all reportable events, the meaning of increasing reporting rates up to 50% of the potential and keeping the same proportion of handling events means a fivefold increase in the number of positions in the risk management department, which we consider to be unrealistic.

- Some say, especially among that objecting risk management, that the majority of factors leading to medical errors are well known, therefore there is no need for reporting, as means of identifying safety problems. In addition, some of the problems are general and shared by many healthcare organizations, such as: the issues of continuity of care, physician-patient communication gaps, wrong side surgery (errors of laterality), quality of medical records and more. Professionals supporting this opinion, suggest that, instead of investing resources in increasing reporting and handling reports, the focus should be on solving the known problems and implementing the solutions widely. These voices were heard when we started working with Maccabi in 1997, and are still heard these days as well.

In our opinion these reservations do not take into account the added values of the adverse event reporting, as presented in chapter 6.8 (Producing value from adverse events reporting) , which go beyond the concrete aspects of reporting. We believe that the value of these advantages is no less, maybe even higher, than the direct benefits of reporting.

Assuming that the increase in reporting adverse events at Macabbi will continue in a linear scale, the expected increase in the next five years is an average of 9% annually, which leads to a total of 45% increase. It seems, that if we adopt this estimation, the benefits of increased reporting exceed the costs and the need for additional resources significantly.

The second reservation does not take into account two important factors:

- The value of accountability as a critical factor in risk management. It can be assumed, that a reporting organization takes responsibility for the event and is more ready to implement the necessary means to prevent its reoccurrence. In our opinion this motivational and cultural factor is at least as significant as being aware of the problem. It can be said, that being aware of the problem doesn't necessarily result in actions directed towards prevention, and the high rates of medical errors, can be considered as supporting this argument.
- The variance between different healthcare systems, in administrative, clinical processes and work interfaces is noticeable. Thus, a general definition of the problems, is insufficient for taking operative steps for their solution, without relating to the unique aspects of each system.

Macabbi's reporting system is a sound one, as we have previously shown, with regard to Leape (2002) and others criteria. It is plausible that the department's activity will continue showing increase in reporting rates. With regard to the resources needed, it seems to us that there is no need for taking further steps to increase reporting rates, except for focused accumulation of events in critical topics in order to enable the department to base its activity in these critical areas on a better based data.

The value of reporting, beyond supplying the risk management department with information for reactive and proactive risk management, is becoming more and more evident in partnerships established between the department and other organs of Maccabi, aimed to achieve better quality of care and sounder patient safety.

Chapter 6.8

Producing value from adverse events.

"The human mind is prone to suppose the existance of more order and regularity in the world than it finds"

Sir Francis Bacon 1620 (The new Organon)

What accounts for value?

Almost all papers published lately, dealing with the issues of risk management and patient safety in healthcare, stress the importance of reporting, as a core principle in a system aiming at lowering the errors rate and improving the quality of care. We will refer to only few of these papers by Berwick, Leape, Vincent and Reason.

It is a common axiom in safety systems that ascribe a primary value to reporting. Thus, the report of IOM – Institute of Medicine, published in 1999, *"To Err is Human",* recommends establishing reporting systems and procedures in health organizations as a crucial step in reducing the amount of errors made by physicians.

It is important for us to deal with the value of reporting, from various aspects, in order to understand what motivates and what prevents the reporting of adverse events in health organizations, and in order to be able to suggest means for increasing the reporting, taking into account the value of reporting to caregivers, health organizations and society in general.

The term 'value' has many definitions – statistical, ethical and financial. From our point of view, we will relate to "value" as a desirable outcome for a certain system. This definition allows a spectrum of values, whether they are defined or abstract, material or spiritual.

It can be claimed that a medical organization ascribes value to the prospect of saving money as result of attention given to adverse events and also to secondary gains, such changing the organizational culture towards “Blame Free” culture and the hope that patients will appreciate the organization’s efforts to prevent reoccurrence of errors.

The handling of adverse events, requires the existence of a professional infrastructure and involves measurable investment of resources. The question of value is actually the question of what advantages the organization gets as a result of handling adverse events. We have referred to that question in chapter 6.7 which deals with reporting.

From our experience in risk management, it is possible to classify the values created by handling adverse events in healthcare organizations, into three phases: the reporting phase, the handling phase and the implementation of recommendations phase.

Barach and Small (2000), referring to barriers and stimulators to reporting of adverse events, analyze those factors from three points of view - individual, organizational and social, relating to three aspects: cultural, legal and financial. In our analysis of the values created in the process of handling adverse events, as presented in the following table, we will use these categories and the three phases.

Point of view	**Value**	**Phase**		
		Reporting	**Investigation**	**Recommendations**
Individual	**Material**	• Lowering the payments for claims		
	Spiritual and Cultural	• Compliance with the standards of medical ethics • Sharing the responsibility with the system. • Catharsis • Feeling of contribution to the quality of care	• Participation in the process of preventing recurrence of errors • Getting professional feedback • Developing a sense of trust in the system	• Deceasing personal involvement in adverse events. • Developing the sense of control over medical errors. • Developing the perception of supporting rather than blaming system.

Point of view	Value	Phase		
		Reporting	**Investigation**	**Recommendations**
Organizational	**Material**	• Lowering the payments for claims • Decreasing errors volume and the attached costs • Lowering the costs of insurance • Increasing the number of patients • Improvement of clinical and administrative processes • Gaining accreditation by authorized bodies		
	Spiritual and Cultural	• Maintaining a public image of modern organization dealing constructively with errors • A cultural statement to the employees of a blame free organization. • Management commitment to learn from errors.	• Developing efficient and constructive work patterns and transferring them to other domains. • Changing the blaming attitude towards process improvement.	• Organizational learning
Social	**Material**	• Lowering the healthcare expenditure		
	Spiritual and Cultural	• Maintaining a public image of a quality healthcare system • Improving trust between the healthcare system, caregivers and patients		

The value of reporting - the core data for prevention efforts.

We have already mentioned that an immediate report of adverse events, shortens the time needed to handle claims and reduces the payment for claims (Lindgren et al. 1995). These findings are based on the implementation of reporting system in 30 healthcare institutions during a period of 14 years.

However, the work above, relates mainly to the advantages of reporting from the legislative aspect and not from the proactive risk management aspect. It may be speculated, that the issue of value of reporting is considered obvious, thus leaving this issue unexplored.

Leape (2002), among others, mentions that the only reporting system which efficiency was studied empirically is the one of “National Nosocomial Infection Survey”. It was found that the rate of Nosocomial infections in hospitals that fully

implemented the reporting program were 32% lower than in hospitals that did not implement the program.

The meanings of reporting and its advantages are also embedded in the reporting process itself and especially in the processed product returned to the physicians in various forms: starting with a personal feedback to the reporter, through recommendations and to an applicative research of a phenomenon stemming from the reported events.

According to Leape (2002), a more profound understanding of medical errors is required in order to develop suitable preventive means and thus the need in an improved reporting system of accidents, errors and near misses. In other words, a reporting system functions as the basic tier of all risk management activities.

Since there are almost no empiric studies, dealing with the contribution of a reporting system to organizations that implement them, the discussion will be based on our experience from the Aviation domain joint with Maccabi's experience.

One can determine three types of advantages stemming from reporting: advantages to the reporter, advantages to the organization and advantages to patients. Despite the classification, it is obvious that the advantages have inter-relations, thus for example, the advantages to the organization are often advantages to the patient and advantages to the reporter are also beneficial to the patient:

- **Advantages to the caregiver:**
    - **Breaking the caregiver's solitude circle** – As we have already mentioned, errors made by doctors are not rare occurrences. A physician that made an error, experiences guilt feelings, shame, anxiety, lack of certainty and often does not know how he should behave. In the absence of a reporting system he may experience feelings of solitude while coping with this stressful situation. . A reporting system might function as a supporting service able to relief his distress.
    - **Competence in case of committing an error** - A reporting system gives the caregivers the feeling there is something that can be done and that the occurrence is not inevitable.

- **Legitimization** – Giving legitimacy to a physician to resume functioning, after being involved in an adverse event and creating the awareness that to err is human.

- **Creating trust relationship between the caregiver and the system** – Regardless the conflict related to reporting, we believe that every caregiver prefers to be part of a system that does not sweep errors under the rug, but handles them in order to prevent reoccurrence.

- **Professional Feedback** – In some cases, the physician's error is caused by lack of knowledge, unfamiliarity with procedures and by an erroneous decision making. In these cases there is ground for a professional dialogue in order to examine the various alternatives he confronted, evaluate each one of them and evaluate the right alternative.

- **An Operative solution for the distressed caregiver**- Serving as an supporting agent for caregivers in distress following their involvement in an adverse event, and providing practical advices regarding how the patient and his family should be treated according to procedures.

- **Advantages for the organization**

  - **Organizational Learning** – Is a very popular term among modern organizations, aiming to create cultural and technological conditions in which the knowledge of the individual in an organization becomes an asset, shared by all organization members. A medical organization that implements efficient reporting system, actually implements organizational learning.

  - **Creating an inter-organizational dialogue** –A reporting system can function as an organizational adhesive between the various sections of an organization, starting with the individual physician, through the medical clinic's managers, district manager, professional referents the headquarters and more. We have witnessed cases that have demonstrated how organizational dynamics aiming to improve a critical process originated from a single adverse event. It is even more prominent in applicative studies, based on the reports, in which representatives of the various organizational sectors took part.

- **Improving the public image and strengthening the trust between patients and the organization** – An organization that deals with adverse events, is considered as more reliable by the patients. This reliability and positive image have great value in the competitive market.

- **Lowering the extent of claims and the claim payments** – It is plausible to assume that a systematic treatment of risk factors decreases the probability of errors, even though studies supporting this assumption are rare.

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- **Seismograph** – Reporting of events can function as an organizational seismograph, for identifying administrative and clinical shortcomings. In addition, it is possible to use the reporting system to evaluate the relative success of preventive activities.

- **Accreditation** – Complying partly with the accreditation terms for healthcare institutions such as JCHAO.

- **Advantages to the patients**

  - **Improving patient safety** – There is a ground to believe that systematic and consistent procedures for deriving lessons learned from adverse events and recommendations, targeted to the system, aimed to prevent reoccurrence, influence the quality of medical care and patient's safety.

  - **Improving the trust relationship between the patient and the health-care system** – Anisson & Wilford (1998), claim that most of the Americans do not trust their healthcare system and analyze the various factors for this distrust. A patient, who will believe that the healthcare system takes care of him, will have more trust in it. Trust is associated with compliance, a meaningful phenomenon in medicine. Patients often refuse to follow the physician’s orders, as a result of lack of trust.

Changes in practice, changes in values - The age of corporization

The western healthcare system, has undergone radical changes in the last decades of the 20th century. McKinlay and Marceau (2002), in their publication: *"The end of the golden age of doctoring"*, has analyzed extensively those changes.

One of the prominent changes is the bureaucratization or the carbonization of medicine. Between 1983-1997, the part of physicians employed as salaried in the USA increased from 24% to 43%. Among young physicians (up to 5 years of experience), this tendency is even more noticeable – from 37% to 66%. It means, that more physicians, are employed today by large frameworks, motivated mainly by financial interests, as opposed to the past when the physician's loyalty was given first of all to the patient. It is obvious then, that health organization, ascribes great value to the financial efficiency of medical care, in order to achieve sounder business results.

However, the health system in Israel, is in an intermediate state, in which the health services are being subsidized by the government and the public health systems is not required to be profitable, being basically nonprofit organizations.

Despite this, since the health system in Israel suffers from chronic under budgeting, which causes from time to time striking in activities of both hospitals and ambulatory health services; it is obvious that financial savings are valuable to the system.

Therefore, the inevitable conclusion is that, a modern health system, motivated by financial interests, ascribes great value to efficiency and the financial aspects. The spiritual and cultural values, that we have presented in the above table are valued by external factors, especially patients and the public.

There are few health systems willing to invest resources for the sake of bearing fruits in the long term, financial in general and spiritual and cultural in particular.

The establishment and operating of a reporting system, that handles adverse events professionally, requires a substantial investment of resources. Therefore, in most cases, health systems, ruled by financial interests, choose not to invest in risk management, since they do not see immediate financial benefits. The awakening in risk management in the United States of America, towards the end

of the 20th century, is related mainly to a move; lead by the government and legislation, and not by initiations from inside the healthcare system.

In Israel, generally and in Macabbi particularly, in retrospect, it may be said that the initiative to deal with risk management is a result of legislating the "Patient Rights Law" in 1996, and a the verdict by the Supreme Court judge, Judge Aaron Barak in 1995, according to which medical documentation, can't be confidential to the patient. In order to dramatize the sequence of events that led to the risk management initiative in Israel, in the mid nineties of 20 century in Israel, one can postulate that the process was associated with managing the risks arising from the situation following the publishing of the "Patients Rights Law", Judge Barak's verdict and increase in the volume of claims due to malpractice. All this as opposed to the thesis that the initiative originated from intrinsic motivation to improve the quality of care and patient safety.

The issue of the financial value of risk management system, might contribute to the health system, can't be approved for two fundamental problems: measurement and causation attribution. There is still no adequate answers for the question how to measure the financial value of a risk management activity. Risk management activity has face validity as a resource saving approach by improving clinical and administrative procedures and decreasing the extent of claims by improving patient safety and quality of care.

Paradoxically, even though, increase in the extent of reporting is an indicator of a successful risk management activity, it doesn't result in lower insurance payments, but on the contrary, since the malpractice insurance companies estimate the extent of risks based on the extent of reporting of adverse events. We can argue that a risk management activity motivates intra-organizational procedures that might contribute to the organization generally, but since this activity is almost always catalytic in nature, it is hard to attribute to it direct financial contribution.

What happens to an organization that establishes a RM operation

Even though, a risk management organ aims to support and assist physicians involved in adverse events, it is perceived by the system as critic, as a result of its exposure to failures and shortcomings. In addition and as we have already mentioned, operating the risk management system requires noticeable investment of resources, while it is impossible to prove its financial contribution. This situation provides ground for organizational antagonism towards risk

management activities. Moreover, when a new organizational entity is established, it expropriates some of the other bodies functions and responsibilities. Thus for example, the legal department's role in risk management was minimized, some of the complaints once handled by the ombudsman are now handled by the risk management department and the manager's role in adverse events debriefing was almost canceled. In this context it is vital to mention that the dilemma: who is responsible for risk management in an organization, the "direct" managers or an entity that specializes in risk management, is an inherent dilemma that expresses itself in various ways, since the foundation of the department. For example, there is a recent eagerness in the districts, to deal with risk management by investigating adverse events, eliciting and implementing recommendations.

Additionally, the relationship with the law department didn't stabilize yet since the latter perceives the department's activity as risky of exposing physicians to claims.*

The managers of many of the organizational units in Maccabi have not assimilated yet their mission to implement the recommendations of the risk management department. From our observations we can retrospect that the activity of the risk management department created a stormy atmosphere that did not ease even after six years of operation. This stormy atmosphere may be related to the following factors:

- **The immunity of the reporters and the reports** – The department's activity is not always clear to the decision makers due to the immunity given to the reporting physicians. The immunity makes it harder to cooperate with the different authorities in Maccabi in the study and lessons learning procedures, which are necessary conditions in developing a positive attitude towards the activity of the department.

- **Limiting the managerial authority** – Managers might feel that the department's activity threats their authority, since it might be interpreted as if it expropriates from them the professional responsibility for learning lessons from adverse events.

- **Super-Authority**- Despite the fact the department is relatively small and not the most senior in Maccabi's organizational structure, it has actually super-authority, since it has the mandate to recommend on actions to be taken following adverse events investigation.

- **Controlling body** – Every caregiver and every unit manager might found himself in a situation in which his activities are reviewed, questioned and investigated as part of handling of adverse events. It is reasonable to assume that at least some of those interactions were not convenient.

- **A managerial bypass entity** – the department conducts a direct dialogue with the caregivers, without the involvement and awareness of the managers. Managers might perceive this direct dialogue as a threat to their managerial authority. Furthermore this dialogue turns around errors and adverse events and occasionally focuses on the systemic aspects and not only personal aspects of the caregiver.

- **Unclear organizational benefits** – As we have already mentioned, the department can't bear out its value to the organization directly and in hard terms of financial contribution, since its activity is performed through others or directly with the caregivers.

In a contentment report regarding the department's activity , published by Maccabi in December 2002, it was found that two thirds of the physicians are satisfied with the department's activity on the parameters of professionalism in handling adverse events (67%), support for physicians (64%), availability (68%) and the response time (61%).

This statistics are encouraging, since they indicate that the main department clients, the caregivers, perceive the effort of the department as satisfactory.

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*It seems as these days (2009), a more harmonious relationship is developing between the RMD and the legislative department.

In the situation described above, it is obvious that the department can function only with complete backup and commitment of the CEO and the other senior managers that share the vision of risk management and examine the contribution of the department in the long term. The department's activity might be considered as a long-term organizational investment, while in the short and middle terms, the activity of the department might arouse antagonism and lack of motivation for cooperation.

Can RM insights from one organization be transferred to another

The question, to what level it is possible to generalize lessons learned in one system to another in the of risk management context, is a core question in every healthcare organization that deals with risk management. Do insights gathered from adverse events in one clinic are relevant and applicable to another clinic? Is an event of gynecologist, working in an outpatient environment is relevant to a gynecologist working in hospital?

One can claim, there is significant variability, between the medical working environments, for example when it comes to the characteristics of the patients' population, characteristics of the physicians and their employment manner, the characteristics of the physical infrastructure etc.

In order to demonstrate this difficulty it is important to mention that Maccabi's clinics are spread all over Israel and provide health services to a variety of population sectors.

On one hand, in order to create a representative database of a certain phenomenon, it should include as many events as possible and on the other hand, events reported from different work environments limit the generalization of preventive actions.

This argument of the applicability of generalization from one medical setup to another, is raised quite frequently by opponents of risk management.

In our opinion, this approach reflects a kind of defense mechanism of healthcare systems, trying to restrict the value of adverse events and the implementations of its recommendation on a wide organizational scale. It is interesting to mention that the aviation approach is absolutely different. The findings of flight accident investigations are distributed as lessons learned to a very wide distribution and not only to a specific population that may be interested in a specific aspect. In this regard Vincent (2003), states:
"Aviation accidents, for instance, are exhaustively investigated, and lessons learned are disseminated widely, with important changes made mandatory by regulatory authorities. In contrast, learning within the health care sector, with some notable exceptions, has generally been fragmentary and uncertain."

In our opinion, the issue of degree of generalization from one adverse event to another, is not relevant at all in the current state of medicine. The extent of knowledge distributed among physicians focused on lesson learned from adverse events, except few organizations, is minimal. Therefore, we recommend that healthcare systems should enable physicians to have the freedom to decide from which events to learn and which to ignore. The systems role should be of one that makes the information available. In addition to the educative role of wide distribution of lesson learned from adverse events, they serves also as an organizational statement that supports the attitude of "To err is Human" and the blame free culture.

Chapter 6.9

Developing the information system

The need for an information system

On March 1997, at a presentation to Macabbi's managing board, intended to portray the background of risk management and the work plans, Dr. Miron, the department manager, defined the needs for the risk management computer system.

The first requirement was computerizing the process of managing adverse events reported to the department. At that time, the department had several hundreds of files, that were not processed in a standardized method and were kept in an archive. The information in those files was not easily available.

The first idea of computerizing risk management stemmed from the need for organizing the files, that accumulated in the early days of the department. In an internal document of the department, dated June 1997, the need was defined as follows:
"Primary 'technical' computerization of the files that were opened, by patient name, physician name, specialty and reporting"

In the process of analyzing the system, which included studying the materials that were accumulated in the files, it became evident that the need for computerizing the information in the files is not the sole need. The information in the files was unsystematic and there was no common concept for investigating the reported events. Thus, before starting the computerization process, there was a need to format the investigation process and fill out many gaps in the events that were already investigated, so they could be recorded in the computerized system. As a matter of fact, the system analysis led to a reopening of about 80% of the closed investigation files, in order to complete missing and relevant information.

On July 13th 1997, in her first activity report to Macabbi's General Director, Mr. Shabtay Shavit, Dr. Miron stated, in regard to the computerized system:
"In explorations, conducted both in Israel and worldwide, there was not found existing software for assisting the medical organization to manage the risks in the outpatient sector. Software used by hospitals was designed for managing claims and costs only. It focuses on retrospective analysis of events and not on their prevention and so it does not satisfy our needs".

As was aforementioned, Eilat was chosen by Macabbi to serve as its consulting firm and to assist the department in consolidating and fulfilling its objectives and goals.

On November 3rd, 1997, after completing the assessment stage, it became clear to us that the department cannot continue to function effectively without a designated risk managing information system. Following the presentation of the assessment results, we submitted a proposal for a primary work plan in which the first product was "building a computerized system for handling the files":
"In the risk management department there are already 300 files of claims and adverse events of various sorts. In addition, averages of about 40 new reports were being received every month. Eilat will specify and develop a computerized tool for handling and controlling the existing files".

According to the above, it seems that the need for a computerized information system, arose close to the time of the department's establishment and that the immediate need was associated with finding a technical solution for being able to use the information from the files that accumulated by then. Still, the system that was finally developed gave a much wider solution and was based on our experience with similar systems in the Aviation in general and in the Israeli Air Force more specifically.

It is important to note that in the mid 1990's, the concept of risk management in medicine was mainly reactive and its goal was to minimize the damage after it had already occurred, especially by minimizing the claims costs. The information systems were developed accordingly, and were targeted at the effective handling of the claim from the time of reporting to its closure.

A computerized system for risk management, from a proactive point of view and without the focus on claims, did not exist, so there was no dilemma whether to buy an off shelf product or develop a system suitable for Macabbi's special characteristics.

Issues of confidentiality of information

Health systems in Israel, and Macabbi especially, are highly computerized. It can be estimated that over 90% of the clinical activity in the outpatient sector in Israel is computerized. An electronical medical record (EMR) is already being used at Macabbi since the early 1990's. The original thought was to base Risk Management application on the existing computerized infrastructure at Macabbi, in which there was a wide information base on three major components of an adverse event: the clinicians, the patients and the medical encounters. Since it was impossible to apply a convenient security solution on Macabbi's main frame system, it was decided that a stand-alone system would be developed with the concept of client-server that would serve the department's personnel only. The downloading of the physicians file from the main frame and updating the risk management system with an updated list of active physicians would create the only interfaces with the main frame. Information regarding medical encounters is received in a printed form at the department and the relevant details are fed into the risk management system. It can be said that such an array, does not allow access of unauthorized personnel into the system. This way the information is protected from unauthorized access according to Prof. Alexander Aviram's commitment to Macabbi's physicians.

In retrospect it is important to note that the issue of "ownership" of the risk management computer system generated organizational disputes between the different divisions, beyond the issue of specifying a solution for the information security problem. The medical division, which is mainly a professional body staffed by physicians, is relatively weak compared to the divisions controlling the central assets and resources of Macabbi, such as organization and methods to which the computer department of Macabbi belongs. These non clinical divisions, measure their power by the degree of control over the resources and ability to influence professional decision-making. The fact that a stand-alone system for risk management was developed in the medical division, without the involvement of other divisions, meant that there was some organizational strengthening of the medical division and a statement regarding the organizational positioning of the risk management department.

Basic modules and functionality

The system was developed with a flexible approach, allowing the handling of a variety of events of different classification categories, from the simple event handled basically– A1 , to a severe event requiring the most in-depth investigation – C3 (See chapter 6.8).

The system had to fulfill the reactive needs of handling adverse events, in addition to creating an information base for the proactive activities.

The system created a common working standard for all the risk-managers, reflected in an unified conceptual language, common working protocols and minimization of variance in the quality of information coded into the system.

The system can be considered as consisting of seven major tiers:

1. **The factual tier** - factual details on the time, place, professionals and patients involved in the event.

2. **The descriptive tier** - information gathered during the investigation, encounters details, procedures, interviews, etc.

3. **The analysis tier** - classification of the event, definition of errors, severity of errors, definition of causality of findings, key words, conclusions and recommendations.

4. **The personal tier**- personal comments of the risk manager regarding the event or the investigation.

5. **The administrative tier** - information serving the managing of the event.

6. **The insurance tier** – includes information regarding the potential for a claim and if there was one, the claims details.

7. **The retrieval tier** - reports, quarries, graphs, statistics.

1. The factual tier

In the factual tier, the following major parameters are included:

- Dates of opening of the file and last update
- Site of the occurrence: district, branch
- Medical specialty : primary, secondary, and tertiary
- Definitions of the event: source of report and type of event
- Patient's personal data: name, ID, date of birth and membership terms.
- Physician's personal data: name, ID, year of birth, specialty, role in the event, occupational status, etc.

2. The descriptive tier

The descriptive tier includes, among others, the following fields:

- Description of the event
- Description of relevant encounters: date of meeting, type of meeting and characteristics of meeting.
- Description of findings – the sequence of events leading to the adverse event.

3. The analysis tier

The analysis tier relates to all those parameters, the risk manager decides upon, based on the factual and descriptive tiers:

- Classification of the event
- Definition of errors in the clinical encounters
- Definition of severity of errors
- Definition of key words summarizing the event: up to five key words out of more than 1300 key words organized in 18 categories.
- Definition of findings as causative or background findings.
- Conclusions from the event investigation
- Recommendations following the event investigation

4. The personal tier

The personal tier in the system is defined as the “private” area of the risk manager, in charge of the investigation. This area allows the risk manager to document thoughts, ideas, dilemmas and work plans, as well as findings, which are not established well enough, to be included in the formal section of the documentation of the event.

5. The administrative tier

The administrative tier serves for managing the case and includes, among others, the following parameters:

- Name of the risk manager in charge of the case.
- Name of the medical consultant that reviewed and approved the investigation prior to its closure.
- Status of the case
- Target dates for applying the recommendations and status of the recommendations.

It is important to note that this is the least developed tier of all the tiers in the system, and there is a need to develop it further in order to manage the whole administrative process of handling the case from its opening to its closure.

6. The insurance tier

This tier includes information regarding the malpractice aspects of the event and the final outcomes of the claim if there was one.

7. The retrieval tier

The retrieval tier includes the various possibilities for retrieving the information from the system for a variety of purposes, from the routine work to projects of applicative research. Retrieving data from the system consists of three major alternatives:

- Predefined reports – reports which are used frequently and therefore were predefined: single event report, number of events in a period of time, number of events according to case status/ risk manager / medical specialty, etc.
- An event locating system allowing pinpointing of events according to each of the parameters in the system. This mechanism can be activated also for locating recommendations.
- Statistical reports based on exporting the data to Excel and statistical analyses based on the functionality of Excel.

At the end of 2009, a new information system for the Risk Management Department is planned to be deployed, after the current system has served the needs of Risk Management Department for almost twelve years. The new system will preserve the basic functionality of the old one, enabling additionally to operate the system via internet, thus enabling the referents to update the system directly. Also, the basic information tiers will be separated from the analysis tiers,

thus improving the ability to keep reporters immunity and lower damage in case of malpractice claim.

The flow of data into the Information System

The computerized system for risk management is used as a core system by all the department's personnel, from the department secretary through the risk **managers and to the department director. The case management process in the** risk management system includes four major stages, though between them there is much interaction with the system for updating, studying precedent cases and report generating.

- **Primary input** – as soon as a report is received, the details are being recorded by the person receiving it: the department secretary or risk managers. The first phase includes coding of details regarding the factual, descriptive and administrative tiers. Information updating – during the managing of the case, according to the type of designated treatment, various details are being added to the primary input and data is being processed for the analytic stage. Updating takes place continuously during the work of the risk manager on the case, so at each given time, the system is fully updated with all the available information in a particular case.

- **Recommendations input** – the creation of recommendations for an event classified as class 2-3 event is a compound process described in chapter 6.10. The first draft of the recommendations is being coded into the system by the risk manager in charge of the case, as soon as they are phrased. After the medical consultant and department managers have reviewed and analyzed the recommendations, they are coded into the system with the status of action items.

- **Follow-up on the implementation of the recommendations** – during this stage, which starts at the approval of the recommendations until their implementation, follow up and updating of status are being carried out in the system.

- **Closure of the case** – following the completion of the implementation of recommendations, the handling of the case is terminated. In the status field, the case receives the “closed file” status. Information in the file cannot be updated or changed after it has been designated “closed”.

What is the meaning of data gathered in the system?

The information accumulated in the risk management system has several limits, which should be taken into consideration, when it is used for decision making:

- **Representation of quantitative scope of a risk** – as we have already mentioned in the Chapter 6.7 elaborating on the reporting system, the rate of reported events out of the total number of reportable events, is relatively low and in general, does not exceed 10%. If a random sample would have been taken, it could be said that the reported events reflect a representative sample of the adverse events population. Since this is not the case, it is impossible to define a general rule able to explain the underlying factors controlling the phenomenon of reporting adverse events by physicians. In our opinion, the meaning of this is that attempts to determine the scope of risks on the basis of the reporting rates are not sufficiently valid. This is not to say that it is impossible to relate severity of the risks on the basis of the information accumulated in the computerized system.

- **Risk severity assessment** – in this case, the question to be asked is whether the computerized database can be used to assess risk severity and create a priority list for preventive activity. From our experience we have learned, that the computerized system can not be used to identify risks and define their severity, but to support hypotheses generated as a result of investigating particular cases or input from other sources, such as field surveys, meetings with colleagues, professional discussions, etc. The meaning of this is that using the database in this context is more for the sake of supporting hypotheses than for identifying risks and relating severity to them. The main reason for this is the inability to consider

the information in the database as representing the risk phenomenon at Macabbi, due to the partial and irregular reporting.

- **Information quality** – the quality of information in the data base is not uniform due to four reasons:

    - **High degree of variance in the quality of investigation over the years** – the department in its early days was lacking experience in investigation, experience that accumulated over the years. In addition, the ability to extract the information from the primary report was not well developed. Therefore, the quality of information for different events which were investigated and coded by the department is not uniform, though there is an evident improvement trend over the years.
    - **Variance in deciding whether to investigate an event or not** – the decision making regarding the classification of the events was not systematic in the first years of the department's existence and was influenced by various organizational factors. In addition, even after the establishment of decision making protocols in this area, due to the increase in reporting rates that was not followed by a due increase in personnel, it is possible that the decisions whether to investigate or not and to what depth, were influenced by personnel and resource limitations.
    - **Personnel changes** – since the department is relatively small, each change in personnel, due to leaving members or hiring new ones, affects the investigation quality. As we have already mentioned, a new risk manager needs between 8 to 12 months to reach a basic professional level of investigation ability. The meaning is that in those times of personnel changes, there is a due decrease in investigative quality.
    - **Variance between risk managers in relating to various fields in the system, especially in the analytic tier**. In the first years of the department's activity, the analytic process was not well established, which means that every risk manager could decide on the parameters of the analytic process almost independently, including: conclusions, key words, severity of error and more. As of today, the process is well defined and controlled to a higher degree and the decisions regarding the analytic parameters, are the result of a dialogue between the risk manager and the department's consultants and directors, a process which allows for some degree of standardization in the information recorded in the system.

The meaning of the above reasons is that the database is largely heterogeneous with regard to quality of handling of the events, and thus in every use of this information the limitations cited above, should be considered.

The spectrum of usage

The computerized system is the main tool in all of the department's activities and is intended, among others, for the following uses:

- **A variety of reports** – the system allows for the creating of different reports for internal routine usage and for other units needs. For example, in processing a case of type 2-3, before the investigation process starts, there is an attempt to identify "precedents" and assess the severity and scope of the event. During the process of precedent check, previous events of the caregivers involved are studied, as well as events that took place at the same site.

- **Publishing case studies** – in 2002, the department decided, despite much dispute around the issue of confidentiality of reported information, to distribute to Macabbi's physicians (3,500), case studies for learning purposes. The analyses are reported anonymously. In addition, the conclusions and recommendations are presented for the physicians to act accordingly. The report is sent to the physicians' home addresses. Physicians' reactions to the case studies are highly positive. The computerized system serves for identifying candidate events for distributing and expanding the base of conclusions and recommendations from similar events.

- **Self Initiated surveys** –the process is actually an applicative research, based on the information accumulated in the database and its expansion via field observations, questionnaires, interviews with professionals involved and more. The contribution of the computerized system in this regard is in indicating the directions of the survey and focusing the process on potential high risk factors. Among the surveys that were

conducted recently: errors in drug administration process, adverse events due to moving from one physician to another and unspecified chest pain as indication for MI Information for districts (organizational units in Maccabi responsible for all its activities in a certain geographical region) – special statistical reports were defined such as a report comparing reporting rates in different districts and different topics. These reports are part of the agenda in professional meetings between the department personnel and district managers, and provide a sense of adequate handling of the reported events by the risk management department, which is important to the reporting physicians.

The Information System as a means of feedback for the risk managers.

As we have already mentioned, the computerized system is a major tool in the department's work and serves as the formal documentation instrument for its activity. The system holds most of the knowledge, which accumulated over the years. An interesting phenomenon in this respect takes place when a risk manager encounters an investigation file from the beginning of his work in the department. In such an encounter, the following insights emerge:

- The gap between the investigation levels is emphasized – the risk manager and the department managers, witness the development that took place in the department over the years. This gap is encouraging, on one hand, but could be just as frustrating, since it creates ambivalence toward the information recorded in the system in the past and the degree of its usefulness. We, personally experienced this phenomenon in other content worlds too, such as Aviation.

- A mechanism of self-feedback regarding the qualities of investigations performed by the risk manager is formed, both from the relation to his own investigations and from those of other risk managers.

- Professional frustration rises due to the gap in investigation quality: *"how comes we didn't notice that…", "we did not ask that….", "we did not recommend that…"*

- It turns out that the information stored in the computerized system, reflects well the famous saying of IT people and which is sometimes denied by users: *"Garbage in, garbage out"* according to which, the computerized system represents the quality of information recorded into it.

- It turns out, that risk managing in medicine is a professional discipline, acquired through experience, under supervision and that the medical background is a necessary condition, but is insufficient in it in order to work effectively and professionally.

It seems that from a wider perspective after some time had past, the information accumulated on the events loses some of its value since it does not adhere to the current standards of handling events. In this respect, the question to be asked is what is the value of the information regarding adverse events if it was produced 5-6 years ago?

Not only did the processes of handling events changed and improved, but also the objects of investigation, which means that the context itself changes: medical technologies change, work procedures change, therapeutic perspectives change, aspects of medical and fiscal policy change. The question that comes up is what the relevant "life span" of information gathered on an event is, way beyond of its documentary value. We hypothesize, that the answer is in the range of about 3 years back. In addition, due to obsolescence and due to basic handling quality of adverse events, it will not be right to use this information, except for statistical purposes.

The process of critical observation from a perspective of time, is true for the computerized system as well. In the stages of analyzing the system according to the department requirements during 1998, it seemed to the department personnel that the system to be developed is too complicated and demanding. From our experience in developing computerized systems for risk management for the IDF and the Israeli Air Force, we expected this natural response and knew that after some time, we will have to upgrade the system significantly due to modifications and upgrades in working procedures, starting new activity areas,

using the system as the main working tool and the development of new technologies.

After approximately three years of work with the system, new needs started to emerge that required the upgrading of the system, especially in the following areas:

- Development of a module for managing the process of handling events– the need for this module emerged after the development of the multi-step handling of an event by different people: the department secretary, risk manager, medical consultant and department managers. In order to allow for the managing of an event efficiently, knowing in what stage the handling of the case is and what has been done in each stage; there is a need for computerizing the management of events.

- The recommendations handling module– assimilating the current process of handling recommendations in the computerized system, including the intra-departmental work processes in the recommendations and working interfaces with outside factors.

- Creation of interfaces with external computerized systems, especially EMR – Electronical Medical Record and standards such as HL-7 and ICD-9, in order to allow importing data into the system: information regarding clinicians, patients, medical encounters, etc.

- Developing flexibility in creating reports and generation of statistical reports with a wider variety of options.

The last version of the system, 2.05, installed in May 2003, includes several modifications that were needed, and toward the end of 2003 a new version of the system, which includes most of the missing functionality described above, will be implemented*.

*As by the end of 2009, a new RM computerized system has been deployed, based on the conceptions of the old one and the technological developments of the current years

Chapter 6.10*

Establishing working interfaces

Background

From our analysis of the relationships within and the interfaces between the Risk Management Department and other central and district departments, we deduced that these have gone through some transformations, influenced by three major factors:

1. **The department's activity** - The declared policy of the department, was mostly preventive. However, its organizational image was a product of its actual activities. This image emerged from a customer (doctors) survey that was published in December 2002. According to 36% of the respondents, the RMD's main function is to prevent legal actions in cases of malpractice, and provide legal defense whenever it failed to prevent the action. 33% of the respondents viewed the department's role as mainly to "prevent or minimize errors." Regarding their appeals to the department, 44% percent of the respondents appealed because they were apprehensive of being sued for malpractice, and 33% appealed in order to receive professional assistance. All this means, that in spite of its declared preventive role, at the time the audit, the department was firstly perceived as a provider of legal umbrellas and of professional assistance, and only secondly as acting to prevent "the next error." However, one of the recommendations that were specified by the respondents was…," *The role of the department in preventing accidents should be emphasized.*

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* In this chapter we will describe the inner dynamics of the Risk Management Department, within the general dynamics at Maccabi. We will try to do our best to be faithful to the changing atmosphere, during the different phases of the development of the department, and will present the meaning of these phases, as we understood them, over the time of our professional relations with Maccabi. This is a complex endeavor, since the structuring and analysis that we present here, was not part of everyday reality at the department, but rather a post factum reflection - a regrettable fact. We believe, that had there been more reflections and learning during the process, some of the errors, that were due to a pioneering spirit and a sense of mission, would have been prevented. We refer to chapter 2, where we broadly discuss our research methods, with an emphasis on the practice-based reflective analysis.

2. **Fundamental changes within the Healthcare systems in Israel and worldwide** - Among the changes that occurred with the proximity to establishment of the Risk Management department and continue to influence its activities are: Publication of the "Patients Rights Law – 1996, the legal precedent set up by Supreme Court Judge Barak in 1995, ratification of the IMA's (Israel Medical Association) treaty and more (see chapter 6.5 - Managing the possible risks of "Establishing the Risk Management Department"). Additionally, during the1990's the necessity arose to deal in a systematic manner with medical errors. Due to Aviation's success in reducing the rate of errors and accidents, an association has been created between Aviation and Medicine, positioning Aviation as a model for Medicine in its struggle to reduce physician errors.

3. **Personal and organizational changes in Maccabi** - Maccabi is a dynamic organization, that strives to foresee demands and expectations of its clients and those of the healthcare system. The RMD, was established during Mr. Shabtai Shavit's tenure as CEO of Maccabi, whose background was in the Israeli security system, and who had no previous experience in managing large healthcare systems. In 2002 Prof. Shuki Shemer replaced Mr. Shavit as CEO. Prof. Shemer, a physician, served previously as Surgeon General for the IDF, and as General Manager of the Israeli Health Ministry. We believe that each of the Maccabi's CEO's, leaded the organization in a manner suitable to his previous professional and managerial experience. These different directions have had direct influence over the Risk Management department's functioning and goals.

The following table, presents the development over seven years of existence, of the relations between the RMD and other central and field organs in Maccabi. We identified three time-periods and six corresponding developmental phases, from a primary stage, that we identified at the beginning of our consulting activities until the first stages of established cooperation between the Risk Management department and other center and field departments. It is important to note, that the passage from one phase to the next, does no mean that the previous phase, is no longer active, rather all the stages are like layers built one upon the other.

Period	Phase	Interfaces with the Center	Interfaces with the districts
1996-1999	1.Antagonism and Stress on immediate results (The state we found in our initial audit)	• Antagonism shown by administrative bodies: HR, Finance, Information systems, the legal department, Ombudsman, MCD (Medical Control Department) • Professional bodies: anticipating results.	Non existent
	2.Marketing Phase	• A series of meetings, with Heads of departments, aimed to establish professional relationships and convince them, that RM is a necessity for promoting patient safety and that cooperation with them is critical for assuring success.	• A series of lectures given by the head of the Risk Management Department at the districts, with the goal of exposing the staff in the districts to the activities of the department. • Meetings with the district managers with the aim of presenting the goals and modes of operations of the department. • Lack of continuous activities, despite the demand for such. The reason was the will to preserve the immunity of the reporting physician and preventing information exposure on adverse events, thereby exposing them to legal actions.
1999-2002	3.Protecting the immunity of the reporting physicians	• Establishing a stand-alone information system that prevents leakage of doctor's reports. • Total non-disclosure of information regarding information included in adverse events reports. • Non-disclosure of lessons learned from adverse events. • Disputes with the legal department regarding doctor's immunity and insurer's interfaces.	• Working directly with the doctors, bypassing the formal organizational structure. • No prompt response to cooperation requests from the field. • A one-way reporting flow of information. Physicians are required to report adverse events, but the obligations of the Risk Management department are not clearly defined.

Period	Phase	Interfaces with the Center	Interfaces with the districts
	4.Mutual signs of willingness to cooperate – from the center and the districts.	• MCD (Medical Control Department) – the idea to use data from medical activities control to locate risks, especially risks emanating from certain physicians activities • Cooperation at local levels, on a personal basis. For example, consulting the senior cardiologist and chief physiotherapist.	• Willingness of district managers to take an active role in the debriefing of adverse events. • Willingness of center managers to receive information about adverse events. • Willingness of physicians to continue participating in doctors/patients simulation workshops, conducted in order to enhance the awareness of the contribution of sound doctor patient communication in prevention of medical errors.
2002→	5.Initial attempts to define responsibility and authority of the Risk Management Department	• Utilization of recommendations as a vehicle in the creation of working interfaces. • Cross organizational Risk Management audits serving as a vehicle for establishing multidisciplinary work groups to deal with specific high risk areas. • Defining exterritorial sectors for direct action by the department: pharmaceutics, nursing, dentistry, laboratories. • Defining standardized procedures for managing recommendations.	• First pilots and experiential work procedures definitions. • Dealing with new complexity after the establishment of a QA department at the end of 2002.
	6.Launching and leading of partnerships	• Cross organizational audits-at the data gathering phase and definitions of intervention plans. • Cooperation projects with professional and administrative managers of departments: medical informatics, gynecology, diagnosis, nursing, mental health. • Leading the writing of standards for critical procedures.	• Joint debriefing of selected adverse events. • Periodical meetings to discuss Risk Management. • Risk Management surveys for new units, starting in the stage of planning.

It is safe to say, that during the years of the department's existence, we have witnessed major changes in its mode of operation. From a semi-secret mode, that was directed to assist physicians in coping with adverse events, to a center stage mode of operation, that is proactive in its nature and directed at improving patient safety.

Like a stone falling in calm waters - Broadening the impact circles.

As heads of the new Risk Management organizational entity, set within an existing organization, with well-defined work procedures, the founders of the new department, had to take one of three possible strategic decisions:

1. Integration within the existing organizational structure, while adopting of the existing work procedures. The implication of this decision would have been that the department, subordinated to the Head of the Healthcare Division of Maccabi, should adopt existing work procedures and interfaces in its center and in the field.

2. Defining unique modes of operation and interfaces, in order to give an optimal answer to the specific goals of the department, and to enable it to function effectively in achieving these goals.

3. To delay the decision, while anticipating the emanation of work procedures, influenced by various forces and needs that exist within the organization.

Following our advice, the heads of the department, decided on the second choice. We assumed, that a new department should establish its sovereignty with a view to the long term. Therefore, we suggested the adoption of the Israeli Air Force ASQAD mode of operation. This mode, allows the entity that is in charge of safety within the organization a large degree of autonomy in defining its modes of operation, as a consequence of its direct subordination to the head of the organization.

However, from the very beginning of the Risk Management Department activity, it became evident that this ambitious aim is for the long run and depends on organizational maturity and proofs of the department's competence. Therefore, in view of Maccabi's specific characteristics as an HMO, we suggested the compromise, which will be presently described.

It is important to note, that at the establishment of the RMD, the issue of the optimal mode of operation in order to achieve maximum affectivity, besides some general guidelines, was not officially discussed. These guidelines, in their turn, were molded into modes of operation different from those of other departments at the center of Maccabi. This deviant mode of operation on the behalf of the RMD, did not bode well for the department, and resulted in resentment against and isolation on the part of other heads of departments, joined with limited recognition of the department's activities and achievements.

The following table presents the working assumptions, that guided the department from its onset , and their implications:

Working assumption	Manifestations	Implications
• The main clients of the department are physicians especially those involved in adverse events.	• Focusing on physicians on the sharp end, and neglecting the promotion of Risk Management understanding and awareness among managers. • Creation of direct working interfaces with practitioners, over the heads of management.	• The caregivers perceive the department, as their address in cases of involvement in adverse events (see the "Quality of Service" survey 2003). • The managers do not feel involved in the handling of adverse events, unless the event is undergoing some legal action. • Antagonism exhibited by managers in the center and the districts who resent the department's operating outside the normal chain of management. • Misunderstanding the goals of Risk Management Department and lack of support from the management • Organizational isolation. The department was not involved in crucial decision making, where its expertise was essential.
Creating awareness in the center and the districts for Risk Management Department's activities is a necessity	• A series of lectures and meetings intended to expose the department's activities to center and districts. • Academic activities and participation in professional meetings within and outside Maccabi.	• Antagonistic reactions from the center and districts, due to feelings of being informed, but not involved in Risk Management. • A feeling, that behind the department's intentions for cooperation with the center and field, there is only rhetoric, without practical backing.

Working assumption	Manifestations	Implications
In order to encourage reporting of errors, those who report should receive administrative immunity	• A caregiver involved in an adverse event is obliged to report directly to the RM department. • The report and all personal details of the caregiver are kept within the Risk Management Department and aren't accessible to the entire organization and any other third party.	• The meaning of the immunity is unclear to some of the caregivers and managers. • Disbelief in the possibility of 'real' immunity within the organization. • Possibly, some of the caregivers 'take advantage' of the immunity and report adverse events in order to avoid disciplinary or legal actions. • Severe limitations on using the data accumulated in the department's data base aiming to prevent reoccurrence of errors.
The debriefing of adverse events, and drawing of conclusions, should be performed, solely by Risk Management Department personnel.	• The process of the debriefing is confidential. The main sources of data, are the caregivers involved and the medical record. • In most cases, the debriefing involves only those in the 'first circle', and avoids wider organizational circles (Reason 1997).	• The depth and width of the investigation, are a function of the Risk Management Department's available resources: the number of risk managers, their experience and professionalism and the other assignments they are involved in. As a result of the increasing number of reports, the deepening of the debriefings and additional assignments, the percentage of the debriefed events decreased over the time. • Difficulties in implementation of recommendations due to the crucial role of the managers who are excluded from the debriefings. • Most of the findings in debriefings relate to those who are directly involved. • Conclusions and recommendations on the organizational level are intuitive and not well founded. • There are hardly any implications on the managerial level.

Working assumption	Manifestations	Implications
Safety and Risk Management activities should serve as an infrastructure for future QA activities.	• Interest and involvement in projects that involve quality aspects. • An effort to adopt an organizational structure and work procedures that will support joint Risk Management and QA activities (RMQA).	• Growing resource allocation, mainly managerial to QA activities, a tendency that culminated in 2001-2 compromising depth of Risk Management activities. • "Marking" QA activities within the organization as belonging to Risk Management Department. • Organizational awareness for QA activities and attempts to become a part of it. • Steps within the organization to create management awareness to the fact that QA and Risk Management are complementary.

Three points should be emphasized:

1. During the years, facing a reality of fast turnover in senior management and changing organizational reality, changes and alterations, were made in the working assumptions hereby presented, but basically most of them, especially those dealing with RM, did not change and are valid in the present.

2. Senior management, particularly at the districts, was on more than one occasion impatient with these principles, and with the department's strict application of them. They found them isolative, patronizing and disruptive of normal work procedures, especially by the disregard to the hierarchic structure of Maccabi.

3. These working assumptions, were the outcome of our reflections on the relations, that were created between the department and the entire organization. They were not defined beforehand at the establishment of the Risk Management department.

We believe, although we cannot be certain, that the working assumptions were the outcomes, not only of the reactions within the organization to the aspirations of the Risk Management Department, but of the professional background and personalities of the risk managers.

Looking for partners to produce critical mass

When the department's debriefings produced, a sizable body of recommendations, the managers found themselves in a substantial paradox. On the one hand, they tried to stick to the principles described above, on the other hand they found themselves isolated in their strive to promote the real preventive role of the department.

On a declarative level, the department received full management backing, as well as their colleagues' support. However, on the operative level, they faced more and more obstacles. By the end of 2001, the number of recommendations on the "waiting for implementation list" was well over 200.

From our point of view, this situation posed a real danger to the very existence of the department, since the circle of Risk Management was cut at its most important link – the return to the scene of the adverse events with the aim of fixing the root causes, responsible for the error occurrence. There was a danger of ineffectiveness at the core of the department's operation.

Recommendations that were implemented, were mostly those that were referred for implementation by the Risk Management department itself. This led to a feeling of effectiveness mixed with frustration that led to pronouncements like: *"if we want something to be done, we should do it ourselves.*

In a strategic workshop, that took place at the end of 2001, and whose target was to shape a strategy and working plans for 2002, the problem of the piling up of recommendations was raised by the head of the department, who defined the situation in very grave terms. On the occasion, we suggested the establishment of a special task force, whose objective would be to cut the number of open recommendations by half during the coming year. This objective was achieved.

With hindsight, it is clear that the paradox described above and its risks were predictable. It was possible to foresee that the principles and modes of operations, that were adopted by the department, would isolate it and cause antagonism and indignation on the part of the managers who felt removed from the process and kept away from Risk Management activities altogether. All this was detrimental to the department at the critical stage of trying to implement recommendations, derived from adverse events and changing the set up that led to errors.

With the understanding that effective Risk Management depends on collaborating with the management in the center and in the field, it also became clear that the usual channels of management, would have to be utilized. For example, in order to start a process of change within Gynecology, the Chief Gynecologist, his superior and senior Gynecologists in the districts, would have to participate in the process and approve it.

It became evident, that turning a recommendation to the Chief of Gynecology in the Risk Management data system, is necessary but insufficient in order to assure its implementation.

It is important to note that in the Aviation, recommendations become directives for action by being endorsed as such by the head of the organization. By adopting the immunity principle above mentioned, findings, conclusions and recommendations from the debriefings of adverse events became protected from the management therefore this aspect of the Aviation model was not applicable and was not implemented.

Thus, the authority of the recommendations, stemmed from the debriefing process, but not from management endorsement. Therefore, professional managers could apparently claim that any recommendation, that was directed at them have, for a variety of reasons, no validity. Those reasons might be incomplete debriefing, wrong professional attitude, unfamiliarity with aspects of the profession's domain, unfeasibility, etc.

From the above said, we may deduce that the operating principles, that were adopted by the Risk Management Department at the beginning of its operations, created in fact a paradox; the severance of the Risk Management process at its most critical stage, that of the implementation of recommendations. This paradox is due to the inability of the senior management to endorse those recommendations, and the seclusion of the professional managers from the debriefing of adverse events.

In the paragraph that deals with the definitions of the Risk Management Department functions, we shall try to get some insights into the factors that were behind the aforementioned paradox. Among these, the necessity to mark and protect the boundaries of Risk Management in general, against other departments attempts to cut “part of the territory” for themselves.

The insights from the organizational feedback loop as means of effectiveness.

In what manner is it possible to define and measure the department's effectiveness? The department defines its major aim as: "preventing the next error", therefore any reference to its effectiveness, should be deduced from this aim. The measurement of the effectiveness of Risk Management activities is critical due to several factors:

- Being a relatively new domain necessitates an accurate measurement of its chosen modes of operation. The importance of Risk Management seems to have face validity, especially after the publication in recent years of the IOM reports and the various activities, lead by the American administration, which followed these publications. However, we did not find any written evidence on the relation between Risk Management activity and reduction in the number of errors and losses ensued by them. Some studies claim that Risk Management shortens the legal proceedings in cases legal steps are taken, and reduces the compensation payments.

- From the standpoint of the RMD, the issue of effectiveness became more and more critical, as time has passed from its establishment. The importance of this issue was stressed by RMD's requirements for additional resources, needed for handling the increasing amount of reports on adverse events. In its yearly reports, RMD highlighted its activity: debriefing of adverse events, lecturing, Risk Management workshops in the districts, leading headquarters activities concerning issues that arose from the department's activities etc.; however it could present no proof for the department's effectiveness.

- In Civil Aviation, the effectiveness of safety measures and Risk Management is measured by the rate of casualties/accidents per mile or per number of takeoffs. Thus, for example, the American NTSB (National Transportation and Safety Board) measures fatalities by the number of fatal casualties per one million miles, and accidents by the number of accidents per 100,000 takeoffs. According to the NTSB findings, between 1983-2001 the rates of accidents dropped from 0.055 to 0.011' and the rate of fatalities decreased from 0.0013 to 0.0003. Similar statistics are presented by the ICAO (International Civil Aviation Organization) and by the FAA (Federal Aviation Administration).

- The measurement of the effectiveness and the outcomes of Risk Management activities demonstrate the difference between Risk Management in Civil Aviation and Risk Management in the Healthcare systems. While in Civil Aviation data is routinely collected and published, in Healthcare, only in rare cases there are agreed indicators, measurement methods and agreed entities whose functions are to gather and publish the relevant data. Although, in Israel each fatality that occurs during a medical process is reported to the Ministry of Health, it is unclear how these reports serve to prevent similar deaths from reoccurring in the future. Thus the need to define Risk Management indicators and to constantly monitor the effectiveness of Risk Management in Healthcare, does not pertain only to Maccabi's Risk Management Department, but to the entire Healthcare system that invests considerable resources in Risk Management activities, and should care to find out how effective they are.

- Risk Management, by its nature poses a mirror in front of the organization and deals with flaws and deficiencies. The entire process of handling adverse events has a potential of exposing the organization to additional risks, for example the possibility that entities outside of the system will get access to privileged information. This leakage of confidential information regarding adverse events may support taking legal actions against the reporting physicians. These risks and others were very tangible to Maccabi's management, while the benefits of Risk Management still required proofs.

- The resources needed for Risk Management - From 1996 to 2003 the department grew in personnel from 0.5 to 7.5 (see chapter 6.5). The growth was an outcome of the growth in reporting, the deepening of the debriefings and the initiation of Risk Management audits. However, Maccabi's management became aware of the need for growing resources, especially in the complex economical reality, common to all HMOs in Israel- permanent under-budgeting. The growing resources that had to be allocated to Risk Management resulted in greater concern by the management to measure and prove the effectiveness of the Risk Management activities in Maccabi.

In the first three years of the department's existence the six, above mentioned factors, were only marginally evident. However, with the passage of time, they became more conspicuous, as the department created more professional relations with center and district entities, and was demanding ever more resources to continue and to develop its activities.

As has already been mentioned, the Aviation model ascribes major importance to the measurement of the safety indicators and their publication. It is commonly claimed, that within the healthcare domain, that it is very difficult to assess directly the effectiveness of Risk Management, due to the complexity of the processes and the practical difficulty in isolating Risk Management activities and proving their impact on errors, accidents and losses. However, after the publication of the IOM report entitled 'To Err is Human' in 1999, President Clinton defined a practical target for Risk Management on a national basis; to reduce preventable deaths (caused by physician errors) by 50% within 5 years. That is to say that the medical systems were to start measuring the effectiveness of their Risk Management operations, using mortality rate as their main indicator.

The heads of the RMD were aware, from day one, that they should exhibit valid effectiveness measurement of their operations. However, in the routine practice, they avoided this aspect and preferred to focus on Risk Management activities, rather than trying to measure their effectiveness. Whenever a negative feedback was received, that questioned the contribution of the Risk Management Department, the need to demonstrate the effectiveness was stressed again, but the impetus would be obscured shortly behind daily activities.

Feedback from the districts, was received mainly in regular meetings between the heads of the department and the districts managers. The districts managers perceived these meetings as an opportunity to express their expectations from the department and the measure of their satisfaction with its activities.

These meetings with the districts' management and personnel, were defined as the 1st goal in Risk Management Department’s 2002 work plan. The goal was defined as following: *"Enhancing the commitment of the caregivers and their professional capability to improve the safety of their clients"*. During 2002, six such meetings took place. They were analyzed and summed up in a report that was prepared by us (EILAT Company): *“New format for Risk Management meetings with district personnel."*

Some important issues were raised in the report:

- **Understanding the functions of Risk Management** – although there has been much activity regarding the subject within the districts, there was still considerable un-clarity, regarding the role of the RMD and its activities. Of special notice was the blurring of the boundaries of the Legal and Risk Management departments.

- **Expectations from Risk Management** – these are divided into different domains:
    - **Providing feedback regarding previously reported adverse events** – this is a recurring demand from all districts managers, who expect that their reporting of adverse events will be followed by proper and timely feedback, relating to the conclusions and recommendations derived from the debriefings.
    - **Providing professional tools to carry out debriefings** –the willingness of district representatives to attend Risk Management and debriefing workshops in order be become competent in the debriefing methodology.
    - **Support in handling of adverse events** – although such expectations exist, their nature was not clear.
    - **Receiving Information** – The districts were expecting to receive lessons learned, based on their reporting of adverse events.

From this analysis, we deduced an existing remoteness and lack of cooperation on the one hand and a will and expectation on the part of the districts to create and strengthen working relations with the department, on the other hand.

The issue, why despite its clear criticality for the future development of the Risk Management Department, the working interfaces with the districts were not clearly defined and formalized, is still unanswered. We believe, the answer is related to the basic assumptions, the RMD adopted from the very beginning of its activities as its modus operandi, elaborated in *"Like a stone falling in calm water - Broadening the impact circles"* in this chapter.

Efforts to establish cooperation – Partial successes

In the period of its existence, and despite the aforesaid, efforts were made by the department to define patterns of cooperation and mutual work with the relevant entities within the organization. However, for unclear reasons these efforts were short-lived and unfruitful in most of the cases.

In August 1998, the issue of cooperation with the districts was discussed by the department. The outcomes of these deliberations were summed up under the title 'Decentralization'. In the conclusions section of the document one can read the following statement, *"We should teach the districts how to debrief… workshop for investigators".*

In 1998, the issue was further emphasized as a part of Maccabi's strategy of decentralizing some functions to the districts. In an undated document from 1998, it was noted among other that *"As a part of the decentralization policy in Maccabi, Risk Management activities within the districts will be institutionalized within the districts"*. In the same document a division of labor and the interfaces between the central Risk Management department and the units in the districts, was also defined. The districts unit responsibilities were defined as: *"Examining and clarifying adverse events, reaching conclusions and recommendations in cases that ended with no significant damage… initiated activities to identify potential risks in the district…".* Although this subject was often discussed by the Risk Management Department, these suggestions were never fully implemented.

In October 2000, the activities of a joint committee of the Risk Management Department and the MID (Medical Informatics Department) 'The Alerts Committee', were summed up. The original idea was to identify potential risks that Maccabi's computerized systems could alert about. Several specific alerts were defined, among them: periodical blood pressure tests, hemoglobin values lower than 6, prescribing Tycledil, low values of white blood cells etc. As far as we know, the recommendations of this committee were not implemented.

In the year 2000, after several meetings a framework of cooperation was defined between the Risk Management department and the physiotherapy unit, according to which:

- The head of the unit will be in charge for receiving adverse events reports from his subordinates.

- Partial debriefing will be carried out at the facilities, were the incident occurred, by local managers.
- Certain cases will be debriefed by the facility manager, under the guidance of Risk Management personnel.
- Before summing up, the debriefing files will be sent to the Head of the Physiotherapy unit for his reference.
- The recommendations from adverse events in physiotherapy, will be jointly discussed with the Head of Physiotherapy.

This framework was realized only in the years 2007-2009, although its principles had the potential of creating a good professional infrastructure and high motivation to deal with the root causes of adverse events in physiotherapy, as early as in the year 2000.

The picture we have outlined here may seem rather pessimistic, despite the willingness of the RMD and other entities within Maccabi to promote Risk Management activities, and despite the initiation of joint projects. From the realization and diligence aspects, the success of Risk Management projects has been limited.

However, it is important to note that during the years of its existence, the department had some major successes which are described in chapter 6.11, which deals with implementing recommendations and multidisciplinary risk audits.

In our opinion it is important to debrief the department's own failures, which may be viewed, as adverse events on its part. We believe, the three discussed projects have some common denominators:

- All three were initiated by the Risk Management department.
- The processes included several meetings that were concluded by mutual understandings.
- These understandings were expected to establish substantial system modifications to the modes of cooperation between the department and the other entities.
- None of the initial plans were followed by a definition of a work plan consisting of: milestones, responsibilities and resources.
- None of the projects were subjected to Risk Management of its own. No effort was made to identify obstacles; objections, the availability of resources etc.

- It is unclear, whether any of the projects were ratified by the senior management.
- None of these projects went through a formal debriefing, thus no lessons were learnt from any of them, in order to improve future cooperations.

In all of these projects we served as Risk Management consultants, and we expressed our positions regarding the aforementioned issues. However, due to our lack of experience in implementing large scale organizational changes in the healthcare domain, we were not aware enough to the impact of the issues raised above.

Recommendations as means of establishing a working dialogue

Recommendations can be viewed, as the main product of the Risk Management processes, although the debriefing process by itself and all other Risk Management activities do influence the risk factors.

Hendrick and Benner (1987), claim that for the recommendations to be accepted, they should be viable and credible and their implementation should result in real improvements. Over a period of fourteen years, Hendrick and Benner investigated hundreds of recommendations, some that were implemented and some that failed during various stages of implementation. They concluded, that successful recommendations have fourteen common denominations that can be divided into three categories:

- A recommendation should be clearly defined and operative.
- Guidelines for implementation should be defined within the recommendation.
- A clear criterion for success should also be presented.

From our experience a valid recommendation, one that can effectively deal with the risk factors, should have the following characteristics:

- **Valid** – a valid recommendation should be an outcome of the debriefing process of an adverse event or a number of cases that represent a phenomenon. If based solely on the experience of risk managers, however experienced they are, a recommendation's chances of being implemented is meager.

- **Relevant** – a recommendation should refer to the actual case, and not to other factors, however important these may be.

- **Acceptable** – a recommendation should be accepted by the person or persons that should implement it.

- **Should be backed by the relevant management level** in order to be transformed from a professional recommendation into an approved system action item.

- **Feasible** – the resources that are required for the implementation, should be proportionate to the risk they may prevent.

- **Avoiding new risks** – an implementation of a recommendation should not result in further, and even graver, risks.

It is interesting to mention, that a basic clinical Risk Management textbook, edited by Vincent (1995), includes no reference to recommendations as the major outcomes of debriefings, or to the significance of phenomenon analysis from clinical Risk Management aspects.

In 2002, the RMD published an internal report regarding its activities in defining and implementing recommendations, covering the years 1996-2002.

In the preface of the report it was stated that:
"The implementation of recommendations derived from debriefings of adverse events is the main challenge (if not the only one), that is facing any Risk Management system that intends to influence reality, namely to minimize the risks of accidents occurring during the delivery of medical treatment".

One of the challenges to implementation that are presented in the report was: **"…** *maintaining a right tension at any given moment, between what is suggested by the Risk Management Department as a solution to problems that were revealed through the debriefing and the actual conditions".* In other words, the recommendation implementation process, should keep a balance between the need to solve problems and the systems capabilities to do so.

According to the report, 632 recommendations were elicited during the period cited, 452 (72%) of which were implemented and 48 (8%) were canceled. Of the 452 implemented recommendations, 123 (27%) were personal in nature, that is they referred to the involved personnel and suggested providing a personal feedback. 145 (29%) of the recommendations, were referred to the Risk Management Department.

The following table presents the recommendations, by professional entity to which the responsibility for implementation was transferred:

In charge of implementation	**Number of recommendations**	**%**
Risk Management Department	145	29
Gynecology	59	11.8
District Managers	54	10.8
Medical Division	49	9.8
Medical Informatics Department	24	4.8
Other	169	33.8
Total	**500**	**100**

Among the recommendations that were referred to the Risk Management department, we may identify six categories:

- **Feedback for the involved personnel** – A phone call or face-to-face conversation between the risk manager and the involved caregiver, in case the risk manager believes, such an interaction may improve the quality and safety of care. The feedback may be provided, by whoever is assumed to achieve the maximal cooperation with the involved caregiver: the risk manager, the clinical consultant of the department, or the head of RMD

- **Caregivers Training** – occasionally, during the debriefing, an insight is formulated that what seemed like an isolated incident has deep roots within the system. One of the most recurring recommendations is to bring into caregivers awareness the lessons learned from adverse events. Choosing the proper instructing method is an important issue. In organizations, as large as Maccabi, which are geographically widespread, existing channels of communication, were often employed: written professional guidelines, periodical meetings with experts and others.

- **Process In-depth examination** – of a phenomenon, a process or a site. This kind of recommendations, are elicited if the risk manager concludes, that the actual case under investigation represents a “tip of an iceberg”, and that the organization may benefit from a deeper understanding of the entire process in which an error occurred.

- **Writing and improving guidelines or procedures** – Such recommendations are normally directed to those in charge of a process or a domain. However, in some cases the risk manager may conclude that the guidelines writing or revision should be done at the Risk Management Department. This way of operation is adopted in order to assure that critical processes would be anchored in proper guidelines, which take into account all insights that emanated from the Risk Management debriefings.

- **Improvements in the information systems** – Most Maccabi’s caregivers, document the encounters in an EMR. The system alerts doctors to data that is meaningful for their decision making, such as critical values in laboratory tests, interactions between active ingredients of medications and general clinical guidelines. In order to preserve the effectiveness of the system regarding these aspects, the quantity of warnings and directives should not be so overwhelming, as to distract the physician from normal mode of work. In certain cases that have critical Risk Management implications, this channel was employed to minimize risks. RMD's role in this type of recommendations, is to specify the alert and to be on watch, as to the volume of alerts in the system.

The following table presents the distribution of the recommendations which were referred to the Risk Management Department. The most prevalent is the feedback category. This is an outcome of the fact that providing feedback, is one of the major functions of the department. In most cases, only the risk manager, who conducted the debriefing, can formulate the proper feedback from the gathered data and its analysis, combined with an understanding of the unique situation the involved caregiver is placed in.

Category	Number	%
Feedback to the involved physicians	51	35.2
Training the caregivers	35	24.1
In-depth analysis of a defined process	26	17.9
Writing and improving guidelines	13	9.0
Improvements in the EMR	8	5.5
Other	12	8.3
Total	**145**	**100**

In order to examine the changes that occurred in the department's perception of the effectiveness of its recommendations over the years, we examined the distribution of the recommendation categories in the period 1996-2002, presented in the following table.

Category	1996	1997	1998	1999	2000	2001	2002	Total
Feedback for the involved physicians	1	3	2	17	11	13	4	51
%	***33.3***	***25.0***	***11.8***	***60.7***	***27.5***	***48.1***	***22.2***	***35.2***
Instructing the doctors	2	8	11	6	2	3	3	35
%	***66.7***	***66.7***	***64.7***	***21.4***	***5***	***11.1***	***16.7***	***24.1***
In-depth analysis of a defined process					15	4	7	26
%					***37.5***	***14.8***	***38.9***	***17.9***
Writing/Rewriting of guidelines		1	1	3	5	2	1	13
%		***8.3***	***5.9***	***10.7***	***12.5***	***7.4***	***5.6***	***9.0***
Improvement in the EMR			3	2		2	1	8
%			***17.6***	***7.1***		***7.4***	***5.6***	***5.5***
Other					7	3	2	12
%					***17.5***	***11.1***	***11.1***	***8.3***
Total	**3**	**12**	**17**	**28**	**40**	**27**	**18**	**145**

It may be observed, that the sector in which recommendations were defined, were changing and unstable over the years. As for 2008- 2009, the majority of recommendations are aimed to improve the EMR, bridge the gaps regarding guidelines and procedures, specialty specific procedural improvements and RM training for caregivers. Personal feedback became a regular part of managing the adverse event, so it is no apparent anymore in recommendations statistics.

Chapter 6.11

From investigating a single Adverse Event to studying phenomena

"Not only will men of science have to grapple with sciences that deal with man but - and this is a far more difficult matter - they will have to persuade the world to listen to what they have discovered"

Bertrand Russell (1872-1970)

What can be learned and generalized from a single event?

As has already been mentioned, the main activities of the RMD, from its establishment until the time of writing this work, focused on handling adverse events in the wide sense: receiving reports, providing feedback to the caregivers, debriefing, coding and storing the data in the information system, defining recommendations and follow up until implementation.

During these years, in addition to the previously mentioned, the department established other channels of activities, which were intended to improve its abilities to learn from adverse events and to assimilate in the organization the lessons that were learnt. Therefore, the percentage of the department's resources, that were dedicated handling reports fell from 100% to around 50% in the years 2002-2003. It may be stated, that during the years, the number of reported cases, was on the ascent, while the resources allocated to these activities descended.

Debriefing is a major Risk Management tool, therefore in this section we shall discuss the validity and value, that can be ascribed to the findings and conclusions of single case debriefing.

There are two opposing approaches to the issue of the significance, that can be attributed to a single case debriefing, as a valid base for Risk Management activities:

- **The Systemic Approach** – considers every adverse event an expression of the latent risks existing within the system (Reason et al. 1997). According to this attitude, the lessons that are learnt from a debriefing, based on systemic approach, that uncovers the defense failures, are valid representations of the entire defense weaknesses in the system.

- **The Limiting Approach** (our definition) – according to which an adverse event has no meaning outside its immediate scene of occurrence. We coined the term as an expression of our experience, and it expresses the attitude according to which it is not reasonable to deduce lessons from a single incident to the entire system.

The adoption of one of these approaches has deep implications for Risk Management. Within the systemic approach, a singe incident, may serve the impetus to far-reaching modifications in the organization, while the other approach limits all changes to the immediate factors within the close proximity of the incident.

The systemic approach, allows for proactive Risk Management, as the outcomes of the debriefing of a single case, while within the limiting approach, only reactive response to single cases is possible.

Presenting these approaches in terms of the 5M model, the accepted model for investigations of accidents and incidents in civil aviation, allows for a comparison between them:

Factor	**The Systemic approach**	**The Limiting approach**
Man	+++	+++
Machine	++	++
Management	+++	+
Medium	+++	+
Mission	++	++

- **The Human Factor** – both approaches value the human factor, but in wholly different manners. The systemic approach tackles the general aspects of the human factors: training, human engineering, cognitive processes of perception, decision making, and memory, while the limiting approach, deals mainly with the issue of responsibility for errors.

- **Management** – the systemic approach, emphasizes the role of management in promoting changes that are required by Risk Management, and in dealing with risks at the systemic level.

- **Medium** – within the limiting approach, the environment (medium) is regarded as supportive of the argument that we cannot generalize from one incident, since the environment is unique to each incident. Within the systemic approach, the environmental factors are viewed as possible contributors to the materialization of the risk; long queues at the clinic, uncomfortable work environment etc.

It is difficult to pinpoint, when exactly the Risk Management department in Maccabi adopted the systemic approach. However, in the work plan for 1999 we found for the first time: *"Initiation of activities to improve processes"* as a goal. This was the first practical reference to systemic aspects, following investigations of adverse events. (See Work Plan 1999)

In 200, this goal was explicitly defined as the main goal of that year: *"Initiating and guiding quality improvement processes, which originate from recommendations derived from reported incidents"* (See Work Plan 2001)

The following two incidents were published in *"Preventing the next error"*, a booklet, that was published by the Risk Management Department in 2001. The booklet was distributed among all Maccabi's physicians, with the aim of acquainting them with the Risk Management approach of Maccabi. We present the incidents in a summary manner, with the sole purpose of evaluating that approach. (See booklet 2001)

- ***Incident A:***

A 41 year old male patient, was referred by the physician for a routine chest X-ray examination, as part of a medical checkup, that was required by his new employer. There were no pathological findings. Eighteen months later, the patient was diagnosed with a primary tumor in the majority of his right lung. In a revision of the x-ray, a shadow, the perimeter of which was 2 centimeters, was observed in the right hemisphere of the lung. The tumor was partially hidden by the collarbone and the ribs. This late diagnosis necessitated the removal of the right hemisphere of the lung, which caused a disability of the lung.

In the debriefing of the incident, it was found that the man was a heavy smoker, a fact that was documented in his medical record. However, the radiologist was not aware of the patients smoking habits.

Previous attempts to convince referring physicians to attach all relevant data to their referrals failed.

Following the incident, two major recommendations were decided upon:

- To define "Smoking Status" as an obligatory field in the medical record of all of Maccabi's patients.
- To implement a process by which data about previous smoking history will be automatically attached to any referral for a chest X-ray examination.

This incident is an example of how a single adverse event can serve as the basis for drawing wider conclusions with implications for the whole system.

However, the question of the borders of the generalization in the Risk Management process remains, of how wide the implications of a single case may be. For example, it could be claimed, that this single case demonstrated the need to examine all aspects concerning the data available to the radiologists; the case may have demonstrated a need to examine all aspects of all data that is available to all specialists. In short, how deep and wide should the investigation be? This is basically a practical matter. According to the RCA (Root Cause Analysis) approach, it is imperative to reach the roots of all the factors that caused the incident, because this is the only way to prevent similar incidents from occurring again. However, due to shortage of resources, this approach in not always practical. It is not economically feasible to investigate in depth all the abnormal incidents that occur in a multi-risk environment. Therefore, this approach, serves in the investigations of large scale accidents, the likes of: passenger plane crashes, mishaps in nuclear reactors, large scale epidemics etc. Since, most incidents are not investigated according to the RCA approach, it follows that the inclusion of such 'routine' investigations to wider systems is limited.

- ***Incident B***

Ticlidil (Clopidogrel) is an anticoagulant medication, prescribed in cases blood dilution is required . It may reduce the count of white blood cells. Early detection of the side effect and termination of treatment with Ticlidil, may stop the count reduction and prevent a serious deterioration. Following the incident, it was

recommended to implement a computerized warning that will pop-up, whenever the medication is prescribed.

"Attention! You have just prescribed Ticlidil, which has caused some deaths in recent years, due to suppression of white blood cell generation. Have you tested white cell count once every two weeks? If leukocyte values are 30 or more percent lower, than the values before the commencement of the treatment, even if the present values are within the norm – it is imperative to consider stopping the treatment".

We may ask, as we did concerning the first case, how widespread the implications of the case may be:

- Would it not be advisable to examine all serious side effects, resulting from medications that are within Maccabi's medication basket, and to seek ways to minimize all possible adverse events?
- Was the above case described inevitable? Were it not possible to know, by the time that Ticlidil was included in Maccabi's medications basket, that lack of due precautions, may result in serious repercussions?

We may conclude that the degree of generalization from a single incident to the whole system depends on the following factors:

- Adoption of the systemic approach by the Risk Management entity, and its acceptance by the organization.
- The severity of the outcomes of the incident – readiness to invest in preventing future accidents is often a function of the severity of losses. Therefore, the degree of inclusion from an incident depends on the severity of the accident.
- Detection of grave and chronic risks during the investigation of an adverse events.

How to set priorities, when everything seems urgent?

It could be claimed, that since Risk Management is usually responsive to appeals from other entities in the organization, it does not initiate activities and thus has no need to set priorities. However, this is only true of the reactive approach to Risk Management. Within the proactive approach, priority setting is a sine qua non.

It is important to note, that within the Aviation model in general and the Israeli Air Force model in particular, the yearly work plans are based on several inputs:

- Analysis of adverse events that occurred in the preceding years, and an attempt to identify new tendencies and their meanings.
- A wider analysis of trends, within the whole system, and their meanings from the Risk Management point of view.
- Points of reference and directives from the senior management.

In our view, Maccabi's Risk Management activities, were mature enough to consider all these inputs only in the years 2002-2003. The first yearly report covering all Risk Management activities, as well as debriefings of adverse events and their meanings, covered the year 2003.

In addition, since the department was usually under-staffed in relation to the number of incidents that were reported or should be debriefed, priority setting and resource allocation, were crucial to guarantee that some proactive Risk Management activities would be performed, beside all the routine reactive activities.

Since, the department adopted the proactive approach, from its very establishment, working plans were defined, discussed and confirmed by the management, from the first year.

The following table presents the essence of the Risk Management department work plans in the years 1997-2001

The first plan for 1997, posts general, long term, strategic objectives. The objectives and assignments are general aimed to establish the infrastructure for future assignments. The department lacked experience in forming operative plans, and the unknown was greater than the known. Therefore, the department based the work plan on the general premises of Risk Management.

The main goal for 1998 was the augmentation of self- initiated reporting by physicians of their own errors, a precondition for effective Risk Management. Several other goals were defined, among them: establishment of a computerized data system, establishing an organizational infrastructure to deal with recommendations, and the establishment of a 'hotline' to receive physician's self initiated reports of adverse events.

The year 1999, was characterized by the intention to institutionalize the department's activities within the organization. Among those, were the obligatory reporting of adverse events, handling of recommendations and setting the debriefing as a part of the organizational culture. Other goals aimed at the absorption of Risk Management activities within the organization, such as the formalities of imparting Risk Management activities to the districts, development and assimilation of the Risk Management doctrines within the organization, establishment of physician/patient communication workshops etc. Physician's reporting of adverse events was declared as compulsory in August 2000.

In 2000, the department started its field activities; these included initiated prevention and improving the quality of physician's self-reports. Some of these goals, were already set for 1999, but due to their complexity, they were continued in 2000. It is important to note, that every year; new layers of operations were added to the existing activities.

In may be stated that in 2001, the department “closed circles”. In order to become effective, within the organization it defined the main goal for that year as *"Starting and accompanying quality improvement processes which follow recommendations from reported incidents".* This was the fifth year of the department's existence, and it became clear, that professional debriefings and recommendations were not good enough to establish an active standing within the organization. In order to insure proper implementation of its recommendations, it was decided that the Risk Management department would take an active role in these processes.

The work plan for 2002 included seven unique aspects which made it an important benchmark:

- The plan was based on a resolution of Maccabi's secretariat, which ratified at the beginning of 2001 the functional model of the IAF's ASQAD. The Directorate is a professional body which: *"Debriefs, advises, inspects and guides on all safety matters in the Israeli Air Force".*

- Supporting the plan with main insights from the department's activities, among these: *"Ambiguity of management hierarchy, lack of uniformity in the definitions of tasks and boundaries of responsibility, a lack of professional cadres in the center and in the districts, the imbalance between centralization and decentralization tendencies*…”

- The plan was based on the current standard of JCAHO - Joint Commission Standards in Support of Patient Safety and Medication/Health Care Error (January 2001). The standard aims at *“Developing and implementing of a long term, continuous program of measurement, evaluation and improvement of performance, and improving patient's safety".*

- The plan was created by following the three major functions of ASQAD: Risk Management, Quality Management of the medical treatment and Research and Development..

- Potential 'obstacles' were determined, concerning each activity within the program. For example, three 'obstacles' were identified regarding the debriefing of adverse events: *"A lower than desired rate of debriefed incidents, lack of cooperation with other departments and problems regarding the interface between the administration and the medical departments".* This attitude can be regarded as 'self' Risk Management, namely the implementation of Risk Management principles to the department's own activities.

- Resources were allocated toward the achievement of each of the four program’s aims. These are specified in the sequel.

- A reference was made to the departments own resources, regarding the need to adjust and develop these toward the implementation of the plan.

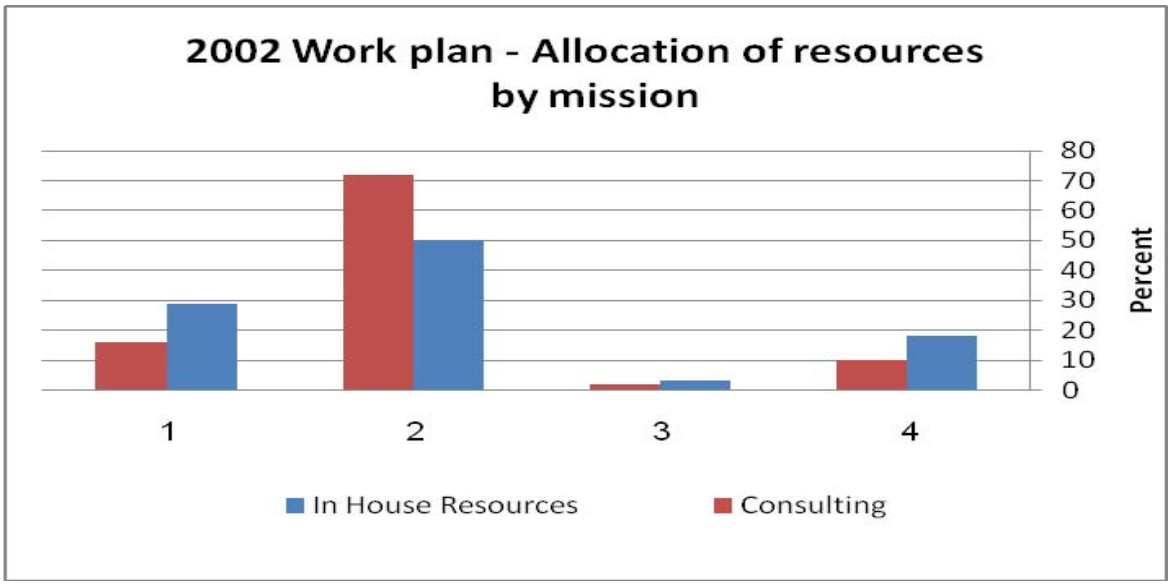
Four main targets were established within the plan:

1. Deepening the awareness of the medical staff to patient safety issues.

2. Treatment of mishaps, and investigation of risk factors.

3. Implementation of the management decree, regarding the positioning of the department as an advisory, controlling, and guiding entity of safety and quality matters, according to the SQAD model.

4. Matching the department resources (Standardization, Personnel Development, Methods and Tools), to the implementation demands.



It is evident that the diagram that most of the department resources, as well as its advisory resources, were allocated to the achievement of the first two targets: Deepening the awareness of the medical staff to the patient safety issue, mishaps handling and investigation of risk factors.

The 2002 work plan reflects a determination to adopt the organizational structure of the IAF's ASQAD. This determination by itself reflects a growing understanding that the organizational structure has a crucial importance for the implementation of the department goals and that the variety of activities developed through the years, necessitates a formal and compatible organizational structure.

2003 work plan represents a partial transformation to the new organizational structure, based generally on the ASQAD model. Shortage of resources and personnel prevented a full transformation. Toward the end of 2002, a Quality Management setup was established as a part of the Health Division in Maccabi, with two functional units:

1. **Quality of the medical service**, headed by Dr. Racheli Wilf-Miron, the former head of Risk Management Department.

2. **Risk Management**, headed by Dr. Michal Gindi.

The transformation to the new organizational structure necessitated a redefinition of the domains of the new entities, their working interfaces one with the other and of both with the center and the districts.

The 2003 work plan reflects three strategic targets:

1. Continuation of Risk Management activities in their current form while establishing a working dialog with the districts, turning Risk Management output into management tools, collaboration of decision makers and of those involved in adverse events in the recommendations drawing processes.

2. A redefinition of all domains of activity of the SQAD setup, its two units and redefinition of all inner and outer interfaces.

3. Stabilization of the new organizational structure, and its positioning as the leading medical Q Management organ within Maccabi.

Five main missions were defined for the Risk Management department:

1. Augmenting the commitment and the capabilities of the medical staff to improve patient safety.

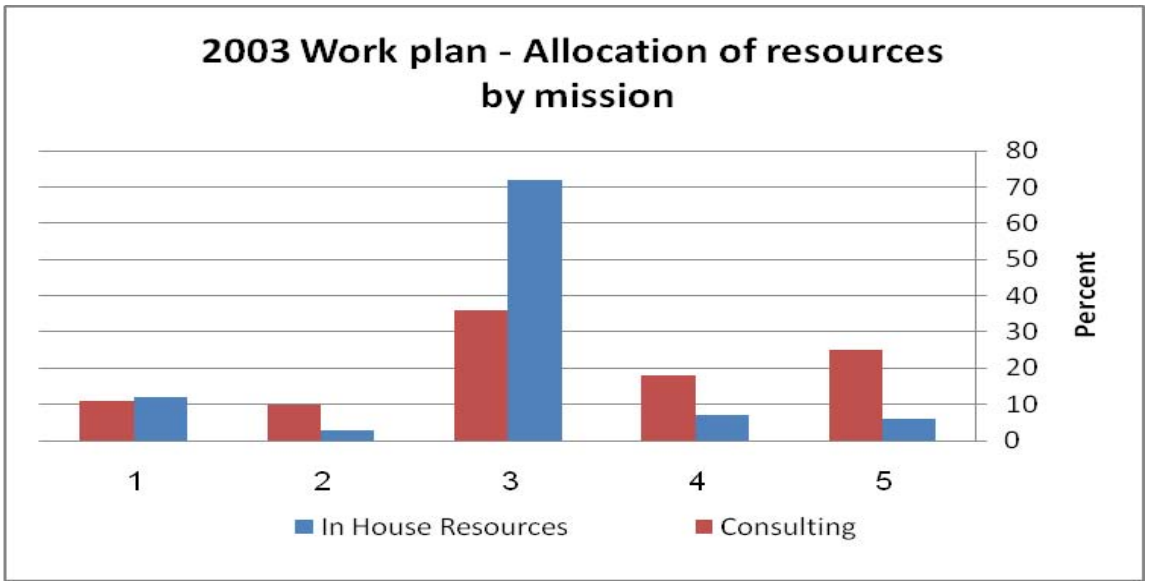
2. Definition and implementation of work patterns with the districts and the attached units.

3. Debriefing of adverse events, and preventing these from reoccurring.

4. Analyzing and investigating risk factors and defining of preventive measures on the organization level.

5. Development of professional and managerial infrastructure for the department.

The allocation of the department's in-house and consulting resources is presented in the next diagram.



It is clear that, like in 2002, most of the department's resources were allocated to the investigation and prevention of adverse events.

Two main targets have been added to the plan since 2002:

- Definition and implementation of work patterns with the districts and the attached units. Although appearing in previous plans this subject gained in stature by being defined as a separate one.

- Investigation and analysis of risk factors and defining systemic prevention plans. This was also not a new domain, but it gained new stature by being 'promoted' as a separate target. It was supported by initiated risk mapping activities, which will be described later in this chapter.

The resources allocated to consulting activities were reduced in 2002-2003 compared to previous years. These were un-proportionally allocated to support all targets; most were allocated to targets 2, 4 and 5.

- ***Work plans 1997-2001***

Year	Targets	Missions	Methods
1997	▪ Improving the healthcare quality ▪ Reducing expenses due to malpractice claims ▪ Improving reputation and public image ▪ Developing tools to appraise activities and outcomes	▪ Allocating and mapping of risk domains ▪ Improving Risk Management quality of service ▪ Management of legal actions ▪ Establishing the Risk Management forum	▪ Proactive clinical approach ▪ Combining Risk Management with QA ▪ Use of statistical tools ▪ Identification of potentially risky behaviors
1998	▪ Improving physician's reporting	▪ Establishing a follow-up committee that meets regularly ▪ Forming and formulating Risk Management concepts, including work patterns with the districts ▪ Establishment of a computerized data system ▪ Promoting 2-3 subjects such as legal consent forms, alerts in the medical record etc ▪ Establishing organizational infrastructure to deal with recommendations ▪ Hot Line for Physicians' reports	▪ Developing a computerized system and feeding 500 files. (Eilat) ▪ Regarding the physician as the department's preferred client
1999	▪ Institutionalizing of an mandatory reporting ▪ Initiating process improvements ▪ Imparting the culture of reporting adverse events ▪ Institutionalizing of recommendation treatment process	▪ Continued development of Risk Management concepts, and assimilating them in the organization ▪ Setting the procedures of Risk Management decentralization in the districts ▪ Checking the feasibility of establishing a Risk Management company conjointly with EILAT ▪ Risk assessment in clinics, in cooperation with independent physicians organization ▪ Establishment of Hot Line, active 12 hours a day ▪ Initiation of physician/patient communication workshops	▪ Handling the reports received by the department. ▪ Consulting professionals in the center and districts regarding risk evaluation and reducing the exposure to them ▪ Instructing the medical staff how to avoid and manage errors ▪ 'Private' real-time Risk Management counseling to physicians ▪ Partnership in planning new services and activities in order to reduce risk exposure ▪ Integration of QA activities through Risk Management activities

Year	Targets	Missions	Methods
2000	▪ Transforming the focus from the center to the periphery ▪ Risk identification by initiated mapping ▪ Implementation of CEO decree regarding increasing medical staff reporting	▪ Developing and running a physician/patient communication workshop ▪ Producing Maccabi's Risk Management dossier ▪ Control and standardization of workflow in the clinics ▪ Risk Management instructions for new physicians ▪ Widening the knowledge base of risk assessment and prevention ▪ Continuing the development of Risk Management data base as means for risk identification, evaluation and recommendations follow up.	▪ Retroactive feeding of 250 debriefed incidents ▪ Systematic and structured analysis of case-files ▪ Active participation in conclusions drawing and defining of prevention plans ▪ Control of recommendations implementation ▪ Compulsory Risk Management instruction of new physicians ▪ Physician/patient communication workshops ▪ Initiated mapping in new established high risk sites ▪ Establishing an Risk Management interface within the medical record ▪ Pilot quality audit at Physician's clinic, combining control and standardization ▪ Marketing Risk Management, articles and conventions
2001	▪ Initiation and supervision of quality improvements, based on recommendations from debriefing of adverse events.	▪ Continued activity of the hot-line- 800 calls anticipated ▪ Continued debriefings of adverse events-at least 300 ▪ Starting quality improvement projects- at least 3 ▪ Three workshops at the districts "Physician/patient communication"	

The following table presents the main characteristics and goals of each year, as they are reflected in the Risk Management work plans. Two cycles are identifiable, the second of which is at its beginning. They are characterized by the following stages: self-definition, operative focusing, institutionalize activities, assimilation and bequeathing and closures.

Year	Main Characteristic	Main goals
1997	**Self definition according to the Aviation Model**	Posing strategic and infrastructural long term goals
1998	**Operative focusing**	Improving reporting of adverse events
1999	**Institutionalize activities**	Establishing reporting of adverse events and recommendations implementation.
2000	**Assimilation and bequeathing**	Field work, proactive Risk Management, increasing physician's reporting
2001	**Closures**	Starting quality improvement following recommendations
2002	**Redefinition of goals and means**	Reorganization along the working principles of SQAD, Internal Risk Management to achieve effectiveness and exhaustion of resources. Standardization of work processes
2003	**Institutionalization of activities and transformation to a quality setup**	Risk Management developing, definitions of working interfaces, starting Quality Management.

What is the meaning of an X number of events sharing similar characteristics?

The topic that we discuss in this section is crucial to Risk Management, as it considers two basic issues concerning the usefulness of debriefing adverse events:

1. Are there any common characteristics of adverse events, or is each incident unique?

2. Assuming, that there are common characteristics, how can this serve preventing reoccurrence of adverse events?

Of course, if there are no common characteristics in adverse events, then debriefing them is meaningless, since the lessons that are learnt, have no use in preventing similar occurrences. In this case the reason for debriefing an adverse event, is related to managing the event in order to minimize losses and provide professional feedback to the involved staff. If we assume, there are common characteristics, then the lessons learnt from one incident may help preventing similar incidents from reoccurring.

A qualitative study, based on analysis of reported adverse events

Despite, the awareness to its beneficial outcomes in preventing future mishaps, initiated mapping of probable risks, was first introduced to Maccabi in the work plan for 2000.

In a report of an initiated risk mapping, dealing with errors in the medication process (2004), initiated mapping was defined as: *"A proactive process of studying and analyzing a phenomenon within the Risk Management domain, based on various sources of information, in addition to reports of adverse events".*

The first attempts to perform risk mapping, were an expression of a desire to deal in a deep and systematic manner with two major risks, which were identified by the Risk Management Department. In retrospective, we may say that despite their significance, or maybe because of it, dealing with them at that time, was beyond the competence of the department and the organization.

- ***Case A – Continuity of Care***

The first issue allocated for initiated mapping was “Continuity of Care”. Modern medicine is characterized, among others, by a fragmentation of the medical process. That is, the patient when approaching medical assistance interacts with more than one physician or medical institution. It is crucial that all institutions share all data concerning the patient; therefore, a great importance is ascribed to the manner by which the patient is transferred between physicians.

Since the transition between physicians is sometimes bumpy, it may present a risk to patient's welfare. For example, a GP in the community may be informed that a patient is sensitive to penicillin. If this information is not available to the hospital staff, they may prescribe penicillin with grave consequences. There are other issues, concerning the transition of patients between physicians, for example: a transition of patients to another physician after their physician departs his duty; transfer of data among specialists, especially in view of Maccabi's policy of enabling patients’ free choice physicians, etc.

Complex technological issues are also involved, especially those concerning interfaces between information systems. In addition, there are, medico-legal issues involved, such as patient’s information immunity and according to Patient's Rights Law.

In order to proved the subject due attention, a committee was formed that comprised representatives from the Risk Management Department, from the districts, and us as consultants. After few months of working on this project, a decision was taken to halt it. Among other reasons for this decision was the difficulty to maintain routine committee meetings.

In retrospect, we may say that the failure to promote the subject, was an outcome of the following factors:

- A lack of a clear, uniform definition of the term 'Transition between physicians', which could have refer to either of the following:
  - Transition from the community (outpatient) to the hospital (inpatient) environments and back.
  - Flow of data between physicians in order to assure Continuity of Care.
  - Departure of a physician and the transition of his patients to another physician.
  - Continuity of treatment while a physician is temporarily missing.

- Lack of knowledge and experience in leading and managing a process of that complexity. This was the first mapping project conducted by the department.

- Lack of a research plan and a clear definition of the subject. The planning and definitions of subject and scope were made in the course of the process.

- A lack experience in cooperation with representatives of the district. This was the first mapping that was carried out by the department in cooperation with the districts.

- The nature of the issue. Transition between physicians is a known characteristic of modern ambulatory healthcare system, which has negative and positive aspects. Actually, there was no need to map the subject in order to conclude that Risk Management is needed to minimize the damages caused by the negative aspects.

- ***Case B - Physician- Patient Communication***

The second issue, Physician- Patient Communication, was selected because of a large number of adverse events, that were attributed to inadequate Physician-Patient Communication. A number of studies focusing in this issue were published in the late 1990's, and which attributed Risk Management value to Physician- Patient Communication, added to the impetus.

Consideration of the issue began at the end of 1999, when it became evident that 15% of all reported adverse events were caused by deficient physician- patient communication.

Studies that dealt with the subject described the typology of communication and the effect of positive communication on the rate of malpractice claims and on the quality of the medical treatment.

Levinson (1994) presented the following findings regarding the subject:

- Within obstetrics: No significant correlation was found between the quality of medical care and the history of legal actions. This finding is consistent with findings of other studies that found that the quality of treatment is not the crucial factor in the patient's decision of whether to sue or not to sue.
- Patients of physicians that had a record of legal actions were less satisfied with the treatment, than patients of physicians who had no such record.
- The same proficiencies in inter-personal communication that decrease the chances of legal actions, effect satisfaction of the patients and improvement in the quality of care.

Levinson et. al. (1997), defined several indicators that distinguish between physicians, in Primary Care, who were legally sued and those that were not:

- A longer duration of the physician/patient encounter.
- More intensive use of facilitation statements.
- Dispensation of more information regarding the encounter.
- Use of humor.

Roter (1997), defined a typology comprised of four physician/patient communication patterns:

- **The Paternalistic** – the physician plays the role of a health guardian of the patient. He defines and implements all particulars of the treatment.

- **Informative consumerism** – the physician supplies technical information so that the patient can choose the treatment which suits him. The physician is in the role of a technical expert. The patient's values are not scrutinized and his sovereignty is preserved.

- **Interpretative Communication** – the physician interprets the values and needs of the patients, so that he can assist the patient in deciding on the course of treatment.

- **Deliberative Communication** – the physician tries to assist the patient in choosing the most suitable option for treatment. The physician goes well beyond dispensing technical data, by employing his moral authority in convincing the patient that a certain treatment is preferable to all others.

The initial Idea, raised by the project team was to find an existing communication workshop, customize it to the medical surrounding and run in with the participation of Maccabi's physicians. The workshop had to fulfill two functions: to gather information on the unique characteristics of physician/patient communication problem in Maccabi, and to address it in a thorough manner.

We observed, some workshops in action, among which a designated workshop which was developed at Beer Sheba University's social work department, for the Soroka medical center. None of the off the shelf workshops was found suitable for Maccabi.

It was decided to develop a designated workshop, according to Maccabi's special needs, by a team that included the deputy of RMD, a professional workshop supervisor and one of our Risk Management consultants. Throughout many design meetings, adverse events were studied and the workshop was developed.

The first pilot workshop was run in February 2000 in the Sharon District, thanks to the willingness of the district manager to participate in it. The workshop took a full day to deliver and it was divided to following sections:

- Opening remarks, given by the district manager
- Introduction of the instructors
- Introduction of the workshop targets and procedures

- Introduction of the participants
- Topic A: Physician- Patient Communication as a possible source for errors and mishaps
- Topic B: Physician- Patient Communication as a professional concept
- Topic C: Physician- Patient Communication – identifying obstacles
- Summing up and a feedback questionnaire

Thirteen physicians, participated in the workshop, most of them GP's. The feedback was very positive; a strong emphasis was put on the importance of case studies as a Risk Management tool.

The following rable presents the feedback for the 1st workshop (on a 1-5 scale)

Topic	**Average**
To what degree did the workshop increase your knowledge of the subject?	3.88
To what degree did the workshop provide you with tools to cope with the subject?	3.77
From the professional point of view, was the workshop conducted well?	4.33

The feedbacks from similar workshops that had been run by the end of 2000 in different districts were almost similar. However, due to a shortage of resources it was decided that not all off Maccabi physicians will participate in the workshops.

In a report submitted by the project team in May 2002, three factors were presented, as being responsible for the difficulties in Physician/Patient Communication within Maccabi:

- The professional perception of the physician, dictates the amount of significance he or she allocates to Physician/ Patient Communication as influencing the quality of care. It seems that regarding this issue, there is a significant variance among the medical specialties.

- The physician compensation concept encourages them to see as many patients as possible in given frame of time. Besides the impact on Physician/ Patient Communication, this system may transmit a hidden message that values quantity more than quality.

- In most cases, the expectations, the cultural background and the values of the patient are disregarded. The physicians, indicate a difficulty to deal with these issues.

The project team reached some general conclusions regarding the project:

- Managing the Physician/Patient Communication, is the core of proactive Risk Management.

- Improving Physician/Patient Communication may significantly reduce Physicians' errors and diminish their damages.

- Managing the Physician/Patient Communication depends on the physician; therefore it is imperative to reinforce the physicians' commitment in this respect.

- The physicians' commitment is influenced by the messages which they receive from the organization, compensation concept is crucial in this respect.

- The absence of one medical entity that is in charge of all aspects of the medical treatment, does not allow for neither professional control, nor nurturing communication with the patient.

- Those who attended the workshops, perceived them in a positive light, and as a mean to improve Physician/Patient Communication.

The team recommended the continuation of the project with different audiences: new physicians, specialists in different domains, administrative physicians and district physicians.

The submission of the report, signaled the termination of the project.

We feel, however, it is important to understand, considering the criticality of the subject and considerable resources already invested, why the project was terminated.

Some factors, similar to those that contributed to the failure of the 'Continuity of Care' project, collaborated to the untimely termination of this project:

- An attempt to define and implement a solution before all particulars of the problem were investigated with regard to:
    - Analysis of the current situation based on a representative survey.
    - A thorough analysis of adverse events representing the subject.
    - A study of the current works and practical trends throughout the world.

- Lack of research experience, and an attempt to define the subject matter and the methods of research while running the project.

- Physician/Patient Communication is a fundamental and very complicated issue, comprising many factors and implications. It was preferable to define and cope with a narrower issue.

- The solution that was selected was visibly impractical due its high cost, coordination problems and the difficulty in delivering the workshop to all of Maccabi's medical staff.

  The following table presents a cost estimate of a full solution.

Item	Cost of unit	Num of Units	Total
Developing a designated workshop	$3,000	15	$45,000
Instruction – cost of the team	$2,000	250	$500,000
Loss of work days by physicians	$600	3,500	$2,100,00
Total			$2,645,000

  Assuming a 10% per year turnover in physicians, an additional sum of $250,000 would have to be invested in providing the new physicians with the required skills.

- The heterogeneity of Maccabi's clinical staff, requires development and customization of the workshops to specific audiences, according to specialization, seniority, function etc.

- ***Case C – Adverse Drug Events – ADE***

In the middle 1990's, ADE has become very popular within the Risk Management community due to three factors:

- The process of medication may be considered as a simple one, when compared to other medical procedures, that involve complex decision making under condition of uncertainty and complex proficiencies that require high level psychomotor skills and high level crew coordination. Therefore, we can assume that it is feasible to improve these processes and to minimize the rate of errors.

- The rates of errors in the issuance of medications are relatively high – between 5%-10% of all prescriptions. Leape (1991) claims that ADE is the leading adverse phenomenon in hospitalization (19% of all medical errors), followed by post operative infections (14%) and technical errors (13%). These findings are based on an analysis of more than 30,000 hospital files in 1984 in the USA. Other studies, conducted in hospitals indicate different rates. One of them states that the rate of severe ADEs, those leading to hospitalization, irreversible damage, or death to be 6.7%. The rate of ADE's causing death was 0.32%. This rate places ADE as the 4-6 cause of death in the USA (Lazaou, 1998). In 1993 ADEs killed 7,000 people in the USA as compared to 6,000 killed in work accidents. Classen et al (1997) report a 2.9%-3.7 rate of ADE among inmates, half of them were preventable. Brennan et al, report a 3.7% rate of ADE among all inmates, 28% of which, were caused by negligence. They surveyed more than 30,000 inmate files in NY and found that 2.6% of ADEs were causes of permanent disabilities and 13.6% caused death.

- Publication of the IOM reports, "To Err in Human" and "Crossing the Quality Chasm", set in motion some processes, at the level of the American administration, that were intended to reduce mortality, caused by preventable medical errors by 50% within five years; reducing ADE seemed like a suitable domain to start with.

In 2002, the Risk Management Department decided to initiate a study within a domain where it can prove effectiveness, and complete a whole process, including a definition of an intervention plan. Following a spate of ADEs, it was decided to focus on this subject.

The process was carried out by a multidisciplinary team that included physicians, nurses, pharmacists and medical informatics and was lead by deputy head of Risk Management Department with our assistance.

- ***Background and Method***

The mapping dealt with medication errors that occur all along the medication process, starting with the doctor's prescription and ending with the patient administering the medication. (Leape, 1998).

Studies, carried out throughout the world, mostly in hospitals, have shown that programs that deal with ADE, tend to have positive results. Studies among ambulatory and inmates patients proved that errors in medication dispensation, especially ADE's, are more common than was reported in conventional studies. ADE's have a great damage potential to the patient, cost a lot to the healthcare system, and are preventable in about half of the cases, since most mishaps are due to the human factor.

Studies that have been carried out since the late 1980s, reported clear recommendations from public, governmental and private bodies, concerning more accurate documentation of ADEs. In addition, many plans intended to reduce ADEs were devised. These were proven successful.

The mapping team posed three main goals for the project:

- To fully map the process of medication dispensation in Maccabi.
- To define all risks, within the different phases of the process and its interfaces.
- To define an intervention plan aimed to reduce the probability of errors in the process, to minimize the damage therein and to implement the plan.

During 1996-2003, 3,400 adverse events were reported to the Risk Management department, 127 out of which had to do with medication dispensation. 109 incidents were analyzed in depth.

Two thirds of the incidents were caused by physicians and the rest by pharmacists, nurses and other clinical staff.

The most common physician errors in this respect were: prescribing the wrong medication, prescribing a medication despite a known sensitivity and errors in dosage.

The project team, employed a variety of methods to gather data: analyzing reported incidents, observations in clinics, nurses' rooms and pharmacies, structured interviews, analysis of the data systems that are employed in the process, etc.

The mapping process came out with a list of 24 risks in different phases of the process, 11- within the physician's domain, 4 in the nurses' and 9 in the pharmacy domain. All risks were described and possible solutions were suggested.

Four risks, were defined as acute and demanding immediate solutions, six were defined as second grade risks and fourteen as third grade. The following is an example of an acute risk and possible means to control it:

The risk

Prescribing a certain medication and its dosage, based on personal acquaintance with the patient and relevant data from the medical record. The risk arises when the personal familiarity is superficial and the medical record is lacking in relevant data.

A possible Control (solution)

To study the feasibility of defining clinical conditions, relevant to making a decision as to what medicine to prescribe, for example chronic diseases and making this information easy accessible by the physician.

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Updating, in the anamnesis sheet, the weight of youngsters, younger than 18 years, at age intervals to be defined by a professional team.

Upon opening the medication module in the EMR, data concerning age, weight, and relevant clinical conditions will be presented automatically.

The teamwork proved, that it is possible to create a multidisciplinary, mission oriented team, and successfully perform a complicated task within Maccabi.

Toward the end of 2004, the project won acclaim from Maccabi's higher echelons. The project's steering committee authorized the intervention plan and allocated the resources needed for its implementation.

The third initiated Risk Management project in Maccabi was successful in its implementation and its outcomes.

In our opinion, the ADE project was successful due to the following factors:

- The topic – ADE may not be the most significant phenomenon within medical Risk Management, however, it is a well-defined one and the risks entailed, are manageable. Previous two topics, are fundamental to medicine, and have serious implications concerning patient safety and quality of care; however, treating them is very complicated, because they are touching on amorphous aspects like 'professional culture', the boundaries of the moral and professional responsibility of the physician etc. The manageability of ADE was the reason for choosing it as one of the first frontiers for Risk Management in healthcare in Britain and the USA.

- Managing the mapping as a project – the previous projects run in the available time of the department managers, while priority was assigned from time to time, especially when a new relevant incident was reported. In contrast, the ADE affair was a fully fledged project, including clear definitions of assignments, timetables and responsibilities. Most assignments were carried out as planned.

- A multidisciplinary team – at the early stages of the project arrangement, it was recognized that in order to assign to all stages their due authority, all interests concerned with ADE should be represented in the team. The team included Risk Management personnel, physicians, nurses, pharmacists, a representative from medical informatics department and us, as Risk Management consultants.

- The appointment of a steering committee – the members of the committee represented Maccabi's senior management, among them also the Head of the "Health Division" in Maccabi. The steering committee, besides its professional contribution, served as an emblem of organizational commitment. The project team, reported to the steering committee at the end of every stage of the project for confirmation and directing.

- Employment of a variety of data gathering methods – the medication process is very common one. All participants in the process are very experienced and have predetermined opinions and positions regarding the risks and the means to control them. In order to overcome these preconceptions, it was very important to study the process from all possible aspects, employing a variety of tools, among which were observations, structured interviews, analyzing of the work environment and tools, and learning from other ADE studies.

This year (2009) a new ADE project was initiated by the RMD, focusing on pharmacist errors, based on a relatively large data base of about 500 reports. This project is conducted as collaboration between the pharmacy division in the headquarters and the RMD.

Chapter 6.12

Lots of data without meaning – EMR as a source of meaningful data and means for implementing improved procedures.

Somewhere the organizational databases contain lots of meaningful information for improving Patient Safety.

The widely quoted studies on physicians' errors, were based on a structured analysis of a relatively large number of medical records. An attempt was made to identify medical errors and deviations from the standard procedures, which were neither identified by the medical system, nor reported by the doctors involved. For example, in the Harvard University study, 30,195 randomly selected patient records were analyzed. It was found, that in 1,333 (3.7%) cases some harm was caused to the patients by physician errors (Brennan, et al (1991).

In Israel, unlike in western medical systems, the ambulatory medical systems are mostly computerized. All Israeli HMO's, including Maccabi Healthcare Services , were computerized, starting in the mid 1980's and throughout the 1990's. The first systems were alpha-numeric, administrative, and they were upgraded to Windows-based systems that include clinical tiers. Currently, it's rare to find an Israeli ambulatory clinic, that documents medical encounters on paper.

Porter (1999), reports that until 1989, when the computerization of the clinical processes started, the main computerized processes were administrative and dealt with members' entitlement and doctors' compensation. Later on, the clinical processes that were computerized included: uniformed recording of medical diagnoses and medications, a direct interface between the laboratories and the doctors' desk computers, automatic distribution of referrals to specialists and medical institutes, etc. Porter enumerates among the system's specifications and advantages:

- Physician support: the system issues clinical reminders. For example when Otitis Media is diagnosed, a prompting window pops up the screen designating the proper antibiotic medication. In addition, specific reminders are presented, based on clinical and demographic data that is

stored in the system. For example*: "The patient did not undergo a routine blood pressure test, would you like to order one now?"*

- Quality control – the system issues a variety of reports, which serve the doctor and his superiors to compare the overall treatment with the common standards.

Additional efforts are under way presently to further computerize private and public hospitals in Israel. Other projects will improve data sharing between the hospitals and the communities.

The Patient's Rights Law, issued in Israel (1996), decreed that all medical information, accumulated during medical processes, belongs to the patients. Following the issuance of the law, new web applications, based on smart card technology, were developed which enable the patient free access to all his medical information.

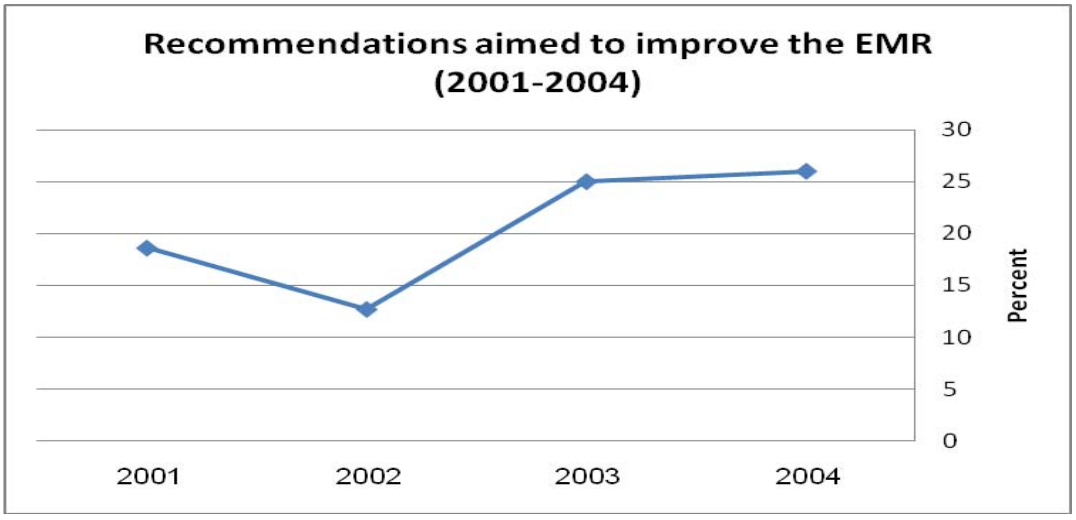
Beyond its managerial and clinical functions, the wide computerization of the medical information has wide Risk Management implications:

- **Continuity of care** – the information systems which document in a systematic and uniformed manner all medical encounters, and are available to all doctors, support medical treatment continuity, which is of utmost importance to the overall safety of the patients. However, the mere existence of the technology, does not insure that continuity, as witnessed in adverse events, in which doctors did not make use of all the available information in their clinical decision making.

- **Medico-Legal aspects** - The first document sought, after by a lawyer, who probes the feasibility of taking legal action against the medical system on behalf of his client, is the medical record. A computerized, well documented medical record, that faithfully reflects the medical process, may serve as evidence for the prosecution as well as the defense in cases of medical negligence. The growing availability of medical information, obliges the doctors to acquaint themselves with this information and consider it while deciding on the treatment processes. Moreover, the doctor is obliged to accurately feed the computerized system, since an inaccurate medical record, may serve by itself as adverse evidence in court.

- **Debriefing** – When a debriefing is required following an adverse event, the extensive medical record (encounters with the primary physicians, expert opinions, lab tests results etc.) is a first source of information regarding everything that occurred before, during and after the incidence. The medical record, enables a reconstruction of the medical process, during which the incidence occurred. This data is than compared to the versions submitted by all involved persons. Without the medical record, the only available source of information regarding the incident would have been the evidence of the people involved and their interpretations of the event. The function and the usefulness of the medical record, can be compared to the use of automatic data collection systems (the black box), and video cameras in Aviation.

- **Recommendations** – Since computerized systems, are a significant aid to the doctors, it is possible to use them to influence work processes, to assist them in their decision making and in avoiding errors. In recent years, the rate of debriefing recommendations to be implemented using the computer systems of Maccabi is growing. It has become evident, that a minor modification of the computerized system may solve major Risk Management problems. For example, sounding an alert about patient's sensitivity to certain medications while writing down a prescription. The following diagram presents the rate of debriefing recommendations, that are to be implemented using the computer systems.



- **Proactive prevention** – The EMR, allows for the implementation of administrative and clinical guidelines that improve the medical treatment and patient's safety. For example, it is relatively easy to implement directives regarding the performance of mammography to women above a certain age and at certain regularity, or to immediately stop prescribing a medication that has been found to be dangerous. Some published studies report the positive contribution of the use of EMR's in computer based clinical decision systems. These systems reduce the probability for errors and ameliorate patient's safety, Johnson et al, (1994).

Traditionally, adverse events serve as 'raw material' for Risk Management processes, although considerable amounts of relevant data are stored in the medical records and other computerized systems, data that can be used for proactive prevention of errors. Researches that analyzed medical records and administrative process data, were able to discern considerable rates of medical errors. However, at present these processes are very costly and suffer from a lack of unequivocal criteria for the quality of the treatment. It is reasonable to assume, that in the future, we shall see better and more cost effective artificial intelligence systems, that will be able to analyze medical processes, to identify errors and pre-warn of them.

For example, during our debriefings of grave adverse events in 'Maccabi', we discerned modifications in patient's encounters behavior, prior to the occurrence of a major adverse event. In most cases, the physicians were not aware of the changes in the encounter behavior and their meaning. This type of patients encounter meta-analysis, can make the physician aware of possible changes in the medical condition of a patient.

How EMR systems can be used to serve Risk Management needs.

At the beginning of 1998, we participated in some meetings between representatives of the Risk Management department and managers of the Medical Control Department (MCD), whose function is to examine and certify the entitlement of members of the medical staff to receive payment for their activities. The information gathered by MCD, and its possible use for risk identification, were the reasons for these meetings. One of the examples demonstrated by the department, was of doctors who refer their patients for biopsies, but neglect to continue the process by reviewing the results and recommending the proper treatment. This means, that some of the patients, whose biopsies indicated

pathology, didn't receive the proper treatment. MCD, can deny payment to doctors who have not completed the process. In addition, the information that is at the disposal of the MCD, enables it to detect those doctors that significantly exceed the norm of certain clinical procedures, and to examine the necessity of each procedure recommended by them.

Although, these meetings did not result in definite directions for actions, a sense that the information gathered by MCD has the potential to contribute to the identification of risks and the management of some of them does exist.

In December 2001, we submitted, at the request of the heads of the RMD, a detailed proposal for *'The application of Medical Control as a tool of Risk Management'*. Among the specific suggestions for use of the information at the disposal of the MCD were:

- Use of the MCD data as exposure indicators in calculating the rate of adverse events that occur in the performance of certain medical procedures. For example, the rate of adverse events in laparoscopy procedures.

- Identification of excesses – for example, excessive performance of certain activities by doctors in certain areas of the country, during certain periods, etc. After establishing the reasons for these excesses, proper actions to reduce them can be recommended.

- The study of other assumptions based on the ongoing risk management activities. For example, the relations between workload and physicians involvement in adverse events, and the study of the influence of demographic variables.

In the end, no risk management operational processes based on the MCD data were developed by now. The main reason for this, was probably the new emphasis at Maccabi on the Centralized Medical Record project. This project was aimed to make all the information concerning the patients and the medical procedures available, to all those who can make use of it in their work, including the RMD.

The characterization phase of the project began towards the end of the year 2000. The aim was to concentrate all the medical information concerning a patient and make it available to the end users.

The formal starting date of the project was on October 10, 2000, at a special seminar, that was lead by Maccabi's head of IT department. The Risk Management Department was represented by its head, Dr Racheli Wilf-Miron, who presented the alerts needed by physicians at the implementation of the Centralized Medical Record. The presentation was the summing up of the work done by the alerts subcommittee that was also lead by Dr Wilf-Miron. The subcommittee, defined the following objectives:

- Patients – improving the quality of treatment by promoting improved healthcare and preventing errors.

- Physicians – reducing exposure to errors, (preventive medicine) and more efficient usage of time.

- HMO – improving total quality and minimizing errors = better economic results.

It is evident, that these three objectives aim at minimizing errors made by physicians, as means for improving the quality of healthcare and reducing the costs of treatments.

Some of the committee's recommendations have been implemented in recent years, among which are alerts on drug interactions, patients' sensitivity to certain medications, irregular outcomes of laboratory tests, including life-endangering indicators and more.

The RMD bases its debriefings of adverse events on two major sources of information: interviews of all staff and management members that were involved in the incident, and a reconstruction of the incident using the electronically medical record. Since, the record is immuned to alterations and editing after it has been stored, it serves as an accurate documentation of the medical process. However, it should be noted that the quality of the medical records, varies with the physician who fill them out.

Summary

Computerized data systems in Maccabi, as well as in all modern medical organizations, have great potential to assist in reactive and proactive Risk Management activities.

Their main contribution in the reactive domain is the wealth of data that they contain, data that facilitates the reconstruction of the medical process prior to and during the adverse event. By reconstructing the causation process and errors, it becomes possible to examine how the incident developed, and to recommend on steps and means to prevent its reoccurrence.

As for the proactive domain, computerized systems enable early identification of deviations from the suggested procedures, prior to error actual occurrence. They support clinical procedures through alerts, memos and clinical guidance, and by the application of preventive medicine.

We observed, that the reactive implementation of the computerized systems is well developed, while first steps are being taken to make use of them in the proactive domain. We are certain, that future developments in both Medical professional culture and technology, will usher in an era when doctors will receive and implement computerized assistance in their clinical functions, resulting in improved healthcare systems and sounder patient safety.

Chapter 6.13

What about ROI (Return on Investment)?

"If you think Risk Management is too expensive, try an accident"

Anonymous

Risk Management activity requires resources.

From the very start, as we introduced our proposal for Risk Management consulting, based on our experience in the Aviation sector, to Macabi's top management, a question was raised by the top managers *"We understand how much this is going to cost us, but we do not quite understand the benefit to us*" (Head of Procurement in 1998).

As we have already discussed in chapter 6.5, the department headcount, grew with the years in order to better respond to the increase in overall activities. The department grew from 1/2 position in 1996 to 7.5 positions in 2003. This increase resulted in a substantial increase in the department's budgeting.

The question whether the expenditure in the Risk Management is worthwhile economically, is a fundamental question for healthcare organizations which are increasingly operating under economic constraints and are required to prove they are not losing money. This is the reality of the of healthcare system in Israel and in other Western countries. Under these circumstances, investing in Risk Management, perceived as an expense, whose results are unclear and certain in the short run, is a question often raised, especially by managers who are in charge of allocating resources in healthcare organizations.

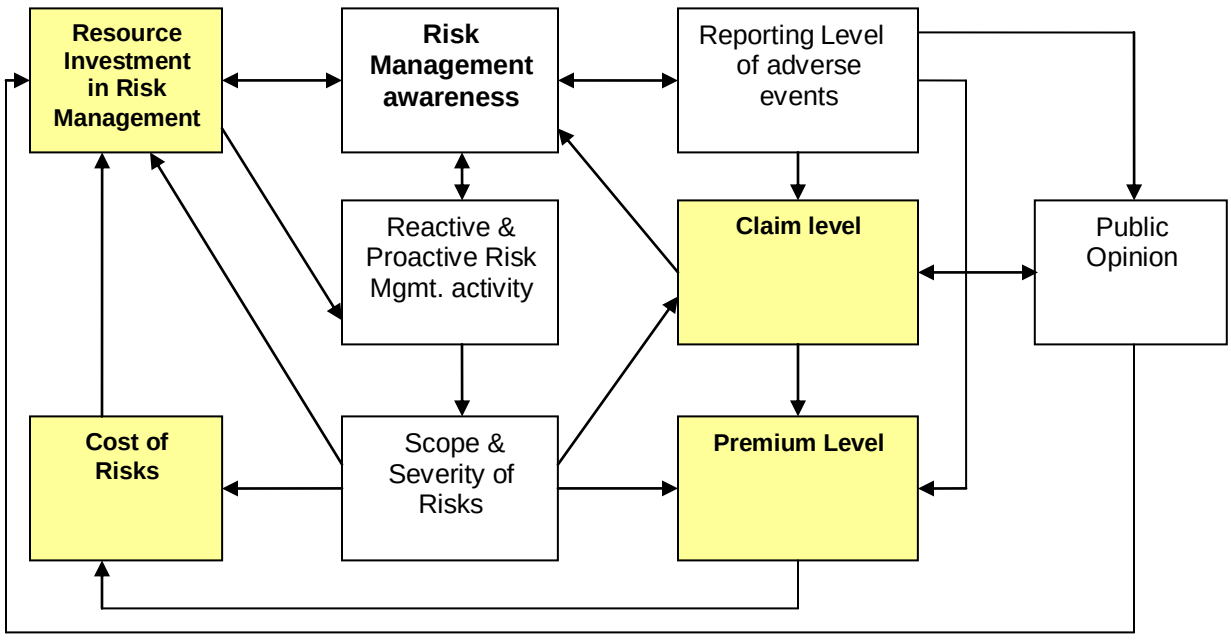
It is important to note, that this question was resolved years ago in the Aviation domain because of the high cost of accidents as compared with the cost of running Risk Management activity. In addition, the insurance companies required the insured to implement Risk Management programs as a pre-condition for insurance.

From its very nature, Risk Management activity is fruitful in the long run. Therefore, vision is required from managers of healthcare organizations in order to be able to invest in the short term while others will reap results in the long term.

It is important to note that this chapter, is not dealing with the many benefits of Risk Management but rather with the economic aspect of investing and profiting from Risk Management.

The basic model showing investments in Risk Management and yields is illustrated in the following diagram. One can notice, that the relationship between investments in Risk Management and cost of risks is complex and linked by variables such as "Risk Management Awareness", "Level of Reporting of Adverse Events", "Claim Level", "Reactive and proactive Risk Management Activity", "Public opinion" etc.

The model is based mainly on our experience in the Aviation sector and serves as an "Awareness Model" used by the Israeli Air Force in order to explain the variations in the level of "Near Accident" reporting and its relationship to lessons learned, level of safety activity and safety awareness.



How much does Risk Management cost?

The reference in professional literature to the costs of Risk Management is mainly from the insurance point of view. This is because evaluating the cost of risk, is used in order to determine the premium paid to the insurance company.

Moscicki and Wrobel (1996), describe the Cost of Risk Index by Barlow, who was President and Risk Manager of Risk and Insurance Management Society in the USA. In 1962, Barlow developed the Cost of Risk Index, which included four main components:

- Insurance premiums and other transfer costs.
- Losses that were not insured – deductibles, amount of loss greater than allowed in the policy and loss not covered in the policy.
- Expenses associated with Risk Management activity – salaries to Risk Management team, fire protection, security, contingency plans, environmental, medical, transportation etc.
- Cost of executing Risk Management plans and insurance.

The authors claim, that the most difficult component to measure is "Risk Management Expenses" due to the fact that there is no uniform and agreeable definition of what this component includes and the complexity associated with collecting the data. These are the reasons why in majority of studies conducted on the costs of Risk management, this component is not defined.

The theoretical dilemma hidden behind the attempt to estimate the cost of Risk Management activity is economical and does not take into account the added benefits of Risk Management activities as described in chapter 6.8.

The dilemma, being mainly economical, presents, on one hand, the cost of Risk Management activities as a component in the CRI – Cost of Risk Index – and, on the other hand, the influence of Risk Management activity on the total CRI value.

Our experience shows, that in most cases this dilemma can not be easily resolved, because the fruits of Risk Management activities are long term while cost calculations are mostly done for the short term.

In Aviation, this dilemma is quite secondary, because one accident, resulting in loss of human life and of the aircraft, is equal, in economic terms, to the cost of Risk Management activities on a wide range for several years. In Medicine, on the other hand, even if a significant harm was caused to a patient, It does not necessarily translate into financial costs, and if it does, it is already imbedded in the insurance policy.

Since the consequences of an adverse event in the medical sector are more remote in time and influence, the dilemma of investing resources in Risk Management is often brought up, mainly by managers and financial managers.

How to measure RM benefits in Healthcare ?

In most modern organizations, those which are not philanthropic or non-profit organizations, the main measurement of success is the financial profit.

Therefore, if we wish to measure immediate results, we encounter an inherent Measurement problem. Head and Horn II (1991), indicate that while measuring the contribution of Risk Management activity, one can consider Result Standards and Activity Standards. They believe that many Risk Management managers do not feel comfortable with good results in a certain year since they are not convinced that their activity is what caused the achievement. They feel that luck may be the reason rather, than their own activity that year. Therefore, Risk Management managers, often prefer to be evaluated on activities which they performed, quantitative and qualitative, but not necessarily on actual results. This approach suffers from apparent detriments in organizations which have business orientation since they do not use the spoken language in the organization, i.e. return on Investment.

The issue of measuring the department's effectiveness, came up mainly at important junctions, while the department was developing: during year end summary and preparation of next year work plan, during discussions on manpower requirements and during discussions regarding organizational changes needed in the department in order to assume quality issues as well (2001-2002).

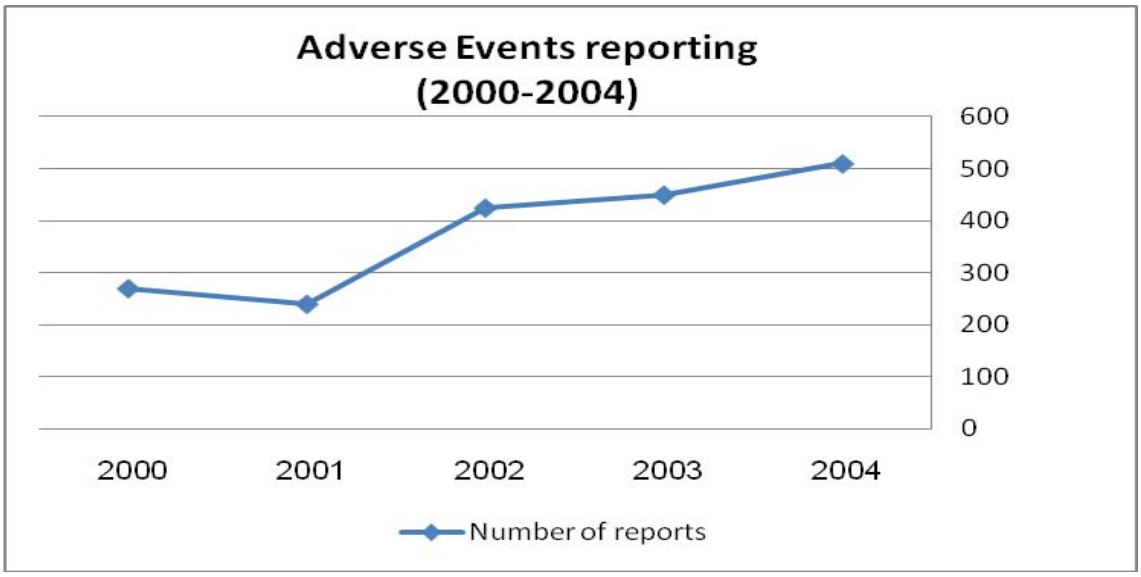
Most of the times, the department chose to show its activities using the Activity Standard approach. This was accepted by the medical staff, but less so by management, which strived to evaluate the department's activities in economic terms.

The indicator adopted by the Risk Management Department to reflect its affectivity, was related to the reporting rate of adverse events in general and particularly to the proportion of self initiated reporting.

In the following diagram, the trend of reporting adverse events in the years 2000-2004, is presented, without reports that were classified as A1 (without harm to the patient, that were handled only basically, see chapter 6.7)

It can be observed that, in these 5 years the reporting level has doubled, which reflects an average early increase of about 20%.

Although, this index, doesn't serve as evidence for the financial gain, due to Risk Management activities, this argument is mentioned by Risk Management professionals, widely as supporting the case of association between increase in reporting scope and improvement in patient safety.



In Aviation, we ound an indirect correlation between the number of "near misses" reports and the number of "major accidents" reports. That is, as the number of reports of minor events increased, while the number of major accidents decreased. The explanation given to this phenomena has to do with the increased awareness to safety. That is, high level of awareness to safety results in more reporting of "near misses" and in more activity intended to prevent accidents.

Although, the data presented in the following diagram is of events in which harm was evident and "near misses", we can consider this as a major achievement, reflecting an increase in Macabi's awareness to Risk Management

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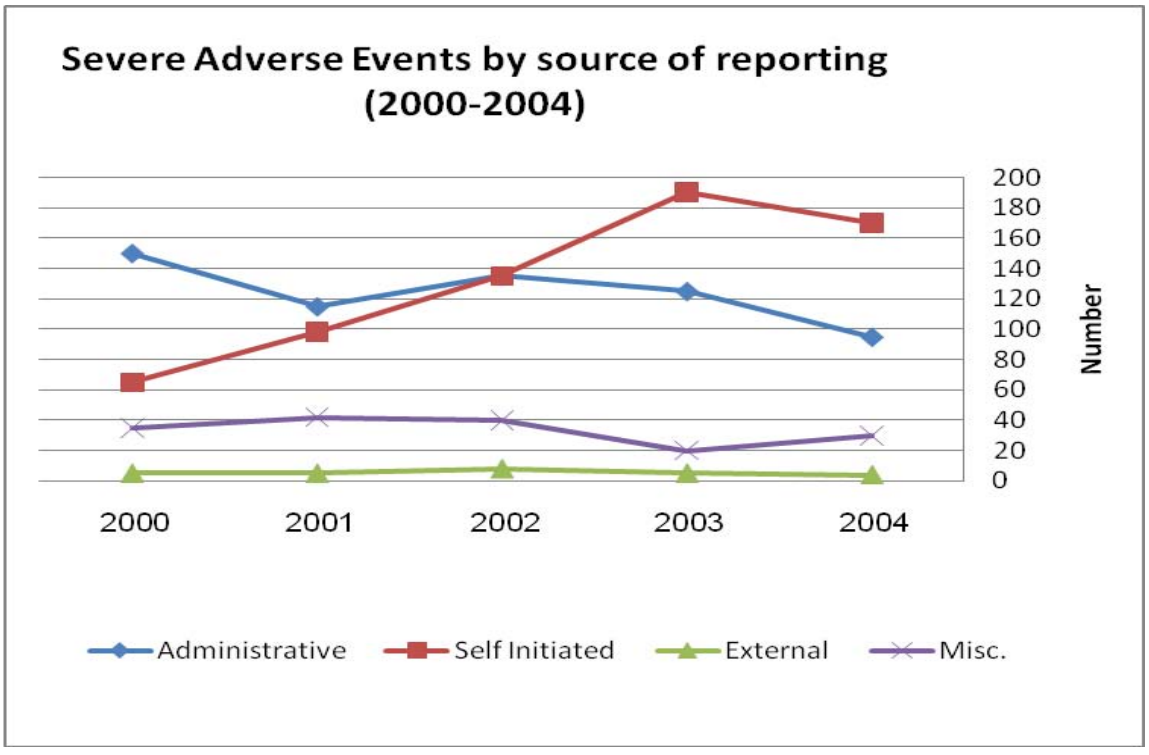
The diagram, which shows the trends of reporting of severe adverse events by source of reporting, stresses the increase in level of awareness to Risk Management by Maccabi physicians. Over the years, their level of reporting of their own errors, increased while that of the administrative source decreased. (see chapter 6.7).



Measuring the financial benefits of RM in Healthcare

It is interesting to show the various points of view voiced during the initial stages of the Risk Management department. We encountered three points of views:

- **From senior management** (General Manager and Head of Medical Division) – strategic view which regards the contribution of Risk Management, not only as means for saving or making money, but also for its intrinsic values as presented in chapter 6.8.

- **From the caregivers** - desire to give the risk management activity a fair chance, while acknowledging the existence of doctor's errors which are not handled in a professional and systematic manner. The caregivers, viewed the Risk Management department as some sort of "confession department" which allowed them to confess about errors, without being judged or punished, while reporting to their direct supervisors could entail an element of blame and punishment.

- **From middle management** - Disbelieve that Risk management activity, will result in any saving and any return on investment. This came out during the meetings we held with the Head of administration for the purpose of closing our contract details with Maccabi. During one of the meetings, when it was hard for us to explain the financial benefits of our activity he said: "*I know how much it is going to cost me, but I am not sure about the value that I will receive".* It is worth noting that after a while, when the activities of the Risk Management department started to show results within Maccabi, the same person became one of the supporters of Risk Management activity.

We found out, that there is almost no literature, which deals with ways of measuring the effectiveness of Risk Management in Medicine. When such a measurement does exist it usually refers to insurance aspects. That is, cost of malpractice insurance and management of claims after harm has already occurred. Troyer and Salman (1986) ed., Head and Horn II (1991), Youngberg (1994) and others.

It is reasonable to assume, that the main reason for that is due to the fact that the volume of Risk Management activity in healthcare organizations is still limited and not significant enough to raise questions regarding their contribution to the organization. The Risk Management activity in healthcare organizations is

mostly limited to being the Point of Contact (POC) to the insurance companies for the compilation of adverse events to be submitted to the insurance companies.

Therefore, we consider the ROI issue also from the point of view of a discipline which, is close to Risk Management – Quality Assurance Management (QAM). McLaughlin and Kaluzny (1994), in a discussion of the advantages of implementing QAM methodology in medicine, considered the economic aspects too. It is important to note that Quality Assurance Management activity is intended to achieve efficiency and not only quality and therefore it is only natural that some of the projects end up saving money while, also improving the quality of the processes.

Work done in this area by Harkey and Vraciu (1992) report about a relationship between profitability and satisfaction of patients in 82 hospitals of Health Trust.

Other works report on "cost of quality", while in fact, the intention is to costs of "No quality", Crosby (1979). According to McLaughlin and Kaluzny, who report estimates of senior medical managers, the costs of "no quality" in medicine runs between 20-40% of the total expenditure of healthcare in the USA.

So why do so many managers doubt the viability of investing in QAQM? Mclaughlin and Kaluzny offer this explanation: The expenditure is here and now while the probability of future savings is unknown.

It is worth noting that this was the exact argument brought up by Head of Administration with whom we discussed our contract.

The results of risk management must be explicit and well communicated.

Head and Horn II (1991), while discussing Standards of Acceptable Risk Management Performance note that:

"One of the major barriers risk management professionals must overcome in gaining recognition for their action is the absence of consensus on standards for judging risk management performance…."

There is no consensus, among professionals in the Risk Management field on how to estimate and measure the effectiveness of Risk Management activity. As noted before, in most cases, the preference is to consider process indicators, rather than results indicators. This is because, among other reasons, results are evident in the long term and are also influenced by many un-controlled variables and not only by the Risk Management activity. For example: Government health care policy, changes in malpractice law suits, legislations, public opinion, etc.

According to Head and Horn II (1991), exposure to damages due to errors and accidents, exposes the organization to costs, which can be divided into 3 categories:

- Property, revenues, life and other valuable assets lost or damaged as a result of the accident.

- Revenues which could have been generated from activities which were not performed, because they were considered as "too dangerous" following accidents in the organization.

- Resources allocated to deal with harms due to accidents and errors, which could have been assigned for other purposes in the organization.

They claim, that Risk Management activity, can lower the costs of losses in the first and second categories and therefore, it is a worthwhile activity for the organization. For example, the economic benefits can be expressed as:

- Costs of accidents for which there is no reimbursement from an insurance company or other external sources.

- Premiums paid to insurance companies or other external sources.

- Costs associated with actions and activities designed to prevent or reduce loses as a result of accidents.

- The managerial cost of managing the risks or its outcomes.

The main outcome of Risk Management activity in Maccabi is expressed in modifying the working procedures, as a result of recommendations implementation, based on adverse events debriefings. This, of course, together with changing the organizational culture towards the principles outlined in chapter 7.

Therefore, indicators which reflect the number of recommendations, issued each year, number of managers to whom these recommendations are referred for implementation and the number of recommendations which are implemented, can become valuable process indices, which reflect the effectiveness of the Risk Management in Maccabi and any other healthcare organization.

For example, in 2004 the department formulated 270 recommendations, which were directed to 27 different managers within the organization for implementation and among them: Chief Nurse, Head of the Diagnostic Division, Head of Medical Division, Head of Pharmacology, MID etc. Before the end of the year, 50% of the recommendations were reported as being implemented.

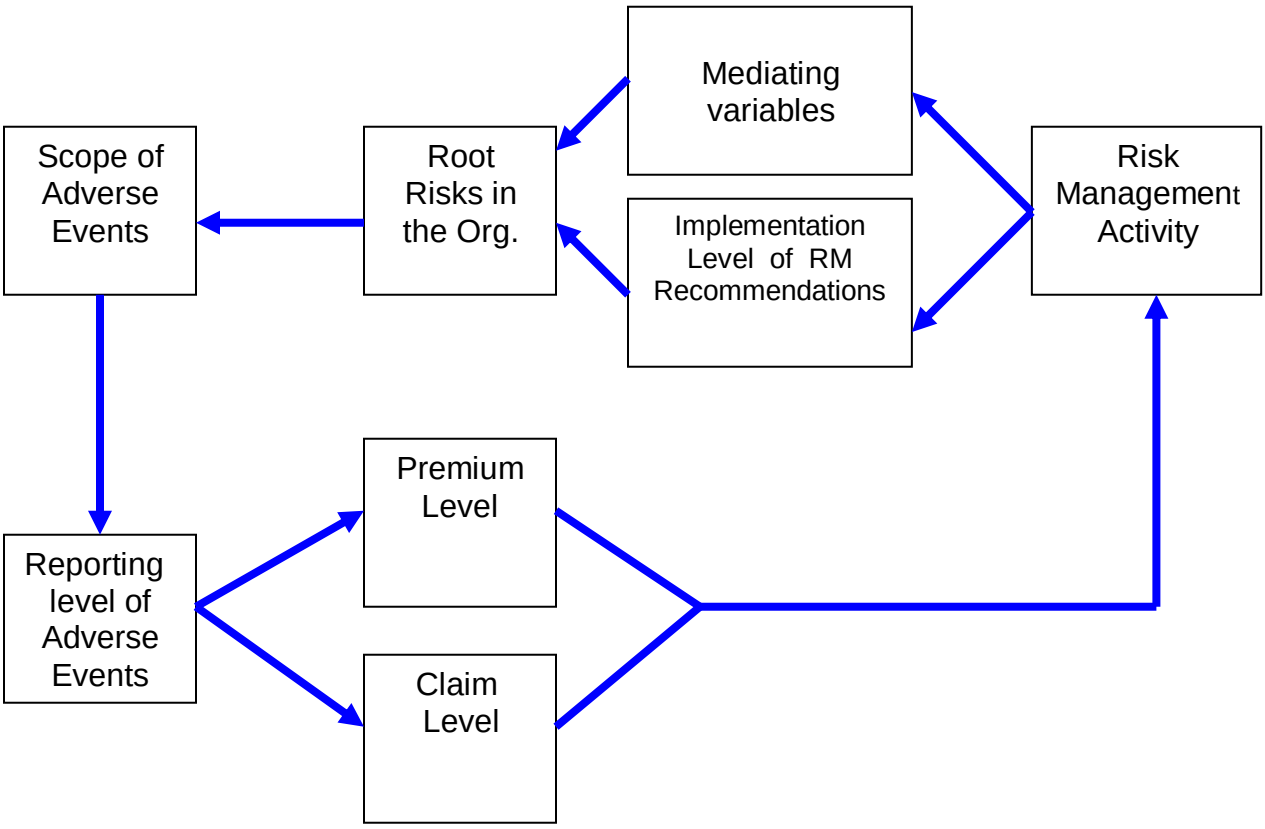
Thus, despite the complexity and dispute among Risk Management professionals, it can be stated that indices based on recommendations, can serve as interim indications of risk management impact in improving patient safety and preserving organizational resources.

Developing measures for monitoring the effectiveness of RM activities.

As we have indicated before, the subject of indices, which may indicate the effectiveness of Risk Management activity in Maccabi became more urgent towards the end of 2001, when the RMD was in the midst of considering merging with the QAM, along with the organizational structure of the Israeli Air force – ASQAD.

One of the main principles of quality assurance in general and in particular in the field of medicine, is the principle of measurement, McLaughlin and Kaluzny (1994). As part of the preparation to work according the IAF's ASQAD, the need arose to present the department's effectiveness using quantitative indices. The difficulties of defining the indices became apparent as presented in this chapter.

It seems, that the model shown below, expresses the directions in the development of indices which may indicate the effectiveness of Risk Management activity in a healthcare organizations.



The organization managers would like to see direct correlation between the Risk Management activity and the level of premiums paid to the insurer and the level of claims. That is, what is the saving in insurance premium for each dime invested in Risk Management?

As we have already presented in the beginning of this chapter, the level of premium and the amount of claims is influenced by parameters, which are not under the control of the RMD, such as: public opinion, government healthcare policy, trends in malpractice lawsuits, court decisions regarding malpractice suits, etc. Therefore, the model described above, presents an indirect correlation between Risk Management activity and the level of insurance premium and amount of claims due to medical malpractice, the indicators which measure Risk Management effectiveness, will be indirect ones.

We feel that the indicators as presented above are not process indicators and not result indicators but rather Intermediate Result Indicators (IRI).

The IRI suggested by us are:

- Mean time between adverse events occurrence and reporting time to Risk Management Department.

- Number of recommendations formulated, compared with the number of events reported and/or investigated.

- Number of recommendations which were implemented as compared with the total number of recommendations.

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- The average time it takes to investigate an adverse event and create recommendations

- Average time it takes to implement a recommendation.

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- Number of "near misses" reports.

- Number of deaths resulting from medical errors, as compared with the overall population treated by the organization and/or the number of medical procedures/encounters provided by the organization.

We feel, that if the above mentioned indicators and their likes, were implemented in the organization, over time , risks level and their influence, should decrease and with them the insurance premium levels and claims against the organization.

Chapter 7*

*The contribution of the Aviation Risk Management Model to Macabi's Risk Management Activities Summary and Discussion**

“If I were able to live my life anew, in the next I would try to commit more error… I would run more risks..."

Jorge Louis Borges (Instants)

"Everything is foreseen, but freedom [of will] is given to every man"

Rabbi Akiba, Akiba ben Yossef (ca.50–ca.135 CE) a leading Judean tanna

Prologue

We would like to summarize this work starting with describing the current situation and positioning of the Risk Management Department and Risk Management in Maccabi.

Most probably, some considerations were omitted by us, not intentionally, but because we described the events and developments from our point of view, being consultants. This means we are a part of these developments but also observing them from an external point of view, they are interpreted by us, based on our previous Aviation experience and emotional involvement in the Maccabi project.

We will refer to events and developments in the last year, 2009, which as many other years was turbulent for the Risk Management Department on one hand and satisfying on the other hand.

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*The main part of this chapter was originally written in 2006, thus most of the facts and considerations are updated accordingly. Though, while editing this chapter we have added some considerations as they are standing by the end of 2009.

The rate of reporting continues to increase, reaching a rate of about 150 reports per month. This stream of reports is causing the Risk Management Department to consider new strategies for handling the reports and its resources allocation. Among the alternatives being considered is to empower

The referents, assigning them more responsibility in the process. The number of referents and their commitment grew over the years.

At the last referents forum held on June 2009, more than 30 referents, representing all of the districts and medical professions, participated actively. This alternative raises many challenges e.g. how to train and supervise all of the referents in order to achieve a standard and high quality process of handling adverse events. Another alternative being considered is to lower significantly the number of events being debriefed and deepening the debriefing process, by focusing on the organizational and human factors and widening the debriefing team.

By the end of 2008, a process of separation between the Quality Directorate, of which the RMD was a part, and the RMD, originated and became a fact in 2009. The rationale for this separation was mixed and consisted of differences in vision and strategies between managers and the will of the Risk Management Department manager to base the Risk Management activities on a sovereign orientation and not as a part of striving towards improving Quality in various domains. As a part of the separation process, the RMD was subordinated to the Head of the Healthcare Division and the Quality Directorate remained under the CEO, as it was until the separation was declared. Anyhow, this move is discrepant with the original idea of establishing in Maccabi of an organizational entity analogous to the ASQAD (Aviation Safety and Quality Assurance Directorate- MAVKA) of the IAF. In our opinion the Quality Directorate took in the last years a very clear approach towards promoting Healthcare Quality in Maccabi, based on the principles published in the IOM report: Crossing the Quality Chasm (2001). In the last year, a special consideration was given to equality of healthcare services provided by Maccabi to its patients. This route with all its significance and contribution to quality of care put in some shade the issue of patient safety and strategies to improve it. The possibility of joining forces, thus sticking to the original Air Force ASQD model, didn't succeed. From the theoretical point of view, we can state that these decisions were based on Risk Management thinking, in order to assure better chances for success for the Risk Management moves and efforts.

In June 2009, the 2nd Ashqelon Patient Safety Symposium took place with about 200 participants, representing all of the Israeli Healthcare professional community. This time, the Symposium was dedicated to various approaches and methodologies of debriefing medical adverse events. The entire forum was divided into 6 working groups that had to fulfill a briefing mission and reflect on it in the plenary session. Each of the groups was headed by a Risk Management professional. Two of the groups were headed by Maccabi's Risk Management Department managers, Dr. Michal Guindy and her deputy Mrs. Orly Manor. Two other groups were headed by ex Air Force fighter pilots with experience in debriefing. The 5th group was headed by Dr. Hasner, Deputy manager of the Ichilov Medical Center and in charge of Risk Management for the last fifteen years. The 6th group was headed by us. We have mentioned this, to illustrate Maccabi's positioning on the healthcare Risk Management arena in Israel, which is without doubt a pioneering and leading one.

Training activities are a major pillar in Risk Management activities, being an efficient way to disseminate knowledge and experience and getting feedback from the participants as to validity of approaches and methods. Just to mention few of the latest encounters in this domain of activity: As we have ready mentioned in this work, we run conjointly with Dr. Guindy, her deputy Mrs. Manor, Adv. Halamish-Shany and RN. Gershtansky on behalf of the Madanes Group (The Malpractice insurer) the Patient Safety Course at the CME (Continuous Medical Education) of Tel-Aviv University Medical School. This year (2009), about 40 students participated in the course and the course got very high students evaluation, 4.2 average score out of 5. In the second semester of academic year 2009/2010, the next class is planned to be open.

As part of a tradition, the Risk Management Department runs a yearly Risk Management course for Macabi's staff. This year we run the 5th class, of the course with 32 participants, including: physicians, nurses, lawyers and managers. Some of the graduates become referents and continue their professional Risk Management education by getting regular supervision from the Risk Management Department team.

WHO (World Health Organization) originated, recently, with the collaboration of the Safety Alliance, the Patient Safety Curriculum for medical students, to be piloted for the 1st time in the upcoming academic year, 2009/10,(Ellis, 2009). The idea that healthcare actually harms patients, has been widely acknowledged in the last decade, (Kohn, Corrigan and Donaldson, 1999, 2001), but until the WHO initiative, little has been done to educate future doctors about this problem and

possible solutions. In several publications considering the issue of Safety and Quality training for medical students (Lockwood et.al, 2004, Sandars et.al, 2007), it was concluded that this issue is far from being a satisfactory part of medical education. Dr. Amitay, an Israeli pilot and a physician, heading the Medical Simulator Center at Sheba Medical Center in Israel, was among the developers of the curriculum. The Tel Aviv University Sacler Faculty of Medicine is among 10 medical schools around the world to pilot the curriculum. Dr. Guindy was assigned to be in charge of this curriculum on behalf of the Tel Aviv University Medical School. Personally, we feel feelings of proud and satisfaction, being Macabi's Risk Management consultants and having the privilege to witness the fruits of our effort flourish.

In the 1st Ashqelon Patient Safety Symposium (September 2007), initiated by IMA, a resolution was passed to develop a curriculum for a certificate course for Risk Managers in Healthcare. These days, after a long pregnancy period, this idea is going to become a reality at the auspices of Ben Gurion University in Beer-Sheba, a one year course is going to be deployed in the 2010/11 academic year, consisting of theoretical courses and practical training with the participation of hospitals. Healthcare funds, insurers, IMA (Israel Medical association) and more. Once again, Macabi's Risk Management Department managers are going to play a significant role in this encounter. For the next years, the intention is to run a M.A. program, specialized in Healthcare Risk Management, with the cooperation of Ben Gurion University School of Management, Department of Health Systems Management, headed by Prof. Fliskin.

The current Risk Management Department's information system is already about 12 years old. It was developed in few months after we started our collaboration with Maccabi and was based on knowhow, we brought from the IAF. These days a new system is about to be deployed, implementing web technology, enabling remote access, essential for the referents routine work interdigitation in the Risk Management Department's routine work. The new system will preserve many of the original functionality with upgraded technology and a clear separation between adverse events handling and recommendations management.

From the very beginning, back to 1997, when the Risk Management Department was established, it adopted with great enthusiasm and commitment the Blame Free Culture principle, that guides the Aviation Risk Management approach worldwide. We may state, with great appreciation, that after 12 years of activity and many internal and external challenges, Risk Management Department and

Macabi as an organization, succeeded soundly in preserving this critical principle.

Between 22-25 February 2005, the 40th IMA (Israeli Medical Association) Convention took place in Jerusalem. The last day of the convention was dedicated to patient safety with the participation of about 200 leaders of Israeli Healthcare system. Dr. Poulsen, Head of Danish Medical association and Prof. Helmreich, a psychologist that specialized in Aviation Safety and Medicine, presented their ideas. A patient safety panel was assembled with representatives of the various organs of the healthcare system in Israel. Dr. Israeli, CEO of Healthcare Ministry headed the panel. We were asked to present the Aviation Risk Management Model (ARMM), as a possible reference to follow.

To our surprise, while preparing the presentation, we became aware of the fact, that there is no a formal publication that outlines the principles of ARMM. The basic ideas of ARMM were more of a consensus how things should work in the Aviation, transferred from one generation to another as a culture is transferred and as opposed to inheritance of a methodology.

In order to be able to present the principles of ARMM, we have summarized the highlights of our experience and perception of what ARMM consists of, in 29 principles grouped in 4 categories:

- 7 concepts
- 7 basic principles
- 8 methodological considerations
- 7 cultural aspects

We will cite (translate) the symposiums resolution,s that actually served as foundations for the intense commitment of IMA to Risk Management, in the following years:

1. *There is no option to establish wide spectrum true and right Risk Management activities, without physicians' partnership and collaboration.*

2. *A process of growth and improvement may arise from reporting and debriefing adverse events.*

3. *Cultural and legislative changes are needed, in order to enable an open discussion that may lead to recuperating and fixing steps instead of disciplinary ones.*

4. *To minimize failures, new medical and information technologies should be incorporated with recognition of their limitations.*

5. *A systemic shortcoming is usually the cause of medical errors, thus, the management is mandated to derive lessons learned and to fix what has to be fixed.*

6. *Debriefing and investigation of adverse events is a mission that has to be based on knowledge and experience, thus should be conducted by first line professionals.*

No doubt, the input from Aviation Risk Management experience, presented by Dr. Helmreich, by some of the participants in the symposium and ourselves, served as a facilitating factor in defining the above resolutions.

Follows, the ARMM, as formulated and presented by us for the first time at IMA's Patient Safety Symposium in Jerusalem 2005.

The principles are presented here in a generalized mode, without referring to specific Aviation terms, so they can be viewed from every contextual point of view, e.g. Healthcare.

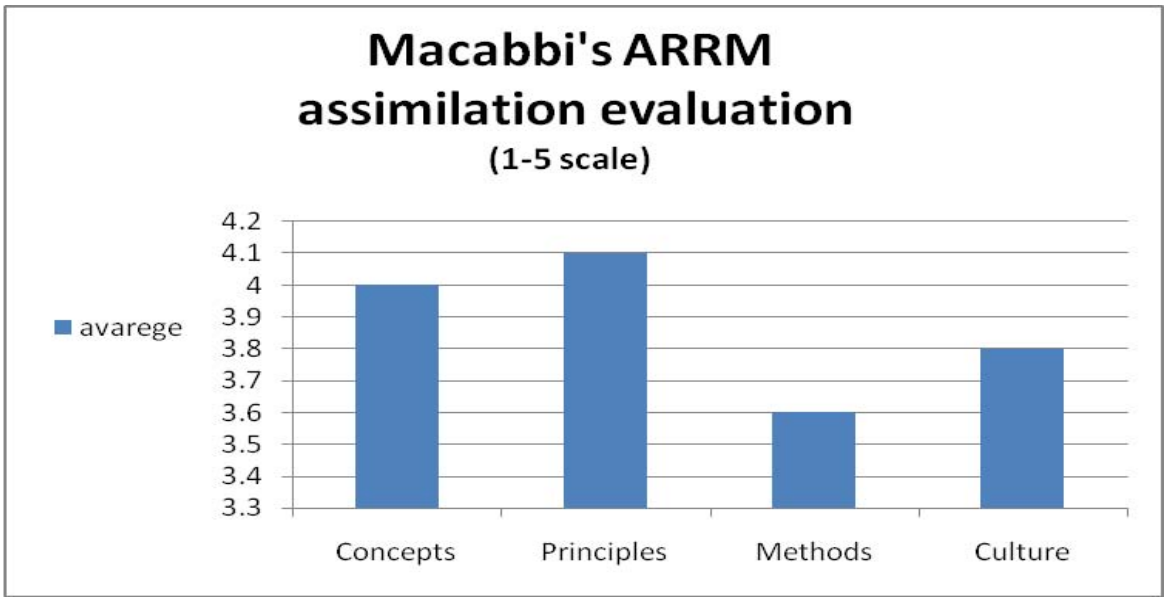
We have evaluated the current assimilation status for each principle in Maccabi, as for the mid of 2009 and presented it in the following table. It should be mentioned, that a dispute may arise as to validity of this evaluations, due the fact that they reflect our subjective point of view. We may assume that if the evaluation was done by Risk Management Department's managers, the scores would be higher.

Principle Category	Principle	Extent of implementation in Maccabi in - 2009 (1=poor, 5=sound)
Concepts	1. Errors are inherent in every human activity	5
	2. Errors should serve personal and organizational learning and improvements processes	5
	3. Personal errors as a result of systemic shortcomings are not punished. Negligence is punished.	5
	4. In most cases the system enables the occurrence of errors, thus the system should be the major object for improvement.	5
	5. Safety and Risk management should be positioned equally to operations in the organization.	3
	6. An ideal of 0 accidents should be promoted and advocated.	2
	7. ROI- Return on Investment argument can't serve as a major argument for Risk Management activities, due to complexity to prove direct ROI.	3
Principles	1. Adverse events reporting supply the critical raw material for Risk Management activities.	5
	2. The immediate factor causing errors is in many cases the Human Factor, but means that may reduce probability of errors are systemic.	5
	3. Safety and Risk Management, are unique professional disciplines, that should be acquired and developed by learning, supervision, experiencing and studying.	4
	4. Safety climate influences the level of risk taking and errors.	3
	5. Managers are responsible for the safety and Risk Management records, as they are for the operational results.	3
	6. Every member of the organization has the potential ability to prevent and error and not just those involved directly in the mission (Sharp end., Reason, 1998)	4
	7. A clear distinction should exist between: managerial debriefing, legislative actions and Risk Management debriefings. Information shouldn't pass between these modes of operation, after an adverse event has occurred.	5

Principle Category	Principle	Extent of implementation in Maccabi in - 2009 (1=poor, 5=sound)
Methods	1. Measuring the rates of errors and events, should provide the basis of Risk Management activities.	2
	2. The error and accident phenomena are multi factorial, thus models for debriefing should be multi factorial too.	4
	3. Risk Management should treat phenomena in addition to particular adverse events.	4
	4. Risk Management activities should be based on a yearly work plan and not just on reacting to adverse events, after they have occurred.	4
	5. Priorities in resource investment in events which causes are severe and not only in those which results are severe.	4
	6. Promoting briefing and debriefing activities as a routine part of any mission or procedure.	2
	7. Emphasis on proactive activities in addition to reactive ones.	3.5
	8. Reporting and debriefing "Near misses" and not just events in which harm, damage or loss was caused.	5
Culture	1. Transparency and equality of all the information and all the involved parties, directly and indirectly, in case of debriefing.	4
	2. Managers' personal commitment to Risk Management and the model is an essential factor for successful Risk Management implementation.	3
	3. An accident provokes a moral obligation to learn lessons and to do whatever can be done, to reduce the probability of reoccurrence.	3.5
	4. Successful Risk Management implementation is conditioned by establishing and maintaining "Blame free culture"	5
	5. Safety and Risk Management education is a basic professional asset, which should be continuously acquired, as an essential part of professional development.	4
	6. A sound professional is one that performs his missions in maximal safety.	3
	7. A "Good organization" is one that performs its missions with minimal rate of accidents.	4

We have calculated average scores for each category and have found that Concepts and Principles got higher scores than Methods and Culture (4.0 and 4.1 as compared to 3.6 and 3.8).

In each category we found principles that were fully assimilated (scores 4-5) and few that were assimilated only partially (scores 2-3)



The weakest assimilation by category is as follows:

- **Concepts** - : *An ideal goal of 0 accidents should be promoted and advocated*. (2)
- **Principles** - : *Safety climate influences the level of risk taking and errors.(3) and Managers are responsible for the safety and Risk Management records, as they are for the operational results (3).*
- **Methods** - *Measuring the rates of errors and events, should provide the basis of Risk Management activities (2) and promoting briefing and debriefing activities as a routine part of any mission or procedure (2).*
- **Culture -** *Managers' personal commitment to Risk Management and the model is an essential factor for successful Risk Management implementation and a sound professional is one that performs his missions in maximal safety*.

We may state, while analyzing the evaluation above, that Maccabi's standing regarding the assimilation of ARMM principles is sound. This is especially significant in light of the fact that the above evaluations were given without "discount", having in mind a strict attitude rather a merciful one.

Summing up ten years of collaboration: successes and failures.

Defining "success" and "failure" in activities as complex as risk management at Maccabi, poses considerable difficulties in a dynamic and intricate organizational reality, changing sometimes as a result of multiple needs, not necessarily related to risk management.

Therefore, in this section, we will deal with successes and failures, as perceived by us and our partners in Macabi, but not necessarily on the level of actual results, as for example: a decrease in the rate of medical errors and in the extent of harm caused to patients.

We will highlight here any factual proofs of successes or failures. The "successes" and "failures" presented in this section reflect retrospection on the activity of the department at the beginning of 2006.

Successes

The successes shown here are part of successful processes and products, which were initiated and managed by the department and they are shown neither in chronological order nor in the order of their importance.

- **An Increase in the Reporting Rates** – As we mentioned in Chapter 6.7, the extent of reports to the department on adverse events increased by hundreds of percents in the course of its activity, from about 200 reports in the first years to more than 1000 reports a year in the last years*.

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*In 2009, about 1,800 reports were reported to the department via various routes.

It is important to mention that beyond the increase in the extent of the absolute reporting, the mix of the reports changed as concerns the source of the reporting, so that the proportional part of self initiated reporting of the care givers on their errors, exceeded the proportional part of the managerial reports being mostly patient complaints, appeals by lawyers and claims. This finding is particularly important, as it reflects an increase in the level of awareness to the importance of reporting as a tool for preventing the next error, the depth of assimilation of the commitment to report, which was introduced at Maccabi and familiarity with the activity of the department.

- **Department Team Growth and Quality System Establishment** - In Chapter 6.6, we described the manner in which the department developed from the aspect of its manpower. The department developed from a norm establishment of a half-time nurse in its first days to a norm establishment of more than 10 physicians and nurses in 2005. In 2000, the department instituted a "Quality System" consisting of two main departments, based on the risk management department and new activity in the quality field. Although we did not study the subject, at first sight it seems that no activity at Maccabi grew in such a dramatic pace during those years, not even information systems, which, by nature, grew most significantly during the last decade.

- **Subordination of the Quality System to the General Manager** – From our experience in Aviation we knew that in order to achieve organizational impact, the Risk Management entity should be subordinated directly to the Head of the organization as it usually is in organization with sound Risk Management activities. We suggested, upon its establishment, that the RMD should be subordinated to the Macabi's CEO. The initial motivation of Risk Management Department's founders was to subordinate the RMD to the Head of Healthcare Division, as it was thought that most of the work interfaces and most of the activity would be associated with medical processes. This was true in most of the cases. However, as we stated already, a considerable part of the recommendations of the department was related to administrative factors and to the medical information systems as well as to the pharmaceutics system. On a level of principle, the goodwill of these factors induced them to realize the recommendations of the department, but not being motivated by their position in the chain of management. Upon the establishment of the quality system, it was clear that in order to achieve broad effectiveness in the organization; it would be advisable to subordinate the system directly to the General Manager and to operate it on his behalf. After

numerous discussions on the subject, part of them were quite vehement discussions, and when the manager of the Quality System was even ready to resign from her position in order to prove the point, it was decided to subordinate the system directly to the General Manager. In the beginning of 2009, after the separation of Risk Management Department from the Quality system, as mentioned above, the Risk Management Department was subordinated to the Head of Healthcare Division, while the Quality Department was left under the General Manager. Although this step was an organizational and personal necessity, we view it as a loss of potential impact that must be compensated by other creative processes and ideas.

- **Establishment of a Field Referents Infrastructure** - Despite the growth in its manpower in the course of the years, the department had to establish a field system of referents in order to enable two-way communication with the field and to encourage the field to initiate Risk Management activities. The establishment of a referents system was necessary to increase the scope of events debriefed, to raise the rate of reporting and to assist in the field level implementation of the recommendations. Although, the indecision in this matter continued for many years, the referents system commenced to crystallize as from 2002, comprising, as at today (2009), thirty persons both from the districts and from the center. In these days the referents concepts has reached a junction and decisions must be taken as to modus operandi of the referents system, the expectations from them, the need to invest resources in training and supervision and regarding various conflicts of interests between their day to day duties and being RM referents..

- **Implementation of a Differential Adverse Events Handling System** - The increase in the reporting volume constituted proof of a rise in the awareness of the contribution of reporting as a result of the activity of the department. From the outset, it had been clear that from each and every reporting something can be learned and can be used as a lever for improving the system as a whole. However, even after adding more personnel, the department couldn't deal in a uniform way with all reported events. To be able to deal with all reported events, it would have been necessary to develop a differential classification and handling system to enable differential and efficient handling. Such a system was developed in 2001 and is implemented with minor modification until today. The system enables making the most of the reported risk management potential from the events reported with the resources being at the disposal of the department.

- **Execution of Organization-wide Multidisciplinary Projects, such as the ADE – Adverse Drug Events Project** - The need to provide administrative immunity to care givers reporting adverse events at Maccabi, caused, unintended by the department, remoteness and alienation between the department and the other factors of the Maccabi head office. To bridge this gap, and to return to the organization the knowledge and insights relevant for controlling the risks in order to improve patient safety, the department initiated multi-disciplinary projects. The last multidisciplinary project carried out dealt with the subject of the medication administration process and was extensively described in Chapter 6.11. The project was successful in that it was able to create a work team, which comprised relevant representatives of all fields of activity at Maccabi, working together for approximately a year and a half on learning about the errors in the process and to suggest appropriate solutions to minimize these.

- **Execution of Proactive Risk Audits** – To carry out pro-active risk management activity, based not solely on reporting, the department performed initiated risk audits in organizational units and on selected subjects. In the beginning, the surveys were on the initiative of the department, resulting from the investigation of adverse events. In recent years. Since 2002, in addition to the initiative of the department to perform risk surveys, requests from managers have been reaching the department to perform risk surveys in their units in order to assist them in locating risks to patient safety and to deal with them in due time. We consider the approach by the managers to perform risk audits in their units, as an expression of confidence in the activity of the department and its team.

- **The Insurer's Appreciation of Maccabi as the most Professional Factor in Israel in the Field of Risk Management** - The Insurer, the Madanes Group, maintains constant work contacts with its major insurants, among them the Maccabi Health Care Fund. Madanes appreciates the risk management activity carried out by the Risk Management Department of Maccabi, which is aimed at managing adverse events and drawing from them conclusions to minimize probability of reoccurrence. Maccabi's unique model of risk management activity based on the Aviation Model attains the appreciation of Madanes. This appreciation is expressed in the current meetings between the two factors as well as in internal forums at Madanes. Starting in 2007, a team was established and budgeted with representatives from Maccabi and Madanes, in order to raise creative ideas as to how minimize malpractice claims due to physicians errors. Among others, the

team initiated training activities aimed to instruct physicians how to ensure patient safety in their practices. .

- **Risk Management Abstracts on Defined Subjects** – During 2004, on the conclusion of the medication administration project, when it became clear to the Department heads that the resources required for conducting such a type of project, were non-existent, the Manager of the Department, Dr. Michal Gindi, raised the idea of a "Risk Management Abstract or Position Papers". The intention was to meet the requirements of the organization for information derived from analyzing the adverse events, as a basis for making organizational decisions. Risk management abstracts are mostly based on the analysis of events stored in the department's data base, and the resources required for making the abstracts are relatively modest – about 200 hours of work. As at 2006, in addition to the current work, every risk manager is involved at any given time in the preparation of a risk management abstract. At the end of 2005, risk management abstracts were completed on the following subjects: Adverse events in treating chronic diseases and adverse events related to Violence in the family. The abstracts were distributed among relevant factors at Maccabi and found a positive repercussion. At the beginning of 2006, the following abstracts are in various stages of work: Breast Cancer, Hospital-Community Interface, Compliance problems and Environmental Aspects in the Physician's Clinic: Secretariat, equipment and availability of physicians. *

- **Ongoing Work with managers at The Head Office and in the Districts for the Implementation of Recommendations based on Investigations of Adverse Events** – At about the end of 2001, when a review was made of handling recommendations status, three facts arose:

    - There was a considerable delay in the realization of recommendations – more than 200 recommendations were not implemented yet.

    - A considerable part of the recommendations were referred for handling by the RMD.

*As for the end of 2009, the RMD is in various stages of summarizing RM insights on various subjects : Continuity of care, Telemedicine - regarding usage of Tele-E.C.G, adverse events in pediatrics, falls in physiotherapy, influenza vaccination etc.

- A majority of the recommendations referred to the department were handled, while many of the recommendations referred to those responsible for handling outside the department, were not implemented.

To deal with the problems related with the implementation of recommendations, it was decided to change the approach to implementing the recommendations and to base it on the following principles:

- Participation of the factor responsible for implementing the recommendation in the recommendation forming process.

- Summary of recommendations, which accumulated in a given period of time within the scope of responsibility of a certain factor and transferring those recommendations for execution by the factor, while stating the event, the arguments for choosing a certain recommendation as a solution, a description of the recommendation (solution) and the expectations for the implementation thereof as far as the time schedule is concerned, the mode and supervision of the implementation process.

- Periodical meetings with all factors responsible for the execution of recommendations at Maccabi in order to examine the implementation status, problems in the implementation process or any other problem solution ideas, which came up in the course of the implementation of the original recommendation.

The new process of managing recommendations was successful as far as the previous approach was concerned. There was greater commitment of the factors responsible for the implementation of the recommendations and also the scope of recommendations implemented increased. The proportional part of the recommendations referred to the department, out of all recommendations, decreased and there was substantially less delay in the realization of the recommendations.

Thus, for example, in the years 2004 and 2005, approximately 50% of the recommendations made, were implemented still in the same year.

Failures

In referring to "failures", we will make a distinction between our failures as consultants and what we consider to be "failures" of the risk management activity at Maccabi, in general. The definition of "failure" as such is subjective and based on our point of view solely. Therefore, it is fair and proper to presume that each and every partner to the process will, to some extent or other, have different points of view concerning the issue of "failures".

Our failures

- **Insufficient understanding of the gaps between the world of Aviation and the world of Medicine in general and regarding risk management in particular** - In 1976, when we started to be involved in safety and risk management in aviation, we encountered a world, which refers to the subject of flight safety in all seriousness and most intensively searches for ways to reduce the rate of accidents. At the end of the 70's and the beginning of the 80's of the previous century, Aviation was in the middle of a transition process from the "pilot error" concept to the systemic concept. At the end of the 90's, when we started our activity in the medical field, medicine was in a stage of discovering the scope of the problem associated with errors during medical treatment. In retrospect, we understood that we did not estimate correctly the extent of the gap between the two content worlds. Our ignorance in the field of medicine led us to presume that it was advanced much more in everything associated to the understanding and handling of the risk management issue. This mistaken presumption, gave rise to an attempt to carry out processes at an accelerated rate, sometimes even without properly preparing the ground for it, as it would be required.
- **Inaccurate evaluation of the degree of difficulty involved in the assimilation of a new concept in a large organization** – We did not estimate correctly the degree of difficulty involved in introducing a new concept into a large organization and into a system, which had been operating in a certain manner for many years. We estimated that the power of the assimilation process of the risk management concept would meet with less resistance, as the concept suggested by us was supposed to solve a problem, of the importance of which the organization was aware and had been looking for solutions for it on its own initiative. To be true, this estimate was based on a certain naivety, but it may well be that without it, we would perhaps have been discouraged from engaging in a process of this kind.

- **Excessive reliance on the personal attitudes of the first department managers** – In the field of risk management, Maccabi was the first medical institution to receive consulting services from us. It had been our work assumption that we will become familiarized with the domain of medicine with the assistance of the department's first managers. In fact, the first managers of the department possessed extensive medical experience both in hospitals and in the community. However, they brought with them also a fair measure of frustration, based on their personal experience. Ultimately, the frustration concerned the belief in the ability to make a change in such a complicated system and so conservative in its approach. Our failure in this respect was related to adopting this frustration as a starting point in the first stages. As time passed, we learned to distinguish between the personal frustrations, based on experiences in the past, and frustrations caused by failure to promote some subject or other. The insights gained from this failure were associated with the creation of a distinction between the professional familiarity with a world of certain domain, personal experiences and the impact these had on the personal approach to the subject of risk management. In retrospect we should strengthen the belief in the ability to make a change in parallel to building professional capability in the department.

- **Getting used to being in a state of mind of "There is nobody to work with"** – At this point, the failure is, in fact, the expression of the previous failure. As we know from our experience, there is no risk management without partners within the organization. From enterprises at the "sharp end", according to the concept of Reason (1997), through intermediate managers and up to organization managers. Though being aware of the importance of a partnership as a critical component in a cultural change, at the beginning of our activity at Maccabi we were affected by the state of mind of "there is nobody to work with", which prevailed in the department during its first days. Later, this state of mind disappeared, when it turned out that many factors in the organization consider the risk management activity to be of much importance and are ready to cooperate in order to identify and reduce the risks to which they and their patients are exposed.

- **Postponing the subject of measuring the effectiveness of the risk management activity to some later stages** – In the Aviation Model, measuring the various parameters is of special value, and in particular, achievements expressed by the rate of accidents and incidents. Over and above all the activity performed with the aim to improve flight safety, great importance is ultimately given to the bottom line: the rate of accidents. For many reasons, at Maccabi, the subject of measurement did not advance at a sufficient rate, although it should have been dealt intensively, already from the first days of the department. As we were emphatic about the problems associated with measuring the rate of medical errors and the extent of resulting damages, no progress was made in this subject. This problem was related to its being dependent on reporting and on the necessity to base it on legal indicators, such as claims, request by lawyers demanding indemnity, complaints, and similar, which in themselves are no indicators reflecting organizational reality, but rather a reality outside the organization, which may be influenced by public state of mind, reference to the subject made by Courts, etc.

- **Failure to formulate the principles of the Aviation Risk Management Model (ARMM)** - In spite of the fact that the aviation model was used by us as our guide; its principles were never formulated nor defined by us in a clear and unequivocal manner. When examining in depth the subject of ARMM's principles, we discovered that not only we have failed to formulate its principles, but to the best of our knowledge, neither had such principles have been formulated by others. When various factors in medicine refer to risk management in aviation, they actually mean the transfer of successful experiences in risk management from the field of aviation to the field of medicine. That is to say, it concerns practical experience rather than principles. Furthermore, we did not find any source, which would serve as a basis for the "Aviation Model". It was more like the 'oral law' and less like the 'written law' with clearly formulated principles. The first time we encountered a problem related to the subject, was when, at a convention of the Israel Medical Association (IMA), held in 2005, we were asked to state the principles of the aviation model. The request to present the principles gave rise to the necessity of formulating those principles, which we did (See prologue in this chapter).

Anyhow, when we started working with Maccabi, the principles of the aviation model were not yet formulated. This issue is particularly important in light of the fact that the basic question of transferring the aviation model from the field of aviation to the field of medicine, is depending thereon. In this context, the subject might actually be reformulated in the following manner: **"Transfer of experience in the field of risk management from aviation to medicine".**

Failures of the Department

It is important to point out that a considerable part of the failures described here found expression in the first years of the activity of the department, while later on, the lessons were learned and failures corrected.

- **Lack of well established organizational procedures and mechanisms to mandate the whole organization to implement adverse event recommendations -** The purpose of the risk management activity is to make changes, which may reduce the probability of risk realization, therefore, recommendations are means for achieving this am. Despite the crucial nature of the subject, it was not intensively addressed from the outset. Much more emphasis was placed on increasing the scope of reporting and on investigating events, whereas the subject of implementation processes for the recommendations was dealt with in later stages. The lack of a concept and mechanisms for implementing the recommendations, created essential gaps between the investigating ability of the department, which developed satisfactorily in the course of the years, and a lesser ability to implement the recommendations.

- **Lack of proper reaction to the feelings of antagonism in the Head Office and in the field towards the activity of the department** – In Chapter 6.5, we referred to the reactions of Maccabi to the establishment of the department. Partly, the reactions were not positive. In our opinion the antagonism towards the activity of the department resulted, on one hand from the necessity to provide privilege to the reports and the reporters, which limited the possibility of sharing the information with the organization, and on the other hand, from the approach of the department itself, which sometimes was felt to be patronizing. Anyhow, this antagonism was seen in the department as a necessary evil, and therefore, no immediate activity followed to restrict and control it.

- **Lack of sufficient differentiation between the activity of the department and the activity of other organs** – In an internal customer survey carried out at Maccabi in 2003, in respect of the RMD's activities , it appeared that many physicians of Maccabi percept the department as being associated with legal handling of adverse events. This lack of differentiation on the part of the physicians of Maccabi might have caused damage to the image of the department. The department did not find it necessary to invest resources in a focused marketing effort in order to create this differentiation. However, in the course of the years, this differentiation was achieved as a result of the field activity of the department. It is reasonable to assume that had the customer survey been carried out today, the missions of the department would have been conceived as being more appropriate to reality.

- **Lack of cooperation between the Head Office and the field in defining and implementing recommendations**– This subject is related to the issue of definition and implementation of recommendations. In its first years, the department perceived itself as an separate entity from the organization, thus failed to consider the resources of the organization as resources, which might be used for solving the problems which were discovered as a result of the investigation of adverse events. In retrospective, it is obvious that this was a wrong attitude, since without the cooperation of those responsible for the implementation of recommendations, the chances of implementation are significantly less.

- **Delay in the establishment of Risk Management referents network**– The need to go beyond the boundaries of department's activities and enable collaboration with the field and the Head Office, was discussed almost from the very day the department was established.

However, on the practical level, this need was not addressed until the end of 2004, when the first risk management course was held on behalf of the department, with the participation of representatives from the districts and from the Head Office. The initial intention and expectation was that the majority of the participants in the course will someday become Risk Management referents, operating on behalf of their frameworks, in cooperation with the department.

Major insights derived from the implementation of the ARMM at Maccabi

Lacking a unique risk management model for the world of medicine, the adoption of a model, which was successful in another domain, constituted a positive starting point, based on the assumption that there is a certain similarity between the domains of medicine and aviation, on which there is not necessarily a broad consensus, as we have already pointed out in several occasions.

Presented in this section are our primary insights derived from the implementation of the ARMM (Aviation Risk Model Management) at Maccabi. These understandings are not presented according to their significance or according to chronological order. It may be correct to say that they are presented in an associative manner, as they arose from our discussions and debates during March 2006.

1. Before starting the implementation of a model taken from another domain, it is of considerable importance to learn first about the new domain and about the specific organization. Since we acted under considerable pressure of time and motivation to start the activity, we limited this stage to a minimum and did not perform it as required.

2. In order to carry out an intervention with good chances of success, there is a wider need to understand the complex professional culture of the world of medicine in general and in Israel in particular, and not only that of the specific organization. It is important to understand that physicians are first affiliated and committed deeply to their profession and only secondly to a particular organization. Physicians swear the universal Hippocratic Oath when joining the profession, thus their commitment is above all professional and less organizational.

3. As a long-term process is involved, mixing varied emotions and interests in the organization, it is of great importance that the senior management will be committed to the process and that the management will not be replaced while the process is in its initial stages. At Maccabi, there was no decrease in the commitment of senior management on its replacement, since the crucial stages of the initial process were implemented within one and the same tenure of both the General Manager and the Medical Manager.

4. It does not seem that the process had fair chances of success without our continuous consulting intervention, which dealt systematically with two crucial aspects: Instruction and professional development of the department's staff and the personal and professional supervision of the staff, during its interactions and confrontations with the world inside and outside Maccabi.

5. It appeared that, in the process of transferring the aviation model to medicine, the aviation model became more pronounced and crystallized into a rule of clear principles, which resulted from the need to "translate" and adjust it to a new professional, cultural and organizational environment. Thus, for example, work assumptions, which in the world of aviation had been self-evident, needed new proof in the world of medicine. E.g. the value of transparency of information for all concerning errors in aviation is clear, is hard to implement in medicine, where it raises complex juridical and ethic problems, due to the emotional involvement of patients and their relatives.

6. The need to learn the professional language and its deep and intimate meaning as a necessary condition for transferring the model from another content world. Thus, e.g., in medicine, "complication" is considered to be an inherent part of the medical treatment process, while in the world of aviation it is by all means an "adverse event".

7. Addressing objections and antagonism in earlier stages of the process and viewing them as an opportunity for cooperation. Denial of existing resistance while claiming that *"they do not yet understand the model, and when they do, they will become convinced"*, may worsen things in later stages and complicate the possibility of relations' rehabilitation.

8. In our opinion, the main contribution of the aviation model to the field of medicine lies in that it serves, in fact, as an important lever to mobilize the organization to provide the subject of risk management a chance to develop, among others, on basis of the prestige and credibility of the world of Aviation, in general and in the eyes of the physicians, in particular. In the eyes of physicians the genes of the ARMM are perceived as good genes, thus despite difficulties and debates about amount of similarity between Aviation and Medicine basic positive attitude exist to accept the model.

9. It is important to implement the changes arising from recommendations following investigations of adverse events, by means of organizational and infrastructural procedures and mechanisms, to assure the survivability of the change. Thus, for example, recommendations, which will be implemented in the computerized system of Maccabi for managing the medical records, will practically become part of the routine work processes and in this way, be optimally assimilated in the organization.

10. The type of our activity for assimilating a model from another content world required, by nature, organizational development skills, as it concerned not only professional intervention, but a large-scale cultural change. This being so, we were, in fact, involved both in professional activity in the content world of risk management and in the activity of bringing about a cultural change, which apparently created confusion in parts of the organization, as well as personal difficulties. Therefore, we consider it right to emphasize the need to differentiate our professional consulting activities in the field of Risk Management from the organization development (OD) activities, which became an apparent necessity in order to assure success.

11. The importance of coordinating expectations with partners in Maccabi while interacting with them in various instances. As it concerned a new activity, it was not clear to the two parties – both to the department and to factors, with which the department interacted with – what might be expected from these relationships. Mostly, the exposure of the activity of the department, whether following lectures, workshops or investigation of adverse events, created on the part of the participants involved in the activity, the wish to continue the cooperation, something which the department was not necessarily in a position to do. It may be reasonably assumed that the failure to attribute sufficient value for coordinating expectations, in part of the cases, gave rise to disappointment and a negative approach towards the department.

12. In Aviation, one of the central characteristics is that the individual is part of a system, and as such, is obligated to behave according to the regulation and procedures of the organization and to act according to the organizational culture. It may be said that, in the evolution of the world of medicine, the physician had been sovereign and it was only in later stages of the institutionalization of the world of medicine, that he became part of a system – McKinlay and Marceau (2000). This process, which is still in development, raises many risks by itself, which we are not sure that are managed sufficiently.

13. It may be said that, already from the early days of aviation, air crew members are committed to team work, whereas ancient medicine was the heritage of individuals, who jealously kept its secrets to themselves. The inherent conflict between being a team player and belonging to an organization, while preserving the autonomy to make medical decisions aimed to the benefit of the patient solely, seems still an open issue. For example in Maccabi a physician isn't authorized to decide for his patient on a costly procedure or test and he has to appeal with his recommendation to a professional committee, which may decide whether to approve the physician's request or not.

14. Quite a significant part of the physicians are working in more than one system, which reduces their feeling of belonging to a defined organization. A prominent example of this phenomenon is the difficulty to assimilate the duty of washing hands when passing from one patient to the next. According to Moss (2004), approximately 5000 patients die every year as a result of infections acquired in British hospitals. Part of these infections is the result of failure to wash hands. This state of matters became clear to us in the course of the process and it constituted and constitutes still an essential difficulty in the assimilation of changes in the organization, which result from risk management activity. In Maccabi, about 1,500 physicians, about 40% of the practicing physicians, are free lancers working also in others systems.

15. The characteristics of ambulatory care are closer in our opinion to those of Aviation. Most of the care in primary medicine is performed in solo practices interrelated in some manner with other parties collaborating in providing healthcare services. The setting of primary care is different in many ways from the hospital setting. Just to mention few of the differences: in many cases primary care has to do with healthy people while hospitals treat acute and chronic states, primary care is based on short interactions while in hospitals usually it’s a matter of days and weeks, in hospitals the care is provided by means of teamwork and radical procedures while in ambulatory setting care is based on symptomatic treatment, maintenance, diagnosis and prevention. The meaning of these differences regarding our work means that ARMM maybe more easily adapted and accepted in ambulatory settings due to its resemblance to the aviation setting and the issue of adaptability of ARMM to hospital settings has yet to be proved.

Considering the original decision to adopt ARMM

Basically, it seems to us that the selected model, named ARMM- Aviation Risk Management Model, is actually a generic model for risk management, that was adopted and successfully implemented in aviation. In retrospect, judging according to achievements and shortcomings in Maccabi, we may say that this model is a sufficiently appropriate model, also for the world of medicine.

Therefore, in our opinion, the issue of replacing the model is not on the agenda, neither on basis of our experience with the Maccabi project, nor on basis of our additional professional experiences in our work with the Madanes Group, the leading insurer for medical malpractice in Israel, as well as other medical institutions, with which we are working, among them some major hospitals in Israel.

All these experiences strengthen our approach that ARMM is valid also for the content worlds outside aviation, as it is, in fact, a generic model.

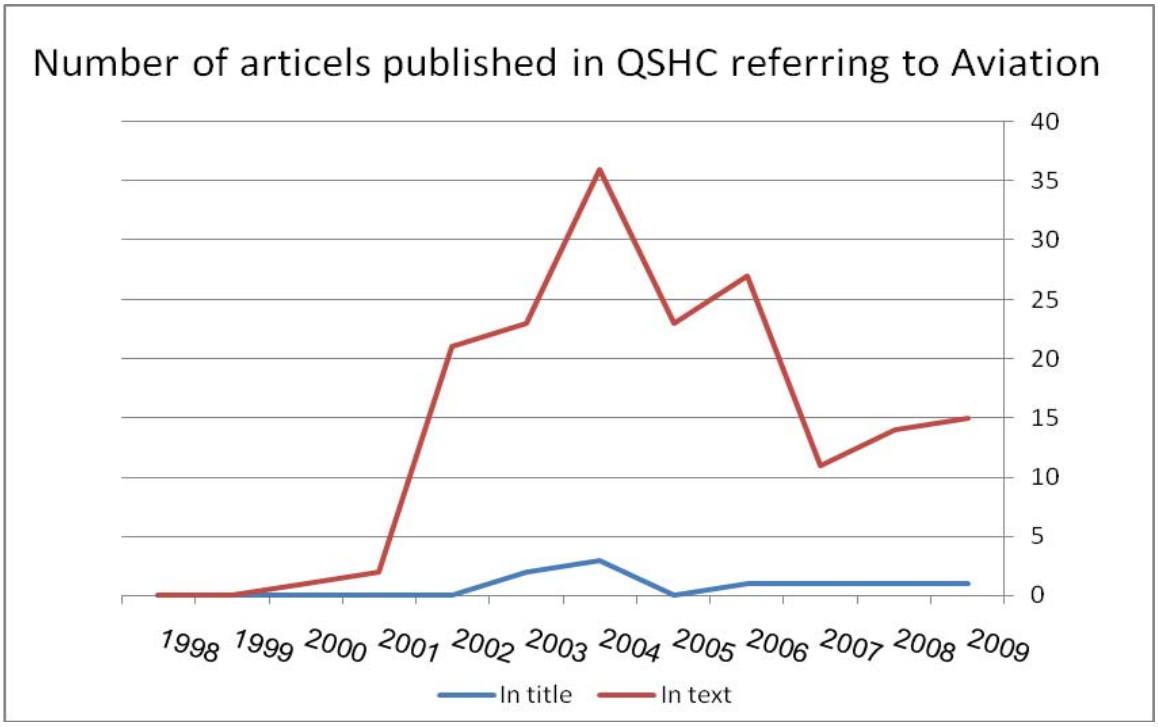
However, as aforesaid, in order to assure a successful implementation of the model, reference shall be made to the insights specified by us hereinabove, because, in most cases, the success of the implementation does not depend on the validity of the model, but rather on other issues, entirely unrelated to it. We found that quite many physicians try to refute the validity of ARMM by stressing the differences between the world of aviation and the world of medicine. Such differences do exist, and the most prominent among them is an essential difference in the extent of uncertainty encountered by the physician in his work, as compared to the civil aviation pilot.

However, the differences should not prevent the implementation of the model, but rather motivate searching for ways to adjust it to the dissimilar reality, Thomas and Helmreich (2002).

Moreover, it seems that the trend of adopting the aviation model as well as similar models from high risk content worlds, such as nuclear reactors, military operations, sea operations, and similar, to the world of medicine, continuous to gain impetus.

To examine the measure of penetration of references from the world of aviation risk management into medicine, we checked the scope of publications containing the word Aviation in the headings of articles and in the articles themselves, in a leading periodical in the field of quality and safety in health care: QSHC Journal

of Quality and Safety in Health Care, of the BMJ Group. The findings are shown in the following chart:



It can be seen that the scope of Aviation references in articles published in QSHC has dramatically increased in the years 2002 – 2004, as compared to previous years. This increase was slightly halted in 2005. It is also possible to observe the state of matters, in which not even one article dealing with aviation (title including the word 'Aviation') was published in 1998 – 2002. Between the years 2007-2009, each year an article was published having the word "Aviation" in its title and many others referring to aviation in the text? No doubt, these data reflects the trend of medicine to get inspiration and encouragement from aviation for improving patient safety. If we will refer to the articles published in QSHC Journal in the last four years, (2006-2009) having the word *"Aviation"* in their titles we will find three articles :

- 2006 - *Understanding diagnostic errors in medicine: a lesson learned from Aviation.* The article advocates adopting the aviation concept of "Situational awareness" and cognitive and systemic factors affecting diagnosis as means of reducing occurrence of diagnostic errors in medicine.

- 2008 – *Aviation is not the only industry: healthcare could look wider for lessons on patient safety*. In this article arguments are raised to look for additional industries to learn lessons regarding safety and not to narrow the scope of search just to Aviation. The authors refer to an accident that occurred recently, stating that Aviation may be not the perfect comparator.

- 2009 – *The effects of aviation style non-technical skills training on technical performance and outcome in the operating theatre*. In one teaching hospital in UK a training based on the aviation CRM (Crew Resource Management) was given to surgical teams specializing in laparoscopic cholecystectomy and carotid endarterectomy. Before and after training results were compared. The results suggested improvement in the non-technical skills, less operative technical errors, cultural resistance to adoption of the training, particularly was difficult to adopt debriefing procedures and challenging authority.

These briefs from recent literature may summarize the state of mind in medicine regarding the ARMM:

- The existing need to learn from others due to lack of experience in medicine.

- The argument for widening the scope of search and not limiting it to Aviation.

- Encouraging results while implementing Aviation proven methodology, mixed with cultural resistance

In our opinion, both the results of our project at Maccabi and the trend of increasing reference to the world of aviation as a source of inspiration for the world of medicine, encourage the continuation of the activity in accordance with the fundamental guidelines, which accompanied us in our joint venture with Maccabi.

Is it time to consider a new model?

Establishing the quality system, in which two units are operating conjointly, created, in fact, a new system with the potential for managing risks in Maccabi from two angles, similar to the System of Safety and Quality Control Administration of the Israel Air Force. Although the new structure was launched at the end of 2002, the issue of the work relations between the two entities comprising the system was in debates for many years and was unresolved. At

the beginning of 2009, it was decided on separation between these two units, as outlined at the beginning of this chapter.

In our opinion, the balance of successes and failures due to implementing ARMM at Maccabi is clearly positive. That is to say, the model justified the investment therein and gave Maccabi an appropriate infrastructure for the risk management activity, as from the establishment of the department until today.

However, it is clear to us today that the model will have to undergo adaptations to the world of medicine, in order to meet in a more precise manner its needs and characteristics. Thus, e.g., the definition of work interfaces between the health care providers, the organization, the insurer, professional unions, Ministry of Health and IMA, will have to find appropriate expression in the risk management model adapted to medicine.

This work sharpens the point that the aviation risk management model actually is a generic model, which was first implemented in aviation with the necessary specific adaptations. Therefore, it may be claimed that, in fact, it does not concern an aviation model, but rather a general model which was successfully implemented in aviation and which may be implemented with adaptations also in other content worlds.

Actually, Aviation constituted a certain type of large field laboratory, wherein the model was tested, underwent adjustments and was successful. As aforesaid, most of the principles of the model are generic.

Consequently, in our opinion, what is required now for Maccabi is not the development of a new model, but rather a better adjustment of the present model to the present needs of Maccabi and bridging the gaps in assimilating the principles which implementation wasn't satisfactory.

And on a wider view of the world of medicine, it may be said that the aviation model, which actually is a generic risk management model, adopted by aviation, is certainly a model suitable to start activity on the basis thereof, while carrying out the necessary adjustments according to the specific characteristics of the medical system, where it will be implemented.

As we mentioned previously ARMM was implemented successfully in Maccabi, which is by its essence an Ambulatory healthcare fund. In retrospect, we may say that primary care shares many common characteristics with aviation, which are nonexistent in the hospital setting. This assumption limits the generalization of the insights we have described above to primary setting only.

Thomas and Helmreich (2002), in a chapter in "Medical Error", a book edited by Rosenthal and Sutcliffe, consider the issue of adjustment of safety models, adapted from aviation to medicine. They claim that many researchers, studying errors in medicine, among them Leape (1994), Berwick & Leape (1999), Kohn Corrigan & Donaldson (2000), suggested that health care systems adopt from aviation the know how in order to prevent errors. Moreover, they claim that few critical reports were published, which look into the likelihood of this suggestion. They sum up their reference by saying that:
"There are differences between health care and aviation, but similarities also abound, and there is a great opportunity for all of us in health care to learn from aviation….Medicine is just learning how to implement these methods for monitoring error in patient care. Their usefulness in actually reducing error and improving patient safety is promising but far from proven.. For example there is no research available even to inform the basic design of incident reporting system..."

As far as we know, our project with Maccabi is a most prolonged and intensive one when considering adopting the aviation risk management model in medicine. Therefore, in our opinion, there is considerable value in the description of the project, its meaning and the insights we acquired in the course thereof. All these might serve as a superior starting point for health care organizations trying to find a way to improve safety in health care.

Epilogue

Aviation Psychology vs. Medical Psychology

In February 2008, while preparing a lecture for the CME Risk Management course in the Medical School of Tel-Aviv University, on the topic "From Aviation to Medicine, we noticed that Aviation Psychology is a well developed discipline, actually we knew it, from 1985 when we for the first time attended the 3rd Symposium on Aviation Psychology at Columbus Ohio.

According to our personal knowledge and the mission statement of AAP as cited in its web site, the Association for Aviation Psychology (AAP) is a non-profit professional organization, founded in 1964:
"Our purpose is to promote aviation psychology and related aerospace disciplines. We address four specific areas:

- *Dissemination of knowledge*
- *Meetings and publications*
- *Improved education and research*
- *Application of psychological principles to aviation safety and welfare: "Our members work in a diverse range of aviation fields, from pilot selection and training, aviation safety research, maintenance human factors, cabin safety, air traffic control, and accident investigation".*

We have searched the web in order to find an analogical discipline in Medicine, which mission statement should be similar to that of AAP.

What we found instead, are the following definitions for Health Care Psychology and Medical Psychology

- **Health Care Psychology**- Objective: students gain basic information and knowledge in the field of applied psychological disciplines. Based on better understanding of **needs and feeling of a patient**, these psychological disciplines contribute to higher quality of health care services.

- **Medical Psychology** refers to an emerging specialty of clinical psychological practice in which psychologists, who have undergone additional specialized education and training, **may prescribe medications in the care and management of patients.** In the United States, New Mexico and Louisiana, and several branches of the military, currently authorize these psychologists to prescribe medications. From 2001, the Ministry of Health in Israel has acknowledged Medical Psychology as a specialty in Psychology, and defined

a clear specialization pattern for this profession. Medical Psychologist, are staffed in 12 major hospitals in Israel and their mission is to assist the medical staff in diagnosis, treatment and research (Yaakobi, 2009).

What is missing is a discipline that will focus on medical staff, the medical environment, interfaces between medical specialties and institutions, team work, ergonomics, communication between the involved parties in providing and consuming care, the sociological aspects if medicine and more. This missing discipline may provide better ways to understand the entire framework of healthcare and of course insights of how to minimize errors and manage risks.

Where are we now?

We are now in a position that, in no aspect , resembles in a way the state of affairs, six years ago, when we started to write this work. Then, we were involved for about 5 years in the Maccabi project, being our first major activity in medicine. Since, then we have been involved in Risk Management consulting in medicine with the Madanes group (the largest Israeli malpractice insurer in medicine), IMA (Israel Medical Association), GPO (Government Physician Organization), MESER (Medical Simulation Center at Sheba Medical Center), CME program at Tel-Aviv Medical School and more. We may say that our ability to provide Risk Management consulting in Medicine, which originated in Maccabi, was fed by our attempt to formalize our experience on one hand and growing confidence that ARMM is of value for medicine, on the other hand.

Almost four years ago, we started a new adventurous project, starting from scratch to consult in Risk Management to MEKOROT, Israel National Water Company. MEKOROT has now a Risk Management Department, staffed with 3 senior engineers promoting Risk Management in the organization, with our assistance. This time we were much more confident that ARMM will contribute significantly to this major utility company to manage its risks. But this is another story, which maybe we will tell someday.

When we started writing this work, we expected from ourselves to be able to share our experience and insights regarding transforming ARMM to Medicine and more precise to a large ambulatory healthcare organization. We were surprised to discover that it was a fascinating journey, that had to do with our personal and professional past, it shaped our present, being influenced continuously by the process of reflecting, writing and understanding the meaning

of our work and no doubt our future. Compared to the starting point of writing this work, although we had all the ground to consider ourselves as professionals then, we know now, that we had still a lot to learn and inquire. Writing this work, challenged us to ask many unanswered questions about what we were doing in our professional practice. Many questions are still unanswered, like the issue of right mixture of soft and hard disciplines to get sound results while implementing Risk Management in a large organization, should the scope of Risk Management activities be limited to a certain critical activity (like patient safety) or be expanded to all organizational activities, what is the right mix between reactive and proactive Risk Management activities and many others. We believe, we have now a deeper understanding of Risk Management philosophy and not only technical knowhow. We believe this deeper understanding will enables us to move more easily between domains and organizations, providing them the deeper meaning of Risk Management and not just "things that work". We believe that this approach may recruit more motivation and commitment, so critical for success in Risk Management doing.

30 years after Captain's G.G. accident

Lieutenant Asaf Ramon was the son of Brigadier Ilan Ramon, the 1st Israeli Astronaut, killed in the Columbia accident, six years ago.

Asaf was killed two weeks ago, (13 September 2009) in an air accident, flying an F-16 fighter, while performing a high G maneuver in an air combat training.

Asaf has graduated the three year flying academy as number one in his class, just three months ago.

Exactly 30 years ago, captain G.G. was killed in an air accident while attempting landing after a night sortie (29 September 1979). We referred to this accident in Chapter 1, as one of our major motivations to commit our careers to Risk Management.

The last accident triggered many publications in the media that enabled the public a more intimate view into fighter pilots live and of course the circumstances of this particular accident and human factors that are present in each and every sortie, potentially endangering it. One of these publications was an article by Dror Ben-David (2009), a former fighter squadron leader that, in our impression, felt a moral duty to share with citizens of Israel, the fighter pilots

cockpit experience. Ben-David describes the extreme physiology of G forces, of cognitive and emotional stresses, typical to combat flying.
A fighter pilot is demanded to make critical decision in fraction of seconds and most of the time he is on his own. Experience means being able to balance wisely between many factors in an extreme environment, aiming to fulfill the mission while preserving personal and team safety. To be a fighter pilot, means to be a juggler. Thus there is no wonder, that a young and inexperienced pilot may drop a ball and cause a fatal accident.

We don't know yet what are the causes and root causes that may explain Asaf's accident, but we are definitely reluctant to tag it is a "Pilot error'. No doubt Asaf was flying the aircraft in the moments before the crash, but he was a part of a system that sent him to his mission, assuming he is well prepared.

What is it all about?

Risk management is about understanding past and present and to mobilize these understandings to save lives, spare sorrow, and essential resources. Risk management is about providing a more optimistic attitude to life, perceiving it as manageable and controllable and not dictated to us by fate only.

Risk Management mandates continuous commitment and vigilance. Complacency harms and in many cases kills. The concept of "Situational Awareness" promoted in aviation to motivate pilots to be continuously aware of the operational arena and which is this days also being promoted to become a part of physicians' attitude, (Wright et al., 2004) should be also adopted by those dealing professionally with Risk Management and Safety issues.

Peter Bernstein (1998) in "Against Gods" tells brilliantly the story of risk as part of mankind's cultural evolution from the ancient days until nowadays. Basic attitudes to risk have to do with our faith to control our lives. As long as mankind perceived live as a matter of fate and determinism, there was no place for risk management. Only in the renaissance, when human beings started to perceive their central role in the creation and the ability to unfold mathematical and physical regularities, the foundations for risk management were established. Bernstein stated this idea in the following way:

"The revolutionary idea that defines the boundary between modern times and the past is the mastery of risk: the notion that future is more than a whim of the Gods and that man and women are no passive before nature. Until human beings discovered a way across that boundary, the future was a mirror of the past or the murky domain of oracles and soothsayers who held a monopoly over anticipated events"

Acronyms

Acronym	Definition
5 M	A model that serves for RM debriefings and addresses 5 tiers of factors: Man, Machine, Mission, Management and Medium.
AAP	Association for Aviation Psychology
AAR	After Action Review
ADE	Adverse Drug Event
AHRQ	Agency for Healthcare Research and Quality
AMIA	American Medical Informatics Association
ARRM	Aviation Risk Management Model
ASHRM	American Society for Healthcare Risk Management
ASQAD	Aviation Safety and Quality assurance Directorate (MAVKA)
ASRS	Aviation Safety Reporting System operated by NASA
CKO	Chief Knowledge Officer
CME	Continuing Medical Education
COSO	Committee of Sponsoring Organizations – a private organization, recognized the world over for providing guidance on critical aspects of organizational governance, business ethics, internal control, enterprise risk management, fraud, and financial reporting
CRI	Cost of Risk Index (Impact of Risk event x Probability of Occurrence)
CRM	Crew/Cockpit Resource Management
DB	Data Base
EBM	Evidence Based Medicine
EILAT	EILAT Ltd. – A private owned Israeli company that specializes in Risk Management and safety in various domains , established in 1987 by Itzik Lichtenfeld and Yossi Tal.
EMR	Electronic medical record
FAA	Federal Aviation Agency
GP	General Practitioner
GPO	Government Physician Organization
HL-7	Health Level Seven, Inc. (HL7), is an all-volunteer, not-for-profit organization involved in development of international healthcare standards.
IAF	Israeli Air Force
ICAO	International Civil Aviation Organization
ICD-9	International Classification of Diseases
IDF	Israel Defense Force
IMA	Israel Medical association
IOM	Institute Of Medicine
IRI	Intermediate Result Indicators
IT	Information Technology
JCHACO	Joint Commission on Accreditation of Healthcare Organizations
MAVKA	IAF's Aviation Safety and Quality assurance Directorate

MCD	Medical Control Department
MCI	Medical Consultants International ltd. – A Madanes group company, the largest medical malpractice insurer in Israel.
Mekorot	Israeli National Water Company
MESER	Israeli Medical Simulation Center at 'Sheba' Medical Center
MI	Myocardial Infraction
MID	Medical Informatics Department
MMI	Man Machine Interface
MOH	Ministry of Health
MRM	Medical Risk Management - A Madanes group company that specializes in Medical Risk Management and operates conjointly with MCI.
NTSB	National Transportation Safety Board
OD	Organizational Development
OJT	On the Job Training
POC	Point Of Contact
PSRS	Patient Safety Reporting System based on the principles of ASRS
QA	Quality Assurance
QAM	Quality Assurance Management
QD	Quality Directorate
R&D	Research and development
RCA	Root Cause Analysis
RM	Risk Management
RMD	Risk Management Department
RMQA	RM & QA Activities
ROI	Return On Investment
SOAP	Subjective, Objective, Assessment and Plan
SOX	Sarbanes–Oxley Act of 2002
TQM	Total Quality Management
VA	Veterans Affairs- a US based Medical Organization providing Healthcare Services to American Army Veterans
WHO	World Health Organization

References :

ACGIH - American Conference of Governmental Industrial Hygienists (2005) http://www.acgih.org/

Andriessen, J. H. T. H. (1978). Safe behavior and safety motivation. *Journal of Occupational Accidents*, 1, 363-376.

Andrews, L.B., Stocking, C., Krizek, T., Gotlieb, L., Krizek, C., Vargish, T., & Siegler, M. (1997). An Alternative strategy for studying adverse events in medical care. *Lancet*, 349, 309-313.

Anderson, D.O, & Starzynski, B. (2001, Oct, 10-12). Successful strategies for cultural transformation are the essential first steps to increase medical error reporting and identify performance improvement strategies. *Partnership symposium 2001, Patient Safety – stories of success*. Fairmont Dallas.

Annison, M.H., Wilford D.S. (1998). *Trust matters, New Directions in Health Care Leadership.* San-Francisco: Jossey-Bass Publishers.

Annenberg, (1998, November 8-10). Enhancing Patient Safety and Reducing Errors in Health Care. A Multidisciplinary Leadership Conference Convened, by: American Association for the Advancement of Science, Annenberg Center for Health Sciences at Eisenhower ,Joint Commission onccreditation of Healthcare Organizations ,National Patient Safety Foundation at the AMA and US Department of Veterans Affairs.

AMIA, (2000). Technology and Health Care Panel: Slips, Mistakes and Faulty Reasoning-The Nature of Human Errors in Medicine. *Annual Symposium Converging Information*.

American Medical Association. (2000). E-8.12 *Patient Information. Code of Medical Ethics. Current Opinions of the Council of Ethical and Judicial Affairs.* Chicago: IL American Medical Association.

Barach, P. & Small, S.D. (2000). Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. *British Medical Journal*, 320, 759-763.

Balas, E.A., Austin, S.M. , Ewigman, B.G., et al.(1995). Methods of randomized controlled clinical trials in health services research. *Med. Care*. 33, 687–699.

Basel 2 (2004) Wikipedia , http://en.wikipedia.org/wiki/Basel_II

Bernstein, P. L. (1998). *Against the Gods, The remarkable Story of Risk*. Willey & Sons Inc.

Becker, H.S., Geer, B., Houghes, E.C., & Strauss, A. (1961). *Boys in white: Student Culture in medical school.* Chicago: University if Chicago Press.

Badihi, Y.(1993). *The formal structure of thinking and its implications to communication and performance errors*. (Research Thesis, The Technion Institute of Technology, Haifa, May 1993).

Ben-David, D. (2009, September 10). Stress Chamber, *Yedioth Achronot* (In Hebrew).

Berwick, D.M., & Leape, L.L. (1999). Reducing errors in Medicine. *British Medical Journal,* 319,136-137.

Berg, J.S., Moore, J.L., Retzlaff, P.D., & King, R.E. (2002). Assessment of personality and crew interaction skills in successful naval aviators. *Aviat. Space Environ. Med.* , 73 (6), 575-59.

Bhattacherjee, A. & Hikmet, N. (2007). Physicians' Resistance toward Healthcare Information Technologies: A Dual-Factor Model. *Proceedings of the 40th Hawaii International Conference on System Sciences* – 2007.

Blumenthal, D., & Kilo, C.M. (1998). A report card on continuous quality improvement. *Milbank Q*, 8;76, 625-48,511.

Boyd, J.E., Patterson, J.E., & Thompson, B.T. (2005). Psychological test profilesbefore training vs. type aircraft flown. *Aviat. Space Environ. Med*., 76(5): 463-68.

Brenan,T.A. (2000). The Institute of Medicine report on medical errors: Could it do harm*? New England Journal of Medicine*, 342, 1123-1125.

Brennan, T.A., Localio, A. R., Leape L.L., Laird, N., Peeterson, L., & Hiatt, H. (1990). Identification of adverse events occurring during hospitalization. *Ann. Intern. Med*, 112, 221-6.

Brennan, T.A, Leape, L.L, Laird, n., et al. (1991). Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study *NEJM*, 324:370-376.

Bruner, J.(1996). *The Culture of Education*. Cambridge, MA: Harvard University press.

Coch, L. & French, J.R.P. (1948). Overcoming Resistance to Change, *Human Relations*, 1, 512-32.

Cohen, M.R. (2000). Why error reporting systems should be voluntary. *BMJ*, 320,17, 86-94.

Corrigan, J.M., Donaldson, M.S., Kohn, L.T., et al. (1999) *To err is Human- Building a Safer Health System,* IOM. The National Academy Press, Washington DC.

Corrigan, J.M., Donaldson, M.S., Kohn, L.T., et al. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*, IOM. The National Academy Press, Washington DC.

Coles, J., Pryce, D., & Shaw, C. (2001, October). *The reporting of adverse clinical incidents- achieving high quality reporting, CASPE Research*, London.

Champagne, F. (2002, Nov). *The Ability to Manage Change in Health Care Organizations*. Discussion paper No. 39, Commission on the future of Health in Canada.

Charles D. (1999). Clinton Aims to Cut Deadly Errors, Washington (Reuters), December 7, 199 http://www.welchco.com/02/14/01/60/99/12/0701.HTM

Christy, R.L. (1975). Personality factors in selection and flight proficiency. *Aviat. Space Environ. Med.* , 46 (3): 309- 11.

Clarke, I.M.C., Morin, J..E. & Warnell, I. (1994). Personality factors and the practice of anaesthesia: a psychometric evaluation. *Can. J. Anesth*, 41 (5), pp 393-7.

Clarke S., & Ward K. (2006).The role of leader influence, tactics and safety climate in engaging Employees' safety participation. *Risk Analysis*, 26, 1175 – 1186.

Clinton, B., (2000), *"Remarks by the President on Medical Errors".*

Creswell, J. (1998). *Qualitative Inquiry and Research Design : Choosing among Five Traditions*. London, New-Delhi, Thousand Oaks: Sage Publications.

Crosby, P.B., (1979), *Quality is Free: The art of Making Quality Certain*, McGraw-Hill, New York.

COSO- (1985). Committee of sponsoring organizations of the Tread way Commission (1985) http://www.coso.org/

Deary, I.J., Graham, K.S. & Maran, A.G. (1992). Relationships between surgical ability ratings and spatial abilities and personality. *J. R. Coll. Surg. Edinb*., 37, 74-9.

Denzin , N.K. & Lincoln, Y.S. (eds.). (2000). *Handbook of Qualitative Research* (2nd ed.), Introduction (pp. 1-28). Thousand Oaks, Ca: Sage Publications.

Denham, R.D. (2005). Patient Safety Practices: Leaders Can Turn Barriers Into Accelerators. *Patient Safety* , Vol. 1 (1).

Dewey, J. (1933). *How we think - A restatement of the relation of reflective thinking to the education process* (revised ed.), Boston: D.C. Health Brilliant.

Eilat Ltd., (1997). *Eilat's Risk Management Activities* (An internal document addressed to Prof. Aviram, Head of Medical Department and Dr. Wilf-Miron, Head of RM Division, Macabbi).

Ellis, O. (2009). Putting safety on the curriculum. *BMJ*, 339, b3725.

Eric, J.T., & Helmreich, R.L. (2002). Will Airline Safety Models Work in Medicine? In: M.M. Rosenthal & K.M. Sutcliffe (eds.) (2002), *Medical Error - What do we know? What do we do?* San Francisco, Ca: Jossey-Bass.

Erickson, F. (1975). Gate keeping and the melting pot. *Harvard Educational Review*, 45, 44-70.

Erickson, K.T., (1976). *Everything in its Path :Destruction and Community in the Buffalo Creek Flood.* Simon and Schuster, New York.

Ferguson, E., James, D., O'Hehir, F., & Sanders, A. (2003). Pilot study of the roles of personality, references, and personal statements in relation to performance over the five years of a medical degree. *BMJ*, Vol. 326. 429-432.

Fitzgerald, C. (1993*). Royal College of Surgeons Validation Study*: Saville and Holdsworth. London (UK): Thames Ditton.

Ford, M.T. (2008). *Implications of Psychological Distance for the Structure and Motivation of Safety at Work*. (A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at George Mason University).

Frankel, A. (2001, Oct 10-12), *Reporting system new approaches*. Partnership symposium 2001, Patient Safety – stories of success, Fairmont Dallas.

French, W. L., & Bell, C. H., Jr. (1990). *Organization development: Behavioral science interventions for organization improvement* (4th ed.). Upper Saddle River, NJ: Prentice Hall.

Freudenheim, M. (2004, April 6). Many Hospitals Resist Computerized Patient Care. *New-York Times*. Available : http://www.Nytimes.com/2004/04/06/technology/06errors.html.

Geertz, C. (1988). Works and Lives: *The anthropologist as author*. Stanford, Ca: Stanford University Press.

Gerowitz, M. B.(1998). Do TQM interventions change management culture? Findings and implications. *Qual. Manag. Health Care*, 6, 1-11.

Guba, E.G., & Lincoln, Y.S. (1989). *Fourth Generation Evaluation*. Newbury Park, Ca: Sage Publications.

Guba, E.G., & Lincoln, Y.S. (1998). *Competing paradigms in quantitative research*. In: Denzin, N.K., Lincoln, Y.S. (eds.). The Landscape of Qualitative Research. London: Sage.

Harkey, J., & Vraciu, R. A. (1992). Quality of Health Care and Financial Performance: Is there a link? *Health Care Management Review* ,17, (4), 55-64.

Haley, R.W., Colver, D.H., White. J.W., et al. (1985). The efficacy of infection surveillance and control programs in preventing nosocomial infections in US hospitals. *Am. J. Epidemiol*, 121, 182-205.

Head, G.L., & Horn, I.I. S. (1991). *Essentials of Risk Management*, Vol. I, (2nd ed.). Insurance Institute of America.

Helmreich, R.L., & Merritt, A.C. (1998). *Culture at work: National, organizational and professional influences*. Aldershot, UK: Asgate.

Helmreich, R.L., Klinect, J.R., Wilhelm, J.A., & Sexton, J.B. (2002). *The Line Operations Safety Audit (LOSA).* In Proceedings of the Third LOSA Week (ICAO) (pp. 1-6), Dubai, United Arab Emirates, October 14-16, 2002.

Hollnagel, E., Kaarstad, M., & Lee, H.C. (1999). Error mode prediction. *Ergonomics,* 42, 1457- 1471.

Howat, D.D.C. (1977). Anaesthesia as a career. *Anesthesia* ,32, 979-93.

IMA 40th Convention, Patient Safety Symposium, Jerusalem (2005) http://www.ima.org.il/imahebnew/T1.asp?p=10&n=6125

ISO/DIS 31000. (2009). *Risk management - Principles and guidelines on implementation*. International Organization for Standardization. http://www.iso.org/iso/catalogue_detail.htm?csnumber=43170

Israeli Ministry of Health. (1996). The Patients rights law 1996. *Book of laws* 1591, 12.5., p. 327.

Johnson, M.E., Langton, K.B., Haynes, B., et al. (1994). Effects of Computer Based Clinical Decision Support Systems on Clinical Performance and Patient Outcome, *Ann. Int. Med*., 120, 135-142.

Jones, B. (2002). Nurses and the “Code of Silence”, In M.M. Rosenthal & K.M.Sutcliffe, (eds.) (2002). Medical Error - What do we know? What do we do? San Francisco, Ca: Jossey-Bass.

Kapur, P.A. & Steadmen, R.H. (1998). Patient simulator competency testing: Ready for takeoff. *Anesthesia and Analgesia*, 86, 1157-1159.

Knight, F. H. (1921). Risk, Uncertainty, and Profit. *Hart, Schaffner, and Marx Prize Essays,* no. 31. Houghton Mifflin: Boston and New York.

King, S. H., McArthur, C. G., & Norman, J. C. (1975). The Surgical Personality a comparison of medical and surgical residents with Rorschach Cardiovascular Diseases. *Bulletin of the Texas Heart Institute*, Vol. 2 (2), 117-128.

Kirwan, B. (1998). Human error identification techniques for risk assessment of high risk Systems–Part 1: Review and evaluation of techniques. *Appl. Ergon*. ch. 29, pp. 157-177.

Kirwan, B. (1998). Human error identification techniques for risk assessment of high riskSystems– Part 2: towards a framework approach. *Appl. Ergon*. ch. 29, pp. 299-318.

Knowledge @ Wharton (2009). Re-thinking Risk Management: Why the Mindset Matters More Than the Model, Published: April 15, 2009 in *Knowledge@Wharton.*

Kotter, J.P.(1995,). Leading Change: Why Transformation Efforts Fail, *Harvard Business Review*, March-April ,59-67.

Ku¨bler-Ross, E. (1969). *On Death and Dying*. New York, NY: Touchstone Press

Kuhn, T. (1962). *The Structure of Scientific Revolutions*. University of Chicago Press.

Kvale, S. (1989). To validate is to question. In S.Kvale (ed.). Issues of validity in Qualitative research. Sweden: *Studenliterarur.* pp. 73-92.

Leape, L.L. (1994). Error in Medicine. *Journal of the American Medical Association*, 272, 1851-1857.

Leape L.L. (2002). Reporting of Adverse Events. *N. Engl. J. Med*., Vol. 347, No.20.

Leape L.L., Brennan T.A., Laird N. et al. (1991). The Nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II, *N. Engl. J. Med*., 324, 337-384.

Leape, L.L., Kabcenell, A., Berwick, D.M., & Roessner, J. (1988). *Reducing adverse drug events*, IHI (Institute for Healthcare Improvement).

Leape L.L., & Berwick D.M. (2005, May 18). Five years after To Err Is Human: What have we learned? *JAMA*, 293, 2384–2390.

Lederer, J. (1986). How Far Have We Come? A Look Back at the Leading Edge of System Safety Eighteen Years Ago. *Hazard Prevention*, 1986.

Leveson, N. (2003). White Paper on Approaches to Safety Engineering. http://sunnyday.mit.edu//caib/concepts.pdf

Leydesdorff, S. (2001). *When the water comes, Memories of survivors of the 1953 flood*. In S. Hussey & P.Thompson (Eds.) The roots of Environmental Consciousness, Routledge.

Lewin, K. (1947). Frontiers in Group Dynamics: I. Concept, Method, and Reality in Social Sciences, Social Equilibria, and Social Change. *Human Relations*, (1), pp. 5-41.

Lewin, K. (1952). *Field Theory in Social Science*. Harper and Raw.

Levinson, W. (1994, November 23/30). Physician-Patient Communication a key to Malpractice Prevention. *JAMA,* Vol. 272 (20).

Levinson W., et al. (1997, February 19). Physician-Patient Communication The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons. *JAMA*, Vol. 277 (7).

Liang, B. A., & Storti, K. (2000). Creating problems as part of the "solution": The JCAHO sentinel event policy, legal issues and patient safety. *Journal of Health Law*, 33(2), 263-85.

Lindgren, O.H, Christensen, R., Mills, D.H. (1991). Medical malpractice risk management early warning systems. *Law and Contemporary Problems*, 54, 22-41.

Linsky, M., & Heifetz, R.A. (2002). *Leadership on the Line: Staying Alive Through the Dangers of Leading*. Harvard Business School Press.

Lippin, T. M., Eckman, A., Calkin, K. R., & McQuiston, T. H. (2000). Empowerment based health and safety training: Evidence of workplace change. *American Journal of Industrial Medicine*, 38, 697-706.

Lincoln, Y.S. & Guba, E.G. (1985). *Naturalistic Inquiry*. Thousand Oaks, Ca: Sage Publications.

Littre, E. (1863). *Dictionnaire de la langue française* ("Le Littré").

Lockwood, J., Sabharwal, R., Danoff, D., & Whitcomb, M. (2004). Quality improvement in medical students' education: the AAMC medical school graduation questionnaire. *Med. Educ*., 38, 234-6.

Mangalwadi, V. R. (1999). *The Legacy of William Carey, A Model for the Transformation of a Culture.* Illinois : Crossway Books.

March, J.G., Sproull, L.S., & Tamuz, M. (1991). Learning from samples of one or fewer. *Organizational Science*, 2, 1-3.

Marcus, G.E., & Fisher, M.M.J. (1986). *Anthropology as cultural critique: An experimental moment in the human sciences.* Chicago: University of Chicago Press.

Markowitz, H. (1952, March). Portfolio Selection. *The Journal of Finance*, Vol. 7 (1), pp. 77-91.

Markowitz, A. J. (Managing Editor) (2001, July 20). Making Health Care Safer: A Critical Analysis of Patient Safety Practice. *AHRQ Publication 01-E058*, Prepared by: University of California at San Francisco (UCSF)–Stanford University Evidence-based Practice Center.

Maslow, A.H. (1943). A Theory of Human Motivation. *Psychological Review*, 50, 370-396.

Maykut, P., & Morehouse, R. (1994). *Beginning qualitative research: A philosophic and practical guide*. London: Falmer.

McCulloch P., Mishra A., Handa A., Dale T., Hirst G., & Catchpole K. (2009, April). The effects of aviation style non-technical skills training on technical performance and outcome in the operating theatre. *Quality and Safety in Health Care,* 18 (2),109 -15.

McKinlay, J.B., & Marceau.L.D. (2002, Number 2). The end of the golden age of doctoring. *Int. J. Health Serv*, 32, 379-416.

McLaughlin, C.P., & Kaluzny, A.D. (1994). *Continuous Quality Improvement in Health Care Theory, Implementation and Implication*. Aspen Publishers.

Menon, S.T. (1999). Psychological empowerment: definition, measurement, and validation. *Canadian Journal of Behavioral Science,* July 1999.

Michel-Kerjan, E. (2009). *Shaping the post- crisis agenda.* Managing Director, Center for Risk Management and Decision Processes, Wharton School, University of Pennsylvania, USA.

Mills, D.H. & von Bolschwing, G.E. (1995). Clinical Risk Management: Experiences from the United State. In Vincent, C. (ed.). *Clinical Risk Management*. BMJ Publishing Group.

Moscicki, R.H. & Wrobel, E.M. (1996). Cost of Risk as a Management Tool. *American Society for Healthcare Risk Management, Annual Conference Proceeding Book*.

Moss, F. (2004). The clinician, the patient and the organization: a crucial three sided relationship. *Qual. Saf. Health Care*, 13, 406-407.

Musson, D.M., Sandal, G.M. & Helmreich, R.L. (2004). Personality characteristics and trait clusters in final stage astronaut selection. *Aviat. Space. Environ. Med*., 75 (4), 342- 49.

Odegard, S. (2000). Safety Management in Civil Aviation- A Useful Method for Improved Safety in Medical Care? *Safety Science Monitor,* Issue 1, Vol. 4, Article 4.

OSHA – Occupational Safety and Health Act (1970), http://www.osha.gov/

Piaget, J. (1983). Piaget's theory. In P. Mussen (Ed.). Handbook of Child Psychology. (4th edition). Vol. 1. Wiley: New York.

Picano, J.J. (1991). Personality types among experienced military pilots. Aviat. Space Environ. Med, 62 (6), 517-20.

Piderit, S.K. (2000). Rethinking resistance and Recognizing Ambivalence: A Multidimensional View of Attitudes Toward an Organizational Change. *The Academy of Management Review*, 25 (4), pp. 783-794.

Porter B. (1999, October). Computerizing the Ambulatory Healthcare Services- the Ambulatory Healthcare System Experience. *Harefua,* Vol. 137 (7-8).

Reason, J. (1990). *Human error.* U. K.: Cambridge University Press.

Reason, J. (1994). *Human Error*. New York : Cambridge Press.

Reason, J. (1997). *Managing Risks of Organizational Accidents*. U. K. Ashgate: Aldershot,

Reason J. (2000). Human error: models and management. *BMJ*, 320, 768-770.

Reason, P. & Rowan, J. (Eds.). (1981). *Human Inquiry: A sourcebook of New Paradigm Research*. Chichester: Wiley.

Reason,P., & Tobert, W.R. (2001). The action turn: toward transformational social science. *Concepts and Transformations*, 6 (1), 1-37.

Reason, P. & Bradbury, H. (Eds.). (2006). *Handbook of Action Research*. Thousand Oaks, Ca: Sage Publications.

Reeve, P.E. (1980). Personality characteristics of a sample of anaesthetists. *Anesthesia*, 35, 559-68.

Reisetter, M., Yexley, M., Bonds, D., Nikels, H., & McHenry, W. (2003). Shifting paradigms and mapping the process: Graduate students respond to qualitative research. *The Qualitative Report*, 8(3), 462-480. Retrieved [May 7, 2007, from http:/www.nova.edu/ssss/QR/QR8-3/reisetter.pdf.

Renhard, R. (2001, November). *The Evidence for Effectiveness for Quality Initiatives in Human Services, A Critical Review . The Centre for Quality in Health and Community Services*, Australian Institute for Primary Care, La Trobe University.

Reynard, W.D., Billings, C.E., Cheaney, E.S. & Hardy, R. (1986). *The Development of NASA Aviation Safety Reporting System* (NASA Reference publication 1114). Springfield VA: NASA, Scientific and Technical Information Branch.

Maccabi Healthcare Fund RMD, (2000, October). *The Alerts Committee Presentation.*

Maccabi Healthcare Fund RMD, (2001, December). *The Implementation of Procedures Control Systems as Means for Risk Management.*

Maccabi Healthcare Found, (2002, December). *Physicians Satisfaction from the Risk Management Department* (Internal publication).

RMD Maccabi HealthCare Fund, (2001). *Physician-Patient Communication Workshops Summary.*

RMD Maccabi HealthCare Fund, (2002, May). *Risk Factor: Physician-Patient Communication – Project Summary.*

RMD Maccabi HealthCare Fund, (2004). *Adverse Drug Events ADE – Project Summary.*

Roland, H.E. and Moriarty B. (1982). *System Safety Management*. New York: Wiley & Sons.

Rosenzweig, P. (2007). *The halo effect: And the eight other business delusions that deceive managers*. The Free Press.

Rosenthal, M.M., & Sutcliffe, K.M. (Eds.) (2002). *Medical Error - What do we know? What do we do?* San Francisco, Ca: Jossey-Bass.

Roter D, et al, (1997, January 22/29). Communication Patterns of Primary Care Physicians. *JAMA*, Vol. 277 (4).

Rowan, J. (1981). A Dialectical Paradigm for Research. In P. Reason & J. Rowan (Eds.). *Human Inquiry*. Chichester: Wiley & Sons.

Rubin, L.D. Jr. (2002). Small Craft Advisory. New York: Atlantic monthly Press, Adapted from *Risk Management Reports*, Vol. 26(12), December 1999.

Sandars, J., Bax, N., Mayer, D., Wass, V., & Vickers, R. (2007). Educating undergraduate medical students about patient safety: priority areas for curriculum development. *Med. Teacher*, 29, 60-1.

Schein, E.H. (1969). *Process Consultation. Reading*: Addison-Wesley.

Schein, E.H. (1980). *Organizational Psychology*, (3rd ed.). Prentice-Hall.

Schein, E.H. (1987a). *The Clinical Perspective in Field Work*. London: Sage publications.

Schein, E.H. (1997). *Organizational Culture and Leadership*, (2nd ed.). San-Francisco: Jossey-Bass Publishers.

Schein, E.H. (2006). Clinical Inquiry and Research. In P. Reason, & H. Bradbury, (Eds.) (2006). *Handbook of Action Research*. Thousand Oaks, Ca: Sage Publications.

Schueneman, A.L., Pickleman, J., Hesslein, R., & Freeard, R.J. (1984). Neuropsychologic predictors of operative skill among general surgery residents. *Surgery* , 96, 288-95.

Schueneman, A.L., Pickleman, J., & Freeard, R.J.(1985). Age, gender, lateral dominance, and prediction of operative skill among general surgery residents. *Surgery*, 98, 506-15.

Sciarra, D. (1999). The role of the qualitative researcher. In M. Kopala & L.A. Suzuki (Eds.). *Using qualitative methods in psychology* (pp.37-48). Thousand Oaks: Sage.

Selecky M.C. (2000, December). *Medication Errors Report and Recommendations*. Secretary of Health.

Shaw J., & Calder K. (2008). Aviation is not the only industry: healthcare could look wider for lessons on patient safety. *Quality and Safety in Health Care*, 17, 314.

Shkedi,, A. (2003). *Words of Meaning Qualitative Research - Theory and Practice*. (In Hebrew). Tel Aviv: Ramot, Tel-Aviv University Publications.

Siem, F.M., & Murray, M.W. (1994). Personality factors affecting pilot combat performance: a preliminary investigation. *Aviat. Space Environ. Med*. , 65 (5, Suppl.) A45-48.

Shortell, S.M., Bennett, C.L., & Byck, G.R. (1998). Assessing the impact of continuous quality improvement on clinical practice: what it will take to accelerate progress. *Milbank Q*, 76, 593- 624,510.

Shortell, S.M., Jones, R.H., Rademaker, A.W., Gillies, R.R., Dranove, D.S., Hughes, E.F., et al. (2000). Assessing the impact of total quality management and organizational culture on multiple outcomes of care for coronary artery bypass graft surgery patients. *Med Care*, 38, 207-217.

Singh, H., Petersen, L.A., & Thomas, E.J. (2006, Jun.). Understanding diagnostic errors in medicine: a lesson learned from Aviation. *Quality and Safety in Health Care*, 15 (3),159-64.

SOX Sarbanes-Oxley Act. (2002). Wikipedia http://en.wikipedia.org/wiki/Sarbanes-Oxley_Act#References

Squire, D., Ciachino, A.A., Profitt, A.W., & Heaney, C. (1989). Objective comparison of manual dexterity in physicians and surgeons. *Can. J. Surg*., 32, 467-70.

Stake, R. (1995). *The art of case research*. Thousand Oaks, CA: Sage Publications.

Stojanović S., & Zdravković Z. (2002). *Motivation for Occupational Safety. Facta Universitatis Series*: Working and Living Environmental Protection, Vol. 2 (2), pp. 179 – 187.

Strauss, A.L., & Corbin, J. (1990). *Basics of qualitative research: Grounded theory procedures and techniques.* Sage Publications.

Steele, R.J., Walder, C., & Herbert, M. (1992). Psychomotor testing and the ability to perform an anastomosis in junior surgical trainees. *BR. J. Surg*., 79:1065-7.

Strebel, P. (1996) Why Do Employees Resist Change? *Harvard Business Review*, May-June ,86- 92.

Sullivan G.R., & Harper M.V.(1996). *HOPE is not a Method*. Broadway Books, a division of Bantam Doubleday Dell Publishing Group Inc.

Tal Y. Segal E. & Lichtenfeld I. (2007). A Workshop based Approach to Risk Management . *The 14th Israeli Annual Symposium on Quality in Healthcare, Proceedings*, 2007

Tel Aviv University Medical School, CME. (2009). Risk Management As Means for promoting Patient Safety. http://medicine.tau.ac.il/index.php/cme/2009-04-23-09-04-59.

Tesch, R. (1990). *Qualitative Research: Analysis Types and Software Tools*. London: Falmer.

Thomas, E.J., & Helmreich, R.L. (2002). *Will Airline Safety Models Work in Medicine*. In M.M. Rosenthal, & K.M. Sutcliffe (Eds.). Medical Error - What do we know? What do we do? San Francisco, Ca: Jossey-Bass.

Troyer, G.T., & Salman, S.L. (Eds.) (1986). *Handbook of Health Care Risk Management*. Aspen Publications.

Tzabar Ben Yehoshua, N. (2001). *Introduction: The History of Qualitative Research, Influences and Trends* (In Hebrew).

Uhlig, P.N., Haan, C.K., Nason, A.K., et al. (2001, March 6). Improving patient care by the application of theory and practice. from the aviation safety community Presented at the *11th International Symposium on Aviation Psychology*. Columbus, OH.

VA, Veteran Affairs, Plans, (2000). No -Penalty Medical Error Reporting (2000, May 31) *New York Times*, p- A21

VA, Veteran Affairs. *PSRS. Patient Safety Reporting System* http://www.psrs.arc.nasa.gov/flashsite/programoverview/index.htm

Vesper, J.L. (2006). *An incomplete History of Risk Management* (Chapter1). In Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple. www.pda.org/bookstore.

Vincent, C.(2003, March). Understanding and Responding to Adverse Events. N *Engl. J. Med*., Vol. 348 (11),1051-1056.

Wanzel, K.R., Hamstra, S.J., Anastakis, D.J., Matsumoto, E.D., & Cusimano, M.D. (2002). Effect of visual-spatial ability on learning of spatially complex surgical skills. *Lancet*, 359, 230-1.

Wischik, D. The history of 'probability'. Statistical Laboratory, Cambridge. http://www.wischik.com/damon

Wilf-Miron, R. (1997, June). *Risk management division- Rationale of activity* (Internal document), Maccabi Medical care & Health fund, Head office.

Wilf-Miron, R. (1997). *Risk management in Macabbi – Background and Work plan*. (An internal presentation for the board of directors of Macabbi).

Wilf-Miron, R. (1997, July 13). *Risk management Division – Activities and Goals*. (An internal document addressed to CEO of Macabbi).

Wilf-Miron, R., Lewenhoff, I. (2001), *Preventing the Next Error: Risk Management in Maccabi Health Care Services* (Printed internally and distributed to all Maccabi's Physicians).

Wilf-Miron, R., Lewenhoff, I., Benyamini, Z. & Aviram, A. (2003). From Aviation to medicine: Applying Concepts of Aviation to Risk Management in Ambulatory Care. *Journal of Quality in Health Care* 2003;12:35-39 .

Wolcott, H. (1973). *The man in the principal's office*. New York : Holt, Reinhart & Winston.

Woods, P. (1979). *The divided school*. London : Routledge & Kegan Paul.

World Health Organization WHO. (2009). *Patient safety curriculum guide for medical schools*. www.who.int/patientsafety/education/medical_curriculum/en/index.html.

Wright, M.C., Taekman, J.M., & Endsley, M.R. (2004). Objective measures of situation awareness in a simulated medical environment. *Quality and Safety in Health Care*, 13(Supplement 1), i65- i71.

Yaakobi, R. (2009). *Medical Psychology: Interrelations between body and soul*. In IMA (Israel Medical Association). Medicine between the Lines (in Hebrew).

Youngberg, B. (Ed.) (1994). *The Risk Managers Desk Reference*. An Aspen Publication. AAP Association for Aviation Psychology, http:// www.avpsych.org.

Zaltman, G., & Duncan R. (1977). *Strategies for Planned Change*. New York : John Wiley & Sons.

Zohar, D. (1980). Safety climate in industrial organizations: theoretical and applied implications. *Journal of Applied Psychology*, 65, 96-102.

Zohar, D. (2003). Safety climate: Conceptual and measurement issues. In J. C. Campbell & L. E. Tetrick (Eds.). *Handbook of Occupational Health Psychology* (pp. 123- 142).

Appendix A: Healthcare Risk Management Organizations

Organization	Internet Address
Agency for Healthcare Research and Quality	www.ahcpr.gov
AMA National Patient Safety Foundation	www.npsf.org
American Society for Healthcare Risk Management	www.ashrm.org
American Society of Consultant Pharmacists	www.ascp.com
American Society of Health-system Pharmacists	www.ashp.org
Doctor Quality	www.doctorquality.com
Institute for Healthcare Improvement	www.ihi.org
Institute for Safe Medication Practices	www.ismp.org
Joint Commission on Accreditation of Healthcare Organizations	www.jcaho,org
Massachusetts Coalition for the Prevention of Medical Errors	www.mhalink.org
National Academy for State Health Policy	www.nashp.org
National Coalition on Health Care	www.nchc.org
National Council on Medication Error Reporting and Prevention	www.nccmerp.org
National Patient Safety Foundation	www.npsf.org
Partnership for Patient Safety	www.p4ps.com
Quality Interagency Coordination (QuIC) Task Force	www.quic.gov
The Advisory Board	www.advisory.com
The Free Medical Journals Site	www.freemedicaljournals.com
The Healthcare Safety Supersite	www.healthsafetyinfo.com
Today on Medscape	www.medscape.com
United States Pharmacopeia	www.usp.org