ANNEX VII

1. Case Registries in the USA

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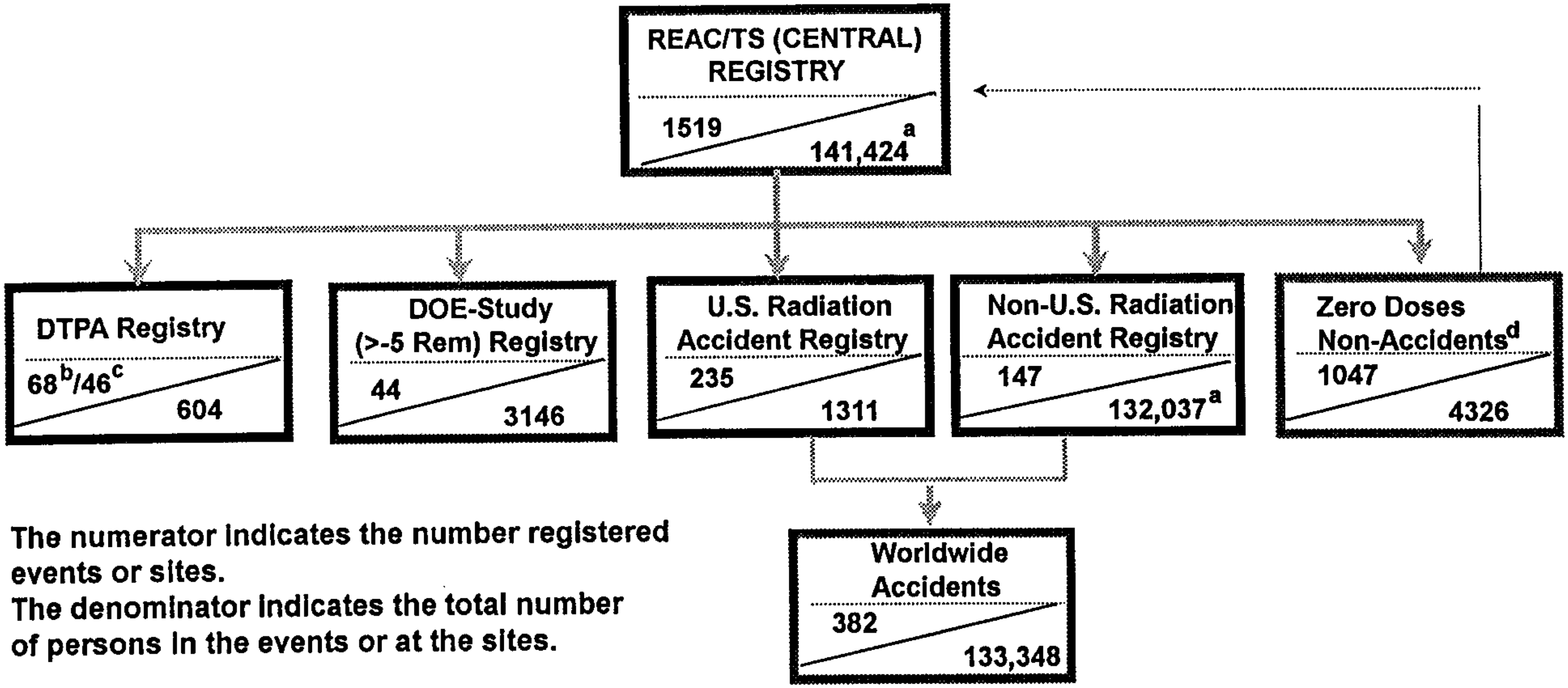
(Summary)

Serious radiation accidents worldwide are documented in the Radiation Accident Registry as part of the program of the Radiation Emergency Assistance Center/Training Site (REAC/TS). This database of medically important information forms a basis for follow-up of accident survivors, development of new therapeutic protocols, and generation of training materials for physicians, nurses, and health physicists. This Registry is updated quarterly and data accumulated through September 1995 is summarized as shown in the attachment.

REAC/TS continues to work with individuals at the national and international levels to expand the Registry database. In this regard, we have assisted the IAEA (Technical Committee, TCM850) in developing a computerized data questionnaire, "A reporting system to collect information on accident with radiation sources and devices and to disseminate it to member states and establishment of a registry database." In addition, the Oak Ridge Institute for Science and Education (ORISE), of which REAC/TS is a part, entered into an agreement (July 1995) with the Institute of Biophysics of the Russian Federation to provide funding for personnel at Hospital 6 in Moscow to encode acute radiation syndrome data for inclusion in the REAC/TS Registry.

STATUS OF REAC/TS REGISTRIES
SEPTEMBER 1995



The numerator indicates the number registered events or sites.
The denominator indicates the total number of persons in the events or at the sites.

a - Includes Chernobyl - 116,500; Brazil - 249; Mexico II - 4,000;
Kyshtym - 10,180; Spain - 27
b - Includes 22 former DTPA co-investigator sites
c - Co-investigators reporting
d - Worldwide

Source: Radiation Emergency Assistance Center/
Training Site Radiation Accident Registries

ORISE-MSD-REAC/TS

2. International Computerized Database

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1. Introduction

The medical management of the acute radiation syndrome (ARS) requires decision support for the following reasons. First, the few known case histories are dispersed over the world. In general, these case histories are not available in a certain hospital at a given time. Nonetheless, in complex medical domains it is useful to have access to comparable case histories. Secondly, due to the dispersed case histories clinical research on the ARS is difficult to pursue. Some 900 case histories of the acute radiation syndrome are available only world-wide. Thirdly, in general only in a few specialised centres knowledge about how to tackle the medical management problem is available.

By providing computerised decision aids the above mentioned problems will be overcome. The first step is formed by the collection of all available case histories in a standardised, comprehensive, and formalised way with a questionnaire. In a second step a database of case histories has been developed. This allows to identify and provide case histories similar to the case presently under treatment by a pattern of indicators. On the other hand, the database must be able to answer to scientific questions. The questionnaire has been named pre computer case report (PCR, Baranov 1995) since it can be filled in with a text processor and automatically be translated into database insert statements. The third step is the development of a knowledge-based assistance system which can serve as a guidance for a physician lacking expertise in ARS medical management in order to optimise the treatment. The stored case histories enable the evaluation and testing of the assistance system. Therefore, the three step development approach from a PCR via a database towards a knowledge-based assistance system will further enhance the quality of the medical management of rare diseases.

Comprehensive knowledge on the mid- and long-term health development of patients after acute radiation syndrome (ARS) is a neccessary condition for developing strategies to reduce, delay or prevent mid- and long-term neoplastic and non-neoplastic health consequences of patients surviving ARS.

A comprehensive and standardised documentation of follow-up examinations forms a basis for gaining new knowledge as well as reassessing the existining scientific consensus. In particular, it can help with the identification of the critical organ systems, of possible mid- and long-term health consequences, and of (early) indicators for these health consequences.

Consequently, newly gained evidence from a clinical database can increase the understanding of underlying pathophysiological processes and improve the existing recommendations for acute care (early prevention) as well as the recommendations for a sound follow-up strategy (monitoring, prevention and treatment). On the long run, this might help to reduce, delay or prevent mid- and long-term neoplastic and non-neoplastic health consequences of patients surviving ARS.

A clinical follow-up database for ARS patients is part of our integrated approach to patient evaluation. It provides a standardised comprehensive documentation of the health data in temporal sequence in English language. It enables us to bring together and share the clinical data from multiple centres involved in the follow-up of ARS cases. And, the use of sound standard database technology increases the availability for scientific analysis (increased accessibility, increased flexibility for queries, and rapid results).

The clinical follow-up database has been developed in co-operation with the Department of Consequences of Acute Radiation Injuries, Institute of Biophysics, Moscow, Russian Federation (N M. Nadejina, I.A. Galstian) and the Scientific Center of Radiation Medicine of Ukraine, Kiev, Ukraine (V.A. Bebeshko, D.A. Belyi).

2. Methodology

2.1 The Pre Computer Case Reports

While trying to increase the knowledge on the acute radiation syndrome a group of international experts (Baranov 1994) sensed the necessity of a database to store all the accessible case histories. Intense brain storming took place which lead to a first edition of the questionnaire. This PCR comprises a description of all organ systems affected by exposure to ionising radiation. Most critical to the overall prognosis are the haematopoietic system, the gastrointestinal tract, the skin, and the central nervous system. During the interactive design process to which the medical experts and computer scientists contributed the set of question types could be reduced thereby enhancing the clarity and precision of the PCR. That can primarily attributed to the fact that knowledge on the nature of medical data emerged. In principal, all clinical signs and symptoms can best be described by their respective names, their presence and if so by their duration, their maximum, and their degree in a 5 grade ordinal scale.

The "Questionnaire for Clinical, Laboratory and Functional Follow-Up of Radiation Exposed Persons" (Questionnaire) has been designed as a tool for comprehensive, structured, and standardised reporting of ARS follow-up examinations. The language used in the questionnaire is English and it defines a common terminological and conceptual standard for radiation exposure follow-up case histories.

The result was a comprehensive questionnaire (95 pages) for recording the anamnestic data since the last follow-up examination and the clinical status with the results of an follow-up examination.

The *Past Medical History* serves for recording information on the period either between the acute phase care and the first follow-up examination or between two follow-up examinations.

The Past Medical History includes

visits to physicians,
re-evaluation of accident radiation doses,
subsequent exposure to radiation or chemicals,
observed health problems,
occupational activities / living conditions,
a review of systems,
information on infections, long-term medication and present health problems, and
a subjective assessment of the quality of life and the physical condition given by the patient.

The *Clinical Status* part serves for recording information acquired during the follow-up examination. After a chapter focusing on general data you will find a repetitive set of questions for every organ system. The sets of questions have a unified structure:

System-oriented chapters (2 - 18):

- findings (physical examination),
- laboratory parameters,
- functional tests,
- diagnoses, and
- diagnostic procedure(s) that helped to establish each diagnosis.

The system-oriented chapters will be complemented by a statement of

- the functional status,
- the survival status,
- a summary on the reported follow-up examination, and
- additional observations.

In the *Annex* of the Questionnaire you will find:

- Lists for recording *repeated measures* such as
  - laboratory tests,
  - special examinations,
  - drug therapy, and
  - non drug therapy.

- A list for filling in the *reference values of laboratory tests* that are (were) applicable for the performing laboratory at the time of the reported follow-up examination. Since different laboratories use different reference values, we cannot give a standard list for this purpose.

- *Location Coding for Skin Disorders.*

- Definition of the *Karnofsky Score.*

- Old and new (= SI) *Units of measurement* in radiation medicine.

The Questionnaire has been tested by four centres. Shortcomings of former versions have been corrected in the final version. It is now used as a main tool for reporting the data from original patient records to the database.

2.2 The Relational Database

The first step of database design is the definition of a conceptual schema. The goal of designing the conceptual database schema is to model the data included in the questionnaire as much as a complete, consistent and coherent image of the reality can be created by filling data into the resulting database. This requires a sufficient understanding of the nature of the data to be included in the database, to find a model that covers the semantics of the data and the underlying medical concepts. The result of this interdisciplinary task was a data dictionary or conceptual database schema of the domain of the ARS. The largest part of this work was directly connected with the design of the questionnaires while some additional issues had to be considered due to the planned use of a relational database management system (RDBMS).

The purposes of the database for case histories of the acute radiation syndrome are twofold:

- to answer scientific questions and
- to rapidly provide case histories comparable to the case presently under treatment.

Relational databases are best apt for scientific evaluation since queries are not limited to previously set access paths. More so, they provide powerful join operations, which are essential for complex queries. The comparison of case histories is similar to a scientific query with multiple join operations. Case histories matching the initial course of the case under treatment are searched. The pattern is defined by medical considerations. Pathophysiologically based indicators are applied for the matching.

The fact that the follow-up examinations are repeated at regular time intervals and that multiple centres are included in the follow-up and the recording process required measures enabling the linkage of all data records belonging to one patient. The intra-centre linkage of repeated examinations could be established by the use of unique patient identifications and by disjoint sets of IDs for each centre. Since some patients where examined in two or even all three centres and due to the wish of bringing all these data together required another measure: a procedure for labelling each questionnaire with an ID of a shared list of codes. This measure allows to link together anonymised data.

At the physical database schema level the decision for an DBMS becomes relevant. Since we used SQL with its underlying relational data model, the options where among the available relational database management systems (RDBMS). The target system is Oracle 7.0, a sophisticated RDBMS.

Actual RDBMS support data security and privacy, access control by passwords, differentiated access rights to the data, multiple users, and automatic checking of integrity constraints. The latter feature helps to ensure plausibility and interpretability of the data stored in the database.

The database storing and managing the data reported by the help of the questionnaire has been developed according to the above described methodology. To make data entry easier and more comfortable computer forms were designed as an interface between the user and the relational database.

2.3 The Knowledge-Based Assistance System

A small number of experts is actually knowledgeable in the realm of the acute radiation syndrome. They have gained their expertise on a limited number of cases gathered over the decades. Therefore, it is of vital importance to collect and condense their experiences in form of a knowledge-based system, which in contrast to knowledge collected on paper can be tested against real cases. Moreover, the availability of their knowledge can be increased, thus, enabling less experienced physicians in remote places to optimally care for accidentially irradiated persons. A first demonstrator of a user-friendly assistance systems has already been developed (Kindler 91).

3. Population of the Database

Fig. 1 shows the state of the population of the database for the acute phase.

Case Histories not Recorded, yet	**Case Histories Recorded in the Paper PCR**	**Case Histories Partially to be Completed Recorded in the Data Base**	**Complete Case Histories Recorded in the Data Base**
from China	4 from Estonia	52 from Russia	154 Russia
from Russia		112 from Ukraine	104 from USA
from Japan		113 from USA	1 from Belgium
from USA			1 from Italy
from Brazil		**277 case histories**	1 from Japan
from Argentine			5 from China
from Mexico			1 from Israel
from Estonia			1 from Norway
from El Salvador			2 from Ukraine
from France			6 from Serbia
			264 case histories

Fig. 1: Current status of the population of the database for the acute phase.

Fig. 2 shows the state of the population of the follow-up database.

Follow-Up Data Available		
	patients	**exams.**
Ukraine	168	>1200
Russia	18	>350
Germany	14	~60
total	**199**	**>1600**

Follow-Up Questionnaires		
	patients	**exams.**
Ukraine	2	20
Russia	14	135
Germany	10	10
total		**165**

Included in Follow-Up Database		
	patients	**exams.**
Ukraine	2	20
Russia	9	69
Germany	0	0
total	**11**	**89**

Fig 2 Current status of the population of the database for the follow-up.

4. Research Questions to be Answered with the Database

What are reliable early indicators for the haemopoietic syndrome?
What are reliable early indicators of skin lesions?
What are reliable early indicators for the GIT syndrome?
What are early indicators of the CNS lesions?
What other organ systems are affected by radiation?
How do the lesions of the different organ systems interact?
What about combined injuries?
What are general therapeutic options in treating the acute radiation syndrome?
How must a database user interface for the comparison on case histories look like?
How can the knowledge, necessary to manage an acute radiation syndrome be put into a knowledge-based advisor?
In what way can pathophysiological explanations observed from alterations serve as a basis for future invention options?

5. International Regulations for the Usage of the Database

Many different international groups have contributed to the International Database, by designing the questionnaires, the database, the user interface, by providing case histories, and by providing funds. To satisfy the interests of all these groups a codex should be developed until the next REMPAN meeting regulating:

- the use of the database by scientists publishing results based on the database,
- the usage in emergency situations,
- the rights of the groups providing case histories,
- the rights of the groups developing the questionnaires and the database,
- the privacy of the patients,
- the funding of the groups maintaining the database and the software to access the software.

Such a codex must be internationally valid and accepted.

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3. Follow-up of Goiania Accident Cases

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(Summary)

In August 1990, several special *in vivo* measurements were performed on individuals internally contaminated during the Goiania radiological accident occurred in Goiania-GO, Brazil, September 1987. These subjects were measured using the Ge detector as well as a large NaI(Tl)8×4 detector. The primary purpose for the Ge measurements was to determine the location of any activity still remaining in any of the *wound* sites on the bodies of those persons who received radiation burns after rubbing the activity on themselves, as well as to obtain evidence concerning the distribution of Cs activity in the body at this late time following ingestion. Two of the subjects showed the presence of significant Cs activity still remaining in *wound* sites, as evidenced by detection of the ^{137m}Ba K x-rays from the decay of ^{137}Cs. Seven of the patients measured showed high levels of x-ray activity in the surface area above the liver. Measurement of these low energy x-rays (≈30 keV) from an organ as deep in the body as the liver indicates a significant amount of activity in that organ and also that Cs is probably not homogeneously distributed.

4. Long-term Follow-up of Atomic Bomb Survivors in Hiroshima and Nagasaki

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The Radiation Effects Research Foundation (RERF) and its predecessor, the Atomic Bomb Casualty Commission (ABCC) have been engaged in the long-term follow-up of a fixed cohort of survivors of the atomic bombings of Hiroshima and Nagasaki in 1945. This cohort study is known as the Life Span Study (LSS) and served as a principal source of epidemiological data for cancer risk assessment (1, 2).

Life Span Study sample

The LSS sample was constructed based on a nationwide survey of atomic bomb survivors conducted at the time of the 1950 National Census. This census enumerated about 284,000 survivors. The LSS cohort includes most survivors within 2.5 km of the bombings who lived in Hiroshima or Nagasaki in 1950 and who met certain conditions that were considered favorable for follow-up and a sample of survivors, comparable in size and matched by sex and age, who were within 2.5 - 10 km of the hypocenter. Roughly, half of the survivors within 2 km are included in the LSS, although this estimate is not precise The portion of the LSS cohort used in the latest analysis includes 86,500 survivors for whom radiation dose estimates are currently available. This represents 93% of all the survivors in the cohort, and consists of about 36,500 survivors with estimated doses less than 0.005 Sv (colon dose) and about 50,000 with estimated doses of 0.005 Sv or higher (a mean dose of 0.20 Sv).

Follow-up

Mortality follow-up starts in 1950. This is done through regular checks on the vital status of all cohort members using the Japanese family registration system known as koseki and obtaining data on causes of death recorded on death certificates. This method of follow-up provides virtually complete ascertainment of vital status and mortality data. Periodical analyses of mortality data in the LSS have resulted in a series of reports (3) Cancer incidence data are available for a subset of the LSS cohort from the Hiroshima and Nagasaki tumor registries which have been in operation since 1958. Recently, comprehensive reports of cancer incidence for this cohort have also been published (4,5,6,7). Currently, preparation is underway for publication of the latest report of the LSS mortality data through 1990. Follow-up results presented bellow are based on the latest mortality data through 1990.

Dosimetry

Individual dose estimates are based on information on distance from the hypocenter and shielding history obtained by personal interviews Since 1987, the DS86 system has been used for radiation dose estimation (8,9). This provides individual estimates of gamma-rays and neutron exposures (shielded kerma) and doses for 15 organs. The most resent analysis includes the latest version of the DS86 system, providing dose estimates of an additional 10,000 persons (unshielded distal survivors with very low doses and some Nagasaki factory workers with high exposures). The LSS data are characterized primarily by low LET gamma radiation, but exposures in Hiroshima include a non-negligible neutron component. To allow for a greater biological effect of neutron than gamma radiation, a weighted organ dose of the gamma dose plus 10 times the neutron dose is used.

Results to date

As shown in Table 1, more than 50% of the LSS sample members were alive as of 1990. By age at exposure, some 85% of the survivors exposed young in life (at ages less than 30 years) were still alive.

Table 1. Cohort survival by age at exposure

Age at exposure	People in 1950	Percent alive in 1990
0-9	17,824	94
10-19	17,557	86
20-29	10,882	77
30-39	12,270	51
40-49	13,489	16
50 +	14,550	1
Total	86,572	56

Solid cancers: To date, a total of 4,687 deaths from cancers other than leukemia have occurred in 50,000 survivors with significant exposures (>0.005 Sv) in the LSS cohort (Table 2). Of these, 341 or 7 percent are considered the excess deaths attributable to radiation. Most of the excess deaths in the survivors exposed as adults occurred before 1985. As a majority of these survivors are deceased, the follow-up is almost completed for this subgroup of the cohort For those exposed at ages less than 30 years, on the other hand, about half of the total excess deaths occurred in the last 5 years of follow-up, as these young survivors are beginning to enter into ages when naturally occurring cancer rates are increased.

Table 2. Cancer deaths among 50,000 A-bomb survivors with significant exposures. Life Span Study cohort, 1950-1990

	Total number of deaths	Estimated number of deaths due to radiation exposure	Percent of deaths attributable to radiation exposure
Leukemia	176	86	49%
Other types of cancer	4,687	341	7%
Total	4,863	427	9%

The long-term follow-up of this cohort population provides valuable data on temporal trends of cancer risk. The temporal pattern of solid cancer risk is dependent upon age at exposure (Figure 1). For those exposed as adults, the ERR of solid cancers has been found to be remarkably constant over the follow-up period. This also means that the excess absolute risk has increased over the entire follow-up period roughly in proportion to the increasing background risk as the survivors have aged. For those exposed as children, the ERR of solid cancers, which was especially high in the early years of follow-up, has begun to decrease in the more recent years. The absolute risks for the young survivors are relatively small as they are based on very low background rates at young ages

The ERR for solid cancer is also higher for women than men. However, in interpreting the sex difference in ERR, one must keep in mind that the background rates for men are at least twice as high as for women

Leukemia: Between 1950 and 1990, a total of 249 leukemia deaths occurred in 86,500 survivors in the LSS cohort. Of these, 86 are considered as excess deaths due to radiation, accounting for 49 percent of 176 leukemia deaths in those with significant exposures (Table 2).

Patterns of leukemia risk are very complex as they are highly dependent on both age at exposure and sex. The most important feature is that most of the excess leukemia deaths occurred in the early years of follow-up, especially in children. The overall leukemia risk has decline steadily over the years, although it still has not completely disappeared. Generally the excess relative risk (ERR) decreases with time (or attained age), but the rate of decrease in the risk is lower (or the decrease is less rapid) for those exposed at older ages. Also, the rate at which the risk declines with time seems less rapid for females than for males

Risk assessment

The LSS follow-up data have been one the major source of information in risk assessment used by various national and international agencies concerned with radiological protection. One of the most important sources of uncertainty in risk estimates is the projection that must be made from the incomplete follow-up. This is especially true for those exposed at young ages. Several projection models can be used to examine the effect of different assumptions about the future course of the solid cancer risk.

In the UNSCEAR 1994 Report, three models were used to project the lifetime risk that an individual would die from cancer (or leukemia) as a result of exposure to radiation (Table 3). In the first model, ERR is assumed constant throughout the lifetime of the survivors. This is a commonly used method but seems somewhat unreasonable since it is now clear that the ERR has been decreasing over the follow-up. In the second and third models, the ERR for the survivors who were less than 45 years old at exposure will decrease linearly starting 45 years after exposure but at different rates of decrease. The second and third models provide somewhat different risk values but there is little information at the present time for choosing between these two models.

The excess leukemia risk in the LSS occurred mostly in the early years of follow-up and appears to be decreasing for the youngest survivors. Therefore, there is no need to consider different projection models.

Table 3. Comparison of estimates of lifetime risk of mortality form solid cancers and leukemia following acute whole-body exposure to 1 Sv (from UNSCEAR 1994 Report)

Projection method	Lifetime risk in percent	Years lost risk per case
Solid cancers		
Constant relative risk[a]	10.9	11.6
Decline to risk for age at exposure 50[b]	9.2	12.3
Declines to zero risk at age 90 years[c]	7.5	13.3
Constant relative risk (UNSCEAR 1988)	9.7	11.4
Leukemia		
Linear-quadratic dose response model	1.1	31
Constant relative risk (UNSCEAR 1988)	1.0	26

[a] ERR constant from 10 years after exposure
[b] ERR constant for first 45 years after exposure, risk then decreases linearly with age. At attained age 90 years, the risk is equal to that for a person aged 50 years at exposure
[c] ERR constant for first 45 years after exposure; risk then decreases linearly with age. At attained age 90, the risk is equal to that for a person aged 50 years at exposure.

Conclusions

The LSS cohort data have provided unique opportunities for studying the nature and magnitude of risk associated with radiation exposure as it is affected by sex, age and time. The most important uncertainty at the present time relates to the temporal pattern of solid cancer risk of those survivors who were exposed early in life. The excess absolute risk for this group is increasing rapidly with advancing age. With nearly half of the excess deaths thus far having occurred during the last five years of follow-up, how the risk for this group of young survivors will behave in the future is one of the most important remaining questions. Although the patterns of leukemia risk are much more complex than those for solid cancers, most of the excess cases occurred in the early years of follow-up. There is much less uncertainty with respect to risk estimates for leukemia.

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Figure 1

Temporal patterns of solid cancer risk