Potassium Iodine Prophylaxis in Case of Nuclear Accident; Polish Experience

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INTRODUCTION

It is now established that both external and internal radiation can be tumorogenic for the thyroid [1,2]. Therefore, in case of radioiodines contamination, thyroid dose, especially in risk groups (pregnant and lactating women, newborns and children), should be kept as low as possible. The accumulation of radioiodines by the thyroid gland can be effectively decreased by administration of pharmacological dose of stable iodine [3,4], although prior to the Chernobyl accident such action aimed to protect the thyroids of large population was not undertaken. The aim of the present paper is to describe the objectives which led to the decision to implement potassium iodine (KI) prophylaxis in Poland in time of Chernobyl accident, and to present the model of prophylaxis and its effiacacy. The side effects of KI in different ages groups and the problems of cost-benefit of this protective measure will be also discussed. Part of these data presented were already published [5,6].

Radiological contamination in Poland following the Chernobyl accident and objectives for decision to implement KI prophylaxis

At the time of the accident, reliable information about its size and possible health consequences were not available from former Soviet Union authorities. In Poland increased air radioactivity and external radiation were first time identified on the night of April 27 and confirmed on April 28 by all Polish monitoring stations. Because of environmental findings in the whole country showing radiological contamination a governmental commission was called in the morning hours of April 29 to assess damage potential and if necessary to protect public health. The commission made several decisions. First, it accepted the scenario of the accident presented by members of the Center for Radiological Protection which stated that the accident was very serious and would lead to a prolonged release of radionuclides including radioiodines. Second, it recommended the following intervention levels:

(1) Whole body committed dose should nor exceed 5mSv
(2) Thyroid committed dose should nor exceed 50 mSv in children and 500 mSv in adults
(3) Thyroid content in children at any moment should not exceed 5700 Bq

Third, the commission defined the population at risk as about 11 million children and adolescents where thyroid uptakes of radioiodines might be higher due to relative iodine deficiency which was suspected in Polish diet.

At 10 AM on April 29, monitoring stations were reporting continuing and growing radiological contamination especially in eastern and central Poland. In the same time neck measurements taken in children at different ages showed, that in some of them, the thyroid content of 131-I was quite high. It was then concluded that at least in 11 Voivodoships (Provinces) the thyroid committed dose in children might well exceed the 50 mSv limit. It was realized that although some thyroid radioiodines uptake already occurred the gland should be protected against continuing radioiodine contamination coming from damaged Chernobyl power station reactor. At this moment Poland had no sufficient supply of KI tablets, however, the Central Pharmacy Organization (CEFARM) had stores of KI in substance sufficient to prepare the KI solution containing about 90 millions doses of 100 mg of KI each.

Potassium iodide prophylaxis in Poland

Evidence from literature [7] showed that mean effect of 70 mg of iodide is similar to that of 100 mg of iodide. The information about side effects of iodide, although they came from observation of small group of patients, suggested that intrathyroidal and extrathyroidal side effects might depend on the final dose of iodide [3,4]. Those, who proposed the final model of prophylaxis realized that total block of radioiodines uptake in Poland is not possible on April 29. On the other hand, it was realized that final burden to the thyroid gland should be reduced to the level which would be relatively safe in terms of possible tumorogenic effects of internal radiation. It was also expected that single dose of iodide would not lead to serious side effects. At noon hours of April 29 the Minister of Health ordered to prepare and distribute KI solution in all hospitals, public health care centers, drug stores, schools, kindergartens and so forth. The KI prophylaxis was mandatory to all under 16 years old and voluntary to all others. Pregnant and lactating women were advised to take prophylaxis. The following protocol was used: 15 mg of iodide for newborns, 50 mg for children 5 years or under and 70 mg for all others. The prophylaxis was first introduced in 11 eastern Voivodoships. On April 30 as the radiological situation further deteriorated, the prophylaxis was ordered to be country-wide It was also decided that a second dose of KI would be distributed if radiological contamination in air would continue to be high. Fortunately, by May 3 air contamination had decreased at least fourfold and in the next days further reduction of radioactivity was observed therefore distribution of a second dose of KI was postponed.

Thyroid committed doses in Poland, efficacy of KI prophylaxis and adverse reactions

In December 1986 a research follow-up programme coded MZ-XVII was approved. This population studies had the following main objectives:

1. To estimate thyroid 131-I committed doses in children and adults living in different regions of Poland and to investigate possible effects of thyroid irradiation;
2. To evaluate the degree of thyroid protection achieved by KI administration and by other protective measures and to obtain estimates of the incidence of intrathyroidal and extrathyroidal side effects of single dose of KI in newborns, children and adults;
3. To evaluate thyroid function of newborns who were exposed to the radiation and KI administration while *in utero* or soon after delivery;
4. To evaluate possible detrimental effects of single dose of KI on subjects with past history of thyroid disorders.

The MZ-XVII programme (1987-1990) was described in detail elsewhere [5,6] Briefly 52,092 randomly selected persons were questioned and 34,391 completed medical and laboratory investigations. The sample represented approximately 0.09% of the population of Poland and its distribution (age, sex, living in towns and villages) was typical for the country as a whole. In addition, in the middle of 1997 we started A second research programme coded PBZ-38-08 and aimed to reexamine the same sample which had been studied under THE MZ-XVII programme. Although the PBZ-38-08 programme will come to the end in 1999, the thyroid dose reconstruction which used the results of population study on iodine intake in diet was already completed in eastern part of Poland.

As previously described in detail [5,6], thyroid burden was evaluated by both the direct method and by an indirect method based on 5 compartmental models of iodine metabolism developed by Johnson [8]. The maximal 131-I thyroid committed doses (without KI prophylaxis) in 12 highly contaminated provinces for children < 1 year old, < 2-5 years, < 6-10 years and adults were 136.2 mSv, 69.4 mSv, 55.1mSv and 30.8 mSv, respectively. These preliminary data on thyroid dose reconstruction suggests also that about 17% of children of all age groups who reached maximal thyroid doses all exceeded 50 mSv limit without protective action. The thyroid maximal doses in the remaining provinces of Poland where radioactive contamination was estimated as average or mild in all age groups were below 50 mSv. However it should be added that in all Poland there were a number of "hot spots" wherein the thyroid doses could have been 6-10 times that of the surrounding areas. More comprehensive results of thyroid committed dose reconstruction will soon be available.

It has been estimated [5,6] that approximately 95.3% of Polish children (about 10.5 million) and 23.2% of adolescents (above 16 years old) and adults (7.5 million) took potassium iodide dose. In 12 provinces where KI prophylaxis was ordered on April 29, the bulk of KI distribution occurred during the next two days. In areas bordering former Soviet Union almost 75% of children were given KI within the first 24 hours of the prophylactics. In the remaining provinces where KI protective action was ordered on April 30, the bulk of children received potassium iodide on May 2. In Ostroleka province where the thyroid burden and the efficacy of single dose of KI were investigated by direct method [5] the dose reduction in subjects who took prophylaxis on April 29 was estimated to be 45% and in those who took KI on April 30 to be 41%. On the basis of indirect method it was assumed that KI dose given on April 29 reduced thyroid burden by about 40% and KI given on April 25 by about 25%. If there were prompt warning from former Soviet Union and if KI prophylaxis were implemented in Poland on April 27 the thyroid radioiodines committed dose reduction would have been close to 67%[5].

The acute and transient intrathyroidal side effects of a single dose of KI were seen only in 0.37% of newborns who received prophylaxis on the second day of life [5,6]. The mild increase of serum TSH and decrease of serum FT4 disappeared after 10 days without treatment. This transient Wolff-Chaikoff phenomenon was without effect on further development of these children and on their thyroid status as examined in the 3rd year of life. Although re-examination of these children in their 10th year of life is not yet completed the preliminary results suggest that neither thyroid irradiation nor KI given on the second day of life affected the function of their thyroid gland. The single dose of KI was without effect upon the course of thyroid diseases in those with the history of thyroid pathology [5].

As previously described [5,6] the number of extrathyroidal side effects after the single dose of KI were more common than could be expected. These reactions were identified in about 4.6% of children and about 4.5% of adolescents and adults. All of these adverse reactions were of hypersensitivity type and all were mild and transient. As estimated [5,6], majority of these reactions disappeared without medical assistance. In addition, acute respiratory distress developed in two adults with chronic obstructive lung disease and well documented allergy to iodides who regardless of this allergy decided to take KI dose. They were cured by hydrocortisone administration.

CONCLUSION

At the time of the Chernobyl accident there was no international agreement on early warning in case of nuclear accident, such regulations, however, are now in place. Therefore it should be expected that if a severe nuclear accident happens, with a risk for public health, KI prophylaxis would be if needed introduced very early. The present evidence [9,10] that even low thyroid doses of radioiodines can lead to thyroid cancer in children, strongly support the need for such protective action for pregnant and lactating women and for children. It also suggests that intervention levels for these risk groups should be lower than previously established. The Polish experience showed that even in the absence of KI tablets protective action (KI solution) can be quite efficiently implemented. As KI tablets at present available have long shelf-time their predistribution seems to be a crucial issue for most effective prophylaxis in case of nuclear accident. In conclusion, it is suggested that the decision to block the thyroid uptake or to reduce final committed thyroid dose of radioiodines depend on the evaluation of radiological contamination, size of population at risk, approved intervention levels and preparedness.

We proved that even a single dose of KI can significantly reduce final thyroid burden and that a single dose of KI is a safe procedure.

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Emergency Response after the Chernobyl Accident in Belarus: Lessons Learned

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INTRODUCTION

The Chernobyl accident is one of the most dramatic reactor accidents that affected different countries and millions of people. Belarus is one of the most contaminated countries due to this accident. Twenty three percent of the entire area of Belarus was contaminated with the long-lived radionuclides with different levels of contamination density.

During about 12 years of the post-accident period, radiation protection of the population of Belarus has been one of the crucial problems aimed at reducing the exposure doses and risk of radiation induced effects. Different protective actions with various levels of effectiveness have been performed during all phases of the accident.

DISCUSSION

At the early phase of the accident, evacuation of about 24,700 people was performed. This measure allows to prevent deterministic health effects among the Belarusian population. At the intermediate and late phases of the accident, about 130,000 of people were relocated. At present, average annual doses for the majority of the inhabitants of settlements located on the contaminated territories do not exceed 5 mSv. Of 2,2 million of Belarusian inhabitants, who were exposed in 1986, less than 300,000 people now receive annual doses in the range of 1-5 mSv. The maintenance of doses at such low levels has become possible due to conduction and maintenance of a number of protective measures. To restrict the internal exposure, the following protective actions were carried out: establishment of permissible levels for radioactive contamination of foodstuffs, conduction of regular control of foodstuffs contamination and a wide range of agricultural protective measures.

One of the most important experience that was obtained, based on the analysis of the effectiveness for different types of the carried out intervention, is connected with the protection of the thyroid gland. After the Chernobyl accident, the majority of Belarusian territory was contaminated with I-131. In five out of 6 regions of Belarus, density of contamination with I-131 ranged from 0.4 to 37 MBq/sq.m. The highest levels of contamination density were registered on the territories closest to the NPP (southern part of Belarus). The contamination decreased with the distance from the NPP.

Because of late warning of the population and incompleteness of measurements for thyroid protection, significant doses were formed to the thyroid glands of Belarusian people. According to the recent estimation, the collective thyroid dose for all population of Belarus is 510,000 person-Sv.[1] This estimation takes into account only doses from ingestion of I-131 and does not count short-lived isotopes of iodine, as well as inhalation of I-131. Children up to 6 years old who lived in the south part of Belarus, received highest thyroid doses. Exposure from I-131 developed conditions for thyroid stochastic consequences among the exposed population.

The level of the thyroid cancer incidence in Belarus before the Chernobyl accident (1971-1985) was low for children (0.04 per 100,000 children population annually) and relatively higher for adults (0.3-2.5 per 100,000 population for men and 1.2-3.9 per 100,000 population for women).[2]

After the accident, the thyroid cancer incidence started to increase and since 1990, the significant increase of the incidence rate among the exposed children was registered. Among children and adolescents who were under 18 years of age in 1986, the incidence rate of thyroid cancer was: 1.15 per 100,000 in 1990; 2.7 per 100,000 in 1991; 3.17 per 100,000 in 1994; 5.0 per 100,000 in 1995; 4.63 per 100,000 in 1996.[3] Similar increase in the incidence was observed among the exposed children of Ukraine and Russia.[3,4,5]

Specialists attribute the increased rate of thyroid cancer to the development of radiation-induced excess cases. Nevertheless, there are some aspects that are still not well known now: effectiveness of internal exposure of I-131 in comparison with external gamma- and X-ray exposure; role of short-lived isotopes of I and Te in the induction of thyroid cancer; role of non-radiation factors in carcinogenesis (iodine deficiency, genetical predisposition, use of stable iodine in 1986, chemical environmental pollutants, endemic disorders of the thyroid that are characteristic for some regions of Belarus, Russia and Ukraine).

The comparative analysis of dose levels for thyroid exposure of different cohorts shows that absolute risk of radiation-induced thyroid cancer after external gamma- or X-ray exposure may be close to the absolute risk of such cancer due to internal I-131 exposure after the Chernobyl accident (Table 1).

Table 1. Absolute risk of excess thyroid cancer after external gamma- or X-ray exposure and due to internal I-131 exposure after the Chernobyl accident

Study	Number of investigated subjects	Age of exposure (years)	Average thyroid dose (Gy)	Absolute risk per 10^4 (PYGy)
A-bomb survivors [6,7]	13000	<15	0.23	2.7
Tinea capitis [8]	10834	<15	0.09	7.6
Pooled analysis of seven studies [7]	120000	all ages	0.09-12.5	4.4
Exposed children of Belarus, Russia, Ukraine [4]	2328000	<14	0.05-0.92	2.3
Exposed children of Belarus [3]	500347	<6	0.23	4.5

Although the risk values are relatively close, these levels were obtained for cohorts of different age groups. The data of the table shows that the question is under investigation, but because of different uncertainties that still exist, the investigations have to be continued.

Recent studies conducted in Belarus try to find the influence of non-radiation factors on the excess of thyroid cancer among the exposed persons. The comparison of iodine excretion level with urine for the regions where the persons with thyroid cancer are living, does not allow to find the relationship between the thyroid cancer and the level of iodine deficiency that is investigated using this method. It is important to take into account that such investigation of iodine excretion with urine was not performed before the Chernobyl accident. There are no consistent data to be compared. Because of that, it is difficult to estimate the real role of iodine deficiency in the increase of thyroid cancer incidence.

Estimation of thyroid doses brings a significant contribution to the uncertainty of risk assessment. For 1.4 % of the Belarusian population of 0-18 years of age, the dose estimation is based on the results of the direct measurements that were performed in 1986. For the rest of the cohort of this age group (2,683,621 persons), the dose estimation is carried out using different methods of dose reconstruction based on radioecological models with high level of uncertainty.

Possibly, different thyroid disorders (goiter, hyperplasia, etc.) that existed before the accident, could also contribute to the total uncertainty of thyroid dose estimation. Dose models are based on biokinetic models and peculiarities of the exposure for normal thyroid tissues of a reference healthy man. There are no dose models for the thyroid that take into account the changes in thyroid volume, functional conditions, the presence of nodules, etc.
After the Chernobyl accident, a significant increase in thyroid cancer among the exposed population and, in particular, among the exposed children was registered. The level of this increase is correlated with doses of exposure within some limits. However, for the correct risk assessment of radiation-induced thyroid cancer, the investigation should be continued.

CONCLUSION

Radiation-induced thyroid cancer is one of the Chernobyl lessons that should be summarized and learned for the purpose of its effective use for protection of people in the case of potential future radiological emergencies.

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Session F, Track 1: Clean-Up Levels

Friday, September 11, 1998
8:00 a.m. - 9:50 a.m.

Chair: Craig Conklin, United States Environmental Protection Agency

Philosophical Challenges to the Establishment Of Reasonable Clean-up Levels

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INTRODUCTION

Limitation of low-level radiation as applied to such issues as projected waste storage, decontamination and decommissioning of nuclear facilities, and in many cases, with the cleanup of contaminated land, can be considered to be properly within the classical system of dose limitation recommended by the ICRP and the NCRP. In these cases, the exposure comes about as the result of the deliberate introduction of a source of radiation with consequences which can be reasonably expected. For example, the decision on waste storage is justified on the basis of justifying the practice which led to the generation of the waste. This is a decision which does not rest with radiation protection issues alone. Clearly, society, commercial interests, and government all participate in such decisions, either by legislative decree or by Federal and State regulation. This is the first principle in the three-part system of dose limitation.

The second principle is related to reducing exposures to as low as reasonably achievable (ALARA), economic and social considerations included. This is a radiation protection issue, and one which will be addressed.

The third element in the system of dose limitation is the system of establishing dose limits for both individual workers and for members of the public. Perhaps the greatest driving force for establishing limits is the need to insure that individuals or groups of individuals are not placed in the position of receiving an inordinately high exposure simply because the collective dose is low. In addition, ALARA considerations may establish the acceptability of a given radiation source, whereas the individual may be exposed to many such sources.

DISCUSSION

For emergencies, the situation is inherently different. Here the exposure is unplanned, and for many scenarios, unexpected. The exposure exists simply as a result of the event having taken place, and the system of dose limitation cannot embody the classical justification step since the exposure is already taking place. What then are the appropriate parts of the dose limitation system that should be applied in the event of an accidental release of radioactive material?

The concepts inherent in the dose limitation system as it applies to introducing a practice are somewhat reversed. The first order of business is to keep individual exposures below the threshold of serious deterministic effects and prevent any unacceptably high risks of stochastic effects in individuals. When exposures are at these levels, action to prevent individual exposures will be obviously necessary. For example, whole-body absorbed dose rates in excess of a tenth of a Gy (10 rads) per month fall into this category. Since, as pointed out above, the justification step doesn't make sense when dealing with an emergency, a simple objective is in order. For exposures resulting from emergencies, ***simply do more good than harm.*** Sounds simple, but of course it isn't. Let's look at one particularly formidable aspect of the detriment associated with any exposure -- anxiety.

"Anxiety" can be associated with a decision not to take an action to reduce exposure by virtue of both reasonable and unreasonable concerns about perceived risk. On the other hand, once the decision maker decides to take an aggressive approach to reducing exposure, the affected public will likewise respond with anxiety. For example, the anecdotal evidence from the former Soviet Union indicates severe psychological stress related to the Chernobyl accident when actions were taken. The Three Mile Island experience suggests that among those for whom emergency actions were not imposed there was also severe psychological stress. Public anxiety over low-level radiation is perhaps the most difficult issue which the decision-maker must address in trying to establish an acceptable and workable approach to handing radiation exposure issues that must be made in the event of a radiological emergency. As a result, decisions are often made on the basis of perceived risks rather than the actual risks related to exposure.

Returning to ALARA (optimization), the second element in the system of dose limitation, the application to an emergency situation is also somewhat different from that applied to introduction of a new practice. Here, we must focus on insuring that each protective measure is evaluated to determine how far the action should be taken based on balancing the cost of the action such that the net benefit from such action is maximized.

The third element -- establishment of a dose limit -- is perhaps the most difficult in that the system of dose limitation for accidents brings us to the establishment of an action level, as mentioned above. For the emergency situation, the source of exposure already exists, and the derivation of an exposure limit must be related to the basic concept of deriving the level where the action will do more good than harm. Perhaps a review of the ICRP's thoughts related to intervention are in order here.

From ICRP Publication 63,[1] "Principles for Intervention for Protection of the Public in a Radiological Emergency," we find Figure 1. We assume that the accident or event has resulted in widespread contamination which will deliver the exposure as depicted in the smooth curve shown in the figure. The ICRP refers to this dose as the projected dose. It is the dose that would be received if no action is taken. The objective in intervening is to intercede so as to eliminate a fraction of the projected dose. That is called the averted dose. It is also clear from this figure that the duration of the intervention is important. However, the relative effectiveness of any intervention decreases with time (i.e., with dose rate). One of the truisms in these decisions is that the cost of introducing some action is quite great, while continuing it is considerably less. Rather than to get into a detailed analysis of how intervention is determined, I would again refer you to ICRP's Publication 63. Table 3 from that report, shown below, introduces some recommended intervention levels.

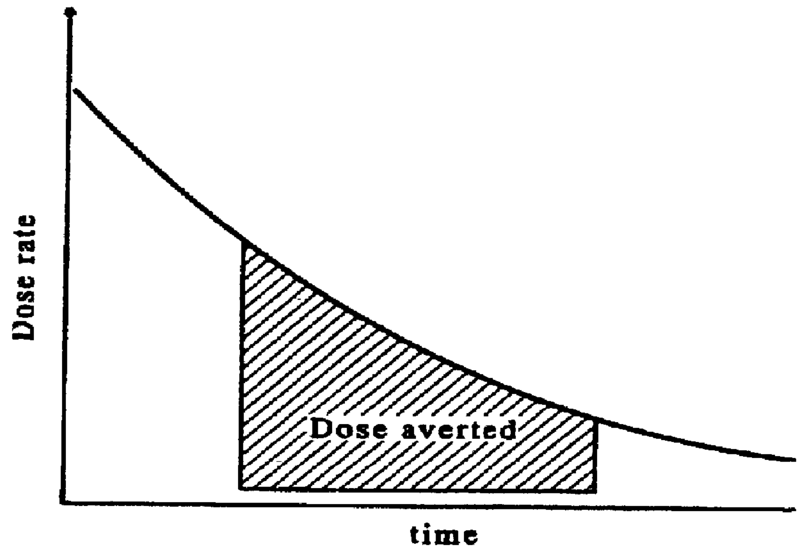

Fig. 1. Effect of intervention in averting dose.

Table 3. Summary of recommended intervention levels*

Type of intervention	Intervention level of averted dose (mSv)	
	Almost always justified	Range of optimised values
Sheltering	50	Not more than a factor of 10 lower than the justified value
Administration of stable iodine – equivalent dose to thyroid	500	
Evacuation (< 1 week) — whole body dose —equivalent dose to skin	5005000	
Relocation	1000	5-15 mSv per month for prolonged exposure
Restriction to a single foodstuff	10 (in 1 year)	1,000-10,000 Bq kg^{-1} (beta/gamma emitters) 10-100 Bq kg^{-1} (alpha emitters)

*Taken from ICRP Publication 63.

The table and the magnitude of the values in it, brings us to my main objective. Fundamentally, that position is that we cannot use the radiation levels like .15 mSv/y (15 mrem/y), or .25 mSv/y (25 mrem/y), or even 1 mSv (100 mrem/y) as our basis for planning the response to radiation emergencies.

The primary difficulty in establishing reasonable action levels is the extraordinary emphasis placed on low dose effects. EPA and NRC are in open disagreement on a clean-up level of 15 or 25 mrem, respectively. This is, perhaps, appropriate when someone has clear responsibilities for paying for remediation (i.e., you degrade the environment, you pay).

Now let us suppose that there is widespread contamination of prime real estate resulting from terrorist events. Let us further suppose that the individual dose will range between .1 mSv and 1 mSv (10 and 100 mrem) per year for seventy years. Using the concepts behind the EPA-suggested 15 mrem, we find the maximumly exposed individual will receive 100 mrem x 70 years - 7 rem or 70 mSv. The individual's fatal cancer risk will be approximately 7 rem x 5 x 10^{-4}/rem or 3.5 x 10^{-3}. Since this exceeds EPA guidance that the public should incur risks of no more than 1 x 10^{-4} to 1 x 10^{-6} fatal cancer risk in a lifetime, it would seem that the residents of our expensive real estate will have to abandon their homes. This would be accompanied with widespread fear and concern by the people who will expect the regulators and the politicians to correct his horrendous health effect.

CONCLUSION

But let us remember that the several million residents of Denver, Colorado, already have faced the same risk from their exposure to an increment of natural background just about that much greater than the exposure to natural background here in Washington. They even build nurseries for little children in Denver. How crass; how careless. Where are the regulators, the public health officials, and the politicians?

My point is that we have created a conundrum of a problem not related to our assumption of linearity but a perception that small risks resulting from radiation exposure are somehow different dependent upon the origin at the exposure. My plea here is to emphasize that we develop a system of action levels that reflect the important differences between emergency response and regulating existing practices.

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