WORKSHOP ON STABLE IODINE PROPHYLAXIS AFTER NUCLEAR ACCIDENTS

Report on a WHO Workshop

Helsinki, Finland
17–19 September 2000
ABSTRACT

In December 1999 WHO issued updated Guidelines on Stable Iodine Prophylaxis after Nuclear Accidents, drawing on new evidence arising from the Chernobyl accident. The Workshop consisted of several presentations on the evidence underpinning the Guidelines and extensive discussion by the participants, who were all responsible at country level for implementing measures to mitigate exposure after nuclear accidents.

The discussions particularly stressed the practical aspects of implementing stable iodine prophylaxis in the way recommended, namely with emphasis on protecting the health of children over much wider areas than the Emergency Planning Zones. The problems encountered vary from one country to another, and so little general guidance could be provided in the Guidelines. These discussions led to a number of recommendations to be followed up by WHO.

Keywords

IODINE – therapeutic use
RADIATION INJURIES – prevention and control
DISASTER PLANNING
THYROID GLAND – Physiology
GUIDELINES
EUROPE
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Scope and purpose

In 1989 WHO’s Regional Office for Europe issued advice on the use of stable iodine\(^1\) to block the uptake of radioactive iodine in the event of nuclear accidents. This was before the marked increase in thyroid cancer in Belarus was recognized, and before the results of a nationwide distribution of stable iodine in Poland following the Chernobyl accident had been assessed.

The incidence of childhood thyroid cancer in the most affected countries, namely Belarus, the Russian Federation and Ukraine, proved to be more widely distributed and more marked than anticipated. It was also the case that in Poland, following the distribution of some 15 million doses of stable iodine (10.5 million of which were administered to children), serious side effects were not significant. On the basis of these observations and a thorough and extensive review of the relevant literature, WHO issued *Guidelines for Iodine Prophylaxis following Nuclear Accident, Update 1999*.

The workshop will be the setting for a comprehensive presentation of the guidelines by the WHO consultants involved in their preparation (day one), followed by extensive discussion, including consideration of issues related to practical implementation of the recommendations (day two). This workshop is therefore most suitable for those who have responsibility for nuclear emergency preparedness at national level, including WHO’s national public health advisers.

**Presentations**

**Historical introduction to the Guidelines**

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In 1989 the WHO Regional Office for Europe issued the first Guidelines on stable iodine prophylaxis following nuclear accidents as part of its follow-up to the Chernobyl accident. This was some two years before the first reports of an increase in the incidence of childhood thyroid cancer in Belarus. As the full extent, both in terms of numbers of cases and their wide geographical distribution (cases were observed up to 500 km from the Chernobyl NPP), became apparent consideration was given to revising the Guidelines. In 1993 publication of the results of a follow-up of the children given stable iodine in Poland immediately following the Chernobyl accident further confirmed the very low risks associated with the administration of a single dose of stable iodine to children. In 1995 an informal working group appointed two consultants to draft a revised version of the Guidelines.

In 1997 it was agreed that the revision should be a global document, jointly co-sponsored by WHO and the International Atomic Energy Agency (IAEA). Accordingly a joint WHO/IAEA secretariat was appointed. During 1998 the draft revision was sent to several experts nominated by WHO and the IAEA and comments considered at a joint meeting of WHO and IAEA with the consultant authors. In September 1998, the draft was finalized by an expert group (individuals nominated by the four Regional Thyroid Associations on the behalf of WHO, and by the IAEA).

In 1999 three of the four Regional Thyroid Associations endorsed the document. Also in 1999 the IAEA requested its advisory committee, the Radiation Safety Standards Advisory Committee (RASSAC), to advise on IAEA’s co-sponsorship of the document. On the advice of RASSAC the IAEA withdrew from co-sponsorship of the “1999 Update”, which was then issued by WHO in December 1999.

In August 2000 the IAEA sought the comments of the States Parties to the Convention on Assistance in Nuclear Emergencies on the “1999 Update”. These comments will be discussed at a joint meeting of the WHO and IAEA in January 2001.

The “1999 Update” contains four essential changes from the 1989 recommendations as follows:

- The concepts of “near” and “far” fields are dropped.
- The importance of the impact of the Chernobyl accident on the risks of radioiodine exposure and of the Polish experience on the risks of stable iodine administration recognized.
- Reference levels for different age groups to take account of differing sensitivities in to radioactive and stable iodine recommended.
- The care that needs to be taken with respect to contraindications for stable iodine is emphasized.
The “1999 Update” is presented as the best expert evaluation of the available evidence on the public health implications of the application of stable iodine to reduce the uptake of radioactive iodine following a nuclear accident. As is usual with “WHO Guidelines” their value rests on the contributing expertise independent of interests other than the public health.

**WHO Guidelines for Iodine Prophylaxis following Nuclear Accidents**

*Dr Wendla Paile*

_Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland_

The Guidelines are intended for emergency planners, civil defence staff, public health authorities and medical personnel. Updated information is given for different population groups concerning benefits and risks from stable iodine prophylaxis, dosage, side effects and contraindications. Practical advice is given concerning storage and distribution of stable iodine, with the aim to facilitate planning of iodine prophylaxis in case of a major nuclear accident.

The very high sensitivity for cancer induction in small children, the higher thyroid doses caused by radioiodine in small children as compared to others, the low cancer sensitivity in older age groups and the higher risk for side effects in elderly people altogether indicates that different intervention levels should be applied for different groups. Thyroid doses to small children should be kept as low as reasonably achievable. The very low risk for serious side effects in children implies that only social and economical costs need to be considered when deciding on the proper intervention level. Although intervention levels are for national authorities to decide, the latest information suggests that stable iodine prophylaxis be considered for children at 10 mGy thyroid dose, that is 1/10th of the generic intervention level expressed in the _International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources_ (BSS). Even at this low dose level, a recognizable increase in childhood thyroid carcinoma may appear within a few years, if the exposed population is big enough, and after such exposure any case of thyroid carcinoma appearing during childhood is most probably due to the exposure.

For young adults, although a real risk for thyroid carcinoma after radiation exposure has not been scientifically established, prudence argues in favour of adopting the generic intervention level. For adults over 40, the scientific evidence suggests that stable iodine not be recommended, unless doses to the thyroid are expected to exceed the threshold for deterministic effects.

The balance of risks and benefits suggests that stockpiling of stable iodine is warranted over much wider areas than are normally encompassed by emergency planning zones and that the opportunity for voluntary purchase be part of national plans.

Before they were issued, the Guidelines were evaluated by a wide range of independent experts. They have been endorsed by three out of four regional thyroid associations. IAEA has been involved in the preparation but has withdrawn from co-sponsoring the document at a late stage, although consensus on the contents had been reached on the expert level. It was agreed between experts from IAEA and WHO that the Guidelines are not to be seen as conflicting with the BSS, which were adopted in 1996, before the high risk for thyroid cancer in children was universally acknowledged. In the BSS it is explicitly stated that intervention levels may be higher or lower than the generic levels, depending on the presence of sensitive groups. This statement makes it possible to adopt the new WHO Guidelines without undertaking a formal change of the BSS.
Iodine prophylaxis in nuclear emergency response

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In emergencies involving a release to the environment of radioactive iodine there is a need for rapid response in order to prevent or mitigate exposure of human beings. Such measures include evacuation, sheltering and food controls as well as iodine prophylaxis. The optimum response will often involve the combined use of these countermeasures.

Precautionary evacuation will pre-empt the need for iodine prophylaxis. Evacuation will be decided upon primarily on the basis of plant conditions and meteorological data. However, persons to be evacuated may be exposed to the radioactive cloud before the start of evacuation or during transport.

Inhalation of radioactive iodine from a passing cloud will be reduced to some degree by sheltering indoors with closed windows and any forced ventilation shut off, but sheltering is by no means completely effective in avoiding inhalation dose.

Sheltering indoors in ordinary houses is a primary protective action and it is relatively simple and fast to implement. If instructions are given to the public to take pre-distributed iodine tablets, this applies equally to persons sheltering indoors.

Even where pre-distribution is not undertaken, combined implementation of iodine prophylaxis and sheltering may be planned. Iodine tablets will then be delivered from various storage places, when the predicted avertable dose to the thyroid exceeds the reference levels for iodine prophylaxis given in the Guidelines (cf. section 5).

There may also be a situation where sheltering is not warranted based on the effective dose averted, whereas the averted thyroid dose approaches the reference levels. In such a situation, combined sheltering and iodine prophylaxis would also be the right decision.

For protection against internal exposure through ingestion, it is generally stated that appropriate control of foodstuffs is preferable to the use of iodine prophylaxis. The dose reduction achieved through a single administration of stable iodine would not be as effective as in the case of inhalation.

Milk is usually the most important ingestion pathway for exposure to iodine-131. In some circumstances, it may be foreseen that the rapid distribution of uncontaminated milk cannot be arranged or planned. This will cause detriment because milk is an essential nutrient for infants and young children. In that case, a daily dose of stable iodine may be given for the time period needed, to those children who show no adverse reaction. However, repeated administration should not be given to neonates (nor to pregnant or lactating women).

The new Guidelines did away with the concepts of the “near field” and “far field” in planning because a sharp distinction in planning requirements was considered impractical. The Chernobyl accident demonstrated that in severe accidents significant doses from radioactive iodine can occur hundreds of kilometres from the accident site, beyond emergency planning zones for evacuation and sheltering.
However, it can be stated with certainty that thyroid doses large enough to cause deterministic effects (hypothyroidism and acute thyroiditis) can be incurred only near the accident site. When doses causing deterministic effects are predicted, iodine prophylaxis should be extended also to adults over 40 years of age.

As there is only limited time for implementation of iodine prophylaxis, prompt availability of the tablets to individuals has to be ensured, if they are to be at their most effective. In the new Guidelines, national authorities are advised that voluntary purchase of iodine tablets by the general public should be allowed.

In the vicinity of nuclear reactors, predistribution to households should be seriously considered, with provision for storage in places that can be controlled by the responsible authorities. Clear instructions should accompany the tablets and the public’s awareness of the procedures should be monitored on a regular basis.

Where predistribution to households is not considered feasible, stocks of stable iodine should be stored strategically at e.g. schools, hospitals, pharmacies, fire stations, police stations, civil defence centres, etc.

Planning should consider the use of redundant distribution areas to minimise delays in implementing iodine prophylaxis. The responsibility for distribution of stable iodine shall be clearly assigned to the appropriate authorities.

The experience of Poland after the Chernobyl accident

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Summary

I am sure that all of us remember the accident at the Chernobyl Nuclear Power Plant which took place on 26 April 1986 at 1.23 a.m. In Poland the evolution of the situation was following.

During the night of 27 to 28 April about 1/3 of the territory of Poland was contaminated with radioactive elements, mostly radioactive iodine and caesium.

With this moment the Special State Committee was established for the evaluation of the situation and undertaking necessary decisions for protecting our country population.

The first decision was to prevent the contamination of the thyroid gland in children and teenagers. The acceptable intervention level of radioiodine accumulation was 50 mSv and our obligation was to do everything to prevent higher contamination. This 50 mSv level was very rigorous but our assumption had a chance to be successful. As we know the stable potassium iodide will block the accumulation of radioactive iodine in thyroid gland after its ingestion or inhalation to the human body for next 24 or even 48 hours and will significantly reduce its accumulation after 48 hours.

To achieve that in early contaminated regions of north and south Poland it was decided to give the stable iodine in one prophylactic dose to children and teenagers. The preparation chosen was the potassium iodide in the quantity of 15—60 mg, dependently of the age of person. On
30 April 1986 the radiological situation became worse and the whole territory of Poland was contaminated (air, water and soil). Then obligatory prophylactic activities were extended to the whole country.

As the effect of that over 10 million children and about 7 million adults received single protective dose of the potassium iodide in form of the Lugol’s solution.

Our prophylactic action was done very precisely and was perfectly organized on a scale unknown up to now. We understood, however, that if we started this action at least two days earlier the reduction of the thyroid contamination would be much higher. Therefore to evaluate the real value of our prophylactic activities we started in 1987, with the assistance of our Ministry of Health, the countrywide programme with following aims:

1. Estimation of radioiodine dose accumulated in thyroids of children, youths and adults who lived in different parts of Poland and evaluation whether these doses could lead to the development of thyroid disorders.

2. Evaluation of thyroid function in those exposed to radioiodine in different trimesters of prenatal life, who were born euthyroid and who were given potassium iodine in first days of life.

3. Evaluation of efficacy of single dose of potassium iodide and estimation of possible intrathyroid and extrathyroid side effects after prophylactic iodide administration.

To realize these aims 12 000 persons, randomly selected, were investigated clinically; the determinations of TSH, T3, T4 and antithyroid autoantibodies were also done in all of them. The results obtained will constitute a part of my lecture. Actually in 1997 we started new project called “CHERNOBYL II”.

This time we would like to see if any late effects of radioactive contamination in 1986 are observed in the thyroid structure and function in Polish population. Once again we randomly selected a group of about 7 thousands persons from the group of 12 000 people, we investigated 11 years ago, to check once more their thyroid status. The work is already done and the results are at the phase of evaluation and the conclusions will be probably ready and presented on seminar organized before the end of this year.

The consequences of a nuclear disaster. Thyroid cancer after Chernobyl

Professor Sir Dillwyn Williams, University of Cambridge, Thyroid Carcinogenesis Group, Strangeways Research Laboratory, Wort’s Causeway, Cambridge

The world’s worst nuclear accident occurred at Chernobyl nuclear power plant in April 1986. It released over $10^{19}$ Bq of radioactivity and there were high levels of exposure to fallout in the population of Northern Ukraine, a large part of Belarus, especially the southern oblasts, and a small part of the Russian Federation. Physicians and surgeons in Minsk and Kiev first reported seeing increased numbers of cases of thyroid cancer in children in 1990, but these reports were treated sceptically in the West for a number of reasons. There was doubt about the accuracy of the pathological diagnoses, the possibility that many of the cases might be microcarcinomas found because of intensive screening and the possibility that the cause of any increase was related to exposure to some other cause than fallout from Chernobyl. A major
reason for disbelief was the evidence that treatment of Grave’s disease with $^{131}$I did not lead to any increase in thyroid cancer.

Currently over a 1000 cases of thyroid cancer have occurred in those exposed as children to fallout in the areas around Chernobyl. This presentation will describe the validation of the diagnoses, the type of cancer, the evidence linking the tumours to exposure to fallout from Chernobyl, the molecular biological findings and their link with morphology, and evidence for a change in tumour type with increasing time since exposure.

**Conclusions and Recommendations**

1. **Reference Levels**

**Conclusions**

- The Reference Level for children of 10 mGy was generally considered to be set correctly.
- The Reference Level for adults over the age of 40 years of 5 Gy was considered to be too high and should be reduced to 1 Gy.
- The concept of Reference Levels should be more fully explained.
- In the Emergency Planning Zones the concept of “Reference Level” to determine the need for intervention may often be secondary to decisions based on “Plant Condition” and result in pre-emptive action being taken. This feature should be explicitly recognized in the overall response plan to an emergency. In this case little harm to health is likely to result from the administration of stable iodine even in the absence of any release.

**Recommendations**

WHO should reconsider the Reference Level for adults over the age of 40 years of 5 Gy and reduce it to 1 Gy.

WHO should advise IAEA of the need to reduce the dose limit for deterministic effects on the thyroid from 5 to 1 Gy in the Basic Safety Standards.

WHO should advise IAEA of the need to review the evidence for the current 100 mGy value for the Generic Intervention Level.

WHO should clarify its definition of Reference Level in any future revision of the Guidelines.

WHO, in collaboration with the IAEA, should review advice on the criteria for the implementation of countermeasures.
2. Information to, and education of, doctors, health care professionals, pharmacists, teachers and decision-makers

**Conclusions**

- There would be considerable benefit in WHO producing fact sheets directed towards these groups. A working group to review existing country initiatives should be convened.
- It was not considered appropriate for WHO to provide information directed exclusively to the general public. This was a matter for national authorities.
- A revision and re-issuing of the appropriate sections of the *Manual on Public Health Action in Radiation Emergencies* should be undertaken.

**Recommendations**

WHO should initiate the preparation of fact sheets giving advice directed to the specialist groups mentioned above.

WHO should revise its *Manual on Public Health Action in Radiation Emergencies* to take into account the *Update 1999*.

3. Information to be learned from further follow-up of Chernobyl

**Conclusions**

- The Chernobyl accident had clearly been highly influential in updating the Guidelines but much remained to be learned from continued follow-up. In the case of thyroid cancer there were substantial difficulties in getting reliable data on excess incidence in adults.
- Study of cases initiated by the Chernobyl accident had revealed considerable insights to the phenomenon of radiation induced thyroid cancer. These should be summarized into a single information source.

**Recommendations**

Further study of the thyroid cancer incidents and other potential health effects in exposed populations was strongly recommended.

WHO should convene a meeting to review the experience gained from the diagnosis of childhood thyroid cancer in Belarus, the Russian Federation and Ukraine.

4. Emphasis on protection of children

**Conclusions**

- It was estimated that the risk per unit dose of induction of thyroid cancer is at least ten times higher for children under seven than for adults. In the same accident situation, the risk may be up to 200 times higher, because children accrue a higher dose through inhalation and ingestion. Special attention to the exposure of children was therefore appropriate.
• Few cancers had been seen in the children in utero at the time of exposure thus suggesting that pregnant women might not be as at risk as has been so far assumed.

• The procedure adopted in Luxembourg of issuing tablets to all the newborn with their “passbook” for immunizations, medical tests, state allowances, etc. was warmly welcomed as an example of an excellent way to ensure availability of stable iodine to the most vulnerable group.

5. Application of stable iodine prophylaxis

Conclusions

• In the case of a prolonged emission of radioiodine, repeated administration of stable iodine prophylaxis to children (but not to neonates) may be justified, as noted in the Guidelines p. 11, for several days or even weeks if circumstances demand, until food and milk control or evacuation are instituted.

• Administration to adults in the Emergency Planning Zones, rescue and emergency workers is justified on the grounds of prevention of deterministic effects.

• Pre-distribution and availability in pharmacies of iodine tablets do not negate the need for stockpiling. It is a national responsibility to ensure the protection of the public at the time of the emergency.

• Although availability of iodine tablets in pharmacies for purchase was useful it was noted that there should be national control of administration.

• Tincture of iodine is not a suitable alternative to tablets or solution of stable iodine. (Lugol’s solution).

• Evaluation of the condition of tablets close to the end of their designated shelf-life, and regularly thereafter, should be undertaken with a view to extending the shelf-life if appropriate.

• It was noted that some countries in transition cannot adequately protect their population with the provision of stable iodine due to economic reasons. Attempts should be made to secure financial assistance for these countries.

• Exchange of information by Member States on the economic and shelf-life aspects of the available stable iodine preparations might give rise to economies.

Recommendations

WHO should assess the needs of countries in transition requiring assistance in the provision of iodine tablets to protect the population to the standards recommended in the Guidelines and seek financial support from other bodies, e.g. World Bank, European Bank, EU, IAEA, etc.

6. Role of the international agencies

Conclusions

• The development of advice on the public health aspects of nuclear emergencies, including guidance on the administration of stable iodine, was a legitimate and necessary subject for WHO engagement.
• There was a need for WHO to be actively involved in the response to (as well as in preparedness for) accidents in order to provide advice to Member States.

• The letter from IAEA of 1 August 2000 to States Parties to the Assistance Convention seeking, apparently at the request of WHO, comments on the Guidelines, was a matter for some surprise and concern. It was important for the authority and credibility of both Organizations, and for Member States, that WHO and IAEA are seen to be in agreement on the issue of iodine prophylaxis.

• Support for the Guidelines by the IAEA was regarded as important but the need for independence, by WHO, from the promotional mandate of the IAEA was also recognized.

• A possible alternative to co-sponsored documents might be that WHO issues, publicly, advice on those aspects which are within its mandate and the IAEA incorporates that advice into formal documents for the basis of planning and preparedness.

• The status of NCRP 55 in the light of the Who’s Guidelines should be sought from the National Council on Radiation Protection and Measurements (NCRP).

• After a fuller evaluation of the comments on the “Update 1999” WHO should consider issuing an addendum to the Guidelines.

**Recommendations**

WHO should seek the current status of NCRP 55 from the NCRP.

WHO should clarify, with the IAEA, its role in the development of advice on the public health aspects of nuclear emergencies in order to present to the Member States and the public a more concerted approach.
Annex 1

PROGRAMME

Sunday 17 September

12:45–13:00  Registration
13:00–13:15  Opening of meeting, and welcoming statements on behalf of WHO and STUK  Presenter
             Dr K Baverstock (WHO)
             Professor S. Salomaa (Finland)
13:15–13:35  Background to the WHO’S Stable Iodine Prophylaxis Guidelines inc. questions  Presenter
             Dr K Baverstock (WHO)
13:35–14:15  The evidence base for Stable Iodine Prophylaxis inc. questions  Presenter
             Dr W Paile (Finland)
14:15–14:55  Emergency planning and the Guidelines inc. questions  Presenter
             Mr L Blomqvist (Finland)
14:55–15:25  Coffee/tea
15:25–16:05  The experience of Poland after the Chernobyl accident inc. questions  Presenter
             Professor M Gembicki (Poland)
16:05–16:45  General discussion on basis for stable iodine prophylaxis  Presenter
             Chairman

Monday 18 September

9:30–10:30  The consequences of a nuclear disaster. Thyroid cancer after Chernobyl  Presenter
             Professor Sir Dillwyn Williams (United Kingdom)
10:30–11:00  Coffee/tea
11:00–12:30 General discussion on the Guidelines for stable iodine prophylaxis  Chairman
12:30–13:30  Lunch
13:30–15:00  Presentations from participants on national arrangements  Chairman
15:00–15:30  Coffee/tea
15:30–16:30  Presentations continued  Chairman

Tuesday 19 September

09:30–10:30  Discussion of participants reports  Chairman
10:30–11:00  Coffee/tea
11:00–12:00 General discussion on implementation of stable iodine prophylaxis  Chairman
12:00–12:20  Chairman’s summary  Chairman
12:20–12:40  Summary from WHO’s point of view  Presenter
             Dr Baverstock
12:40–12:45  Close of meeting
Annex 2

PARTICIPANTS

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