Report of the working group on the use of iodine in the event of a radiation hazard situation

STM 2022

Contents

Introduction

On 29 March 2022, the Ministry of Social Affairs and Health appointed a working group to consider the recommended use of iodine in the population in the event of a radiation hazard situation. The task of the working group was to plan the allocation of the recommended use of iodine in radiation hazard situations to different age groups, taking into account different illnesses, to design guidelines for the administration of iodine, especially for children, and to make recommendations for households and communities on how to prepare themselves. In addition, the working group was tasked with clarifying the division of labour between the authorities regarding the use of iodine and the provision of guidance, and ensuring the availability of iodine and its planned and timely distribution. The working group prepared an update of the guideline of the Ministry of Social Affairs and Health on the provision and distribution of iodine tablets (15.4.2002 (Dnro 78/02/2001)). The working group's term of office was from 1 April 2022 to 15 June 2022.

This report presents the working group's view on the recommended use of medicinal iodine as part of the management of a radiation hazard situation. Attached is the working group's proposal to the Ministry of Social Affairs and Health for an update on the Ministry's guidance on the provision and distribution of iodine tablets.

Organisation of the working group's work

The decision to set up the working group is annexed to the report. The working group met 8 times during its term of office.

The working group has also consulted the following expert in support of its work:

Mika Mäkelä, Professor, Head Physician, Specialist in Paediatrics and Paediatric Allergology HUS Diagnostic Center, Allergic Diseases and University of Helsinki

Why and for whom iodine tablet prophylaxis is needed in a radiation hazard situation

Nuclear power plant accidents in Finland and neighbouring areas and iodine prophylaxis

A nuclear reaction produces radioactive iodine as uranium fissions. In the event of an accident, it is possible that radioactive iodine may be released into the environment, which may cause radiation exposure, particularly to the thyroid gland, in the general population. In addition to domestic nuclear reactors, quantities of radioactive iodine with an impact on public health could be released into Finland from nuclear facilities in the neighbouring regions of Sweden and Russia.

Timely ingestion of iodine tablets can significantly reduce the radiation dose to the thyroid gland from radioactive iodine isotopes in the pollution clouds. The optimal time to take iodine tablets starts 24 hours before exposure and continues for two hours after exposure. The iodine tablet limits the dose to the thyroid gland for another six hours after exposure, but its dose-preventing effect is only 50% compared to an iodine tablet taken within the optimum period.

Sheltering indoors is the primary protective measure to protect the population

The ingestion of iodine tablets is a secondary protective measure in the event of a radiation hazard situation arising from nuclear facility accidents. The primary protective measure is indoor protection, which effectively prevents any radiation exposure resulting from the event, not only exposure from radioactive fallout. The use of iodine tablets complements this protection.

In the case of fallout from a nuclear explosion, the protective effect of iodine tablets is significantly less than after a nuclear power plant accident. Compared to a nuclear power plant accident, a nuclear explosion releases significantly more short-lived and other radioactive substances, which

means that radioactive iodine accounts for a much smaller proportion of the total radioactive substances causing exposure.

A surface explosion causes radioactive fallout up to hundreds of kilometres from the explosion site. Again, taking iodine tablets protects the thyroid, but health effects from other radioactive substances are much more likely.

In long-range deposition, radioactive substance is released from the atmosphere for weeks after the explosion. The food chain is the main route of exposure in long-distance fallout. However, iodine tablets cannot protect against such long-term exposure, as they can only be taken in two doses at most. Such exposure to iodine from long-distance exposure should therefore be prevented by measures to prevent contamination of the food chain, if necessary.

In the Chernobyl accident, high doses of radioactive iodine caused an epidemic of thyroid cancer in Ukraine, Belarus and Russia

There is very limited evidence from Poland on the ability of timely iodine tablet prophylaxis to prevent thyroid cancer caused by radioactive iodine. In Poland, 10 million children and adolescents were given timely iodine in solution after the Chernobyl accident. In Ukraine and Belarus, the epidemic of thyroid cancer in children and adolescents observed after the Chernobyl accident was caused by very high doses of radiation received through cow's milk. However, more than 99% of those affected were cured by surgery.

Significant radiation doses of thyroid radiation to children and adolescents unlikely in Finland

An important additional factor contributing to the thyroid cancer epidemic in Ukraine and Belarus was the widespread indigenous iodine deficiency in children and adolescents, which significantly increased the thyroid doses received by children and adolescents from cow's milk. In Finland, such high thyroid doses to children and adolescents from radioactive iodine are unlikely in the case of nuclear facility accident sites, as exposure through milk can be effectively prevented. In addition, iodine deficiency is not common in Finland because of the iodine added to food. The most likely route of exposure to radioactive iodine in Finland is via the respiratory tract. It is therefore unlikely that in the event of a severe nuclear accident, Finnish children and adolescents would receive the high thyroid doses mentioned above. Doses of iodine from radioactive pollution clouds in drinking water can also be effectively prevented by official measures.

WHO recommendation on iodine prophylaxis

The 1999 World Health Organisation (WHO) iodine recommendations were revised in 2017 following the Fukushima accident[1]. These conditional recommendations are based on very limited literature and very weak scientific evidence on the ability of iodine prophylaxis to prevent thyroid cancer. The conditionality of the WHO recommendation means that the positive effects of taking

[1] https://www.who.int/publications/i/item/9789241550185

iodine tablets in the event of a radiation hazard situation outweigh the adverse effects, even though there is no good evidence for the effectiveness of iodine prophylaxis in preventing thyroid cancer. However, the strong evidence on the ability of iodine prophylaxis to reduce thyroid doses in the event of a radiation hazard situation supported the recommendation.

The WHO recommends that iodine tablets should be available primarily in homes, and secondarily where children spend long periods of time, i.e. in nurseries and schools. As a third option, WHO recommends strategic stockpiling with plans for mass distribution. WHO recommends that any authority responsible for the distribution of medicines, down to the grassroots level, should be able to answer questions from the public about the relevance of iodine prophylaxis in the event of a radiation hazard situation.

WHO stresses that pregnant women, breastfeeding mothers, children and adolescents are the most vulnerable groups for whom iodine prophylaxis should be a priority. WHO does not recommend iodine prophylaxis for the general population over 40 years of age, as no association between exposure to radioactive iodine and thyroid cancer has been observed in adults. The exception to this is emergency workers, who may receive such high doses of radioactive iodine that this could have an impact on thyroid function.

Dosage of iodine tablets for different age groups

The recommended dosage is based on the WHO recommendation, as applicable.

130 mg potassium iodide (100 mg iodine) for 12-40-year-olds and pregnant women

65 mg potassium iodide (50 mg iodine) for children aged 3–12 years

32.5 mg potassium iodide (25 mg iodine) for children aged 1 month to less than 3 years

16.25 mg potassium iodide (12.5 mg iodine) for infants less than 1 month of age

A single dose is usually sufficient. In exceptional cases of prolonged radiation hazard situations, re-dosing may be considered. WHO does not recommend repeat doses in prolonged situations for newborns, pregnant women or breastfeeding mothers.

Side effects of potassium iodide are very rare. Caution should be exercised in patients with thyroid gland disorders. The protective role of potassium iodide on the thyroid gland is limited in patients with hypothyroidism receiving thyroxine or other thyroid hormones.
Potassium iodide is not recommended for those who have had their thyroid gland removed. If you have hyperthyroidism, dermatitis herpetiformis or vasculitis with reduced complement levels (hypocomplementemic vasculitis), you should not take iodine tablets containing potassium iodide.

Allergy associated with the use of contrast agents does not prevent the use of iodine tablets.

Working group recommendation on age limits for iodine tablets

In view of the above, the working group recommends that in the future, iodine tablets should be recommended in the event of a radiation hazard situation due to a nuclear accident for the general public **up to the age of 40 and for pregnant women** to protect the foetus, as recommended by WHO. The recommendation of both WHO and French specialists in internal medicine[2] states that it is unlikely that potassium iodide tablets will be of any use to people over the age of 40 (excluding pregnant women).

The above-mentioned age limit does not apply to emergency workers or emergency helpers at high risk of exposure. These persons have the potential to be exposed to such high levels of iodine that taking iodine tablets is justified for them regardless of their age.

Acquisition, storage and distribution of iodine tablets

In the event of a radiation hazard situation, the most vulnerable groups are young children and pregnant women (foetuses). Potassium iodide is not currently available on the Finnish market for dosing children under the age of 3, so this age group should be protected by public procurement. The supply of 65 mg potassium iodide suitable for children under 3 years of age would be subject to an exemption or special authorisation, depending on the product. For the procurement and distribution of medicinal iodine, it would be most appropriate to use existing channels for the procurement and distribution of medicinal products. The purchase of medicines for hospitals is normally carried out by five voluntary procurement networks. The university hospitals in each specific catchment area are responsible for the operation of the procurement networks. There is no procurement mechanism for the outpatient pharmaceutical market: pharmaceutical companies or importers allocate products to Finland in accordance with their sales strategies.

The working group proposes that the procurement and distribution of iodine tablets to pregnant women and to the parents of children under the age of 3 should be carried out by the health care arranged by wellbeing services counties. It would be advisable to purchase and distribute a package size of 65 mg of potassium iodide suitable for the whole family, for example, 10 tablets.

After the expiry date (5 to 10 years), the potassium iodide product, which is available from the pharmacy, is suitable for use in children over the age of 3 years.

The working group does not recommend emergency stockpiling of iodine tablets. There are a number of distribution problems associated with the emergency stockpiling of iodine tablets, which make it very difficult to distribute tablets quickly and widely enough in the event of an accident. In practice, in the event of an accident, it would probably not be possible to distribute iodine tablets in emergency storage to the right target group. The distribution arrangements discussed above are already effective in ensuring that families with children who would most benefit from iodine tablets would have access to them when needed. Even the benefits of a successful timely distribution of iodine tablets from an emergency stock would be very small in a real-life situation. WHO also recommends that iodine tablets should be stored primarily in homes or where children spend long periods of time (e.g. in schools). The safety benefit of emergency stockpiling of iodine tablets would therefore be very small in relation to the costs involved.

[2] M. Agopiantz et al. / Annales d'Endocrinologie 77 (2016) 1–6

Instead, the working group recommends stockpiling potassium iodide, which is the raw material for iodine tablets, in cooperation with domestic pharmaceutical companies in slowly evolving situations, such as a threat of war. Potassium iodide is simpler to store than finished tablets, and storage enables the production of iodine tablets in slow-developing situations where the availability of raw materials for iodine tablets is poor.

Self-preparedness of the population

The working group recommends precautionary measures for children over three years of age and adults up to 40 years of age, which would be carried out with iodine tablets purchased by households from pharmacies, as hitherto. Households should ensure that their stocks are maintained and prepared by regularly renewing out-of-date tablets in the same way as for other medicines used by households.

Iodine tablets should also be available where children and adults up to 40 years of age spend longer periods of time. It may be appropriate to maintain stocks of iodine tablets in some public institutions, businesses and communities and their shelters, for example. The working group recommends that a responsible person be appointed to maintain proper storage conditions for the medicine, update the stock regularly and purchase the products.

Communicating preparedness to the public

Communication of the preparedness needs of households for iodine tablets should emphasise the importance of continuous self-replenishment of iodine stocks. This will help to avoid purchase peaks that are out of line with normal demand and which cannot be met by the pharmaceutical supply chain. Communication should emphasise that the use of iodine tablets is only a support measure to the primary protective measure of sheltering indoors.

In specific situations such as the Russian invasion of Ukraine or nuclear power plant accidents around the world, the message of primary indoor protection and the message of the most important age groups for its use should be proactively and immediately repeated in cooperation with the authorities. In this way, any potential peak in demand for iodine tablets would not be translated into a shortage of medicines, causing additional concern in the population. In addition, the remaining stocks could also be targeted through pharmacy advice to the target groups most in need in households, namely children over three years of age and adults up to the age of 40.

Division of labour between authorities in preparedness

The Ministry of Social Affairs and Health (STM) and its subordinate agencies Finnish Medicines Agency Fimea and STUK, as well as the emergency services, are the main authorities that provide guidance on the precautions and recommended intake of iodine tablets.

Ministry of Social Affairs and Health

The Ministry of Social Affairs and Health guides the preparation for iodine prophylaxis and makes recommendations on the use of iodine prophylaxis.

In the event of a radiation hazard situation, the Permanent Secretary of the Ministry of Social Affairs and Health decides, on the basis of a recommendation based on the risk assessment of the STUK, to issue a recommendation for the iodine prophylaxis of the population.

RADIATION AND NUCLEAR SAFETY AUTHORITY IN FINLAND (STUK)

STUK is the expert authority on radiation safety. As part of its tasks, STUK prepares a strategy for protective measures in case of radiation hazard situation, which is published in STUK Guideline VAL 1: Protective measures in a radiation hazard situation. This guideline also lists the indicative action levels for taking iodine tablets, which is the predicted dose to the thyroid gland of an unprotected person of 100 mGy for adults and 10 mGy for persons under 18 years of age and pregnant women.

In the event of a radiation hazard situation, STUK will provide recommendations to the competent authorities on the necessary protective measures to be taken based on the radiation situation, its predicted evolution and the resulting radiation doses.

The Finnish Medicines Agency Fimea

Fimea monitors the quality, safety and availability of medicinal products on the market, such as those containing potassium iodide, as well as the operators of the legal supply channel for medicinal products. Fimea's task is to provide a situation assessment of the availability of medicines and to communicate the availability of medicines based on information provided by the pharmaceutical industry.

Emergency services

In the event of a radiation accident, the emergency response is managed by the emergency services. The emergency services in charge of management is informed of the decision of the Permanent Secretary of the Ministry of Social Affairs and Health recommending the use of iodine tablets. The emergency services is responsible for issuing instructions and regulations on protection and for emergency warnings and communications by the authorities. The emergency services will use the emergency warning or other communication channels, as appropriate, to communicate information on sheltering indoors or evacuations and the use of iodine tablets.

APPENDIX: Working group proposal for iodine tablet guidance