

The Krakow Declaration on Iodine

Tasks and Responsibilities for Prevention Programs

Targeting Iodine Deficiency Disorders

The EUthyroid Consortium

Short running title: Krakow Iodine Declaration of the EUthyroid Consortium

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Joint Declaration

Iodine deficiency disorders (IDD) represent a global health threat to individuals and societies. The adverse effects of iodine deficiency are diverse and impose a significant burden on public healthcare systems. Although this fact is well established, IDD prevention programs receive surprisingly little attention from policy makers, opinion leaders and the public. European epidemiologists, endocrinologists and nutritionists investigating IDD under the umbrella of the Horizon2020 research and innovation action EUthyroid (Project ID: 634453, <http://euthyroid.eu/>) are increasingly concerned about the deteriorating commitment of policymakers to address public health strategies against IDD in the European populations.

Background

With very few exceptions such as Iceland, Europe is an iodine-deficient continent. Adults living in iodine deficient regions carry a high risk of goiter, thyroid nodules and hyperthyroidism. Subclinical hyperthyroidism, as a common and frequently undiagnosed IDD, is tightly associated with an increased risk of mortality and coronary heart disease. Moreover, iodine deficiency during pregnancy and breast-feeding is widespread in Europe and adversely affects the development of the child. Even mild or moderate iodine deficiency of the mother affects the synthesis of thyroid hormones and may impair brain development, neurocognitive function and reduces offspring IQ. During pregnancy, women have a sharply increased need for iodine, which is frequently not covered by food sources and iodine supplements. Due to a lack of valid data, we are uncertain about the scale of the problem but estimates suggest that up to 50% of newborns in Europe are exposed to iodine deficiency.

Iodine deficiency can readily and inexpensively be prevented by iodine fortification, usually by provision of iodized salt. More specifically, iodized salt should replace non-iodized salt in nearly all food production, at least in areas where fortification would not increase risk of excessive iodine intake. This approach will not increase total salt intake, which is in line with current dietary recommendations. However, challenges in implementation remain, particularly in Europe due to fragmentation and a diversity of approaches. The EUthyroid consortium has been collecting experience on national IDD prevention programs. The Krakow Declaration on Iodine aims to define the most important tasks for optimal IDD prevention when programs have been introduced and to point out the responsibilities for the different tasks.

Ensuring a Euthyroid Europe

We, the signatories of the Krakow Declaration on Iodine call on policymakers, public health officials, scientists and the public to join forces to ensure that existing strategies to prevent IDD are implemented across Europe to reach and secure a sufficient iodine status across Europe. In particular we call for:

- **Methods of IDD Prevention:** Regulators and policymakers should harmonize obligatory Universal Salt Iodization to ensure free trade of fortified foodstuffs in Europe. Similarly, iodized animal feed requires regulatory approval to ensure free trade within the EU.
- **Control of IDD Prevention:** National governments and public health authorities have to perform harmonized monitoring and evaluation of fortification programs at regular intervals to ensure optimal iodine supply to the population.

- **Support for IDD Prevention:** Scientists, together with public-health care workers, patient organizations, industry and the public, should support measures necessary to ensure that IDD prevention programs are sustainable, as appropriate within a rapidly changing environment and further social awareness of the issue.

Methods of IDD Prevention

Universal Salt Iodization

Universal salt iodization is the preferred strategy of IDD prevention and is recommended by WHO, UNICEF and the Iodine Global Network (IGN) as the most cost-effective method. The promotion of universal iodization of salt is not antagonistic to policies aimed at limiting salt uptake to reduce hypertension as a risk factor for cardiovascular disease. Limiting daily salt uptake to less than 5 grams and ensuring iodine sufficiency with fortified salt can be pursued in synergy to ensure optimal implementation and promotion of good health.

- Responsibility for regulation and execution: Governments and public health authorities
- Responsibility for production and quality control: The food industry

Obligatory Principle

Although grade-A scientific evidence is missing, obligatory prevention programs by universal salt iodization are preferred over voluntary programs for better control, higher effectiveness and lower costs.

- Responsibility for decisions: Governments and public health authorities
- Responsibility for providing evidence: Scientists

Dosage of Iodine Fortification

The optimal dosage of iodine for fortifying salt needs to be based on up-to-date results of monitoring and evaluation studies.

- Responsibility for decisions: Governments and public health authorities
- Responsibility for providing valid findings: Scientists

Transnational Harmonization

Within a globalized economy with extensive trade of food stuffs across borders, harmonization of national IDD prevention programs is an important priority within the EU to support free movement of goods. Currently the EU constitutes a fragmented market with different national regulations pertaining to carriers of iodine (potassium iodide or iodate) and methods of IDD prevention (mandatory or voluntary programs). This encourages the food industry to provide non-iodized products to avoid trade barriers. With the exception of Iceland, all salt marketed or used in the EU member and candidate member states for alimentary purposes should be fortified by a universally set minimum amount of iodine. Adopting an agreed upon universal minimum concentration of salt iodine will allow the safe and effective improvement in the consumption of iodine throughout the EU. Individual member states would be allowed to regulate salt iodine content depending on the severity of iodine deficiency in their geographical regions, provided that the locally required salt iodine content is equal to or is higher than universally set minimum amount of iodine.

- Responsibility for decisions: National and EU trade and public health authorities

Control of the IDD Prevention Program

Monitoring Iodine Status

IDD programs are embedded within a rapidly changing environment of eating habits, food products and regulatory frameworks. The iodine status of populations can be affected by many factors including changing food patterns, level of iodized salt in foods, differing effectiveness of information campaigns or law amendments. There is a requirement for regular monitoring studies that have to be representative of the target population and must provide valid results.

- Responsibility for initiating and funding the monitoring: Governments and public health authorities
- Responsibility for providing valid findings: Scientists

Evaluation

Monitoring cannot replace the evaluation of IDD prevention programs that are based on observing primary outcomes of the prevention strategy including any trend in incident thyroid diseases and related treatments. Adequate data sources have to be provided for analyses of effectiveness and the monitoring of potential harms.

- Responsibility for regulation and funding: Governments and public health authorities
- Responsibility for providing adequate data: Public registries, health insurance companies, hospitals, pharmacies etc.
- Responsibility for providing valid findings: Scientists

Standardization and Harmonization

Scientists have to be aware of potential bias in their studies. Monitoring and outcome studies must be standardized to ensure valid data for evidence-based policy decisions. Data should be harmonized as far as possible to enhance the trans-national comparability between different IDD prevention programs and to identify benchmark countries.

- Responsibility: Scientists, data provider for outcome studies

Measures Accompanying the IDD Prevention Program

Advisory Boards

Structures are needed to support governments and public health authorities in accepting responsibility and fulfilling their tasks. Advisory boards should comprise major stakeholders in the field of IDD prevention including thyroidologists, epidemiologists, health economists, pediatricians, gynecologists, nutritionists, communication scientists, patient organizations, representatives of industry and consumer groups.

- Responsibility for initiating and funding: Governments, public health authorities

Information Campaigns

IDD prevention programs, especially those that are voluntary, must be accompanied by public-information campaigns.

- Responsibility for initiating and conducting: Governments, public health authorities
- Responsibility for advising governments and public health authorities and providing facts and information: Scientists, nutritionists, medical practitioners, patient organizations and industry

Support us:

We, the signatories of the Krakow Declaration on Iodine ask for support from all stakeholders across Europe and beyond to pool resources and expertise to ensure

that our future generations will be able to realize their full potential without any limitation resulting from exposure to iodine deficiency.