Standard Operating Procedure (SOP)

Intervention components

Ambulatory Care Setting

Version 2.0

1. Aim and background

This Standard Operating Procedure (SOP) focuses on how to conduct the intervention in the ambulatory care study arm of the EUthyroid2 project. The overall aim of the intervention is to increase the awareness of young women (18 - 24 years old) of the importance of iodine and the risks of iodine deficiency. Furthermore, the iodine level in the participating women's urine samples is going to be evaluated (See SOP Nr. "Urine sampling"). The first urine sample will be taken the day the intervention is delivered. The second urine sample should be provided 2-4 weeks and the final urine sample 6-8 months after the intervention was delivered.

Four core intervention components were scientifically developed and pretested to achieve an improvement in the women's awareness of the topic. In the following paragraphs, the four components will be described and their application will be explained. There will be references to other SOPs and training videos which are part of your structured training for the EUthryoid2 study. Training will include 1) training videos, 2) instructions from your regional contact person and 3) a role play training. Should you not have access to the other documents and materials, please contact your local project contact person. Regional study management [INSERT CONTACT] will be your contact person for training and other issues in the organisation of the study.

2. For whom is this SOP?

This SOP is for all regional study management teams and ambulatory care facilities involved in the EUthyroid2 study. Each regional study management received the English template of this SOP and translated it into their local language so that the respective implementing partners (ambulatory care facilities) may use them for conducting the study. Adaptations of the SOPs content needs to be aligned with the authors of the English SOP template.

3. Abbreviations

BUHS	Bangladesh University of Health Sciences
ICP	Islamia College Peshawar, Pakistan
JU	Jagiellonian University, Poland
IMR	Institute of Marine Research, Norway
SOP	Standard Operating Procedure
SURREY	University of Surrey, UK
QUB	Queen's University Belfast, UK

4. Overview of the core intervention components

The four core intervention components to be implemented in your ambulatory care facility consist of an iodine feedback tool, a brief educational conversation by the healthcare professional, an iodine factsheet and a video on iodine (Figure 1). Please read paragraphs 6-9 to learn more about the core components.



Figure 1. Overview and order of the four core intervention components. (*free license by freepik **free license by rocketpixel via freepik)

5. Iodine feedback tool

When do the participants fill out the iodine feedback tool?

The iodine feedback tool is the first of the four intervention components and should be filled-out after the participants enrol in the study (see SOP "Participant Management/Data management") and fill out the outcome questionnaires (see SOP "Participant Management/Data management") on measurements). It is important that the feedback tool be filled out after the outcome questionnaires to avoid that the answers in the outcome questionnaires are influenced by the iodine feedback tool. Furthermore, the feedback tool should be filled out <u>before</u> the educational conversation with the healthcare professional.

What is the iodine feedback tool?

The iodine feedback tool consists of a short questionnaire, comprised of four questions, (see Attachment 1) asking study participants about their daily intake of iodine sources. Based on their answers, they will receive one of two feedback options (see Attachment 1) providing them with information about their personal intake of iodine food sources. The aim of the tool is to create curiosity and awareness of the topic of iodine intake. Therefore, it is important that right after the participant fills out the feedback tool, an educational conversation (see point 3) with the healthcare professional takes place, where the participant is educated in more detail.

How do participants fill out the iodine feedback tool?

There are two possibilities how the iodine feedback tool can be filled out. The first option includes a digital device (e.g. iPad, laptop, smart phone, etc.), whereas the second option includes a paper-based version.

Option 1 - digital: The iodine feedback tool is implemented in LimeSurvey, which is also the platform over which the participant fills out the outcome of the questionnaires. For this, a digital device is needed. LimeSurvey is programmed in a way that it shows one of the two feedback options to the participant, depending on what they opted for.

Option 2 – paper-based: A staff member hands out the iodine feedback tool to the participant in paper-form, which includes the participants' ID. After the participant fills out the tool, she will read the evaluation instructions and calculate her score to find out which feedback applies to her answering pattern. The participants' filled out iodine feedback tool will have to be collected by the designated staff member.

6. Education by the healthcare professional

After the participant has filled out the iodine feedback tool, a healthcare professional designated for this task by your facility, educates her on iodine in more detail. It is preferable that this conversation takes place in a private room, e.g. the healthcare professional's office, instead of a public room, such as a hallway or front desk. The education can be conducted in a one-to-one conversation or in a group setting. In case you or your institution decides to conduct group educational sessions, please contact your regional management as this needs to be documented for the implementation monitoring. The following topics must be covered in the conversation:

- Importance of iodine for health
- Consequences of iodine deficiency
- Recommendations for daily iodine intake
- Specific iodine food sources in your country, including information of iodised salt and the use of iodine supplementation
- Importance of healthy nutrition during pregnancy for the offspring, including iodine
- Specific iodine recommendations before/during pregnancy

The healthcare professionals are provided with a short guideline, which includes a checklist for the educational conversation (see Attachment 2 and 3). Also, training will be provided for you on how to conduct the conversation before recruitment starts. Please contact your regional study management when you encounter problems to conduct the conversation as planned.

During the conversation, the healthcare professional hands out the iodine factsheet to the participant and refers to its content, e.g. the iodine sources. Furthermore, country-specific information should be verbally explained as well (see Attachment 5). In the training, before recruitment starts in your facility, specific attention will be paid on how to conduct the conversation in a motivating way (see Attachment 2 and training content). Lastly, refer to the QR code on the factsheet which accesses a video on iodine, especially targeted for the participants. Encourage the participant to watch it in their free time (at a place and time of their choice).

Please make a short documentation on the conversation in LimeSurvey, e.g. length of conversation in minutes and how many people were present (e.g. alone, with a parent, spouse or translator). See Attachment 3 on what the short documentation includes. The documentation is connected to an individual healthcare professional ID. Only the ID will be visible for the researchers evaluating the documentation. Personal data (e.g. name) will not be visible nor relevant for the evaluation of the documentation.

7. Iodine factsheet

The iodine factsheet (see Attachment 5) will be provided to the ambulatory care facilities by the EUthyroid2 regional study management, who receive it from the EUthyroid2 research partners. The factsheet will be printed out for the facilities. As described under point 3), the factsheet is to be utilised by the healthcare professional during the educational conversation. It is important that the healthcare professional refers to the factsheet and hands it out to the participant to take it home. The factsheet contains a concise summary of the most important facts on iodine, recommendations and iodine sources and may therefore be a helpful information source for the participants. A contact person for further iodine-related questions is included in the factsheet. Please refer to that contact person if the participating women have further questions.

8. Video

The iodine video is accessible to the participant via the factsheet, which contains an individualised QRcode. Participants may scan the QR-code with a private device, e.g. smartphone. They are automatically directed to the video content which contains the most important information on iodine. The healthcare professional should point to the QR-code and inform the participants about the video during the educational conversation. The participants may choose when to watch the video in their free time.

You have the possibility to watch the video for the participant during training.

9. Additional intervention component

The following sections apply only to the respective study regions addressed.

Bangladesh:

To increase the possibility of behavioural change (e.g. cooking habit, grocery shopping) the participants' families will also receive a short factsheet on iodine. The healthcare professional hands out the family factsheet to the participants and asks them to give it to their family members, e.g. parents at home (Figure 2).



Figure 2. Overview of all intervention components in Bangladesh. (*free license by freepik **free license by rocketpixel via freepik)

Norway:

To enhance iodine-rich cooking habits, women in the intervention group receive an iodine cookbook from the healthcare professional. The cookbook contains iodine-rich meal suggestions (Figure 2). The healthcare professional should recommend the cookbook. You have the possibility to see the content of the cookbook during the training.



Figure 2. Overview of all intervention components in Norway. (*free license by freepik **free license by rocketpixel via freepik)

Pakistan:

To increase the possibility of behavioural change (cooking habit, grocery shopping) the participants' families will also receive a short factsheet on iodine. The healthcare professional hands out the family factsheet to the participants and asks them to give it to their family members, e.g. parents at home (Figure 2).



Figure 2. Overview of all intervention components in Pakistan. (*free license by freepik **free license by rocketpixel via freepik)

Poland:

As participants will be recruited over nurse-appointments at schools, most of them will be living with their parents. To increase the possibility of behavioural change (cooking habit, grocery shopping) the participants' parents will also receive a short factsheet on iodine. The healthcare professional hands out the family factsheet to the participants and asks them to give it to their parents at home (Figure 2).



Figure 2. Overview of all intervention components in Poland. (*free license by freepik **free license by rocketpixel via freepik)

10. Appendix/Referrals

- Attachment 1 lodine feedback tool
- Attachment 2 Guideline for the educational conversation
- Attachment 3 Checklist for the educational conversation
- Attachment 4 Documentation of the conversation with the women
- Attachment 5 lodine Factsheet for the participants



Iodine Feedback Tool

The following questions are designed to determine whether you are consuming a healthy amount of iodine.

«barcode»





1. How many portions of cow's milk and yoghurt do you consume?

One portion= One glass of milk (200 ml) or one pot (125-150 g) with yoghurt.

	Points
Less than three portions/day	0
Three or more portions/day	1

2. How often do you consume white sea fish?

White fish include fish species such as cod and haddock. It does not include the oily fish species such as salmon, mackerel, and herring.

	Points
Less than two times per week	0
Two or more times per week	1

3. Do you use dietary supplements containing iodine?

If you take a multivitamin and mineral tablet, check if it includes iodine. Be aware that the labelling iodine can be given as iodine, iodide, potassium iodide, and sodium iodide. This does not include seaweed or kelp supplements.

	Points
Once a week or never	0
2-4 times per week	1
5 times or more per week	2
I am not sure	0

4. Do you use salt with iodine (labelled as iodised salt) for cooking and baking?

	Points
Never or rarely	0
Several times per week, but not always	1
Yes, I always use salt with iodine	2
l am not sure	0



Iodine Feedback

0-1 points:	Based on your answers, it is a good idea to make more healthy iodine
	choices. Even small changes may have a great impact on your iodine
	intake.
≥ 2 points:	Based on your answers, you have healthy iodine habits. It is good to eat
	a varied diet.







Guiding Instructions for role-play training with healthcare professionals in the EUthyroid2 study

Why a role-play training?

Preparing the healthcare professionals (HCPs) to conduct the intervention in the EUthyroid2 study is crucial for successful intervention delivery. First, HCPs will be provided with training videos on the intervention via the EUthyroid2 website. The training videos cover information on iodine, the intervention, urine sampling and motivational conversation techniques. Before starting the intervention, practicing the intervention delivery in an in-person training session, which is to be organised by the regional management, will ensure HCPs are prepared to deliver the intervention as intended. The advantages of a role-play training include (1) HCPs can consolidate the information from the videos by retrieving it in practice, (2) increased self-efficacy about educating on iodine, (3) HCPs can ask questions and clarify uncertainties and (4) good intervention adherence and feasibility are being facilitated.

Time & place

The regional management will organise one in-person training session for all HCPs that are involved in conducting the intervention to allow for exchange between HCPs and provide practice opportunities. The training session should last 1-3 hours, to ensure enough time for practice and questions and to avoid straining the healthcare professionals.

The location of the training session requires a large enough room (e.g., meeting room) with space for all HCPs and the possibility to split up and spread out in the room in smaller groups. The in-person training session should take place AFTER HCPs had the opportunity to access the training videos and intervention material, including the checklist for HCPs.

Preparing and running the training session

Time	Who?	What?
Before the	Facilitators	Prepare the room to create a welcoming atmosphere (e.g., chairs
session	(e.g., regional	in a circle, prepare prompts for presentation and practice,
	management	nametags). If possible, consider providing drinks and refreshments
	staff)	(e.g., tea, coffee, biscuits).
10-15 min	Facilitators,	HCPs arrive. Introductions and nametags. Check attendance
	HCPs	(facilitator).
10-15 min	Facilitators	Welcome, short presentation on the agenda, distribute iodine
		factsheet and checklist for HCPs, facilitators answer any questions
		from HCPs.
10-15 min	Facilitators	Demonstrate an educational conversation with colleague or a HCP
		volunteer.
30-45 min	HCPs	In groups of 2-3 people, HCPs practice the educational
		conversation. 1 HCPs fills the role of the conversation lead, 1 HCPs
		is the study participant, and 1 HCP will observe and provide
		feedback to the conversation lead. Take turns until everyone has

Table 1. Exemplary in-person training session agenda



		practiced the role of conversation lead. Facilitators offer support
		to HCPs when questions arise.
10-15 min	Facilitators,	Come back as a whole group and reflect on the role-play
	HCPs	experience, share feedback and answer any remaining questions.
10 min	HCPs	HCPs complete T2 questionnaires.
10 min	Facilitators	Hand-out certificates, highlight contact details during the
		intervention period, thank you and goodbye.
After the	Facilitators	Pack-up and clean-up the room.
session		

Abbreviation: HCP = Health Care Professional

Materials to prepare / bring to the training:

1) Short presentation

Prepare a short presentation in your preferred format (e.g. power point presentation, free talk, poster, etc.) to outline the agenda of the training session. The agenda can be based on the exemplary session timeline, for instance:

- 1. Welcome and thank you for participating in EU-Thyroid 2 as HCPs
- 2. Short background of the intervention
- 3. Content of the educational conversation (refer to training videos, iodine factsheet, checklist for HCPs and if applicable additional country-specific material)
- 4. Demonstration of an educational conversation
- 5. Practice educational conversation
- 6. Reflections, questions, HCPs complete questionnaire, hand-out certificates and goodbye

2) Intervention materials that are relevant for HCPs

Provide the following in appropriate number:

- Iodine factsheet for women
- Checklist for healthcare professionals.
- additional material:
 - Poland, Pakistan, Bangladesh: the family factsheet
 - Norway: the iodine cookbook

3) Additionally provide:

- Nametag (e.g., tape) and pen's
- Training certificates for each HCPs at the end of the training (Appendix 1: Template)
- T2 questionnaires for the healthcare professionals. Please see the SOP on what to consider for handing out the questionnaire and data transfer.
- Optional: Drinks and refreshments







Checklist for healthcare professionals

Dear healthcare professional,

Thank you for your willingness to participate in this important study. This document is intended to help you engage with the participants of the EUthyroid2 study. To ensure that the participating young women receive all the information they need about iodine nutrition, it is important that you communicate with them on the following topics that are also part of the factsheet, which you will hand out and refer to during the conversation.

- The importance of iodine for the participant's own health
- The consequences of iodine deficiency
- · Recommendations for daily iodine intake
- Important dietary iodine sources
- Importance of healthy nutrition during pregnancy for the baby's health, including iodine
- Specific iodine intake recommendations during pregnancy

When you explain about the different iodine sources, please elaborate on iodised salt and combining various iodine sources, plant-based drink, iodine sources in a vegetarian or vegan diet, and avoiding the consumption of seaweed or kelp supplements. See the following exemplary formulations:

- iodised salt and combining various iodine sources:
- "While salt is fortified with iodine in many countries, iodised salt is not widely available in the UK, always check the label to see if salt is iodised and try to combine different iodine sources."
- iodine sources on a plant-based or vegetarian/vegan diet: "If you follow a vegetarian or vegan diet, please look at your iodine sources more closely (name possible sources: vegetarian diet, e.g. cow's milk, cheese, yogurt, eggs, iodised salt; vegan diet, e.g. iodised salt, iodine-fortified plant-drink, iodised salt, iodine supplements). Unlike cow's milk which is a good source of iodine, milk-alternative drinks (e.g. soya/oat/almond) have a low iodine content unless they are fortified, and most products on the market do not have added iodine. If you are switching to a plantbased milk alternative, it is important to check the label and choose a product that is fortified with iodine. You may also need to consider a suitable iodine-containing

supplement to meet iodine recommendations. Look for one with a dose of around 150 μ g/day."

- plant-based drinks: "If you consume plant-based drinks, check the label, because only some products are iodised."
- avoidance of consuming kelp or seaweed: "Kelp and seaweed may have a very high concentration of iodine and may lead to an excessive iodine intake. Avoid consuming these foods regularly and do not use kelp or seaweed supplements as an iodine source."

Furthermore, please include a short explanation on a **plantbased (vegetarian/vegan) diet during pregnancy:** "If you follow a vegetarian or vegan diet, you need to plan it even more carefully to provide all the nutrients you and your baby will need while you are pregnant. Considering a suitable iodinecontaining supplement to meet recommendations is important. For pregnancy, multivitamin and mineral supplements that contain iodine – many, but not all of them do – should provide 150 µg per day. The rest of the requirement for pregnancy should be met by dietary iodine sources. For more information on planning the diet or advice on supplements, visit: <u>https://</u> www.bda.uk.com/resource/iodine.html."

To be able to engage with the participating women in a personalised way, we recommend applying the techniques you learned during the training for this study. Should you have not learned about these techniques, please contact: <u>EUthyroid2@qub.ac.uk</u>.

If the participating women have questions about other medical topics, such as the treatment of existing thyroid disorders, acknowledge their concerns (e.g. "I hear what you say" or "These are important questions") and explain how they can proceed with their concern: "The time we have today is to discuss about iodine and the prevention of iodine deficiency. If you have specific medical questions, please consult a specialist [name specialist and if possible contact information]." Then try to redirect back to the topic: "Let's talk about the importance of iodine for health and what you can do to ensure sufficient iodine intake."

The following checklist can help guide you through the conversation with the participating women.

Checklist

		C
1.	Briefly introduce yourself (name and profession).	0
2.	Tell the participating young woman that you are happy she decided to participate in the study as you think that it is an important topic.	0
3.	Explain what is going to happen in the next few minutes (she will get information on iodine, she will receive a factsheet and obtain information on the next study procedures).	0
4.	State that this exchange of information is two-way. You are really interested to hear her thoughts and opinions on what will be discussed.	0
5.	Ask the participating young woman about her knowledge on iodine, ideally using an open question: " <i>What do you know about iodine?</i> " (you may also refer to the outcome of the iodine feedback tool).	0
6.	Provide information from the factsheet (see factsheet) in your own words. Try to avoid using too many medical terms and if you do so, try to explain their meaning in an easy language. Point to the iodine sources on the factsheet. Discuss:	
	importance of iodine for own health	\bigcirc
	consequences of iodine deficiency	0
	• recommendations for daily iodine intake (for adults: 150 μg per day, the upper tolerable iodine intake is 600 μg per day)	0
	important iodine sources	\bigcirc
	 importance of healthy nutrition during pregnancy for the baby's health 	0
	 specific iodine intake recommendations before pregnancy (150 μg per day) and during pregnancy (250 μg per day) 	0
7.	Additionally, inform the participating young woman about other important information that is not included in the factsheet – information we describe to you in the paragraphs before this checklist:	
	iodised salt and combining various iodine sources	\bigcirc
	 iodine sources on a plant-based or vegetarian/vegan diet 	\bigcirc
	plant-based drinks	\bigcirc
	 avoidance of using kelp or seaweed supplements as a source of iodine 	0
	avoidance of regular consumption of seaweed, particularly brown seaweed such as kelp	\bigcirc
	• carefully planning of the diet to include iodine sources in case of a plant-based (vegetarian/ vegan) diet during pregnancy	0
8.	Ask if the participant has any questions. If yes, try to answer the question to the best of your knowledge. If you are unsure about the answer, refer to the contact person on the factsheet.	0
9.	Either ask the participating young woman what she thinks about the information she has received (this way, the participant is asked to reflect on the topic which may deepen awareness of the topic) OR kindly ask her to teach you back the most important points (which supports comprehension and memorising).	0
10.	Recommend her to pay attention to ensure sufficient intake of iodine in everyday life. Highlight that even small changes are important to improve iodine intake.	0
11.	Point out that there is a link/QR code to a video on iodine that you recommend the participant to watch.	0
12.	Inform about the 2nd (in 2-4 weeks) and 3rd measurements (in 26-35 weeks).	0
13.	End the conversation and say goodbye.	\bigcirc

Thank you for participating in the EUthyroid2 study!

If you have any questions, you can contact us: EUthyroid2@qub.ac.uk





UK Research and Innovation





Consider your iodine intake for your health!



Iodine is a micronutrient that plays an important role in your body. It is needed for the proper production of your thyroid hormones, which are necessary for growth, metabolism and brain development.



What happens if I get too little iodine?

Not taking in enough iodine may lead to iodine deficiency disorders. For example, the thyroid gland, which is in the neck, cannot produce the right amount of thyroid hormones, which may lead to negative health effects. The most visible effect is a condition named "goitre", where the thyroid gland starts to swell and increases in size. Also, if the thyroid gland does not get enough iodine, it may lead to thyroid diseases (too little or too much of the thyroid hormones are produced).

Since the thyroid hormones are important for metabolism, iodine deficiency may lead to problems regulating body temperature, fatigue, tiredness, and weight changes. Thanks to a global campaign to add iodine to salt, goitre and the more severe effects of iodine deficiency have largely disappeared. However, moderate iodine deficiency is still a problem across different countries, including the UK.

What happens if I get too much iodine?

Excessive iodine intake can also lead to the production of too much thyroid hormone and can potentially cause disturbances in the thyroid hormones, the same as with too little iodine. The European Scientific Committee on Food has set a tolerable upper intake level of iodine: 600 µg (micrograms) per day. This means that you should not have an iodine intake that is higher than 600 µg (micrograms) per day.

Therefore, getting the correct amount of iodine is important for good health!

Are you getting the recommended amount of iodine?

The World Health Organization (WHO) recommends an intake of **150 micrograms (µg)** iodine per day in adults to prevent iodine deficiency. Below are some examples of iodine sources in the UK:





Iodised salt, check the label: while salt is fortified with iodine in many countries, iodised salt is not widely available in the UK, always check the label to see if salt is iodised.

Plant-based diet: it can be very difficult to meet the recommended intake of iodine if you are following a mostly plant-based (e.g. a few days a week), or vegan diet. This is because plant foods (such as fruits, vegetables, and cereals) have a very low iodine content. Unlike cow's milk which is a good source of iodine, milk-alternative drinks (e.g. soya/oat) have a low iodine content unless they are fortified, and most products on the market do not have added iodine. If you are switching to a plant-based milk alternative, check the label. You may also need to consider a suitable iodine-containing supplement to meet iodine recommendations. Look for one with a dose of around 150 μ g/day, and do not use a seaweed/kelp supplement (as this can lead to excess iodine intake).

Prepare for a healthy pregnancy!





During pregnancy, there are increased needs for iodine, folic acid, iron, and omega-3 fatty acids to meet the needs of both the mother and the baby (for more information, visit: <u>https://www.nhs.uk/pregnancy/keeping-well/have-ahealthy-diet</u>). Some women already know that it is important to take enough folic acid not just during pregnancy, but also before it. This way, the body is best equipped for pregnancy and for the healthy development of the baby from day one of pregnancy. However, not many women know that sufficient iodine intake before pregnancy supports their own and the baby's health.

Consuming sufficient iodine is important to support the baby's healthy brain development and proper growth. Iodine is also important to reduce the possibility of premature birth or low birth weight.

If you follow a vegetarian or vegan diet, it needs to be even more carefully planned to provide all the nutrients you and your baby will need while you are pregnant. For more information, please visit: <u>https://www.bda.uk.com/resource/</u> <u>vegetarian-vegan-plant-based-diet.html</u> for planning your diet or advice on supplements.

How much iodine is recommended before and during pregnancy?



The recommended amount of iodine for adults (including the period **before pregnancy**), is **150 µg** iodine per day. However, **for pregnant women**, the World Health Organization (WHO) **recommends a higher iodine intake**, **250 µg of iodine per day**, to prevent iodine deficiency and ensure a healthy development of the baby and the woman's own health. Some, but not all, pregnancy multivitamin and mineral supplements contain iodine, check the label as they should not provide more than 150 µg per day.

If you are planning to get pregnant soon, prepare for a healthy pregnancy by paying particular attention to your diet. For more information on a healthy nutrition during pregnancy, visit: <u>https://www.bda.uk.com/resource/pregnancy-diet</u>, or ask your dietitian, doctor or other healthcare professional.

Check out our video on iodine!



Do you have any questions?

If you have any questions on iodine, don't hesitate to contact us: iodine@surrey.ac.uk



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Remember: Iodine is important for your health, make sure to include different iodine-rich foods in your diet!