Standard Operating Procedure (SOP)

Healthcare Professionals

Ambulatory Care Setting

Paper-based data collection

Version 2.0

1. Aim

This SOP serves as a guideline for the health care professionals of the participating ambulatory care facilities for the preparation, implementation and follow-up of the EUthyroid2 study.

Scope of the SOP

The scope refers to all participating health care professionals of the ambulatory care facilities involved in the EUthyroid2 ambulatory care setting.

2. Abbreviations

DM	Data Management
ID	Identification number
PM	Participant Management
Pseudo-ID	Pseudonym Identification number
QR-Code	Quick Response Code
SOP	Standard Operating Procedure
T	Timepoint

3. Background

The participating ambulatory care units will recruit study participants, inform them and conduct the study following a uniform procedure. The number of study participants to be recruited per institution depends on the total number of participating institutions in each study region (cluster) and will be announced by the regional management.

The regional management will also indicate whether an organisation will carry out the intervention alongside the data collection or whether it is part of the control group and will only carry out the data collection.

Furthermore, the regional management will indicate whether a participant receives an interview or not.

This SOP serves as a minimum standard for all settings. Documents are provided in English and should be translated into local languages by the Regional Management of the participating study regions. Any changes beyond this basic SOP must be reported to the Steering Committee.

4. Preparation and equipment

4.1. General Equipment

- Room that is suitable for the clarification and conduct of the study
- Sanitary facilities for urine sampling
- Refrigerator of temporary storage of urine samples
- Options for storing study documents in a lockable cabinet
- Pens

4.2. General Equipment provided by regional management

- Device for playing training videos
- Training videos
- In exceptional cases: if no freezing or refrigeration facilities are available: cool bags and ice packs

4.3. Equipment provided by regional management before Training (T0-1)

- A4 envelope labelled **HP-PM 1** containing:
    - Consent form with printed Pseudo-ID
    - A5 return envelope labelled **"HP-PM 2"**
- 2nd A4 envelope labelled **HP-DM 1** containing
    - Questionnaire for T0-1 for healthcare professionals
    - A5 return envelope labelled **HP-DM2**

4.4. Equipment provided by regional management after Training (T0-2)

- A4 envelope labelled **HP-DM3** containing
    - Questionnaire for T0-2 for healthcare professionals
    - A5 return envelope labelled **HP-DM4**

4.5. Equipment provided by regional management at Baseline survey (T1)

- A4 envelope labelled **P-PM 1** containing:
    - consent form with printed pseudonym
    - Contact information sheet
    - Appointment card
    - Study information
    - A5 return envelope labelled **" P-PM 2"**
    - Urine cup collectors labelled with participant ID number and time point of measurement (T1).
- A4 envelope **DM1** containing (only if paper-based questionnaires are used):
    - ID- containing Questionnaire for T1
    - Factsheet and Iodine Feedback Tool questionnaire (only intervention group)
    - A5 return envelope labelled **DM2**

4.6. Equipment provided by regional management when 50% of baseline survey achieved (T0-3)

- A5 envelope **HP-DM5** containing:
    - Questionnaire for T0-3 for healthcare professionals

- A5 return envelope labelled **”HP-DM6”**

4.7. Equipment provided by regional management for process evaluation interview (T0-4)

- Not applicable

4.8. Equipment provided by regional management at first Follow-up survey 2-4 weeks after Baseline survey (T2)*

- A4 envelope **P-PM3** containing:
  - 2 Appointment cards (if appointment for T3 is still open)
  - C1 return envelope labelled **"P-PM 4"**
  - Urine cup collectors labelled with participant ID number and time point of measurement (T2).
- A4 envelope **P-DM3** containing (only if paper-based questionnaires are used):
  - ID- containing Questionnaire for T2
  - A5 return envelope labelled “**P-DM4”**

4.9. Equipment provided by regional management at second Follow-up survey 6-8 months after first Follow-up survey (T3)*

- A4 envelope **P-DM5** containing:
  - ID- containing Questionnaire for T3
  - Urine cup collectors labelled with participant ID number and time point of measurement (T3).
  - A5 return envelope labelled **P-DM6**

* If no envelopes are handed over at the follow-up appointments, the participants have received them at home beforehand.

5. Before Training of Healthcare professionals (T0-1)

5.1. Informed Consents from Healthcare Professionals

- A member of the regional management will open the A4 envelope labelled **HP-PM 1** and collect the informed consent from you. You will receive a copy.
- The second signed copy of the consent form is for the participant management and will be placed in the A5 envelope labelled **HP-PM 2** and sealed..

5.2. Questionnaire to Healthcare Professionals (that will deliver the intervention)

- A member of the regional management will open the A4 envelope labelled **HP-DM1** and hand over the Questionnaire for T0-1.
- You will fill the questionnaire.
- The completed questionnaire is then placed in the A5 envelope labelled **HP-DM2** and sealed.
- The staff of the study regions will collect the envelopes **HP-PM2 and HP-DM1**.

6. Training of Healthcare professionals

6.1. Training on Information and Consent

Before participating in the study, each potential participant must be informed about the aim of the study, the voluntary nature of participation, the study procedure, storage of data and urine samples, renewed contact, data protection and revocation.

Therefore, you must have read the study information and watched the training videos.
If you conduct the study on the control group, you only receive the training videos that are relevant to them.

Furthermore, you must be able to inform the study participants of their rights.

The following inclusion and exclusion criteria must be observed:

Inclusion criteria:

- Female
- Age 18-24 years at the time point of recruitment
- Attending the specified settings
- Understanding of the local language

Exclusion criteria:

- Known thyroid disease
- Existing pregnancy at the time-point of recruitment or planning pregnancy during the intervention period
- Lactating women

6.1.1. How to obtain the consent of the study participants

1. Inform

While the study information is explained, you should give a brief summary of what the participant can expect during the conversation and in the study.

- Organisational and time frame:
  - Time frame: Baseline (T1), 1st follow up (T2: 2-4 weeks after baseline); 2nd follow up (T3): 6-8 months after T1
  - Data and urine sample collection
  - For the intervention group: short explanation on the intervention, but not too detailed to not influence first measurement (information material in different forms about health and nutrition, especially with focus on iodine).
  - Ask if there are any questions on the course of the intervention study
- Then the potential participant receives:
  - the participant information and
  - the informed consent form
- Each participant must be given sufficient opportunity to ask questions and basic aspects of the consent form must be addressed.
- By agreeing to participate and by signing the consent form, the participant gives their written consent and at the same time assures that they have understood everything and that there was an opportunity to ask questions, which can, however, also be done at any later stage.

If a participant does not yet wish to consent at the time of the study clarification, she can be offered a new appointment for the baseline (T1). This will be noted on the appointment card and given to the participant. Optionally, an appointment can also be arranged later by telephone.

2. Conducting the consent

- You go through the sections of the consent form with the participant
- Educating the participant requires an increased level of attention regarding data protection
- Each participant is declared that she has a right to complete or partial revoke her consent at any time without giving reasons.
  - Revocations of the consents must generally be declared in writing or verbally to the regional management (contact data is written on informed consent)
  - By revoking a consent, the participant prohibits EUthyroid2 from carrying out a process that they had previously consented.

Aspects after explaining the study information and consent forms

If the participant expresses the wish to read through the informed consent or individual sections of it again in silence, this must be ensured and any questions can then be clarified in a conversation.

Criticism and questions from the participants

The participant must be informed that they can ask questions at any time, including by telephone after visiting the ambulatory care setting. If a question cannot be answered directly by an employee on site, for example, because it requires specific knowledge, this should be communicated openly and the question should be passed on to the regional management so

that they can contact an appropriate expert, if necessary. The participant should be informed of this procedure and a prompt response should be ensured.

If the participant does not want to participate in a specific part of the intervention during the course of the study, they can refuse to do so at any time, even if consent has previously been given in writing. In this case, the study should be explained in more detail in order to eliminate possible concerns.

6.2. Training on Intervention (only applies to organisations assigned to the intervention group clusters)

All healthcare professionals who are assigned to intervention group clusters must watch the EUthyroid2 training videos in order to be prepared for delivering the intervention to the study participants. The videos will give you the information on important knowledge on iodine, the study itself, the intervention components, how to conduct the education on iodine and how to sample urine from the participants. Regional management will ensure access to the training videos, which will be integrated into the EUthyroid2 website.

After watching the training videos, regional management will organise a role play training for you to practice the educational conversation on iodine, which is a crucial intervention component. Place, date and any relevant instruction will be provided by regional management to you.

6.2.1. Overview of the core intervention components

The four core intervention components to be implemented consist of an iodine feedback tool, a brief educational conversation by you, an iodine factsheet and a video on iodine (Figure 1). To learn more about the core components you should watch the training video 1.

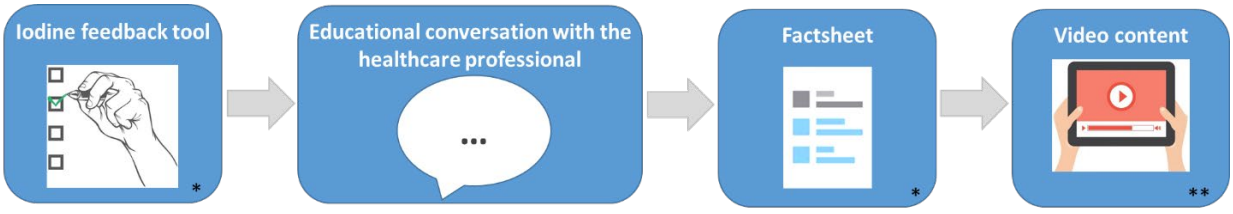

Figure 1. Overview and order of the four core intervention components. *(*free license by freepik **free license by rocketpixel via freepik)*

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 "Guideline and checklist for the educational conversation"). 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).

6.2.1.1. 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 outcome questionnaires (baseline survey T1). 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 before the educational conversation with you.

What is the iodine feedback tool?

The iodine feedback tool consists of a short questionnaire, comprised of four questions, asking study participants about their daily intake of iodine sources. Based on their answers, they will receive one of two feedback options (see Attachment) 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 6.2.1.2 "Education by the healthcare professional") with you takes place, where the participant is educated in more detail.

How do participants fill out the iodine feedback tool?

A staff member of your facility, hands out the iodine feedback tool to the participant in paper-form. 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.

6.2.1.2. Education by the healthcare professional

After the participant has filled out the iodine feedback tool, you educate her on iodine in more detail. It is preferable that this conversation takes place in a private room, e.g. your 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 the performing ambulatory care facility decides to conduct group educational sessions, the regional management needs to be informed before 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 recommendations of iodine supplementation
- Importance of healthy nutrition during pregnancy for the offspring, including iodine
- Specific iodine recommendations before/during pregnancy

You are provided with a short guideline, which includes a checklist for the educational conversation (see Attachment). Also, training will be provided on how to conduct the conversation before recruitment starts. **The regional management should be contacted when problems to conduct the conversation as planned encounter.**

During the conversation you hand 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). 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 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).

6.2.1.3. Iodine Factsheet

The iodine factsheet (see Attachment) is to be utilised by you during the educational conversation. It is important that you refer to the factsheet and hand 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.

6.2.1.4. Video content

The iodine video is accessible to the participant via the factsheet, which contains an individualised QR-code. 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. You 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.

Before the participant will be educated you should have watched the video to know the content

6.2.2. Additional intervention component

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

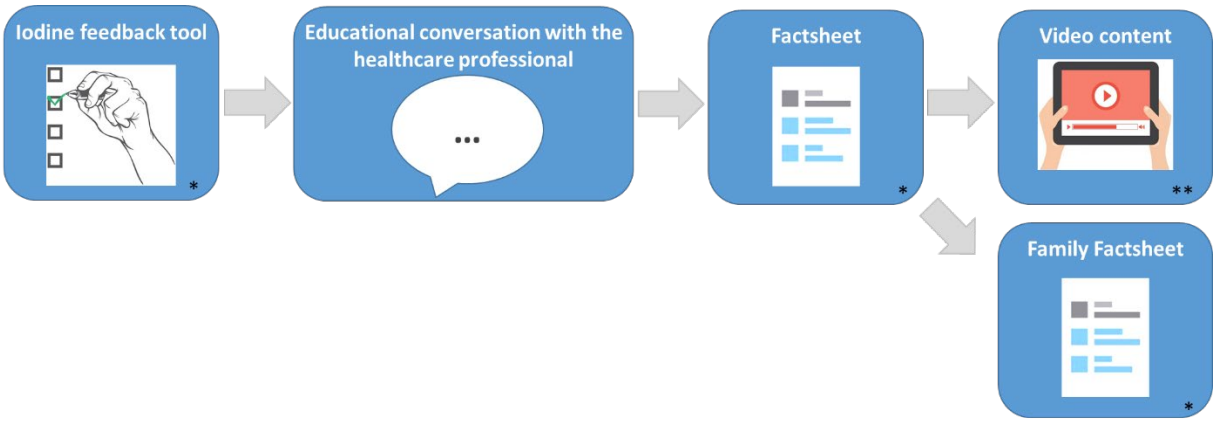

Figure 2. Overview of all intervention components in Bangladesh. *(*free license by freepik **free license by rocketpixel via freepik*

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.

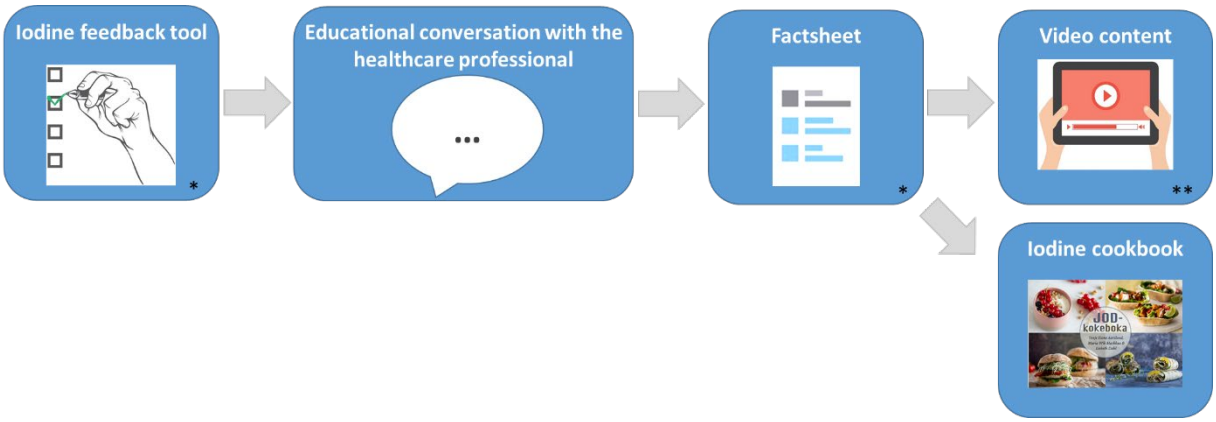

Figure 2. Overview of all intervention components in Norway. *(*free license by freepik **free license by rocketpixel via freepik)*

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).

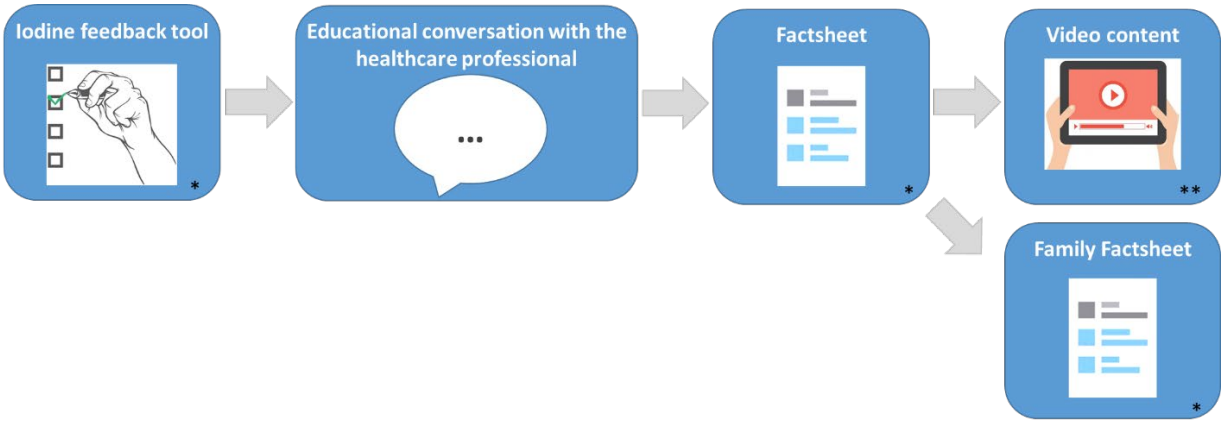

Figure 2. Overview of all intervention components in Pakistan. *(*free license by freepik **free license by rocketpixel via freepik)*

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).

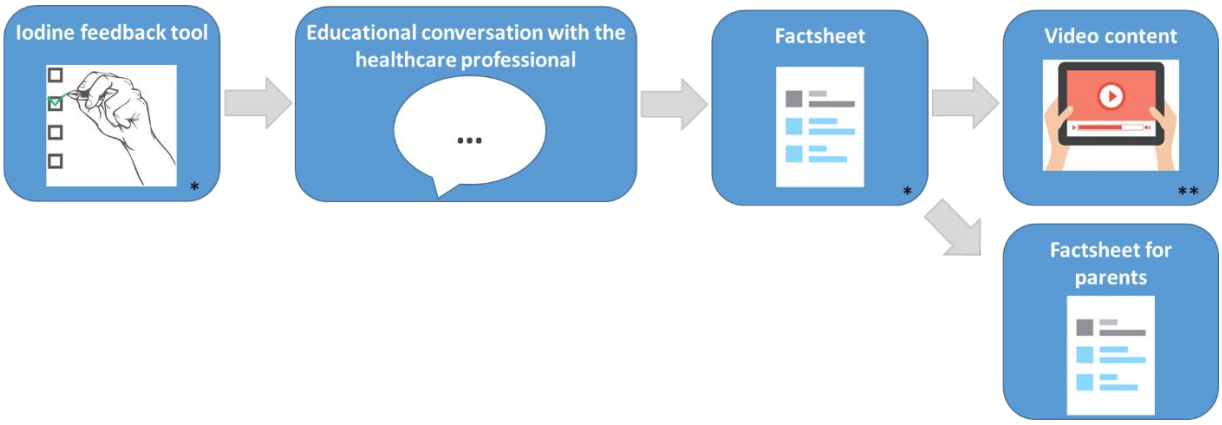

Figure 2. Overview of all intervention components in Poland. *(*free license by freepik **free license by rocketpixel via freepik)*

7. After Training of Healthcare professionals (T0-2)

- A member of the regional management will open the A4 envelope labelled **HP-DM3** and hand over the Questionnaire for T0-2.
- The health care professional will fill out the questionnaire.
- The completed questionnaire is then placed in the A5 envelope labelled **HP-DM4** and sealed.
- The staff of the study regions will collect the envelopes **HP-PM4**.

8. Conducting the study

8.1. Informed Consents from Participants and appointment management (T1)

- You open the A4 envelope labelled **P-PM1.**
- The informed consent will be collected as described above. The participant will receive a copy.
- The participant is then asked to enter their contact details on the contact information sheet.
- You will arrange an appointment for the 1st follow-up after 2-4 weeks and, if the participant agrees, the 2nd appointment after 6-8 months after the intervention/baseline. Dates are entered on the contact information sheet and on the appointment card.
- The appointment card is given to the participant.
- If it is not possible to make an appointment, this can also be made by telephone at a later date. In this case, the participant calls the ambulatory care facility and arranges the appointments. The ambulatory care facility then forwards the appointments to the participant management.
- The completed contact information sheet is then placed in the A5 envelope labelled **P-PM2** together with the second signed copy of the consent form and sealed.

8.2. Questionnaire from participants (T1)

- You will open the A4 envelope labelled **P-DM1** and hand over the questionnaire for T1 and the urine cup collector.

- The completed questionnaire is then placed in the A5 envelope labelled **P-DM2**. Keep the envelope open.
- Only Intervention group: the intervention is carried out as described above under "6.2. Training on Intervention"
- During the intervention the iodine feedback tool will be filled by the participants.
- After the participant filled out the Iodine Feedback Tool form, she will read the evaluation instructions and calculate her score to find out which feedback applies to her answering pattern.
- The completed Iodine Feedback Tool form is then placed in the A5 envelope labelled **P-DM2** already containing the filled Awareness Questionnaire.
- Now the A5 envelope labelled **P-DM2** can be sealed.
- The staff of the study regions will collect the urine samples obtained and the envelopes **P-PM2** and **P-DM2** at least once a week.

8.3. Urine sampling from participants (T1)

- The participant receives the urine cup collector (marked with participant ID number and T1). Give the instructions on how to collect the urine sample (given in the SOP for collection of urine samples).
- Make sure that the collector is labelled with the correct time: **"T1"** at the first timepoint, **"T2"** at the second timepoint, **"T3"** at the third and last timepoint
- You should go through the procedure and steps to collect the urine sample with the participant (see Attachment "Steps to collect a urine sample: Instructions to the participant").
- The participant should be requested to collect a spot urine sample during the day. The urine sample should not consist of the first void after night (no morning urine).
- The urine should be stored in a refrigerator until delivering at the study site.
- If the participant has not received the urine cup collector before, have forgotten to collect urine or bring the urine sample to the appointment, the participant should collect the spot urine sample during the appointment at the study site.

8.4. Questionnaires and audio files from Healthcare professionals (T0-3)

- Once half of the sample is recruited, a member of the regional management will contact you for process evaluation (process evaluation questionnaire T0-3 and interview T0-4)

Process evaluation questionnaire:

- You open the A5 envelope labelled **HP-DM5** and take out the the Questionnaire for T0-3.
- You fill out Questionnaire.
- The completed questionnaire is then placed in the A5 envelope labelled **HP-DM6** and sealed.
- The staff of the regional management will collect the envelopes **HP-DM6**.

8.5. Interview for process evaluation from Healthcare professionals (T0-4)

Process evaluation interview:

- Regional management will interview two healthcare professionals who delivered the intervention per region and will receive all necessary information by the project partners
- The interview will be audiotaped

8.6. Appointment management (T2)

- You open the envelope labelled **P-PM3** and if not yet done before arrange an appointment for the 2nd Follow-up (6-8 months after T1)
- If an appointment was already arranged before, you reminds the participant on the date for T3.
- Dates are entered on the appointment card.
- 1 appointment card will be given to the participant.
- The second appointment card is then placed in the C1 envelope labelled **P-PM4** sealed.
- If it is not possible to make an appointment, this can also be made by telephone at a later date. In this case, the participant calls the ambulatory care facility and arranges the appointments. The ambulatory care facility then forwards the appointments to the participant management.

8.7. Questionnaire for participants (T2)

- You will open the A4 envelope labelled **P-DM3** and hand over the Questionnaire for T2 the urine cup collector.
- The completed questionnaire is then placed in the A5 envelope labelled **P-DM4**.
- The staff of the study regions will collect the urine samples obtained and the envelope **P-DM4** at least once a week.

8.8. Urine sampling from participants (T2)

- See procedure under 8.3 Urine sampling from participants (T1)

8.9. Questionnaire from participants (T3)

- You will open the A4 envelope labelled **P-DM5** and hand over Questionnaire for T3 and the urine collector with yellow lid.
- The completed questionnaire is then placed in the A4 envelope labelled **P-DM6** and sealed.
- The staff of the study regions will collect the urine samples obtained and the envelope **P-DM6** at least once a week.

8.10. Urine sampling from participants (T3)

- See procedure under 8.3 Urine sampling from participants (T1)

8.11. Interview with participants (T4)

- Four participants per region will be contacted by the regional management and interviewed for process evaluation.
- **The interviews are conducted by a designated staff member from the regional management and not by you who delivered the intervention to them.**
- The interviews should be conducted after the respective participants filled-out their last questionnaires (T3) to avoid influencing their answering behaviour.
- The interviews will be audiotaped.

9. Appendix/Referrals

- Attachment 1 Guideline for the educational conversation
- Attachment 2 Checklist for the educational conversation
- Attachment 3 Iodine feedback tool paper
- Attachment 4 Iodine Factsheet for the participants
- Attachment 5 Iodine Factsheet for the family (only for Poland, Bangladesh and Pakistan)
- Attachment 6 Steps to collect a urine sample: Instructions to the participant