

Standard Operating Procedure (SOP)

Teachers

Educational Setting

Paper-based data collection

Version 1.0

Scope	Baseline Survey and Follow-up		
Valid from	01.01.2024		
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Changes			
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1. Aim

This SOP serves as a guideline for the teachers of the participating schools for the preparation, implementation and follow-up of the EUthyroid2 study.

Scope of the SOP

The scope refers to all participating teachers 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 schools 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 schools in each study region.

The Regional Management will indicate whether a teacher and a participant receive 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 if the teachers do not have sufficient knowledge of English to understand and act according to the SOPs. 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
- Room that is suitable to conduct and record an interview
- Options for storing study documents in a lockable cabinet

4.2. General Equipment provided by Regional Management

- Access to all study and teaching materials via the “ABC of Iodine” on the EUthyroid2 website.

4.3. Equipment provided by Regional Management before training (T0-1)

- A4 envelope labelled **T-PM 1** containing:
 - Consent form with printed Pseudo-ID
 - Contact information sheet for teachers
 - A5 return envelope labelled **T-PM 2**

4.4. Equipment provided by Regional Management for informing the students and parents (T0-2)

- A4 envelope labelled **St-PM 3** containing
 - Consent form with printed Pseudo-ID
 - Contact information sheet for students (name, date of birth, home address, school and class)
 - A5 return envelope labelled **St-PM 4**

4.5. Equipment provided by Regional Management at Baseline survey (T1)

- A4 envelope **St-DM1** containing:
 - ID- containing Awareness Questionnaire
 - Iodine Feedback Tool in paper-form
 - A5 return envelope labelled **St-DM2**

4.6. Equipment provided by Regional Management at first Follow-up survey 2-4 weeks after Baseline survey (T2)

- A4 envelope **St-DM3** containing
 - ID- containing Awareness Questionnaire and Process Evaluation Questionnaire
 - A5 return envelope labelled **P-DM4**

4.7. Equipment provided by Regional Management for process evaluation right after first Follow-up survey (T0-3)

- A4 envelope **T-DM3** containing
 - ID- containing Questionnaire about implemented intervention components
 - ID- containing Awareness Questionnaire
 - A5 return envelope labelled **T-DM4**

4.8. Equipment provided by Regional Management for interview with subgroup of teachers (T0-3)

- A4 envelope **T-DM5** containing
 - ID for interview file
 - Guidelines for Interviews
 - Audio-recording device
 - A5 return envelope labelled **T-DM6**

4.9. Equipment provided by Regional Management at second Follow-up survey 6-8 months after intervention (T3)

- A4 envelope **St-DM5** containing:
 - ID- containing Awareness Questionnaire
 - ID for interview file
 - Guidelines for Interviews
 - Audio-recording device
 - A5 return envelope labelled **St-DM6**

5. Before Training of Teachers (T0-1)

5.1. Informed Consents from Teachers

- A member of the Regional Management will open the A4 envelope labelled **T-PM 1** and collect the contact data and informed consent as described in the SOP “Informed Consents and Revocations”. The teacher will receive a copy.
- Appointments are set for the data collection (ideally for all time points)
- *If no follow-up appointments can be made at T0-1, the Participant Management team will contact the teacher at least 3 days before the end of the period to arrange an appointment.*
- The second signed copy of the consent form and the contact data sheet is then placed in the A5 envelope labelled **T-PM 2** and sealed.
- The envelope **T-PM 2** be collected by a member of the study Regional Management or sent by post.

6. Training of Teachers

6.1. Training on Information and Consent (only if the teacher obtain the consents of the students/parents)

A member of the Regional Management can obtain the informed consents of the students and/or their parents. Alternatively, this can be also done by the teacher.

In this case, before participating in the study, the teacher will inform the potential students and/or their parents about the aim of the study, the voluntary nature of participation, study procedure, storage of data, renewed contact, data protection and revocation before

Therefore, the teacher must have read the study information and watched the training videos. Furthermore, they must be able to inform the study participants of their rights.

The following inclusion and exclusion criteria must be observed:

Inclusion criteria:

- Age 13-17 years at the time point of recruitment
- Attending the specified settings

6.1.1. How to obtain the consent of the study participants

1. Inform

A member of the Regional Management will explain the study information and give a brief summary of what the students can expect during the study either to the student and/or the parents.

- Organisational and timeframe:
 - Time points for data collection: baseline: 1st follow up; 2nd follow up
 - Data collection
 - 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 person potentially giving consent receives:
 - the participant information and
 - the informed consent form
- Each student/parent 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 student/parent 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.

2. Conducting the consent

- During the consent process, a member of the Regional Management or a trained teacher goes through the sections of the consent form with the participant in group of other students and parents or individually if a student or parent prefers.
- Data protection procedures are explained
- Each student/parent is declared that she/he has a right to revoke her/his consent completely or partially 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 student/parent prohibits EUthyroid2 from carrying out a process that they had previously consented.

- If the parents or students would like more time to think about it, the consents can also be submitted later within 7 days.
- If the parent does not attend the presentation, the student will later provide the information material and consent form to the parent. In this case, the signed declaration of consent can be submitted to the school within 7 days.
- A second signed copy of the consent form is placed in the A5 envelope labelled **St-PM 4** and sealed.
- The member of the Regional Management will collect the envelopes labelled **St-PM 4**.

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.

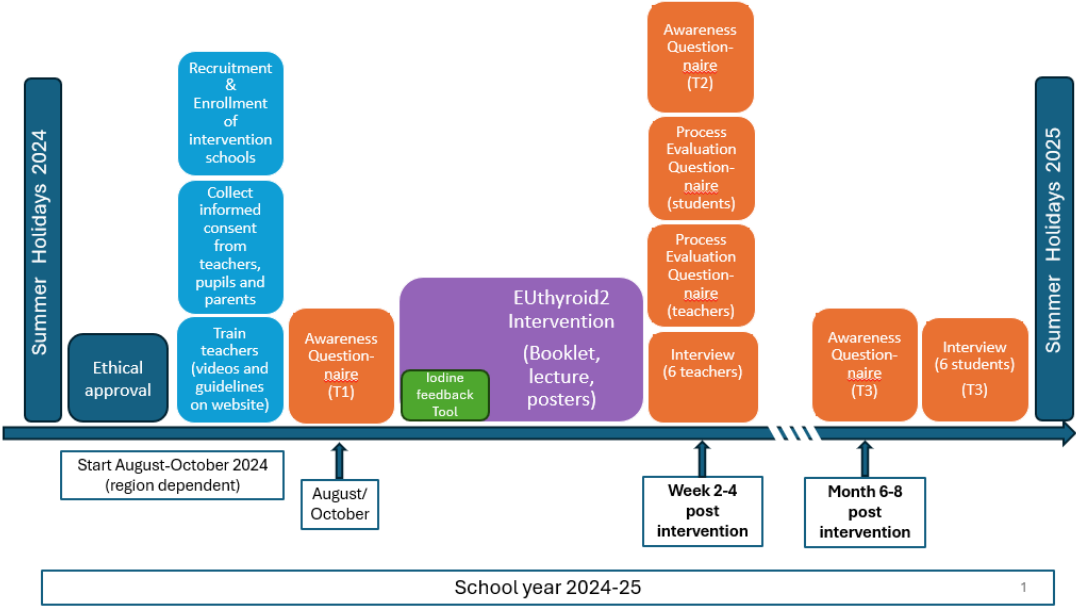
If the participant does not want to participate in a specific part of the intervention during the course of the study, they can refuse to do so at any time, even if consent has previously been given in writing. In this case, the study should be explained in more detail in order to eliminate possible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

7. The Intervention

The intervention is structured as a three-step model (“ABC of Iodine”) consisting of three modules combining four intervention components, supplemented by online material on the EUthyroid2 webpage <https://euthyroid2.eu/>.

All components are scientifically developed and pretested to achieve an improvement in adolescents’ awareness of the topic. In the following, the modules and components will be described, and their application explained.

Study timeline:



8. Overview of the three-step model: The ABC of Iodine

The model consists of a flexible three-step model with three modules (Module A, B, and C), where students can work with various themes, do exercises and assignments, and collaboratively develop mini-projects within one or more themes. The activities for each theme are structured to complement each other and provide a natural progression in the tasks. Module A is mandatory, while Module B and C are optional. Thus, there is a variety of options for how to structure the teaching based on what each class is capable of and has time to engage with.

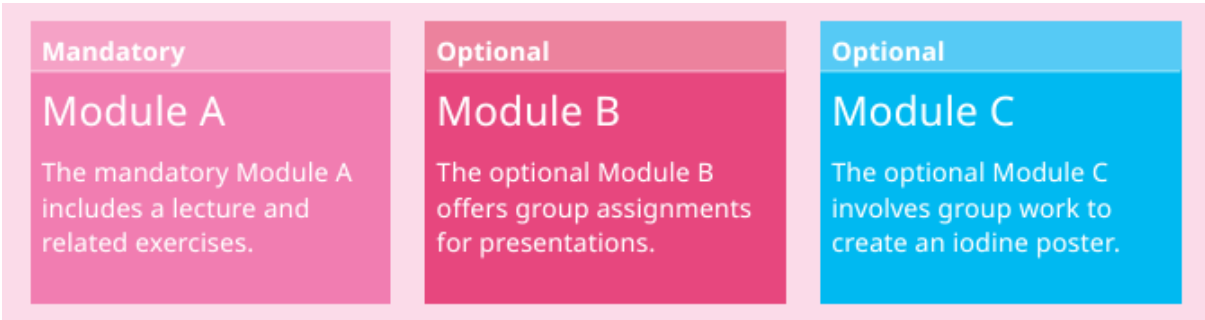


Figure 1. Overview and order of the three modules in the ABC of Iodine.

Module A is mandatory to teach. It consists of traditional in-class instruction in the form of one lecture (35-45 minutes), supported by a power point presentation or posters, and exercises corresponding to the topics taught in the lecture. Exercises are planned as individual active learning (done either as homework or in class).

Module B is optional and consists of five active cooperative learning assignments that students can work with in groups and subsequently present for their fellow students in class. This way, it becomes possible for students to work on different assignments, while still being presented with the findings and results achieved by each respective group.

Module C is optional and consists of an inquiry-based learning assignment. In groups students design a poster for an imagined nutritional campaign on the importance of iodine. Regions can make local/regional competitions among schools or school leadership can choose a local winner poster.

8.1. The intervention materials

The following teaching resources and materials (Figure 2) to be implemented in the educational institution are available:

- 1) An Iodine Feedback Tool
- 2) A lecture on iodine and health presented as a PowerPoint presentation or posters, and related exercises
- 3) A booklet: “The ABC of Iodine”
- 4) Access to all materials via the EUthyroid2 website by clicking on “ABC of Iodine”

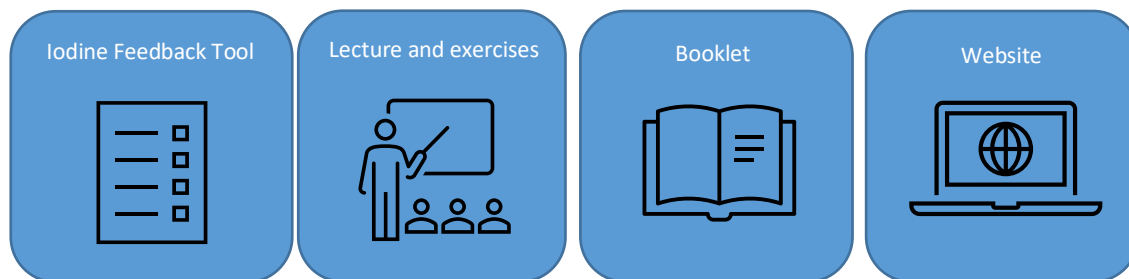


Figure 2. Overview of the intervention materials.

Please read paragraphs 9.-12. to learn more about the core materials.

9. Iodine Feedback Tool

When do the students fill out the Iodine Feedback Tool?

The Iodine Feedback Tool is the first 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”). 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.

What is the Iodine Feedback Tool?

The Iodine Feedback Tool consists of a short questionnaire, comprised of four questions, (see appendix 1) asking students about their average intake of iodine sources. Based on their answers, they will receive one of two feedback options (see appendix 1) providing them with information about their personal intake of iodine food sources. The purpose of the tool is to generate interest and awareness regarding iodine intake. Thus, it's essential that soon after the students complete the tool, the teacher presents the lecture (see point 11 below: Lecture) to provide the students with a more detailed education on the topic.

How do students 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 other option includes a paper-pencil version.

Option 1 - digital: The Iodine Feedback Tool is implemented in LimeSurvey and available on the EUthyroid2 website under “ABC of Iodine”. The tool is programmed in LimeSurvey in such a way, that it shows one of the two feedback options to the participant, depended on the answers they entered.

Option 2 - analogue: Regional Management provides the Iodine Feedback Tool as paper-form. The teacher hands out the Iodine Feedback Tool to the students in paper-form. After the students have filled out the tool, they will read the evaluation instructions and calculate their score to find out which feedback applies to their answering pattern.

10. Booklet

The booklet is core in the classroom materials. It supports teaching and gathers all learning resources for Module A in one easily accessible place for the students. The booklet includes both an overview of the three Modules (A, B and C) and covers the content of the lecture. All exercises, assignments and tasks are compiled here, allowing the students to use it as both a reference book and a workbook. The booklet provides a background on global iodine status, followed by facts surrounding iodine deficiency. The roles of iodine in bodily functions, specifically metabolism, growth, and its significance during pregnancy and neurodevelopment in infants, are covered. An overview of iodine intake and its associated health outcomes, both from deficient and excessive intakes, is provided and recommended intakes for various demographics, including pregnant and breastfeeding women, are presented. Lastly, the iodine cycle and its primary sources is explained, and guidance on portion sizes. Exercises from Module A are included, together with an overview of assignments from Module B. Additional resources for working with assignment 1-5 in Module B is available through the EUthyroid2 website under ‘ABC of Iodine’. The booklet concludes with the introduction of Module C consisting of a poster competition, emphasizing the facilitation of changes in health behaviours through an imaginary national nutritional campaign where students are to craft their own iodine campaign posters.

Teachers should read through the booklet to prepare themselves for their teaching – notably if they have limited knowledge on iodine and iodine-related health.

11. Lecture on iodine and health, and related exercises

The lecture, along with the booklet, constitutes the main components of Module A and covers all themes required to fulfil the intended learning outcomes for Module A. The lecture can be conducted either using a PowerPoint presentation or using the provided educational posters, depending on the teacher's preference and the availability of a laptop and projector in the classroom. If the lecture is conducted without the PowerPoint presentation, the teacher has access to teaching posters via the EUthyroid2 website under “ABC of Iodine”. The posters cover the main topics presented in the PowerPoint presentation.

Lecture given in PowerPoint format: In the PowerPoint presentation, slides summarise all topics covered in the booklet and address each topic individually, with supporting information, explanations, and details included in the note’s section for the teacher's reference and use, if desired. All answers to

the exercises in Module A are also comprised in the slides, or in the notes, and can be printed from the EUthyroid2 website under 'ABC of Iodine'.

12. Educational posters with key messages

If the teacher conducts the lecture without using the power point presentation, the educational posters can support the delivery. The four educational posters present main topics and key info addressing the topics covered in the PowerPoint presentation and in the booklet.

13. Online Teacher Resource (ABC of Iodine)

The online teacher resource can be accessed through the EUthyroid2 website (<https://www.euthyroid2.eu/>) and is the main entry for enrolled schools in the educational setting and will provide teachers and students with all the information, teachers' guidelines and tutorials, and materials that they need to participate in the project. To get access to the teachers' material teachers will receive a password from the Regional Management.

To provide teachers with a quick and easily accessible introduction to the materials and how they can be used in the intervention, each section includes short instructional videos. These videos describe the teaching materials, offer examples of how lessons can be structured, and explain how the Iodine Feedback Tool functions.

The aims of the "ABC of Iodine" are to provide a clear and easily accessible overview of the intervention structure, to display the available teaching resources and classroom materials, and to ensure that teachers' guidelines are readily accessible to teachers. Additionally, it aims to make classroom materials easily accessible to students and to facilitate the student work on Module B and C by providing additional resources, e.g. guidelines for developing questionnaires (assignment B1) or an overview of national iodine fortification programmes (assignment B3).

If the teacher chooses to implement all or parts of Modules B and C, the students will create various products, such as posters in Module C and collect data through their questionnaire in assignment B1.

Every student who has successfully created a poster and/or conducted a questionnaire study will receive a certificate of participation (see Appendix 2). In addition, students can win prizes for their work (see Appendix 3 "Poster competition" and Appendix 4 "Prize for best survey")

The posters (in original, as a photo or as PDF) and filled questionnaires are collected by the Regional Management.

14. Conducting the study

14.1. Informed Consents from students and/or their parents (T0-2)

- A member of the Regional Management or a trained teacher will open the A4 envelope labelled **St-PM3** and collect the informed consent as described in the SOP "Informed Consents and Revocations". The student and/or parent will receive a copy.
- The second signed copy of the consent form is then placed in the A5 envelope labelled **St-PM 4** and sealed.
- The envelope **St-PM 4** be collected by a member of the study Regional Management or sent by post.

14.2. Questionnaire from participants (T1)

- The teacher will distribute the envelopes labelled **St-DM1** to the addressed students.
- The students will open the envelope and complete the questionnaire
- The completed questionnaire is then placed in the A5 envelope labelled **St-DM2** and sealed. **No name should be written on the questionnaires or the envelope labelled St-DM2.**
- The teacher decides when the Iodine Feedback Tool will be used. But it should not be used before the Awareness questionnaire was filled the first time.
- After the students filled out the Iodine Feedback Tool form, they will read the evaluation instructions and calculate their score to find out which feedback applies to their answering pattern.
- The completed Iodine Feedback Tool form remains with the students and is not collected
- The envelope **St-DM2** can be collected by a member of the Regional Management or sent by post.

14.3. Implementation of the intervention in the classroom

- The intervention is carried out as described above.
- 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.

14.4. Questionnaires and interviews from participants (T2)

- The teacher will distribute the envelopes labelled **St-DM3** to the addressed students.
- The students will open the envelope and complete the questionnaires.
- The completed questionnaires are then placed in the A4 envelope labelled **St-DM4** and sealed. **No name should be written on the questionnaires or the envelope labelled St-DM4.**
- The staff of the Regional Management will collect the envelopes **St-DM4**.

14.5. Process evaluation (T0-3)

- The teacher will open the A4 envelope labelled **T-DM3** and fill the Awareness questionnaire.
- The completed questionnaire is then placed in the A5 envelope labelled **T-DM4** and sealed. **No name should be written on the questionnaires or the envelope labelled T-DM4**
- The envelope **T-DM4** can be collected by a member of the study Regional Management or sent by post.

14.6. Process evaluation interview for a subgroup of teachers (T0-3)

- Teachers chosen for interview will be the interview file ID from **T-DM5** to the interview room.
- Teachers are interviewed by a member of the Regional Management. The Regional Management is not allowed to know the name of the teacher.

- The interview will be audiotaped
- The audio file will be labelled/named with the interview ID.
- The interview file is then placed in the A4 envelope labelled **T-DM6** and sealed. **No name should be written on the questionnaires or the envelope labelled T-DM6.**
- The staff of the Regional Management will collect the envelopes **T-DM6**.

14.7. Questionnaire from participants (T3)

- A member of the Regional Management will come to the school and hand over the envelopes **St-DM5** to the teacher.
- The member of the Regional Management will take the audio recording device and wait in the room where the interview will be conducted.
- The teacher will distribute the envelopes **St-DM5** to the addressed students.
- The students will open the envelope and complete the questionnaire.
- Students chosen for interview will bring the interview file ID from the envelope **St-DM3** to the interview room
- Students are interviewed by a member of the Regional Management. The Regional Management is not allowed to know the name of the student.
- The interview will be audiotaped
- The audio file will be labelled/named with the interview ID.
- The completed questionnaire and the interview file is then placed in the A5 envelope labelled **St-DM6** and sealed. **No name should be written on the questionnaires or the envelope labelled St-DM6.**
- The envelope **St-DM6** can be collected by a member of the study Regional Management or sent by post.

15. Appendix/Referrals

- Appendix 1 Iodine Feedback Tool
- Appendix 2 Certificates of participation
- Appendix 3 Poster competition
- Appendix 4 Prize for best survey

Appendix 1: Iodine Feedback Tool

Appendix 2 Certificates of participation




EUthyroid2

Certificate of participation

THIS CERTIFICATE IS PRESENTED TO

NAME OF STUDENT

FOR SUCCESSFUL PARTICIPATION IN THE EUHYROID2 POSTER COMPETITION
DD/MM/YY.

EUTHYROID2 SCIENTIFIC COMMITTEE

REGIONAL MANAGER

EUthyroid2 is funded by the European Union and UK Research and Innovation

 Co-funded by the European Union  UK Research and Innovation




EUthyroid2

Certificate of participation

THIS CERTIFICATE IS PRESENTED TO

NAME OF STUDENT

FOR SUCCESSFULLY CONDUCTING YOUR OWN QUESTIONNAIRE AS PART OF
THE EUHYROID2 PROJECT
DD/MM/YY.

EUTHYROID2 SCIENTIFIC COMMITTEE

REGIONAL MANAGER

EUthyroid2 is funded by the European Union and UK Research and Innovation

 Co-funded by the European Union  UK Research and Innovation

Appendix 3 Poster competition

Rules of the poster competition

- Every student who participates in the Euthyroid2 study and creates a poster can take part in the Poster Competition.
- Students should submit along with the poster, a short note (50-100 words) explaining the topic and content of the poster).
- No responsibility will be taken for Lost, Late, or misdirected entries.
- The organizer reserves the right in its sole discretion, to cancel, terminate, modify, or suspend the competition at any point in time.
- The competition will not only judge the youth based on their creative abilities but also trigger their thought process towards the awareness of iodine deficiency.
- The entry is limited to one per person and multiple entries will be deemed invalid.
- Students should make posters according to the topics of ABC of Iodine
- The participating students agree that in the event of a poster prize being awarded, the posters will be published on the Euthyroid2 website

The format for the poster is:

- A3 size (11.7 * 16.5 inches) with margins (0.5 inches) on all sides
- Either a hand-drawn/painted/printed poster are allowed
- The topic theme should be clearly mentioned in the top margin of the poster
- The poster should not contain any personal details such as name, age, name of the college/school, gender, and location of the participant.
- The same should be mentioned separately in the form at the time of submission.
- The poster can be submitted in the original, as a photograph of the original in the size 20x30 or as a PDF

Judgement Criteria

The posters are evaluated by an internal jury consisting of two members of the Euthyroid2 Scientific Committee and two local teachers according to the following criteria:

- Relevance to the theme
- Artistic Composition
- Originality
- Creativity

Announcement of the winners

1st prize level

Prizes worth €25 will be awarded for the best poster from each grade level of the participating school.

The winners will be announced within 1 month after all classes of the participating school have completed the intervention.

2nd prize level

The winners of their schools are automatically entered into the national prize draw for their grade level and have the chance to win a prize worth €100.

The winners will be announced within 1 month after all participating schools in the country have completed the intervention.

Appendix 4 Prize for best survey

Judgement Criteria

The survey is evaluated by an internal jury consisting of two members of the Euthyroid2 Scientific Committee and two local teachers according to the following criteria:

- Response rate
- Number of correctly and fully completed questionnaires
- Structure of the survey
- Quality of survey result

Announcement of the winners

1st prize level

Prizes worth €25 will be awarded for the best survey from each grade level of the participating school.

The winners will be announced within 1 month after all classes of the participating school have completed the intervention.

2nd prize level

The winners of their schools are automatically entered into the national prize draw for their grade level and have the chance to win a prize worth €100.

The winners will be announced within 1 month after all participating schools in the country have completed the intervention.