**“Enhance your Thesis”**

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| **Audience** | **Master students** |
| **Year of study** | **Secondary year of master’s studies** |
| **Number of ECTS credits** | **2.0 ECTS credits (workload of 50 to 60 hours)** |

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Please remember that the resources at hand **can (and should) be adapted** to your specific needs and context. The HEIRRI resources have been **designed to be flexible**, so we encourage you to think about including **local cases**, adjusting the **timings** of the course to your needs, and also adapting some contents to your specific **field or discipline**.

**SYLLABUS**

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| **Element** | **Description** |
| **Title** | Enhance your Thesis |
| **Cycle** | EHEA: Second cycle  EQF level: 7  Degree level: Master |
| **Year of study** | Second year of master’s studies |
| **Number of ECTS credits** | 2.0 ECTS credits (workload of 50 to 60 hours) |
| **Learning outcomes (LO)** | On completion of this course students will be able to   1. apply concepts of RRI to discuss research and innovation (R&I) processes and their outputs; 2. assess possible societal implications and impacts of concrete research activities; 3. acknowledge and react constructively to suggestions from their peers regarding their own research work; 4. and to propose adaptations to better align a research project with societal needs, values, and expectations. |
| **Mode of delivery** | This course combines different modes of delivery. In class, students will participate in problem-based learning (PBL) activities, deliver prepared presentations, and actively participate in discussions. A short input lecture on RRI will be given by the course instructor. A significant part of the course consists of independent work of the students (desk research, preparation of presentations, and a final report). |
| **Prerequisites and co-requisites** | Students should already have a topic/research question for and at least a preliminary design of their master’s thesis research. |
| **Course content** | The course provides room for investigating, reflecting, and discussing societal implications and possible impacts of research and innovation processes. As reference points for this deliberation, different concepts of Responsible Research and Innovation (RRI) will be used.  Students will discuss a research or innovation case example (“What are ‘responsible’ research and innovation?”) before turning to their own master’s theses. Together with their colleagues, each student will identify and discuss RRI aspects of their thesis (“Present your thesis”) and then individually further explore on them (“Investigate your thesis”). They will present and discuss their findings, and reflect how they could practically deal with them (“Enhance your thesis”). . |
| **Recommended or required reading and other learning resources/tools** | There is no required reading for this course. However, the following texts and tools might be helpful when reflecting upon and investigating RRI aspects of the master’s theses:   * Kuhlmann, S., Edler, J., Ordónez-Matamoros, G., Randles, S., Walhout, B., Gough, C., & Lindner, R. (2016). *Responsibility Navigator*. Karlsruhe: Fraunhofer ISI. Retrieved 9 February 2017, from http://responsibility-navigator.eu/ * RRI Tools (web): RRI Toolkit. https://www.rri-tools.eu/search-engine * RRI Tools (web): Self-reflection tool. https://www.rri-tools.eu/self-reflection-tool |
| **Planned learning activities and teaching methods** | At the beginning of the course, the course instructor will give a presentation of different concepts of RRI. Later on, the instructor mainly serves as moderator of discussions and supporter for the students in their independent inquiry.  Students will have to   * analyse a R&I case example in a group exercise; * present their master’s theses in a lightning talk; * actively participate in discussions on RRI aspects of the theses of others; * do desk research on the wider implications of their research project; * and give an oral presentation and write a final report on their findings. |
| **Assessment methods and criteria** | The following activities and outputs of the students will be assessed:   * Active and constructive participation in discussions. * Lightning talk on master’s thesis. * Presentation of the results of their desk research. * Written final report on their findings regarding the RRI aspects of their thesis. |

“Enhance your Thesis”

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| **Part 1** | **Activity** | **Duration** |
| **Unit 1** | Scenario presentation and question formulation | 1h |
| Sharing the questions and categorisation | 40’ |
| Constructing an RRI definition | 20’ |
| **Unit 2** | Introduction to RRI | 45’ |
| Discussion | 45’ |
| Reflection | 30’ |
| **Part 2** | **Activity** | **Duration** |
|  | Lightning Talks | 2h |
| Neo-Socratic dialogue | 2h |
| **Part 3** | **Activity** | **Duration** |
|  | Online Forum | 1-2 weeks |
| **Part 4** | **Activity** | **Duration** |
|  | Students’ presentations | 1h |
| Sharing dimensions’ feedback | 15’ |
| Discussion | 45’ |
| Final Report | - |

**PART 1. WHAT IS “RESPONSIBLE” RESEARCH AND INNOVATION?**

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| **Part 1** | **Activity** | **Duration** |
| **Unit 1.** | Scenario presentation and question formulation | 1h |
| Sharing the questions and categorisation | 40’ |
| Constructing an RRI definition | 20’ |
| **Unit 2.** | Introduction to RRI | 45’ |
| Discussion | 45’ |
| Reflection | 30’ |

**Unit 1. Reflecting on responsibility**

**Goal:**

*The goal of this unit is for the students to reflect upon and discuss the meaning of responsibility, based on a case example.*

**Learning outcomes:**

After this unit, the students should be able to:

* To reflect upon the meaning of responsibility
* To learn about RRI from a specific case example
* To discuss what RRI is
* To relate research processes in their own field of study with the case example
* To gain insight on how RRI can be applied to practical research
* To understand the role of responsibility in research processes
* To identify the potential impact of research on individuals, groups or society

**Materials:**

* RRI transversal scenario video or PBL. **See Transversal Scenario Guide or HEIRRI PBL GUIDE in the Annex.**
* Large cardboard/paper
* Coloured pens
* Other creative material of choice

**Description of the activity:**

**Part 1. Scenario presentation and question formulation (1h)**

At the beginning of the class, the students will be divided into small groups. Each group will sit together and they will be given cardboard/paper and coloured pens. The teacher can choose between two options to present a scenario to the students: the transversal scenario (Ageing/Food videos developed by HEIRRI) and the set of HEIRRI PBL scenarios. The course participants will then either be shown a video or given a PBL scenario, consisting of a realistic made-up case example which reflects the aspects of RRI. Students are to pay close attention to issues that appear related to the concept of “responsibility” in the presented scenario.

**Part 2. Sharing the questions and categorisation (40’)**

After watching the video or PBL scenario, the groups are to discuss and decide on some key questions related to responsibility. Each group should present a limited number of questions, those they believe to be most relevant. The number of questions can be adapted according to the number of students in the course and also the number of groups formed.

The students should write these questions in large letters on the cardboard/paper provided and then hang them on the wall (or a similar method) so as to make them visible to all. It could be useful to organise the questions from the different groups before putting them on the wall. In this way, questions can be grouped into related topics. Each group presents the questions they have formulated and these are discussed with the whole class as a group. Then, the teacher can help to categorize questions to identify key ideas associated with responsibility.

Other formats of presentation are equally as effective, depending on the situation. The students can also use blackboards/whiteboards etc. Even so, it is recommended they have some material to write ideas down before deciding on their final questions.

**Part 3. Constructing an RRI definition (20’)**

Finally, each group should write a definition about what responsibility in research and innovation processes means to them.

***Adaptation possibility 1.***

*If the students are already knowledgeable on the concept of RRI, the activity will be slightly different. Each group of students should concentrate on a different aspect of RRI or one specific concept related to RRI, and they should discuss the case example against this very specific background.*

*Thus, each group could focus on a different RRI aspect such as Gender Equality, Ethics, Sustainability, Public Engagement etc. In the same way, each group of questions can be hung on the wall (or a similar method) when the discussion is finished.*

**Duration of the activity:**

Total duration: 2 hours

* Part 1. Scenario presentation and question formulation (1h)
* Part 2. Sharing the questions and categorisation (40’)
* Part 3. Constructing an RRI definition (20’)

**Teacher’s role: how can the teacher facilitate the activity?**

In this learning activity, the course teacher should help the students focus their questions on the topic of responsibility and formulate them in a constructive manner. The concept of responsibility should be interpreted here not only in a negative way (“who should be responsible for preventing negative effects on R&I”, “who should be accountable in case of damages”), but also in a positive way (“who should safeguard that R&I seeks and reaches benefits -social, environmental, economic, etc.-”, “who and how guarantees that research processes follow shared ethical and social values”). This should allow them to provide new approaches to research and innovation. In case the students have difficulties to identify aspects about responsibility in the case example, the teacher can guide them by the lines of questioning on responsible innovation proposed by Stilgoe et al. (2013) about the purpose, the process and the product. Furthermore, in the **Transversal Scenario Guide** and the **HEIRRI PBL guide**, added in the annex, the teacher can find different reflecting questions of concrete examples that can use to facilitate the activity if students have difficulties to formulate them.

**Purpose questions:**

*Who has decided to investigate this particular question or innovate in this particular area?*

*Why are researchers doing it?*

*Are these motivations transparent and in the public interest?*

*Who will benefit?*

*What are they going to gain?*

*What are the alternatives?*

**Process questions:**

*How should standards be drawn up and applied?*

*How should risks and benefits be defined and measured?*

*Who is in control?*

*Who is taking part?*

*Who will take responsibility if things go wrong?*

*Who is responsible for guaranteeing that things are done the right way?*

*How do we know we are right?*

**Product questions:**

*How will the risks and benefits be distributed?*

*What other impacts can we anticipate?*

*How might this change in the future?*

*What don’t we know about?*

*What might we never know about?*

*Who is responsible for the effects produced by the – anticipated and/or non-anticipated- uses of products?*

To guide this activity some of these tips are useful:

* When the teacher explains the dynamic, it is important to communicate and control the timing of the activity.
* It is also important to integrate all small group ideas during the sharing.
* The teacher can guide each group discussion and also promote the participation of all the members of the group.

**Unit 2. What is responsibility?**

**Goal:**

*The goal of this unit is for the students to understand the concept of RRI and what it entails in a research process.*

**Learning Outcomes:**

After this activity, the students should be able to:

* To reflect upon the meaning of responsibility
* To learn about RRI from a specific case example
* To discuss what RRI is
* To relate research processes in their own field of study with the case example
* To gain insight on how RRI can be applied to practical research
* To understand the role of responsibility in research processes
* To identify the potential impact of research on individuals, groups or society

**Materials:**

* RRI introduction. See PowerPoint presentation **Introduction to RRI**
* Student’s questions from Unit 1.
* Creative material (cardboard, pens)

**Description of the activity:**

**Part 1. Introduction to RRI (45’)**

The teacher will give a presentation on RRI to facilitate a common knowledge basis for the subsequent discussion.

For the introduction to RRI, **See PowerPoint presentation: Introduction to RRI**.

**Goal:**

*The aim of this activity is to provide the students with a general view of RRI.*

**Learning outcomes:**

After this activity, the students should be able to:

* Identify the main aspects of RRI
* Comprehend the general meaning of responsibility in research and innovation.

**Materials:**

PowerPoint presentation: **Introduction to RRI.**

**Description of the activity:**

The teacher will give the students a brief presentation on RRI.

**Part 2. Discussion (45’)**

The students will then have to try and answer the questions they initially posed related to the video case example. This discussion will take place amongst the whole class, with the teacher acting as a moderator. The students can add words or sentences as answers to the questions on the wall, so as to provide a general vision to the whole class.

**Part 3. Reflection (30’)**

As a final result, the students, in their original groups, should rewrite their own definition of responsibility and propose some strategies to incorporate RRI in the case example. In the case of the **adaptation 1,** the students should come up with a definition for the specific concept or aspect of RRI they chose to work on.

**Duration of the activity:**

Total duration: 2 hours

* Part 1. Introduction to RRI (45’)
* Part 2. Discussion (45’)
* Part 3. Reflection (30’)

**Teacher’s role: how can the teacher facilitate the activity?**

In this learning activity, the course teacher should be aware of the students’ prior knowledge and beliefs, which appeared in the first session with the questions they posed and the definitions they built. She/he should link these questions and definitions with the RRI framework presented, emphasizing the similarities, differences or discrepancies. The teacher should encourage the students to critically analyse their own beliefs on responsibility and make them realise the RRI aspects they did not consider.

To guide this activity some of these tips are useful:

* The teacher should control the timing and structure of the activity
* It is also important to integrate all small group ideas during the sharing.
* The teacher can guide the final discussion to reach a definition but also promote the participation of all the members of the group in the discussion.

**PART 2. PRESENT YOUR THESIS**

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| **Part 2** | **Activity** | **Duration** |
|  | Lightning Talks | 1h30’- 2h |
| Neo-Socratic dialogue | 2h-2h30’ |

**Activity 1. Lightning talks**

**Goal:**

*The aim of this activity is to develop a brief oral presentation of the students’ research projects for their theses and for them to receive feedback from other course participants.*

**Learning outcomes:**

After this activity, the students should be able to:

* Clearly communicate their research projects in a short period of time
* Understand the other participant’s research projects
* Identify RRI aspects present in the research projects
* Identify RRI deficits in the research projects

**Materials:**

* Pechakucha dynamic guide
* 5x5 dynamic guide

**Description of the activity:**

The aim of this activity is for each student to give a lightning talk on their research projects for their theses. The students should outline their topic and research design, its rationale and how they want to implement it. To do so, the participants can choose between two different presentation dynamics or formats: Pechakucha 20x20 or 5x5.

Pechakucha 20x20

Pechakucha 20x20 is a presentation format in which the students show 20 images or slides, each one for 20 seconds, so the total duration of the oral communication is about 7 minutes. The images advance automatically and the presenter talks along to the images. In this way, the student has to limit themselves to the duration of each slide, for the presentation to be coherent and understood by the rest of the class.[[1]](#footnote-1)

5x5 Presentation Model

The 5x5 presentation format is a communication tool where the presenters have 5 minutes to present 5 slides to explain their thesis. They have one minute per slide, so it has to be simple and clear. This format is shorter, but each slide can contain more information than the Pechakucha method.

**Total duration of the activity:** 2 hours

If there is time leftover after the presentations, the students can further reflect and discuss the notes they have taken on the research projects.

**Teacher’s role: how can the teacher facilitate the activity?**

In this learning activity, the course teacher will have a rather passive role and will function as a moderator if necessary. This activity is just to present the students’ theses, so, the teacher hasn’t a very active role. Organising the schedule of the session, control the timing of each oral presentation and ask for doubts or clarifications to the audience and the presenter after each communication will be the main actions of the teacher. It is important to highlight that this session is the previous step for discussing how RRI can be incorporated in each student thesis. This activity has not a clearer link to RRI as the other ones but is necessary to proceed on the further and deeper discussion on how students can make their projects more responsible.

**Activity 2. Neo-Socratic Dialogue**

After the presentations, there will be a discussion on RRI aspects that may be of relevance to the projects. Together with the thesis author, students should identify relevant starting points for further individual inquiry. This format of discussion, including the course participants in the decision-making process, mirrors a public engagement activity. The Neosocratic Dialogue (NSD) can be used as a tool to initiate reflection on the R&I processes.

According to Littig and Griessler, “NSD is a form of guided, systematic communication on basic moral issues carried out in a group of 8-12 participants”. In this sense, it is a form of joint ethical reflection.[[2]](#footnote-2) For this discussion, both ethical and other RRI aspects will be discussed.

The NSD approach has the potential to advance critical thinking of students and can also work as a tool for strengthening interdisciplinary work, because NSD empowers participants in their ability to argue consistently, to listen actively and to interact with other people in a constructive way. A NSD discussion group consists of heterogeneous participants and thus can be used in interdisciplinary courses–e.g. on questions affecting different fields of study.

Littig and Griessler say that “The starting point for a NSD is a fundamental ethical or philosophical question that should be answered not empirically, but by means of reflection. This question must be of personal relevance to the participants and be formulated by the students in a way that allows them to identify examples in their own environments or professional practices in which it plays a central role. The dialogue itself initially draws on one (or a small number of) concrete experience(s) supplied by the participants, which they can all readily understand and relate to.”2 So, in this case, the question will refer to an RRI aspect identified by the students in one or more of the research project theses.

At the centre of neo-Socratic dialogue lays reason-oriented, mutual understanding on the part of the participants in a step-by-step analysis of a fundamental issue.2 NSD will sensitise students towards interdisciplinarity and raise awareness for different ethical aspects in research and innovation processes. Moreover, NSD should also enable participants to learn systematic ethical argumentation, which can be considered an important tool for future researchers. It is a useful tool for strengthening students’ reflexivity in their own research practices/in their research/study fields, and it allows them to improve their dialogical abilities.

According to Littig[[3]](#footnote-3), NSD can contribute to creating “socially robust knowledge”. This concept points at the increasing scepticism towards the omnipotence and reliability of academic knowledge in resolving social behaviour problems and decision processes. To achieve a greater level of acceptance in society, academic knowledge must be augmented by other forms of knowledge and demonstrate not only its intra-scientific validity, but also its “social robustness”. The latter can be achieved by involving as many different stakeholders as possible in the research, decision-making and negotiation processes.

**Goal:**

*The aim of this activity is for the course participants for each individual student to receive feedback on their thesis regarding RRI from the other course participants, by actively engaging in a discussion based on NSD.*

**Learning outcomes:**

After this activity, the students should be able to:

* Analyse a research project in depth
* Identify RRI aspects present in the research projects
* Identify RRI deficits in the research projects
* Acknowledge and react constructively to suggestions from their peers regarding their own research work

**Materials:**

* Neosocratic Dialogue guide
* Creative material (cardboard, paper, coloured pens, blackboard...

**Description of the activity:**

During each student’s presentations, it is important that listeners note the key points relevant to RRI in the project. This relates to RRI aspects that are well-represented in a project as well as aspects that are lacking. It is necessary to communicate the importance of this note-taking to students, as it is essential for the discussion to work properly.

The students will then have to group the research projects according to the RRI aspects that need improving. The initial questions for the NSD will be formulated according the RRI aspect that needs addressing.

According to Littig, the NSD follows this procedure3:

* Before the discourse commences a well formulated, general question is devised.

The students in this course can use the questions that were formulated in the first session. These questions are relevant to the concept of *responsibility*, and also to more specific issues of RRI.

* The first step is to collect concrete examples experienced by participants in which the given question plays a key role.

In this case, the examples correspond to the students’ research projects or their observations in their research environment, such as good practices or misconducts.

* The group selects one example, which will be the basis of the analysis and argumentation throughout the dialogue. This analysis usually starts with a concrete judgement based on the selected example and relating to the original question.

After all the presentations, the course participants should divide the research projects into groups. In this manner, the students will have to decide on a specific RRI issue that each project needs to improve on. If this is not clear, they can also treat a project in a more general manner. For example, they can decide on a group of projects that need to improve on their ethical implications. The participants will then choose one case example to analyse, while at the same time the analysis can apply to the rest of the projects in the group.

For the projects that haven’t been classified, or that need to improve in many aspects, the conclusions from all the groups may be useful.

During the discussion, students can refer to their own cases if they consider it to be helpful, or if they are seeking direct advice.

* Crucial statements made by the participants are written down on a flip chart or board, so that all can have an overview and be clear about the sequence of the discourse.

All the suggestions and ideas that come up during this session should be useful to all the course participants, and made readily available.

It could be useful for the course teacher to collect all this information, which they can then give out to all the participating students, in an online format for example.[[4]](#footnote-4)

**Total duration of the activity:** 2 hours

**Teacher’s role: how can the teacher facilitate the activity?**

In this learning activity, the course teacher will have a rather facilitator role and will function as a moderator if necessary.

The teacher has the following tasks3: to ensure that participants mutually understand each other, refer to their own experience, proceed step by step, remain focused on the issue under discussion, participate equally in the dialogue, explain their contributions thoroughly, substantiate their judgements, strive for consensus, and make progress in the dialogue.

Moreover, the teacher documents the reasoning of the dialogue. They do not contribute to the content of the dialogue directly. According to Littig3, the participants of a NSD have to abide by the following rules, although Birnbacher[[5]](#footnote-5) recommends lessening some of the strict procedural rules depending on the situation.

* Each participant's contribution is based upon what (s)he has experienced, not upon what (s)he has read or heard.
* The thinking and questioning are honest. This means that only genuine doubts about what has been said should be expressed.
* It is the responsibility of all participants to express their thoughts as clearly and concisely as possible, so that everyone is able to build on the ideas contributed by others earlier in the dialogue.
* Participants should not concentrate exclusively on their own thoughts. They should make every effort to understand those of the other participants and if necessary seek clarification.
* Anyone who has lost sight of the question or the thread of the discussion should seek the help of others to clarify where the group stands.
* Abstract statements should be grounded in concrete experience in order to illuminate such statements.
* Inquiry into relevant questions continues as long as participants either hold conflicting views or have not yet reached clarity.

**PART 3. INVESTIGATE YOUR THESIS**

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| **Part 3** | **Activity** | **Duration** |
|  | Online Forum | 1-2 weeks |

After having discussed and identified first possibly relevant RRI aspects of their theses, students have to conduct further inquiry on them. They will be assigned to independently search for and go through reports, guidelines, or articles dealing with these matters. They should investigate if and how others have dealt with similar problems within their area of research and how certain strategies of (not) addressing these issues played out. If available, students can also turn to dedicated organisational units within their higher education institution that deal with relevant RRI matters (e.g. an office for gender equality, an ethics board, etc.).

This part of the course mainly builds on independent study of the course participants; however, the course teacher should be available via email or face-to-face in consultation hours if there is the need of support on behalf of the students.

Another option is to offer an online forum on an e-learning platform where students can exchange, ask and answer questions, and start discussions on various topics.

**Online Forum**

**Goal:**

*The goal of this activity is for the students to independently search for and find relevant reading material regarding RRI for their thesis.*

**Learning outcomes:**

After this activity, the students should be able to:

* Research RRI bibliography
* Identify relevant sources of information
* Analyse the reading material and conceptualize effective approaches to address RRI

**Materials:**

* E-learning platform

**Description of the Activity**

Students should independently search for relevant reading material for their particular research project thesis. Furthermore, students can seek advice from the teacher if necessary.

The participants should upload an article of choice onto the online forum, to share with the rest of the course. This article should be accompanied by a short text describing the main points stated in the article and why this article is relevant to their research.

All the participants should collaborate to the online learning platform. Students are allowed to comment and discuss topics related to RRI on this forum, as they would do in class. These interactions and exchanging of ideas or resources may prove very useful for students’ individual research projects.

**Duration**

The students should be allowed 1 to 2 weeks to find and post the article.

**Teacher’s role: How can the teacher direct the activity?**

In an online forum, which is similar to a debate, the teacher should act as moderator.

The teacher should answer students’ questions, suggest further reading if it is necessary to each particular case, and guide the students towards exemplary cases that could possible help them in relation to their research. If the teacher wants it, he or she can provide the students with a list of papers to read and make the students choose one of them to perform the online forum activity, however, Master students should be capable of selecting a good article for themselves. The teacher can also play a more active and dynamic role to engage students in the forum for further discussion. If it is wanted, the teacher can make questions related to responsibility and research or about controversial research topics to start a discussion on the forum online, also he or she can provide more papers to read and discuss deeply the main ideas of each article.

The teacher can gather the information posted on the forum after the 1 or 2 week limit and create a report on the main points that have flourished as a summary for all students.

Here we add some useful bibliography that the teacher can provide to the students during the online forum if she or he wants to play a more active role in this activity:

* Gibbons, M. (1999)Science’s new social contract with society. *Nature, 402*, C81-84
* Iatridis, K., & Schroeder, D. (2016). The Basics of Responsible Research and Innovation. In *Responsible Research and Innovation in Industry. The Case for Corporate Responsibility Tools* (pp. 5–30). Heidelberg/New York, NY/Dordrecht/London: Springer. DOI:10.1007/978-3-319-21693-5\_2
* Owen, R., Macnaghten, P., & Stilgoe, J. (2012). Responsible research and innovation: From science in society to science for society, with society. *Science and Public Policy, 39*(6), 751–760. DOI:10.1093/scipol/scs093
* Stilgoe, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. *Research Policy, 42*(9), 1568–1580. DOI:10.1016/j.respol.2013.05.008
* Taebi, B., Correljé, A., Cuppen, E., Dignum, M., & Pesch, U. (2014). Responsible innovation as an endorsement of public values: the need for interdisciplinary research. *Journal of Responsible Innovation, 1*(1), 118–124. DOI:10.1080/23299460.2014.882072
* Von Schomberg, R. (2013). A vision of responsible innovation. In R. Owen, J. Bessant & M. Heintz (Eds.), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (pp. 51–74). West Sussex: John Wiley. DOI:10.1002/9781118551424.ch3

**PART 4. ENHANCE YOUR THESIS**

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| **Part 4** | **Activity** | **Duration** |
|  | Students’ presentations | 1h |
| Sharing dimensions’ feedback | 15’ |
| Discussion | 45’ |
| Final Report | - |

**Goal:**

*The goal of Part 4 is for the students to improve their research projects in terms of RRI, by integrating the input from previous sessions, the individual research carried out and the contributions from their peers.*

**Learning outcomes:**

After this activity, the students should be able to:

* Assess possible societal implications and impacts of concrete research activities
* Acknowledge and react constructively to suggestions from their peers regarding their own research work
* Propose adaptations to better align a research project with societal needs, values, and expectations
* Identify technical outcomes associated with the RRI process

**Materials:**

* *Feedback* forms for RRI dimensions
* RRI Report Rubric

**Activity 1. Students’ presentations**

Students must give a short presentation on how they propose to improve their research project in terms of RRI, based on the input received in previous activities and the individual research carried out. This will be followed by a debate with all the students in which different approaches to address RRI in the projects will be discussed.

In order to organize an effective discussion, it is recommended to start with all the students’ presentations. In the meantime, all peers will have the task of suggesting improvements on a specific RRI dimension, using a ***feedback* form.** **(See Annex)**

**Activity 2. Sharing dimensions’ feedback**

When the presentations are finished, the students that focused on each dimension will meet and share their suggestions for improvement for 10 minutes.

**Activity 3. Discussion**

Afterwards, each dimension group will present their conclusions about how each project can be improved from the point of view of that specific dimension.

**Duration of the three activities:** 2 hours

* Activity 1. Student presentations (1h)
* Activity 2. Sharing dimensions’ feedback (15’)
* Activity 3. Discussion how projects can be improved (45’)

**Teacher’s role: How can the teacher facilitate the activity?**

The teacher should act as a moderator of the session. At the beginning, it is important to clarify the purpose of the session and the dynamics. The teacher will have to explain how the feedback of the research projects is organised, distribute which students are giving feedback from each dimension and give some time for the students to read the feedback forms.

During the final discussion, the teacher should help to conclude participants’ contributions and add give a rich feedback to each project.

**Activity 4. Final report**

As a final assignment, students have to write a final report summarising and reflecting the findings and insights from their investigation and discussions with colleagues. It is recommended that the report is structured on the following four questions:

* Which are the key points of RRI that should be considered in your field of research?
* How could your Masters’ thesis project be modified to better integrate RRI?
* What issues of RRI have you been able to implement in your Masters’ thesis and how do you assess them?
* Which possibilities do you see to integrate RRI in your future professional life?

Report can be assessed with the final report rubric, added at the Annex. It is suggested to give them to the students prior to write the report to orient them in the writing.

**SURVEYS AFTER IMPLEMENTATION**

The HEIRRI project has developed surveys for post-project application of HEIRRI training programmes and materials. These surveys follow the design used for pilot evaluation, with a few additional open-ended questions, based on adaptations, difficulties encountered and opinions on the future of RRI in education.

Please respond to the relevant surveys after using the teaching resource at hand:

1. Survey for **students**: <https://www.surveymonkey.com/r/3PBQYZN>

2. Survey for **teachers**: <https://www.surveymonkey.com/r/3P37NG7>

For public engagement events:

3. Survey for the **public** (museum events): <https://www.surveymonkey.com/r/36L8Z6R>

4. Survey for **facilitators** (museum events): <https://www.surveymonkey.com/r/3P6WY2V>

Please remember that the resources at hand can (and should) be adapted to your specific needs and context. The HEIRRI resources have been designed to be flexible, so we encourage you to think about including local cases, adjusting the timings of the course to your needs, and also adapting some contents to yo**ur specific** field or discipline**.**

**ANNEXES**

* ANNEX 1. Transversal Scenario Guide
* ANNEX 2. HEIRRI PBL Scenarios
* ANNEX 3. Feedback forms for RRI dimensions
* ANNEX 4. RRI Report Rubric

**ANNEX 1. TRANSVERSAL SCENARIO GUIDE**

This is a guide to assist teachers in using the transversal scenario videos (“On ageing” and “On food”), in a higher education institution context. The videos are to be used to teach and learn about the concept of Responsible Research and Innovation (RRI).

**Transversal Scenario – AGEING**

**Topics:**

* Biomedical Research
* Politics and Gender Studies
* Psychology
* Environmental Sciences
* Economics and Socio-demography
* Technology
* Cultural Studies
* Public Health and Public Health Policies

**Learning Outcomes:**

* To discuss what Responsible Research and Innovation (RRI) is
* To relate research processes in their own field of study with the scenario
* To gain insight on how RRI can be applied to practical research
* To understand the role of responsibility in research processes
* To identify the potential impact of research on individuals, groups or society

**Reflection questions (to formulate after watching the video):**

* How can Biomedical research contribute to fighting the ageing process?
* Which would be the biological consequences of an extended life expectancy? How would that effect chronic diseases and their treatment?
* If life expectancy was extended, how would that effect the economy? Which model of public health policies would be implanted to support the growing population?
* How would technology contribute to this scenario? What new technological devices would appear in the market?
* How would this scenario impact urban planning?
* Would this scenario be environmentally sustainable?
* How would different countries and economies (developed vs. developing countries) approach the treatment for ageing? Could it result in new social inequalities?
* How would different cultures react to this new treatment for ageing? Would there be differences?
* What would be the risks and the benefits of this scenario? Are there nowadays alternatives to this kind of research?

**How can an RRI approach be implemented to research and innovation on ageing?**

**A real case example:**

*HackWithPeople[[6]](#footnote-6)* is an initiative that wants to rethink the way in which assistive technology is created and increase the quality of life of the ageing population. They want to achieve that by breaking economical, technological and specialization barriers.

This initiative has created a set of technological tools to co-create, together with the involved stakeholders, assistive solutions. With this initiative and this system of co-creation, the team has already successfully developed a fall detector and a prototype to recognise situations, among others.

More information about this initiative here:

<http://grasia.fdi.ucm.es/hackwithpeople/about.php>

**Script of transversal scenario video – “On Ageing”**

<https://youtu.be/geM3uCh4qYM>

SUSAN

I am going to retire soon. At least from this job, it’s been a long time. I have 2 kids, which is a lot nowadays, and 2 grandchildren. Family is an important part of my life. I want to spend more time with them. It is not common to have a united family nowadays. Well, I have many passions, I was thinking of becoming a musician but I will always be an expert in the field of health maintenance I guess. My name is Susan, I am still president of the Health Research Institute in the UK and I am going to retire soon. I do think about taking some time for a more creative approach to life, without the pressure I have now. It is not that I don’t like pressure but it is something that I’ve been doing for a long time. Well, in general terms, health maintenance is keeping your body at its optimal performance rate. Keeping it young and preventing it from ageing. The revolutionary idea was to attack ageing as a sickness. Metabolism is extremely complex, as are the number of pathologies derived from aging. We stopped attacking pathologies and we started solving these intermediate damages caused by metabolism. For instance, as we get older, many different types of errant and unwanted proteins, the chemical by-products of metabolism, build up and accumulate between our cells. Collectively these are known as forms of amyloid, a term that might be familiar to you in connection with Alzheimer's disease. We learned how to stimulate the immune system to attack these compounds. Some of the compounds were very difficult to digest for the immune system cells, but we solved the problem by using enzymes discovered in bacteria.

INTERVIEWER

And this is preventing people from ageing?

SUSAN

Well, not entirely, no. But it is slowing it down dramatically.

INTERVIEWER

Can you tell us how old you are?

SUSAN

I am 110 years old, and my life expectancy nowadays is 150, so I have 40 more years to go.

*Video CUT (TedTalks, news pieces, etc.)*

INTERVIEWER

Tell us: at the time aging therapies appeared, how did they affect the world?

SUSAN

They changed the world. Of course, for the good in my opinion. In a general sense, extended youth, new business opportunities emerged… Imagine for a moment, back in 2016, people were at the top of their strength for just 10 years, between their 20s-30s. I mean, we were not useful in evolutionary terms after our 30s, but now we are fertile for longer periods. This is a dramatic change in biological, philosophical and anthropological terms. The sense of hurry, of rush in our society... sickness related to aging was delayed. Of course, everyone needed psychological attention associated to the treatments to withstand this change.

INTERVIEWER

Were there also problems related with that change? Don’t you think that the economic situation nowadays, with poverty indicators rising, is a consequence of this change? Human rights associations are also addressing the need for some laws to regulate this unbalance. The wealthier and more powerful people are the ones who live longer. And nowadays there are still almost 1 billion people in the world that are poor and cannot access the treatment.

SUSAN

Yes, research is private and expensive, so there are many social differences. But this is starting to change and the technology is democratizing. The UN and the World Bank are trying to stipulate some common laws. And there are other issues that concern the governments. Governments were interested in increasing the “productive” life of their citizens by investing in public health, but it was a long-term bet, which is not popular with politicians. And elders stopped being elders anymore. We can take care of ourselves, take care of our children, grandchildren. And we have the wisdom of 110 years and a healthy body. We are of very big asset for our society.

INTERVIEWER

One of the main problems nowadays is the availability of natural resources to feed the growing population. This scientific advancement has taken its toll on the environment.

SUSAN

Yes, but also new businesses have emerged to solve that, and there have been recent advancements, for example, underground farming to allow large areas for crops in countries with no more usable land, high efficiency seeds and also the imprint of protein that is replacing cattle raising in developed countries is decreasing CO2 emissions and making meat completely affordable.

INTERVIEWER

And on the human side, what has been the most difficult part?

SUSAN

For me, the most difficult part of this huge change was in the success rate of the therapies between different individuals. This meant that I lost a husband and also a son. There is still a large gap between the age expectancy of men and women and death is a very dramatic event in the western world now. Even more than it was before. Maybe we need more spiritual guidance now.

INTERVIEWER

What about the people who want to stay out of the therapy?

SUSAN

Well, if you think about aging as a disease, who wants to be sick? It is not part of a natural process. It is like defending not intervening in complicated births because dying in childbirth is natural. We are creating our own path on what’s natural.

INTERVIEWER:

Well, that is not my point, I was thinking about freedom of choice and maybe, the need to understand ourselves as humans, maybe from a philosophical point of view. I would like you to listen to the words of a philosopher from de XX century, if it is ok for you.

SUSAN

Of course, go ahead.

([Alan Watts words](https://www.youtube.com/watch?v=qK1BJkBJdtY))

**Transversal Scenario – FOOD**

**Script of transversal scenario video – “On Food”**

<https://youtu.be/te9qffJPgHE>

*Fermentation is an ancestral technology that has been present in all cultures and civilizations around the world. It has been essential for the preservation of food in seasons of scarcity. Historically it had a huge impact on the gastronomic culture and the flavour palette in different areas around the globe depending on food substrates, climatic conditions, and microorganisms present in a specific place. People developed skills to use microorganisms to convert food and established a close relationship with them.*

BERNAT

I am very interested on fermentation since I believe that it is a process with a huge potential from a gastronomical point of view. Lately I’ve been working on legumes and on finding innovative ways to transform them through this fermentation processes. My name is Bernat Guixer, I hold a PhD in organic chemistry and I work in a restaurant applying my scientific knowledge on the development innovative ingredients.

*Legumes are a significant source ofprotein,dietary fibre,carbohydrates anddietary minerals; and like other plant-based foods, contain nocholesterol and little fat or sodium. But, even though their qualities seem so beneficial, in developed countries, this consumption is decreasing dramatically. In some places like Spain, the consumption has dropped 75% in 40 years.*

BERNAT

Why? Is it a matter of fashion? the market reality? the lack of time to cook legumes? We applied the process of producing tempeh through fermentation to local legumes and check if the output was interesting. The challenge was to apply the process of fermentation to white hocked beans that are cultivated in our region.

*Fermentation has always been linked to climatic conditions, especially when humans were not able to control them in a laboratory. Temperature, humidity and substrates of a region determined the varieties that naturally grew and the microorganisms available in the environment. On the other hand, every region has its cultural features and this two facts, for centuries, have linked culture and food.*

BERNAT

The fermentation process of tempeh is driven by a fungus that needs certain conditions of temperature and humidity. When these conditions are met, the fungus generates a mycelium that compacts the beans and starts transforming them. This is our starting point for the innovation. I am working in a scientific organization, but this does not mean that I can’t work with a scientific approach. I am applying my scientific knowledge to navigate in the process of developing new products that need to taste delicious but that can also be used in other fields. Also, this process started as an open source project in the Nordic Food Lab and has been published in a peer-review journal and shared in different conferences, so the information is available.

*There are serendipitous findings in culinary research. When low temperature cooking techniques are applied to tempeh, some interesting modifications happen. After a couple of days of low temperature cooking, the colour of the tempeh shifts from pale to orange, and the taste becomes sweet and with umami notes.*

BERNAT

We realised, that the shift of the product was significant and we coined a new name to avoid misleading the consumer. I’m finding imaginative ways to deliver interesting products to the kitchen, but also providing possible research topics that can be explored in collaboration with researchers in the academy. This product might have many other commercial uses that could affect many different stakeholders. The use of proximity crops instead of global ones like soy, would affect local producers. Restaurants, companies of processed food, private consumers... But beyond that it could affect the preservation of crop diversity. By maintaining the use of local seeds, using our ancestral varieties, we favour the survival of this seeds and we preserve the diversity of legumes.

*When think about soybean products, a global product in opposition to proximity seeds, the first thing that comes to mind are healthy food staples like tofu, edamame or soy milk. But in reality, a typical soybean is more likely to end up in a ham-and-cheese sandwich or a chicken nugget than a block of tofu. 70–75 percent of the world’s soy ends up as feed for chickens, pigs, cows and farmed fish. The remainder is used in a variety of industrial applications, including biodiesel production, or for direct human consumption.* Growth in demand is largely attributable to the increasing preference for meat among the growing middle class in emerging economies, which has brought with it higher demand for animal feed.

BERNAT

The product won’t be the cheapest of all if it is commercialized. This is for sure. I work in a company with commercial interests of course, but the restaurant is willing of spending money and time to develop technologies that will be later applied to consumer products or technologies. Thickening agents, for instance, is a culinary tool that has been used in hospitals to help people with difficult swallowing. I don’t know if these crop fields can affect other crops. And also, any fermentation process involving microorganisms has to be deeply analysed concerning safety to discard histamines or other harmful toxins. Maillard reactions in the cooking (that give browned food its distinctive flavour) can bring also carcinogenic by-products, as in many other cooked products in our everyday life. The cultural relationship that humanity has with cooking in not balanced in terms of gender. While women have been attributed the role of cooking in the majority of households, high cuisine is still a man’s world.

*In the field of food, professionals are concert not only about nutritional value but also about the appreciation of the product by society. There could be a synthetic meal perfect from the nutritional point of view that nobody liked. As human beings, there is a need to make meals enjoyable.*

BERNAT

We don’t have any information on the opinion of the public about our products but chefs are the ones concerned about what the consumers like. But not only that, they are stimulating the consumers with new flavours, new proposals and experiences. Do we need to take always into account the nutritional values of food? Or the enjoyment of food? Or maybe both? That’s were variety offers versatility.

The Roca brothers: the chef, the sommelier and the pastry chef of the restaurant, usually state that: “Traditions are legitimated avant-garde”, meaning that any present tradition was necessarily an innovation in the past, which people legitimated over time.

*Culinary avant-garde is challenging the gastronomy of today pushing its boundaries. Somehow it is a way to point topics that might need an update, as well as proposing ways and suggesting alternatives to improve the gastronomical world of tomorrow. And this may be really broad, from plating to considering approaches for food sustainability.*

**ANNEX 2. HEIRRI PBL SCENARIOS**

**TABLE OF CONTENT:**

* Introduction to the Problem Based Learning Methodology
* HEIRRI PBL scenarios
* PBL scenario 1: The Island of Dr. Schultz
* PBL scenario 2: House of Climate Change
* PBL scenario 3: Male Contraception
* PBL scenario 4: A Voyage into the Past
* PBL scenario 5: Cyberville
* PBL scenario 6: The forgotten sleeping sickness
* PBL scenario 7: Deception
* PBL scenario 8: What’s your score?

**INTRODUCTION TO THE PROBLEM BASED LEARNING METHODOLOGY**

**Problem-based learning (PBL)** is an instructional learner-centred approach organized around the investigation and resolution of messy, real-world problems. Students work in small groups with a tutor that acts as a learning facilitator. PBL empowers learners to become problem solvers, seeking to identify the root problem and the conditions needed for a good solution and in the process, they become self-directed learners.

The key characteristics of the method described by Barrows are:

1. Students must have responsibility for their own learning, so students determine why they need to learn and which resources they will use to acquire the missing knowledge.
2. The problem simulations must be ill-structured and allow for free inquiry. Problems in the real world are ill-structured (or they would not be problems). A critical skill developed through PBL is the ability to identify the problem and set parameters on the development of a solution.
3. Learning should be integrated from a wide range of disciplines or subjects. During self-directed learning, students should be able to access, study and integrate information from all the disciplines that might be related to understanding and resolving a particular problem—just as people in the real world must recall and apply information integrated from diverse sources in their work. Multiple perspectives lead to a more thorough understanding of the issues and the development of a more robust solution.
4. Collaboration is essential. The point of self-directed research is for individuals to collect information that will inform the group’s decision-making process in relation to the problem. It is essential that each individual share coherently what he or she has learned and how that information might impact on developing a solution to the problem.
5. A closing analysis of what has been learned from working with the problem and a discussion of what concepts and principles have been learned are essential. Given that PBL is a very engaging, motivating and involving form of experiential learning, learners are often very close to the immediate details of the problem and the proposed solution. A final assessment about what has been learned and how they can use the information in future situations is necessary to consolidate the learning and ensure that the experience has been reflected upon.
6. Self and peer assessment should be carried out at the completion of each problem. These assessment activities related to the PBL process are closely related to the previous essential characteristic of reflection on knowledge gains. The significance of this activity is to reinforce the self-reflective nature of learning and sharpen a range of metacognitive processing skills.[[7]](#footnote-7)

**Teacher’s role**

The teacher’s role in PBL is to facilitate the students’ learning process, so their task is to stimulate group discussions and critical thinking, to generate an environment that is both comfortable for the students and in which all the members participate, to evoke the students’ prior knowledge, to provide the necessary tools for the students to build up their knowledge, to guide the students as to which sources to use and to evaluate the process and the results obtained. The teacher should avoid giving mini lectures and instead, orient the students through questions.[[8]](#footnote-8)

**Materials**

* PBL scenarios.
* Evaluation rubric.

**Description of the Activity**

*In a small group of students*

The PBL activity is organized in tutorial sessions with small groups of students (6 to 10 people). Each group has a tutor who takes on the role of learning facilitator.

For this module, we suggest working with different groups of students (depending on the number of students), with each group working on a different problem. In this way, in the final sharing session, students can discuss different approaches of RRI applied to different scenarios. However, there is also the possibility to have all the groups working on the same problem and sharing the different approaches to it at the end.

The resolution of a PBL exercise will be organised into the following stages:

**Session 1 (1h30)**

1. Presentation of the PBL Scenario. 15’. The session begins with the reading of the problem (or viewing/listening, depending on the format). It is recommended to allow some time after a group reading for each student to think of which questions the problem has evoked in them. Then, all the questions in the group are shared. It is recommended for one of the members of the group to write these questions on the blackboard or a similar medium, so all the participants can see them.
2. Brainstorming. 30-45’. It is important to give the students some time for brainstorming, so they come up with as many ideas as possible. During this stage, it is also possible to ask the students to come up with explanatory hypothesis for the questions posed, and for them to identify that which they need to learn to answer these questions.
3. Work plan: 30-45’. All the questions that have come up must be structured, grouping together those questions that are related. At the end of the session, the students should have a work plan for their research: which terms and concepts they need to clarify, which questions they want to investigate and which resources they will use to do so. They also distribute these tasks among the group members; the group can decide whether they want to divide up the topics or if they will all research the same one, but consulting different sources.

**Teacher’s role: how can the teacher facilitate the session?**

During this session, the tutor can help in defining the questions. Based on the questions formulated by the students, the tutor can help reformulate them so as to make them more specific or precise. The tutor can also help the student’s prior knowledge emerge, related to the studied scenario, making what they need to learn clearer. As to the learning resources, the tutor can also orient the students. The students are normally not directly provided with bibliography to consult, but they can be guided towards the type of source to use (handbooks, original papers, review papers, interviews with experts, etc.) or help them identify the areas of knowledge that their questions address. [[9]](#footnote-9)

Autonomous research**:** The students, individually or in groups, research the topic at hand. It is necessary for them to have a few days for this to allow them to go into detail on the topic.

**Session 2** **(1h30):**

1. Sharing the research: 1h. the students share the research they have done, the different sources they have consulted are contrasted and they try to answer the questions they initially posed
2. New work plan: 30’. Generally, after having delved into the problematic scenario and the group discussion, new questions arise. So, it is interesting for the students to ask themselves new questions, so as to go into further detail on the subject.

**Teacher’s role: how can the teacher facilitate the session?**

It is important for the students to have carried out a critical analysis of the sources of information they have consulted. In this manner, one of the tutor’s tasks in this session is to make sure this has been done, questioning the sources used and the student’s analysis of them, the tutor can help the group to further advance in the problem that is being studied. 63

Autonomous research**:** The students, individually or in a group, research the topic at hand. It is necessary for them to have a few days for this research to allow them to go into detail on the topic.

**Session 3** **(1h):**

1. Closing the problem: 40’. In the first part of the session, the students share the new research they have carried out and they come up with conclusions. These conclusions should be focused on answering the questions posed and/or proposing possible solutions to the problem identified. The process they have followed to analyse and solve the problem should be presented in the form of a group project after a few days (a report, an oral presentation, a mind map, etc.)
2. Auto-evaluation: 20’. After coming up with the conclusions on the problem itself, it is worth the while to reflect upon what has been learnt during the process and in which situations might this information be useful in the future. It is also recommendable to realize an auto-evaluation of the learning process, both individual and in the group.

**Teacher’s role: how can the teacher facilitate the session?**

The tutor should help the students synthesize that which has been learnt during the process of solving the problem, to identify the key ideas and to transfer this information into other contexts. The tutor must also help guide the development of meta-cognitive abilities, encouraging reflection on the learning process.63

**Session 4 (2h):**

1. Presentations: In finishing the PBL, the students’ groups are asked to give an oral presentation to their classmates, involving a discussion on the final conclusions. This presentation should be structured according to the questions posed upon analysing the problem. Each group presentation should not be longer than 15 minutes.   
   Presentations can be evaluated with the following rubric either by the teacher and the classmates for peer-assessment. We suggest sharing the rubric with the students at the beginning of the unit for them to understand what is expected by the problem analysis.[[10]](#footnote-10)

*In a large group of students (20 or more)*

In this case, PBL is also organised in tutorial sessions but with a large group (more than 15-20 students). The tutor acts as the learning facilitator of the whole class. If there is not the possibility to have one tutor for group and the activity has to be implemented with the whole class, the students will work in smaller groups (4-5) in the same classroom while the teacher walks around giving support to them, so the tutor acts as a multi-facilitator of different groups at the same time. In this case we suggest that each group of students has a different problem to discuss different approaches in the sharing session. The activities during each session are exactly the same as PBL with smaller groups. The tutor can distribute its time between groups and guide the small groups during the process. This kind of PBL requires a greater effort of the teacher because its difficulty of guiding different problems and groups at the same time, but it is also feasible and effective.

**Evaluation is a key element of PBL**

Given that the objectives of PBL are based both on knowledge and the process, the students should be evaluated in both these dimensions. Due to the fact that this method is centred on the learner, it is expected that the students should participate in the evaluation process.

To evaluate the process, it is recommended that the tutor assesses the students’ participation in the tutored sessions via an observation grid. This grid should also be given out to the students so they can use it to evaluate their own group classmates and themselves. The final participation evaluation of each student is the average between the own group classmates’ and the tutor evaluations.

To evaluate the acquired knowledge, it is normally done through the students’ presentations or through exams. In this case, it is recommended to evaluate the students via oral presentations with the whole group in class, as it has been previously described. Oral presentations can be assessed with the PBL rubric by the teacher and the peers. **PBL rubric for oral presentations**

|  |  |  |  |
| --- | --- | --- | --- |
| Evaluation criteria | Not achieved | Half achieved | Achieved |
| Identification of the RRI aspects | There is no evidence of the students having questioned the problem from an RRI perspective. | The students have questioned some relevant aspects of RRI related to the problem. | The complexity of the problem is recognized and key questions on different aspects of RRI related to the problem are asked. |
| Critical analysis and creativity | There is a superficial analysis of the problem, with no evidence or data.  No different approaches to the problem are considered.  The ethical principles related to the problem are not questioned.  The proposals to integrate RRI in the problem are not original. | There is a description of the problem and an evaluation of the risks and benefits, with some data.  Different approaches to the problem are described, but not justified.  Opinions on the ethical principles related to the problem are expressed.  Some original ideas on how to integrate RRI in the problem with the available resources are proposed. | The description of the problem and the evaluation of the risks and benefits are based on evidence and data.  Different approaches to the problem are described and well justified.  Different arguments regarding to ethical principles related to the problem are elaborated.  Disruptive ideas are developed to integrate RRI in the problem with the available resources. |
| Presentation structure and audio-visual support | Disorganised structure.  The quantity of information is not adequate for the established time.  The audio-visual support has errors in form or content and does not help in the comprehension of the presentation. | Clear and organised structure.  The quantity of information is not adequate for the established time.  The audio-visual support has some errors in form or content and on some occasions, does not help the comprehension of the presentation. | Clear and organised structure.  Good synthesis of information.  The presentation meets the established time.  The audio-visual support is clear, there are no errors in form or content and it is useful in improving the comprehension of the presentation. |
| Use of the information sources | Many of the sources are not reliable.  The sources are not referenced in the presentation. | Some of the sources are reliable and some are not.  Not all the tables and figures are referenced. | Different sources are used.  The sources used are reliable.  The tables and figures are well referenced. |

**Observation grid to evaluate students’ participation in PBL tutorials**

|  |  |
| --- | --- |
| RESPONSIBILITY | * Respect the timing * Shows knowledge on the PBL objectives * Seeks information and studies it |
| KNOWLEDGE CONSTRUCTION SKILLS | * Integrates the problem information into prior knowledge * Recognises the different dimensions in the problem * Shows the ability to form hypothesis * Collaborates in the construction of a work plan * Seeks relevant information and critically analyses it * Justifies comments with adequate references * Actively and pertinently participates * Well managed and organized time-wise * Takes action to correct weak points |
| ORAL COMMUNICATION | * Synthesizes the information * Presents the information in an organized manner * Clear and concise expression |
| COOPERATIVE WORK | * Contributes to organizing the discussion * Is tolerant with both equals and tutor * Waits for an intervention to finish before interrupting * Knows how to listen and receive criticism |

**HEIRRI PBL Scenarios**

In the following pages, you can find a set of PBL scenarios designed to learn different aspects of RRI. Each scenario is composed of the problem and the tutor guide.

Students will only receive the problem, through this it is expected that they will formulate questions that drive them to acquire the learning outcomes. In the tutor guide, just for the facilitator, there are some of developed questions that the students might formulate. In case they deviate a lot from learning outcomes, the tutor can use the reflecting questions to focus the discussion on RRI topics. This is just a guide, students can formulate different questions that are useful to discuss RRI topics, furthermore, the tutor or facilitator can think about and add more questions related to the scenario.

**PBL scenario 1: The Island of Dr Schultz**

* **A short story inspired by “The Island of Dr Moreau”, by H.G. Wells**

The small boat finally neared the island, and I could make out the shape of the trees and buildings. I had been looking forward to this assignment for weeks now, my first article for the science section. The recent organ crisis had forced the authorities to plough ahead with what was once their long-term plan, creating quite a stir. I was on my way to one of the few facilities in the world working with “chimaeras”.

They had asked me to write a story about the soon-to-be new “organ pool”. At the time, organ donations were at an all-time low. Organ donors were practically non-existent and the average human lifespan was about 95 years, so people who were donors were normally already too far gone. The solution devised by Dr Leopold Schultz, a developmental biologist, was to create organs from scratch, by growing them in animals. The ideal animal host was the pig, due to its size and similarities with the human race. As an emergency measure, many centres were authorised to work on this technique all over the world to maximise the research capacity. At that time, they were still in the experimental phase, eliminating the embryos before they were born. The centre I was visiting was on an island off the coast of Hawaii.

I arrived in the late afternoon; I stared up at the surrounding jungle before I was quickly ushered through the long corridors of the main building, straight into Dr Schultz’s office. He greeted me with a slow smile, and gestured towards a chair in front of his desk. The room was bare and there was nothing on the walls, only a small window behind the desk. “Welcome, Mr Larkin, we’ve been looking forward to your visit. Our research has been progressing rapidly, you’ll be glad to hear.” He had a slight drawl to his speech, seeming only half aware of what he was saying. “My assistant will show you around the labs tomorrow morning, it’s too late now”. And with that, I was whisked off to another room, my chambers for the next few days. Again, the room was almost empty, consisting only of a bed, table and chair.

They had left me dinner on the table, so I assumed I was to eat alone. That said, I highly enjoyed the dish of roast pork and vegetables they had left, and probably had one glass of wine too many, as I promptly fell asleep. I had strange dreams that night, of creatures in the jungle, and woke up feeling quite disoriented.

The whole morning went by in a whirlwind as I was given a tour of the massive building. Dr Schultz’s assistant showed me many different laboratories and equipment I couldn’t even begin to comprehend. He introduced me to a young scientist, Dr Diane Deacon, who was kind enough to explain what it was they were actually doing. She described the process they used, which consisted of injecting human cells, which are programmed to become a specific organ, into the blastocyst of a pig, so that these cells would go on to become a human organ growing inside a different species. The idea was to eventually allow these animals to grow to adult stage, at which point they would then be sacrificed and the organs removed ready for transplanting. I wondered if it was really necessary to kill an animal for every organ needed, but I soon lost that train of thought as I was rushed to the next laboratory.

I was left to myself that afternoon. I decided to wander the building on my own. After a while, I was decidedly lost. All the rooms, laboratories and corridors looked the same to me, and judging by what I had seen upon entry, the building was huge. There didn’t seem to be many people around, so I continued on my stroll, assuming that I would find someone eventually. I reached a door that appeared to be slightly different to the rest. There was a code pad next to the door, but it was slightly ajar. I opened it cautiously and was greeted by strong smells and animal noises. I stepped from a sterile corridor into an airy, sunny and very large room that looked a lot like a barn. Both sides of the large space were lined with pens, all of them containing pigs. I don’t know how many there were in total, too many to count. As I walked along, they all neared the fences, seeming rather curious and friendly. I got quite distracted and was soon scratching away at their necks and snouts, having a delightful time. I kept walking along, admiring all the different specimens, feeling quite awed at the number of animals. I couldn’t help thinking of the fate that awaited them, although I tried to brush the thought away.

As I neared the end of the barn, I noticed the pigs were younger. And the last pens were full of piglets! I couldn’t help smiling and making baby noises as I kneeled down to touch them, what funny little animals they are. As I was repeating the process at the last pen, I don’t know how long I had been in there by then, I noticed something strange. One of the piglets seemed a bit different. As the others rushed towards the fence sniffling and snorting, one stayed back. This behaviour made me look at it more closely; I worried it might be ill or injured. As soon as I did, I felt a shiver go down my spine.

The creature looked like a piglet, and at the same time, it did not. I found myself staring at its face, especially its eyes. There was something oddly disturbing about this animal, and I could not figure out what it was. I suddenly realised that the pig was staring right back at me, with what seemed like despair in its eyes, almost human. I instinctively got my camera out and took some photographs of the animal. Even so, I found I could not look at it directly any more, as I was filled with a feeling of revulsion.

I quickly retraced my steps and left the barn. I wandered the long corridors for some time until I eventually found my room. I closed the door behind me and sat down on the bed. I knew something was terribly wrong.

**TUTOR GUIDE:**

**Learning outcomes**

After this activity, the students should be able to:

* Understand the meaning of the concept “chimera” and the origin of the word
* Analyse the possible applications of this type of research
* Define the manner in which this research is carried out
* Evaluate the possible risks involved in this type of research
* Asses the ethical issues/impacts related to this type of research
* Examine the possible security measures to be implemented in this type of research
* Determine if this type of research is transparent and of public interest
* Investigate if there are possible alternatives to the solution sought by this type of research

**Reflection questions**

**How would you define a chimera? Which is the origin of the word?**

The origin of the word chimera, and the idea of a chimera can be traced back to Antiquity. The word used to describe a fabulous creature.

* In Greek mythology, the Minotaur had a man’s body and a bull’s head, and Pan was half man, half goat.
* Many Egyptian gods had a human body and a beast head, such as Sobek, Anubis, and Horus.[[11]](#footnote-11)

The Ancient Greek poet Homer depicted the mythological Chimera[[12]](#footnote-12):

“First, dire Chimaera’s conquest was enjoin’d;

A mingled monster of no mortal kind!

Behind, a dragon’s fiery tail was spread;

A goat’s rough body bore a lion’s head;

Her pitchy nostrils flaky flames expire;

Her gaping throat emits infernal fire.” (Homer 1836)

Another description can be found in the Theogony, where Hesiod describes Chimera67:

“She [Echidna] was the mother of Chimaera who breathed raging fire, a creature fearful, great, swift footed and strong, who had three heads, one of a grim-eyed lion, another of a goat, and another of a snake, a fierce dragon; in her forepart she was a lion; in her hinder part, a dragon; and in her middle, a goat, breathing forth a fearful blast of blazing fire.” (Hesiod 1914)

Nowadays, “chimera” describes a living organism that contains cells or tissues with different genotypes.66

Lensch et al. propose the following definition of ‘chimera’: “The term chimera […] indicates organisms comprised of cells from two or more individuals of the same or different species. Today, the most common usage describes cellular combinations at the pre-implantation blastocyst stage of development, […] also […] other entities created by introducing cells at later stages, including in adult recipients[[13]](#footnote-13),[[14]](#footnote-14).”

Another definition is proposed by Behringer: “A chimera is an individual composed of somatic and, in certain cases, germ line tissues derived from more than one zygote. […] If the donor tissue and recipient are of different species, then an interspecific or cross-species chimera is generated. 68,[[15]](#footnote-15)”

The UK Academy of Medical Sciences suggests this definition for chimeras:

Chimæras are formed by mixing together whole cells originating from different organisms. The new organism that results is made up of a ‘‘patchwork’’ of cells from the two different sources. Each cell of a chimæra contains genes from only one of the organisms from which it is made. (…) Primary chimæras are formed by mixing together two early embryos, or an early embryo with isolated embryonic cell types obtained from a different embryo or cultured stem cell line. The resulting chimæra has cells of different origins, in many tissues. Secondary chimæras are formed experimentally by transplanting (or grafting) cells or tissues into animals at later stages of development, including late fetal stages, post-natal or even adult animals. The donor cells are only present in a few tissues.67

**Which scientific fields could have a possible interest in animal-human hybrids? What advantages can you see in the creation of these chimeras?**

The main interest, which is also the one that is receiving the most attention, is the production of human organs in animals, which now seems possible due to recent technological progress. The objective of this research is to be able to provide organs for transplantation into humans, due to the severe organ shortage.1 In Europe in 2013, there were at least 60,000 people on the organ transplant list. 66,[[16]](#footnote-16)

There are other applications for the use of animal-human hybrids in research.

* To test the potential of human pluripotent cells. In this case, human cells are injected into a mouse morula, and the chimeric embryo is analysed shortly afterwards. These experiments are limited to early embryos (10 days), within the limit for research on human embryos). It is possible that central nervous system tissue containing both mouse and human cells could be found in this chimera. 68
* To study metabolic diseases in an aging population, such as the EU-funded project ‘Health and the Understanding of Metabolism, Aging and Nutrition’ (HUMAN). They want to create “humanised” mouse models with human donor liver and pancreas cells. This would allow them to study the functions of genes in human organs and how these can influence the risk of metabolic disease, in combination with factors such as diet. The project would involve two groups: very old and healthy individuals and individuals with metabolic diseases. This project involves maintaining chimeric animals until old age. 68, [[17]](#footnote-17)
* Animal-human hybrids have also been used for: research into human haematopoiesis, the development and function of the immune system, infectious diseases, autoimmunity, cancer, and regenerative medicine.
* They have also been used as research tools for the creation of vaccines against deadly diseases such as malaria, dengue, Hepatitis B, HIV and Hepatitis C.
* They have been employed for the study of the human cell development, maturation and migration.67

**How would an animal/human hybrid be created?**

In the case of producing chimeras for human organs, the animal (the carrier) would have to be altered genetically so as to inhibit the development of a specific organ or organs. Then, human iPSC (induced pluripotent stem cells), which can propagate indefinitely and give rise to any other cell type ion the body, would be injected into the blastocysts of these genetically altered animals. In this manner, the “missing” organ in the animal would be made up entirely of human cells, which should differentiate and spread throughout the body.66,[[18]](#footnote-18) In practice, the production of viable hybrid embryos has proven difficult using this technique.73

**What are possible risks involved in creating animal-human hybrids?**

As it is mentioned previously, pluripotent cells are a powerful type of stem cell that can become any cell type in the body. There is concern that these human cells, when combined with animal embryos, could develop into brain cells, sperm, or egg cells in the chimeras.66 This means that there is the risk, although minimal, of these pluripotent cells migrating in the animal host and possibly contributing to the formation of different organs or tissues in the animal.

iPSC cells should only be used when they are to replace cells or tissues that are absent due to a gene knockout. This limits the colonization of undesired organs or tissues by human cells, such as the brain. The risk of forming other organs is very small due to the fact that human cells are expected to be less competitive than pig cells, if they are in a pig microenvironment (the pig embryo), unless a specific cell type has been impaired by genetic means (the organ to be replaced).66

There is also the concern of zoonoses, described by the WHO as “any disease or infection that is naturally transmissible from vertebrate animals to humans.” It is thought that retroviruses integrated into the genome of some animals could be transferred to humans. There is the risk that human tissues developed in animal hosts could be the source of new zoonoses. The fear is that although the effects of theses retroviruses are known in animals, there is no way to predict what they could cause in humans. Also, there is the concern that human organs may become contaminated by residual animal cells or proteins that could later elicit a potentially harmful immune response in the organ receivers. 66

**What ethical issues are involved in the creation of animal-human hybrids?**

The main ethical issues involved in the creation of human/animal chimaeras are: animal welfare, human features, human consciousness and the production of human gametes.

Animal welfare – Some consider that experimentation involving pigs is already strictly regulated in order to avoid unnecessary animal suffering. In this manner, the fact that chimeric animals are raised for the purpose of human organ culture should not cause more ethical debates than raising them for consumption or other types of research.66 On the other hand, the fact that the animals are to be raised with the sole purpose of carrying the human organs until the required size, and are to be sacrificed on the day of the transplant provokes different reactions. The number of animals it would require having a decent sized organ pool raises animal welfare concerns.66

Human features – It is argued that an injection of iPSC into animal embryos could somehow affect the physical appearance of said animal. This is explained by the capacity of these cells to develop into any kind of tissue. The creation of human/animal chimeras blurs the boundary between two species, and induces questions on human identity.66

The idea of this boundary being crossed causes certain resistance in the general public. Even so, although the idea of mixing human and animal genes is not often considered by the public and the notion of creating a chimera does not seem real to the general public, it is already a standard practice in science (for example in some of the research fields mentioned above).66

Human consciousness – Also related to the capacities of the iPSC, there is certain concern over the possibility of animals developing some level of human consciousness, due to human cells migrating to the brain and developing into neuronal tissue. One chimera study reported that mice containing human glial cells in their brains were seen to perform much faster in memory and learning tests than the control group of mice. This raised the question if these “humanized” mice might be cognitively enhanced.[[19]](#footnote-19)In other animals, these effects could be much more noticeable.

Questions arise such as:

Could a significant contribution of human cells to the animal brain modify the characteristics of the recipient species? Would this affect the evaluation of the moral status of the animal, especially in the case of large animals, such as pigs and particularly nonhuman primates?

If the presence of human cells in the brain of an experimental animal resulted in some form of human consciousness, the creation of animal/human hybrids would be considered ethically unacceptable. This is because one of the considerations to distinguish animals from humans is based on consciousness.66

Human gametes - Humanization of animals bearing human organs could also result in the production of human gametes. Human embryos could be created using these gametes. The worst-case scenario would be that a pig producing human sperm could accidently mate with a sow or vice versa.66

Another ethical concern is the protection of the human subjects involved in the clinical trials. This is related to the risk of zoonoses, as the effects on humans are still not known.66

Also, there is certain debate about the subject of “human dignity”, referring to the fact that creating these hybrids would give the animals a human status, “human dignity”, and would therefore have to be treated as such.67

**Why should security measures be implemented?**

Security measures must be implemented strictly to minimise all the risks mentioned above, and to avoid as many ethical grey areas. In this manner, to prevent the worst-case scenario of a humanized pig brain (or another animal), it is essential to define a maximal limit of human chimerism in the animal brain that should not be exceeded.66

For example, the U.S. National Research Council and the Institute of Medicine recommended limits on chimera research in 2005[[20]](#footnote-20),[[21]](#footnote-21), including that no human stem cells can be added to primate embryos and that animal human hybrids not be allowed to breed. The current NIH guidelines state that breeding animals in which human stem cells might have formed gametes is prohibited, and human-primate experiments are forbidden. Even so, there is no rule that prohibits the injection of human iPSC into animal embryos and allowing the chimeras to develop.66 Aside from gestation attempts in human and non-human primate surrogates, all other chimera research is potentially allowable, although always subject to review by the appropriate animal research and stem cell committees.74, 72

One form of prevention could be to genetically modify human iPSC so as to make them incapable of differentiating into neural cells in the animal hosts, or to include “suicide genes” that would activate in the case of neural differentiation.66 At the same time, pigs with human organs could all be sterilised, to prevent their reproduction, and further minimise the risk of breeding with human gametes. Similarly to the inhibition of differentiation into neural cells, the human iPSC could also be genetically modified so as to prevent their differentiation into gametes, or also include “suicide genes” to be activated in the case of germinal differentiation.66 To further impede the possible breeding of human/animal hybrids, it is essential for the conditions in which the animals are held and used for experimentation to be very secure and isolated, to avoid any escapes and also possible zoonoses transmission.

Researchers believe that the percentage of human cells that are to be injected into animal blastocysts should be lower than 1%, in this manner the risk of creating animals, piglets, with human features is supposedly very low. So, a maximum threshold of human cell contribution should be established before the experimentation and then be strictly implemented. Also, it would be recommendable to perform pre-birth diagnoses on the animal hosts so as to detect any possibility of appearance of human features. Ultimately, only foetuses without any human feature would be allowed to term.66

**Are the motivations for this research transparent and in the public interest?**

The creation of human/animal chimeras, the production of human organs in animal hosts, not only raises ethical issues, but also legal issues. This research is subject to different to different legal frameworks in different countries.For example, the case of a researcher wanting to experiment with generating human pancreas in pigs in Japan who had to relocate the research group to the USA due to Japanese opposition.75 Here are some examples of the regulations in different countries: 66

In France, the law stipulates that the creation of a chimeric human embryo is forbidden. It also forbids the introduction of allogeneic or xenogenic cells into a human embryo. However, the law is unclear about whether it is illegal to introduce human cells into animal embryos.

In the UK, it is not forbidden to create an animal chimera by grafting human embryonic cells or embryonic cell lines into animals. Even so, transferring a predominantly human embryo into an animal “foster” mother is forbidden.

The German law prohibits combining a human embryo with animal cells, but not the introduction of human cells into an animal embryo. The German Ethics Council highlights the importance of finding a balance between expected medical benefits, respect of animal welfare and the need for an interdisciplinary scientific discussion on the subject.

The US National Research Council and the Institute of Medicine recommend limits on this type of research, among them that no human stem cells be added to primate embryos and that animal human chimeras not be allowed to breed.

In Japan, the law currently limits research on human animal chimeric embryos, by not allowing the development of these embryos beyond the appearance of the primitive streak and their transfer into an animal uterus.

As mentioned before, there is no rule that prohibits the injection of human iPSC into animal embryos and allowing the chimeras to develop.66 Aside from gestation attempts in human and non-human primate surrogates, all other chimera research is potentially allowable, although always subject to review by the appropriate animal research and stem cell committees.72,74

**Are there alternatives to this solution?**

To able to justify the development of human organs in animals, there has to absence of medical alternatives.66

There are other means to be considered that may be possible in the near future: pig organs could be used for xenotransplantation. There is current research into the prevention of organ rejection or zoonoses transmission, by deletion of the main pig genes responsible for xenogeneic organ rejection. Also, breeding pigs in which all the porcine retroviruses have been inactivated. Another possibility is the differentiation of human iPSC in vitro for cell based therapies for various diseases. In this field, a recent advance was the exploitation of iPSC self-organising properties in vitro, to form “organoids”, 3D tissue with therapeutic potential.66

At the same time, we need to consider if there are other ways to improve the current availability of viable organs for donation.

**PBL scenario 2: House of Climate Change**

**Episode 02 Season 1**

*The Administrator of the U.S. Environmental Protection Agency (EPA) is waiting outside, just in front of the door to the office. The President is in a meeting with the Vice President about some news headlines, so the EPA Administrator has been told he cannot go in yet. He is nervous, it has only been two months since he was given the position of EPA Administrator, and it is well known that the President has a difficult character. Today they have to talk about a slightly prickly subject.*

- We’ve finished now! Mr. Petersen! Come in, we’re waiting for you! – He hears from inside the office.

*Petersen goes into the office. Wow, it has changed a lot! The gold curtains in the office ooze a crude and vulgar glamour.*

- Sit, Petersen, sit. And what did you say you wanted to talk about today?

-Well, we have a never-ending list of subjects...we need to decide which are the environmental priorities for the EPA so we can start establishing measures and regulations.

-Ah well...so, you’re the expert, where do we start?

- The first item of the day is climate change.

- Climate change? – The President brusquely interrupted Petersen – Lies...

- Well, according to some scientific studies the effects of climate change are getting ever more serious: the atmosphere and the ocean have warmed, the amounts of snow and ice have diminished, sea level has risen... The current level of CO2 in the atmosphere is 400 ppm and we could say that...the safety level is 350 ppm. – Petersen is uneasy, he knows how little the President likes this subject.

- Oh really? This is what scientists who don’t have a clue about anything say...they don’t want to be a part of the gas and petrol revolution that will bring jobs and prosperity back to the North Americans. This trash don’t want us to be the most prosperous country on Earth, they don’t want us to rebuild our roads, or our schools, or the public infrastructures...they want to ruin us! They are anti-Americans! – The Presidents, livid with rage, seems like he is at one of his party’s meetings. Petersen tries to hide his disagreement; it isn’t the first time he is present during one of the President’s speeches with airs of superiority.

- Mr President, I’m sorry for insisting, but if we don’t act immediately, the levels of CO2 emission will go up 70% by 2050. – Petersen is shaking; disagreeing with the President is synonymous with being fired. – Maybe it isn’t necessary to slow down the gas and petrol revolution that you mentioned, but we could collaborate... There are alternatives: for example, renewable energies, hmm, what do you think?

- So now it turns out that the EPA administrator is a HIPPIE! Are you from Greenpeace or what? – The President’s face keeps getting redder...

- Wait, I haven’t finished, there are more alternatives. Have you ever heard of CO2 capture? It seems to be quite efficient, although it has certain costs. Besides, Mr. President, Europe is pressuring us...

- Always Europe... They can’t stand that we are a world power and they aren’t. I don’t understand why the devil we have to listen to some countries that aren’t even capable of coming out of a crisis that started 10 years ago. They’re inventing all of this; can’t you see that, Petersen?

- I’m not sure that they’re inventing it, Sir. Europe has decided on a 180 billion Euro budget for Climate Action projects for 2014-2020.

- Very well Petersen. Let’s talk in economical terms; I think we’ll understand each other better. So, what do you propose we do to keep the annoying European Commission happy?

- Well, we could look into these alternatives that I mentioned earlier. I think that CO2 Capture could be an option.

- And what is this?

- CO2 Capture and Storage is a process that consists in separating CO2 from the industrial and energy sources, then transporting this CO2 to geological formations where it is stored, and in this way it is isolated from the atmosphere in the long term. It is actually a technology that allows us to mitigate Climate Change during some time.

- Let’s get to the point, how much money are we talking about?

- Well, it is expensive technology. But there are more things to have in mind: let’s say it has certain risks and certain benefits. On one hand, it greatly reduces the CO2 emissions and it seems like it is one of the few alternatives to the situation we find ourselves in now. On the other hand, there are some inconveniences related to CO2 storage, and also, the general public’s opinion is contradictory. So… - Petersen doesn’t know how to say it – Money has to be invested, meaning that we would have to pay the countries that store the CO2.

- That what? So we don’t only have to pay for the technology, we also have to pay other countries? Are you mad? Do you think I will give North American money to Asians? Or even worse, to Africans? Do we look like charity givers? This will ruin me, what do you think the true North Americans will say of all this? – The President’s face isn’t red anymore, his skin is now a violet colour, and his eyes are coming out of their orbits.

- Hmm I don’t know what the true North Americans will say about this, but I have already told you that society’s view on this subject is contradictory; there are various perspectives on the problem.

- Mr. President! – The President’s Image Consultant enters the office. –It is time for your weekly tanning.

**TUTOR GUIDE:**

**Learning outcomes**

After this activity, the students should be able to:

* Discuss the purpose of CO2 Capture and Storage research.
* Analyse the possible applications of CCS.
* Define the manner in which CCS research is carried out.
* Discuss who is taking part in CCS research process and implementation.
* Evaluate the possible benefits and risks involved in CCS technology.
* Asses the possible impacts related to CCS technology.
* Argue if CCS technology is socially acceptable.
* Investigate if there are possible alternatives to the solution sought by CCS technology.

**Reflecting questions**

**Why is research on CO2 capture and storage (CCS) being carried out?**

Effects of climate change are becoming more serious. In fact, the concentration of CO2 is close to 400 ppm, while safe levels are around 350 ppm. Also, the global political systems seem to be paralysed to reach an international agreement to reduce the Greenhouse gas emissions.[[22]](#footnote-22) In the report “Intergovernmental Panel on Climate Change (IPCC)” written in 2014 they stated:

“Warming of the climate system is unequivocal, and since the 1950s many of the observed changes are unprecedented over decades to millennia. The atmosphere and the ocean have warmed, the amounts of snow and ice have diminished, the sea level has risen, and the concentration of green gases has increased.”[[23]](#footnote-23) Scientists have understood that it is time to act, and as combustion of fossil fuels is increasing and the development of renewables is still marginal, research is focused on mitigation options in short and long term, such as CO2 capture and storage, to act against climate change, stabilise the present level of greenhouse gases and bridge the gap to more long term sustainable solutions.77

**Why is CO2 capture and storage research relevant for society?**

The Tragedy of the Commons, formulated by Garrett Hardin, states that: “The individual benefits as an individual from his ability to deny the truth even though society as a whole, of which he is a part, suffers.”[[24]](#footnote-24) Climate Change is a good example of this economic theory: the gains of exploiting a limited resource and consequently emitting CO2 are conferred to a few; but the consequences, in this case of climate change, affect society as a whole. Because of the benefits of the few, there is a lack of incentive to limit or reduce this resource, so, as some studies have predicted, if there is not a collective action and society does nothing to act against climate change, we, as a whole, are potentially extending the impacts onto generations even further into the future.[[25]](#footnote-25) Some nations are trying to reduce carbon and the use of fossil fuels and CCS is presented as a transition technique to abandon the fossil fuel era as well as a temporary solution/mitigation of the Climate Change effects.80 In fact, the International Energy Agency (IEA) has declared that in the current context of an increase in fuel consumption the costs of reducing the global CO2 emissions in 2050 to 2005 levels will be a 70% higher if CCS is not used.4 So, as in the present context, the causes and effects of climate change are dispersed in time, the agency is fragmented and institutions are inadequate to provide solutions, research in CCS is seen as a possible solution to solve the current situation and avoid the worse effects of Climate Change.80

**Are the motivations to do this research transparent in the public interest? Who is taking part in the decisions process?**

For the public in general and many stakeholders, CCS, which has been a recurrent topic in policy agendas, is a rather unknown technology, which is a barrier for the discussion of large-scale CCS technology research and implementation.77 As some studies present, the public awareness of this technology is low and the perceptions of the general public are influenced by the information provided, how CCS is framed, and which level of trust the public has regarding the information provider.[[26]](#footnote-26) Other studies, Upham and Roberts (2010), have found that if the public is given little information without the chance to ask their concerns, which seems like what has happened up until now, their perspective is dominated by uncertainty and a negative perception of the technology, not willing to give support to CCS.80As Gough and Boucher explain in their article: “Including the opinions and values of lay citizens will require additional effort to enable a diverse population of actors to engage in, and take into account of, the ethics of CCS in decision making and process. Future Climate Change impacts and CCS risks are uncertain, so the trust in actors and the process of decision making is key to the social acceptability of adopted mitigation pathway.”80

However, there is a lot of literature examining societies’ view of CCS. CCS communication researchers have suggested to partner CCS developers with credible partners such as environmental NGOs to increase the publics’ trust within the technology and its possible risks and benefits.[[27]](#footnote-27) Despite this situation, it seems that CCS decision making and process has not had an effective public engagement because Institutions in European countries have not favoured the early communication and engagement in this technology. According to Breukers and Upham: “Local stakeholders are given the opportunity to respond to ready-made plans without having the chance to discuss and influence project design and location.”[[28]](#footnote-28)

**Which are the risks and benefits of this technology? How will the risks and benefits be distributed?**

The main benefits of the CCS technology are related to the decrease of the atmospheric levels of CO2 and the establishment of energy practices that are better for the environment and the resulting climate change mitigation. On the other hand, the risks of this technology are related to the potential leakage of CO2 from geologic sinks or storage sites, which could result in significant release of CO2 into the atmosphere and also cause harmful effects on human health. There is a lot of controversy related to this issue, in fact, the benefits can be realised over a finite period, also, the effects can persist over a very long period of time and, probably, with the application of this kind of technology, there will be an extension on fossil fuels use.80

Costs and benefits of CCS technology are unequal, as it happens with CO2 emissions. Costs are associated to the storage and are local, short term and shouldered by vulnerable populations; while benefits, associated to Climate Change mitigation, are global and long term. So, in this context, the balance between costs and benefits is connected to social, financial and intergenerational justice. CCS technology will allow humanity to continue to use fossil fuels while reducing emissions, this will directly affect future generations who will manage the storage sites, if a climatically problematic legacy has not been created. Furthermore, host communities, financed and compensated by developed countries and identified as the new growing economies, could suffer CCS’s risks and impacts related to health and the safety of the environment for the profit of the whole society. 80

**What impacts of this technology can be anticipated?**

The future ecologic impacts of CCS technology are related to CO2 leakage. Local terrestrial and marine ecosystems could be harmed close to the injection points of this technology. Also, some geological and hydrogeological impacts could be produced in the longer term.[[29]](#footnote-29) Concerns surrounding geological storage include the risk of seismic activity causing a rapid release of CO2, part of the possible harm to people and wildlife in the vicinity. For storage sites under water, there are concerns about chronic exposure of marine ecosystems to high CO2 levels.[[30]](#footnote-30)Furthermore, there are more possible risks apart from ecological and climate destabilization. In fact, there is also the possibility of a financial risk: future conditions could cause greatly increased carbon prices. Also, there are political risks too: institutions with an interest in CO2 storage may manipulate the regulatory environment in their favour.85

**What are the alternatives to this kind of technology?**

Regarding the IPCC 2015 report: “CCS is the only technology which can reduce emissions on a significant scale from fossil fuel power plants and these industrial processes. It is also important to note that renewable technologies are not mitigation substitutes to CCS in the industrial sector. To achieve the global goal to limit temperature increases to no more than 2°C, the scale of change and the level of low-carbon technology deployment are enormous. All emissions reduction solutions are necessary, in all sectors of the economy.”[[31]](#footnote-31)

According also to Webbersten et al. (2014), the only solution in the short run to counteract Climate Change and reduce CO2 emissions is CCS. In the long run, there has to be a transition to greater resources efficiency, where renewable energies play the most important role.77

These are some examples of reflecting questions that can be used to introduce students to the reflection on responsibility and scientific advances. However, we have added more useful questions, extracted from the article from Boucher and Gough (2012), *Mapping the ethical landscape of Carbon Capture and Storage*, to promote a deeper reflection.

-Does CCS conform to the suspected interests of future generations and is it of greater benefit to less advantaged generations?

-Does CCS conform to the interests of all social groups and is it of greater benefit to less advantaged social groups?

-Does CCS conform to the suspected interests of nonhuman species, valued environmental qualities such as biodiversity and ecological sustainability?

-Does the technology conform to the provision of appropriate environmental services for all?

-Does CCS conform to an appropriate distribution of rewards, incentives and liabilities (including the financial opportunity cost investing in other technologies; demand reduction and other production options)?

-Does CCS provide some benefits to any actors?

- Does CCS prevent harm to any actors?

-Does CCS affect any actors’ capacity for self-determination and freedom to shape their own understandings and decisions?

-Is information disseminated about CCS accurate, thorough and sufficient and does it come from appropriate and balanced sources, communicated with sufficient transparency?

-Does CCS conform to the actors being responsible and accountable for the consequences of the risks they take?

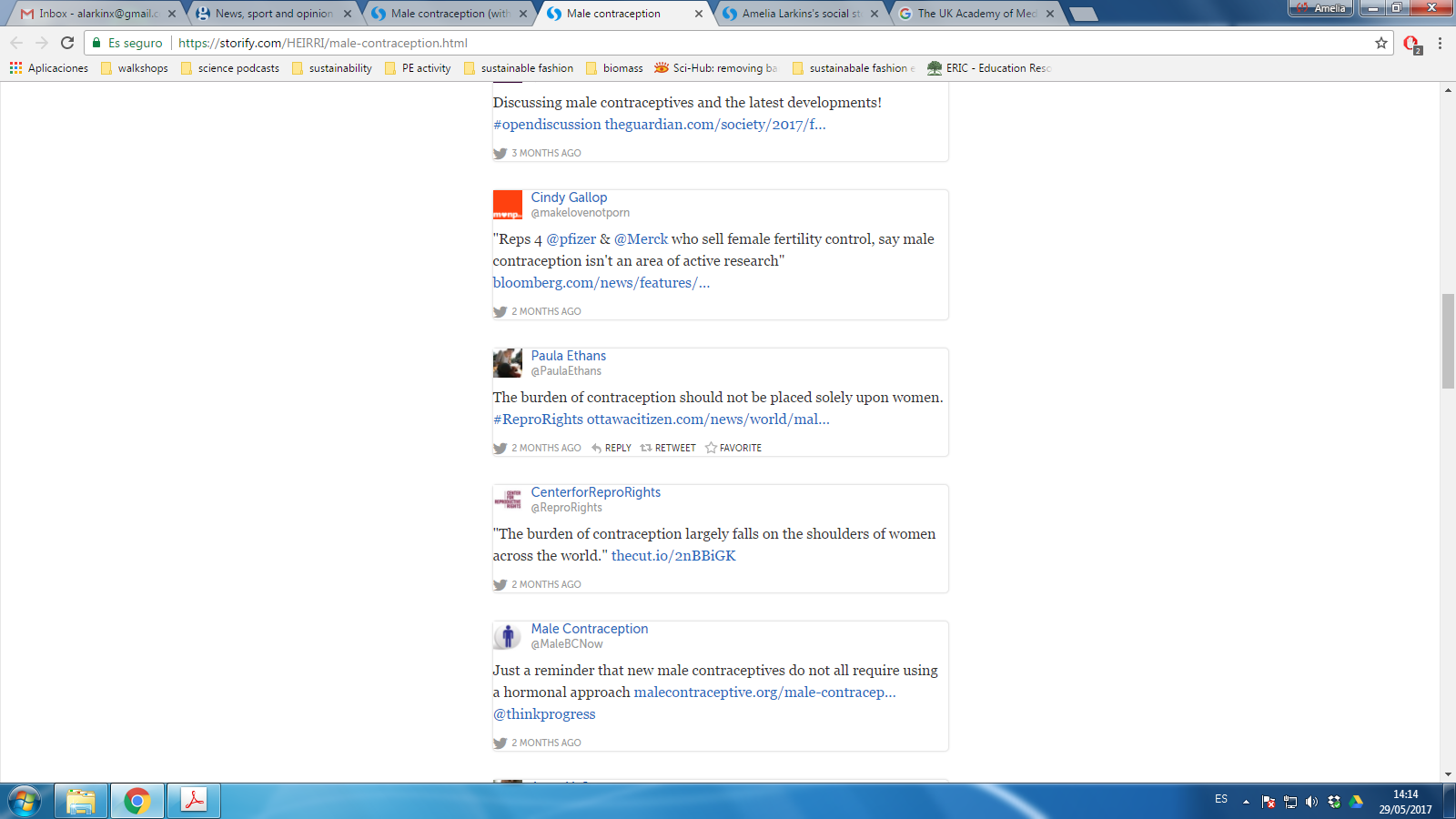
-Are scientific, technical and engineering practices and knowledge of a sufficient standard to ensure the effective, safe and reliable operation of CCS developments?

-Are managerial, regulatory and legal practices and knowledge of a sufficient standard to ensure the effective, safe and reliable operation of CCS developments?

-Does CCS deviate from or transform any social understandings or human values regarding what is right and what is the right way to progress, deal with problems and search for solutions?

-Does CCS deviate from or transform any social understandings or human values regarding nature, natural processes or human relationships with nature?[[32]](#footnote-32)

**PBL scenario 3: MALE CONTRACEPTION**

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This scenario is a “storify”, a collection of tweets from the beginning of 2016 from various sources related to the topic of Male Contraception. To view the full version, see:

**<https://storify.com/HEIRRI/male-contraception.html>**

**TUTOR GUIDE**

**Learning objectives**

After this activity, the students should be able to:

* Explain the history of male contraception research and development
* Investigate the current options of male contraception in development
* Examine the different types of male contraception
* Analyse the advantages and risks involved
* Asses the gender balance in this field of research
* Evaluate other possible ethical implications of this type of research
* Discuss the advantage or not of involving the general public in this kind of research
* Determine the current state of this research in the world, and the possible challenges it faces

**Reflection questions**

**When did research into male contraceptives first start? Why are researchers doing it?**

There has been much improvement in modern female contraceptive methods, but there are still unmet needs for family planning in women. It is essential for countries to provide modern contraceptives, high quality services and improve the access to these services. In this manner, we can allow people to achieve the desired number of children, beneficial to women, families and society. So as to achieve this goal, the development of contraceptive methods for men is a priority. At the moment, the options for men are the condom and vasectomy (a minor surgical procedure which is considered irreversible).[[33]](#footnote-33)

The condom was invented over 400 years ago, and since then no other reversible options for men have been developed.[[34]](#footnote-34) Even though testosterone was first developed and studies for therapeutic use in the 1930s89, clinical trials for the first hormonal male contraception began in the 1970s.88

Many countries started developing new male contraception in the 1970s, supported by government agencies, including China, India and the United States. Hormonal male contraception trials were promoted by the World Health Organization (WHO), the United States National Institute of Child Health and Human Development and other organizations.[[35]](#footnote-35)

**Have there been any advances in this research?**

At the moment, the male contraceptives available to the public are a vasectomy (which is a minor surgical procedure considered irreversible) and the condom (which has a high user failure rate).88 Current developments in this field include long-acting injectable and transdermal gels, also new androgens that may have both androgenic and progestational activities.88

A number of studies have confirmed that there are methods for male contraception that can be achieved with androgens alone or together with progestins that have contraceptive efficacy comparable to current female hormonal methods. These studies included a trial in China that involved over 1000 couples who received injectabletestosterone undecanoate. These studies also confirmed that in most men, if not all, hormonal male contraception is reversible.90

The development of male contraception has been supported by the World Health Organization, Contraceptive Research and Development program, the Population Council and the Contraceptive Research Branch of Eunice Kennedy Shriver National Institute of Child Health and Human Development during the last decade. They support male contraceptive clinical trials in new orally bioavailable androgens and a transdermal method. Also, they support research into identifying and developing new methods of male contraception.90

**What types of male contraception exist?**

There are two main types of contraception, hormonal and non hormonal.

Hormonal methods are the closest to reaching the market, they are based on administering androgens alone, or combined with progestins.91 These methods have proven effective and are generally accepted by both partners. Researchers target: differentiation of germ cells, maturation of sperm, factors inhibiting sperm motility and function.[[36]](#footnote-36)

Some male hormonal contraceptives work by using utilize hypothalamic–pituitary–gonadal negative feedback, which suppresses spermatogenesis, without causing hypogonadism.89 In the 1990s, two important studies, led by the WHO, proved that if spermatogenesis is suppressed and there is a very low level of sperm output, the contraceptive efficacy in males is as effective as female hormonal methods. This can be achieved by administering exogenous testosterone.89,90 Subsequent studies have focused on shortening the suppression phase and improving rates of severe oligozoospermia. This research has combined testosterone-based male hormonal contraceptives with progestins.89 It has been demonstrated that sperm suppression is enhanced when testosterone is combined with progestin.89 Also, progestins allow reduced levels of androgens, without compromising their effectiveness. This can reduce undesired side effects such as acne and male pattern hair loss. 89

Non hormonal methods are often more appealing to the general public. There are a number of non hormonal targets being investigated. This is due to the advance in the understanding of molecular and cellular mechanisms of the regulation of spermatogenesis and sperm maturation. These techniques target a specific protein. They are in preclinical stages and have a lot of promise, but clinical studies have not been started.90 Also, there are new mechanical approaches to vas occlusion that are in development, one of which is similar to a reversible vasectomy.91

Currently, there is a non hormonal long acting reversible contraceptive for men in development. It consists of hydrogel that can be implanted into the vas deferens in the male, thus preventing the passage of sperm. Studies in rabbits have proved it is efficient, durable and it has a rapid onset.[[37]](#footnote-37)

The history of contraceptive use in women can help guide contraceptive development for men, suggesting that daily methods may often be preferred, but long-acting methods are very likely to be more effective. Current male hormonal contraceptives in development want to provide multiple options for patients, with ongoing development of daily gels, long-acting injections and implants lasting up to 1 year.89

**Which are the advantages of research into male contraception?**

Additional male contraceptive options could have significant and important public health benefits by preventing unplanned pregnancies.89 Male hormonal contraceptive options have been studied in over 2000 men, with normal spermatogenesis. Once the administration of contraceptives was stopped, these men returned to normal testicular function, including normal spermatogenesis. This means that hormonal methods are considered to be reversible.89

**What about the risks?**

So far, no trials to date have exceeded 2.5 years of use, limiting the understanding of long-term risks and benefits. Moreover, clinical studies conducted over the last several decades point to areas requiring further study.89

On administering testosterone, there were side effects such as acne, oiliness of skin, weight gain, decrease in HDL cholesterol, increases in haematocrit and haemoglobin and sleep-related breathing disorders.88 Even so, as mentioned previously, it has been proven that testosterone combined with progestin gives better results and reduces the possibility of side effects.

Asian men respond more effectively than men of other races to male hormonal contraception methods. Ethnic variation means that hormonal contraceptives are not equally as effective in all men, although the mechanisms of this variability are still unknown.89

The risk of temporary recovery of spermatogenesis in men on a daily contraceptive with ‘typical use’ may limit the effectiveness of this contraceptive option. This is due to the large difference in effectiveness between the ‘perfect use’ of contraceptives and the ‘typical use’.89

**What is the gender balance when it comes to contraception? Is it balanced?**

Unintended pregnancies are an important health risk worldwide, with significant social, health and economic impacts. These unplanned pregnancies can lead to an increase in abortions, which expose women to an increased risk of death or health problems in many countries.89 Many of these unwanted pregnancies can be avoided by the use of contraceptives. In a study that surveyed over 9000 men in nine countries and four continents, in 55 to 81.5 % of couples, both partners were involved in selecting the method of contraception.88

The development of reliable, reversible and affordable male contraceptives which can be used by millions of sexually active men is important. This would allow men to participate in family planning and enhance reproductive health of the couple.91 There is a significant gap in the contraceptive options available to mean and women, especially in effective reversible choices for men.[[38]](#footnote-38) Both men and women have the option of condom use, as there are both male and female condoms.

Women at present rely on methods such as different forms of the contraceptive pill, other various hormonal options and sterilization.[[39]](#footnote-39) In the last decades, there have been many advances in reversible hormonal contraceptive options for women, such as pills, patches, injections, intrauterine devices and implants.89

On the other hand, men have the options of: coitus interruptus, abstinence or vasectomy (which is irreversible).94

So, the development of new methods of contraception has been mainly female-directed. Even so, despite this one-sided approach to contraceptive provision, a third of couples that practice contraception world-wide use a male method.[[40]](#footnote-40)

**What are other ethical implications of male contraception development?**

The majority of male hormonal contraceptive trials have only involved men with normal baseline semen analyses. Because of ethical considerations, the inclusion of men with subnormal sperm motility, morphology or concentrations has been avoided in the majority of studies. This is due to the risk of subsequent infertility in using an experimental contraceptive. Potential users of these contraceptives are more than likely to include men with subnormal sperm parameters. Only one trial to date has looked at the effect of a potential male hormonal contraceptive on sperm concentrations of men with subnormal sperm parameters.89

**Has the general public been consulted on this topic? What is the public opinion on male contraceptives?**

According to recent surveys, over 50% of men would accept a new male contraception method and their female partners would trust them to take a contraceptive.88 The method with the highest acceptability is a daily pill or a monthly injectable.88 44 to 83 % of men would use a male contraceptive pill, which was a higher number than the injectable. Acceptability was varied amongst the men involved in the study, and it was seen to be influenced by their knowledge of other contraceptive methods and their cultural background.88

In another study, mentioned before, which involved 9000 men in countries and four continents, 28.5 to 71.4 % of men surveyed expressed willingness to use a new male method of contraception with wide variation among different racial and ethnic groups. The attitude towards a new form of contraception also varied according to the relationship status. In a study in England both men and women had favourable attitudes to a male contraceptive pill. Although women had a more positive attitude to the new male pill, they had less trust that men would use it effectively. Men in a stable relationship had a more positive attitude toward a male pill than those in casual relationships.88

In addition, recent international surveys suggest widespread interest in a reversible male hormonal contraceptive in communities of varied races, religions and ethnicities.89

**What is the current state of contraception and research into contraception in the US and EU?**

One of the major obstacles for the development of male hormonal contraceptives has been a lack of funding to support clinical trial efforts. 89

At the moment, male contraception is limited to withdrawal, abstinence, condoms and vasectomy. Studies have shown that male methods account for over 10% of contraception use worldwide, and 25% of contraception use in developed countries.89 However, research has shown that both men and their female partners are willing to use novel methods, including hormonal contraception, provided it is effective, reversible and well tolerated.91 Even so, the pharmaceutical industry has deserted the field of research in male contraception, partly because of unclear registration requirements and partly because of a perceived lack of acceptability and profitability.91

Over the last decade, pharmaceutical and biotechnology companies have halted research and development of male contraceptives. The reasons for this are unclear. Some suggest that it may be due to concern about limited financial returns, safety regulation problems, religious opposition, general bias that family planning is a “female issue” etc. 89

**What are the challenges?**

Progress in the field of male contraceptives has been slow, even though there have been studies that support the acceptability, safety and efficacy of a male hormonal contraceptive. The two major challenges, from a scientific perspective, are the lack of consistent efficacy among all the users of a contraceptive and the possible challenge of multiple agents involved (as some methods require combining different delivery modalities). The high regulatory bar for safety must also be taken into account, greatly diminishing support for male contraceptive development in recent years.89

**PBL scenario 4: A voyage into the past**

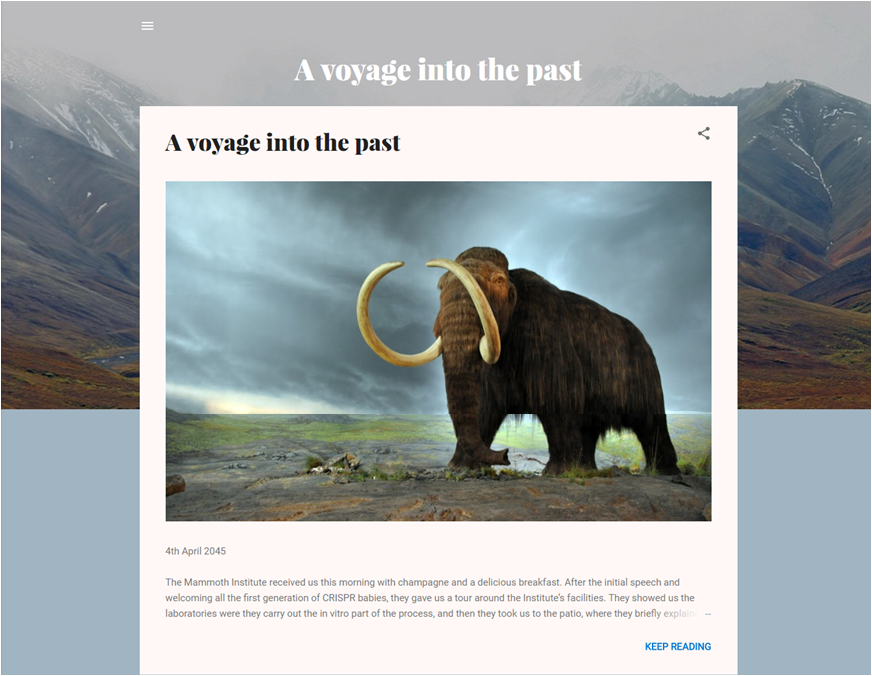
**4th April 2045**

The Mammoth Institute received us this morning with champagne and a delicious breakfast. After the initial speech and welcoming all the first generation of CRISPR babies, they gave us a tour around the Institute’s facilities. They showed us the laboratories where they carry out the in vitro part of the process, and then they took us to the patio, where they briefly explained the areas where they keep female Asian elephants. They have them divided into two groups: the ones that are waiting to be impregnated, and the ones who are already pregnant. We finished off the day with a formal dinner; the guests included all the people who collaborated on the development of our generation. It was really interesting to share our experiences with them.

**5th April 2045**

At 7 o’clock this morning, the guides who work at the Institute drove us in their jeeps to the outer part of the facilities. After an hour in silence, we finally saw the herd. The females and their mammoth offspring, guided by the matriarch, were grazing around the tundra. The amount of food these animals eat is incredible, the moose and the caribous actually looked a bit wary. It was quite impressive to see the first generation of mammoths being reinserted into their original habitat. It’s hard to believe that animals that were extinct 10.000 years ago are so well adapted to their current environment. When we got back inside the Institute, they saw us off with another fantastic dinner. It was a real experience for the first CRISPR babies to be able to see the release of the first generation of mammoths.

See the scenario link here: <http://heirripblcrispr.blogspot.com.es/>



**TUTOR GUIDE:**

**Learning Outcomes**

After this activity, the students should be able to:

* Discuss the purpose of CRISPR research.
* Analyse the possible applications of CRISPR and its relevance in society.
* Discuss who is taking part in the CRISPR research process and implementation.
* Evaluate the possible benefits and risks involved in CRISPR technology.
* Asses the possible impacts related to CRISPR technology.
* Argue if CRISPR technology is socially acceptable.

**Reflecting questions**

**Why is research on CRISPR being carried out?**

CRISPR is a powerful gene editing tool that can alter the genes of a wide range of organisms with relative precision and ease. In fact, this technology offers a new perspective and a set of possible applications in the biomedical research field that were considered science fiction a few years ago. This is why CRISPR seems too good for society to refuse.[[41]](#footnote-41) According to Jasanoff et. al (2015) in *CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation: “*Scientist have a right to “push research to limits” and that restraint is warranted only where the research entails technically defined risks like endangering public health. This reflects not only the desire to satisfy curiosity but the hope that progress in knowledge will produce victories against diseases.”96 CRISPR has opened a big set of possibilities in research: generation of customised genes and cell therapy, more targeted treatments, and direct editing of disease causing genes in human embryos and it has become one of the scientific revolutions of this century. 96

**What are the possible CRISPR applications? Why is CRISPR research and its applications relevant for society?**

CRISPR genome editing technology has allowed scientists to consider a whole raft of projects that seemed impossible few years ago. CRISPR applications are as varied as agriculture, drug development or de-extinction of animals. Here are some examples of the multiple CRISPR applications.[[42]](#footnote-42)

-Disease control: Scientists think that CRISPR could be useful in different areas of the agriculture and livestock field. One example that is being studied is to use CRISPR to counteract the loss of honeybees around the world, which is mostly cause by diseases and parasites, or also to create pigs resistant to viral diseases.97 Furthermore, CRISPR could be used to manipulate embryos’ DNA and prevent human heritable diseases from being passed on.[[43]](#footnote-43)

-Making drugs: the CRISPR technique can be used, for example, to produce vaccines that are suitable for the population allergic to eggs. Also, it can be an advance for pharmaceutical companies because of the potential use of creating drugs using domesticated animals: The EU has approved a goat that produces an anti-clotting protein in its milk.97

-De-extinction: Some research groups are studying how to use CRISPR technology to restore extinct species. One example of this application is carried out by a Harvard research group whose aim is to transform endangered Indian elephants into woolly mammoths or cold resistant elephants.97

-Vector Control: CRISPR technology gives a new perspective on the idea of genetically modifying mosquitoes to prevent the spread of diseases such as dengue o malaria.97

-Better Food Production: CRISPR technology can be used to produce transgenic animals for human consumption with better properties and avoid the cull of animals.97

-Improving pets: Some companies are using this technology to customise pets according buyers’ requests.97

-Disease Model: CRISPR technology has been used in biomedical research to study some diseases, such as the influenza virus, and also creating new animal models.97

Some of these various applications are more controversial than others; in fact, CRISPR has opened up a new field of study focused on the ethical implications of this technology. However, the possible medical advances related to this technology seem relevant to society. As Jasanoff et. al (2015) explain in their article, in the case of the US, 10% of the population are rare genetic disease carriers. CRISPR offers a new possibility in medicine to save individuals and families from fatal economic, psychological and health consequences of this kind of diseases. CRISPR brings promises of salvation to patients suffering from incurable conditions.96

**Who is taking part in the decision process?**

Although many experts have appealed for a CRISPR public debate, and taking into account that possible future applications are related to human genome modifications, the decisions on how far CRISPR should go have to be accountable to society as a whole, however there has not been a practical debate yet.96,[[44]](#footnote-44) CRISPR is one of the most revolutionising technologies of the last decades in science but also in society. Due to its potential, its applications and its benefits and risks, the ethical implications of this technology have to be analysed. This analysis should be done, not only by scientists or politicians, but by the broad public to decide its acceptance.[[45]](#footnote-45) Furthermore, the call for broad public dialogue has to respect the possible ideas from the public that may differ from the experts’ about how to live with emerging technologies. As Jasanoff et. al (2015) explain in their article: “The impulse to dismiss public views as simply ill-informed is not only itself ill-informed, but is problematic because it deprives society of the freedom to decide what forms of progress are culturally and morally acceptable. Future deliberations on CRISPR should actively rethink the relationship between science and democracy.”96

**Who will benefit from this research? How are the benefits distributed?**

As it seems, CRISPR might produce different therapies for human diseases as well as other scientific advances. A big number of individuals will benefit from them, but only if they have access to these treatments.

The unfair distribution of health resources is well known by the scientific community, however, in their point of view, science is not in charge of solving economic and political problems. The finality of the contract between science and society is to provide new knowledge. According to Jasanoff et. al (2015): “These days it is expected (and indeed required by law) that publicly funded discoveries with economic potential should be commercialized: science, in this view, best serves the public good by bringing goods to market. CRISPR is no exception. A patent battle is taking shape between the University of California, Berkeley and the Broad Institute, with predictions that upward of a billion dollars in royalties are at stake.”96 In this context, it is possible that biomedicine’s commercial potential prioritizes developing treatments for affluent patients or developed countries than public health needs.96

**Which are the risks and benefits of this technology?**

The main benefits of CRISPR technology are related to medical applications, which promise a very precise personalised medicine, bridging the gap between genetic information and disease therapies.100 Furthermore, CRISPR represents an advance in science due to its potential to control diseases transmitted by mosquito vectors such as dengue, malaria or the sleeping sickness, by changing the mosquito to make it sterile, and cover, in this manner, a public health problem.[[46]](#footnote-46)

On the other hand, all these technology applications have costs or risks. In first place, editing the genome counteracts natural selection in population and the diversity of human variants. The consequences are not predictable and cannot be anticipated yet, since variant alleles may have important advantages in different contexts and situations. Furthermore, the benefits described before could lead to an ecological destabilisation and produce unpredictable repercussions in ecosystem equilibrium.100

The specific example of the PBL scenario, un-extinction, would raise some risk-benefits questions, and this wide range of questions emerge in every possible CRISPR application. In this case risks are related to the ethical concerns of resurrecting an extinct species, the ecological problems that can result from introducing these new species into the environment, the legal restrictions of un-exctinct animals, etc.100

**What other impacts of CRISPR can we anticipate?**

It is a difficult issue to strike the balance between CRISPR for the public good and private benefit. Risk assessment away from the social context can produce a disparity in health and health care access.96 Furthermore, as Daniel Kevles argued: “the likely adoption of genetic technologies like CRISPR for pursuing eugenic selection had largely shifted from government programs to consumer demand. Methods of selecting against particular genetic conditions were in more widespread use in 2015 than ever before, but the public understood their use to reflect individual choices rather than state coercion.”[[47]](#footnote-47)This situation reflects ethicists’ concerns, which suggests that an unequal access to such technologies could lead to genetic classism. Also, genome editing will pass on for generations through the germ line and this situation could produce unintended and unpredictable consequences.98

These are some examples of reflecting questions that can be used to introduce students to reflection on responsibility and scientific advances. However, here we add more useful questions, extracted and modified from the article Grunwald (2011), *Responsible Innovation: Bringing together Technology Assessment, Applied Ethics and STS research*, to promote a deeper reflection.

-Which social groups are affected by CRISPR? Could or should these social groups help decide about responsibility in CRISPR applications?

- Do the questions under consideration concern the policies or can they be delegated to groups or subsystems? What consequences would a particular distribution of responsibility have for the governance of CRISPR technology?

-What is responsible and what is irresponsible in CRISPR technology development? Is there consensus between the affected and involved actors?

-What is the hypothetical worst scenario of CRISPR technology impacts?[[48]](#footnote-48)

**PBL scenario 5: CYBERVILLE**

Scenario: PODCAST

Can modern information and communication technology sustainably improve quality of life and community living?

Participants:

* Representative from information-technological company, Purple (JH)
* Town mayor (A)
* Smart city researcher/expert (K)
* Town inhabitant1: older person (L)
* Town inhabitant2: young student (engineering/audiovisuals) (J)

On this week’s episode of This European Life, CYBERVILLE, we bring you a story that is happening right now. The town of Cyberville is about to become a real-life laboratory, a large-scale communications and technology experiment. The town has teamed up with Purple, and together they are turning the whole town into what we call a “Smart City”.

Today on our show, we want to understand what exactly a “Smart City” *is*, and what do the inhabitants of Cyberville think about it. We are joined by a representative from Purple, Jack Harrison (JH), the mayor of Cyberville, Antonia Gladders (A), a renowned expert on the subject of Smart Cities, Kieran Monkeith (K), and two inhabitants of Cyberville: Laia Codina (L), who is 76 and a 23-year-old engineering student, Julia Solervicens (J).

Smart Cities are something that is on everyone’s mind. As the Internet of Things comes online — especially in light of recent remote hacking incidents of “Things” like a baby monitor and a car — we can’t help thinking that as every aspect of our lives becomes fully networked, we have to increasingly address issues of privacy, security and system vulnerabilities.

Let’s start off the debate by asking Kieran to introduce us to the concept of Smart Cities.

K: We define Smart Cities as the systematic application to and pervasive penetration of cities by information and communication technologies. The purpose is to use urban informatics to improve the efficiency of services for the community.

Let’s see what our mayor thinks of the situation…

A: So, in what ways is Purple thinking of turning Cyberville into a Smart City?

And from Purple…

JH: Well, our idea is to mainly focus on transport and health. We are especially interested in improving the public transport system in the town, with the aim to improve traffic and the citizen’s experience. As to health, we would like to centre our work on improving quality of life for the more elderly citizens.

Now let’s give our citizens a voice!

L: And how do we know that we can trust you? Won’t you be putting cameras into my house?

JH: Well Ma’am, that’s not exactly the idea…

K: Let me try and explain better Mrs. Codina. What Purple would like to do is to improve the communication between elderly citizens and hospitals for example, so if there is a problem or an emergency, the service could be much better.

L: I still don’t trust them. I don’t want anybody coming into my home…

A: Don’t worry Laia, I will make sure nothing of the sort happens. My first and only concern is the wellbeing of this town, and I will not allow such an invasion of privacy.

And our young student seems keen on the subject too…

J: I’m interested in the technology you use for this kind of projects. How will you manage to get the oldies to participate and learn how to use it?

L: Respect, girl!

JH: It will be very basic, easy to use and won’t cause any problems. Also, it won’t be invasive at all. Benefits for everyone involved!

K: One of the main ideas is to able to control people’s blood pressure from their homes. Blood pressure can be monitored and automatically recorded in an online-diary in a home-telemonitoring process performed by the patients themselves. These diaries can then be accessed by the doctors at the local hospital.

L: And how would that help anyone?

A: Well, I think it would highly benefit the hospitals and patients, as many short and possibly unnecessary visits would be avoided, clearing up many hours and saving a lot of time.

J: How would this work exactly?

JH: We have an online system in which the patients could enter their data. They can also add other information apart from their blood pressure, such as diet, medication, activities etc, so they can be very closely monitored.

L: I don’t think I’d be very good at that…

A: I’m sure we can all figure it out together; I think it’s a wonderful idea.

L: And who can look at my information? I don’t want my nosy neighbour Rita knowing what I had for lunch!

K: The whole idea of this new technology is that all personal information is private and can only be accessed by a patient’s doctor. It is highly unlikely that your neighbour Rita would be able to hack the system…

J: But people can hack anything nowadays! I read about it on techfreaks.com.

JH: Don’t worry, Orange has very strict privacy laws and very efficient security systems. It will be virtually impossible to damage or access the system we are going to set up in Cyberville.

A: In fact, we are ready to begin installation of the household systems next week. And soon after, we will offer a short course for those of you who would like to start using it. Everyone can get involved!

J: Wait, does this mean that this has already been approved? The project is going ahead?

JH: Oh yes, Mayor Gladders signed the contract months ago! We are full speed ahead!

J: But this is the first I’m hearing of it!

K: Sometimes it’s better to surprise the citizens, getting people involved in the decision-making process often causes more problems than solutions. This way, the main innovations have been decided by experts and no one has to worry about anything.

JH: The transport improvements are already installed too, we’re just waiting for the go-ahead from the mayor.

L: WHAT? PEOPLE ARE ALREADY SPYING ON EVERYTHING WE DO?

J: Mayor, this is unacceptable! Nobody knows about this! I’m going to organize a university strike…

L: And I’m going to tell everyone at Monet’s Café!

A: No, please, I made this decision to benefit you all! You’ll see, you’ll love it!

**TUTOR GUIDE:**

**Learning outcomes**

After this activity, the students should be able to:

* Understand the meaning of the concept “Smart city”
* Analyse the possible applications of Smart Cities
* Reflect upon the reason for the creation of a “smart city” and its possible benefits
* Evaluate the possible concerns or risks of “smart cities”
* Asses the ethical issues/impacts related to this topic
* Determine if this type of research is transparent and of public interest
* Discuss the importance of involving the general public in the decisions related to “smart cities”

**Reflection questions**

**How would you define a “Smart City”?**

The concept of “Smart City” has been defined in different ways. Here are some examples:

“The systematic application to and pervasive penetration of cities by the Information and Communication Technologies (ICTs)” [[49]](#footnote-49)

“Territories with high capacity for learning and innovation, which is built-in the creativity of the population, their institutions of knowledge creation, and their digital infra-structure for communication and knowledge management.” [[50]](#footnote-50)

“Cities which have embraced ICT as a development strategy, being pioneers in embedding digital infrastructure and systems into their urban fabric and utilising them for entrepreneurial and regulatory effect.” [[51]](#footnote-51)

There are two broad understandings as to what makes a city smart, keeping in mind many different definitions of a “smart city”. The first is the concept of “everywhere”. This refers to the notion of pervasive and omnipresent devices built in to the fabric of urban places. Some examples are: fixed and wireless telecom networks, digitally controlled utility services and transport infrastructure, sensor and camera networks, building management systems... These are used to observe, manage and control the flows and processes in a city, often in real-time. Also involved in “everyware” are the devices used by the citizens themselves, such as smart phones, to engage with and navigate the city. These devices also produce data about the people using them, such as their activity and location.

The second understanding as to what makes a “smart city” is that its economy and governance is driven by innovation, creativity and entrepreneurship (carried out by “smart people”). In this case, ICT are important as a platform for the realisation of these new innovations and ideas. 106

According to Hollands, there are five main characteristics that make a “smart city”:[[52]](#footnote-52)

* widespread embedding of ICT into the urban fabric
* business-led urban development and a neoliberal approach to governance
* a focus on social and human dimensions of the city from a creative city perspective
* the adoption of a smarter communities’ agenda with programmes aimed at social learning, education and social capital
* a focus on social and environmental sustainability 107

**What are some of the main applications of “Smart Cities”?**

“Smart cities” have many different applications, some are related to the day-to-day life of urban citizens and some are related to the efficient management of urban infrastructure systems. The data that is collected contributes significantly in helping urban infrastructures to operate more efficiently. There are various examples, such as in electricity systems, waste water, general waste, buildings, transport...

The generation of data and its subsequent analysis allows for the creation of new services to be offered to the citizens of a smart city.104 One of the most common examples are those that are traffic related. For example, cameras and transponders placed around a city will send information on the movement of vehicles around a transportation network. This data will help monitor the flow of traffic, thus allowing for the adjustment of traffic light sequences and speed limits, also permitting the automatic administering of fines for traffic violations. Another use for the same camera system could be related to police activity in a city. Police could monitor live images so as to be able to react more efficiently and directly, by allocating appropriate resources to specific locations. Also, by using a sensor network all around the city, environmental conditions data could be collected to measure levels of air pollution, seismic activity etc. 106

Here are some more examples of technologies provided by a “smart city”, compiled by Kitchin.[[53]](#footnote-53)

|  |  |
| --- | --- |
| ***Domain*** | ***Example technologies*** |
| Government | E-government systems; online transactions; city operating systems; performance management systems; urban dashboards |
| Security and emergency services | Centralised control rooms; digital surveillance; predictive policing; coordinated emergency response |
| Transport | Intelligent transport systems; integrated ticketing; smart travel cards; bikeshare; real-time passenger information; smart parking; logistics management; transport apps; dynamic road signs |
| Energy | Smart grids; smart meters; energy usage apps; smart lighting |
| Waste | Compactor bins and dynamic routing/collection |
| Environment | IoT sensor networks (e.g., pollution, noise, weather; land movement; flood management); dynamically responsive interventions (e.g., automated flood defences) |
| Buildings | Building management systems; sensor networks |
| Homes | Smart meters; app controlled smart appliances |

**Why do you think there is a tendency towards Smart Cities?**

The perspective of the inhabitants of a city tend to be that of wanting a more efficient system, but also a more sustainable and resilient urban system. In short, the citizens want a better quality of life. 104

Kitchin outlines a series of “promises” about “smart cities”, that they: 108

* Will tackle urban problems in ways that maximize control, reduce costs, and improve services, and do so in common-sense, pragmatic, neutral and apolitical ways through technical solutions.
* Will create a smart economy by fostering entrepreneurship, innovation, productivity, competiveness, and inward investment.
* Will enable smart government by enabling new forms of e-government, new modes of operational governance, improved models and simulations to guide future development, evidence-informed decision making, and better service delivery, and by making government more transparent, participatory and accountable
* Will produce smart mobility by creating intelligent transport systems and efficient, inter-operable multi-modal public transport, better and dynamic routing, and real-time information for passengers and drivers.
* Will make smart environments by promoting and creating sustainability and resilience and the development of green energy.
* Will create smart living by improving quality of life, increasing choice, utility, safety and security, and reducing risk.
* Will produce smart people by creating a more informed citizenry and fostering creativity, inclusivity, empowerment and participation.

The idea exists that “everyware” will give a more cohesive and smart understanding of a city. This could improve efficiency and sustainability; this interconnectedness should improve the performance of public services. It also provides a supporting infrastructure for business activity and growth and stimulates new forms of entrepreneurship. 106

**How is a town/city adapted to become a Smart City?**

For an urban space to become “smart”, it means that it the infrastructures and users in this space must be equipped. This involves many systems with which to collect data, such as sensors and cameras. This will allow the collection of data from GREEN infrastructures (tress, parks, etc.), BLUE infrastructures (water pipes etc.) and GREY infrastructures (disposable waste, disposed waste, waste water pipelines, water treatment plants, etc.). At the same time, data can also be collected from the buildings in the urban space, for example on their energy consumption. 104

**What are the main concerns about Smart Cities?**

According to Finger et Al, “The citizens, the nongovernmental organizations, civil society more generally, as well as city administrators and especially city politicians have not yet fully appropriated what digitalization of urban infrastructure systems does and, potentially, could or could not mean for them.”104

There are important concerns as to what living in a “smart city” could mean for the privacy of the citizens and also what privacy harms could come from the sharing, analysis and misuse of urban big data. Also, there are concerns related to the security of the technology involved. This includes the consequences of a possible hacking, theft or data breach for the citizens involved.108

The main concerns are more to do with automated forms of data generation. People are less concerned about the directed and volunteered data provided, considering it to provide useful insights into city life, helping to better understand and manage a city. There is concern related to the automated forms of surveillance, sensor networks and “the internet of things”. Also, people are worried about them or objects being traced. 106

Some examples of automated forms of surveillance are: traceable “smart cards” to be used in public transport, automatic number plate recognition (scanned by cameras) to discern the owner of a vehicle and provide input to intelligent transportation systems, automatic meter reading and automated monitoring of public service provision, such as chips on rubbish bins to detect whether the waste has been collected or not. 106, [[54]](#footnote-54)

Moreover, there are a large number of objects and machines all around cities that are part of “the internet of things”, carrying out their work automatically, communicating their use and if mobile, traceable. These include automatic doors, lighting and heating systems, security alarms, wifi router boxes, entertainment gadgets, television recorders, and so on. These objects or machines can send data between them. At the same time, people are constantly using mobile phones or tablets, with built in GPS systems that can be traced. 106

All these forms of data transmission are growing at an alarming pace; by 2013 over ten billion objects were connected to the in internet of things, with this set to rise to over 50 billion by 2020. [[55]](#footnote-55)

Kitchin outlines a series of “perils”, that about the effects of “smart cities”. 108

* Treats the city as a knowable, rational, steerable machine, rather than a complex system full of wicked problems and competing interests.
* Promotes a strong emphasis on technical solutions and overly promotes top-down technocratic forms of governance, rather than political/social solutions and citizen-centred deliberative democracy.
* Solutions treat cities as ahistorical and aspatial and as generic markets, promoting one-size fits all technical fixes rather than recognising local specificities.
* The technologies deployed are positioned as being objective, common-sense, pragmatic and politically benign, rather than thoroughly political, reflecting the views and values of their developers and stakeholders.
* Promotes the corporatisation and privatisation of city services, with the developers of smart city technologies capturing city functions as market opportunities which are run for profit rather than the public good, and potentially create propriety technological lock-ins.
* Prioritises the values and investments of vested interests, reinforces inequalities, and deepens levels of control and regulation, rather than creating a more socially just and equal society.
* The technologies deployed have profound social, political and ethical effects: introducing new forms of social regulation, control and governance; extending surveillance and eroding privacy; and enabling predictive profiling, social sorting and behavioural nudging.
* The technologies deployed potentially produce buggy, brittle and hackable urban systems which create systemic vulnerabilities across critical infrastructure and compromise data security, rather than producing stable, reliable, resilient, secure systems.

**What are the ethical implications of Smart Cities?**

Three issues that can be related to the “smart city” phenomenon, described by Finger et al, are:104

* *Technology* *push or demand pull?*: the idea that smart cities are being pushed into development new ICTs, without allowing for real needs and demands of the citizens to be heard, that could possibly be solved with technology.
* *Consumers or citizens?* This refers to the fact that the promotion of “smart cities” most often comes from the operators, who are pursuing their own commercial interests. The objective of these operators is ultimately to produce services they can sell to consumers, instead of services that are in the public interest.
* *Leadership*: this issue is concerned with the fact that the ideal situation would be for civil society and their political representatives to “adapt” their concept of “smart city” to their public policy objectives, instead of being driven by technology vendors.

**Are the motivations to do this research transparent in the public interest? Who is taking part in the decisions process?**

Research derived from the collection of data from “smart cities” is not always open in nature. Some of the data is generated by local governments and some is generated by private companies.[[56]](#footnote-56)

**PBL scenario 6: The forgotten sleeping sickness**

The Sleeping Sickness is a potentially mortal disease caused by parasites transmitted by infected tsetse flies.

During 2014 there were 3796 cases of this disease and 21 million people at risk. If this disease isn’t treated, it is inevitably fatal.

The story of this disease started 25 years ago. Back then, the sickness disease was the leading cause of death in African villages. The only available treatment, a drug called melarsoprol, was a by-product of arsenic, and it was practically poisonous. During the nineties, hope arrived in the form of the approval of a new and safer drug, eflornitina.

*T. Brucei* and red blood cells, Parasite museum, Tokyo

“During 2014, 3796 cases were registered. The total is estimated to be around 30000.” World Health Organization (WHO)

Unfortunately, a few years later, the pharmaceutical company responsible for the production of this drug, Marion Merrell Dow, came to the conclusion that it wasn’t profitable and they stopped its production. The company’s research and innovation department started to investigate into new applications for the compound and they discovered that it played a part in the inhibition of the appearance of facial hair. In this manner, they put eflornitina back on the market, as a cosmetic product, with great success. However, the people affected by the sickness disease were still without this treatment, with only melarsoprol available.

Nowadays, the organization DNDi (Drugs for neglected disease initiative) is investigating how to improve the treatment for this forgotten disease.

**TUTOR GUIDE:**

**Learning objectives**

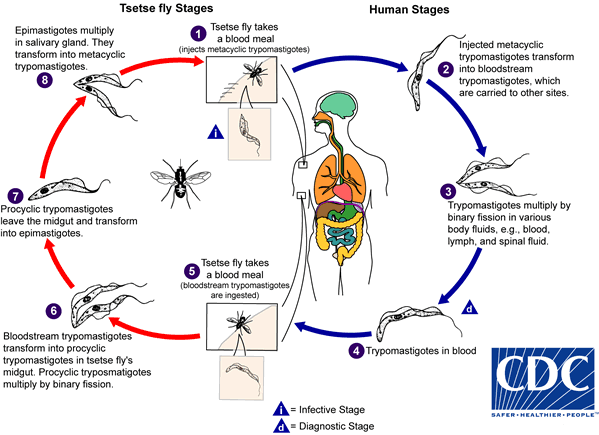
After this activity, the students should be able to:

* Describe the parasite and its life cycle
* Describe the symptoms, diagnosis and treatment for the sleeping sickness
* Describe the drugs used for its treatment and the current lines of research related to the cure for the sleeping sickness
* Identify the epidemiology of the sleeping sickness
* Identify the actors involved in the research, innovation and development process. Discuss which criteria are used to decide on the research, innovation and development of pharmaceuticals
* Determine the ethical acceptability of scientific research in the development of new drugs
* Propose alternative governance models to assure RRI in health, such as the DNDi
* Discover other forgotten diseases
* Identify the actors involved in the application for and obtaining of patents
* Analyse the pros and cons of the patent system
* Discuss the meaning of open source and the possible benefits

**Reflection questions**

**How would you describe the parasite and its life cycle?**

According to the WHO, “human African trypanosomiasis, also known as the sleeping sickness, is a parasitic disease which depends on a vector for its transmission. The parasites involved in this disease are protozoa from the genus *Trypanosoma*, which are transmitted to humans through bites from the tsetse fly (genus *Glossina*) that have become infected from feeding from other humans or animals that were hosts for the parasite.”

**Life cycle**

**Which are the symptoms, diagnosis and treatment for the sleeping sickness?**

**Infection and symptoms**

According to the WHO, “The disease is mostly transmitted by bites from the tsetse fly, but there are other ways in which people are infected:

* Mother-to-child infection: the trypanosome can cross the placenta and infect the fetus.
* Mechanical transmission through other blood-sucking insects is possible; however, it is difficult to assess its epidemiological impact.
* Accidental infections have occurred in laboratories due to pricks with contaminated needles.
* Transmission of the parasite through sexual contact has been documented.

In the first stage, the trypanosomes multiply in subcutaneous tissues, blood and lymph. This is also called haemo-lymphatic stage, which entails bouts of fever, headaches, joint pains and itching.

In the second stage the parasites cross the blood-brain barrier to infect the central nervous system. This is known as the neurological or meningo-encephalic stage. In general, this is when more obvious signs and symptoms of the disease appear: changes of behaviour, confusion, sensory disturbances and poor coordination.

Disturbance of the sleep cycle, which gives the disease its name, is an important feature. Without treatment, sleeping sickness is considered fatal although cases of healthy carriers have been reported.”

#### What is the disease management for the sleeping sickness?

According to the WHO, “disease management is made in 3 steps:

* Screening for potential infection. This involves using serological tests (only available for *T.b.gambiense*) and checking for clinical signs - especially swollen cervical lymph nodes.
* Diagnosing by establishing whether the parasite is present in body fluids.
* Staging to determine the state of disease progression. This entails examining the cerebrospinal fluid obtained by lumbar puncture.

Diagnosis must be made as early as possible to avoid progressing to the neurological stage in order to elude complicated and risky treatment procedures

The long, relatively asymptomatic first stage of *T. b. gambiense* sleeping sickness is one of the reasons why an exhaustive, active screening of the population at risk is recommended, in order to identify patients at an early stage and reduce transmission by removing their status of reservoir. Exhaustive screening requires a major investment in human and material resources. In Africa, such resources are often scarce, particularly in remote areas where the disease is mostly found. As a result, some infected individuals may die before they can ever be diagnosed and treated.”

**Which are the drugs used for its treatment and the current lines of research related to the cure for the sleeping sickness?**

According to the WHO, “in the first stage, the trypanosomes multiply in subcutaneous tissues, blood and lymph. This is also called haemo-lymphatic stage, which entails bouts of fever, headaches, joint pains and itching

In the second stage the parasites cross the blood-brain barrier to infect the central nervous system. This is known as the neurological or meningo-encephalic stage. In general, this is when more obvious signs and symptoms of the disease appear: changes of behaviour, confusion, sensory disturbances and poor coordination.”

Also, “the drugs used in the first stage (haemo-lymphatic stage) are safer and easier to administer than those for second stage (the neurological stage). Also, the earlier the disease is identified, the better the prospect of a cure. The assessment of treatment outcome requires follow up of the patient up to 24 months and entails laboratory exams of body fluids including cerebrospinal fluid obtained by lumbar puncture, as parasites may remain viable for long periods and reproduce the disease months after treatment.

Treatment success in the second stage depends on drugs that cross the blood-brain barrier to reach the parasite. Such drugs are toxic and complicated to administer.

In total five different drugs are used for the treatment of sleeping sickness. These drugs are donated to WHO by manufacturers and distributed free of charge to disease endemic countries.”

**Drugs used in first stage treatment:**

* **Pentamidine:** discovered in 1940, it is an antiprotozoal and antifungal agent from the aromatic diamidine drugs group. The mechanism of action of pentamidine is unknown and it can vary, depending on the organism being treated. Pentamidine can interfere with the incorporation of nucleotides in the DNA and RNA. It may also inhibit the oxidative phosphorylation and the biosynthesis of DNA, RNA, proteins and phospholipids. Last of all, pentamidine can have antagonistic actions towards folates (by inhibiting the synthesis of folates, thus preventing the synthesis of DNA and RNA). It is used for the treatment of the first stage of *T.b. gambiense* sleeping sickness. Despite non-negligible undesirable effects, it is in general well tolerated by patients.
* **Suramin:** discovered in 1920, it is an antihelmintic drug which inhibits enzymes that intervene in the parasite’s metabolism of DNA and protein synthesis. It is used in the treatment of the first stage of *T.b. rhodesiense*. It provokes certain undesirable effects, including urinary tract and allergic reactions.

**Drugs used in second stage treatment:**

* **Melarsoprol:** discovered in 1949, it is used for the treatment of both forms of infection. It is derived from arsenic and has many undesirable side effects, the most dramatic of which is reactive encephalopathy (encephalopathic syndrome) which can be fatal (3% to 10%). Melarsoprol is a pro-drug (meaning that once it has been metabolized, it turns into the active ingredient) which is metabolized into melarsen oxide, its active form. This form incatives the pyruvate kinase, thus inhibiting the energy production chain in the parasite. It is highly toxic as it also acts upon the host. An increase in resistance to the drug has been observed in several foci, particularly in central Africa. It is currently recommended as first-line treatment for the *rhodesiense* form, and as second-line for the *gambiense* form.
* **Eflornithine:** this molecule, less toxic than melarsoprol, was registered in 1990. It derives from ornitithine, and it inhibits the enzyme ornithine decarboxylase, thus inhibiting the synthesis of polyamines such as spermine and spermidine. It is only effective against *T.b. gambiense*. The regimen is complex and difficult to apply.
* **Nifurtimox:** It started to be used in 1965. It is a 5-nitrofuran which generates free radicals that react with the nucleic acids of the parasite, making them break. The host’s cells are protected from the free radicals by the presence of additional enzymes such as catalases, peroxidises, superoxide dismutases and the antioxidant glutathione.

 A combination treatment of **nifurtimox** and **eflornithine** was introduced in 2009. It simplifies the use of eflornithine by reducing the duration of treatment and the number of IV perfusions, but unfortunately it has not been studied for *T.b. rhodesiense*. Nifurtimox is registered for the treatment of American trypanosomiasis but not for human African trypanosomiasis. Nevertheless, after safety and efficacy data provided by clinical trials, its use in combination with eflornithine has been included in the "*WHO List of Essential Medicines*" and is currently recommended as first-line treatment for the *gambiense* form. Both drugs are provided free of charge by WHO to endemic countries with a kit containing all the material needed for its administration.

### **Public private partnership**

According to their website “In 2000 and 2001, WHO established public-private partnerships with Aventis Pharma (now Sanofi) and Bayer HealthCare which enabled the creation of a WHO-led control and surveillance programme, providing support to endemic countries in their control activities and the supply of medicines free of charge.

The partnership was renewed in 2006, 2011 and 2016. The success in curbing the number of sleeping sickness cases has encouraged other private partners to sustain the WHO’s initiative towards eliminating the disease as a public health problem.”

WHO provides the anti-trypanosome medicines free of charge to endemic countries through public-private partnerships with Sanofi (pentamidine, melarsoprol and eflornithine) and with Bayer HealthCare (suramin and nifurtimox). The conditioning and shipment of medicines is done in collaboration with MSF-Logistics.

In 2014 a coordination network for human African trypanosomiasis was established under WHO leadership to ensure strengthened and sustained efforts to eliminate the disease. The stakeholders include national sleeping sickness control programmes, groups developing new tools to fight the disease, international and non-governmental organizations, and donors.

**New approaches**

Even though the first choice of treatment is the combination of nifurtimox and eflornitina (NECT, Nifurtimox-eflornithine combination therapy) in the secong stage of the disease, its use is limited to the hospital setting. Nowadays, two new drugs are being studies at a clinical level:

Fexinidazole, a 5-nitroimidazole, which is also a pro-drug that is metabolized quickly in vivo, producing sulfoxide and sulphone, sulphone being the more active metabolite.

SCYX-7158, a benzoxaborole derivative, whose mechanism of action is still unclear.

Both these drugs have been proven effective in animal models with an African trypanosome infection; they can both be administered orally, are capable of crossing the blood-brain barrier and seem to be effective with short-term treatments.

**Which is the epidemiology of the sleeping sickness?**

According to the WHO, “human African trypanosomiasis takes 2 forms, depending on the parasite involved:

* *Trypanosoma brucei gambiense* is found in 24 countries in west and central Africa. This form currently accounts for 97% of reported cases of sleeping sickness and causes a chronic infection. A person can be infected for months or even years without major signs or symptoms of the disease. When more evident symptoms emerge, the patient is often already in an advanced disease stage where the central nervous system is affected.
* *Trypanosoma brucei rhodesiense* is found in 13 countries in eastern and southern Africa. Nowadays, this form represents fewer than 3% of reported cases and causes an acute infection. First signs and symptoms are observed a few months or weeks after infection. The disease develops rapidly and invades the central nervous system. Only Uganda presents both forms of the disease, but in separate zones.
* Another form of trypanosomiasis occurs mainly in Latin America. It is known as American trypanosomiasis or Chagas disease. The causal organism belongs to a different *Trypanosoma* subgenus and is transmitted by a different vector.”



They also state that, “ther parasite species and sub-species of the *Trypanosoma* genus are pathogenic to animals and cause animal trypanosomiasis in wild and domestic animals. In cattle, the disease is called *Nagana*. Trypanosomiasis in domestic animals, particularly in cattle, is a major obstacle to the economic development of affected rural areas.

Animals can host the human pathogen parasites, especially *T.b. rhodesiense*, of which domestic and wild animals are an important reservoir. Animals can also be infected with *T.b. gambiense* and act as a reservoir to a lesser extent. However, the precise epidemiological role of the animal reservoir in the gambiense form of the disease is not yet well known.”

**What have been the major human epidemics?**

The WHO states that there have been several epidemics in Africa over the last century: one between 1896 and 1906, mostly in Uganda and the Congo Basin; one in 1920 in a number of African countries, which was controlled thanks to the work of mobile teams that monitored the people at risk; and the most recent epidemic started in 1970, due to the relaxation of the measures taken in 1920 and lasted until the late 1990s. in 1970 the disease reappeared, reaching epidemic proportions, but the efforts deployed by the WHO, the national disease control programmes, the bilateral collaboration and the NGOs during the nineties and first years of the current century allowed for this tendency to be reversed. Since the number of new human African trypanosomiasis cases reported between 2000 and 2012 dropped by 73%, the WHO neglected tropical diseases roadmap targeted its elimination as a public health problem by 2020.

Sleeping sickness threatens millions of people in 36 countries in sub-Saharan Africa. Many of the affected populations live in remote rural areas with limited access to adequate health services, which complicates the surveillance and therefore the diagnosis and treatment of cases. In addition, displacement of populations, war and poverty are important factors that facilitate transmission.

According to the Who website, “The disease incidence differs from one country to another as well as in different parts of a single country.

* In the last 10 years, over 70% of reported cases occurred in the Democratic Republic of the Congo (DRC).
* The DRC is the only country that currently reports more than 1000 new cases annually and accounts for 84% of the cases reported in 2015.
* Central African Republic is the only country that declared between 100 and 200 new cases in 2015.
* Countries such as Angola, Burkina Faso, Cameroon, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Gjana, Guinea, Malawi, Nigeria, South Sudan, Uganda, United Republic of Tanzania, Zambia and Zimbabwe are reporting fewer than 100 new cases per year.
* Countries like Benin, Botswana, Burundi, Ethiopia, Gambia, Guinea Bissau, Kenya, Liberia, Mali, Mozambique, Namibia, Niger, Rwanda, Senegal, Sierra Leone, Swaziland and Togo have not reported any new cases for over a decade. Transmission of the disease seems to have stopped in some of these countries but there are still some areas where it is difficult to assess the exact situation because the unstable social circumstances and/or difficult accessibility hinder surveillance and diagnostic activities.”

**Which actors involved in the research, innovation and development process Discuss which criteria are used to decide on the research, innovation and development of pharmaceuticals**

Research and innovation into new drugs is carried out in different fields:

* Research in universities and research centres with public funding
* Research in private companies with public funding (subsidies, prizes, credits)
* Research and development with private funding, remunerated via the market instead of public funding, and incentivised via the intellectual property system, a mechanism to foment innovation which is part of the governmental policies.

Recent studies show that the resulting products from research financed by the public sector have a higher therapeutic effect than those that derive from research in the private sector.

One of the current systems to encourage innovation is the patent system, but whether or not this system can encourage inventions in fields where there is no real market can be questioned. One of the problems of this system which is driven by patents is that the profitability of the investment in innovation is generally integrated into the price of the resulting products. On the other hand, in the new initiatives and mechanisms of financing, the objective is not to finance the cost of research and development of the product with the final price of the product in mind, which means that they disassociate the cost of research from the price of the product.

The WHO has established a record in which the data from clinical research is generated and made public. The publication of the results in these trials is of interest to public health and science in general.

**Which is the ethical acceptability of scientific research in the development of new drugs?**

In a statement from 2009, the WHO declared that “WHO considers equitable access to safe and affordable medicines as vital to the attainment of the highest possible standard of health by all. WHO Member States reaffirmed their commitment to these principles in May 2008, with the adoption of a resolution on the "Global strategy and plan of action on public health, innovation and intellectual property" (WHA61.21). Among other important objectives, the resolution expressed Member States' commitment to improving the delivery of and access to all health products and medical devices by effectively overcoming barriers to access.

In this context, the recent events related to the handling of medicines in transit and the potential consequences for the supply of medicines in developing countries are of major concern to the organization. This issue has been raised in the meeting of the WHO Executive Board in January 2009 and was a subject of discussion in the recent WTO TRIPS Council.

In relation to this issue, WHO is continuing to follow developments and consulting with Member States and relevant international intergovernmental organizations. WHO also understands that there is ongoing dialogue among the parties concerned to resolve the matter. Given the public health impact of this issue, WHO remains ready to provide, upon request, technical and policy support to Member States.

Ensuring that the interests of trade and health are appropriately managed also means that the flow of legitimate medicines, including generic medicines, is not impeded.”

The ethical principles that have to be respected in the development and production of medications are:

**The principle of autonomy.** Autonomy refers to the capacity to give oneself rules or guidelines without the influence of outside pressures. The preferences and values of the patient are fundamental from the ethical point of view.

**The principle of beneficence.** The obligation to act for the benefit of others; by promoting their legitimate interests and doing away with prejudice.

**The principle of non-maleficence.** To intentionally abstain from carrying out actions that may cause damage or be harmful to others.

**The principle of justice.** To treat each person appropriately, with the aim to reduce situations of inequality (ideological, social, cultural, economic, etc.)

**What is RRI? Propose alternative governance models to assure RRI in health, such as the DNDi**

RRI is a transparent and interactive process through which social actors and innovators become responsible for each other, taking into account the ethical acceptability, sustainability and society in the process of innovation and its resulting products. The European Commission has identified six key issues of RRI: ethics, gender equality, science education, governance, open access and public engagement (commitment with society/population). In the frame of RRI, new organization models in the field of health have appeared, such as:

**DNDi:** is a collaborative non-profit organization, dedicated to the research and development of drugs, based on the patients’ needs, which is developing new treatments for forgotten illnesses. The international research community, the public sector, pharmaceutical companies and NGOs all collaborate in this organization to develop said treatments. The main goals of the organization are:

* To develop 16-18 treatments before 2023
* To expand and build Research and Development networks between different regions
* To create new entities to achieve the development of treatments for forgotten diseases.

**Discover other forgotten diseases**

Forgotten diseases are those which, even though they cause some of the highest morbidity and mortality rates in the world, they are ignored by the pharmaceutical development system. These diseases incapacitate or kill millions of people and they represent an important medical need that should be addressed. This type of diseases represents a global problem for public health, but the R&D of pharmaceutical companies is almost always oriented towards gain and is centred around the production of drugs to treat sickness that affects the population of more develop countries.

Some examples of forgotten diseases are:

* Malaria
* Sleeping sickness
* Chagas disease
* Visceral Leishmaniosis
* Lymphatic fibrosis
* Dengue fever
* Schistosomiasis

**Other reflecting questions:**

Which stakeholders take part in the patent system?

What is the importance of patents? How do they work?

What ethical dilemmas should be considered in the patent system?

Are there potentially harmful impacts involved in the patent system? How can they be prevented?

How can an open access system be implemented? What are the benefits and problems involved?

 What are the possibilities and limitations for ‘open-source’ approaches in life sciences?

**Recommended bibliography:**

* 2013. Promoting access to Medical technologies and innovation. Intersections between public health, intellectual property and trade. WHO
* Gold ER, Kaplan W, Orbinski J, Harland-Logan S, N-Marandi S (2009) Are Patents Impeding Medical Care and Innovation? PLoS Med 7(1): e1000208. doi:10.1371/journal.pmed.1000208

**PBL scenario 7: Deception**

**Adapted from the book: Research Methods in Psychology by [John J. Shaughnessy](https://www.thriftbooks.com/a/john-j-shaughnessy/216307/), [Jeanne S. Zechmeister](https://www.thriftbooks.com/a/jeanne-s-zechmeister/216306/), [Eugene B. Zechmeister](https://www.thriftbooks.com/a/eugene-b-zechmeister/216308/), McGraw-Hill Education, 9th edition, 2012**

RESEARCH PROPOSAL:

The research project will involve 60 students, from the ages of 16 to 20. These students are volunteers who have signed up to participate in a research project that is investigating “attitudes of today’s teenagers”.

These students will be assigned to different discussion groups. There will be four people in each discussion group. They will be given a set of 20 questions to answer, and they will be instructed to discuss each question with their group before writing down the answer.

Among these questions, a section will be related to the consumption of alcohol in teenagers. Some of the questions will be about prevention methods and how to avoid teenage drinking and driving. In each group, there will be a debate moderator, appointed by the investigator, to guide the discussion.

Unknown to the students, some of the participants in the discussions are not volunteers. These participants are working for the investigators; they will be referred to as confederates. Thus, the students will be randomly assigned to different groups:

* groups with zero confederates
* groups with one confederate
* groups with two confederates

These confederates have previously received instructions on what to say and how to act during the debate on the questions related to alcohol consumption. They have been provided with a script to follow.

This script revolves around the argument that people who are of a legal driving age (16 or 18), and also people who are old enough to vote (18) should be considered old enough to make their own decisions when it comes to drinking. Also, they should say that it is up to each individual to decide if they want to drink or not, and therefore it is not fair to intervene if a person under the legal drinking age decides to consume alcohol. The confederates should also admit to drinking alcohol at least three times, one of them recently.

In this manner, depending on the number of confederates in the group, the experimental manipulation involves either zero, one or two people declaring that they don’t think students should be responsible for avoiding situations in which alcohol is available to minors or even to intervene when a fellow student makes the decision to drive after having consumed alcohol.

The evaluation of the experiment will be assessed by analysing the written answers given by the volunteers. At the same time, these group discussions will be recorded without the knowledge of the participants, and also analysed.

Once the experiment has been concluded the investigators will disclose the nature of the deception and the reasons for the tape recordings to all those involved in the research.

**Learning outcomes**

After this activity students should be able to:

* Understand the meaning of “deception” in psychological experiments
* Define the manner in which research is carried out using deception
* Analyse the possible applications of using deception in research
* Evaluate the possible risks involved in using this kind of techniques in psychological experiments
* Asses the ethical issues/impacts related to the use of deception
* Examine the possible security measures to be implemented in this type of research
* Determine if this type of research is transparent and of public interest
* Investigate if there are possible alternatives to the solution sought by this type of research

**Reflection questions**

What is deception in psychology?

Why is deception used in psychology?

What are the possible risks of using deception in a psychological experiment?

What ethical issues are involved in the use of deception?

Are the motivations for this research transparent and in the public interest?

Are there alternatives to the use of deception?

Under what conditions is it always unethical to deceive research participants?

How is debriefing beneficial to both participants and researchers?

How should researchers treat the information obtained from participants in order to protect them from social injury?

What is informed consent? Should researchers always obtain informed consent?

**Recommended bibliography**

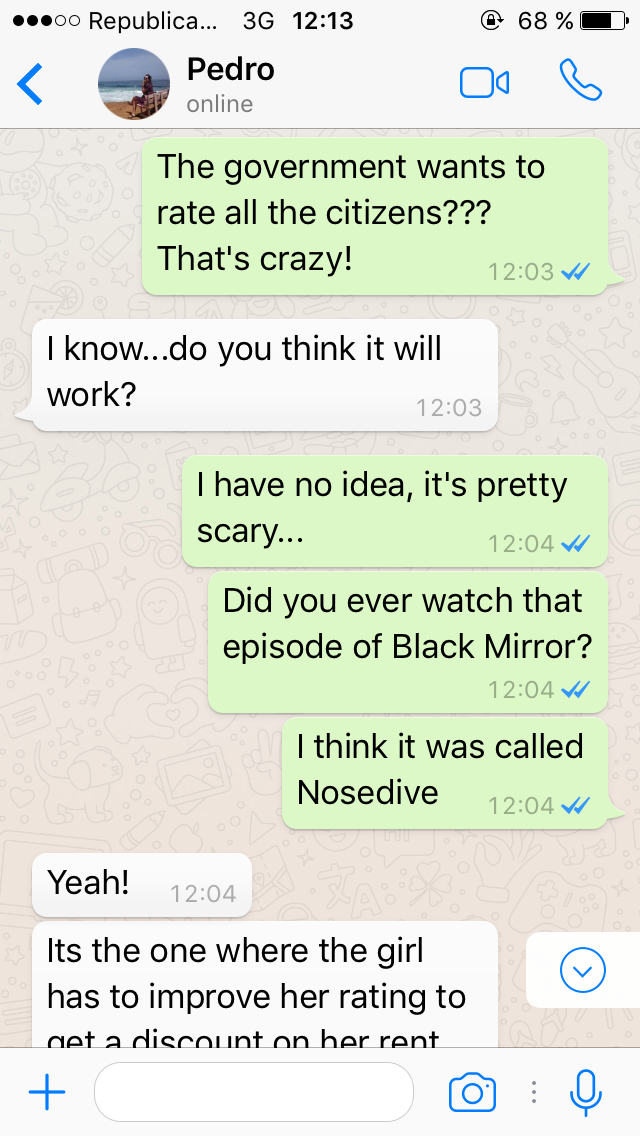
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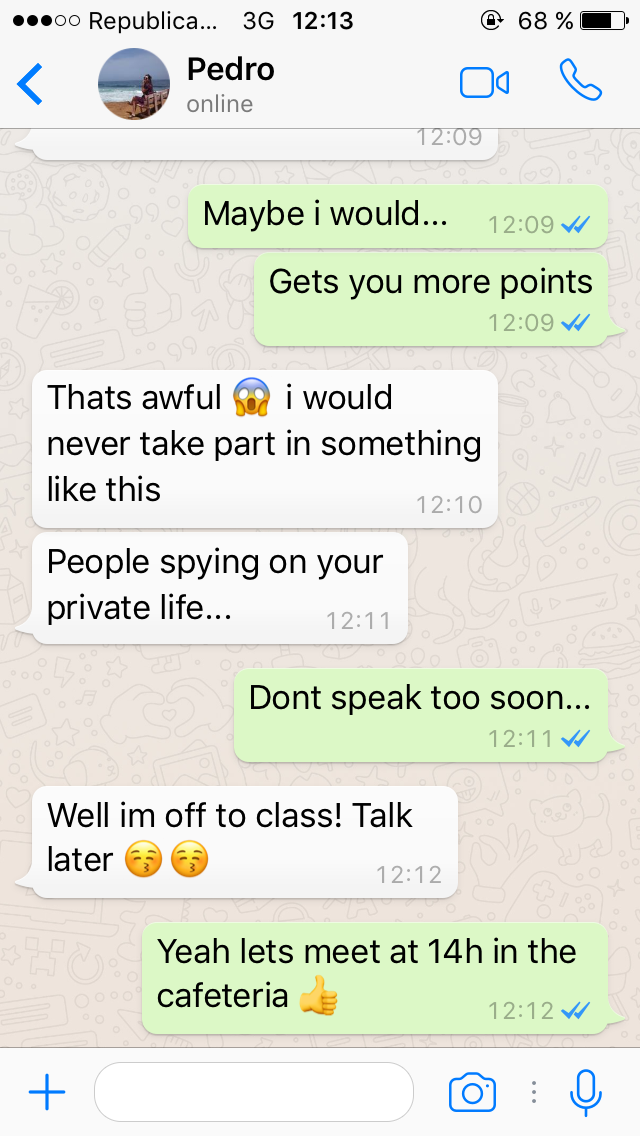
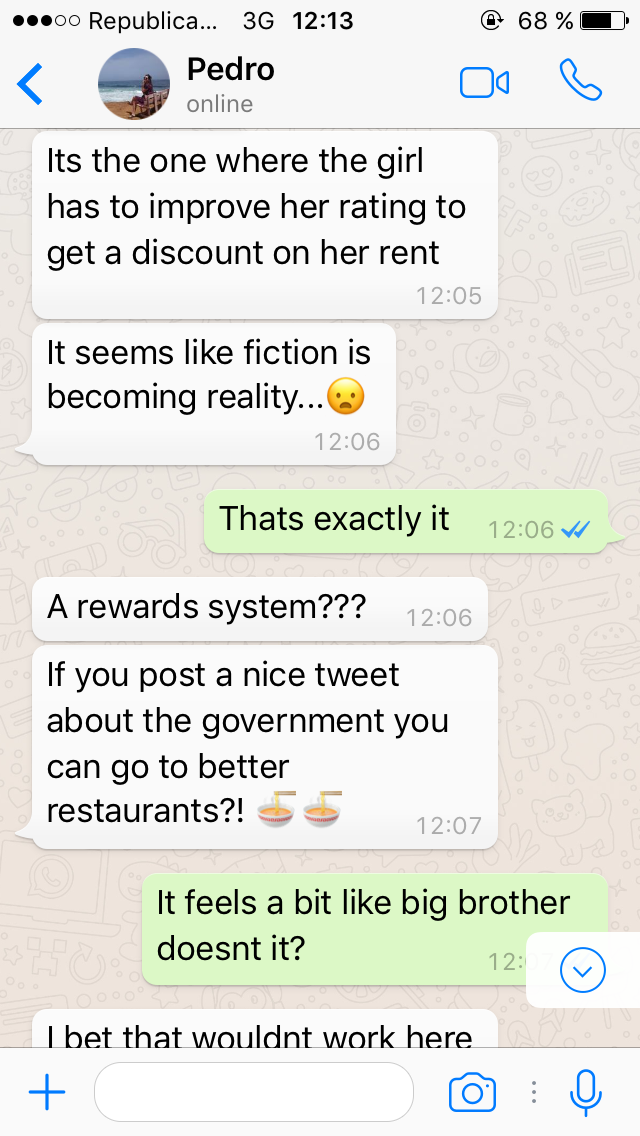
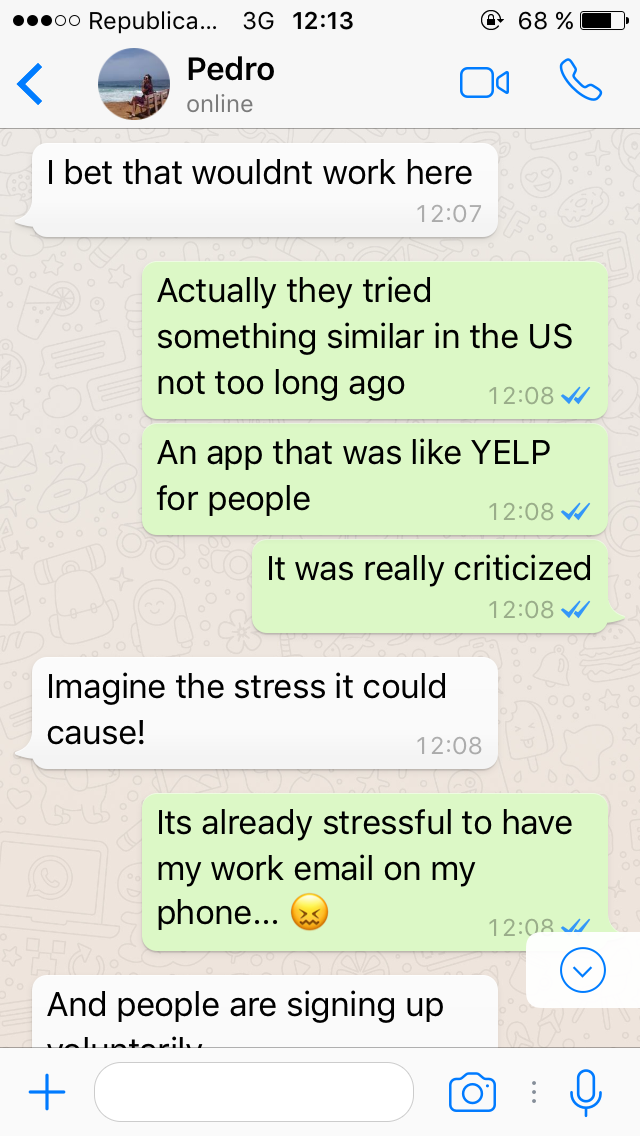
**PBL scenario 8: What’s your score?**

*Conversation on instant messaging app between two friends:*

* Good morning! How was last night?
* Hey! Great! We stayed up until 2 am talking. I’m a bit worried. Did you see the article I posted?
* No…send me the link
* Read the whole thing! <http://www.wired.co.uk/article/chinese-government-social-credit-score-privacy-invasion>
* The government wants to rate all the citizens? That’s crazy!
* I know…do you think it will work?
* I have no idea…it’s really scary though. Did you ever watch that episode of Black Mirror? I think it was called Nosedive.
* Yeah! It’s the one where the girl has to improve her social rating to get a discount on her rent! It seems like fiction is becoming reality.
* That’s exactly it.
* A rewards system??? If you post a nice tweet about the government you can eat at a better restaurant???
* It feels a bit like Big Brother doesn’t it?
* I bet that this wouldn’t work here…
* Actually, they tried something similar in the US not too long ago, an app that was like YELP for people. It was really criticized.
* Imagine the stress it could cause!
* It’s already stressful to have my work email on my phone…
* And people are signing up voluntarily before it becomes mandatory!
* Maybe I would…gets you more points
* That’s terrible! I would never take part in something like this!
* Don’t speak too soon…
* Well, I’m off to class! We can talk about this later…xxx
* Yeah! Let’s meet at 14h at the cafeteria! Xx





**Learning outcomes**

After this activity students should be able to:

* Discuss the purpose of creating a social credit system
* Analyse the possible applications such a system in society
* Discuss the actors taking part in the research process and implementation
* Evaluate the possible benefits and risks involved in creating a social credit system
* Asses the possible impacts related to a “people-rating” technology on society
* Argue if this technology is socially acceptable

**Reflection questions**

What are possible risks involved in creating a system to rate people and their interactions?

Who will benefit from this research?

What aspects are taken into consideration when creating such a system? What aspects should be taken into consideration?

What ethical issues are involved in the creation of such a system?

Should security measures be implemented? How could this be done?

What impacts of this technology can be anticipated?

Are the motivations for this research transparent and in the public interest? Who is taking part in the decisions process?

Who would own and have access to the data collected? Could this data be sold?

Has the general public been consulted on this topic? What is their opinion?

**References in the scenario:**

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**ANNEX 3.****FEEDBACK FORMS FOR RRI DIMENSIONS**

The feedback forms for RRI dimensions are based on the “Report on the quality criteria of Good Practice Standards in RRI”, by RRI Tools, these tables can help the teacher in the discussion on the quality criteria for the different dimensions of RRI. We recommend teachers read carefully the criteria and the questions to think about criteria and adapt them to their students’ profile.

<https://www.rritools.eu/documents/10184/107098/D1.3_QualityCriteriaGoodPracticeStandards.pdf/ca4efe26-6fb2-4990-8dde-fe3b4aed1676>

**Diversity and inclusion *Feedback* form**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Questions to think about criteria** | **Suggestions of improvement** |
| Engaging a variety of stakeholder groups | * Is there a wide range of stakeholders involved? * Is there diversity within the stakeholder groups involved in terms of gender, ethnicity, class, age and other demographics? |  |
| Variety of means of stakeholder engagement | * Are relevant stakeholders involved from early stages of the R&I trajectory onwards? * Are different methods and techniques for engaging specific stakeholder groups in dialogue taken into consideration? |  |
| Engagement of public(s) | * Are the right publics involved in the right phases of the R&I trajectory? * Are different possibilities explored or activities undertaken to facilitate the development of capabilities of publics to contribute to a science-literate society*)*? |  |
| Attention for appropriate R&I models and methods | * Is there diversity within the objects of research, in terms of gender and other demographics? *(e.g., are not only male animal models used?)* |  |

**Openness and transparency** ***Feedback* form**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Questions to think about criteria** | **Suggestions for improvement** |
| Honest and clear (re)presentation of the practice details | * Are all objectives, aims and goals honestly and clearly represented? * Is there a declaration of interests and affiliations of all actors? * Are all methods honestly and clearly represented? * Are there policies on open access and information sharing and are they accessible to stakeholders? |  |
| Open and clear communication about the processes of deliberation and decision-making | * Is there an explanation of the exact role of actors in both the deliberative and decision-making process? * Is there feedback on how the input of different actors is used or what the impact of their input was in the practice? |  |
| Open and clear communication about the results of the practice | * Are preliminary, intermediate and final results shared with all actors involved and/or affected? * Are uncertainties in and limitations of the practice identified and shared? * Is there clarity about ownership and accountability, not only of positive, but also of negative outcomes and impacts? |  |
| Appropriate means and content of communication and education per actor | * Are alternative ways of communicating or educating appropriate to the diversity of actors involved and affected, being taken into consideration? * Has it been considered what information can and should be shared with whom? |  |

**Anticipation and reflection** ***Feedback* form**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Questions to think about criteria** | **Suggestions for improvement** |
| Analysis of the background, current situation and context of the (planned) research or innovation. | * Has the influence of other innovations/research on the course of this practice been taken into consideration? * Have efforts been put in the practice into addressing potentially diverging definitions of the problem at stake? * Have efforts been put into giving a role to societal values, perceptions and interests in defining the problem addressed in the practice and the further course of the practice? |  |
| Envisioning of plausible futures | * Is there active identification and consideration of immediate, mid-term and long-term social, environmental and economic impacts and consequences of the practice? * Have alternative research and innovation trajectories been considered? |  |
| Variety of impacts | * Are ethical, legal, social and environmental aspects and impacts of the practice sufficiently addressed? |  |
| Addressing roles in RI trajectories | * Are actors involved aware of and open for reflection on their role responsibilities and accountability? |  |

**Responsiveness and adaptive change** ***Feedback* form**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Questions to think about criteria** | **Suggestions for improvement** |
| Structure for seeking and incorporating feedback | * Are methods for incorporating feedback being explored and implemented? |  |
| Flexible process management | * Is it possible to change the course of the research and innovation practice in response to changing stakeholder’s needs / interests / values / perceptions? * Is it possible to change the course of the research and innovation practice in response to interim results or conflicting data? |  |
| Development and implementation of evaluation strategies | * Are evaluation strategies or frameworks actively being developed and implemented? |  |
| Flexible attitudes to revise views and actions | * Are the individuals involved willing and able to revise their views and actions? |  |
| Application of results | * Are (affected) stakeholders willing and equipped to apply new knowledge, values/norms and competencies? |  |

|  |  |
| --- | --- |
| **Criteria and** | **Indicators** |
| RRI key points identification in the research project  (25%) | * Possible societal implications and impacts of the research project have been assessed * The identification of RRI key points more relevant for the field of research are justified by contrasting their own beliefs with the literature research. * The four RRI dimensions (Diversity and inclusion, Openness and transparency, Anticipation and reflection, Responsiveness and adaptive change) are reflected in the key points identified. |
| Strategies to integrate RRI in a research project  (25%) | * Different methods and approaches to incorporate the RRI key issues identified into a project are included (such as public engagement activities, protocols to guarantee research integrity or gender perspective, etc.) * The objectives, feasibility and impacts of implementing these actions are clear. |
| Implementation and assessment of RRI  (25%) | * There are evidences that the student has questioned some aspects of responsibility in his/her own research and has put in practice, at least, the ones corresponding to the individual practice, such as research integrity or assessment of social impacts of the research * Different nature of evidences are used to assess the RRI implementation strategies |
| Reflection about RRI in the future professional practice  (25%) | * Weaknesses and strengths of RRI implementation in the specific field of research are analysed * Specific strategies to implement RRI in the specific field of research are planned |

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