PATHWAY PROJECT

INTERNATIONAL CAREER PATHWAYS AND ONLINE CURRICULUM FOR TRANSLATIONAL SCIENTISTS

EDUCHALLENGE

IMPLEMENTATION HANDBOOK



This project has been funded with support from the European Commission. This publication (communication) reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.





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PART 1 INTRODUCTION



INTRODUCTION

Translational Medicine encompasses the continuum from identifying an idea to its development into new therapies for human diseases. A translational scientist is someone who understands the needs of the patient, the perspective of medical specialists and who can generate opportunities within science and its connection to industry. A successful translational scientist is a bridge builder between all these different stakeholders.

In order to nurture the specific bridge building qualities, we have developed an educational challenge (educhallenge) which focusses on perspective taking. By reviewing current complex case studies that involve different points of views from different groups of stakeholders within Translational Medicine, students learn what it takes to come to an agreement and unite in order to work together towards patients' benefits.

By stepping into another person's shoes and experiencing the same case from different perspectives, translational scientists will be one step closer to becoming the best bridge builders they can be. Skills garnered from this course will help individuals to address the challenges facing drug development today, and bridge the divide between concept and patient. In our opinion, these skills are key elements for working in such a crossfunctional platform today.



Further information regarding this project can be found on the website: www. pathwayproject.eu



LEARNING OBJECTIVES

After a Pathway Educhallenge the student is able to:

1	RECOGNIZE EACH DIFFERENT STAKEHOLDER IN A SPECIFIC CASE
2	DESCRIBE THE TENSIONS BETWEEN ALL STAKEHOLDERS
3	PRESENT A SPECIFIC CASE FROM THE PERSPECTIVE OF EACH STAKEHOLDER
4	FIND A COMPROMISED SOLUTION WITH THE ENTIRE GROUP
5	APPLY THESE SKILLS TO WORK TOWARDS A COMMON GOAL WITHIN COMPLEX MULTIDISCIPLINARY PROBLEMS



PART 2 HOW TO SET UP A PATHWAY EDUCHALLENGE

HOW TO SET UP A PATHWAY EDUCHALLENGE

Who do you need:

- Group of early career translational scientists to be divided into 3 or 4 smaller groups
- 3 or 4 participating faculty members
- 1 or 2 debate mediators preferably experienced translational scientists
- External experts and stakeholders from the specific case study topic or similar



What do you need:

- Suitable room
- Laptop/Beamer
- 3 or 4 flipovers and markers
- Handouts for all students



PREPARATION (120 MINUTES)

A	Define a real-life situation or case within Translational Medicine with twists and an unexpected ending in which different stakeholders are present (see examples)
B	Write a paragraph with general background information, but without revealing what happens in the end
C	Capture this in a 5 to 10-minute PowerPoint presentation
D	Define 3 to 4 stakeholders with different views and priorities
E	Describe the position of each stakeholder in a few sentences and include 2 to 3 challenging questions from their perspective regarding the case
F	Compile different handouts for each stakeholder, including the general background information and specific information and questions for each stakeholder (see b and e)
G	Invite 1 or 2 debate mediators to support the session and briefly prepare them by explaining their role in fueling the debate and the standpoints of the different stakeholders
H	Invite external experts and stakeholders from the specific case study topic to sit in the audience during the debate, they will be available for questions during the wrap-up
I	Prepare a 5-minute wrap-up PowerPoint presentation explaining the twists and turns that the case went through and what ended up happening

SESSION PART 1 (45 MINUTES)

	Welcome the students, outline the session, introduce the debate mediator(s),and give the introductory PowerPoint presentation
	Randomly divide all students into groups representing each
	stakeholder and appoint a member of the faculty to join in (preferably with knowledge of the field, but unfamiliar with the specific case study)
C	Let each group separately define their responses to the challenging questions on their handout and prepare their standpoints for the upcoming debate
	Have each group stand and present their position on the case to the others in 2 to 3 minutes and point out what information they need from the other stakeholders to resolve the case



SESSION PART 2 (45 MINUTES)



- A Give the debate mediator(s) the floor and let them begin by emphasizing the different positions of each group
- B Let students debate the case for the next 20 to 30 minutes
 challenging each stakeholders position, the debate mediators are expected to fuel the discussion
- Emphasize the need for collaboration and compromise in order to move forward and try to get all parties to agree on the next steps for the case
- Give each group the opportunity to formulate final remarks



WRAP UP (30 MINUTES)

A	Give the wrap-up PowerPoint presentation		
B	Invite the external experts and stakeholders to share their experiences with this case or a similar one, and encourage questions from students		
C	Make sure there is enough time to answer all questions		
D	End session		



PART 3 EXAMPLE CASES CASE TEMPLATE

EXAMPLE CASE BY DANONE NUTRICIA RESEARCH

Case Scientific publication picked up by the media

Title Improving the health of children with a food supplement? Not so fast!

Background information

Iron deficiency (ID) and vitamin D deficiency (VDD) are common among young European children because of low dietary intakes and low compliance to vitamin D supplementation policies. Milk is a common drink for young European children. In collaboration with and funded by Industry a clinical study aiming to investigate the effect of a micronutrient fortified young-child formula (YCF) on the iron and vitamin D status of young European children, resulted in an excellent scientific paper in a top journal. The conclusion of the study is that micronutrient-fortified YCF use for 20 weeks preserves iron status and improves vitamin D status in healthy young children in Western Europe.

You heard the current practice and recommendations in toddler nutrition, and you learnt the outcome in terms of nutritional status in toddlers. You also learnt how this can be solved (as one of the options) by supplying a micronutrientenriched Young Child Formula (YCF). What to do with the data, how and where to communicate, strategy, targets, interests, risks, and next steps?



EXAMPLE CASE BY DANONE NUTRICIA RESEARCH

Stakeholder perspectives

- 1. **Parents:** You normally do not read scientific papers, so are unaware of the YCF study results. Now you know, what should happen with the outcome of the study in the interest of your child? How should this happen, preferably and optimally to your opinion? How do you feel about the data? Do you trust or doubt it? Would you feed your child YCF or cow's milk and vitD droplets?
 - 2. Nutritional Company: Together with scientists from a university clinic you published results of how supplying your YCF product can solve a nutritional problem in toddler nutrition. How do you cascade this data preferably and optimally down to your stakeholders (who are they?), to be most impactful and adding to your credibility (and profit)?
 - 3. **University**: In collaboration with and funded by industry you carried out a clinical study resulting in an excellent paper in a top journal. How does the public look at your independence as a researcher, and how can you remain unbiased and refrain from financial and/or ethical 'conflicts of interest'?
 - 4. **Governmental**: You know it is hard for parents to implement your nutritional guidelines for toddler nutrition while refraining from using supplemented foods; you strongly oppose their use. You advocate the use of vitD droplets to children up to 4 years of age, but you are aware of the low compliance to this recommendation. How do you perceive the results of the study, what should be done with the data? Are you prepared to adapt your recommendations?

EXAMPLE CASE BY DANONE NUTRICIA RESEARCH

Wrap up

What really happened: the scientific publication was picked up and broadcasted by several media outlets. This however, led to a public discussion and dissension regarding the independency of the science and the applicability of the intervention. Involvement of multiple governmental bodies and scientists did not bring the clarity to the parents in the advice on how to supplement the diet of their children with iron and vitamin D.



EXAMPLE CASE BY GHENT UNIVERSITY

Case	Extremely high cost for life-saving medication
Title	Baby Olivia
Background information	Baby Olivia is 10 months old and suffers from spinal muscular atrophy, a rare inherited neuromuscular disease, which is life- threatening. The prognosis is that she will die before her 2nd birthday. Fortunately, a new therapy has recently been developed by a large international pharmaceutical company. It concerns gene therapy which needs to be administered once intravenously. A phase 1 study has been performed on 15 patients and showed no major safety concerns. Additionally, an open label phase 2 study on 22 patients showed an important clinical improvement in the majority of patients. A small group of patients experienced no effect at all.The medication doesn't cure the disease, the atrophic muscles will not be regenerated, but further damage is prevented. As such, it can be expected that Olivia could have a longer life-expectancy with acceptable quality. Other than some motoric disabilities, she could probably live an independent life. However, this therapy is extremely expensive (2 million euros per treatment) and considered the most expensive medication in the world. Also, it is not (yet) reimbursed.

EXAMPLE CASE BY GHENT UNIVERSITY

Stakeholder perspectives

1. Parents: Your baby is critically ill, but promising treatment exists. Due to the extremely high cost and lack of reimbursement, it is not really accessible for your child. How do you feel about this? Who do you believe is responsible for this situation? How would you proceed? Would you accept the situation or take further steps?

- 2. **Pharmaceutical Company**: For years you have invested in the development of a new drug for a rare disease, which finally has been approved by the FDA. However, regulating authorities of most countries do not reimburse this therapy. Are you willing to lower the price so more patients can benefit from it? Do you keep the pricesetting and hope that the public opinion will push regulating authorities to pay in this specific case?
- 3. **Governmental**: Your team needs to advise the minister of public health on the reimbursement of new medication. Olivia's parents contacted your team to inquire for financial help to pay for her medication. Shortly after you refused this request, the case got national media attention. Do you reconsider your decision? Are there other ways to help Olivia?

Wrap up

Despite repeated requests, the pharmaceutical company doesn't want to lower the price for Olivia. Also, the government doesn't want to make an exception for reimbursement. Of course, Olivia's parents want to do whatever they can to give their daughter all possibilities. By organising several activities, they raised 10.000 euros. Because they felt a lot of people were eager to help their daughter, they sought media attention and started a large action in which people could send text messages in order to donate 2 euros. In this way, the parents collected more than 2 million euros in 4 days and were able to pay for the treatment. Shortly after, Olivia received the treatment and is doing well at the moment; her treating physicians already see some clinical improvement.

CASE TEMPLATE

Case	
Title	
Background information	
Stakeholder perspectives	1 2 3
Wrap up	