

The POLKA Project: Empowering patients through PLAY DECIDE



2nd Workshop of Council of Rare Disease Federations

Patients ' Consensus on Preferred Policy Scenarii for Rare Diseases



Brussels, December 3th 2009

2nd Workshop of Council of Rare Disease Federations

What is the Polka project?

- Pillar 1: To empower patients and collect patients' opinions on selected topics through deliberative debates
- Pillar 2: To guide the implementation of the policy on European Reference Networks and National Centres of Expertise
- Pillar 3: To organise the 5th European Conference on Rare Diseases (ECRD) 2010 and more

Principles of deliberative debates

- Policy makers understand the need to involve society (and patients) so that decisions on science and technology reflect public needs and concerns
- But how can society become more effectively involved in decision-making beyond giving our views in polls or surveys?

PLAY
DECIDE



Empowerment?

- Make rare disease patients and their supporters stronger
- Play Decide: A way to learn and to develop and structure discussion:
 - Get more knowledge on a complicated subject in an easy way
 - Get experience in discussion and advocacy in a safe environment
 - Contribute to the collective opinions of rare patients in Europe

Using Play Decide will make it easier for you to advocate and to discuss with policy makers and others



Selected topics

Cluster one: Access to treatment and orphan drugs:

- Centres of expertise
- Cross Border Healthcare
- Is there any upper limit on what we should spend on a single patient? – Orphan Drugs as a case

Cluster two: Genetic issues

- Diagnosis, information of the patient, genetic counselling
- Neonatal screening
- Stem cell research
- Pre-implantation genetic diagnosis



Process of Kit Development

1. Outline issue
2. Identify Experts
3. Interview for outline of issue and fundamental documents
4. Draft kit materials
5. Review by 1st round of experts - vote and comments
6. Review by 2nd round of experts - vote and comments
7. Trial session with EURORDIS, ECSITE, other PO and general public
8. Translation in 23 EU languages
9. Translation validated by PO



Next Steps - I

- 2 topics are ready for translation
 - Neonatal screening
 - Cross-border healthcare
- 2 topics are ready for trial
 - Is there an upper limit for spending on a single patient? – OD
 - Diagnosis, information to the patient, genetic counselling
- 2 previously existing games are updated
 - Stem cell research
 - Pre-implantation genetic diagnosis
- 1 topic designated for Delphi-like method
 - Centres of Expertise



Next Steps - II

- Available games will be translated into 23 languages and validated by volunteer patient representatives
- They will be made available on the Play Decide website, currently www.playdecide.org mid January 2010
- RD patient organisations will organise Play Decide sessions across Europe



How does it work?

Xenotransplantation as an example

Decide on Xenotransplantation

INSPIRED BY DEMOCS.ORG

Introduction
Xenotransplantation is a surgery that involves the use of live cells, tissues and organs from a non-human animal source, transplanted into humans. Talking about xenotransplantation is important because it raises key questions such as:

- Is it morally right to breed genetically modified animals to use their organs for human transplant?
- Is xenotransplantation acceptable or too risky?
- How long should we go on replacing organs and cells in a human life?
- What restrictions can the regulatory authorities reasonably require from animal transplant patients and their families in order to protect the population?
- How do we balance individual liberties and availability of medical treatment with the remote risk of an epidemic from transferring an animal virus into the human population?

Policy positions

1. It is ethically wrong to transplant live animal organs into human patients.
2. It is too risky to transplant live animal organs into human patients.
3. Only transplant animal organs into human patients if the benefits are sure and very large and if the benefits definitely outweigh the risks.
4. Transplant animal organs into human patients provided the risks are shown to be reasonable.

Aims of the game

- Clarify what your opinions are
- Work towards a shared group vision
- Let your voice be heard in Europe
- Enjoy discussing!

Story card

Place story card here

Info card

Place first Info card here

Info card

Place second Info card here

Initial thoughts

Write down your initial thoughts, use White cards to add issues

Issue card

Place first Issue card here

Issue card

Place second Issue card here

Challenge card

Place Challenge card here

PREPARE:
Each participant gets a placemat.

• Participants read the Guidelines and Three stages

• Moderator may talk everyone through the game, inform about yellow cards and challenge cards

Guidelines

You have a right to a voice: speak your truth.
But not the whole truth: don't go on and on.

Value your life learning.

Respect other people.
Allow them to finish before you speak.

Delight in diversity.
Welcome surprise or confusion as a sign that you've let in new thoughts or feelings.

Look for common ground.
'But' emphasises difference; 'and' emphasises similarity.

Three stages

1. Information
Clarify your personal view on the subject, reading and selecting the cards which you feel are most important for you. Place your cards on the placemat and then read them aloud to the other players. ± 30 MIN.

2. Discussion
Together with the other players, start discussing and identify one or more larger themes that you all feel relevant. Everyone gets a chance to speak. Put your cards on the table to provide your arguments for each theme. ± 30 MIN.

3. Shared group response
Reflect on the theme(s) that the group has identified and the cards that sustain the arguments. As a group, can you reach a positive consensus on a policy position that reflects the group's view? You can formulate a new common policy, if you wish. ± 20 MIN.

... plus one

4. Action
Go to www.playdecide.org to:

- Submit the results of your group to the Decide database;
- See how other European countries think about this issue;
- Read more about this subject;
- Download a game kit to play with your friends or colleagues;
- Learn how you can make a difference after playing Decide.

1 2 If you need to interrupt an ongoing conversation, use your 'talk money'- you can do it twice during this phase.

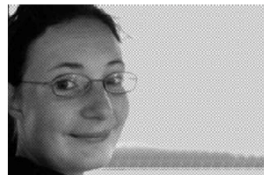


Stage 1- Information

- Participants read Introduction
- True life stories help participants to measure the consequences of their choices. Participants circulate story cards and pick one that they find important and place it on the mat. They then present it to the group

Story card 01.

Sophia's story



I am an animal technician. Its amazing how attached you can get to the pigs we breed. It is hard to see them go, but this has to be done. What would be really wrong would be to treat these animals badly just because we know that in the end they are going to be put down as part of an experiment. We owe it to them to care for them. I know it isn't natural that they spend all their life indoors, and often in isolation, but I still think they have a good life.

Story card 02.

Dr. Sharon Taylor



I've worked for ten years to enable pig hearts to be successfully transplanted into humans. I've seen the terrible suffering at first hand of people born with congenital heart diseases. My son, Toby, was born with a weak heart. He could barely walk and couldn't play with other children. We waited for a donated heart to be found, but he died before one was available. I don't want other children and families to suffer in the same way that Toby suffered. That's why I believe xenotransplantation is important.

Story Card 03.

Ben's story



I'm waiting for a heart transplant. My heart has been dodgy for years, but a car accident last summer was such a shock to my system that it has been erratic ever since. Doctors say that the likelihood of finding a donor heart is slim. I've heard about xenotransplantation - transplanting a pig heart into humans. I am a vegetarian, and don't want to do this, but the idea gets more appealing the longer I wait. I just want to watch my daughter grow up again and to be well.



Stage 1- Information (30 min.)

- Information cards: Participants read randomly the cards, pick up 2 of them and place them on the mat to share with the group.
- Each participant presents her or his cards
- White cards can be used for new cards

<p>Info Card 01.</p> <p>What is xenotransplantation?</p> <p>Xenotransplantation covers:</p> <ul style="list-style-type: none"> • The transplant of whole organs • Cell transplant therapies • Bioartificial Liver Devices (BAL) – where pig liver cells are used to perform the essential functions of the natural liver. 	<p>Info Card 02.</p> <p>Traditional transplants</p> <p>Since the first heart transplants, live (human) organ transplantation has been the preferred approach to transplantation.</p>	<p>Info Card 03.</p> <p>The organ gap</p> <p>There are 5 patients waiting for an organ transplant for every organ donated. This shortfall is known as the 'organ gap'. It is serious because there are not usually alternative treatments.</p>
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Stage 1- Information (30 min.)

- Issue cards: Participants read randomly the cards, pick up 2 issues they would like to discuss.
- Each participant presents her or his cards on the mat

Issue Card 01.

Don't humans eat pigs anyway?

Some say if we kill pigs to eat, surely we should use their organs to save life?
Others say it's not the same - eating animals is natural, but using their organs is artificial.

Issue Card 02.

What use of pigs should we allow?

Should we put human genes in pigs, or pig organs in humans? Should we allow pig cloning in order to delete certain genes?

Issue Card 03.

Waiting lists

Currently, there are long waits for human organs, involving decline in health, considerable anxiety, and the loss of life. Supporters argue that enough animals could be reared to overcome this.



Stage 2- Discussion

- Players are engaged into discussion
- Yellow cards are for all participants – in order to keep them focused and fair

Guidelines: Yellow Card!

Use the yellow card to help the group stick to the guidelines. Wave it if you feel a guideline is being broken or if you do not understand what is going on.

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Stage 2- Discussion

- 16 cards may be used by the moderator to address challenges raised by the subject and to give a new turn to the discussion if the discussion does not progress by the players

Challenge Card

Can we justify spending money on this research given the inequalities in health care between Europe and developing countries?

Challenge Card

Do you think that human needs are more important than the needs of those without a voice- nature, animals, embryos?

Challenge Card

“We should maximise human life and pursue all avenues of research to help people who are ill.”

Do you agree with this statement?



Stage 2- Discussion

- The participants collect their cards into clusters and identify one or more larger themes that they all feel as relevant.

Which conclusions does this cluster lead you to?

Cards in this cluster:

Info cards numbers:	Issue cards numbers:	Story cards numbers:	Any white cards?



Stage 3 – Shared Group Response (20 min.)

- Read the 4 policy scenarios
- The group decides on a possible policy scenario, or proposes its own policy. With or without consensus.

Policy positions for Xenotransplantation

Position 1.

It is ethically wrong to transplant live animal organs into human patients.

2.

It is too risky to transplant live animal organs into human patients.

3.

Only transplant animal organs into human patients if the benefits are sure and very large and if the benefits definitely outweigh the risks.

4.

Transplant animal organs into human patients provided the risks are shown to be reasonable.

5.

This group's own policy position response:



Stage 3 – Shared Group Response

- Participants individually record their support for each policy position or choose to abstain.
- The organiser of the event uploads the results online.

Policy positions for Neonatal screening

Position 1.	2.	3.	4.	5.
National health care systems can decide on providing national neonatal screening for diseases that are treatable or not and can decide on access of genetic data with no need for approval from the EU or other independent body.	Like policy one but with an independent EU body which coordinates and checks on what national neonatal screening should be done and according to which code of practice.	European legislation to ensure that neonatal screening is to be used for major genetic treatable diseases or when it is demonstrated medical utility. A special authorization must be obtained from an independent European organisation for neonatal screening for serious diseases and abnormalities that cannot be treated or prevented. Genetic data to be protected by the independent body.	Licensing and strict monitoring and evaluation on European and national level. An independent body to be created by the EU to record tests carried out, to approve neonatal screenings or not and to protect genetic data.	This group's own policy position response:

Support						+++
						++
						+
Acceptable						-
						--
Not acceptable						---
Abstain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Upload
For uploading the voting results, go to:
www.playdecide.org
password: vote



Stage 4 – Uploading Results

Decide
INSPIRED BY DEMOCS.ORG

Play
DOWNLOAD
Results
UPLOAD

Xenotransplantation
Nanotechnology
Stem cells
Genetic testing
Neuroscience
HIV/Aids
Climate change

Worldwide results
Europe as a whole
European countries

Results Pre-implantation Genetic Diagnosis
Europe as a whole, 4 november 2009
result of 115 games

Support 1. 2. 3. 4. 5.

Accept 0

Not acceptable

Abstain

> TO EXTENDED RESULTS

Fifth policies

Portugal, 28.10.09
Everyone agreed with the conditions described in the third policy but only under the monitorization mentioned in the fourth

Italy, 19.09.09
POLKA Projectorganised by UNIAMO FIMR6 Participants:1 patient acondroplasia5 patient associations'representatives2 Tuberosus Sclerosis Compleximmunodeficienze primarie

Denmark, 09.05.09
Polka project

After loading results of your individual session you will be able to compare results from others in your country, in Europe, and around the world.



Stage 4 – Uploading Results

Event Sessions Report

Project Far far away, behind the word mountains, far from the countries Vokalia and Consonantia, there live the blind texts.

Project name

Facilitator Far far away, behind the word mountains, far from the countries Vokalia and Consonantia.

Details required if it's a registered user with profile

Type of facilitator

Name organization

Name facilitator Email

Please be sure to select the project POLKA when uploading results on the new website.

In the meantime, please enter the name POLKA into the field for a 5th policy position whether there is one or not.



Stage 4 – Uploading Results

Event	Sessions	Report
<p>Report</p> <p>Only possible if results where added</p> <p>Far far away, behind the word mountains, far from the countries Vokalia and Consonantia, there live the blind texts. Separated they live in Bookmarksgrove right at the coast of the Semantics, a large language ocean.</p> <p>Auto generated report</p> <p>On 15th of november 2008, 80 participants got together at the Waag in Amsterdam, the Netherlands. During that event, 10 sessions where played with the decide kits Polka (FR), Nanotechnology.</p> <p>The results for the Nanotechnology plays where mostly in favour of policy position 1 (Rapid nanotechnology expansion, minimum regulation. Promote rapid expansion of nanotechnologies, with the minimum of regulation, to ensure its benefits are realised as quickly as possible.) and policy position 2 (Proceed with nanoscience but regulate. Allow scientific research in</p>		
<p>Case study</p> <p>Only possible if user is registered</p> <p>Far far away, behind the word mountains, far from the countries Vokalia and Consonantia, there live the blind texts. Separated they live in Bookmarksgrove right at the coast of the Semantics, a large language ocean.</p> <p><input type="checkbox"/> Create case study</p> <p>Previous Save</p>		

After loading results of your individual session a report will be generated that summarises the results.



Follow the leaders...

- RDD - Rare Disorders Denmark
- Finnish Association of People with Physical Disabilities
- Seminar for students of MPH programme – PARIS 13
- HUFERDIS - Hungarian Federation of People with Rare and Congenital Diseases
- EURORDIS – Summer School and AMM

*...have already organised or plan to organise
Play Decide sessions!*

*The most active organisations will win a prize –
40,000€ all in all!*



Can we help? YES!

- Passing on experience and inspiration
- Let us come and visit you in time for your annual meeting, rare disease day event, or any other opportunity and help you to
 - organise training of moderators
 - organise Play Decide sessions

Contact Anna Kole before you leave to arrange a date!



Can you help? YES!

- Quick validation of translation into your language
- Translation of 5th policy scenarii
- Share your experience – photo documentation welcome 😊
- Organise lots and lots of games! For everybody!



Success depending on...



IT TAKES

2

TO
TANGO

BUT

MANY

TO
POLKA



credits

A project by:

Eurordis: Yann Le Cam

Rare Disorders Denmark: Lene Jensen

Fundacio Doctor Robert: Prof Josep Torrent i Farnell

National Commissioning Group NHS UK: Dr Edmund Jessop



Collaborating partners:

Dr Frits Lekkerkerker Dutch Steering Committee on Orphan Drugs and Rare Diseases

Dr Kerstin Westermark COMP & Medicinal Products Agency, Sweden

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