

DRIVE

DIABETES-REVERSING IMPLANTS
FOR ENHANCED VIABILITY AND LONG-TERM EFFICACY



Patient Panel

6-8pm, Thursday 28th July 2016

**Royal College of Surgeons in Ireland,
St Stephen's Green, Dublin 2**

Report

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Executive Summary

The DRIVE Patient Panel was held in the Royal College of Surgeons in Ireland in Dublin on July 28th 2016. 16 diabetes patients or parents/spouses of diabetes patients discussed the potential risks, benefits and challenges and opportunities for DRIVE's β -System diabetes reversing implant technology with scientific and medical experts from the DRIVE Consortium. The outcome was positive as a number of potentially important considerations for the design, development, production, marketing and clinical application of the implant were identified through discussion with the diabetes patients. Patient comments, opinion and suggestions for improvement to the technology are summarised in this report.

Introduction

In order to link DRIVE to society through science-society dialogues on chances, risks and ethical aspects of DRIVE, a Patient Panel was held at the Royal College of Surgeons in Ireland (RCSI) in Dublin, on July 28th 2016. The goal of DRIVE's Patient Panel was to engage in a two-way dialogue at eye level between scientists/medics and patients, in order to overcome the classical one-way communication with scientists/medics in the role of experts providing information and public in the role of lay-people receiving information. In these dialogues, participants were first introduced to the field of innovative research in islet transplantation for diabetes through expert presentations during the panel and a hearing with experts. With the support of an independent neutral facilitator, the participants in a second step discussed the benefits, risks and ethical/social aspects in the field. As a result, the patients "assessed" the work of DRIVE's scientists from their special point of view with relevance to societal insights and values and outlined recommendations for the project and other societal sectors such as politics and industry. In this dialogue, both scientists and non-scientists learned from each other. In addition, political, administrative and industrial bodies will benefit from the participants assessments as their judgments and associations point out the level of acceptability for decision makers.

Purpose

The main goal of a new therapy is to offer better quality of life and to prolong life for patients affected. However, in most cases, patients are not included in the development of such innovative therapies. The Patient Panel thus aimed to integrate patients in the early development of a new diabetes treatment through face to face discussion with the researchers. Participants were recruited by inviting interested attendees of a previously held [RCSI MyHealth public lecture](#) on the management of diabetes "[The Rise and Rise of Diabetes in Ireland](#)", followers of DRIVE's twitter and facebook accounts and through the Type 1 Diabetes Dublin Support Group. A wide variety of adult patients and parents of children with diabetes were involved, representing the spectrum of diabetes patient stakeholders in Ireland, but with a majority of Type 1 diabetes patients, reflecting the current focus of islet transplant therapy.

The Panel

The Patient Panel was composed of an "expert panel" made up of researchers from the DRIVE Consortium and RCSI and 16 "patient panellists" who attended out of the 36 who registered for the event. All patient panellists were diabetes patients or had a child/spouse with diabetes. The expert panel included an expert in clinical islet transplantation, consultants in diabetes and endocrinology, medical device design experts, tissue engineering and stem cell scientists, biomaterials experts, an expert in pharmacy practice and pharmacoeconomics and a diabetes educator and pump trainer with a background in psychology. Two of the expert panel also fell into the "patient panellist" category, providing a unique perspective. Patient panellists covered the spectrum of diabetes patients, with the majority being Type 1, but also 2 Type 2 patients and 2 parents of diabetes patients. The panellists ranged in age from young adults to the elderly and both genders were well represented. Their current management of their diabetes ranged from taking oral medication and diet alone (Type 2 patients) to insulin injections, to insulin pump users and those with the latest continuous glucose monitor (CGM)-linked insulin pumps.

The Panel Discussion

The Panel discussion was guided by an experienced facilitator of patient focus groups, Ms. Michelle Flood, RCSI Lecturer in Pharmacy Practice. The schedule of the tasks given is set out in Table 1. The panellists were split into four discussion groups, each group containing 2 members of the expert panel. The groups then carried out the tasks together, discussing the main points that came up. The panellists' remarks were noted during each task.

Table 1: Schedule of tasks for Patient Panel discussion

Time	Task	Explanation/Rationale
6.00pm-6.05pm (5 mins)	Introduction to Session	Welcome participants and provide an overview of the session
6.05pm-6.20pm (15 mins)	Introductory Activity 'Empathy Map' Task	-Participants will work together in groups to try and explain what is important to them about their treatment (or the treatment of their child, spouse etc.) using a template (Important to get patients involved from the start, speaking to each other and considering practical issues related to core themes to facilitate more interaction/focussed discussions later)
6.20pm-6.35pm (15 mins)	Overview of current islet transplant procedure (P. Johnson – clinical islet transplantation expert)	-Ideally focus on the core patient-relevant aspects of the current islet transplant therapy -Patients to fill in a template in workbook to encourage them to actively engage with the talk
6.35pm-6.45pm (10 mins)	Overview of DRIVE diabetes reversing implant technology (G. Duffy – stem cell and biomaterials scientist and DRIVE Coordinator)	-Ideally focus on the core patient-relevant aspects of the proposed DRIVE implant technology -Patients to fill in a template in workbook to encourage them to actively engage with the talk
6.45pm-7.00pm (10 mins group & 5 mins reporting back)	Groups complete flip-chart table to aggregate their notes from the workbook and prioritise them	-Getting participants to work together and generate an affinity map based on their individual ideas helps identify clusters of ideas or common themes -Divergent perspectives relevant to smaller patient groups can also be identified
7.00pm-7.15pm (15 mins)	Theme 1: Adoption	Structured discussion of the themes relating to these areas, facilitated by the experts
7.15pm-7.30pm (15 mins)	Theme 2: Practicalities	
7.30pm-7.45pm (15 mins)	Theme 3: Concerns	
7.45pm-7.55pm (10 mins)	Feedback from Groups	Feedback on main themes arising
7.55pm-8.00pm (5 mins)	Concluding Task/Remarks	Final Task: 'If you could change one thing about the technology'

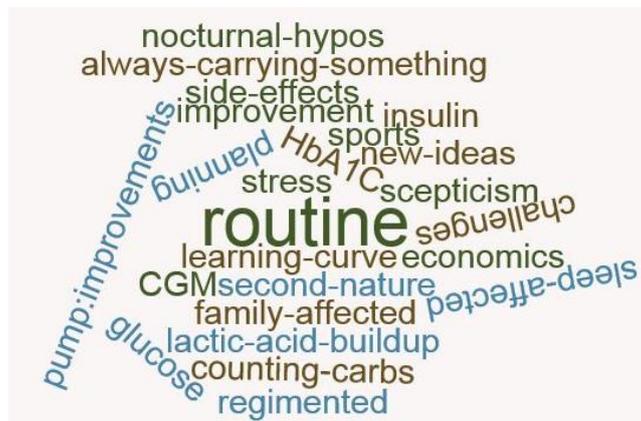
Task 1: Empathy Map

Panellists were asked to answer three questions designed to introduce them to each other and build empathy within the groups. Their answers are represented as word clouds below.

1. Who is in your group?



2. How do current treatments affect your day to day life?



3. What would an ideal treatment be like?



Task 2: Affinity Map

Following the introductory discussion, the panellists were given 2 short presentations. The first was by DRIVE's clinical islet transplant expert Prof Paul Johnson on the current clinical islet transplant procedure, focusing on the patient experience in terms of preparation, the transplant procedure itself and the follow up treatments and effect on patient life. The second presentation by DRIVE coordinator Dr Garry Duffy was an introduction to DRIVE's biomaterial implant technology (the β -System). Again the presentation focused on what it would be like for the patient to receive this implant, which is designed to enhance islet transplantation by maximising islet survival and function and make this therapy available to a wider population of diabetes patients through the removal of the need for systemic immune suppressive drugs, which have negative side effects.

Patients were tasked to record their answers to the following questions individually during the talks and then after a discussion within their groups, decide on the most pertinent answers/discussion points to each question. Below is a summary of the most pertinent points from the group discussions.

1. What sounds positive or exciting to you about DRIVE's β -System treatment?

- Possibility to be insulin free/independent
- Benefits outweigh the risks
- Better immune drugs
- Not a major operation
- Possibility to get your life back
- Normality
- No hypos
- Non-invasive procedure
- No self-monitoring blood glucose

2. What sounds most worrying or concerning to you?

- Need for immunosuppression
- Current availability of the therapy and strict inclusion criteria
- A reaction to the implant
- How well controlled are the anti-rejection drugs?
- Do anti-rejection drugs make other transplants more difficult?
- Risk of anti-rejection drugs causing cancer
- What about pregnancy?
- Lack of details available currently
- Effects on fertility

3. What impact could these treatments have on you/your child/spouse's life and why?

- Personal decision regarding risks
- Why is the treatment currently only for the brittle diabetics – why can't I choose?
- Do we have proof that uncontrolled diabetes is less/more dangerous than taking immunosuppression?
- Improved quality of life
- Freedom to have a more normal life
- Impact on parent's concern
- Increased career options
- Increased life assurance costs
- Increased health insurance costs

Task 3: Barriers to adoption

This task was designed to get patients opinions on the potential barriers to uptake of the DRIVE β -System implant. In the first part, patients were asked to identify things that would hold back the uptake of the implant. These were discussed under 3 main categories: adoption, practicalities and concerns.

Once the barriers were identified, the group discussion then turned to ways to overcome the barriers.

Barrier	Strategies to overcome barriers
Adoption	
Access	Cost savings to the state – avoid drug costs
Accident – who tells ER doctor about implant?	
Costs	Government support/insurance cover
Risk of new treatment – not tested	Full clinical trial before approval
Risk of trauma to the implant - sport	Robust implant/deeper site of implantation
Visibility of the implant	Deeper implant
Lifespan of device	Refillable device
Practicalities	
Time off work for surgery/recovery	Establish timelines for recovery beforehand
Airport scanner	Letter from doctor
Invasiveness of surgery	Minimally invasive devices/surgeon skill
Potential for fibrosis	Thorough testing of biomaterials
Growth of child – impact on effectiveness	Modular devices – different sizes
Supply of islets	Stem cell sources of islets
Limitation on playing sports	Robust device/deep implant
Concerns	
Interfere with blood flow, body function	Accurate placement of device
Long term biocompatibility	Proven long-term biocompatible materials
Will I get too old to have the implant	Strict criteria for implant
Increased risk of implant with age	Ability to monitor implant function
What if it stops working?	Ability to refill without surgery
What if it bursts?	Durable implant, biocompatible materials
Pregnancy - how will the implant affect	Site of implant important

Task 4: Change one thing

Finally panellists were asked what one thing they would change about the DRIVE β -System implant, irrespective of practicalities. Below are the responses.

- Make it available quickly
- Keep going with the research to get there sooner rather than later
- Use stem cells from the patient to produce α and β cells for the implant
- Make it so you can't feel the implant
- Universal access for all patients with diabetes who choose to have the treatment
- Make sure it is covered by health insurance
- Get rid of immunosuppression – a barrier to adoption
- Make sure it is replaceable (for children) and refillable (adults) to ensure good life span
- Make sure it is impact proof and won't burst by choosing a deep implant site
- Ensure a minimal impact on lifestyle

Conclusions

The overall opinion from patients on DRIVE's research was excitement and optimism. It was felt that although there are barriers to be overcome, the DRIVE project is on the right track. This feedback from patients will be extremely valuable in guiding the design, development, production, marketing and clinical application of DRIVE's diabetes reversing " β -System" implant technology.

Thanks

The DRIVE Consortium would like to extend a heartfelt thanks to the patients who gave up their time to participate in the Patient Panel. We would also like to thank the invited expert panellists and the facilitators from RCSI, especially Michelle Flood, for her excellent running of the Patient Panel.