Patient Engagement and Research Ethics

(Lidewij) Eva Vat
Agenda

• Strategy for Patient Oriented Research (SPOR)
• Patient Engagement
• Ethics - (Inter)national context
• Ethics - Newfoundland and Labrador
Strategy for Patient-Oriented Research (SPOR):

• A nationwide initiative led by The Canadian Institutes for Health Research (CIHR).
• Focused on improving outcomes for users of Canada's healthcare system
• Aims to create a research culture oriented around achieving real-world impacts for patients and their families
Core elements of SPOR

- Support for People and Patient-Oriented Research and Trials (SUPPORT) Units
- SPOR Networks
- Capacity development
- Improving the clinical trials environment
- Patient engagement
Support for People and Patient-Oriented Research and Trials

- Jurisdictional (Provinces, Territories) Units
- Creating resources necessary to support and grow and sustain patient-oriented research within each province
- Priorities are identified through consulting patients in that region.
Each SUPPORT Unit is built upon the same core functions.
NL SUPPORT

-Opened Nov. 2014
-A collaboration between:
  - IBM
  - Memorial University
  - Provincial Government (DHCS, BTCRD, RDC)
  - NLCHI
  - Federal Government (ACOA, CIHR)
  - Other jurisdictional agencies with a stake in patient-oriented research
-Located in the Craig L. Dobbin Research Centre
The requirements for support are:
• Research must be patient-oriented
• Research must include a focus on NL
• Research should address provincial priorities decided between NL SUPPORT and the community
**NL SUPPORT - Funding opportunities**

- **Patient Oriented Research grant** $75,000 (EOI Nov 15th)

- **Health professional grant** $10,000 Rolling program (deadline March 2018)

- **Education funding**, masters and PhD, Spring and Fall

- **Patient Oriented Research grant** $75,000 Indigenous communities (EOI, spring 2017 closed)
FREE education opportunities:
• Monthly webinars
• Face-to-face workshops
• On request sessions

Keep an eye on our newsletter/blog
http://nlsupport.eventbrite.ca (sign up page)

University course in Patient and Public Engagement
(launched fall 2017)
What is Patient-Oriented Research?

Research that:
1. focuses on **patient-identified** priorities
2. **engages** patients as partners
3. improves patient **outcomes**

*Putting patients first!*
Key concept: patients as partners

Us as partners vs us as subjects

Working together

Studying the subject

Reference: Patients Canada: Alies Maybee, SPOR Team Lead, Brian Clark, Annette McKinnon, Emily Nicholas Angl. ‘Partnering with citizens in research’ Jan 2017
### Spectrum of Engagement in Health Research

#### Levels of Patient & Researcher Engagement

<table>
<thead>
<tr>
<th>Patient’s Goal</th>
<th>Learn/Inform</th>
<th>Consult</th>
<th>Involve</th>
<th>Collaborate</th>
<th>Empower/Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Promise to the Patient</strong></td>
<td>To suggest ideas/opinions informally. To learn all I can.</td>
<td>To more formally provide opinion/feedback.</td>
<td>To work directly &amp; honestly with research team.</td>
<td>To partner on equal footing with researchers in all aspects of research.</td>
<td>To make decisions &amp; lead research activities.</td>
</tr>
<tr>
<td>“We will respect you, hear you, &amp; keep you informed.”</td>
<td>“We will value you &amp; seek your input.”</td>
<td>“We will work directly with you.”</td>
<td>“We will partner equally with you.”</td>
<td>“We will follow your lead &amp; support your decisions.”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How can this be done?</th>
<th>Learn/Inform</th>
<th>Consult</th>
<th>Involve</th>
<th>Collaborate</th>
<th>Empower/Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>In an open atmosphere for sharing ideas/suggestion/knowledge.</td>
<td>Priority-setting, cafes focus groups, working groups.</td>
<td>Working groups, cafes, health panels.</td>
<td>Patients as co-investigators &amp; as members of Research Advisory Committees.</td>
<td>Patient Advisory Committees/ Patients as principle investigators.</td>
<td></td>
</tr>
</tbody>
</table>

SPOR Patient Engagement Framework

Engaging patients across the continuum of research

Priority Setting
Governance
Conduct of research
Knowledge translation

“The international experience with engaging citizens and patients in research has shown that involving them early in the design of studies, ideally as early as at the planning stage, leads to better results.” (2012)

SPOR Patient Engagement Framework

GUIDING PRINCIPLES

- Inclusiveness
- Support
- Mutual Respect
- Co-building

VISION

Patients are active partners in health research that will lead to improved health outcomes and an enhanced health care system.

Core areas for action:

- Governance and decision-making
- Capacity-building
- Tools
- Resources

Public involvement in research: impact on ethical aspects of research

- Making research more relevant
- Helping to define what is ethically acceptable
- Improving the process of informed consent
- Improving the experience of participating in research
- Dissemination of research results to both the participants and the wider public

Is ethics approval required for patient engagement in health research?
INOLVE (UK)

- Statement on patient and public involvement in research and research ethics committee review (2009)
- Resource document: examples of the impact of public involvement in the ethical design and conduct of research (2014)

Patient-Centred Outcomes Research Institute (PCORI) (US):

- Eager to develop a white paper on the ethics of patient engagement in research

UK: Public involvement is part of the application form for ethics approval

CIHR Ethics Policy Project

Objective: to develop an ethics guide for researchers, patients and REBs when patients are co-partners in research.

Origin: The Working Group on Patient Engagement of the SPOR SUPPORT Units identified an emerging need to complement the SPOR Framework and TCPS 2 with ethics guidance on patient engagement in research, including active examples.

• You do not need to apply for ethics approval to engage patients as partners in research.

• In reviewing an application the Research Ethics Board (REB) will need to address any ethical issues that may arise from patients being involved in conducting and managing the research.

• When you submit an application for ethics review for your research, you should fully describe how patients contributed or will be engaged.
How do I record patient engagement in an application?

- Project team information
- Conflict of interest
- Appreciation
- Dissemination
- Confidentiality
- Required information

What might be ethical issues related to patient engagement in health research?
Ethical considerations

**Project Origin: Issues identified by SPOR SUPPORT Units**

- Undue pressure on patients to participate
- Power imbalances
- Barriers to patient contribution and compensation
- Inadequate time and training provided to patients
- Lack of protection of personal information in sharing of research findings
- Inequitable sharing of benefits
- Respect for communication patterns favoured by patients
- Lack of involvement by REBs

Ethical considerations across the research lifecycle

Reference: INVOLVE: Briefing notes for researchers, February 2012
http://www.invo.org.uk/posttypepublication/involve-briefing-notes-for-researchers/
NL SUPPORT  www.nlsupport.ca
CIHR  http://www.cihr-irsc.gc.ca/e/41204.html

• Follow us on Facebook and Twitter
  • NL SUPPORT Twitter and Facebook

• Sign up for our newsletter
  • https://medium.com/support-letters
Contact

Eva Vat, Training and Patient Engagement lead
- eva.vat@med.mun.ca

Dr. Brendan Barrett, SUPPORT Lead
- bbarrett@mun.ca

Catherine Street, SUPPORT Director
- catherine.street@med.mun.ca