Patient-Generated Data for SPOR Research Projects - *September 10, 2018*

Notes and Next Steps

A meeting was held on September 10, 2018 at Women's College Hospital, which brought together 38 patients, caregivers, researchers, developers, and policymakers to discuss the priorities and principles for patient-generated data in Ontario. BeACCoN has committed to supporting Ontario SPOR projects to develop, test and adapt patient-generated data collection methods and explore strategies to link patient-generated data with other data (primary and community care, hospital and administrative data). As a first step, this workshop was held to better understand project requirements around patient-generated data and how BeACCoN can best support SPOR researchers.

Objectives for the day

After introductions and a welcome, BeACCoN defined the objectives of the day – which were to:

- Understand the priorities for patient-generated data from key stakeholders:
    - Patients
    - Policymakers
    - Researchers
    - Developers
- Understand the principles for patient-generated data from stakeholders
- Begin to map priorities and principles for patient-generated data initiative in Ontario
- Agree next steps and way forward

Context

BeACCoN began considering this initiative earlier in the year when creating a strategic vision for the next two years. BeACCoN provided attendees with the background context of the project.

- BeACCoN Advisory Committee was held on May 2nd, 2018
- BeACCoN proposed a project looking at patient-generated data to:
    - Continue to work on review of outcome and experience measures that have been reported by patients and caregivers
    - Engage patients and caregivers in a process to better understand what they want to report and how it should be used
    - Develop a strategy to guide the rapidly evolving opportunities to develop and use these data

Earlier in 2018, the Canadian Institutes of Health Research (CIHR) released a funding opportunity to create a SPOR National Data Platform. Patient-generated data is central to the success of SPOR. BeACCoN was part of the RAPID-HC grant proposal that was submitted in partnership with many sites across the country. The RAPID-HC proposal that was submitted to CIHR will include and link administrative data, EMR data, and patient-generated data. RAPID-HC will create a national portal where data can be stored, linked and accessed. The proposal included that a Patient-Generated Data Centre (PGDC) be based in Toronto and it would act as a national resource for SPOR research that will focus on principles and priorities and that will bring together SPOR researchers, patients, and developers.

Patient Generated Data Project Overview

After the BeACCoN Advisory Committee and the RAPID-HC proposal was submitted, a project was presented that would include four main phases:

Phase 1: Establishing the Framework	Phase 2: Establishing the Principles	Phase 3: Establishing the Value	Phase 4: Defining the Future
- Engage with patients and caregivers on **principles and co-design** - Work together to develop **shared standards and approaches** - Help ensure the development and testing of **tools** is **consistent with principles**	- Engage with patients and caregiver partners on: **what data should be collected, who should collect it, how it should be collected, who should have access to it and how they should be informed** - Understand key data topics including **consent, privacy, and data governance**	- **Partner with SPOR projects** to develop, test and adapt patient-generated data collection methods actively involve patients and caregivers in co-design - **Explore strategies to link patient-generated data with other data** (primary and community care, hospital and administrative data)	- **Increase scope of patient-generated data to include other forms of data:** images, sensors, biological samples, etc. - **Work with new developers** using metabolomics or genomic data - Expand the scale of data collection by **partnering with other research projects and providers**

Principles and Priorities for Patient-Generated Data

During the workshop, each stakeholder group presented their priorities, challenges, and principles regarding patient-generated data. *Please see attached slide deck for detailed presentations*.

Feedback from Breakout Groups

After the presentations, breakout groups were held by stakeholder type (i.e. patients, policymakers, researchers, and developers). Each group was asked to consider what their key principles, priorities, and challenges are. Each group had time to discuss together and then reported back to the larger group their top selections in each category.

Patients

Principles

Top four principles:

- ***Patients as Expert Partners***
    - Patient do not want to only be advisors – they want to be co-designers and involved in every aspect (i.e. security, design, collection, etc.)

- ***Permission Based Use of Data***
- ***Access to Our Data***
  - The data has to be easily accessible
  - This means having the space to access it, any machinery that is necessary (i.e. laptop) and Wi-Fi if necessary
- ***Trust***
  - When trust is broken it is a very big deal
  - This goes to the design – how do we trust who is looking at our data without an audit trail?
  - They should be built with audit trails – this is whether or not you choose to look at it – but if you want to be able to see it and go through it then it is there and you have that option

Other important principles:

- Transparency
  - Need to be able to see who is looking at it, who is using it, and why?
- Integrity
- Respect
- Purposeful Data Collection
  - Sometimes the data is looked at through such a narrow lens that so much data that was collected is not used in the end (even if the collection is for the user)
  - This comes back to the intent of the data collection
- Permission-Based Use of Data
  - Touches on privacy – coming back to the data owner giving permission
  - Operationalized as a consent and privacy
- When trying to narrow these principles down patients decided that respect ties in to many of the overarching principles (i.e. patients as partners, permission-based use, and purposeful data collection)

Priorities (i.e. What Data?)

- Data that we trust
  - For example, do not always trust the data that is included in EMRs
- Patient reported data from patient co-designed sources
  - Many times the tools, surveys, etc. that collect data from patients did not have patients involved in the process of designing it and therefore patients do not necessarily trust these tools, and in turn, the data that they collect
  - May lead to answering questions that are irrelevant to patients

Challenges

- Consent
  - Is very complex
  - Has many of its own sets of issues and challenges

- Governance – with patient partners involvement
    - How we use it? Who gets access to it?
    - This is part of the process that really requires true patient-engagement
    - Who gets to decide what is being collected? Who gets to decide who gets to see it?
    - This also relates to penalties, fines, etc. if it is misused
    - Patients want legislation and regulation around this misuse of data so that there are consequences if people use their data improperly
- Access
    - Utility of data – it is not enough to only provide the data but to provide it in a way that people can actually use it and easily access it
    - Cannot be something that is too opaque to understand, access, or use
    - It is about actually gaining access to the records and then the ease of being able to do that
- Data Residency
    - Again this comes back to the utility of data – if provided with something that is too opaque or difficult to understand or access it is no longer useful
- Protection from Harm

<u>Policymakers</u>

Principles

- One point of collection from multiple uses
    - Single survey in home and community care
- Transparency
    - Understanding what data is collected for what reason
- Patients as Data Custodians

Priorities (i.e. What Data?)

- Open data access
    - Single point of access
- Use for greater good
- Standardization
    - Are there ways for us to come to consensus on how/why we collected data

Challenges

- Understanding what data we already collect, how is it used
- Data linkage for health use but also for social determinants of health
    - Ministries struggle to link their data even for planning
    - Time and capacity to dig into all this data that we collect – how do we align resources to do this work?
- Data in real-time and available
- Idea of creating a Patient Data Stewardship Council

    - Panel of patients/public who would help inform government and others (ie. the data privacy commissioner), on their expectations around data
    - Creating a legitimate and transparent forum for questions of data to be determined (ownership, reporting, etc)

Researchers

Principles

- Stewardship
    - Transparency (collected by who, how and privacy and security measures)
        - Why the data is being collected, how it is being used and who has access to it (informed consent), who is collecting it and where it is going
        - Will the data be sold?
    - Especially important for Indigenous communities
    - Accidental release would be a very big issue
- Patient Centeredness
    - Improve patient and family care at the centre, this is dependent on patient engagement
    - Need to focus on how this is going to help the patient and inform their care
    - Most data is not collected in this way, that is just an incidental output
    - Make an explicit focus on reducing health inequities – this term is flexible – it is not just about it being fed back to patients but also fed into the care team
    - Patient-engagement within this – how and to what level?
    - Patient centeredness defined by their engagement – feedback loop
- Utility
    - Must serve a meaningful purpose that has been articulated

Priorities (i.e. What Data?)

- Linkage to other type of data
    - It needs a national scope – not just Ontario
    - Linking beyond PREMs and PROMs, to other data to make it valuable – across sectors and jurisdictions
        - i.e. linking in geotracking and other types of data
- Social justice
    - Already an existing digital divide and we need to address this and not add to it – stratifying based on complex needs – need to help those who will most benefit
    - The priority should focus on those who are the worst off – who are the people who just are not engaging in the health care system – start with acknowledging that we may be contributing to this divide
- Collecting and using this data
    - How to do both

Challenges

- Specificity and temporality of consent
- Patient voice – in analysis and dissemination

- Using data in real-time for improvement and research

Developers

Principles and Priorities

- Types of data: generated data and third party data
    - Patient-generated data includes passive data from personal health devices (e.g. from wearables), and active (e.g. from surveys)
    - There could also be a third category of caregiver-generated data (e.g. surveys completed by caregivers)
- Ownership
    - Patients owning the data and designating access to their own data
    - Would need developers and procurement to give access to share this data
- Access
    - Patients should have reasonably easy access to their data (with reasonable cost)
    - If patients could more easily access their data, it would be easier to explicitly ask for and get consent to use their data
- Ability to Share
    - Patients should be able to decide how their data is used and designate access
    - It should be easier for them to share their data with both researchers and clinicians
- Transparency
    - Patients should know how their data is being used and who it is being used by
    - Ideally, patients would be able to see the uses of their data listed the way transactions on your bank accounts are listed
- Data portability and moving away from custodian mindset
- Create a business model for developers that puts a value on having data that can be shared
    - A key facture for success in competitive market for venture capital to support developers is access to data that is collected through the application and making shared data an asset can increase value

Challenges

- Custodianship
    - The paternalistic system of protecting data makes it difficult to access
    - If data is collected for one purpose, it cannot be used for another
- Data portability
    - Inability to access and link patient data for both care and research
- Developing a new business model that values shared data
    - Currently value is often defined by control or ownership of data collected through the application and in order for the data to be shared there is the need to develop a model where a value can be placed on sharing data
- Cost of access
    - Many vendors' business models are built on holding/owning data, and so the costs of accessing data are very high
- Scale
    - A lot of investment is made in start-ups and there is less support to scale

    - Developers want to service large groups

- Consent
    - Particularly difficult where AI is involved because the intention is discovery instead of asking specific questions
    - We can't be sure how the data will be used
- Patients need to be given something in return for sharing their data
    - The data they provide to researchers should benefit their health and be passed onto other clinicians
    - There is a belief that patients will be willing to provide data if it supports the patient-provider relationship

Discussion

Network and Collaboration

- Consider a social network analysis to see who else in the system is collected data and where it is collected
    - Ross Upshur doing work looking at ethics of data
    - HQO patient engagement group
    - Maria Santana in Calgary – looking at national priorities for patient centeredness
- Inventory/Map of what is being done in Ontario
    - Determining who needs to be at the table, as well as what data is currently being generated
- Many of the funded SPOR projects are covering similar territory and running into similar challenges – they should be approached to discuss their experiences together
- Collective impact (being used by SPOR) can inform our governance of this groups
    - Organizations that build networks with a backbone to help agree on a vision, priorities, shared measurement, and promote communication and collaboration
    - Bringing everyone to work together in the same ways
- Gaps in care related to everyone working in different ways but we need to lead the charge around this work, it is not going to be ministries, it is going to be patients and providers
- Canada has very few registries when compared to other countries (i.e. Sweden)
- Registries allow for intervention at the local level and population level
- Sweden is the size of Ontario – need to engage with the Ministry and the LHINs to make something like this happen

Consent

- May need to educate patients on where else data is being collected about them (i.e. municipalities)
- Important to build trust, privacy and consent, and data standards since this is an emerging industry
- There is a path dependence – the decisions we make now will influence how this data is used going forward
    - Consent and trust are big issues here
- Idea of using the banking model
    - Put it somewhere safe, but can take it out when you want

  - You own it – you tell what can be done with it
- We also need to view this as a customer ehealth perspective – can patients see the data that is collected about them?
- Legal jurisdictions will need to be considered – the data moves globally and will need to consider this movement of data
- Need to focus on consent in principle and practically (how will it be done)
- Mapping out custodianship of the data
  - But important to look at limitations of each data set for when we are ready to use the data
- Flip the consent model on its head
  - Current legislation does not talk about patient ownership of data
- PHIPA is working on looking at this type of language
  - Trying to figure out the challenges and what PHIPA can do to help groups
  - Need broad, but robust, rules that engage and protect patients

Patient Engagement – Using data not just for research but for quality and care

- Clients and caregivers will need to be engaging around both their care and their data
- There is work underway that is looking at the impact that the patient engagement movement has had on ministry policy/program design and all the way down to the provider care level
- There needs to be a way to incorporate the patient perspectives at point of care in real-time. There cannot be data that is generated only for researchers and not for on the ground clinical level of care.
- Need to set-up principles for co-design in this space
- It needs to be about giving value back to the patients
- Patients need something tangible in return
  - For example, when administering surveys etc. they need to know why they are filling it out
- Often it is too late when patients get on the teams once the grant has been approved – they need to be engaged before as well, while being mindful of how much they are willing and able to contribute (i.e. they may be ill and need to mindful of that)
- Patient voice needs to be retained in analysis and dissemination
- Patient Advisory Committee may be useful – often it becomes that researchers work directly with the physicians and sometimes it is separate – need to be careful of unintended hierarchy
- Suggestion to look to the HIV community who has been good at building capacity for patients

Linking of Data

- There will be a need to link the data sets with social services and municipalities
- Issues are also cost and waste
  - There is a lot of data out there but it needs to be linked across sectors and municipalities so that there is no duplication of efforts
- There is a need to integrate social determinants of health (SDOH) and bring that scale to this work (this also includes social isolation data)
  - Some people have collected this data but it is difficult to integrate – need to work on some of the system issues of integrating this type of data
- How can the data be used to improve care in real time

- Data sources need to be able to talk to each other – i.e. in diabetes, checking eyes but also feet
- Ministries need to share their data across ministries (i.e. education with health)
- We need to work on building the capacity of providers and health organizations to use this data
    - The front line providers (or even those higher up) cannot use this data
    - Our ability to collect data is outstripping our ability to use it
- No organization should embark on data collection without the capacity to use it right now
    - We need to assess: what is your ability to use it right now? How are you going to use it?
    - Patients and community can be a part of this – the concept of "nothing about us without us" from the HIV community
- If we create a data repository that has implications – such as, will need to consider what level of specificity we are asking patients for their data to be used
- These challenges have been met with trust that there are positive use cases with government
- Trust is complicated by the linkage
    - There is data that is already being collected that no one has access to
    - For example, health insurance and insurers – they collect info to improve their work

New Technology

- It is inevitable that this will relate to AI and machine learning
- We need a better understanding of the predictive lens – AI and machine learning to understand the "so what?" of the data collection

Next Steps:

- BeACCoN to facilitate subgroup of SPOR researchers to stay connected on common issues and challenges
- BeACCoN to work with Patient Advisors Network (PAN) to determine which priorities need to be addressed when re-working PHIPA

Appendix A: List of Attendees

Geoff Anderson, BeACCoN

Onil Bhattacharyya, BeACCoN

Ivy Wong, BeACCoN

Julie Dunning, BeACCoN

Dara Gordon, Women's College Hospital Institute for Health System Solutions and Virtual Care (WIHV)

Miin Alikhan, Toronto Central LHIN

Bernadee Koh-Bilodeau, Health Quality Ontario

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Carolyn Steele Gray, Bridgepoint Collaboratory

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Trevor Jamieson, St. Michael's Hospital

Andrew Pinto, St. Michael's Hospital

Aashka Bhatt, Diabetes Action Canada (DAC)

Conrad Pow, DAC

Annette McKinnon, PAN

Emily Seto, IHPME - University of Toronto

Glynnis Burton, Toronto Central LHIN

Melissa Chang, UHN Connected Care

Cathy Whiteside, DAC

Kathryn Fisher, McMaster University

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Karen Okrainec, St. Michael's Hospital

Shannon Weir-Seeley, CIHI

Ena Ujic, WIHV

Barb Guiao, Ministry of Health and Long-Term Care (MOHLTC)

Amy Olmstead, MOHLTC

Katie Tucker, Graduate Student

John Semple, Women's College Hospital

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Kate Keefe, OTN

Ron Beleno, Caregiver

Joe Cafazzo, Centre for Global eHealth Innovation

Julia Roy, QoC Health

Aryn Gatto, QoC Health

Anne Hayes, MOHLTC

Gillian Booth, St. Michael's Hospital

Eddy Nason, Ontario SPOR Support Unit (OSSU)