**Patient-Generated Data 2.0 Workshop – Informing an Approach for Ontario**

 ***April 15, 2019***

**Notes and Next Steps**

This meeting brought together about 35 patients, researchers, developers, and policymakers to discuss the patient-generated data (PGD) initiative in Ontario (Appendix A). This is the follow-up to a workshop about patient-generated data in September 2018 hosted by Better Access and Care for Complex Needs (BeACCoN) and the Patient Advisors Network (PAN), which highlighted priorities and challenges around PGD.

In January 2019, BeACCoN contracted PAN to create a framework and principles for patient-generated data. PAN is a Canadian, federally incorporated, not-for-profit group. They are made of a community of people who have received health services or cared for those who have, and who are committed to improving health care as advisors for the good of all across Canada.

BeACCoN and PAN co-hosted a workshop in order to determine which principles and standards of patient-generated data resonate with key stakeholders and how they could help support and inform an initiative in Ontario.

**Objectives for the day**

* Explore models of patient-generated data that could inform an approach in Ontario
* Look at the current state of patient-generated data in greater detail, including
	+ The types of PGD being collected, how it’s being collected, and for what purpose
	+ The benefits, opportunities, and challenges of PGD use
	+ Governance structures
	+ The patient engagement process
* Discuss a draft framework and principles for patient-generated data

**Context**

In September 2018, BeACCoN held a workshop attended by patients, policymakers, researchers, and developers to discuss the priorities, and challenges that important stakeholders have regarding patient-generated data. Please find the report from our first PGD workshop on the BeACCoN website, [here](https://docs.wixstatic.com/ugd/6ac9da_5f5c591fa5f9404994aa00493553c5ae.pdf).

Common priorities among the stakeholders included:

* **Streamlining access** to data – data sharing agreements, REBs, dual use considerations; portability of the data
* **Data linkages**-- integration with electronic medical records, linking across data sets
* **Creation of standards** -- standards around data sets; national to support cross-jurisdictional initiatives
* **Updating privacy and ethics regulations** – modernize to include PGD and streamline
* **Developing value models** – needed to support private sector innovation and ensure new types of data capture

Challenges noted by the stakeholders included:

* **Consent** – developing consent structures
* **Governance** – including patients in data governance
* **Awareness** – understanding what is out there
* **Partnering with patients** – recruiting, onboarding, roles
* **Real-time data** – access to real-time data
* **Costs** – cost of data access; cost and access to resources to manage and use PGD

The Patient-Generated Data 2.0 Workshop engage the same types of stakeholders to provide an overview of how their organization and/or projects use PGD, and to provide feedback on a draft list of principles for PGD.

Our initiative is aligned with the provincial government’s goals in improving the patient and caregiver experience and achieving better patient and population health outcomes. We envision that patient generated data will play a large role in the near future in the provincial government’s vision to transform the health system. In March 2019, the provincial government released the Patient Declaration of Values for Ontario, developed by the Minister’s Patient and Family Advisory Council (PFAC). Many of these values are directly applicable to the growing patient-generated data initiative in Ontario (Appendix B).

**An Overview of Patient-Generated Data**

During the workshop, Dr. Onil Bhattacharyya provided a brief overview of patient-generated data, including a definition for PGD, examples of what patients want, types of PGD collection tools, and the potential future of PGD use. *Slides are available on the BeACCoN website*,[*here*](https://docs.wixstatic.com/ugd/6ac9da_f5f0443c1c0f484daa42a6d6c2e5388d.pptx?dn=Overview%20of%20Patient-Generated%20Data.pptx).

BeACCoN presented the definition used by the US Office of the National Coordinator for Health Information Technology, defining patient-generated data as “*health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern*”.

**Current State of Patient-Generated Data**

After the overview, various attendees provided a brief presentation about the ways their organization use PGD as a part of their projects/programs. *Slides are available on the BeACCoN website*,[*here*](https://docs.wixstatic.com/ugd/6ac9da_4fcf1cb996a446158664735b2784cd98.pptx?dn=PGD%20Show%20and%20Tell.pptx).

**Draft Principles for PGD**

Upon completion of the attendee presentations, Alies Maybee presented draft principles for PGD.

**Group Discussion**

After the draft principles were presented, the participants engaged in a group discussion. All participants were asked to consider whether the principles presented resonated with them, whether there were any principles present that should not be there, and whether there were any principles that were missing.

**Principles**

Alies Maybee and Samira Chandani from PAN created a draft list of principles to be presented at the Patient-Generated Data 2.0 Workshop. They established six principles in total: access, transparency, consent, trust, purpose, and patient partnership. Each of these principles was followed by a detailed description (Appendix C).

Overall, there was a unanimous agreement that none of the proposed principles should be removed. The principles resonated with all participants and were determined to be appropriate. However, there were some discussion about each of the proposed principles except the last one, patient partnership, signifying that more details and clarity about the principles were needed. Additionally, some participants suggested the addition of a few more principles. More details on the discussion can be found below.

Access

Under the core principle of “access” in the draft list, PAN elaborated that “Patients as owners have a right to access their data”. There were suggestions that the word “custodian” be used instead of “owner”, as custodian has a greater legal connotation.

Furthermore, it may be beneficial to clearly define the terms being used and make a clear distinction between data and information. If, for example, a provider creates private notes about a patient, then that information should count as being under the provider’s custodianship.

Participants also wished to understand how “equity” could fit in. It is clear that there is a system where inequities in access exist (e.g. someone living on the streets who does not have access to a smartphone). If a list of principles for PGD are being established, then it would be beneficial to acknowledge equity.

Transparency

Related to the principle of “transparency”, some patient partners emphasized that there needs to be more public awareness about the facetsrelated to patient-generated data (e.g. frequently used terms and their definitions, concepts such as consent around PGD, data custodianship, etc). There is also a need to work on the education piece of patient-generated data so that important stakeholders, such as patients, could be duly informed and able to lend their voice to important discussions.

Consent

There was no argument that it would be necessary to have consent as a principle. However, the discussion around consent proved there were many things to consider. Of utmost importance was how to determine access and use patient-generated data for the public good, whilst still ensuring that patient-generated data is protected.

Consent preferences are likely to vary depending on the purpose that PGD is being used for. For example, individuals may be more willing to provide consent for PGD use in areas such as research, public health, and quality improvement. They may, however, be less likely to provide consent in a for-profit situation.

Also important to the situation is to clarify and/or determine whether an active or passive consent process is required. Should individuals be asked to consent for the use of PGD for every new situation? Or should they consent to sharing their data, then receive information about what their data is being used for, and be able to withdraw consent at if they do not want their data to be used for a particular purpose?

There was some confusion amongst participants about whether the principles being presented were for the current context or whether they could also be applicable for a future state. Under their consent principles, PAN stated that there should be a “permission based use of data”, signifying that patients would ultimately decide who has access to their data, for how long, and for what purpose. However, participants also pointed out that within their principles, PAN also stated that the data collected should be used for the “greater good”. Participants discussed how these two points potentially contradict one another – if PGD is automatically used for the greater good, then that may mean patients don’t get to decide who has access to their data and what they are using it for.

Trust

The principle of trust was split into two parts. First, patients need to trust the governance and security of their data. Second, patients need to trust the integrity of those who collect and use their data. While the group agreed that it is appropriate for the concept of trust to be split into two parts, it was suggested that the onus should be placed on the organizations rather than on patients. First, organizations need to become trustworthy. Second, organizations need to earn the trust of patients.

Purpose

There was an overall agreement that the collection of patient-generated data should have a meaningful use. Patients need to identify what meaningful use means to them and what they want their data to be collected and used for.

Some participants expressed the idea that meaningful use and access are related to one another. All individuals should be able to have access to their own data, as they are ultimately the “owners” or “custodians” of their information. They should be able to access this information regardless of where it comes from (i.e. patient information stored in two different hospitals) or what it’s being used for.

Furthermore, in order to have meaningful access to information, the data must be presented in a way that allows for meaningful use. For example, having PDFs containing large volumes of information would not be beneficial for anyone, and would essentially act as an obstacle towards meaningful access.

Suggestions of principles to add:

* **Portability** – ability to move data between systems
* **Utility / Meaningful use** – ability to understand the data to impact actions

**Standards Discussion**

Alies Maybee and Samira Chandani from PAN created a draft list of standards for PGD which was presented at the workshop. They established eleven standards in total and provided a brief description for each of them. They created eleven standards in total: involvement of patients/caregivers, alignment with Principles for PGD, clear governance structure for stewardship of PGD, clear purpose for using PGD, selection of PGD data in consultation with patient/caregiver partners, easy collection and use of PGD, co-design consent mechanisms in consultation with patient/caregiver partners, observe privacy laws for the appropriate jurisdictions, data stored and backed up in a Canadian jurisdiction, security measures in place and communicated clearly, and care providers to act proactively on PGD (Appendix D).

**Feedback from Breakout Groups on Draft Standards**

All attendees were given a handout detailing a draft list of proposed standards around patient-generated data. Participants were broken in six groups, composed of varying numbers of patients, researchers, developers, and policymakers. Groups were give 15 minutes to discuss the proposed standards together and then report back to the larger group.

There were mixed opinions about which standards should remain and which should be removed. There was ample discussions about each of the standards and several suggestions of standards that should be added to this list. Additionally, quite a few of the participants wondered whether these standards were definable. Some participants found them generic, as words such as “governance” and “involvement” can mean different things to different people. Participants agreed that there needed to be more clearly defined terms. Participants ultimately agreed that it would be best for PAN to stick to creating only principles for now. It would be difficult to develop universal standards as they are contextual. For more details, please see the discussion below.

Involvement of patients/caregivers

Overall, the group agreed that it was vital to have patients and caregivers involved throughout the process – whether that was being part of the data governance, being involved in research projects, at the policy level, or during the development of PGD collection tools and applications.

Clear governance structure for stewardship of PGD

While attendees from the workshop agreed with some of the points made under this standard, they further elaborated that a stewardship and governance accountability model should be tied to decision making. Furthermore, there was some agreement that there needed to be one accountable entity.

Participants also noted that there needs to be clarity on what a good process would look like. It would not be sufficient to simply hold a meeting and have a conversation about what kind of structure should be in place. There needs to be clear details and transparency about who is part of the governance structure and what each person’s responsibilities entail.

Clear purpose for using PGD

Participants believe that this standard will ultimately come down to risk vs. benefit. The risks that individuals may faceby consenting to have their data used could be offset by the benefit it brings to themselves and/or to others. Some patients at the workshop expressed that they would not be bothered if their data was used for different purposes than previously expressed and agreed upon as long as they received an alert about it. However, the group pointed out that each patient would have a different level of security that they’re willing to tolerate. Ultimately, there may need to be standardized categories for levels of risk, to enable people to choose their level of risk, and then tailor their options according to their chosen risk level. For example, one can opt in to have their PGD used for research, but opt out to have it used for quality improvement. However, there cannot be too many categories which could become overwhelming and possibly even alarming for some people. One group suggested that preferences should be listed in clusters of four or five, and that this risk level be chosen via consent forms. Ultimately, there was consensus that there cannot be too strict a purpose for the data. Otherwise, it would make it very difficult to make it available for future or other use.

Selection of PGD data in consultation with patient/caregiver partners

Participants pointed out that this standard was very similar to the first standard, “involvement of patients/caregivers” and should perhaps not be included as a separate standard. Instead, the description of the first standard could be elaborated to include this information.

Easy collection and use of PGD

Participants agreed that the focus should be on reducing patient burden and ensuring that the tools being used are proactive. The group also identified data overload as being a key challenge and believe it is crucial that users of PGD do not have an unwieldy amount of data to sift through. They require only the data that is useful and relevant for their purposes, and the tools and techniques that are used should reflect that.

Co-design consent mechanisms in consultation with patient/caregiver partners

While there was no disagreement that patient and caregiver partners should be involved in the co-design of consent mechanisms, it was emphasized that the co-design element should be practical and in tune with the patient/caregiver’s skillset and expertise. The patient and caregiver roles need to be clearly defined. Ultimately, however, participants had more to say about consent in particular, than the co-design process for consent mechanisms.

While there was no disagreement that there needs to be a consent framework, there was a lot of discussion, and no consensus of what that framework should entail. The consent framework could ask individuals for their patient-generated data immediately, in real time. However, providing consent could also mean that once their consent is given, a person’s data may be used later as well.

There was some consensus that a consent framework should be more open, instead of very rigorous, again returning to the idea of making patient-generated data available for the “greater good”. Participants agreed to keep the purpose of using patient-generated data localized in a few key areas, such as public health, care, quality, planning, and improvement.

Data stored and backed up in a Canadian jurisdiction

There was no consensus around this standard. While many participants believed that PGD should be stored and back up in a Canadian jurisdiction, just as many did not have any qualms about having data stored in other countries, such as the United States. As long as there are good privacy and security regulations in place, some participants felt it did not matter if the data was stored in another country.

Security measures in place and communicated clearly

Participants were in agreement that organizations should make it clear what kind of process they undergo and have in place,including what security measures they use. If this information differs between their projects, organizations need to make that clear. Based on what these processes are, patients may change their consent.

Suggestions of standards to add:

While attendees agreed overall with the standards that were presented at the workshop, there were also some themes discussed that did not fall in the categories listed above. Participants listed some additional standards that they believed should be added to the list:

* **De-identified data** – There was a lot of discussion that was generated around de-identified data and how that process would work. This included questions around what level data should be de-identified, and if all data is de-identified, does a consent form still need to be signed?
* **Reconciliation** – patients and users should be able to reconcile incorrect data or data that doesn’t reflect their experience
* **Consent for incapacitated individuals** – the consent process would have to be different for individuals who cannot consent themselves, but participants were unsure about how to begin to address this topic.
* **Data hub and education** – There needs to be an education component around these standards. Patients need to clearly understand who has their data, how it is stored, the laws and regulations that govern PGD use, and proper transparency of how this is all done.
* **Data quality –** Data must be complete and purposeful in order to be relevant to stakeholders and be used appropriately

**Next Steps:**

Our patient partners from PAN have reviewed and analyzed the discussions and materials from the patient-generated data workshops, as well as information generated from PAN discussions and PAN survey results. They have used the feedback they received from these sources to refine their principles for patient-generated data.

Based on the discussions from the April 15th workshop, in the short term PAN’s work will focus solely on creating robust principles for patient-generated data. Although the need for standards around patient-generated data is important, that work will be delayed as we work to focus on principles.

PAN will work on an updated version of the principles which will then be reviewed by workshop attendees and external stakeholders, and then iterated upon. PAN will then finalize their list of principles for PGD. *These will then be posted on the BeACCoN website and shared widely with stakeholders.*

As a final note, BeACCoN and PAN have decided to use the term “patient-generated health data” (PGHD) from now on, as it is the term most commonly used in the literature.

**Appendix A:** List of Attendees

Onil Bhattacharyya – Associate Professor, Department of Family and Community Medicine, University of

Toronto; Frigon Blau Chair in Family Medicine Research, Women’s College Hospital

Geoff Anderson – Research Lead, BeACCoN; Professor, Institute of Health Policy, Management and Evaluation, University of Toronto; Adjunct Scientist, Institute for Clinical Evaluative Sciences (ICES); Adjunct Scientist Women’s College Hospital Research Institute

Ivy Wong – Network Director, BeACCoN

Simone Shahid – Network Manager, BeACCoN; Research Assistant, WIHV

Alies Maybee – Patient Advisor, Patient Advisors Network (PAN)

Eddy Nason – Ontario SPOR Support Unit (OSSU)

Conrad Pow – Senior Project Manager, Diabetes Action Canada

Bernadee Koh-Bilodeau– Project Lead, Health System Performance, Health Quality Ontario

Payal Agarwal – Innovation fellow, Women’s College Hospital

Greg Webster – Director, Acute and Ambulatory Care Information Services, Canadian Institute for Health Information (CIHI)

Peter Andru – Manager, IM Service Relationships Unit, Ontario Ministry of Health and Long-Term Care (MOHLTC)

Amy Lang – Director, Patient, Caregiver and Public Engagement at Health Quality Ontario

Samantha Kearney – MOHLTC

Glynnis Burton – Consultant, Health Analytics and Innovation, Toronto Central Local Health Integration Network (TC LHIN)

Nathalie Sava – Senior Planner, Health Analytics and Innovation, TC LHIN

Melissa Chang – Director, Strategy & Change, University Health Network (UHN) Connected Care

Charles Goddard – Acting Senior PM, UHN Digital

Eric Sutherland – Executive Director, Data Governance Strategy, CIHI

Payam Pakravan – Vice President, Strategy and Analytics, Ontario Telemedicine Network (OTN)

Trevor Jamieson – Medical Director, IT Implementation and Innovation, St. Michael's Hospital; Lead, Virtual Care, WIHV

Tamar Frank – Senior Consultant, Advisory, KPMG LLP

Chelsea Colbert – Sidewalk Labs

Josh Williams – Senior Program Consultant, MOHLTC

Alexis Wise – Director of Health and Human Services, Sidewalk Labs

Carolyn Steele-Gray – Scientist, Bridgepoint Collaboratory in Research and Innovation, Lunenfeld-Tanenbaum Research Institute; Investigator, Health System Performance Research Network, University of Toronto.

Julia Roy – Chief operating Officer, QoC Health

Jay Shaw – Scientist**, WIHV, Women’s College Hospital;** AMS Phoenix Fellow in Ethics and Governance of Artificial Intelligence for Health; Assistant Professor, Institute of Health Policy, Management and Evaluation, University of Toronto

Emily Seto – Lead, Health Informatics, Institute of Health Policy, Management and Evaluation, University of Toronto; Research Scientist, Centre for Global eHealth Innovation, UHN

Kate Keefe – Director, Strategic Planning and Policy, OTN

Emre Yurga – Manager, Economic Analysis and Evaluation at Strategic Policy and Planning Division, MOHLTC

Joe Cafazzo – Executive Director, Healthcare Human Factors and Wolfond Chair in Digital Health, University Health Network; Associate Professor, University of Toronto

Kathryn Fisher – Assistant Professor; Statistical Analyst, Aging, Community and Health Research Unit, McMaster University

John Riley – Associate Director Ontario SPOR SUPPORT Unit (OSSU)

Catharine Whiteside – Executive Director, Diabetes Action Canada (DAC) – A SPOR Network in Diabetes and its Related Complications

Emily Nicolas Angl – Director of Health Engagement and Communications, Reframe Health Lab

Anne Hayes – Director of Research, Analysis, and Evaluation Branch, MOHLTC

Lorraine Lipscombe – Scientist, WRCI; Director, Division of Endocrinology, Department of Medicine; Staff Physician, Division of Endocrinology and Metabolism; Medical Co-Director, Endocrine Clinic, Women's College Hospital; Associate Professor, Division of Endocrinology and Metabolism, Department of Medicine; Associate Professor, Institute of Health Policy, Management and Evaluation, University of Toronto; Senior Adjunct Scientist, Institute for Clinical Evaluative Sciences (ICES)

**Appendix B**: Patient Declaration of Values for Ontario

Respect and Dignity

* We expect that our personal health information belongs to us, and that it remain private, respected and protected.

Accountability

* We expect a health care culture that values the experiences of patients, families and caregivers and incorporates this knowledge into policy, planning and decision-making.

Transparency

* We expect our health records will be accurate, complete, available and accessible across the provincial health system at our request.

**Appendix C: Draft Principles by PAN**

**Overview**

PAN has taken the work of the first Workshop Sep 10, 2018, and the survey of our community to refine the principles for working with PGD. The PAN survey confirmed the principles identified in the workshop and refined on them.

**Principles**

**Access**

* Patients as owners have a right to access their data
* Patient access can support self-management
* Patient and care provider access can support shared decision-making

**Transparency**

* Patients are informed who, how, what and why their data is being collected and used
* Patients receive follow-up information about the PGD work
* Public education about health data is needed to support the goal of transparency

**Consent**

* Permission-based use of data – patients decide who has access to their data, for how long and for what purpose
* Consent applies to both de-identified and identified data
* Consent to protect from harm eg: data becoming available to employers, insurance companies or government agencies providing supports
* Patients are reluctant to consent for profit-making purposes as opposed to the great good

**Trust**

* Patients trust the governance and security of their data
* Patients trust the purpose and integrity of those who collect and use their data

**Purpose**

* Data is collected and used for a purpose that patients agree with eg: personal care
* Data is collected and used for the greater good

**Patient Partnership**

* Patients are experts on their own data and as “owners” of the data should partner on PGD work
* Partnering with patients enriches the data and the work
* Patients need control over their data
* Patients may need training to be effective on PGD work

**Appendix D: Draft Standards by PAN**

## **Descriptions of Standards**

1. **Involvement of patients/caregivers**

The involvement of patients/caregivers becomes an essential part of every element of a) data governance and b) any PGD project whether research, policy, clinical collection and use, development of PGD collection tools/applications.

1. **Alignment with Principles for PGD**

Work on any PGD project including the development of tools and apps is done in alignment with the PGD principles (*see draft Principles Handout.*)

1. **Clear governance structure for stewardship of PGD**

The governance structures for healthcare organizations, academic and research institutions, research projects, government at all levels is clear, transparent, is understood by and involves appropriate stakeholders including patients/caregivers.

There is a governance structure at the highest level that works in coordination with the lower levels of governance. This is clearly understood by all including the public.

1. **Clear purpose for using PGD**

Any work using PGD has a clearly stated purpose that is known and agreed upon by all appropriate stakeholders including patients/caregivers. If the data will have more than one purpose, that is clear and known as well.

1. **Selection of PGD data in consultation with patient/caregiver partners**

For any PGD work, the data that will be collected and/or used is selected in consultation with patient/caregiver partners.

1. **Easy collection and use of PGD**

The tools and methods of collecting and using PGD are straightforward and easy to implement by all users. This includes ease of use and comprehension for users who enter data into collection tools like surveys, respond to phone interviews, or allow a device/app to collect data.

It also includes easy selection and reporting of the data for those users who plan to employ the data for their work.

1. **Co-design consent mechanisms in consultation with patient/caregiver partners**

An element of establishing trust requires appropriate levels of consent that are co-designed with patient/caregiver partners. The consent mechanism responds to patient/caregiver partners’ need for ease of use and understanding of the choices offered.

1. **Observe privacy laws for the appropriate jurisdictions**

The work clearly adheres to the Canadian, provincial and municipal privacy laws and regulations. This may mean a careful understanding of the implications of the laws in various jurisdictions to come up with a comprehensive privacy framework for the specific work.

The EU’s GDPR standard and the US PIPEDA and other nation’s laws can be factored in if the work involves international partners.

1. **Data stored and backed up in a Canadian jurisdiction**

Currently cloud applications store data in various places or jurisdictions. Canadian health data including PGD should be explicitly held, stored and backed up in a Canadian jurisdiction so that it is subject to Canadian laws and not the laws of other countries. This contributes to patient/caregiver trust.

1. **Security measures in place and communicated clearly**

The commonly accepted security measures are in place for the work and are communicated to all stakeholders including patients/caregivers in a clear and proactive manner.

1. **Care providers to act proactively on PGD**

If any care providers and/or clinicians have access to PGD about some or all of their patients, they have a duty to proactively act on that data to ensure timely diagnosis and quality treatment. They also have a duty to inform patients that their decisions are based in part on PGD. This supports the need for transparency.