Patient Advisors
Network

Independent
Informed
Connected

Person Generated Health Data (PGHD) Principles:

Through the Patients and Caregivers Lens

A collaboration between

Patient Advisors Network (PAN)

and

Better Access and Care for Complex Needs (BeACCoN)

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Sep 30, 2019

Version 1.0

Version History

Revision History

Date	***Version***	***Description***	***Name***
	1.0	Initial version; developed by co-leads, Alies Maybee and Samira Chandani on behalf of the Patient Advisors Network (PAN)	Alies Maybee Samira Chandani,

Disclaimer

The contents of this document reflect the views of the authors, PAN and BeACCoN and not necessarily that of the individual workshop participants or their respective organizations.

Sponsor Acknowledgement

The **Patient Advisors Network** (PAN) would like to thank our sponsors, funders and partners, the **Better Access and Care for Complex Needs** (BeACCoN) Team. Their strong support has been invaluable and encouraging.

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ACKNOWLEDGEMENTS

We would like to acknowledge the dedication, thought and input provided by the patients, caregivers and other stakeholders who attended the workshops in Sep 2018 and Apr 2019 and participated in discussions both in person and online:

PAN INNOVATION TEAM

- Annette McKinnon, Emily Nicholas Angl, Munira Ratansi, and Ron Beleno

PAN COMMUNITY

- Survey and discussions with the PAN Community

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EXECUTIVE SUMMARY

PURPOSE

This document is a result of collaboration between BeACCoN and PAN which has been commissioned to identify and describe principles for PGHD through the lens of patients and caregivers. We hope these principles will serve to inform and guide any changes in policy, practice and PGHD tool design to protect against misuse and support beneficial use.

AUDIENCE

This document has been prepared for BeACCoN and its stakeholders: Patients and caregivers, developers and innovators, healthcare practitioners, policy makers and researchers.

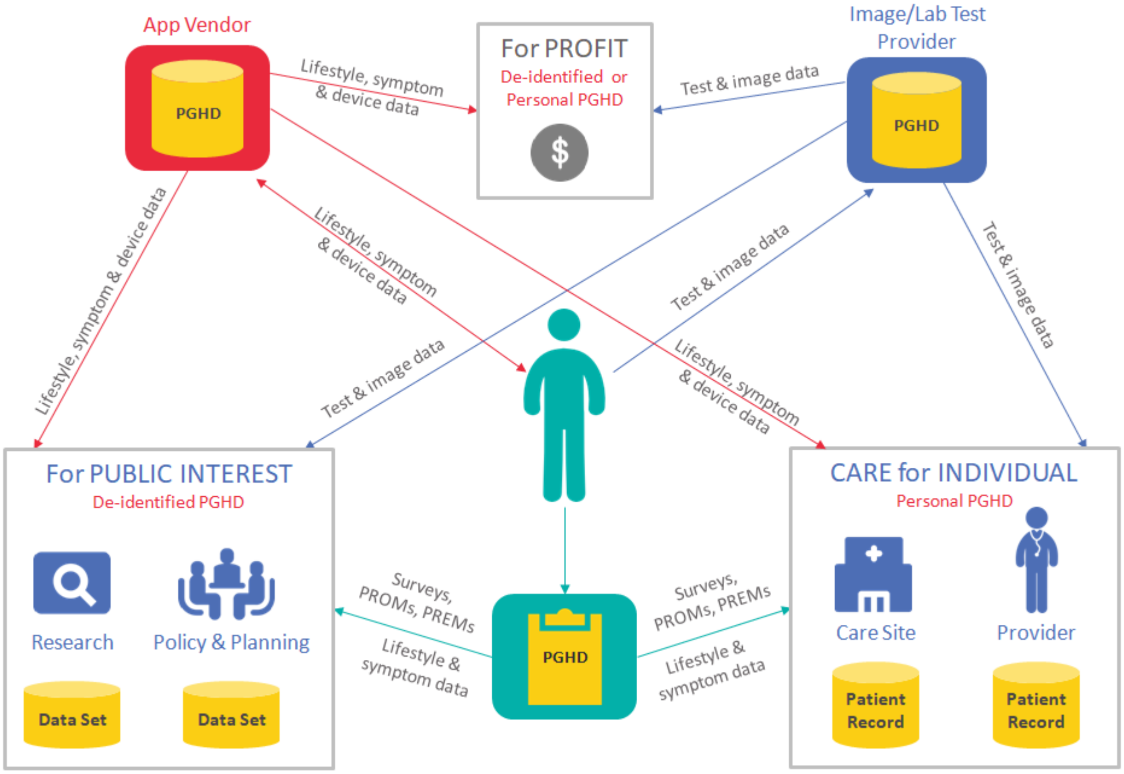
ABOUT PGHD

While the more widely-used term is “**Patient Generated Health Data**”, we have elected to use the less frequently-used term “**Person Generated Health Data**” since not everyone sees themselves as “patients.”

PAN’s proposed definition of PGHD

“PGHD is personal health or wellness-related data that is systematically created, recorded, gathered or inferred by or from patients or caregivers to help manage, maintain and/or improve health and wellness. “

TYPES and USES of PGHD



TYPES OF PGHD

Patients and caregivers provide different types of systematically collected data in various ways:

- Surveys of patient experience or outcomes either on paper or online (PREMs and PROMs)
- Feeds from medical devices commissioned by a provider and sent wirelessly eg: Holter monitor
- Symptom data from devices and apps chosen by the patient eg: blood glucose monitoring,
- Test results and images coming from the evidence of patient bodies like blood tests, genomic testing, and images with internal views of patient bodies like MRIs, x-rays
- Lifestyle data (or wellness data) from devices, wearables and apps chosen by the patient to measure activities like food consumption, smoking, weight and movement

USES OF PGHD

In some cases PGHD is used solely by the individual generating the data particularly in the case of app data for weight loss and other lifestyle management apps. This document is not concerned with this level of use. However, when this personal data is requested and/or shared with others, then the uses around this fall under care provision, for the public interest and for profit. The principles apply to these uses.

PRINCIPLES

PATIENTS/CAREGIVERS AS PARTNERS: Diverse patients/caregivers are partners in all aspects of PGHD.

- Patient/caregiver partners with diverse backgrounds and viewpoints enrich PGHD work.

PURPOSE: Collection, sharing and use of PGHD is driven by purpose and governed by ethics.

- Purpose is governed by ethics pertaining to context.
- Purpose for collection and use of PGHD can be general or specific.

ACCESS: Patients have immediate and equitable access to their PGHD and see who has accessed it.

- Owners of PGHD apps, devices, labs, imaging provide immediate access to patients/caregivers.
- Access to PGHD apps, devices, labs, imaging and data is equitable.
- Patients/caregivers are able to see who has accessed their PGHD.

CONSENT: Patients/caregivers have the right to knowledgeably consent, remove consent to their PGHD and understand accountability for misuse without compromising care.

- Education is provided to understand the implications of sharing PGHD as a result of informed consent.
- Those who are unable to consent have protections.
- There is enforceable accountability for consented use of PGHD.
- Consent procedures and mechanisms are equitable.
- PGHD tools have the function to add and remove consent and delete data.
- Parameters around removing consent are available when consent is granted for sharing and using PGHD for the public interest.
- Removing consent does not put the patient at risk for their health.

TRANSPARENCY: Information about the vendor and the PGHD tool is available, accurate and presented in a clear and understandable manner.

- Patients/caregivers are educated and informed about the role of the PGHD tool owner/vendor and others involved in the data flow.
- Health and digital health literacy is a priority to improve comprehension among patients/caregivers and PGHD vendors.
- Communications are comprehensible to people with diverse backgrounds.
- PGHD tool information is easily available when needed.

HARM PREVENTION and TRUST: PGHD policies, safeguards, tool design and data quality are in place and create trust for patients and users.

- Concern for privacy does not prevent benefits from sharing PGHD.
- Providers are supported in use of PGHD which mitigates stress.
- Providers review PGHD for personal care to provide more accurate diagnosis and treatment.
- The use of PGHD can lead to more accurate or appropriate policy, planning and research.
- Caregivers can input and view the data on behalf of patients leading to more complete and accurate PGHD.
- Safeguards are kept up to date to protect people from exposure of their private information.
- Design of PGHD tools mitigates the harm resulting from security breaches.
- Quality data and tool design can reduce errors and poor decisions.

UTILITY: PGHD data and tools are shared and designed to be useful.

- Use of PGHD is balanced with privacy needs.
- Compatibility with other health data increases the usefulness of PGHD.
- PGHD is portable.
- PGHD tools are designed to support data quality.
- PGHD tools are easy to use.
- PGHD tools that support equity are more useful.

CONSIDERATIONS

Some considerations have arisen in the process of developing the principles and should be thought about as the principles are being applied.

- New approaches for protection of health data
- Data ownership and patient control
- Unregulated holders and users of PGHD
- Data duration and availability

SUMMARY

We hope these principles will provide common purpose and direction for the development of tools, laws, policies and practices centred on the patient and caregiver. Since there is growing involvement by the private sector in healthcare and in particular in PGHD, these principles should cover the shared responsibilities of both the regulated and unregulated sectors.

BACKGROUND

The Patient Advisors Network (PAN)

The **Patient Advisors Network (PAN)** (www.patientadvisors.ca) is a national grassroots community of practice of and for patient and family advisors. Advisors are people who have received health services or cared for those who have, and who are committed to improving healthcare as advisors for the good of all across Canada. This commitment extends to collaborating on digital health and other projects.

As an organization, PAN is able to pull together and share the experience and wisdom of many people partnering in many ways for the improvement of all aspects of healthcare.

Better Access and Care for Complex Needs (BeACCoN)

BeACCoN (www.beaccon.ca) is Ontario's Strategy for Patient Oriented Research (SPOR) network for Primary and Integrated Health Care Innovations. The Canadian Institutes for Health Research (CIHR) developed SPOR in part to promote patient partnership in health research.

The BeACCoN network is based on partnerships between research, policy and practice. Its intent is to create a learning network. This network encourages the development, evaluation and scale up of new approaches to the delivery of integrated and cost-effective primary care services. The integration is vertical through the health care system and horizontal across multiple sectors.

Partnership between PAN and BeACCoN

The BeACCoN team did environmental scans of principles for PGHD and found that none were done from the patient/caregiver lens. "Ultimately, it appears that while principles *related* to PGHD exist, there are no specific ones that are directly about PGHD itself."[1] (*See **Appendix B** for the full report*.)

BeACCoN has commissioned PAN to address this gap.

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[1] Appendix B: Second Environmental Scan on PGHD, by Simone Shahid, BeACCoN pg. 8.

INTRODUCTION

As the world moves rapidly into the digital health era, we, as citizens, need to pay close attention to how our health data is being collected, used, stored and managed. We need to step forward to help guide how our data is handled. We need to push for protections and supports for beneficial use.

There are two fast moving trends that are converging.

First is the growing patient/caregiver engagement (PE) movement both as involved citizens in healthcare systems and also as patients who actively manage their own care. This movement has come about in part because of the massive change in healthcare needs from acute to chronic over the last 50 or so years. Patients now tend to be more proactive when managing chronic conditions. It has also come about in Canada because of citizens' altruistic need to jump in and collaborate to help improve healthcare.

Second is the explosion of big data, individual apps and extreme sharing including health data. With Facebook, Google and other tech companies in the news currently, we are only just learning how urgent it is that we find out more about the world of data and the gaps in citizen protection and control.

We cannot let decisions about digital health be made without citizen input. PAN has taken this on starting with these principles for Patient (or Person) Generated Health Data (PGHD). We believe the involvement of patients/citizens in all aspect of digital health data will enrich the policies, practices, products and research that results. This is especially urgent in the area of person generated health data which exists in the wild frontier of innovation.

Purpose

The purpose of this document is to identify and describe principles for PGHD through the lens of patients and caregivers to help inform further discussions about how to govern the collection, management, sharing and use of PGHD. We hope these principles will serve to inform and guide any changes in policy, practice and PGHD tool design to protect against misuse and support beneficial use.

The document does not offer recommendations to translate these principles into action but leaves that to others more versed in doing so.

Process

To inform this work, PAN surveyed its Community, had in depth discussions on its member forum as well as meetings to gather insights from experienced patient and family advisors from across Canada. Additionally, PAN and BeACCoN held two stakeholder workshops: Sep 10, 2018 and Apr 15, 2019 (*see list of attendees under Acknowledgements.*)

Drafts were sent to the PAN Community and key stakeholders for feedback and further discussions.

The BeACCoN Team did two environmental scans on PGHD. (*See Appendix A and B for details*.)

Audience

This document has been prepared for BeACCoN and its stakeholders:

- Patients and caregivers
- Developers and innovators
- Healthcare practitioners
- Policy makers
- Researchers

ABOUT PERSON GENERATED HEALTH DATA (PGHD)

"Person" vs "Patient" Generated Health Data

While the more widely-used term is "**Patient Generated Health Data**", we have elected to use the less frequently-used term "Person Generated Health Data" since not everyone sees themselves as "patients." Caregivers may also provide valuable PGHD related to themselves as caregivers to the people they care for. The term "Health" clearly identifies the nature and intent of the data so the term "patient" is not required.

Understanding PGHD

To understand Person Generated Health Data, we took a look at the definitions, then the categories or types of data that is generally considered PGHD, some of which have been around for a while and some of which are new or emerging. We also looked at how this data is or can be used. And we looked at the various descriptions and definitions to identify common understanding of the defining characteristics of PGHD.

The definition and diagram below shows the result of our examinations.

DEFINING PGHD

There are no official definitions of PGHD. However, the following Office of the National Coordinator for Health Information Technology (ONC) definition is widely used: "health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern"[2].

We looked at a number of other definitions for PGHD whose main elements include some or all of the following:

- Data are health related
- Data are created, recorded, gathered, or inferred by or from the patient or caregiver
- Data come from outside the clinical setting or healthcare contexts
- Purpose of the data is to address a health concern
- Sharing or distribution of the data is by the patient or caregiver

PAN's proposed definition of PGHD

"PGHD is personal health or wellness-related data that is systematically created, recorded, gathered or inferred by or from patients or caregivers to help manage, maintain and/or improve health and wellness. "

In our definition, we have refined some of these elements (see below) to more accurately represent our understanding of PGHD:

Data is health and wellness related

While the majority of PGHD is health related, some can be lifestyle data that is used to manage, maintain and/or improve health and wellness but is not always seen as strictly health data per se. Examples include step recording and food tracking.

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[2] https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data

Data is systemically created, recorded, gathered, or inferred by or from the patient or caregiver

PGHD can be created by device sensors “reading” aspects of the patient’s body (e.g. step counters). Patients/caregivers can log device readings manually or the medical devices may automatically record their readings digitally. Surveys like Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) gather patient information on paper, by phone interviews or online. Whether qualitative or quantitative, these data are acquired in a methodical, systematic manner and are not ad hoc or one time pieces of data.

PGHD is not data recorded and interpreted by the care provider in his/her official patient record (EMR or EHR) during an encounter (in person or virtual) for his/her understanding of the patient for diagnostic and treatment purposes. PGHD does not include informal health information sent by email to care providers.

Where the data come from does not define the PGHD

While most of the PGHD is created outside a healthcare context, sometimes surveys and the like are done within a healthcare setting before or after an appointment or within the context of a research project.

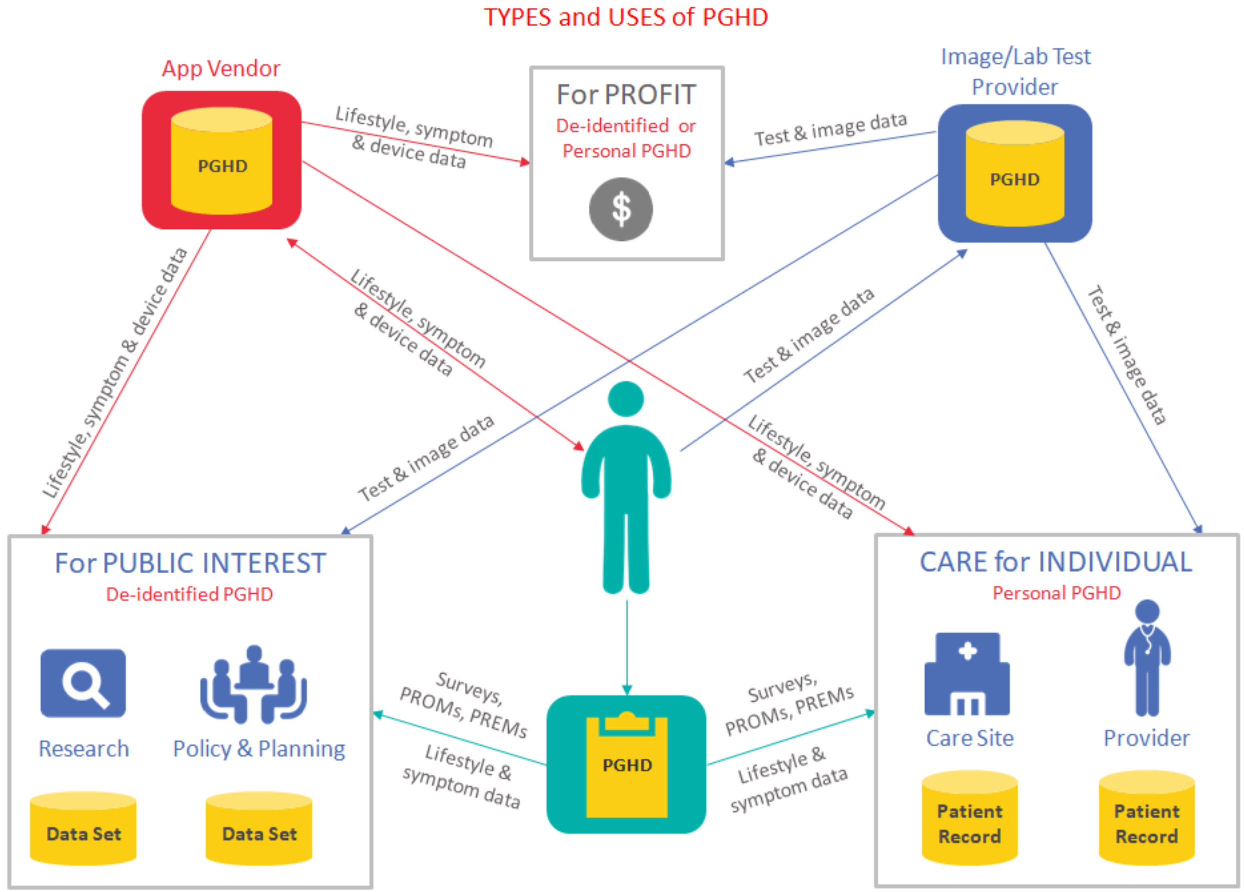
PGHD is to help manage, maintain and/or improve health and wellness

PGHD is not confined to addressing a health concern but can frequently be collected to promote wellness or maintain good health.

PGHD can be shared both directly by the patient or caregiver and as a result of a provider request.

The patient/caregiver can sometimes explicitly share their PGHD however, sometimes the sharing is done through a request by the care provider for tests, images and device data that provide information about the patient.

AN OVERVIEW OF PGHD



[3]

TYPES OF PGHD

Patients and caregivers provide different types of systematically collected data in various ways:

- Surveys of patient experience or outcomes either on paper or online (PREMs and PROMs)
- Feeds from medical devices commissioned by a provider and sent wirelessly eg: Holter monitor
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USES OF PGHD

In some cases PGHD is used solely by the individual generating the data particularly in the case of app data for weight loss and other lifestyle management apps. This document is not concerned with this level of use. However, when this personal data is requested and/or shared with others, then the uses

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[3] All Icons made by Freepik from www.flaticon.com

around this fall under care provision, public interest use and for profit. The principles apply to these uses.

PGHD for care provision

Patients/caregivers may share PGHD from their devices or apps for the purpose of receiving care or maintaining wellness with care providers. In some instances, the patient has tests, imaging or devices to collect information from their body directly. Care provision may be delivered by non-regulated health providers.

When PGHD it is shared for use by the care provider and made part of the patient record, it becomes formally and legally Personal Health Information (PHI) falling under the rules and laws that govern PHI. The patient record may be paper but more commonly is a digital application like an Electronic Medical Record (EMR) or Electronic Health Record (EHR).

PGHD may also be collected often in the form of surveys, for the purpose of quality improvement at the practice level.

PGHD for the public interest

Research, policy and planning use de-identified PGHD for the public interest. Data used for these purposes contributes to a Learning Health System which ultimately positively influences the delivery of care. In a broader system, PGHD is especially pertinent to influence a Learning Wellness System for improved quality of life.

When PGHD becomes part of the data sets used for research, policy or planning, it falls under the rules and laws that govern these data sets.

PGHD may also be collected often in the form of surveys, for the purpose of quality improvement at the system level.

PGHD for profit

Third party app providers gather and store PGHD inputted by those that buy, subscribe and use the apps. It is not always clear whether the app provider or their contractors look at or use this data. This can be personal, identified data or de-identified PGHD. In some cases they indeed sell or use PGHD for profit, in others they charge for the use of the app.

Labs and image providers can also sell PGHD for profit to pharma and other companies that produce products for patients.

PRINCIPLES

The principles seen through the lens of patients and caregivers set out below are described in a summary statement and description followed by sub-principles and their descriptions. This structure has enabled us to explore some of the nuances and more fully elaborate these principles. We do not attempt to offer recommendations on how to make these principles actionable.

PATIENTS/CAREGIVERS AS PARTNERS

Diverse patients/caregivers are partners in all aspects of PGHD.

While patients/caregivers are sometimes involved as partners, involvement across the health system is uneven or often absent. Patients and their caregivers are experts in the health of the patient and their experiences of health systems. As such, they need to be involved in the development of PGHD tools, the selection and gathering of data, the storage, the management, maintenance and governance and the use of PGHD. Some of the benefits for their involvement are:

- On an individual level, patients can enhance their ability to partner in their own health and contribute to shared decision-making using their PGHD.
- On research projects, patients share their usually de-identified PGHD as research participants. As partners in research, they can offer their expertise and perspective to new discoveries and new treatments to the potential advantage of others like themselves.
- In policy work leveraging PGHD, patient/caregiver partners can focus the policy work on the needs of patients/caregivers and collaborate to interpret the data from the patient/caregiver perspective.
- Working as partners within healthcare organizations who are using PGHD for quality improvement of service delivery, patients/caregivers can bring a wealth of experience and perspective to the understanding of the PGHD.
- As partners in the co-design of PGHD tools, patients/caregivers can provide the focus and insight to designing tools that support improved patient outcomes and experiences as well as the right security, privacy, consent and protections. Patients can help identify features that are important and valuable to them. The advantage for digital health vendors is potentially a more useable and more saleable tool.
- Patients/caregivers can be involved with the design of PGHD governance systems and laws to ensure they support protecting patients.
- Patients/caregivers as full members of all governance bodies overseeing PGHD data and its use can bring the patient/caregiver perspective.
- Mechanisms and parameters for consent should be co-designed with patients/caregivers who grant consent to reflect the parameters of consent they desire. The options for consent need to encompass a reasonable range of views on sharing limitations. Those with PGHD covering their mental or sexual health may want more specific consent control than others, for example.

These partnerships can help foster accountability to patients/caregivers and support a more person-centric approach to PGHD.

Patient/caregiver partners with diverse backgrounds and viewpoints enrich PGHD work.

Since patients come from all languages, cultures, genders and backgrounds, patient/caregiver partners must reflect that diversity. Developing protocols and designing initiatives to encourage inclusion of those patients who don't usually step forward as well as those who are knowledgeable will provide a richer range of perspectives and experiences and lead to better health outcomes for all patients.

PURPOSE

Collection, sharing and use of PGHD is driven by purpose and governed by ethics.

There needs to be a purpose for the sharing and use of PGHD. PGHD is often collected by the individual for the purpose of their own self- management. When the PGHD is shared, the patient and the recipient of the PGHD need to be clear on why it is being used. Some examples of purposes for sharing are:

- With care providers to help their care team with diagnosis and treatment either at patient's own instigation or by provider request; and
- For research, policy or planning to benefit the community

When developing a tool, device or application to collect PGHD, consider the purpose and potential uses for the data.

Purpose is governed by ethics pertaining to context.

The ethical implications of the purpose should be clear within the area the PGHD is being shared and used whether it is in a healthcare practice or a research project.

Purpose for collection and use of PGHD can be general or specific.

The purpose may be more general covering an area or direction (e.g.: to support research in a broad area like diabetes now and in the future) especially if the data is sufficiently de-identified. Research can also be specific (e.g.: to do research on a specific aspect of diabetes in a specific population.)

In care provision, the purpose can be general, examining lifestyle information to understand the health status of the patient. It can also be specific like the collection of heart monitor data to deal with a heart issue.

Anonymized data can no longer be connected back to the Personal Health Information (PHI). It is no longer considered PHI.

De-identified data can be linked back to the PHI in spite of removing identifiers and scrambling dates etc. to make re-identification extremely difficult.

ACCESS

Patients have immediate and equitable access to their PGHD and see who has accessed it.

When patients generate their own data, they control the data and who has access to it, however in some cases PGHD is generated by apps, devices, labs, imaging that is outside their direct control. By law, patients have a right to access their health data and that should include their PGHD.

Owners of PGHD apps, devices, labs, imaging provide immediate access to patients/caregivers.

Some methods of gathering PGHD are owned by others like clinics, hospitals or third party vendors. These owners should have a responsibility for ensuring patient/caregiver users have access to their own data, as some do already. Access should be unquestioned and immediate without forms and arbitrary decision-makers in the way.

Access to PGHD apps, devices, labs, imaging and data is equitable.

If there are obstacles to access, then it is not really access.

Equitable access means there are no barriers like cost, time delays, or technology ownership that limit access to the PGHD tools and data. It means there are provisions for those challenged by having a hearing, vision or other impairment. It also means accommodating people who are not literate in the language, in understanding the basics of health, in technology and providing support, or mitigating these barriers.

Patients/caregivers are able to see who has accessed their PGHD.

Audit trails at a granular level would show who else has accessed the data. Appropriate penalties need to be in place when wilful re-identification or access is detected.

CONSENT

Patients/caregivers have the right to knowledgeably consent , remove consent to their PGHD and understand accountability for misuse without compromising care.

Patients/caregivers across languages, cultures and abilities, need to understand what they are consenting to, how to remove consent and the implications for doing so. Consent can be for the collection, sharing, use and deletion of their PGHD. Care should not be compromised by the removal of consent or deletion of PGHD. They also need to know who is accountable for their PGHD and what to do if they perceive misuse.

Education is provided to understand the implications of sharing PGHD as a result of informed consent.

Patients/caregivers and others need to have a thorough understanding of all aspects of consent and consequences of sharing both for potential harm and anticipated benefits.

Implied consent is the assumption of permission inferred by the actions of the patient or the circumstances.

Explicit consent requires a formal oral agreement or recorded acknowledgement.

Summarized from the CMPA Consent: A guide for Canadian physicians update Jun 2016

People need to understand the **parameters of consent**. Consent may apply to options like the type of data e.g: heart rate or steps taken. It may apply to levels like summary versus detailed data; view only versus view and use; identified versus anonymized versus de-identified (able to be re-identified). Consent can be for specific individuals, for teams, for those in the circle of care, for organizations. Consent can be for a timeframe – a year, life of the project, forever. Consent can be renewable and withdrawn.

Patients/caregivers need to know if PGHD is going to be linked to, or integrated with, other health data when consenting.

Patients/caregivers need to understand the **purposes and uses** of their PGHD. Patients/caregivers need to know whether the use of their PGHD is for profit versus by government or non-profit entities. Consent could be offered in options: a) for quality improvement including scale and spread b) population health planning; c) policy development; d) research.

People need to understand who is able or unable to consent to the use of the PGHD and who can **consent on behalf** of another person. People need a good understanding of the legal implications of a Substitute Decision-Maker (SDM) or Power of Attorney (POA). (*See link for the hierarchy of SDMs*

https://www.makingmywishesknown.ca/the-substitute-decision-maker-hierarchy-in-ontario/)

Those who are unable to consent have protections.

Children and those who are not deemed competent to decide for themselves cannot provide consent currently. Their Substitute Decision-Maker (SDM) or Power of Attorney (POA) have some rights to act on their behalf. The current laws and practices need to include handling, sharing and use of PGHD. If the patient's health means they fluctuate in and out of the ability to provide consent, when their capacity returns, SDM should stop unless the patient specifically consents.

Caregivers without SDM or POA should be able to provide PGHD with their observations on behalf of the person they are caring for. There should be recognition legally identifying caregivers who are not in a legal relationship with the patient ie: friends.

There is enforceable accountability for consented use of PGHD.

Accountability for care provision and public interest use of PGHD is given to a person, team or organization through consent. These teams or organizations must hold their staff, members and contractors accountable. There must be clear penalties for misuse. Consent to use PGHD profit must also be governed by clear penalties for misuse.

Consent procedures and mechanisms are equitable.

Consent procedures and mechanisms need to remove barriers to address language literacy, appropriate languages, and accessibility for those with hearing, vision and other impairments. Consent language and explanations should include both gender and cultural sensitivity. Consent should be the same across Canada so that patients are treated the same no matter where they live.

PGHD tools have the function to add and remove consent and delete data.

Patients need the ability consent and to remove consent. This means that devices and apps used to set up sharing of PGHD must include the functionality to start and stop the sharing. Patients/caregivers should have the function to delete existing data within the tool.

Parameters around removing consent are available when consent is granted for sharing and using PGHD for the public interest.

Any individual or group requesting PGHD data for research, policy or planning needs to make explicit when sharing can be stopped, how to stop it and the consequences of stopping at the time when the initial consent is requested. Separately, this should include information about how previously shared data can be deleted or not, how this is done and who is accountable for doing so.

Removing consent does not put the patient at risk for their health.

If the patient were to stop sharing PGHD vital to their diagnosis and treatment, their health could be at risk. A reasonable balance between providing control to the patient through consent and ensuring their well-being needs to be in place.

The forms used by government agencies are legal documents and the same documents should be used by community service organizations and other healthcare entities. This will prevent disputes over definitions or language.

TRANSPARENCY

Information about the vendor and the PGHD tool is available, accurate and presented in a clear and understandable manner.

There needs to be clear communication to the patients about why, how and who is collecting and using the data, how and what is being collected and used. This information needs to be simply presented and validated for comprehension by diverse patients. Transparency demonstrates respect.

Patients/caregivers are educated and informed about the role of the PGHD tool owner/vendor and others involved in the data flow.

When people share information using a PGHD tool, it is stored and managed by the tool owner/vendor. The goal of this owner/vendor in managing their PGHD needs to be clearly communicated especially if there is any profit being made by the owner/vendor. The agenda, accountability and obligations of the owner/vendor need to be clearly communicated as well as actions that the patient can take if there have been violations. The ramifications of violation are clear especially to vendors.

Health and digital health literacy is a priority to improve comprehension among patients/caregivers and PGHD vendors.

When people don't have strong health or digital health literacy levels, even the best communications can be difficult for them. Campaigns and other efforts to help improve the people's capability to comprehend the information are needed for transparency.

Communications are comprehensible to people with diverse backgrounds.

Communications needs to be written at an acceptable grade level for patients/caregivers and presented clearly using Plain Language standards. To reach all patients/caregivers, consideration for language and cultural diversity is key in how information is conveyed and tested. (*See the Bibliography for Plain Language links.*)

PGHD tool information is easily available when needed.

PGHD tool instructions and help should be available when and where it might be needed so that the user is informed at the appropriate location in the tool. This applies to all tools like surveys, applications, devices and the like.

Consent forms should be on the initial screen and should be simple, clear and explicit.

HARM PREVENTION and TRUST

PGHD policies, safeguards, tool design and data quality are in place and create trust for patients and users.

Patients/caregivers need to be able to trust the safeguards around PGHD like governance, privacy, security and data integrity. Users need to be able to trust the PGHD tools they use will not open their private data to unauthorized people. Patients/caregivers need to know clinicians and others will be held accountable with repercussions if harm occurs to the patient through the collection and use of PGHD or by the people who share their data.

Researchers, planners and policy makers need to be able to trust the quality and completeness of the PGHD.

Concern for privacy does not prevent benefits that come from sharing PGHD.

There is a trade off between using PGHD and privacy. The current approach to interpret privacy for the least amount of risk could mean we will miss the benefits of sharing PGHD.

Providers are supported in use of PGHD which mitigates stress.

Health system funders and managers need to make changes to support the extra work providers will need to do to incorporate PGHD into their practices. Without these changes, providers may be harmed for example, by overwork and lack of adequate compensation. Unless the system adequately funds and supports the use of PGHD, the providers will experience harm from the burden of use.

Providers review PGHD for personal care to provide more accurate diagnosis and treatment.

Providers may also avoid use of PGHD and make treatment and diagnosis decisions on incomplete data. In cases where the patient and provider have agreed that PGHD will be shared, the provider and care team must review the data. Failing to assess PGHD when diagnosing or treating the patient may inadvertently harm the patient. It may negatively affect diagnosis and treatment decisions.

Not using PGHD when it is available can lead to decisions made on an incomplete understanding of the patient or the population. According to the WHO, "Four out of every ten patients are harmed during primary and ambulatory health care. The most detrimental errors are related to diagnosis, prescription and the use of medicines."[4] If providers had PGHD to round out their data on a patient, their diagnoses and treatments might be more accurate and contain fewer errors.

The use of PGHD can lead to more accurate or appropriate policy, planning and research.

If those involved with policy, planning and research can but don't assess PGHD, populations may be harmed by the omission of valuable data that could alter results due to incomplete data. As the use of PGHD grows, the risks of inaction may start to become greater.

Caregivers can input and view the data on behalf of patients leading to more complete and accurate PGHD.

Harm can come from caregivers' lack of ability to input data on behalf of the patient that is pertinent to the patient's care. If caregivers cannot view the data, they may not be able to provide optimal care for their patient.

Safeguards are kept up to date to protect people from exposure of their private information.

Current laws, policies and procedures need to be updated to include considerations for protection around PGHD. Where existing safeguards are inadequate or inappropriate for dealing with PGHD due to its unique nature, new ones need to be created. Current safeguards for consideration include:

- Privacy and confidentiality laws including the need to look at the impact of consent on privacy
- Governance structures
- Up-to-date security measures need to be in place and kept current
- De-identification and re-identification protocols
- Data governance policies; and
- Policies and processes for data linkages

Without safeguards to the data, breaches can expose patient's private information to stigma.

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[4] https://www.who.int/news-room/detail/13-09-2019-who-calls-for-urgent-action-to-reduce-patient-harm-in-healthcare

This area of technology is changing rapidly. The types of technologies that are coming on stream like artificial intelligence (AI) and new forms of testing like genomics will put a demand on our systems to safeguard patients. Constant vigilance is required. Deep knowledge of and relationships within the personal health data ecosystem will be needed by those responsible for creating and maintaining safeguards. A system of ongoing reviews and updates of safeguards will be needed to keep on top of the rapid changes.

Design of PGHD tools mitigates the harm resulting from security breaches.

The applications and devices, especially those that depend on the internet, are vulnerable to hacking and data breaches. They need to be designed to prevent harm from misuse of PGHD and privacy breaches. Design needs to protect the users from bad actors who cause harm to patients through the stealing and misuse of their data. Design needs to include the highest standards for user identification, access and authentication (IAA) and data security. Design needs to include deterrents like audit trails which can help identify those who would cause harm. Consider validating tools for use within healthcare.

As much as possible, applications and devices need to be within the reach of Canadian law or that of trusted jurisdictions.

Quality data and tool design can reduce errors and poor decisions.

Poor data design and data collection tools can lead to poor data quality and missing key pieces of data. This can negatively impact results and decisions based on the inadequate data.

UTILITY

PGHD data and tools are shared and designed to be useful.

The PGHD and the tools need to be designed and structured to be useful to users. Users can be patients, caregivers, delegates, providers, administrators, planners, researchers and others.

Use of PGHD is balanced with privacy needs.

Currently privacy legislation and regulations tend to present barriers to easy sharing and use of data. There needs to be a better balance so that data can be useful for care provision and for the greater good. Taking a person-centred point of view of the sharing and use of the data in legislation and regulations will create a better balance between privacy and utility.

Compatibility with other health data increases the usefulness of PGHD.

The infrastructure and data standards should contribute to the compatibility of PGHD with other health data. The more that the PGHD can be linked with, or integrated into other health data, the more useful it becomes. Barriers to integration negatively impact the utility of PGHD.

PGHD is portable.

Portable PGHD can be not only useful, but life-saving. This is apparent when patients travel or when they meet with other providers. Portability for the patient is having a personal device that can hold/access their data no matter where they are.

PGHD tools are designed to support data quality.

Data quality is necessary for the data to be used. The design of PGHD tools needs to ensure the data is accurately recorded and has functions to support audit, review and modifications as appropriate. Unreliable, inaccurate data is not useful and can cause harm.

PGHD tools are easy to use.

People are reluctant to use or keep using tools that they find challenging to use or don't provide value or are too functionally rich so can become overwhelming. The design and format of PGHD tools need to consider the various types of users and tailor the views and functionality of the tools accordingly.

PGHD tools that support equity are more useful.

The tools need to be useful to patients/caregivers regardless of language, culture, background, or literacy level to any other barriers to equity. Any testing of the tools should include the full range of potential users.

CONSIDERATIONS

These following considerations have arisen in the process of developing the principles and should be thought about as the principles are being applied.

New approaches for protection of health data

Over the last few decades technology has advanced with artificial intelligence and immense storage and computing capacity. This has led to the view that data is the new "gold". It is seen as something to be mined for profit. In the internet age, data know no boundaries. The old ways of providing protection may not be sufficient for this changing landscape. This paradigm shift requires new approaches to protecting and managing all data and especially emerging types of data like PGHD. One example of a new approach is the concept of a data bill of rights[5]. There may be other approaches also worth exploring. A New York Times article suggested some options such as putting a value on personal data or seeing data as a tradable asset or as labour asserting that privacy is not the only issue.[6]

Data ownership and patient control

Is it necessary for a patient to "own" their health data? Is access and control by the patient sufficient? Currently the ownership of health data in regulation is seen as a custodial role the providers and the health system perform on behalf of patients. The data governance laws delineate the role of Health Information Custodians (HICs) in Ontario and other jurisdictions in some cases have something similar. Things are changing. Lines are getting blurred. With PGHD, especially app data becoming more and more prevalent, patients already have control of portions of their health data.

A paternalistic, top down approach no longer works in a world where data flows like water through and across jurisdictions and alternate players like app vendors and device makers who control health data. How do we develop accountability structures to protect against misuse by other system and non-system players? How do we create a system to leverage the benefits both for the individual and for society of sharing health data? There needs to be further exploration into the concept of data ownership, control,

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[5] https://www.technologyreview.com/s/612588/its-time-for-a-bill-of-data-rights/

[6] https://www.nytimes.com/2019/07/25/business/calls-mount-to-ease-big-techs-grip-on-your-data.html

accountability, redress for misuse and protection from harm. This exploration must involve patients and caregivers who are those who will be deeply affected by the approaches we, as a society, adopt.

Unregulated holders and users of PGHD

The current laws and regulations assume control over the regulated providers but more and more players who are unregulated hold and use health data eg. Personal Support Workers (PSWs), volunteers, Not-for-Profits like Meals on Wheels, third party vendors like Telus Health, Apple Health and other smaller vendors many of whom may be transnational. When patients/clients provide PGHD to non-regulated health providers, there needs to be protection so that the data cannot be shared further without consent or misused.

Data duration and availability

When PGHD becomes part of PHI, it should be securely stored, managed and available to the patient/caregiver, their family and circle of care for the life of patient and beyond. Often it is important that family members have the key medical history of their parents and siblings even after they have passed on, to identify any genetic predisposition. This will help patients answer family medical history questions accurately.

SUMMARY

We hope these principles will provide common purpose and direction for the development of tools, laws, policies and practices centred on the patient and caregiver. Since there is growing involvement by the private sector in healthcare and in particular in PGHD, these principles should cover the shared responsibilities of both the regulated and unregulated sectors.

APPENDIX

(*See attached appendices as separate documents*.)

Appendix A: First Environmental Scan on PGHD, Jul 30, 2019

Appendix B: Second Environmental Scan on PGHD, Sep 25, 2019

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