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# Patient Contributed Data (PCD) White Paper

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## Chapter 1: Introduction

The use of technology such as devices, apps, and sensors makes it easier than ever before for people to self-monitor their health and participate in their own care. Many people collect and correlate data from a wide variety of environments and settings, tracking everything from biometric data to mood and behavior and gathering data related to care of their health conditions – these are considered Patient Contributed Data (PCD). Data gathered in this fashion can be correlated information, such as symptoms and treatment activities, or external factors, such as weather or pollution. In the process, individuals can construct a robust picture of what happens to their health and wellbeing *between* direct encounters with their clinicians or the medical system. Individuals may also collect their medical records on paper and electronically and may choose to share such historical medical information with others. When PCD is shared with health professionals, it enhances the ability to gain rich insights into people's health as they go about their daily lives. This information can offer a depth of insight that has not been available in the past and can illuminate previously unappreciated patterns and trends in the person's health.

This White Paper is the culmination of a two-year effort from a sub-workgroup chartered by the HL7 Patient Empowerment Workgroup. The Patient Contributed Data sub-workgroup has met weekly since August of 2020 with a diverse group of stakeholders interested in understanding “What constitutes Patient Contributed Data and what are the barriers to incorporating it in medical care?” In this process, we have paid special attention to questions about how this data are or should be represented, where it should be stored, what rights are associated with it, and how it can be incorporated into care for individuals and populations. The patient journeys in this white paper showcase how PCD can be used for care but also illustrate barriers to communicating PCD effectively and using it to collaborate with care teams.

### **Audience**

The audience for this white paper includes medical professionals, health technology professionals, standards developers, policy makers, and individual patients. Our goal is to highlight a component of health data that is frequently ignored or under-estimated, so that we can bring attention to the way its exclusion impacts individuals and limits opportunity for partnership.

### **Why does PCD Matter?**

Patients and their care partners are the closest observers of their own health. They may self-track PCD in order to manage diseases, symptoms, lifestyles, or behaviors. People may collect and use PCD to understand their health without sharing it with healthcare professionals. There is also value when patients choose to share PCD with their clinical care team for the purpose of collaborating to understand their health, determine diagnoses, remotely monitor and manage their health, measure the effectiveness of treatments, and detect patterns in their health experiences.

PCD may also be useful for researchers seeking to broaden their base of research data and understand day-to-day variations in life with illness. People may choose to contribute PCD for Community Science projects or directly to researchers. These efforts can lead to medical discoveries, advance population health, and protect public health.

There is a full definition of PCD in Chapter 2: Definitions, which is further expanded in Chapter 4: History. For purposes of the discussion in this white paper, PCD includes a wide variety of data including, but not limited to: personal profile and demographics; patient comments on clinical history and requests for corrections; health history; family health history, medication information (prescription and over-the-counter); health assessments; biometric tracking; symptoms and observations, whether reported by devices and apps or manually tracked; lifestyle tracking, such as diet, mood, or exercise; patient reported outcomes; patient treatment goals, preferences, and priorities; clinical care goals; patient experiences; administrative data; relevant external data such as pollen count or temperature; data or documents held in the custody of the patient.

Currently, there are few standards governing how PCD is collected, stored, transmitted, trended, or used. This lack of standards limits the effectiveness and use of this type of data. In fact, the absence of this information may lead to errors in treatment or delays in care. Standards that currently do exist are underused, potentially out-dated, difficult to apply to person-centered care models of care, or reflect a different understanding of the value of PCD compared to the one we apply here. One of our project goals has been to identify areas for further standards development regarding PCD.

This project intersects with issues of patient consent for use of PCD, the ability for patients to determine who has access to their data, the ability to see who has accessed their information, and a clear definition for the intent of use by those who access the data. These are reflected in Chapter 6: Principles but are not the main focus of this white paper.

## **Methodology and Approach**

To address the topic of Patient Contributed Data, the Patient Empowerment Workgroup charged a subgroup with exploring the issues and coming up with an assessment of the situation and recommendations for addressing issues and barriers. The sub-workgroup was chaired by Maria Moen and Jan Oldenburg. Attendees varied during the time the group was convened but included several representatives from Europe as well as individuals with a wide range of backgrounds from the US.

During the course of our work, we interviewed patients and professionals who are tracking their own PCD or making use of it in their work. Some of the people we spoke with included:

- Kate McCurdy from Pictal Health shared her work creating health histories that include a visualization dimension.
- Rada Hussein, PhD, with the Ludwig Boltzmann Institute for Digital Health and Prevention talked about her work incorporating PGHD into the Austrian Health Record. Rada became a member of our group.

- Adrienne Pichon, Columbia PhD candidate, shared work looking at PCD for collaborating to manage enigmatic conditions. Adrienne became a member of our group.
- The Public Health Informatics Institute discussed their study on self-measured blood pressure monitoring (sponsored by CDC).

In addition, we interviewed representatives from HL7 Workgroups doing work that aligns with the PCD topic. These conversations included:

- Gora Datta and Matthew Graham, who spoke to us about Intersections with the Mobile Health workgroup.
- John Ritter spoke to us about the PHR Functional Model version 2.
- Rachel Richesson guided us on HL7 vocabulary conversations.
- Todd Cooper helped us understand device interoperability and standards.
- Terrie Reed helped us understand why UDI matters for patients.

Members of the committee included the following, with some attending less than they wished because of sub-optimal meeting scheduling in their time zones.

- Maria D. Moen, ADVault, Inc. (CoChair)
- Jan Oldenburg, Participatory Health Consulting, Inc (CoChair)
- Adrienne Pichon, Columbia University, Department of Biomedical Informatics
- Robert Stegwee, Trace-Health and HL7 Europe Board
- Victoria Tiase, Utah School of Medicine, Biomedical Informatics Department
- Rada Hussein, Ludwig Boltzmann Institute for Digital Health and Prevention
- Danielle N. Sill, Public Health Informatics Institute
- Rita Torkzadeh, Consultant and SME for the project
- Ashley Griffin, Stanford University and Department of Veterans Affairs
- Tammy Hamrick, Allscripts
- Shivum Bharill, Symmetrichs
- Terry Reed, Symmetrichs
- Erin Roche, American Immunization Registry Association
- Michelle Barry, Availity
- Matthias Pocs, Stelar Security Technology Law Research and CEN/TC 251
- Timon Grob, Philips
- Nancy Lush, Patient Centric Solutions

During the course of our work we also reviewed and discussed a wide variety of seminars, articles, and studies that discussed topics related to Patient Contributed Data, including barriers, use cases, and histories. We also brought stories from peers, patients, patient advocates, and activists into the work.

Individuals paired up to write chapters and sections of the document while others — including external clinicians, patients, and experts — contributed thought-leadership to our work and initiated topics that enriched the product we created.



Our hope is that this paper starts a broad, much-needed discussion and appetite for PCD in the greater medical and standards community.

### **Summary**

We believe that the ability to exchange PCD and establish ways of promoting its value will lead to enhanced patient empowerment for patients themselves. It may also help redress the power imbalance in medical care and treatment that sometimes means that patients' recounting of their experiences are ignored or devalued by clinicians.

We welcome feedback, perspectives, and dialogue about PCD and the recommendations we set forth as a service to patients and an effort to improve effective clinical care and research.

## Chapter 2: Definitions Relevant to Patient Contributed Data

This section defines the term Patient Contributed Data (PCD) as well as other terms we use in the context of the white paper.

### Patient Contributed Data (PCD)

For purposes of this white paper, PCD is defined as:

*Any data, information, or insights created, collected by, or originating from a person regarding his or her health and care. It is particularly relevant when shared with one or more clinical care team members for the purpose of collaboration around the person's health.*

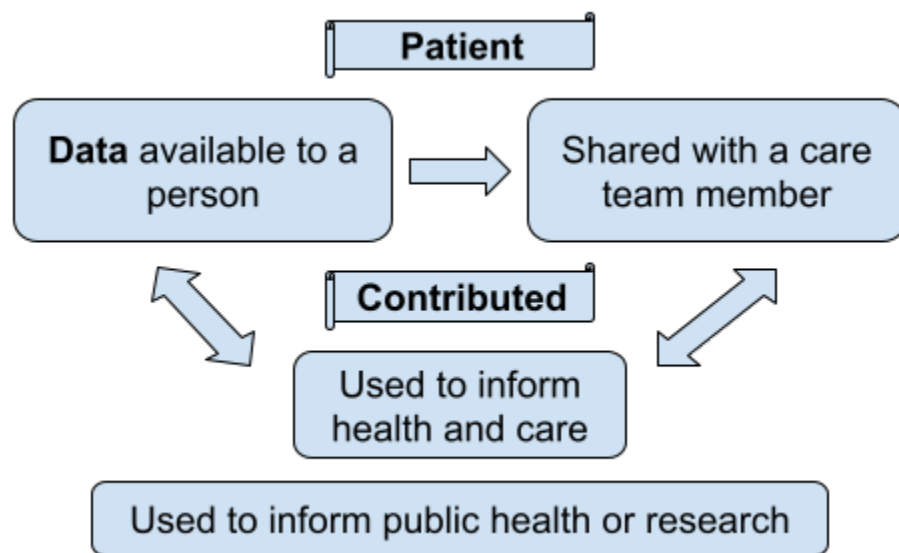


Figure 1. Illustration of PCD in the context of the health system

This work is intended to update and expand previous definitions to better reflect the current initiatives that focus on consumer engagement and the standards and practices that are becoming the norm in healthcare delivery. Patient contributed data includes both structured and unstructured data. The data can be collected and stored in a variety of ways — electronic, verbal recordings, on paper, in apps, or via connected devices. For purposes of exchange and standards discussions, we are primarily focused on the data after it is transformed into some sort of electronic medium.

Although the term “data” is in our definition, we are primarily interested in the way data can be used to inform understanding and produce insights or wisdom. We think of this as a collaborative process, informed by the person’s knowledge of their body and history and clinicians’ medical knowledge and understanding.

### Sub-categories of Patient Contributed Data

There are subcategories of PCD. Each has complexity and may bring up different issues for the health system and for individuals.

- Solicited data. This is data that a member of the person's care team has requested that the individual track, either for a limited period of time or as a long-term way to understand and manage a condition. Examples might include home blood pressure readings, peak flows, sleep, diet, or exercise. Data created as a result of home monitoring programs is appropriately placed in this category as well. Solicited PCD is often incorporated into the EHR and may be gathered by way of an app, device, or questionnaire supplied by the care provider or health system. It is more generally accepted than some other forms of patient contributed data.
- Unsolicited data. This is data that the individual provides without an initiating request from a care team member. Individuals may use a variety of tools to collect the data, including wearables, sensors, apps, devices, or paper. The person may use the information gathered to better understand their illness or may share it with clinicians or family members for purposes of understanding and managing their health. Data that begins as unsolicited may become solicited when patients and clinicians find it useful in the collaboration around care and treatment.

Whether the patient contributed data is solicited or not, both individuals and clinicians frequently experience frustration in finding straightforward ways to share and exchange this information—and the insights that may accompany it—as anything other than “blob” text.

As noted in Chapter 7: PCD Standards Overview, it is common for data collected by patients to be “validated” by a clinician before being entered into an EHR. This is due, in part, to the medical record serving as a legal record as well as for medical purposes. As discussed elsewhere in this white paper, more detailed provenance for PCD as well as clarity about its role as a person's observation of their own health may simplify this definition.

### Personal Health Environment

We have also referenced the concept of a Personal Health Environment in this white paper. We have described a Personal Health Environment in Chapter 2: Definitions and 5: The Health Data Ecosystem. A personal health environment moves beyond a medical record towards a space where individuals have access to their clinical data, can perform meaningful action on it, and combine it with PCD they might be tracking from home. It also offers an opportunity for individuals to store PCD from a variety of apps, devices, or systems in one coherent location. Leveraging a personal health environment allows individuals to collect and store personal health data longitudinally. This supports patients in sharing data with other health care institutions and performing independent analyses on combinations of their health data from various sources. It differs from a Personal Health Record in that the environment incorporates data of a variety of types, as well as the app and device ecosystem that may surround and feed into the personal health environment.

## **Community or Citizen Science**

Community Science may also be referred to as Citizen Science. It is scientific research conducted, in whole or in part, by nonprofessional scientists.<sup>1</sup> Citizen and community science is sometimes described as public participation in scientific research, participatory monitoring, or participatory action research. One key usage for PCD is to contribute to Community Science projects to extend knowledge and research.

## **Patient/Individual/Person**

Our focus is on PCD when used in collaboration with health professionals, so we frequently refer to “patients” in the course of this White Paper, including in the overall name of the white paper. We want to acknowledge, however, that individuals may collect and track data about their health or activity before they are patients under a healthcare professional’s care. In addition, patient is a role in connection with the medical system and much PCD is collected outside of that role. As a result, we refer to patients interchangeably with individuals and persons to emphasize the person’s agency in collecting and using this data.

## **Clinician/Care Team Member/Provider/Healthcare Professional**

We also sought to be inclusive in our terminology for the people in the healthcare system that may play a role in assessing, collaborating, creating, or authorizing entry of PCD in a healthcare context. We most frequently use Care Team Member or Care Team as the most inclusive term, but in various contexts we use all of these terms.

## **Learning Health System**

AHRQ defines a learning health system as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice.<sup>2</sup> As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.

Learning Health Systems:

- Have leaders who are committed to a culture of continuous learning and improvement.
- Systematically gather and apply evidence in real-time to guide care.
- Employ IT methods to share new evidence with clinicians to improve decision-making.
- Promote the inclusion of patients as vital members of the learning team.
- Capture and analyze data and care experiences to improve care.
- Continually assess outcomes as well as refine processes and training to create a feedback cycle for learning and improvement.

## **Summary**

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<sup>1</sup> <https://education.nationalgeographic.org/resource/citizen-science/>

<sup>2</sup> <https://www.ahrq.gov/learning-health-systems/about.html>

Our goal is to emphasize the validity and expanded knowledge offered by patient contributed data and its role in facilitating collaboration between individuals and their care teams (both family and clinical) to support person-centered care. We are aware that patient contributed data can be an area of tension between care team members and patients in the current healthcare infrastructure, especially when it is unsolicited. The relevance of symptoms, the accuracy of data, and what matters all can be subject to differences of perspective. A framework for incorporating patient contributed data, making sure the data is available, accessible, usable, and shareable does not eliminate these issues, but creates an opportunity to address them collaboratively and respectfully. Throughout this paper, we highlight the importance and insight that patient contributed data provides to care teams in order to provide better support to patients and empower them in their care.

## Chapter 3: Vision Statement

The future of healthcare is preventive, collaborative, and personalized. Patient contributed data is not only data generated by the patient, typically referred to as patient-generated health data, but also data that is collected by or originating from a person to optimize their health and medical care. The enrichment of clinician-originated data from electronic health records by inclusion of patient contributed data enables patients, care team members, policy makers, and researchers to see a wider perspective on a person's health than characteristically produced by episodic and/or synchronous healthcare visits. Capture and integration of patient contributed data can be a valuable source of empowerment and agency for patients and their families, especially when it is used in collaboration with a clinical care team to impact diagnosis or treatment of a person.

Our vision is that patients and their patient contributed data are valued as contributors to their own health and citizen science. As such, patients will be encouraged to collect this type of data, whether from wearables or apps. We believe that the data in these tools should be standardized so exchange and collaboration of it can be simplified and harmonized. The data that patients choose to share will be available to clinicians and researchers (based on the patient's permissions) to use in collaboration with other clinicians and with the patients themselves to solve health problems, ultimately empowering collaboration between patients and their care teams.

Patient contributed data can remove the white-coat effect that can inadvertently cause incorrect readings due to anxiety induced by clinical settings and the presence of medical professionals. For example, many individuals have higher blood pressure in clinical settings because of the anxiety associated with going to the doctor, which does not provide a true representation of a person's blood pressure. Collection and use of this type of data can help both patients and care team members understand a person's documented conditions and symptoms for more proactive, efficient, and effective ways to:

- Assess health status and fluctuations therein
- Diagnose conditions (especially complex and enigmatic conditions)
- Identify and understand correlations and associations (of triggers, symptoms, etc)
- Optimize treatment, prevention, and intervention

We envision a future in which every patient has access to a Personal Health Environment. A Personal Health Environment would serve as a place to store and connect patient contributed data from sources such as wearables, implantables, at-home medical devices, apps, and self-tracking modes. It would also create a place where data stored in EHRs and available to patients through Application Programming Interfaces (APIs) can be aggregated and normalized. A Personal Health Environment would allow for an individual's data to be accessible at the right time and the right place, with provisions around which data is available to the care team based on the individual's preferences. This just-in-time context would allow for individuals to release parts of their record to the people they choose and would enable them to better formulate and tell their stories. Additionally, this would prevent an EHR or clinical data warehouse from being

overwhelmed by personal data, as the individual can pick and choose what is sent based on the context of what the person feels the provider in question should have access to, limiting the amount of data an EHR receives at a time. Such an environment need not be solely mobile-app- centric due to storage constraints, but should allow data to be retrievable and presented via an app, with the entire longitudinal record stored elsewhere (e.g., such as in the cloud). A Personal Health Environment could enable development of tools to search the data for correlations, personal priorities and patterns that could provide insights into a person's diagnoses, symptomatic triggers, and potential treatment options.

Use of patient contributed data leads to individuals being provided with better, more personalized care that takes into account the person's goals of care, treatment preferences, and quality of life priorities, ultimately leading to individuals feeling empowered to make decisions and advocate for their health. Our aim is for patients and their patient contributed data to be valued by clinicians, researchers, and caregivers so as to serve as a valued information source alongside electronic health record information. Multiple projects showcasing the importance of patients and their patient contributed data can be seen in activities such as post-COVID groups. Currently, we even see patients themselves, such as Dana Lewis, serving as principal investigators on projects that highlight the value of patient's evidence for their conditions.<sup>3</sup> Most notably, the Patient-Centered Outcomes Research Institute (PCORI) was funded to empower patients and others in their healthcare choices through comparative clinical effectiveness research and involve patients across the continuum of PCORI's work, from research topic selection to dissemination and implementation of results.<sup>4</sup>

Patients may also band together to use this data to contribute to or lead Citizen Science projects that collect data from a broad group of individuals to understand how health is experienced on a daily basis. Today there are examples, such as the Most Citizen Science Heart Rate Experiment<sup>5</sup> or the Citizen Science Long COVID project<sup>6</sup> that helped identify the condition. With the wide-spread availability of tools to track body systems, we expect these projects using person-contributed health information will expand and grow.

Recently, patient-contributed data has been rendered even more useful, through techniques of pattern recognition due to the ability to combine multiple data sources, which can result in interactive visualization, making it possible to detect patterns in masses of personal data that might not be identified in EHR data alone. When patient contributed data is provided in the context of continuous investigation, health improvement and population health research, it can accelerate learning across the entire health ecosystem, generate deeper understanding of conditions, and fuel development and evaluation of new treatments. This type of citizen science approach can generate new insights rooted in patient perspectives.

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<sup>3</sup> <https://diyyps.org/2022/07/05/new-research-on-glycemic-variability-assessment-in-exocrine-pancreatic-insufficiency-epi-and-type-1-diabetes/>

<sup>4</sup> <https://www.pcori.org/about/about-pcori>

<sup>5</sup> <https://www.most.org/citizen-science-heart-rate-experiment/>

<sup>6</sup> <https://www.nih.gov/citizen-scientists-take-challenge-long-haul-covid-19>

## Chapter 4: The History of PCD

Patient Contributed Data (PCD) has existed since the first practitioner asked a patient “where does it hurt?” People have tracked their pain, symptoms, eating habits, exercise, and emotions for many years either formally or informally. It is only recently that we’ve had technology that has made tracking and communicating this type of information easier.

We began to consider these data to be important and a source of information in the 1990’s and the early 2000’s. A 2005 study that looked at the accuracy of the data patients report to physicians noted, “Historically, much of clinical information stored in an EHR has always reflected information reported by patients to their providers, who then document that information in the record.”<sup>7</sup> The study went on to conclude that patient contributions are a useful and under-appreciated source for creating a more accurate and complete medical record.

In 2012, ONC asked RTI International to produce a paper on Patient Generated Health Data (PGHD).<sup>8</sup> In the white paper, RTI International defined PGHD as, “clinically relevant data captured outside traditional care settings.” The full definition notes:

***Patient-generated health data (PGHD) are health-related data created, recorded, or gathered by or from patients (or family members or other caregivers) to help address a health concern.***

***PGHD include, but are not limited to,***

- *health history,*
- *treatment history,*
- *biometric data,*
- *symptoms, and*
- *lifestyle choices.*

***PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways:***

1. *Patients, not providers, are primarily responsible for capturing or recording these data and*
2. *Patients decide how to share or distribute these data to health care providers and others.*

This Patient Contributed Data White Paper makes several key distinctions that expand the above ONC definition and are the reasons we renamed the topic Patient Contributed Data (PCD) rather than Patient Generated Health Data (PGHD):

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<sup>7</sup> Wuerdeman L, Volk L, Pizziferri L, Tsurikova R, Harris C, Feygin R, Epstein M, Meyers K, Wald JS, Lansky D, Bates DW. How accurate is information that patients contribute to their Electronic Health Record? AMIA Annu Symp Proc. 2005;2005:834-8. PMID: 16779157; PMCID: PMC1560697.

<sup>8</sup> Shapiro M, Johnston D, Wald J, & Mon D (2012). *Patient-generated health data. White paper.* RTI International. Prepared for Office of Policy and Planning, Office of the National Coordinator for Health Information Technology

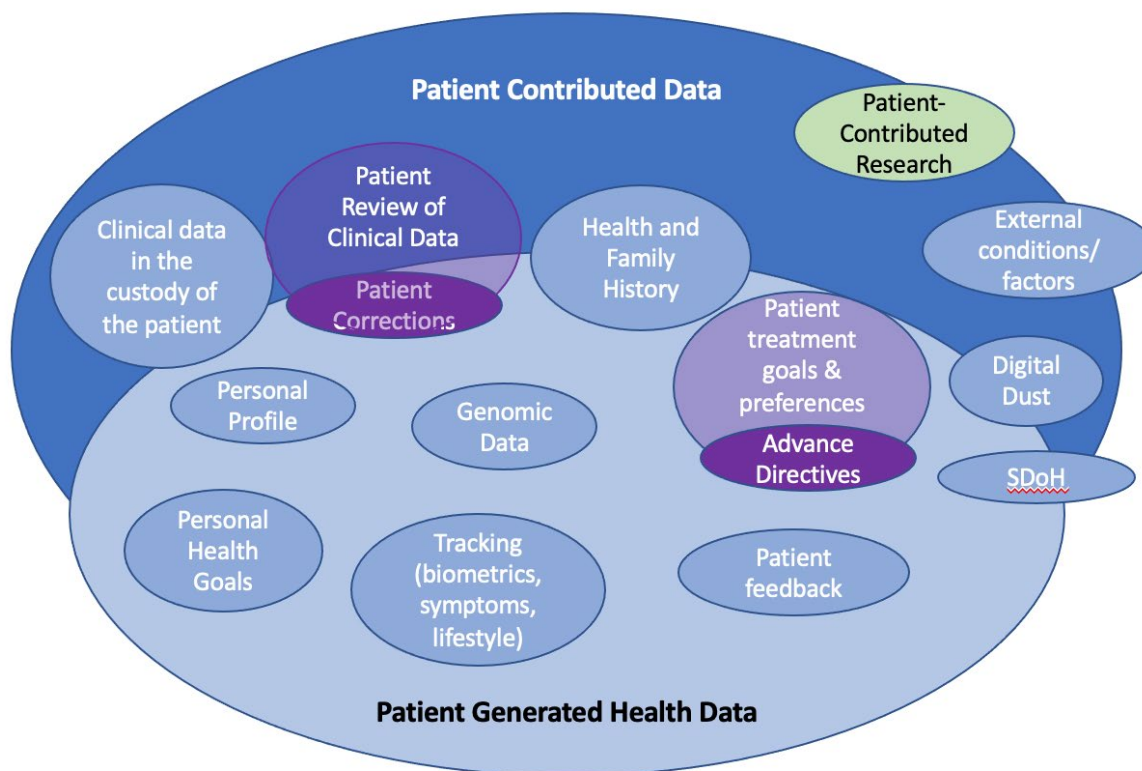


- The person may choose to share all or part of their data with various members of their distributed healthcare team, with family members and friends, or with researchers.
- A broad list of types of PCD is included in Table 1 at the end of this section. Because some patient contributed data overlaps with data produced in a medical context. We propose a set of descriptors for patient contributed data that can inform and illustrate the richness of PCD and the effort needed to incorporate it into clinical practice in meaningful ways. (See Chapter 9: Descriptors for this approach to analysis of PCD.)
- While the ONC definition of PGHD explicitly *excludes* data collected in a clinical setting and through encounters with providers, our definition includes some of that data with the following clarifications:
  - Data from a patient-completed medical or family history may be gathered and recorded in a clinical setting but often is contributed by the individual.
  - Patient values, priorities, and preferences that are documented in a clinical setting verbatim, and do not include the perspective of or interpretation by the clinician, should be considered PCD.
  - A patient may be the custodian of data from previous clinical settings. This will become more common since the establishment of rules associated with the 21<sup>st</sup> Century Cures Act, which requires certified EHRs and providers “to publish APIs that allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law.”<sup>9</sup> We consider such patient-directed exchange of clinical data between care providers to be PCD.
- Patient contributed data may also include data that is sent automatically to providers from devices, implants, sensors, and wearables. While such data are often categorized as device-contributed data, they are generated by the individual’s body and should, we believe, be considered “patient contributed” whether the process is active or passive. We make this distinction in part to clarify that individuals should be able to consent to sharing such data as well as determining who should receive it.
- Our definition emphasizes data that is shared within a healthcare environment. While the emphasis is on sharing, data that individuals track for themselves is included even if it is not shared with a health professional. We are interested in strategies that determine how such data can be used in collaboration with clinical care teams and researchers to enhance understanding, diagnosis, treatment, and collaboration between patients and clinical care teams.

The distinction we are drawing between Patient Generated Health Data (PGHD) and Patient Contributed Data (PCD) is best understood through the following Venn Diagram.

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<sup>9</sup> <https://www.federalregister.gov/d/2020-07419/p-245>



**Figure 2. Venn Diagram of PCD in relation to PGHD**

Note that Patient Corrections and Patient Treatment Goals and Preferences are highlighted in purple because HL7 teams are working on Implementation Guides to specifically address these areas. Both are also chartered by the Patient Empowerment Workgroup.

Discussion of the data in the Venn Diagram is expanded in the next chart. Some of this data can only come from the individual. Some of it is also collected in clinical settings, but the source, provenance, and frequency may be different than when it is patient-contributed or generated. For example, blood pressure may be collected in any clinical encounter. A person may also track, trend, and report blood pressure at home, on a device of their choosing or one distributed by their doctor. Devices that collect data may be connected to apps that add visual depictions or insights. For these reasons, when we are discussing person contributed data (PCD), metadata, particularly provenance, assumes extra importance. The chart below is adapted from a chart included in “Integrating patient voices into health information for self-care and patient-clinician partnerships: Veterans Affairs design recommendations for patient-generated data applications.”<sup>10</sup> It also incorporates social determinants of health (SDoH) concepts emanating

<sup>10</sup> Woods SS, Evans NC, Frisbee KL, Integrating patient voices into health information for self-care and patient-clinician partnerships: Veterans Affairs design recommendations for patient-generated data applications, *Journal of the American Medical Informatics Association*, Volume 23, Issue 3, May 2016, Pages 491–495, <https://doi.org/10.1093/jamia/ocv199>

from the Gravity Project.<sup>11</sup> We have also prepared in Chapter 9: Descriptors, the start of a taxonomy for describing PCD that's inspired by the SNOMED CT Concept Model.

Data Category	Data Type	Example Data Elements
Personal Profile and Administrative Preferences	Personal Profile	<ul style="list-style-type: none"> <li>• Life goals</li> <li>• Values (“who I am,” “what matters to me”)</li> <li>• Preferred name and pronouns</li> <li>• Caregiver(s)</li> <li>• Photograph</li> </ul>
	Personal (administrative) Preferences	<ul style="list-style-type: none"> <li>• Notifications (e.g., text reminders, broadcast messaging)</li> <li>• Communication (e.g., secure email, online communities, language preferences, communication frequency, preferred communication type)</li> <li>• Delegation or individual(s) acting on the patient's behalf</li> <li>• Privacy preferences</li> </ul>
	Administrative Data	<ul style="list-style-type: none"> <li>• Demographics</li> <li>• Contact information</li> <li>• Caregivers/Care Partners</li> </ul>
Personal Goals	Personal Health Goals	Personal statement of health goals, which may or may not be clinical in nature. These goals may reflect health impacts on lifestyle (I want to dance at my daughter's wedding or I want to be able to walk to church)
	Patient Treatment Goals and Preferences	<ul style="list-style-type: none"> <li>• Patient goals for care (may be condition specific)</li> <li>• Advanced directive(s)</li> <li>• Treatment preferences (e.g., less medication or physical therapy rather than surgery)</li> <li>• Episode of care plans (e.g., how to handle a condition exacerbation)</li> <li>• Personal goals (as distinguished from clinical goals for the patient)</li> </ul>
	Patient Agenda	<ul style="list-style-type: none"> <li>• Pre-visit agenda identifying issues and needs</li> </ul>
Clinical Care Goals	Clinical Care Goal(s)	<ul style="list-style-type: none"> <li>• Specific steps or SMART goals</li> <li>• Patient comments on healthcare team goals</li> <li>• Created by the clinical team</li> </ul>

<sup>11</sup> [https://www.healthit.gov/sites/default/files/facas/2021-04-08\\_Gravity\\_Project\\_Presentation.pdf](https://www.healthit.gov/sites/default/files/facas/2021-04-08_Gravity_Project_Presentation.pdf)

<b>Data Category</b>	<b>Data Type</b>	<b>Example Data Elements</b>
Health History	Health History	<p>Supplemental medical, surgical, and military history, such as:</p> <ul style="list-style-type: none"> <li>• Conditions</li> <li>• Procedures</li> <li>• Symptoms</li> <li>• Therapies</li> <li>• Regimens</li> <li>• Treatments</li> <li>• Immunizations</li> <li>• Allergies</li> <li>• Previous medications.</li> </ul> <p>Note: may be relayed orally, written, or the result of an API-based download from a provider EHR</p>
	Family History	Supplemental family history
	Medication Information	<ul style="list-style-type: none"> <li>• Prescription medication information, externally prescribed and/or obtained</li> <li>• Over-the-counter medications and supplements</li> </ul>
	Health information held in the custody of the patient	<p>This is information encompasses the following:</p> <ul style="list-style-type: none"> <li>• Documents</li> <li>• Electronic data generated from APIs created from EHR data</li> <li>• Relevant documents such as previous reports or images</li> </ul>
Patient Feedback	Health Assessment	<ul style="list-style-type: none"> <li>• Health risk appraisal (HRA)</li> <li>• Condition screenings</li> </ul>
	Patient Experience(s)	<ul style="list-style-type: none"> <li>• Patient satisfaction with their care or the customer experience</li> </ul>
	Patient Reported Outcomes	<ul style="list-style-type: none"> <li>• Condition, quality of life, or experience assessment</li> <li>• Treatment or therapy follow-up</li> </ul>
	Patient Review of Health Data	<ul style="list-style-type: none"> <li>• Patient comments on review of health record data such as medications, allergies, problem list, notes</li> <li>• Requests for corrections</li> </ul>

Data Category	Data Type	Example Data Elements
Personal Data Tracking	Biometric Tracking	<ul style="list-style-type: none"> <li>Blood pressure, pulse, weight, blood glucose level, temperature, peak flows, sleep, etc.</li> <li>Biometric data uploaded via app or device</li> </ul> <p>Note: this category refers to data that can be tracked numerically on some sort of generally-accepted measures</p>
	Symptom Tracking	<ul style="list-style-type: none"> <li>Symptoms, condition reporting, exacerbations, or side effects</li> <li>Patient-reported targeted assessments</li> <li>Pain level tracking</li> </ul> <p>Note: some symptoms may be tracked as biometric data but it primarily incorporates more qualitative measures, even if they are on a numeric scale</p>
	Lifestyle Tracking	<ul style="list-style-type: none"> <li>Diet, exercise or sleep tracking</li> <li>Social interaction tracking</li> <li>Personal behaviors and habits (such as smoking, alcohol use, reported exercise)</li> <li>Mood tracking</li> </ul>
	Multimedia Observations	Photograph or video assessment to support a healthcare visit or provide as a component of care
Genomic Data		This constitutes a person's genomic information, which may be collected by a health professional in the context of health care or may be contributed by individuals who have contracted to have their genome tested directly.
Digital Dust		Digital Dust is generated as a byproduct of consumers' daily Activities. It includes social media posts, Internet search histories, location and proximity data. This data is frequently harvested for marketing purposes, but also may be used to derive health status, such as depression or mood. Despite being derived from an individual's actions, there's little current privacy protection or consent requirements over use of this data in healthcare settings.
External Data		Data that may correlate to an individual's symptoms or mood (e.g., someone's symptoms may be correlated to such things as weather, pollen count, pollution index, etc.)

Data Category	Data Type	Example Data Elements
Social Determinants of Health (SDoH)		<ul style="list-style-type: none"> <li>• Food, transportation, job, housing, or financial insecurity or inadequacy</li> <li>• Lives in a food desert</li> <li>• Lives in an area with environmental pollution, wildfires, water shortages, etc.</li> <li>• Family or intimate partner violence</li> <li>• Stress</li> <li>• Lack of access to quality education</li> <li>• Social isolation</li> <li>• Racism</li> </ul> <p>Note: These are a mix of patient-contributed and demographic information</p>

**Table 1. PCD Data Categories and Data Types**

In 2017 ONC commissioned Accenture to “develop a white paper on the capture, use, and sharing of PGHD in care delivery and research settings through 2024 that can be leveraged to create a PGHD policy framework.”<sup>12</sup> Although the execution of these ideas has somewhat stalled, the execution of the vision framed in the white paper is important to support the ongoing implementation and use of PCD.

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<sup>12</sup> [https://www.healthit.gov/sites/default/files/onc\\_pghd\\_final\\_white\\_paper.pdf](https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf)

## Chapter 5: The Health Data Ecosystem

The collection of health data for managing problems, keeping track of preventative activities and services, maintaining personal longitudinal health data, and proactively managing health involves a complex ecosystem that includes many entities, actors, and tools. An individual might see dozens of different providers over a lifetime, determined by changes in jobs, geography, insurance carrier, or fluctuations in health status. Each provider might have a set of records and maybe a portal for patients to view, download, or contribute data. Harmonizing these data across various providers and systems creates an enormous burden for an individual. Moreover, with growing technological innovations, individuals are increasingly monitoring their health through wearables, apps, implanted devices, or manual tracking. There is also growing interest in sharing these data and goals with caregivers and providers. These factors, in part, have contributed to an evolving and complex health data ecosystem that is becoming more person-centric to facilitate individual access, personalized decision-making, and insights derived from personal health data.



Figure 3. The evolving health data ecosystem (Source: Vayena et al.)



Recently, there have been numerous policies and global initiatives to improve patient access and engagement with their health data. In the US, regulations including Meaningful Use, 21<sup>st</sup> Century Cures Act, and the Interoperability and Patient Access final rule have sought to facilitate access to medical records to improve population health.<sup>13,14,15</sup> A recent component of the legislation focuses on allowing patients to use a third-party app of their choice to engage with their health information. This has led to a growing number of tools and service entities that support patients in accessing, organizing, and sharing their own health information.

Individual access to health data has also been a primary component of the EU strategy for the digital transformation of health and care. However, as health systems across the EU are national or regional in nature, with no direct involvement at the EU level, coordination and regulation in the area of digital health has been on a voluntary basis only, such as the European eHealth Network.<sup>16</sup> Much has been achieved within the boundaries of national health systems, but each with a slightly different aim and with different tools. This will likely change with the proposed regulation on the European Health Data Space, which cites as its main aim *"to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalized medicine, official statistics or regulatory activities (secondary use of electronic health data)."*<sup>17</sup>

Several global digital health initiatives have also launched to improve access and use of personal health data. For example, the Global Health Digital Partnership is a collaborative effort between 30 countries and the World Health Organization to support digital health implementation, share global best practices, and multinational projects to advance health.<sup>18</sup> As part of this partnership, the HL7 International Patient Summary was created, which is an electronic health record that contains essential data elements that can be accessed and used across country borders.<sup>19</sup> The EU and US established a collaboration on health IT and eHealth

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<sup>13</sup> Office of the National Coordinator for Health Information Technology. Health IT Legislation. 2021. <https://www.healthit.gov/topic/laws-regulation-and-policy/health-it-legislation>

<sup>14</sup> Office of the National Coordinator for Health Information Technology. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. 2020. <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>

<sup>15</sup> Centers for Medicare & Medicaid Services. Interoperability and Patient Access. 2020. <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

<sup>16</sup> European Commission. eHealth Network. 2022. [https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/eu-cooperation/ehealth-network_en)

<sup>17</sup> European Commission. Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. 2022. <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022PC0197&from=EN>

<sup>18</sup> Office of the National Coordinator for Health Information Technology. The Global Digital Health Partnership. 2021. <https://www.healthit.gov/topic/global-digital-health-partnership>

<sup>19</sup> Office of the National Coordinator for Health Information Technology. International Patient Summary. 2021. <https://www.healthit.gov/topic/global-digital-health-partnership/international-patient-summary>



towards empowering individuals and improving health outcomes.<sup>20</sup> This effort focuses on improving transnational interoperability, workforce development, and fostering digital health innovation.

In addition to the regulatory efforts and global health collaborations, the health data ecosystem has advanced with technological innovations and the proliferation of consumer-facing apps. Patients are generating and interacting with data from apps to manage their health and wellness, and memorialize their personal values, preferences and priorities for care which may also impact future care delivery. Patient-targeted health and clinical decision support (CDS) is happening on phones at the point of data collection for health improvement (e.g., “You have not walked enough steps today to meet your goal.”). A number of apps and wearables send behavioral nudges to promote wellbeing, a few of which are personalized based on an individual’s unique baseline. There is increasing use of patient-focused CDS for detection of cardiac abnormalities<sup>21,22</sup> and management of chronic conditions.<sup>23</sup> Some of these apps are condition-specific and may be customized to track symptoms over time or facilitate comparisons with other data (e.g., environment, dietary intake, sleep) to determine specific triggers.<sup>24</sup>

CDS tools that incorporate patient contributed data in combination with EHR data may be valuable for shared decision making and improved patient outcomes. Research has demonstrated the value in this type of data for certain conditions, such as hypertension, where at-home measurements sent to a provider were associated with improvements in clinical biomarkers.<sup>25</sup> While data standards promoted by the ONC address traditional EHR data types (e.g., medication lists, allergies, immunizations, tests results), these data and many other types of patient contributed data are not captured using current standards when collected by patients. There may also be overlaps in clinical and self-reported data, such as blood pressure or blood glucose, but it is unclear if at-home devices follow the same standards for storing and transmitting data as compared to those used in clinical settings.

### **From a Personal Health Record to a Personal Health Environment**

- Historically, patients and families have used paper documents or low technology approaches to store medical records and monitor their health, such as wallet cards,

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<sup>20</sup> Office of the National Coordinator for Health Information Technology. Collaboration with the EU. 2020. <https://www.healthit.gov/topic/collaboration-european-union>

<sup>21</sup> Lubitz SA, Faranesh AZ, Atlas SJ, McManus DD, Singer DE, Pagoto S, Pantelopoulos A, Foulkes AS. Rationale and design of a large population study to validate software for the assessment of atrial fibrillation from data acquired by a consumer tracker or smartwatch: The Fitbit heart study. *Am Heart J*. 2021 Aug;238:16-26.

<sup>22</sup> Google. New Fitbit feature makes AFib detection more accessible. 2022. <https://blog.google/products/fitbit/irregular-heart-rhythm-notifications/>

<sup>23</sup> Wu Y, Zhou Y, Wang X, Zhang Q, Yao X, Li X, Li J, Tian H, Li S. A Comparison of Functional Features in Chinese and US Mobile Apps for Diabetes Self-Management: A Systematic Search in App Stores and Content Analysis. *JMIR Mhealth Uhealth*. 2019 Aug 28;7(8):e13971.

<sup>24</sup> ImproveCareNow. IBD Resources. 2022. <https://www.improvecarenow.org/tools>

<sup>25</sup> Kalagara R, Chennareddy S, Scaggiante J, et al. Blood pressure management through application-based telehealth platforms: a systematic review and meta-analysis. *J Hypertens*. 2022 Jul 1;40(7):1249-1256.

“baby books,” USB flash drives, or spreadsheets. With the rising volume of electronic data across disparate systems, personal health records (PHR) have emerged as one of most mature approaches for managing health information. Nearly two decades ago, the Markle Foundation’s Personal Health workgroup convened to discuss the state-of-the-art in managing personal health information. The workgroup defined the PHR as “an electronic application through which individuals can access, manage and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment.” Their early vision was that PHRs would enable individuals to access and coordinate comprehensive, lifelong health information and exchange necessary parts of it.<sup>26</sup>

Currently, there are a number of PHRs that support different aspects of health information management and exchange. Based on their functionality, PHRs can be categorized into three types of systems: standalone, tethered, and interconnected.<sup>27,28</sup>

- **Standalone PHRs** require users to manually input and maintain their personal health information. These standalone systems lack interoperability but do allow for portability where users could manually import or export data to/from other systems.
- **Tethered PHRs** are usually an extension of a health care system’s EHR and are often referred to as patient portals. Tethered PHRs typically allow patients to view their health history, send secure messages to their care team, view test results, refill prescriptions, upload external provider test results or other documents, and schedule appointments. Data are controlled by the health care system which limits health record portability and these systems may not be interoperable with other health information systems.
- **Interconnected PHRs** support data from various sources such as EHRs, health insurance plans, and pharmacies. Data can be consolidated across different health systems and users can also input data. Because of these advanced functionalities around data control, data portability, and interoperability, interconnected PHRs are considered the most patient-centric type of PHR system. PHRs have traditionally been more commonly used in the EU and elsewhere than the US, as difficulties with data interoperability have stalled their use.

With the growing adoption of data standards such as FHIR, recent innovations have focused on interconnected PHRs and environments that allow individuals to combine data from various sources and contribute their own data. For example, Apple’s Health app allows users to aggregate their health records from multiple health systems and include patient contributed data, such as physical activity or blood pressure values. The Health app is currently available in the UK, Canada, and the US, and patients can share app data with select providers.<sup>29</sup> Similarly,

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<sup>26</sup> The Personal Health Working Group. A public-private collaborative: final report. Markle Foundation’s Connecting for Health 2003:1-58. <https://markle.org/publications/1429-personal-health-working-group-final-report/>

<sup>27</sup> Tang PC, Ash JS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. J Am Med Inform Assoc. 2006 Mar-Apr;13(2):121-6.

<sup>28</sup> Detmer D, Bloomrosen M, Raymond B, Tang P. Integrated personal health records: transformative tools for consumer-centric care. BMC Med Inform Decis Mak. 2008 Oct 6;8:45.

<sup>29</sup> Apple. Health Records. 2022. <https://www.apple.com/healthcare/health-records/>

CommonHealth is the Android complement to the Apple Health app.<sup>30</sup> OneRecord allows integration of both health records and claims data, which is available on iOS, Android, and the web.<sup>31</sup> The Patients Know Best initiative in the UK also provides a location to add, access, and share health information with care teams or caregivers. It is available through the web, mobile, and NHS app and supports connections to wearable devices and symptom monitoring.<sup>32</sup> In the Netherlands, the notion of a *personal health environment* was introduced, which moves beyond a medical record towards a space where individuals have access to their clinical data, can perform meaningful actions, and combine it with additional data they might be tracking from home. The Dutch Patient Federation “PHE on Air” program encourages people to engage with and choose their personal health environment.<sup>33</sup>

In alignment with our vision, leveraging a personal health environment allows individuals to collect and store personal health data longitudinally. This supports patients in sharing data with other health care institutions and performing independent analyses on combinations of their health data from various sources. HL7’s PHR workgroup focuses on supporting functional and information requirements for PHRs and PHR systems (PHR-S). Of note, the HL7 PHR workgroup differentiates the PHR and PHR System (PHR-S). The PHR is described as the underlying record (e.g., data, information, images, videos, graphs) that is maintained through the software functionality of the PHR-S. In this paper, we do not differentiate between PHR and PHR-S but collectively refer to both the underlying record and software functionality as a “PHR” unless in the context of an HL7 Functional Model.

The HL7 PHR-S Functional Model (PHR-S FM) defines a standardized model of the functions and conformance criteria that may be present in the PHR-S.<sup>34</sup> Information is expected to be sent, received, or exchanged from multiple systems, such as EHRs, payers, pharmacies, health information exchanges, public health, or clinical trials systems. Developed in harmony with the HL7 EHR-S FM, the PHR-S FM (release 2, 2021) contains four core sections: 1) personal health, 2) supportive, 3) record infrastructure, and 4) trust infrastructure. Each section below contains a list of functions to provide a framework and common understanding of tools that can be expected to be implemented in PHRs.

1) Personal health functions enable individuals to manage information about their healthcare. These functions are designed to encourage and allow an individual to participate actively in their healthcare and better access the resources for self-education and monitoring.

- Personal health
- PHR account holder profile
- Manage historical clinical data and current state data

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<sup>30</sup> CommonHealth. 2022. <https://www.commonhealth.org/>

<sup>31</sup> OneRecord. 2022. <https://onerecord.com/>

<sup>32</sup> Patients Know Best. 2022. <https://patientsknowbest.com/>

<sup>33</sup> Netherland Patient Federation. PGO on Air. <https://www.patientenfederatie.nl/pgo-on-air>

<sup>34</sup> HL7 EHRS-FM Release 2: Personal Health Record System Functional Model, Release 2. 2021. [https://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=88](https://www.hl7.org/implement/standards/product_brief.cfm?product_id=88)describe

- Wellness, preventative medicine, and self-care
- Specify personal health goals or provide information about cultural, religious, or spiritual preferences that should shape care received
- Manage health education
- PHR account holder decision support
- Manage encounters with providers

2) Supportive functions assist with the administrative and financial requirements associated with the delivery of healthcare and provide input to systems that perform medical research and promote public health.

- Provider Information
- Financial management
- Administration management
- Manage other resources

3) Record infrastructure consists of functions common to EHR-S record management, particularly those functions foundational to managing record lifecycle (e.g., origination, attestation, amendment, access/use, translation, de-identification, archive) and record lifespan (e.g., persistence, continuity, audit, encryption).

- Record lifecycle and lifespan
- Record synchronization
- Record archive and restore

4) Trust infrastructure consists of functions common to a PHR-S infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems.

- Security
- Audit
- Registry and directory services
- Standard terminology and terminology services
- Standards-based interoperability
- Business rules management
- Workflow management
- Database backup and recovery
- System management operations and performance
- Standard or preferred clinical models and clinical model services

The PHR-S FM starts to encompass many functionalities of a personal health environment, but will likely need to incorporate additional components around patient contributed data. These components might include functions to standardize, aggregate, and facilitate insights from heterogeneous data streams for patients and their care teams. Much progress is underway driven by recent initiatives and policies that promote access to data and standardization. These standards support innovative tool development that aggregate data from multiple sources and

interact with user-friendly analytic tools. The increasing role of patients in personal health management and the notion of a personal health environment can lead to a paradigm shift, where patients move beyond access to data and additionally have the opportunity to manage, control, and use that data to better their health.

## **Recommendations**

To bring our vision of a personal health environment to fruition, we recommend including additional components that would extend those of the PHR-S FM. These functionalities include (but are not limited to):

- De-duplication and harmonization of clinical data when pulled from various sources using APIs
- Data curation for communicating one's health story to new care teams or others including visualization and timeline tools
- Incorporation of PCD measurements and correlations with health exacerbations or external data (e.g., pollen counts, ambient temperature, air quality, etc.)
- Patient-mediated data exchange where an individual selects which data to share and with whom to share it
- Development of additional data standards for personal health data (e.g., wearable, environmental, behavioral data, etc.)
- Effective health information management privacy and security safeguards

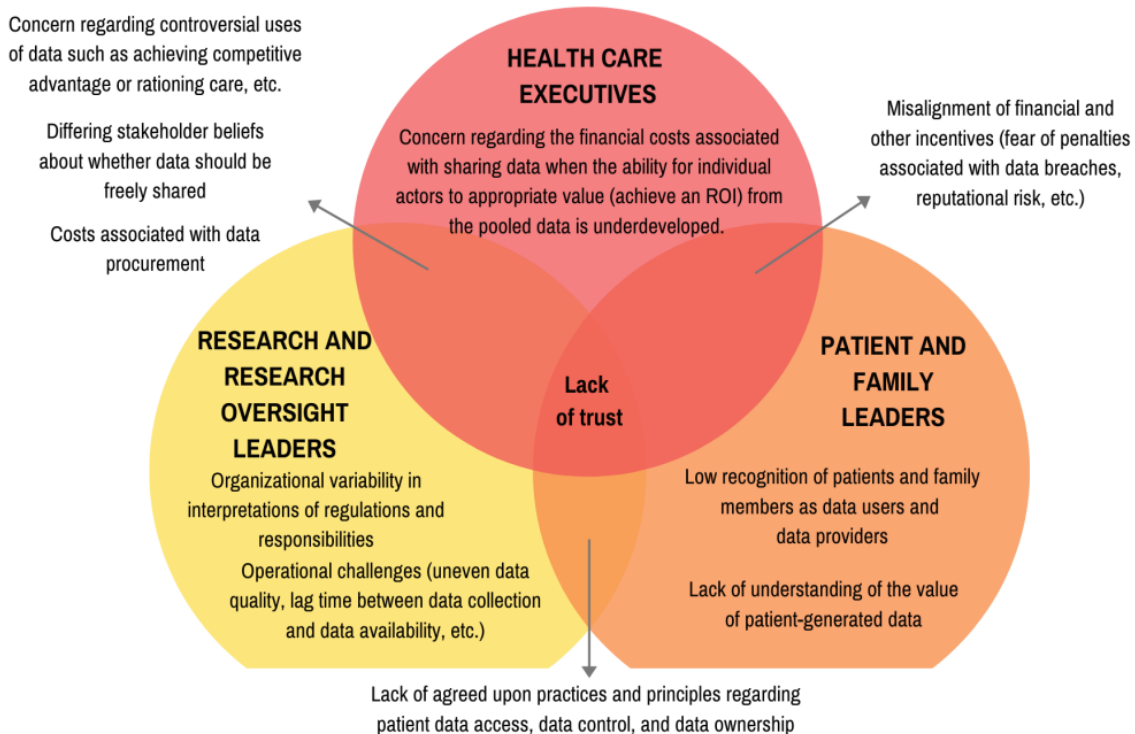
## **Summary**

Personal health management is facilitated by both clinical data and patient contributed data. Early advancements in personal health management primarily focused on the PHR-S, and there are an increasing number of health tracking tools that now also support health management. We expect the existing health data ecosystem to continue evolving over time, with novel patient-directed tools for health improvement and disease management that include more complete data. We propose that patients are the best positioned, and arguably the most motivated, to identify the many sources of health care received and health data accrued over their life. However, reducing the individual burden of complex data management tasks with a person-controlled health data ecosystem would support improved health outcomes and scientific discovery. This drives our vision for a broader personal health environment, which will require developing and optimizing existing tools, regulations, and standards across the growing volume and variation of personal health data.

## Chapter 6: Principles Regarding PCD

PCD includes various types of data ranging from device-contributed data to parts from the EHR (see Chapter 2: Definitions). These solicited or unsolicited data are widely exchanged between person/patient (or caregivers), care team members, and researchers within the PCD ecosystem (see Chapter 5: The Health Data Ecosystem). For seamless exchange of PCD between all parties, a rigorous PCD governance framework should be implemented and monitored on a regular basis. This framework should equally balance between protection of persons, PCD sharing and interoperability (see Chapter 7: PCD Standards Overview) for enhancing healthcare services and promoting innovation.

The National Academy of Medicine's (NAM) Leadership Consortium: Collaboration for a Learning Health System addressed the lack of agreed upon principles regarding data ownership, stewardship, governance, rights, and responsibilities as shown in Figure 4.<sup>35</sup>



**Figure 4. Cultural, ethical, regulatory, and financial barriers to data sharing, linkage, and use**  
(Source: Whicher et al.)

This NAM Leadership Consortium identified the core ten principles for stewards of the digital health infrastructure and data to be: personal, safe, effective, equitable, efficient, accessible,

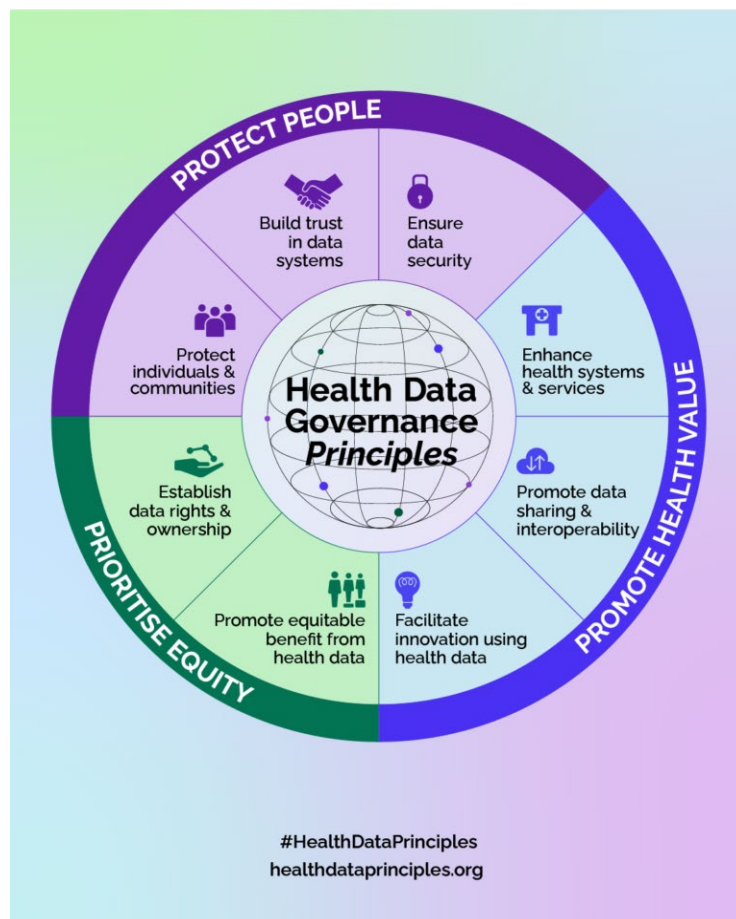
<sup>35</sup> Whicher D, Ahmed M, Siddiqi S, Adams I, Zirkle M, Grossmann C, Carman KL, Editors. 2021. Health Data Sharing to Support Better Outcomes: Building a Foundation of Stakeholder Trust. NAM Special Publication. Washington, DC: National Academy of Medicine.



measurable, transparent, adaptive, and secure.<sup>36</sup> These principles are also comprehensively covered by the recently launched Health Data Governance Principles as described in this chapter.

## Health Data Governance Principles

On April 7, 2022 (World Health Day), the Health Data Governance Principles (<https://healthdataprinciples.org/principles.html>) were launched as the first global set of principles that guide the use of data in health systems. More than 200 digital health experts have developed these Principles from 130 global organizations.



**Figure 5. Health data governance principles**

The Principles are grounded in human rights and equity to support public health systems that can deliver health to all. Thus, they balance the rights of individuals with the rights of

<sup>36</sup> Abernethy A, Adams L, Barrett M, Bechtel C, Brennan P, Butte A, Faulkner J, Fontaine E, Friedhoff S, Halamka J, Howell M, Johnson K, Lee P, Long P, McGraw D, Miller R, Perlin J, Rucker D, Sandy L, Savage L, Stump L, Tang P, Topol E, Tuckson R, Valdes K. 2022. The Promise of Digital Health: Then, Now, and the Future. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/202206e>.

organizations and public health. This creates a common vision where all people and communities can share, use and benefit from health data.

The Principles are clustered around three key objectives: protect people, promote health value, and prioritize equity. These Principles should be supported by the national regulatory framework for health data governance. We use the Health Data Governance Principles to develop a guiding framework for creating a comprehensive strategy for PCD sharing, privacy, and governance (Table 2, below).

<b>Governance Principles</b>	<b>Objectives</b>	<b>Selected core elements and recommendations</b>
<b>Prioritize equity</b>	Objective 1: Prioritize equity through establishing PCD data rights and ownership	<ul style="list-style-type: none"> <li>- Define clear governance roles and responsibilities</li> <li>- Codify PCD rights and ownership</li> <li>- Extend data rights and ownership to products and services</li> </ul>
	<u>Guiding examples:</u> PGHD governance across regulatory regimes in the U.S  <u>Used framework:</u> EU GDPR	<u>Recommendations:</u> Establishing PCD rights and ownership needs to move from a dependence on regional data regulation toward new generic data protection laws, similar to the GDPR in the EU.
<b>Protect people</b>	Objective 2: Protect people through building trust and representing the patients' perspective on PCD	<ul style="list-style-type: none"> <li>- Establish transparent and accessible PCD processes and systems</li> <li>- Ensure patients are included in guidance and decision-making regarding PCD policies and data use</li> </ul>
	<u>Guiding example:</u> Digital Health Europe project  <u>Used tool:</u> The Data Futures Partnership in New Zealand	<u>Recommendations:</u> Building trust is the cornerstone of data sharing. This requires creating buy-in from stakeholders and introducing a framework for citizen-controlled data sharing.
<b>Promote health value</b>	Objective 3: Promote health value through enhancing systems and services representing the health system's perspective on PCD	<ul style="list-style-type: none"> <li>- Evaluate the benefits of PCD</li> <li>- Promote data sharing and PCD interoperability</li> <li>- Facilitate innovation using PCD</li> </ul>



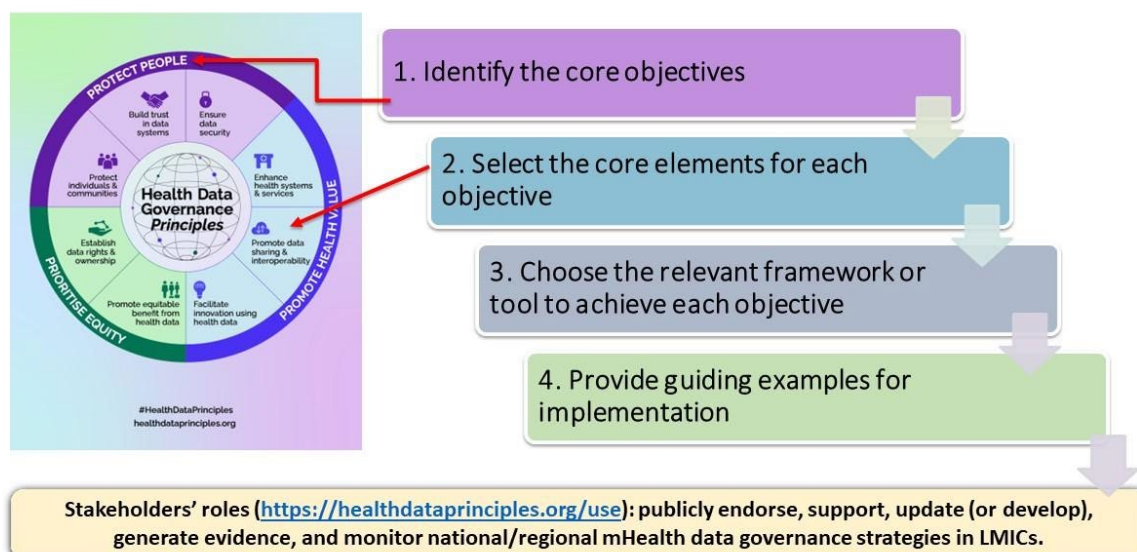
	<p><u>Guiding examples:</u></p> <ul style="list-style-type: none"> <li>- Principles and norms governing responsible data sharing in international health research</li> <li>- Principles for better data interoperability in healthcare</li> </ul> <p><u>Used tool:</u> The WHO guidance on the ethics and governance of AI in health.</p>	<p><u>Recommendations:</u> Providing new real-time rich-data PCD is to clinical care will promote innovation and requires:</p> <ul style="list-style-type: none"> <li>- catering a governing framework for data sharing in international health research.</li> <li>- having better use of data through data interoperability and collaboration between stakeholders</li> <li>- developing a governance environment for AI and big PCD analytics, such as the WHO's guidance on ethics and governance of AI in health.</li> </ul>
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**Table 2. PCD Governance Mapped to Health Data Governance Principles**

We also applied the same approach to provide a guiding framework for creating a comprehensive strategy for mHealth data sharing, privacy, and governance in Low- and Middle-Income Countries (LMICs). This customized framework for mHealth data governance in LMICs has been accepted as a perspective article for the journal of the American Medical Informatics Association (JAMIA) publication. It will be published in the JAMIA focus Issue for the “Global Health Informatics: Advancing health informatics research and applications globally in a COVID-19 pandemic world” by December 2022. The detailed methodology is illustrated in the graphical abstract of the submitted perspective (Figure 6).



A guiding framework for creating a comprehensive strategy for mHealth data sharing, privacy, and governance in low- and middle-income countries (LMICs)



**Figure 6. Graphical abstract of the JAMIA submitted perspective**

The following sections provide more details about the PCD framework objectives.

## **Objective 1: Prioritize equity through establishing PCD rights and ownership**

PCD governance should be based on strong and clear data-related rights, such as the EU PGHD General Data Protection Regulation (GDPR) and the discussion draft on the American Data Privacy and Protection Act (ADPPA).<sup>37</sup> Under the GDPR law, the individual owns the rights to their data (**citizens have rights to control their data, which differs from data ownership**). This also matches with the US draft federal privacy bill (sec. 203. individual data ownership and control).<sup>38</sup> We should also consider human rights, including the right to protection and safety and the right to benefit equitably from data contributed, both at individual and community levels.

### *Define clear PCD governance roles and responsibilities*

To ensure PCD rights and ownership, it is essential to define various PCD roles wherever health data is stored, including *data owner, data custodian, data processor, data steward, data trustee, and data use beneficiary*. Identifying these roles should clarify who has the right to do what and who must ensure these rights are upheld.

As per our definition of PCD (see Chapter 2: Definitions), we need to adopt a PCD regulatory framework (using the existing data governance guidelines in HIPAA and GDPR) to identify:

- The rights and the roles of the PCD main actors (a person, family members, other informal caregivers, and healthcare providers).
- ownership of different types of the PCD data (Patient-Generated Health Data (PGHD), medical records, etc.)

### *Codify PCD rights and ownership*

The identified rights and ownership should be codified in legislation and policy in alignment with current national (regional or global) data protection regulations frameworks. These will include definitions of ownership, such as:

- PCD is owned by the individual (mainly the PGHD), community providing the data, healthcare providers (EHR).
- Rights associated with PCD include such things as the right to control the use of data, the right to decline participation in data collection, the right to withdraw data from a system, the right to obtain benefit from your own data.

PCD ownership implies that individuals have a right to know, determine, and control how their data are used, and to benefit equitably from such data. The right to access data may be different from owning that data according to PCD data type and the linked PCD stakeholders' roles and responsibilities.

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<sup>37</sup> <https://www.commerce.senate.gov/2022/6/what-they-are-saying-american-data-privacy-and-protection-act>

<sup>38</sup> <https://www.commerce.senate.gov/services/files/9BA7EF5C-7554-4DF2-AD05-AD940E2B3E50>

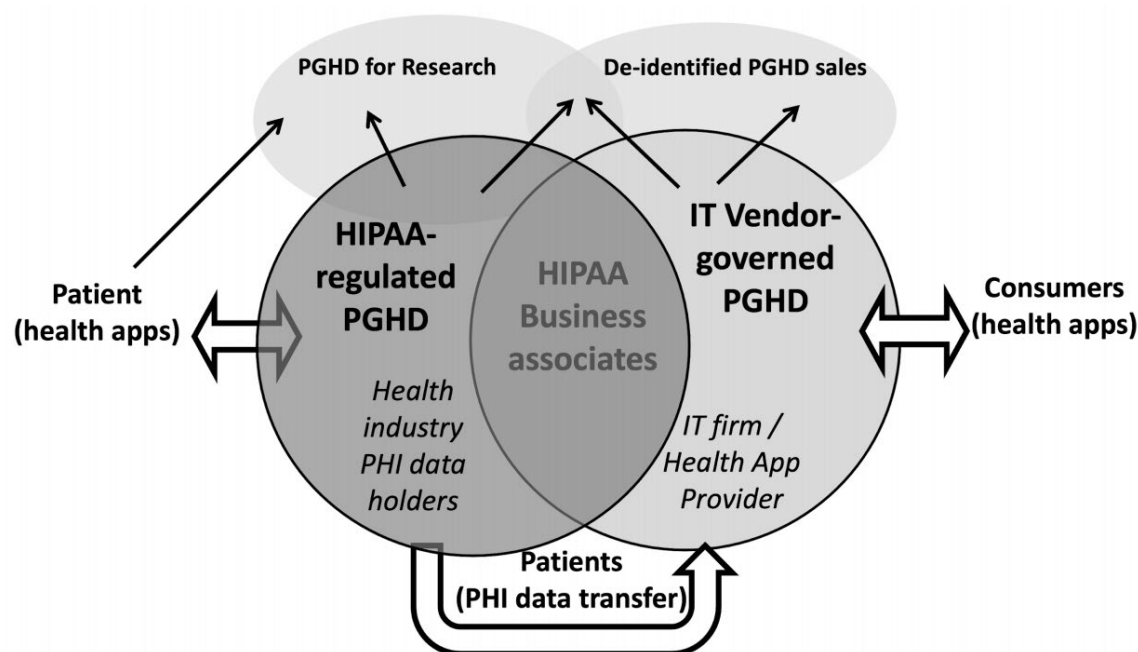
### *Extend data rights and ownership to products and services*

The identified PCD rights and ownership should be extended to related products and services created from such data, such as Artificial Intelligence (AI). This means that the secondary use of PCD data in research, such as creating AI tools, should also not be used to cause harm to individuals or communities.

Similarly, individual and community ownership over their data extends to the right to equitable benefit-sharing from the products and services built from their contributed data. These services may include behavioral phenotyping and targeting individuals with similar behaviors.

### Guiding example

Winter et al. addressed the challenges and opportunities with governance of PGHD for patient care or research.<sup>39</sup> They highlighted that PGHD and PCD may be created outside the clinical setting and governed by mHealth technology providers' privacy policies and intellectual property rights. Consequently, they fall outside of conventional health data regulations (like HIPAA), until PGHD are integrated into a clinician's HIT systems, when governance of incorporated PGHD falls under HIPAA regulations. Meanwhile, patients can access, control, and share their data with their healthcare providers. With more PGHD interoperability and no proper governance regime, PGHD can be transferred, sold or used beyond the control of the individuals in non-beneficial (or even harmful) ways.



**Figure 7. PGHD governance across regulatory regimes in the U.S. (Source: Winter et al.)**

<sup>39</sup> Winter J, Davidson E. Harmonizing Regulatory Spheres to Overcome Challenges for Governance of Patient-Generated Health Data in the Age of Artificial Intelligence and Big Data (December 15, 2020). TPRC48: The 48th Research Conference on Communication, Information and Internet Policy, Available at SSRN: <https://ssrn.com/abstract=3749529> or <http://dx.doi.org/10.2139/ssrn.3749529>.

The EU GDPR<sup>40</sup> stimulated a global discussion about data privacy and protection and specified how organizations must deal with personal identified data. Currently, many jurisdictions are moving towards GDPR-compatible regimes. Winter et al. explored three existing data protection regimes relevant to PGHD in the United States that are currently in tension with one another: federal and state health-sector laws, data use and reuse for research and innovation, and industry self-regulation by large tech companies. They then identified three types of structures (organizational, regulatory, technological/algorithmic). The US might also move from a dependence on regional data regulation toward a new generic data protection law, such as the recently introduced Federal Privacy law. Table 3 summarizes the main GDPR principles and individuals' rights. However, national rules for health data processing and sharing differ in the EU member states. This necessitates harmonization of the GDPR implementation across the different countries. Molnár-Gábor et al. highlighted the divergences in the rules for genetic and health data sharing in four member states (Germany, Greece, Latvia, and Sweden).<sup>41</sup>

With the recent approval of the EU Data Governance Act (DGA), individuals will have more control over sharing their data<sup>42</sup>. Data sharing and data altruism across the EU will be managed via novel personal information management tools, such as personal data spaces or data wallets.

GDPR Principles relating to processing of personal data	Rights of the data subject
<u>Lawfulness, Fairness and Transparency</u> Processing personal data lawfully, fairly and transparently	The right to be informed: Data subjects have the right to be provided with certain information from a data controller that has collected their data.
<u>Purpose Limitation</u> Processing personal data for specified purpose (based on clear informed consent)	The right of access information: Data subjects have the right to obtain confirmation from a data controller as to whether or not their personal data are being processed and, if so, to access that data and certain information.
<u>Data Minimization</u> Limit the amount of personal data you hold	The right to rectification: Data subjects have the right to correct inaccurate personal data held by a controller and to complete personal data that is incomplete

<sup>40</sup> <https://gdpr-info.eu/>

<sup>41</sup> Molnár-Gábor F, Sellner J, Pagil S, Slokenberga S, Tzortzatou-Nanopoulou O, Nyström K. Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden. *Semin Cancer Biol.* 2021 Dec 9:S1044-579X(21)00294-7. doi: 10.1016/j.semcancer.2021.12.001. Epub ahead of print. PMID: 34896635. Data Futures Partnership. Government of New Zealand; 2015.

<sup>42</sup> <https://www.consilium.europa.eu/en/press/press-releases/2022/05/16/le-conseil-approuve-l-acte-sur-la-gouvernance-des-donnees>

<u>Accuracy</u> Keeping personal data accurate and up-to-date	The right to object to processing: Data subjects have the right to object at any time, on situation-specific grounds, to the processing of personal data concerning them. The controller shall no longer process the personal data unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights, and freedoms of the data subject or the processing is necessary for the performance of a task carried out for reasons of public interest.
<u>Storage Limitations</u> Retaining personal data with a set-timeframe	Right to object and automated individual decision-making: Data subjects have the right not to be subject to any individual decision based solely on automated processing, including profiling, if such a decision leads to significant ramifications (legal and otherwise), subject to certain exceptions.
<u>Integrity and Confidentiality</u> Safeguarding the rights of individuals	Right to erasure ('right to be forgotten'): data subjects have the right to request that the controller of their personal data erase certain data concerning them which has been made public, taking account of available technology and the cost of implementation. The controller shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data of the request.
<u>Accountability</u> Providing information security	The right of data portability: Data subjects have the right to receive their personal data from a controller in a structured, commonly used, and machine-readable format and have the right to transmit those data to another controller without any hindrance from the controller providing the data.
<u>International Transfers</u> Limitation of the data transfer to non-compliant countries	The right to restrict processing: Data subjects have the right to set restrictions on the processing of their data by a controller in certain instances.

**Table 3. Summary of the EU GDPR Principles (column 1) and Individuals' Rights (column 2)**

## **Objective 2: Protect people through building trust (patients' perspective on PCD)**

PCD necessitates the creation of a framework for citizen-controlled data sharing. For this to work, one of the prerequisites is building an individual's trust in data systems. That requires the co-development of PCD governance systems in a participatory and transparent manner with individuals. The regulations and guidelines should be accessible, understandable, and followed in practice to build trust. Trust requires safeguarding data, ensuring privacy, and establishing transparent and inclusive data collection, processing, storage, analysis, use, sharing and disposal processes.



The ONC white paper on PGHD highlighted the main patients' concerns are about data privacy and security and how their data will be used by researchers and companies. These doubts may prevent patients from sharing their PCD. Consequently, willingness to share data is impacted by the degree of trust.

### *Establish transparent and accessible PCD processes and systems*

Transparency in PCD governance is required to create buy-in from stakeholders, especially patients, around PCD processes. The Data Futures Partnership in New Zealand defines transparent data use with three dimensions: value, protection, and choice.<sup>43</sup> Thus, all PCD stakeholders can understand how and why data are collected (value); how data are stored, analyzed, and used (protection); and how the systems and processes that support PCD governance operate (choice).

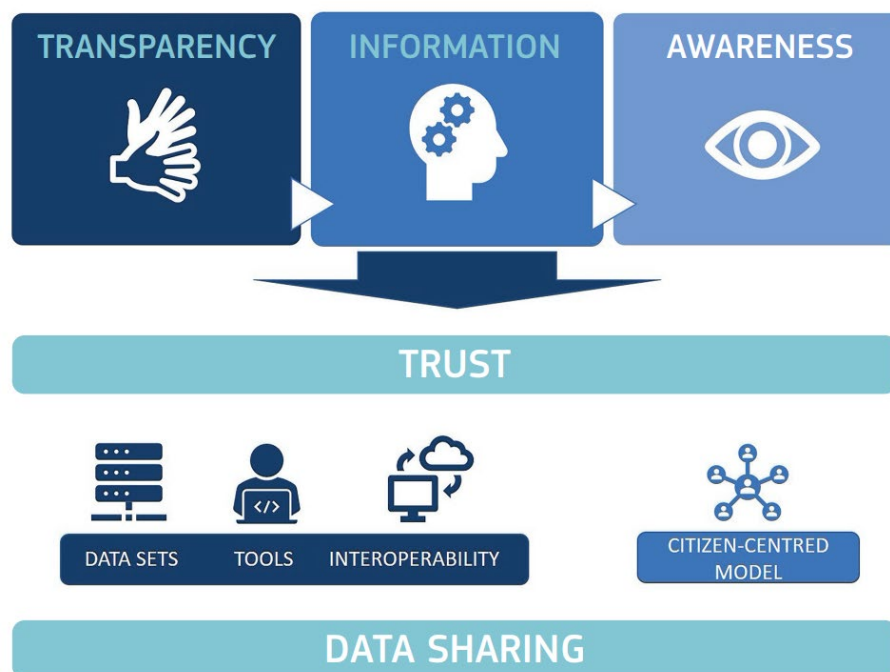


**Figure 8. Transparent data use dial to be used for displaying the answers  
(Source: Data Futures Partnership in New Zealand)**

### Guiding example

<sup>43</sup> Data Futures Partnership. Government of New Zealand; 2015.  
<https://www.stats.govt.nz/assets/Uploads/Retirement-of-archive-website-project-files/Corporate/Cabinet-paper-A-New-Zealand-Data-Futures-Partnership/nzdf-partnership-overview.pdf>.

The Digital Health Europe project<sup>44</sup> introduced a framework for citizen-controlled data sharing to motivate and provide the conditions for citizens to be able to share their own data.<sup>45</sup> On the policy level, it addresses transparency, information, awareness, and trust-building. Technically, it focuses on data sets, tools, and interoperability. All framework activities adopt a citizen-centered model. Accordingly, appropriate activities can be planned, and actions can be taken to realize this framework.



**Figure 9. Framework for citizen-controlled data sharing**  
(Source: Digital Health Europe consultation paper)

**Trust is the key word** in this process. To gain trust:

- Information must be clear
- Rules need to be transparent
- Implementation must be easy.

**Figure 10. Key stakeholders' message**

### **Objective 3: Promote health value through enhancing systems and services (health system's perspective on PCD)**

<sup>44</sup> [digitalhealtheurope.eu](https://digitalhealtheurope.eu)

<sup>45</sup> Digital Health Europe project. Citizen-controlled health data sharing governance consultation paper (October 2020). <https://digitalhealtheurope.eu/results-and-publications/consultation-paper-citizen-controlled-health-data-sharing-governance/>

PCD governance should enable meaningful use of data to enhance health system efficiency and resilience as well as benefit individuals. PCD can actively contribute to the transformation of health systems into value-based systems.

### *Evaluate the benefits of PCD*

The secondary use of PCD in medical research and policymaking has excellent potential in advancing medical sciences and healthcare. To this end, PCD will be highly needed by research institutions and academia for research and development purposes. All stakeholders may legitimately require appropriate, secure access to data. Citizens who contribute data must also fully understand how their data may contribute to research and development.

### Guiding example

Kalkman et al. conducted a systematic review of the principles and norms governing responsible data sharing in international health research.<sup>46</sup> They identified four themes (societal benefits and value; distribution of risks, benefits, and burdens; respect for individuals and groups; and public trust and engagement) under which relevant principles and norms can be grouped. This work can lead to creation of a harmonized governance framework for data sharing in health research.

Main themes	Norms and principles
Societal benefits and value	Accessibility, Data quality, Sustainability, Scientific progress/value, Promote health and well-being, Interoperability, Scientific validity, Societal benefit, Duty to share, Collaboration and capacity building, Health-related public interest, Improved clinical care, Enhance healthcare decision-making, Social value, Individual benefit, Improve public health, Efficiency.
Distribution of risks, benefits and burdens	Benefit-sharing, Reciprocity, Risk-benefit evaluation, Equity and fairness, Protection of intellectual property, Attribution, Proportionality, Ownership, Recognition and attribution.
Respect for individuals and groups	Respect/protect privacy, Protect confidentiality, Ensure data security, Respect individuals, Respect individual rights, Individual autonomy, Respect dignity of individuals, Respect (the dignity of) communities, Prevent discrimination, Legal compliance, Protect life, health and well-being, Respect families, Respect welfare of individuals.

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<sup>46</sup> Kalkman S, Mostert M, Gerlinger C, van Delden JJM, van Thiel GJMW. Responsible data sharing in international health research: a systematic review of principles and norms. *BMC Med Ethics*. 2019 Mar 28;20(1):21. doi: 10.1186/s12910-019-0359-9. PMID: 30922290; PMCID: PMC6437875.



Public trust and engagement	Transparency, Accountability, Engagement/participation, Maintain public trust, Maintain integrity, Responsibility, Professionalism, Health democracy, Solidarity.
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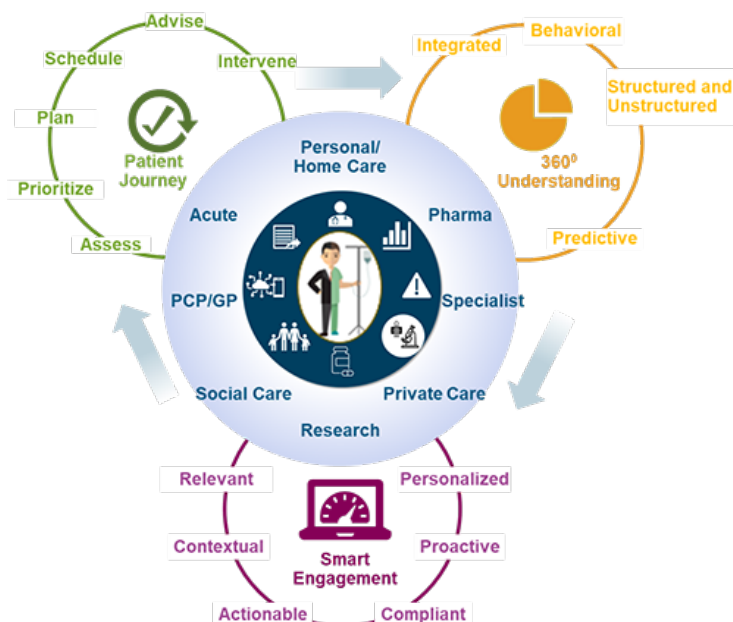
**Table 4. Themes and principles (Adapted from source: Kalkman)**

### *Promote PCD interoperability*

In Chapter 7: PCD Standards Overview, we discussed interoperability standards for PCD. Interoperability will make sharing PCD between systems simpler and more secure while preventing potential errors during manual data transfers. Concepts like data portability, open data, community data, data trustees, and data exchanges may also be considered as part of the sharing and interoperability mechanism. Recently, the FHIR for FAIR (Findable, Accessible, Interoperable, and Reusable) implementation guide was introduced to provide guidance on how HL7 FHIR can be used for supporting FAIR health data implementation and assessment.<sup>47</sup>

### Guiding example on principles for better data interoperability in healthcare

Knudsen highlighted the importance of having better use of data through data interoperability and collaboration between stakeholders in data-driven, data-rich contexts (like PCD).<sup>48</sup> Better use of data will also enable the three capabilities that affect all stakeholders: smart engagement, the patient journey, and 360-degree understanding. PCD can play a crucial role in achieving the three capabilities, as described below.



**Figure 11. Data interoperability and collaboration between stakeholders in data-driven, data-rich contexts (Source: DXC Technology)**

<sup>47</sup> <http://build.fhir.org/ig/HL7/fhir-for-fair/>

<sup>48</sup> HIMSS. Guiding Principles for Better Data Interoperability in Healthcare: <https://www.himss.org/resources/guiding-principles-better-data-interoperability-healthcare>

Smart engagement is realized when data is presented in a relevant, personalized, and contextual way. Using these principles, patients can have an active role in managing their healthcare through digital health tools.

The patient Journey (across the healthcare ecosystem, including at home) should be supported with real-time data to enable coordinated clinical and administrative frameworks to deliver high-quality care.

All stakeholders can have access to a 360-degree understanding of all relevant data. To achieve this goal, data standardization is a prerequisite.

Finally, Knudsen highlighted the following five principles to achieve better data interoperability:

- Principle 1: Healthcare providers need access to data beyond silos
  - Use data from all systems to provide the whole picture
- Principle 2: Healthcare providers need rich data interoperability
  - The ability to share clear, consistent patient data is integral to driving patient-centric care. PCD will play a central role here.
- Principle 3: Healthcare providers need real-time, actionable insights
  - Establishing a real-time data feed from core applications and into a centralized data repository.
- Principle 4: Respond to challenges with automated workflows
  - Monitoring real-time data leads to taking intelligent steps based on the structure or content of the data. Specific automated workflows can be configured to initiate these steps, interventions, notifications, alerts or tasks.
- Principle 5: Data must be shared using industry standards
  - Interoperability requires both syntax and semantics standardization, such as FHIR.

#### *Facilitate innovation using PCD*

PCD is expected to provide new (real-time, rich data) data sets to clinical care. AI and big data analytics can be widely applied to integrated data sets, leading to new tools or innovative healthcare services. This requires developing a governance environment that can enable innovation and effectively support new digital technologies and new kinds of data uses.

## Guiding Report

The WHO has recently published WHO's guidance on ethics and governance of AI in health.<sup>49</sup> The report identifies the ethical challenges and risks with the use of AI in health. The six core identified principles are: (1) Protect autonomy; (2) Promote human well-being, human safety, and the public interest; (3) Ensure transparency, explainability, and intelligibility; (4) Foster responsibility and accountability; (5) Ensure inclusiveness and equity; (6) Promote AI that is responsive and sustainable.

## **Conclusion**

In this chapter, we tackled the lack of agreed upon principles regarding data ownership, stewardship, governance, rights, and responsibilities. We created a PCD governance framework using the Health Data Governance Principles. We identified relevant objectives for PCD protection, sharing, and interoperability. To realize these objectives, collaborative participation from patients, communities, health systems (healthcare providers, insurance providers, systems developers, apps and devices providers, and others), and governments is essential for improving global health equity and outcomes.

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<sup>49</sup> World Health Organization. Ethics and governance of artificial intelligence for health: WHO guidance. Geneva: WHO; 2021 (<https://www.who.int/publications/i/item/9789240029200>).

## Chapter 7: PCD Standards Overview

Patient Contributed Data, information originating from or supplied by individuals regardless of type of content or format, is represented and captured by the many tools individuals may use to assess, record, track, and manage their health and other data over their lifetime. Increasingly individuals also use technologies and devices to interact with other people and entities involved in their health care. Some of these tools generate and share data on a person's behalf or enable individuals to directly contribute information to other parties that provide services and may share in care management.

### Integrating PCD in clinical care

Healthcare professionals may give preference to certain information individuals share, such as quantitative data from prescribed implanted, wearable, or home-use medical devices.

Healthcare professionals may even be motivated to solicit data from patients if, for example, they are rewarded for collecting or using qualitative information from patients, engaged in a study, or committed to a program that incorporates such data.

Data that individuals create and maintain for themselves, if shared with clinicians, is more often subject to “validation” due to concerns around accuracy or trust.<sup>50</sup> Some of these concerns may be valid for untested devices or apps. However, poor provenance, or lack of detailed metadata describing and distinguishing patient contributed data from institutional data, may be the larger barrier to recognizing and accepting data that individuals share with other actors in the healthcare ecosystem.

Without clear provenance describing the origin of data, health care professionals and organizations may hesitate to accept data they do not recognize or that might add workflow burden, such as if they have to spend extra time and resources to identify the source and integrate content. Nevertheless, a variety of healthcare stakeholders view provenance as helpful, if not essential, where validation is considered necessary.<sup>51</sup>

To support interoperability, the ONC sponsored projects to assess data provenance and launched a challenge focused on improving metadata standards.<sup>52</sup> ONC took a step further with 21st Century Cures Act (Cures) interoperability rules by including provenance metadata in the

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<sup>50</sup> <https://ahima.org/media/c3ndnv2r/ehi-task-force-report-revision.pdf>

<sup>51</sup> <https://ahima.org/media/c3ndnv2r/ehi-task-force-report-revision.pdf>

<sup>52</sup> <https://www.healthit.gov/topic/scientific-initiatives/advancing-health-data-and-metadata-standards>; <https://oncprojecttracking.healthit.gov/wiki/display/TechLabSC/DPROV+Home>; <https://www.healthit.gov/buzz-blog/interoperability/places-data-onc-announces-data-provenance-challenge>; <https://www.cccinnovationcenter.com/challenges/provenance-challenge/>

adopted United States Core Data for Interoperability (USCDI v1)<sup>53</sup> standard to explicitly represent the origin of data in (API-based) granular data exchange (and aggregation).

Technologies and standards are evolving that address fundamental elements of recognizing provenance (including identity) and integrating data, as well as the different ways and reasons individuals contribute data for self-management, shared care, and public good. We describe some of these efforts while spotlighting select patient journeys to highlight potential dependencies and opportunities to make progress on available or emerging standards.

We also note potential gaps with standards that may not sufficiently address certain use cases or individual's unique needs or preferences, such as accessibility considerations that may impact the technology used. For example, technology may need to accommodate patients with cognitive or physical impairments or other barriers such as preferred language. Individuals may prefer lower-tech voice or text communication methods over internet-reliant channels such as a patient portal accessed through a smartphone. Caregivers may support data collection on behalf of the patient and selected technologies should meet the needs of caregivers as well.

## Recommendations

We believe that in order to harvest the full potential of patient contributed data, it is important that it is recognized and managed as important to individuals and healthcare overall. We have several additional specific recommendations:

- PCD, whether generated from wearables, sensors, implanted devices, apps, or other devices, should be captured and wherever possible held in standard formats. Much PCD overlaps with data collected in clinical venues where standards already exist. These standards should be applied to consumer-level data and the devices and apps that collect it.
- Many existing clinical standards would benefit from the direct inclusion of patient contributed data. Think, for example, of incorporating patient-defined goals directly into care plans alongside clinical goals or ensuring that data from a home blood pressure device could be easily harmonized with clinical blood pressure data.
- Incorporate patients and/or members of the PCD workgroup into standards review and development work to ensure capture of the full range of needs and perceptions into IG creation.
- Although not all PCD belongs in the EHR, when it matters to incorporate it, we need to have the ability to write FHIR code into EHRs to capture this data as discrete data elements. API-enabled “write” capabilities should be investigated to understand its maturity and potential to support integrating PCD and potential future Health IT certification. ONC’s Final Rule implementing 21st Century Cures Act interoperability requirement suggests HL7’s US Core IG could also be updated/expanded to support/profile “write” services.<sup>54</sup>

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<sup>53</sup> <https://www.federalregister.gov/d/2019-02224/p-351>

<sup>54</sup> <https://www.federalregister.gov/d/2020-07419/p-1210>

- Provenance: Data for which an individual is the source needs to be attributed to that person. Recommendations made to ONC on updating USCDI Provenance data class to include Author should continue, given that current metadata is limited to Organization and Time Stamp. Organization and Time Stamp are insufficient to convey PCD that's incorporated into the medical record and distinguish it from data gathered in a health system context.
- There have been several independent efforts attempting to define functional requirements or expectations for personal health applications. This includes recommendations for certifying consumer or personal health applications.<sup>55</sup> HL7, through the Patient Empowerment WG, should review current and past efforts within and outside HL7 and coordinate with active initiatives in developing potential certification criteria for personal health apps (and devices).

Ultimately, we envision that identification and improvement of standards enabling the integration of various types of data sourced from individuals will enable more complete and collaborative person-centered care.

To help realize this vision, we strongly encourage standards bodies to incorporate patients and members of the Patient Empowerment workgroup in their standards development work to ensure that the needs of patients with regards to PCD, are prioritized if not fully accommodated.

## Potential PCD Standards

Based on the study of many different standards relating to PCD, we propose a first set of PCD standards to be developed (further). They are detailed in Table 5 below, along with the identification of available standards to build upon and the dependencies and opportunities for collaboration.

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<sup>55</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=476](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=476) and [https://www.healthit.gov/isa/sites/isa/files/webform/uscid\\_webform/2126/Mobile%20Health%20App%20CA%20%26%20Certification%20Guidance%20Concept%20Note%20%20-%20Gora%20Datta.pdf](https://www.healthit.gov/isa/sites/isa/files/webform/uscid_webform/2126/Mobile%20Health%20App%20CA%20%26%20Certification%20Guidance%20Concept%20Note%20%20-%20Gora%20Datta.pdf)

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
<p>US Federal law requires a standardized core set of data classes and constituent data elements, the USCDI, be available to patients and exchanged by health care organizations.</p> <p>HL7 has created US Core Profiles to meet USCDI requirements. Several that include PCD not clearly represented..</p>	<p><a href="#">US Core Profiles</a> for USCDI Data Classes:</p> <ul style="list-style-type: none"> <li>• Allergies and Intolerances</li> <li>• Assessment and Plan of Treatment (includes SDOH Assessment)</li> <li>• Care Team Members</li> <li>• Clinical Notes</li> <li>• Clinical Tests (w/results)</li> <li>• Diagnostic Imaging</li> <li>• Encounter Information</li> <li>• Goals (Patient/SDOH)</li> <li>• Health Concerns</li> <li>• Immunizations</li> <li>• Laboratory</li> <li>• Medications</li> <li>• Patient Demographics</li> <li>• Problems</li> <li>• Procedures</li> <li>• Provenance</li> <li>• Smoking Status</li> <li>• Unique Device Identifier(s)</li> <li>• Vital Signs</li> </ul>	<p>USCDI consists of classes of data elements representing information captured from different systems as well as provided by the patient including (but not limited to):</p> <ul style="list-style-type: none"> <li>• Demographics (include identity, race and ethnicity, sexual orientation and gender identity, and other data)</li> <li>• Health Insurance Information/Status</li> <li>• Goals (Patient and SDOH)</li> <li>• Problems (includes SDOH Problems/Health Concerns and dates from diagnosis and resolution)</li> <li>• Health Status (Includes Health Concerns, Functional Status, Disability Status, Mental Function, and Smoking Status)</li> <li>• Clinical Tests (currently only reflects those performed in lab though perhaps could be expanded to include self-administered at-home tests)</li> <li>• Observations</li> <li>• Assessments and Plan of Treatment (includes SDOH assessment)</li> <li>• Vital signs (e.g. where capture from remote sensing devices)</li> </ul>	<p>Depends on technology available though certified electronic health record technology (CEHRT) likely in US health care settings.</p> <p>Patient Access API requirement should enable individual access.</p>	<p>Several current or potential future data classes contain elements often asserted or informed by individuals.</p> <p>Example possible gap: HL's <a href="#">QuestionnaireResponse</a> Profile as published does not appear to support a patient recording answers.</p> <p>US Core Profiles relying on PCD should reflect the patient as the source.</p>



PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
Data contributed by individuals or a personal device must be attributable to the person providing it whenever, wherever, and however it is created, shared, stored, modified or transformed. This requires identifying a person's identity (who) or identifying device and context for creating or sharing data and often relies on metadata to be effective.	<p>HL7 Resource Provenance:  <a href="https://www.hl7.org/fhir/provenance.html">https://www.hl7.org/fhir/provenance.html</a></p> <p>HL7 FHIR R4 (v4.01: R4 – Mixed Normative and STU)  <a href="https://www.hl7.org/fhir/provenance-definitions.html">https://www.hl7.org/fhir/provenance-definitions.html</a></p> <p>Basic Provenance  <a href="https://www.hl7.org/fhir/us/core/STU3.1.1/basic-provenance.html">https://www.hl7.org/fhir/us/core/STU3.1.1/basic-provenance.html</a></p> <p>Profile sets min expectation for Provenance resource to support lineage of information:  <a href="https://www.hl7.org/fhir/us/core/STU3.1.1/StructureDefinition-us-core-provenance.html">https://www.hl7.org/fhir/us/core/STU3.1.1/StructureDefinition-us-core-provenance.html</a></p> <p>US Core Provenance resource:  <a href="https://www.hl7.org/fhir/us/core/StructureDefinition-us-core-provenance.html">https://www.hl7.org/fhir/us/core/StructureDefinition-us-core-provenance.html</a>  <a href="http://hl7.org/fhir/us/core/StructureDefinition/us-core-provenance">http://hl7.org/fhir/us/core/StructureDefinition/us-core-provenance</a></p> <p>HL7 FHIR® US Core Provenance Participant Type IG STU3 Rel 3.1.1</p> <p>Unique mobile health app identifier (UMHAI) being developed in the <a href="#">HL7 mobile health work group</a> to identify specific applications,</p>	<p>Metadata  Time-Stamp  Target  Identifiers</p> <p>US Core Provenance resource focuses on:</p> <ul style="list-style-type: none"> <li>• Timestamp: date/time author created, updated, or deleted the data</li> <li>• The Target Resource: Resource the Provenance record supports</li> <li>• Author</li> <li>• Author Organization</li> <li>• Transmitter (system transmitting information)</li> <li>• Transmitter Organization (organization responsible for transmission)</li> </ul>	<p>Provenance may be captured within documents, resources (as they are created or updated) and is often supported by context-specific elements describing type and purpose of event.</p> <p>PurposeOfEvent  PurposeOfUse  AuditEvent</p> <p>RESTful events</p>	<p>Federally Required Auditable events and tamper-resistance:  <a href="https://www.healthit.gov/sites/default/files/170%20315%28d%29%282%29%20Auditable%20Events%20and%20Tamper-resistance.pdf">https://www.healthit.gov/sites/default/files/170%20315%28d%29%282%29%20Auditable%20Events%20and%20Tamper-resistance.pdf</a></p> <p>Opportunities:</p> <ul style="list-style-type: none"> <li>• Engage AHIMA</li> <li>• Press ONC on Author metadata in USCDI. ONC had proposed Author for inclusion and left it out of UCSDI v1.<sup>57</sup></li> <li>• Engage HL7 Security Workgroup that publishes/updates Provenance related artifacts to better understand spec, adoption, and PCD-supportive enhancements*</li> </ul> <p>* HL7 notes within Basic Provenance guidance it “plans to gather additional input and include the HL7 Basic Provenance Informative guide for C-CDA and FHIR”</p>

<sup>57</sup> <https://www.federalregister.gov/d/2020-07419/p-499>

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
	devices, and individuals. <sup>56</sup>			
PCD solicited from a person before, during, after, or in-between encounters for purposes related to pre-visit or intake questionnaires, health assessments/screening, care planning and shared decision making, evaluation, and research.	<p><a href="http://hl7.org/fhir/R4/questionnaire.html">http://hl7.org/fhir/R4/questionnaire.html</a></p> <p><a href="http://hl7.org/fhir/R4/questionnaire-response.html">http://hl7.org/fhir/R4/questionnaire-response.html</a></p> <p>From HL7: QuestionnaireResponses can be authored by clinicians, patients, or patients' relatives. QuestionnaireResponse makes a distinction between the author, the subject and the source of information.</p> <p>Patient Reported Outcomes HL7 FHIR Patient Reported Outcomes Implementation Guide</p> <p>Link from 2020 PCD analysis: <a href="http://www.hl7.org/fhir/us/patient-reported-outcomes/2018Sep/">http://www.hl7.org/fhir/us/patient-reported-outcomes/2018Sep/</a></p> <p>HL7® FHIR® Patient Reported Outcomes Implementation Guide (Continuous Integration Build)</p> <p><a href="https://build.fhir.org/questionnaire-response.html">https://build.fhir.org/questionnaire-response.html</a></p> <p>ISA reference: <a href="http://hl7.org/fhir/us/patient-reported-outcomes/2019May/index.html">http://hl7.org/fhir/us/patient-reported-outcomes/2019May/index.html</a></p>	<p>Data Type: Single-value or grouped answers/ answer-set</p> <p>Grouped structured set of questions and their answers.</p> <p>Assessments Surveys Forms</p> <p>HL7 Examples: Health Hx Screening for health or social risks (SDOH) Intake forms</p>	<p>Manual capture via app and/or web-based interface/portal in response to request (though there could be pre-populated elements?)</p> <p>PRO collection thru stand-alone app or SMART on FHIR App (tethered to EHR) How are responses stored? (Cerner via FHIR Document resource)</p> <p>SMS conversion for users with limited internet access?</p>	<p>Related standards:</p> <ul style="list-style-type: none"> <li>• Structured Data Capture (SDC)</li> <li>• SDC Questionnaire Response</li> <li>• SDC Adaptive Questionnaire</li> <li>• SDC Adaptive QuestionnaireResponse</li> </ul> <p>Opportunities: Engage HL7 FHIR Infrastructure Work Group that publishes/ maintains <a href="#">SDC</a> and active initiatives like the Gravity Project leveraging Questionnaire standards</p>

<sup>56</sup> <http://www.hl7.org/Special/committees/mobile/projects.cfm?action=edit&ProjectNumber=1733>

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
	<p>ONC note: The creation and scoring of PRO measure instruments and interpretation of data is dictated by the organizations/ institutions that create, test, and validate them.</p>			
<p>Lifestyle and biometric data that may be solicited or actively collected, or unsolicited and often passively generated.</p> <p>Example: Exercise monitored by manually recording exercise frequency or automatically tracked step count.</p>	<p>HL7 Physical Activity IG</p> <p><a href="https://build.fhir.org/ig/HL7/physical-activity/">https://build.fhir.org/ig/HL7/physical-activity/</a> includes LOINC <a href="#">Exercise Vital Sign (EVS)</a> question-set proposed for capturing (and measuring) physical activity level based on responses to:</p> <ul style="list-style-type: none"> <li>• 89555-7 (days-per-week)</li> <li>• 68516-4 (minutes-per-day)</li> </ul> <p>LOINC 82611-5/ panel for device generated physiologic</p>	<p>Quantitative Point in Time (EVS) survey</p> <p>OMH data uses SNOMED Openmhealth schemas specify format and content of data</p> <p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>• <b>Blood Glucose</b></li> </ul> <p><b>Physical Activity:</b></p> <ul style="list-style-type: none"> <li>• <b>Step Count</b></li> <li>• Calories burned</li> </ul>	<p>Personal Health Devices (wearables, mhealth)</p> <ul style="list-style-type: none"> <li>-Manual recording</li> <li>-Automated tracking via standalone app</li> </ul> <p>Solicited questionnaire with LOINC EVS</p> <p>OMH: Data pulled from 3rd party APIs</p>	<p>HL7 Physical Activity IG builds on Gravity SDOH work (this approach relies on solicited PCD using structured questions and answers)</p> <p>Recommend Patient Empowerment engage HL7 Work Groups that have developed or are working on mobile health app and devices standards:</p> <ul style="list-style-type: none"> <li>• Devices Work Group</li> </ul>

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
	<p>observations:</p> <ul style="list-style-type: none"> <li>Heart rate</li> <li>Body temperature</li> <li>Activity level (Acceleration)</li> <li>Respiratory wave amplitude</li> <li>Heart rate variability</li> <li>Systolic blood pressure</li> <li>Diastolic blood pressure</li> </ul> <p>Open mHealth FHIR</p> <p><a href="#">IEEE Standard for Open Mobile Health Data</a></p> <p>Unique mobile health app identifier (UMHAI) being developed in the <a href="#">HL7 mobile health work group</a> for system apps to support PCD interoperability.</p> <p><a href="#">Continua Guidelines</a></p> <p>FHIR PHD Implementation Guide 0.3.0 - STU 1 (2nd ballot)</p>	<ul style="list-style-type: none"> <li>Position/location</li> <li><b><i>Minutes (exercise)</i></b></li> <li>Orientation</li> <li>Sleep</li> </ul> <p><b>Vitals:</b></p> <ul style="list-style-type: none"> <li>BodyTemperature</li> <li><b><i>Weight</i></b></li> <li>Heart rate</li> <li><b><i>Respiratory rate</i></b></li> <li><b><i>Body height</i></b></li> <li><b><i>Blood pressure</i></b></li> <li><b><i>Diastolic blood pressure</i></b></li> <li><b><i>Systolic blood pressure</i></b></li> <li><b><i>Body Mass index (BMI)</i></b></li> <li>Oxygen saturation</li> </ul> <p><b>Open mHealth prioritized italicized and bolded data elements</b></p>	<p>(PCD generated by devices that export continuous data not in scope (for new IG)?)</p>	<ul style="list-style-type: none"> <li>Mobile Health Work Group</li> <li>Orders &amp; Observations</li> <li>Others?</li> </ul> <p>Additional opportunities:</p> <ul style="list-style-type: none"> <li>Engage Physical Activity Alliance sponsoring HL7 initiative</li> <li>Engage HL7 Patient WG publishing the Physical Activity IG</li> <li>Open issues highlight questions about appropriate observations: <a href="https://build.fhir.org/ig/HL7/physical-activity/openissues.html">https://build.fhir.org/ig/HL7/physical-activity/openissues.html</a></li> <li>Engage with HIMSS/ PCHalliance</li> </ul>
<p>Implanted Medical Devices (Prescribed)</p> <p>Post-market surveillance</p>	<p>UDI Device: <a href="http://hl7.org/fhir/R4/device.html">http://hl7.org/fhir/R4/device.html</a> (US Core Implantable Device Profile is intended to only be used for implantable devices)</p> <p>Health device communication: IEEE Std 11073-20601-2019</p>	<p>As an administrative resource UDI has 2 components:</p> <ul style="list-style-type: none"> <li>Device identifier (DI) which uniquely identifies the device</li> <li>Production identifier(s) which enables tracking a device from manufacturing to use</li> </ul>	<p>Standalone or connected</p>	<p>While US Core Implantable Device Profile is for implantable devices it could be updated for non-implantable devices where implementation of a general non-implantable Device Profile is demonstrated.<sup>58</sup></p>

<sup>58</sup> <http://hl7.org/fhir/us/core/future-of-US-core.html#future-candidate-requirements-under-consideration>

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
Collaborative care planning; Multiple Chronic Conditions (MCC)	FHIR; SMART on FHIR;  “Interoperable” ecare plan for MCC  IHE Dynamic Care Planning Profile	Patient-facing app interoperable e-care plan applications and a FHIR implementation guide  Person/plan information; health and social concerns; patient and clinician goals; interventions; health status evaluation and outcomes	Patient mobile SMART on FHIR app  Data extracted from point-of-care health systems and transferred across settings.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9233246/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9233246/</a>
Amendments/request s for corrections  Amendments/requests for corrections: Individuals should be able to electronically request corrections to their health records where they identify errors to prevent perpetuating any incorrect data that is shared. This supports HIPAA's “right to request corrections”	Patient Empowerment Work Group IG: <a href="https://build.fhir.org/ig/HL7/fhir-patient-correction/index.html">https://build.fhir.org/ig/HL7/fhir-patient-correction/index.html</a>  Provenance to record/track requests and any amendments			Opportunity: Recruit implementers to pilot/test Patient Empowerment Work Group IG: <a href="https://confluence.hl7.org/display/PE/Patient+Requests+for+Corrections+FHIR+Implementation+Guide+Project">https://confluence.hl7.org/display/PE/Patient+Requests+for+Corrections+FHIR+Implementation+Guide+Project</a>
Longitudinal personal health records (PHRs) or personal health environments enable individuals to securely aggregate, contribute, and use health data from different systems to support their health	HL7 PHR-S Functional Model ( <a href="#">PHR-S FM</a> ) <a href="#">/ISO/HL7 16527</a> :  Consumer Mobile Health Application Functional Framework ( <a href="#">CMHAFF Project</a> ) leverages HL7 PHR-S and EHR-S Functional Models) for apps; <a href="http://www.hl7.org/implement/standards">http://www.hl7.org/implement/standards</a>	Functional models define features and expectations for personal health technology infrastructure that enables individuals to create and maintain interoperable longitudinal health records.		There have been independent projects/efforts attempting to define functional requirements or expectations for personal health applications. This includes recommendations for certifying consumer or personal

PCD standard need or Use Case	Available, Applicable and/or potential PCD Standard(s)	Type of Standard(s) or Data	Capture and exchange/ transport (Methods)	Potential Dependencies, Opportunities and gaps
needs including for collaborative care across their lives.	<a href="#">dards/product_brief.cfm?product_id=476</a>  ISO/TR 14292, prepared by Technical Committee ISO/TC215, Health Informatics ( <a href="https://www.iso.org/standard/54568.html">https://www.iso.org/standard/54568.html</a> )	Functional standards provide a framework for security, privacy and trusted integration of data generated from apps into Personal Health Record (PHR) and Electronic Health Record (EHR) systems as well as into other types of data repositories (e.g., personal data stores, population care systems).		health applications. <sup>59</sup>  Opportunity: HL7 and the Patient Empowerment WG should review current and past efforts within and outside HL7 to leverage and build upon, and coordinate with active initiatives/ workgroups in developing/refining standards relevant to PCD, and suggesting potential certification criteria for personal health apps (and devices).
Low-tech preferences should accommodate people who prefer or can't use high-tech methods of contributing data	<a href="https://www.loc.gov/preservation/digital/formats/fdd/fdd000431.shtml">https://www.loc.gov/preservation/digital/formats/fdd/fdd000431.shtml</a>	SMS	Texting, audio, video with no app required	Support enegagemeng while addressing digital divides  Streamline patient intake, visits and follow-up

**Table 5. Potential PCD Standards**

<sup>59</sup>

[https://www.healthit.gov/isa/sites/isa/files/webform/uscid\\_webform/2126/Mobile%20Health%20App%20CA%20%26%20Certification%20Guidance%20Concept%20Note%20%20-%20Gora%20Datta.pdf](https://www.healthit.gov/isa/sites/isa/files/webform/uscid_webform/2126/Mobile%20Health%20App%20CA%20%26%20Certification%20Guidance%20Concept%20Note%20%20-%20Gora%20Datta.pdf)

## Chapter 8: Patient Journeys

In this section, we present five patient journeys to highlight the value of patient contributed data (PCD) and illustrate the importance of key principles that we have presented. Each patient journey provides a summary about the person, their circumstances, and their main objectives. A medical history is provided alongside a narrative of how PCD was used (or not used) in their care. In each patient journey, a table provides an overview of each patient's PCD records along with details. Challenges with the journey and PCD are highlighted along with future directions that could overcome barriers and limitations of PCD, along with general recommendations for guiding development around PCD. While these patient journeys are based on real-life examples and experiences, they are fabricated composites and do not represent actual individuals.

### Acknowledgements

Thank you to our colleagues and community members who have provided their personal and clinical experience and expertise to reviewing and providing feedback on these patient journeys, particularly those who provided specific comments: Melissa Beauchemin, Lisa Grossman Liu, Oliver Bear Don't Walk IV, Peter Elias, MD, Noémie Elhadad.



## Patient Journey A: Ann, Moving and setting up a new patient-centered care team

Ann is a 63-year-old white woman who is employed as a writer for the local newspaper. She has received care for moderate persistent allergic asthma since childhood. Ann has recently moved across state lines and is looking to transfer her lengthy health history from the various providers she has seen over the years while identifying a new care team that will appreciate her PCD as much as her former team.

When Ann's illness was unmanaged both as a child and as an adult, she used to visit the emergency department (ED) about twice a year. Over time, she and her former care team relied on clinical guidelines alongside her PCD to guide their approach to treatment and figure out the best regimen that works to control Ann's symptoms. Using the stepwise approach for management of asthma,<sup>60</sup> they determined that step 4 treatment is optimal and have worked to avoid escalating to step 5, a key priority as she moves to a new city and experiences pollen season for the first time in her new home. Her current regimen includes: a daily and as-needed combination medium-dose inhaled corticosteroid plus formoterol in a single inhaler (SMART inhaler) used for both ongoing control and reliever therapy (rather than high dose inhaled corticosteroid plus short-acting beta-antagonist for quick-relief therapy), high-dose oral prednisone for acute episodes, and a multi-component allergen-specific mitigation strategy (e.g., air purifiers with HEPA filters, pillow and mattress covers, and antihistamines during pollen season). This effective personalized regimen was developed over time through medication trials where she experimented with dosing under the supervision of her doctor. During this period, Ann and her provider gained insights that suggested that a low-dose SMART inhaler was insufficient for controlling symptoms and insufficient prednisone doses made acute episodes last longer. She also learned substantial insights about her triggers and how to avoid them to prevent or mitigate most flare-ups, leading to significantly fewer ED visits annually. Understanding her symptoms and response to treatments and the environment led to insights that help support the overall objective of keeping Ann's asthma well-controlled, with the potential to step down in treatment and avoid stepping up.

While her care team appreciated her input and insights from PCD, it took time to reach an arrangement that worked for both Ann and her clinical care team. Initially, one of her previous providers felt overwhelmed by the amount of PCD she was tracking and was unsure how to incorporate the information into her care. During this period, because her data were not being used, Ann felt her

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<sup>60</sup> Cloutier MM, Baptist AP, Blake KV, Brooks EG, Bryant-Stephens T, DiMango E, Dixon AE, Elward KS, Hartert T, Krishnan JA, Lemanske Jr RF. 2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. *Journal of Allergy and Clinical Immunology*. 2020 Dec 1;146(6):1217-70.

personal knowledge was disregarded and her opinions on treatments that worked best for her were overlooked. Through discussions over time, Ann and her care team collaboratively worked out what was most useful to each clinician.

It has taken considerable effort on Ann's part to establish a trusted care team and a care regimen that works for her, where her clinicians are receptive to her self-tracked data and willing to use it to fine-tune her care. She is worried that when she moves to a new healthcare system, her new doctors (or her insurer) will want to re-start the trial-and-error process of figuring out where she fits in the guidelines, agnostic to the patient's particular circumstances, rather than an approach informed by the patient's prior experience and tailored to what works for her. She is nervous that her new care team won't trust her right away and won't value her self-reports or PCD in the way that her former care team relied on her input, especially since other providers in the past have dismissed her PCD when they didn't know how to use it to improve patient care. She is concerned about having her symptoms (and ideas about triggers) dismissed and worries that she will have to repeat previous medication trials, which could lead to longer episodes or symptom relapse. As a result, in setting up her new health home, she wants to find a doctor who is willing to work together and build trust in their collaborative partnership; however nothing in the patient record within the EHR allows her previous team to communicate about her active involvement and the value of her contributions to her care.

Ann has noted the importance of PCD in providing effective and efficient care for her asthma and allergies. Full detail into the PCD used and shared with providers can be found in Table 6. A summary of the PCD she is currently using and plans to use when establishing a new health home in her new state is below.

- **Personal health history records**

- Ann has compiled her personal health history records across the different hospitals and clinics where she has been treated over the years. They consist of paper records from older care. Ann was delighted to learn that because of the 21st Century Cures Act, she could use an API to access and download her data from her recent providers, but she has not found a great way to share those data with her new care team. While the data were created in formal healthcare environments, they were in the patient's custody and are thus considered PCD—not to mention that most health systems are not sure how to accommodate them. These records help to fill in gaps, but Ann wonders how her new healthcare providers will treat this information – will they consider it to originate from a formal healthcare setting or will they consider it contributed by the patient?

- **Monitoring logs**

- Ann maintains monitoring logs, both for **personal illness data** and **environmental factors** that may impact her health. She began tracking with unstructured paper logs, and over time developed more personalized templates, spreadsheets, and visual features. These monitoring data have **helped Ann generate insights for self-discovery of environmental and lifestyle factors that exacerbate or trigger her symptoms**. For example, she plotted her daily log of peak flow readings and overlaid air quality measures, pollen count, ambient temperature, and ambient humidity. This allowed her to note that her peak flow was most negatively influenced by air quality and ambient humidity, which has helped her predict and mitigate asthma flare-ups by limiting outdoor exercise when those factors are in her personal “danger zone”. Moving to a new geographic location is likely to mean changes in her reactions due to a different environment with new triggers, so this is critical to monitor.
- Beyond independent use, **Ann has also shared these monitoring logs with her care team and plans to share them when establishing her new one**. Early on, her self-tracked data were disregarded by some of her providers and some even mentioned that Ann was wasting their time, which prompted her to stop bringing it for a while. When an early career doctor became her primary care provider, the dynamic shifted to a more patient-centered one that emphasized collaboration and balanced decision-making responsibility. At one visit, Ann brought up an insight from analyzing her monitoring data, and the doctor engaged with the investigative process. She encouraged Ann to bring her logs with her to subsequent visits to use together. Over time, they decided on more specific measures to track that would aid health assessment from the medical perspective. PCD that began as unsolicited became solicited and valued for care. Rather than limiting the use of self-tracked data to independent patient use, sharing this type of information with providers and reviewing the health experiences together yielded important insights and health benefits that Ann could not have achieved on her own. Further, PCD can be helpful to establish and navigate partnerships with her new care team.

Type of Data	Description	How captured (incl active/pass) & stored	How used (incl solicited/unsolicited)	Benefits & Drawbacks	Issues & Challenges to Highlight
Personal health history records	Ann has collected her previous medical records, lab reports, documentation of medication allergies, prior	Some more recent records were able to be sent electronically through the EHR; Ann was also able to download raw	<i>Solicited</i> Requested by new healthcare system to supplement files transferred automatically  <i>Unsolicited</i>	<i>Benefits</i> Fills in gaps in medical history and critical medical details (e.g., even though it was noted in several places in the old record, Ann’s allergy to penicillin was not	Not all records could be compiled; some remain digital, stored in the EHR of the old healthcare system and are no longer accessible to the patient

	treatments, and ED visit dates (but no notes)	<p>data through APIs from previous providers, but she does not know how to submit those records to new providers</p> <p>A large portion needed to be manually compiled, both digitally and paper-based</p> <p>Files are both paper-based in a folder carried to each visit or electronically stored on the patient's personal computer</p>	Patient brings folder of records to visits to verify information and provide supplemental information	<p>transferred over to the new system and required the patient's attention and input to address)</p> <p><i>Drawbacks</i> Because the records were in the patient's custody, they may be considered "less trustworthy"</p> <p>Records may be messy, with duplications and/or errors</p>	<p>Provenance is missing; documentation of origin or chain of custody is missing</p> <p>Ann is unable to synthesize the records or correct errors</p>
Contact and personal information	Current contact and personal information	Structured paper or electronic form at initial new patient visit	<p><i>Solicited</i> Given to new healthcare system to set up new patient chart</p> <p><i>Unsolicited</i> Unsuccessful repeated attempts to correct error in address data viewed in patient portal by filling out office forms</p>	<p><i>Benefits</i> Maintain up-to-date contact information for communications and billing</p> <p><i>Drawbacks</i> Frustrating for patient to continue correcting persistent error</p>	Errors can continue to persist in the address field on the patient records, where the old data keeps overwriting the new information inputted into the system
Personal illness data log	Log of personal illness data – tracking symptoms	Self-tracked using a customized tracking system	<i>Solicited</i> After she began bringing her spreadsheet paper logs	<i>Benefits</i> Rich, holistic picture of the patient's illness experience,	Difficult to integrate into the EHR (including: raw data, aggregated data, textual

	<p>and health behaviors, including:</p> <ul style="list-style-type: none"> <li>• peak flow</li> <li>• prednisone dosage</li> <li>• other concurrent infections</li> <li>• other breathing issues</li> </ul>	<p>Ann created herself – a weekly paper log that she manually enters into a spreadsheet</p>	<p>to her former care team, they found it useful and asked her to continue tracking</p> <p><i>Unsolicited</i> The patient will bring her (now improved) spreadsheet logs and trended information to her new care team and request that they be integrated into her care</p>	<p>from their perspective</p> <p><i>Drawbacks</i> Large volume of granular data, difficult to analyze and detect trends</p> <p>Providers worry about visit time and workflow interruptions</p> <p>Patient-specific log without standardization to other EHR data (she created the tool herself)</p>	<p>summary, insights derived); when integrated, usually only as blob text in an unstructured data field rather than discrete data, or is attached as a document that gets buried and becomes difficult to find and not searchable; may not be transmitted as part of the patient's record</p> <p>Difficult to integrate into the clinical workflow without appropriate tools (e.g., customizable visualizations, computational support)</p>
Environmental data log	<p>Log of environmental factors that the patient tracks and correlates with her personal illness data, including:</p> <ul style="list-style-type: none"> <li>• air quality</li> <li>• wind patterns</li> <li>• garbage and pollution levels</li> <li>• pollen count</li> <li>• ambient temperature</li> <li>• ambient humidity</li> </ul>	<p>This log compliments the personal illness data log, and is manually curated and overlaid onto the illness data</p> <p>After the illness data were established as helpful and trends began to emerge, hypotheses about environmental factors led to the patient creating a section on her personal illness spreadsheet paper log to extract</p>	<p><i>Solicited</i> With her former care team, these logs started to be helpful to care, so the patient and her providers began to investigate hypotheses about environmental factors that impact her symptoms and response to treatments; together, they determined some useful metrics to track, and the patient has added more over time that have emerged as relevant</p> <p><i>Unsolicited</i> The patient brings her logs with her to clinical visits regardless of providers soliciting this information,</p>	<p><i>Benefits</i> Adds important data about triggers and other relevant factors that often get left out of healthcare discussions, because they don't seem to be linked and doctors don't feel like environmental data are within their purview</p> <p><i>Drawbacks</i> Since doctors rarely encounter this type of data, they can be unsure about how to integrate into assessment and care</p>	<p>No way to integrate into the EHR except by printing and scanning as blob text or image</p> <p>Difficult to integrate environmental data into the bigger picture of a patient's health status, and to use this data source within the clinical workflow</p> <p>Have to pull data from different data sources, apps, publicly available data sources, personal sensors, or home monitors</p>

		<p>environmental data from various sources (such as the national weather service, EPA's Air Quality Index) and enter them into the spreadsheet</p> <p>In the future, such data could be extracted from publicly available datasets</p>	including visits with her new care team		
<p>Plot of monitoring data (personal illness data overlaid with environmental data logs, from above)</p>	<p>Simple visual summary that plots the illness and environmental log data on top of each other</p> <p>The patient also has graphed several year-over-year summaries of the data to show seasonal patterns and impacts</p> <p>The patient uses this visual to seek and document insights independently and conduct personal experiments with self-management,</p>	<p>Logs compiled in spreadsheet pages, then plotted in the same excel workbook</p> <p>The excel workbook is saved on the patient's personal computer, and PDFs are shared electronically, printed, or in-person on the patient's tablet</p>	<p><i>Solicited</i> With her established care team, she would bring a simple printout of relevant data to visits to share and use together</p> <p>Her new provider welcomes her data and even suggests an inhaler that tracks usage and location, which enables her provider to see the data that Ann chooses to share</p> <p><i>Unsolicited</i> The patient will bring her printout to her clinical visits, even if not requested</p>	<p><i>Benefits</i> Provides a quick, simple way to review and analyze the data, which helps with assessment and identify trends</p> <p>Smart inhaler provides a valuable passive data source</p> <p><i>Drawbacks</i> Providers may not have the time or expertise needed to use such a resource</p>	<p>No way to integrate into the EHR; this type of patient data can generally only be added in a picture or PDF format into the general visit notes (unstructured)</p> <p>Difficult to integrate using this type of patient data into the clinical workflow</p> <p>Even difficult for the patient to show to the doctor in the context of a visit</p>

	she also tries to use this curated personal resource for collaborating with providers				
Narrative summary	The patient has synthesized her complex health history, key insights and triggers, and current health status into a short paragraph	Written in plain text and presented alongside simple figures that plot summaries of data over time  Stored on the patient's personal computer, and sent via email or the portal, printed for visits, or shared in-person on the patient's tablet	<i>Unsolicited</i> The patient sends before her visit and brings a printout with her to clinical encounters	<i>Benefits</i> Quick way to communicate a summary of the patient's health journey, especially new providers  <i>Drawbacks</i> Not all providers are prepared to or willing to review	No way to easily integrate open text narratives into the EHR, so it is generally not added to the patient chart or is added as blob text buried in the chart

**Table 6. Ann's PCD records and how they were used for care**

Ann encountered numerous challenges when moving and setting up a new health home within a new healthcare system. Many of these issues with care could have been prevented if PCD was accepted and used.

- Ann encountered **logistical challenges** related to moving across healthcare systems. Transferring records is not generally simple, and for Ann, required substantial effort to get requested data sent from several old providers to the new providers. Even though her old provider and new provider used the same EHR vendor and were able to transmit the data without Ann needing to assist, the data flowed incompletely and inaccurately due to the different customizations of the EHR, and a lot of information came in as unstructured blob text rather than as discrete data elements. When entered as a narrative or graph, information gets locked into that narrative or graph. Data from other sources were unable to be transferred electronically and had to be mailed in paper form or faxed. **Interoperability** remains a significant challenge.
- **Errors** arose as a result of the non-streamlined method of gathering records. Information that was previously documented (e.g., penicillin allergy) did not make it into the new record, which threatens Ann's safety. Other data that was transferred still



contained errors (e.g., up-to-date home address), even errors that Ann attempted to correct (i.e., the correction request did not follow the data). Records in the patient's custody (e.g., old files brought in folders) could help fill these gaps and avoid errors that could threaten patient safety. Mechanisms for **patient correction requests** could mitigate this issue.

- **Lack of engagement with the PCD that Ann brought into her clinic visits and limited provider knowledge about how to use these data for patient care** disrupted the patient-provider relationship. In the past, Ann shared her health summary and logs with her care team and was discouraged when the doctor did not see value in dedicating effort to this investigative work. Especially without tools to support understanding and using PCD, they considered it a waste of time. It wasn't until she assembled her trusted care team that her primary provider understood the importance of incorporating this information into Ann's care. Nevertheless, even when useful for care, these data often do not have a way of becoming incorporated into the EHR in a way that validates it, because there is no clinical tool or institutional policy for how, where and when this data is stored. Further, Ann's previous care team, where she had established positive and collaborative relationships, had no way to communicate how valuable the patient's efforts and engagement with PCD were in establishing optimal care and could have helped the new care team see the importance of including Ann's PCD from the start.

Some limitations of using PCD can be overcome, so there are some future directions that could further help Ann and her care.

- **Smart devices and sensors** - After Ann moved and successfully established a care team that values her collaborative involvement in care, Ann's new primary provider welcomed her data tracking and suggested that she switch to a smart inhaler that tracks her usage and locations. She can choose to send data from the app to her provider who views it in a companion app. This improves data collection and solidifies the patient-provider relationship and trust that Ann was seeking.
- **Passive data** - Capturing data about illness and environmental factors can be burdensome, and can introduce issues with errors or consistency; using passive data (e.g., from publicly available datasets, from smartphone sensors, from other apps) could reduce the effort required for logging useful data and improve data quality and consistency across contexts (e.g., locations, patients, device type).
- **Tools for using PCD** - Features for visualizing, analyzing, investigating, documenting, and communicating about PCD and trends or other insights would provide valuable and much needed support.

## **Patient Journey B: Earl, Cancer diagnosis and treatment pathway with family care partners**

Earl is a 79-year-old Black Hispanic man who was self-employed as a gardener until he retired about 10 years ago. He speaks both Spanish and English, but is more comfortable with Spanish and often has trouble with medical terminology in English. He recently received a stage III rectal cancer diagnosis and is beginning treatment with radiation and chemotherapy, followed by surgery. His wife and daughter are his primary care partners and play active roles within the care team, although they both work full-time jobs. The patient lives in a family home with his daughter and wife, so he is often home alone and must care for himself and avoid emergency situations. The daughter works as a clinical research coordinator and is currently transitioning from full-time work-from-home back into the office part-time, so the family is interested in implementing more low-tech remote monitoring technology. The family's goals are to coordinate care and treatment, ensure safety at home, and respond to shifting health needs and crises.

The patient was in his usual state of health until about a year ago, when he began having pain and discomfort with bending, sitting, and during bowel movements. His provider instructed him on diet, but his condition continued to deteriorate. When he began having rectal bleeding, he received a misdiagnosis of diverticulitis and began another treatment that did not resolve his symptoms. The patient went to the emergency department (ED) after a bout of rectal bleeding would not stop for several hours. They admitted him to the hospital where he was diagnosed with rectal cancer (stage III). He remained in inpatient care for several days to stabilize his condition and for further scans and testing. This diagnosis was unsurprising, given that the patient's father died of rectal cancer around age 60; but the family history did not trigger testing for rectal cancer, which could have shortened the time to diagnosis. The patient, together with his wife and daughter, began seeing a care team at a cancer institute at a nearby university hospital. After about two weeks of imaging and clinical consultations, the family was presented with the available options and the recommendation from the doctor. Together with this guidance, they decided on a treatment plan, which the doctors have said is "with curative intent". The patient underwent surgery to create a colostomy and place a port-a-cath for use in chemotherapy. The week before treatment was scheduled to begin, Earl's condition deteriorated slightly and resulted in a fall, which delayed treatment for another week. He needed IV medications to correct for high calcium in his blood, which caused his cognitive and motor symptoms. Due to low platelet count and bleeding from his fall, he also required blood product transfusions to support healing. This incident scared the family and could have been prevented. He is currently undergoing chemoradiation to shrink the tumor before it can be surgically removed. After surgery, depending on the pathology of the remaining tumor tissue, the doctors will consider up to 6 months of adjuvant oral chemotherapy. He wants to remain independent and safe in his home environment, particularly when alone.

Earl and his family use PCD to compile useful information from different family members and to coordinate care. They use mostly low-tech methods and information is mainly compiled in a family chat group. The patient and family track more or less depending on

their needs and what is useful for a particular purpose. Their goals are not to use data for long-term purposes, but to facilitate care, safety, and treatment. Full detail into the PCD used and shared with providers can be found in Table 7. A summary of PCD collected and used by the family and care team is below.

- **Diagnosis** - Even though the family tried to share a summary of PCD and key details compiled from the family chat with providers as Earl began seeking care for his symptoms, patient and family reports of symptoms were disregarded and did not help in receiving a diagnosis. In fact, misdiagnoses led to a delay in diagnosis and initiation of treatment.
- **Coordinating care** - PCD has proven valuable in coordinating care, especially with family involvement. Some of this communication happens via the patient portal, where Earl as well as his wife and daughter all use the same login because proxy accounts are not enabled at the organization where he gets care. Although communication through the patient portal began as unsolicited, the care team values this input and have requested that the family continue sending information through that channel.
- **Pain management** - The palliative care team, responsible for managing cancer-related pain and other symptoms during treatment, did solicit data related to pain and pain management. This partnership and collaboration between the patient and their family together with the palliative care team and primary providers was valuable in finding a regimen that works for the patient to get his pain under control as safely and quickly as possible, and then monitor at a higher level for the long-term. The patient and his family engaged in short-term tracking when establishing and calibrating the pain management regimen, to aid in figuring out what works to manage the patient's pain. Once a stable regimen was found, they stopped collecting and sharing this detailed, granular data and currently only collect high-level details about pain levels in a more coarse granularity.
- **Respond to acute episodes and prevent ED visits** - In the period between when the ostomy was placed and chemotherapy started, the patient experienced a cascade of minor events that ended in a fall that resulted in a visit to the ED. Although the family had noticed that Earl had started becoming disoriented and wobbly, these physical and cognitive clues on their own were insufficient for preventing an injury that further delayed the start of treatment. The ED doctor even suggested that the family wasn't able to care for Earl, but they had no way to assert that they had noticed he was acting "off" so that they could investigate for an underlying medical cause. It wasn't until the patient's primary oncologist ordered and examined additional labs that they noticed high levels of calcium in the blood, which was likely responsible for the episodes and treatable with a transfusion and IV medications. The family wants to use their insights and intuition to prevent future issues.

- **Toileting/Ostomy**

- When Earl first began noticing GI issues and problems with toileting, prior to his cancer diagnosis, he began keeping track of this information in a notebook that he kept in the bathroom. This was helpful to answer questions from his primary oncologist and colorectal surgeon. After the surgery to place the ostomy, he tracked output and GI symptoms on a calendar in his notebook until he was comfortable with his body's patterns so that he could notice when something was "off." Now he only tracks as needed (e.g., after a bout of diarrhea it takes longer for output to start up again, so he tracks to know if he should be concerned about a blockage).
- Since the ostomy is new and requires some dexterity, the patient cares for his ostomy with help from his daughter. Since the ostomy wafer base needs to be changed every 5-7 days to prevent failure of the device, they have started marking the calendar with a circle inside of a circle to note the date they placed a new one.
- The ostomy nurse sent the family home with about two weeks' worth of ostomy supplies and explained how to set up an account with a medical supplier to deliver future orders. They need to avoid running out of supplies and to know what to order to meet the patient's needs. The supplier also requires details, mandated by insurance, about the remaining stock of supplies and how long they are expected to last for the patient. This information is hard to track, but the calendar that they use to self-track ostomy base changes has helped the family keep track of a need to reorder, and potentially for cost saving for insurers.
- The family keeps a folder of information from the ostomy nurse and the home health nurse that they were provided for patient and family training in ostomy care. This information would be useful if integrated into an app.

- **Patient wellness, ADL, manage treatment side effects, promote recovery** - The patient's wife often tries out new apps to support Earl's wellness and recovery. She primarily looks for apps to support things like nutrition and mental health. She found an app, however, that allows Earl to tell the virtual voice assistant, easily using voice commands, when he takes his medications. That has helped Earl and the family manage his medications. For recovery related to physical health, the physical therapist also provided an app for completing exercises independently outside of sessions. It is overwhelming to Earl to have so many apps, so he sticks to the family chat group and toilet diary.

Type of Data	Description	How captured (incl active/pass) & stored	How used (incl solicited/ unsolicited)	Benefits & Drawbacks	Issues & Challenges to Highlight
Patient portal clinical data and messaging	The patient and care team rely on the patient portal to access care information, message providers, and share relevant data with the care team	<p>The patient and family interact with clinical data via the portal</p> <p>The daughter sends messages to providers through the patient portal, sometimes including patient generated data</p>	<p><i>Solicited</i> The providers requested the family reach out via the portal for non-emergency questions about treatments</p> <p><i>Unsolicited</i> The providers have not requested the PCD that the daughter sends (e.g., pain spikes, nausea lasting more than two days, and episodes of confusion or disorientation) and do not know what to do with it at first, but over time request that the family continues because it helps care coordination and remote monitoring</p>	<p><i>Benefits</i> The patient and family can stay connected and communicate about emerging concerns; also helps with routine remote monitoring</p> <p><i>Drawbacks</i> No access to proxy accounts, so family uses the patient account to communicate with providers and manage care</p>	<p>Lots of information in lots of places, and sometimes organized in different avenues</p> <p>No way to track the metadata or to note the source (e.g., patient vs family authoring notes in portal messages)</p>
Pain and symptom data	<p>The patient and family started logging pain and other symptoms as they became more debilitating, before diagnosis</p> <p>When the pain was most severe during the period when they were working to calibrate a pain management</p>	The family has documented symptom data using various methods, including in text (SMS), on a clipboard or journal, or on a whiteboard that is shared by home health aides; the daughter takes photos of the	<p><i>Solicited</i> Palliative care solicited pain information and asked for it to be tracked (either formally or in their heads); the family tracked pain and symptoms in great detail for about two months early in care, but now only logs monthly or weekly levels and notes major flare-ups</p>	<p><i>Benefits</i> Useful information to gain insight into the patient's status and to calibrate medication regimen</p> <p><i>Drawbacks</i> Potential for active tracking to be burdensome</p> <p>Lack of standard methods to track</p>	

	<p>regimen with palliative care, the family documented very detailed, granular pain data</p> <p>Now that pain is managed, they only log severe pain flares or high-level (weekly or monthly) pain levels</p>	<p>clipboard notes and whiteboard before it is erased</p> <p>The daughter sends these photos to the group message (below) to archive and compile them</p>			
Medication management	<p>The patient's medications are managed together with his wife and daughter, who keep an updated list</p> <p>Weekly pills are loaded into a pill organizer, and missing doses are noted</p> <p>A smart pill top counts up from the last time a bottle was opened, which the family uses to prevent opioid overdose and also to estimate how often the patient is taking opioids (e.g., to report on success of pain management)</p>	<p>Regular pills are stored in a pill organizer, and the daughter refills it each weekend, noting any missed pills on the whiteboard before she begins the next week</p> <p>Smart pill top counts up from last time a bottle opened</p> <p>Photos, notes, and insights compiled in the group chat (below)</p>	<p><i>Solicited</i> Providers ask for updated medication lists</p> <p>Palliative care asks about missed doses, and if regimen is working to manage pain successfully</p> <p><i>Unsolicited</i> The medication list is often still wrong at new visits or pre-op; the family corrects the record each time and also when picking up prescriptions from the pharmacy</p>	<p><i>Benefits</i> Can help prevent errors due to medications</p> <p><i>Drawbacks</i> No straightforward way to manage, and errors persist</p>	Despite correcting the medication list several times, errors persist and continue to cause trouble in the patient's record

	regimen)				
Family group chat via messaging app	The family communicates via a group chat, which also serves as a log over time of symptoms and other experiences of illness; the family uses the group chat to send pictures and other information to compile and archive in one place	<p>Together, the family uses the group chat to compile:</p> <ul style="list-style-type: none"> <li>• chat text with conversations and descriptions of health status and experiences</li> <li>• pictures of the shared whiteboard</li> <li>• pictures of clipboard tracking sheets</li> <li>• pictures of the patient, including to log the progress of sores</li> <li>• pictures to document context</li> <li>• notes on medication schedule, dosage, missed pills, time since last opened (smart pill bottle top), side effects</li> <li>• help needed</li> </ul>	<p><i>Solicited</i> Helps the patient and family respond to questions asked by the provider, by consulting the group chat record</p> <p><i>Unsolicited</i> Helps the patient and family bring up concerns and questions in clinical encounters</p>	<p><i>Benefits</i> Time stamped and easy to interact with</p> <p><i>Drawbacks</i> Unstructured and messy</p> <p>Not simple to use for patient care</p>	This particular data source is informal and specific to this family and scenario, although individualized approaches similar to this are likely to arise



Voice data	The patient uses a virtual voice assistant to send messages to the group chat, including voice memos where he explains his experience of illness if a flare-up or concerning situation arises; he also uses it with an app to track when he takes his medications	Virtual voice assistant to send text and voice memos to the group chat	<i>Unsolicited</i> Provides evidence to back up complaints of symptom severity	<i>Benefits</i> Easy to capture, accessible  <i>Drawbacks</i> Difficult to use for patient care	Very informal and uncommon way to document and share experiences of illness
Smart home sensors	The patient was recently recruited to participate in a research study to use smart home sensors (e.g., camera, motion) to aid in independent living	(future) e.g., motion sensors, activity sensor, biometric data, camera		<i>Benefits</i> Passive tracking and analysis  Automated emergency detection  <i>Drawbacks</i> Expensive to implement if not part of research or supportive project  High tech	Not widely accessible, does not solve problems with social services and the availability and affordability of care aides/ providers

**Table 7. Earl's PCD records and how they were used for care**

Earl and his family have faced challenges and barriers to accessing care and avoiding crises with care.

- **Prescription issues** - Due to the lack of medication reconciliation, "old" medications have been left in place rather than cleaning the medication history to assure the right medications for the right problems are listed in the chart in order to avoid errors.

- For Earl, gabapentin is not helpful for his pain or symptoms from treatment and gives him nightmares, which he learned from tracking with his palliative care team. But the hospital continues to prescribe this medication (e.g., after surgery) and the pharmacy continues to fill it (e.g., after discharge), despite the patient and family asking for it to be removed from the prescription list and a note added about the patient not tolerating it.
- After the ostomy surgery, the patient and family took several weeks to get in a routine that stabilized digestion and output. But despite his established daily routine with a single dulcolax pill in the morning, the hospital continues to give miralax, even after telling the pre-op nurse about this regimen and then speaking to the floor nurse once Earl arrived to the inpatient floor.
- Discharge instructions often include directions to take acetaminophen for pain relief, however the patient is allergic to this medication. While this information is documented in the chart, there is no way to integrate this into the discharge instructions to prevent the patient from mistakenly taking a drug that could cause an anaphylactic reaction.
- **Family and care partner proxy accounts** - The patient and family interact with the EHR via the patient portal. But they do not have the ability to create proxy accounts at their organization, so the family uses the patient's account to communicate with providers and manage care. Issues with proxy accounts bring up concerns about sharing, consent, and privacy, as well as data provenance.
- **Crisis prevention** - No way to combine clinical data with PCD for real-time monitoring outside the clinic and especially when the patient is at home alone, e.g., to prevent an ED visit by finding labs that are abnormal along with family reports of cognitive impairment symptoms.

Various technologies and solutions could improve care for patients like Earl in the future.

- **Smart home technology and sensors** could be used for remote monitoring to automatically detect falls and infer ADLs.
- **Tracking ostomy supplies in an app** could simplify re-ordering monthly supplies and improve cost effectiveness for insurers. It would be even simpler if the ostomy device itself had smart functionalities to support daily living and track supplies used against what is delivered and on-hand (e.g., sensors in the wafer to detect output, prompt and log bag and wafer changes, and monitor and alert about over-filling or leaks in the barrier seal to prevent spills).
- Most EHRs allow **proxy accounts** currently, but sites need to enable the capability and that still lags. All of the communication would be simplified and Earl's privacy would be better protected if they had the ability to enable proxy accounts.
- Additional **virtual voice assistant** skills would make some of the routine tracking Earl and the family are doing simpler and better integrated into their day-to-day activities.

## Patient Journey C: Markus, Sports out-patient and home-based Cardiac Rehabilitation (CR) with rich data capture

Markus is a 57-year-old Austrian man who recently had a heart attack. His cardiovascular risk factors comprise: overweight, hypercholesterolemia, smoking, arterial hypertension, and a sedentary lifestyle as he does not engage in any type of sports or significant exercise. After his heart attack, he stayed in the hospital for 1.5 weeks and therefore completed **phase 1 of Cardiac Rehabilitation (CR)**. He was then referred to a center-based cardiac rehabilitation program as an outpatient for phase 2. His initial assessment was performed by a staff physician at the Reha-Zentrum Salzburg, at the University Hospital Salzburg, Austria.

Before **CR phase 2 initiation**, the care team had access to Markus' medical history and medications (via ELGA, the national EHR in Austria) to retrieve the medical indicators related to cardiac risk factors (blood pressure, lipids, blood glucose, etc.) and the disease underlying his myocardial infarction, i.e. coronary artery disease. The provider also conducted the initial assessment of Markus' exercise capacity, lifestyle risk factors (physical activity, diet, smoking, arterial hypertension, and alcohol), psychosocial health (depression and anxiety), and adiposity (waist circumference). With this initial assessment, Markus and his care team were able to identify the needs for the phase 2 of the CR program and agree on his personalized goals. In addition to the clinical goals for his cardiac health, Markus has several personal goals that motivate him to continue, including the desire to return to work, but also to get back to golfing with friends and to be able to keep up with his grandchildren. Phase 2 was successfully completed, but goals were not yet reached. So, it was decided to apply for phase 3 CR, which was granted by his pension plan.

For **CR phase 3**, Markus and his physician collaboratively identified an **activity prescription** according to Markus' preferences. It was also revealed that during phase 3 there will be an episode of 3-month **home-based CR program**. Several digital applications were suggested to Markus that could assist him during that phase. As he does have average digital skills, he is willing to commit to use such apps and avoid traveling to the clinic. He aims to control his cardiovascular risk factors (mainly high blood pressure and cholesterol) and increase his cardiovascular fitness to reduce the risk of disease progression and future cardiovascular events. Also, he is motivated to pursue further healthy behavior changes. Although Markus is not very engaged with technology, he finds a sense of satisfaction in using the **smart CR app**, recommended by his rehab team, to track his progress and communicate with his care team, and he is already using it during the initial phase 3 CR, in order to be well prepared for the home-based phase.

The **activity prescription** calls for Markus to perform at least 150 minutes and even better 300 minutes of moderate exercise per week for 4-6 weeks, in addition to regularly logging his weight, blood pressure, and blood glucose. In case he wishes to exercise more intensively, exercise times of 75 minutes and even better 150 minutes per week would suffice. This seems like a lot of tracking for Markus, since he's not been very involved in either his health or digital technology. However, his rehab team supported him in

getting the CR app and related tools set up. At home, his daughter helped him coordinate the devices and make sure everything was working together.

The **smart CR app** enabled Markus to easily record his physical activity through his new smartwatch, log his weight, monitor and record his blood pressure (with the ability to link to a Bluetooth connected device and streamline blood pressure readings straight into the app), assess daily caloric intake and his dietary content of fat, saturated fat, sodium, and other nutrients in addition to eating habits. Tracking his diet has been the hardest for Markus and he is pretty sporadic about doing so. His wife and daughter also help him in tracking these activities, entering the measurements when needed or when it feels like too much for Markus. Also, Markus worked on improving his skills in using the CR app and other health apps.

On a weekly basis, all recorded data from Markus' smartwatch and CR app were transferred to his physician via passive data sharing. Markus had to enter his weight from the app connected to his digital scale (active sharing). The physician required all this data to assess Markus' risk factors during CR phase 2 (solicited). His clinician was able to assess Markus's risk factors weekly and make relevant decisions on the required intervention plan and/or education. For example, when Markus did not achieve the physical activity goals in one week, his rehab team was able to customize the activity plan for the following week to fulfill the activity target (perform at least 150-300 min a week of moderate-intensity or 75-150 min a week of vigorous-intensity aerobic physical activity or an equivalent combination thereof). In addition, the clinician was able to share educational material on sustaining healthy lifestyles with Markus when he noticed that he could not lose weight during the first weeks. Markus also received educational material that helped him in smoking cessation.

These data enabled Markus to successfully accomplish CR phase 3, especially during the COVID-19 lockdown, when he was unable to visit the cardiovascular clinic as regularly. Also, self-tracking, personalized goals, and shared decisions motivated Markus to sustain his behavior change towards a healthy, physically active lifestyle to prevent future attacks. Accordingly, Markus plans to use a **CR self-referral tool** also after CR phase 3, when he will **engage independently in phase 4**, i.e., lifelong secondary prevention<sup>61</sup>.

This **CR connected health model** (integrating clinical care and cardiac telerehabilitation through PCD) enables Markus to stay in his home environment and capture rich data that support his health goals and have the potential to support his long-term priorities. These data are shared with his care team to monitor his cardiovascular risk factors and understand how he is progressing. This also

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<sup>61</sup> Niebauer J. Cardiac rehabilitation in Austria. Wien Med Wochenschr. 2018 Feb;168(1-2):46-49. doi: 10.1007/s10354-017-0607-x. Epub 2017 Nov 3. PMID: 29101493; PMCID: PMC5775378.

has a direct benefit to Markus through improving the quality and outcomes of his care plan. That matches with research results showing that **heart attack survivors who complete rehabilitation are 40% less likely to experience another attack**<sup>62</sup>. Full detail on the PCD use in cardiac rehabilitation<sup>63</sup> can be found in Table 8.

Type of Data	Description	How captured (incl active/pass) & stored	How used (incl solicited/unsolicited)	Benefits & Drawbacks	Issues & Challenges to Highlight
Personal profile	Name, date of birth, insurance ID, email, photo, etc.	Stored in ELGA (Austrian EHR)	<i>Solicited</i> Data are retrieved by the clinician and clinic administrators to facilitate clinic operation		
Health data review	Care team's comments on the review of health record data – medications, health problems (e.g., hypertension, diabetes, obesity, psychosocial health: depression, anxiety, etc.)	Stored in ELGA	<i>Solicited</i> Data are retrieved/edited by the clinician  Markus has reviewed the information in his portal and has contacted his General Practitioner (GP) to correct an element of his health history that suggests he has a family history of diabetes	<i>Benefits</i> PCD as a part of cardiac telerehabilitation, enabled the establishment of a <i>CR connected health model</i> , for: improved quality of care and outcomes, reduced readmissions, improved quality metrics, and increased readiness for value-based payment initiatives	Need to improve the <i>CR referral mechanisms</i> by introducing self-referral tools, in which PCD can play a key role in registering new patients in CR programs

<sup>62</sup> American College of Cardiology- CardioSmart: <https://www.cardiosmart.org/topics/cardiac-rehabilitation>

<sup>63</sup> <https://www.heartfoundation.org.au/recovery-and-support/cardiac-rehabilitation-for-health-professionals>

Health assessment	<b>Medical risk factors-</b> Lipid management, blood pressure, diabetes  <b>Lifestyle risk factors-</b> Physical activity, tobacco use, alcohol use  <b>Condition screening-</b> stress, weight management (healthy diet)		Data entered by the physician through the hospital information system  Patients are able to review the data but not enter comments	<i>Benefits</i> Supporting person-centered cardiac rehabilitation	
Medication information	Information on prescribed medication and tracking medication intake	Stored in ELGA	Data are online retrieved/edited by the physician; while patients have online view access only  There's one medication that he refuses to take since he is afraid of potential side effects; although he is not "allergic" to it, he contacted his care team accordingly	<i>Benefits</i> Better medication adherence	
Biometric tracking and lifestyle data	<b>Exercise:</b> step count, sedentary time, heart rate, ECG, self-reported physical activity, Borg scale, and respiratory rate	All of these data can be collected through wearable devices, weight scale, step-counter, and digital health apps  Either active (user entry) or passive (directly from the	Data is transferred by the patient to his clinicians through CR app  Care team can record the main findings in ELGA	<i>Benefits</i> The home-based cardiac telerehabilitation phase motivates patients to commit to the CR program, especially during the COVID-19 lockdown that led to the direct benefits to patients,	Improving the ecosystem for CR connected health in Austria  Enabling the PCD interoperability with ELGA  Patients are not allowed to directly transfer their PCD to ELGA

<p><b>Weight and diet:</b> weight, blood lipids level, Body Mass Index (BMI), 24h food recall, pictures of meals, diet scores, Kcal intake</p> <p><b>Blood Pressure (BP) control:</b> systolic BP, diastolic BP, average BP</p> <p><b>Diabetes control:</b> blood glucose, insulin dosage, HbA1c</p> <p><b>Smoking:</b> self-reported, co measurements, urinary cotinine, blood cotinine</p> <p><b>Psychosocial:</b> health literacy, knowledge tests, quality of life, depression scales, anxiety assessment, and sleep monitoring</p>	<p>smartphone, smartwatch, pedometer, sensor device)- according to the user preference and selected tools/apps</p> <p><b>Physical activity:</b> Validated self-report: e.g., EPIC Physical Activity Questionnaire; objective measures: physical activity monitors and apps (e.g., fitness tracker, smartwatch Fitbit, Apple watch), step counters (e.g., pedometry); difficulty Questionnaire (FDQ) for upper limb ADLs</p>	<p>mainly:</p> <ol style="list-style-type: none"> <li>1) reducing the risk of heart attack and hospitalization</li> <li>2) fewer symptoms, such as angina and fatigue</li> <li>3) improved exercise performance</li> <li>4) increased quality of life and ability to perform daily living activities</li> <li>5) better understanding of heart disease and its management, and improved mood</li> </ol> <p><i>Drawbacks</i></p> <p>Overload of information and too much tracking to be sustained</p> <p>Physician's concerns on time/skills to handle this massive amount of information</p> <p>Quality of data and circumstances of collection</p>	<p>Need for a national regulatory framework for digital health reimbursement</p> <p>Adopting international and/or relevant European certification frameworks for digital health apps, sensors, etc.</p> <p>Patient engagement and empowerment to use digital health apps (including human factors, trust, and interpersonal relationships with technology)</p> <p>Upskilling healthcare professionals to analyze massive data (in addition to addressing liability/ethical concerns)</p> <p>Need for visualization and Artificial Intelligence (AI) tools to easily integrate PCD into cardiac rehabilitation workflow</p>
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Care goal	Date, description, and achievement status	Collaboratively created with the patient and entered by the physician (active)	Data are entered/ retrieved by the clinician Patients have review/read access only	<i>Benefits</i> Better patient engagement and sustained motivation for adopting healthy lifestyle  Better uptake of cardiac rehabilitation by patients through home-based cardiac telerehabilitation program and CR self-referral tools	
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**Table 8. Markus' PCD records and how they were used for care**

In this home-based cardiac telerehabilitation program, some **barriers and concerns** arise<sup>64</sup>:

- **Data Protection-concerns** - Markus had concerns about his data protection. However, he trusts that the EU General Data Protection Regulation (GDPR) is appropriately adopted. He also questioned what this new relationship with his clinician would look like. Can he send his data at any time and how/when to communicate through online channels? His team reassured him that most of the uploads were automatic and told him he could update his weight any time—but should choose the same day of the week to do so.
- **Tracking and reporting tools** - On the other hand, Markus' care team wonders about the work overload and the extra time needed for analyzing massive amounts of PCD. The team's main concern was the new ethical obligation required from their side to consider these new types of data. Mainly, there are still some concerns about the quality of the PGHD and the circumstances of their collection.
- **System-level integration of PCD** - Above all, despite the ELGA infrastructure that has been built on healthcare interoperability standards, it does not support PGHD integrity. Moreover, patients still have no right to write PCD into their EHR. That necessitates changing the ELGA laws and the related workflow to incorporate PCD. By the same token, health

<sup>64</sup> Scherrenberg M, Wilhelm M, Hansen D, Völler H, Cornelissen V, Frederix I, Kemps H, Dendale P. The future is now: a call for action for cardiac telerehabilitation in the COVID-19 pandemic from the secondary prevention and rehabilitation section of the European Association of Preventive Cardiology, European Journal of Preventive Cardiology, Volume 28, Issue 5, May 2021, Pages 524–540, <https://doi.org/10.1177/2047487320939671>

insurance plans should be adapted to cover the digital health model. In summary, PCD interoperability does not just depend on solving technical issues but also concerns human factors, trust, interpersonal aspects, relationships with technology, legalization, sociotechnical systems, and workflows.

There are some **future directions** that may help patients like Markus, as follows:

- To resolve the above-mentioned barriers, there is a need to launch a **national initiative for integrating PGHD with ELGA**<sup>65</sup> (and EHRs from other countries). This initiative will set up a framework to address the barriers and all stakeholders' concerns, resolving the relevant technical, legal, social, and ethical aspects. The initiative should be **person-centered** where stakeholders actively participate in designing patient empowerment and engagement programs for motivating patients in adopting the personal care model. This will also include programs for upskilling healthcare providers to optimally practice the participatory medicine that necessitates patient-provider collaboration.
- At a minimum, there should be a **national certification body** established for accrediting the digital tools, apps, sensors, etc., (for instance, the ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps—Quality and reliability) as well as introducing a regulatory framework for digital health reimbursement and coverage models in health insurance plans (for instance, the German Digital Healthcare Act – DVG on November 7, 2019 (DiGA) and mHealth Validation Pyramid to assess the quality and effectiveness of digital health applications and similar national initiatives in the other European countries).
- On the other hand, introducing the **universal device identifier (UDI) for each device**, as well as an identification system for apps, such as the unique mobile health app identifier (UMHAI) being developed in the HL7 mobile health work group, will highly support PCD interoperability in cardiac rehabilitation, especially with the introduction of the **European Health Data Space (EHDS)** initiative<sup>66</sup>. This initiative won't only share CR clinical data and PCD for the primary use of data (treatment and clinical care), but also facilitate the use of PCD for secondary use of data (in research and policy-making). This will also open the door for incorporating more data like mobility, weather, etc. collected by smartwatches and apps to explore more CR

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<sup>65</sup> Hussein R, Crutzen R, Gutenberg J, Kulnik ST, Sareban M, Niebauer J. Patient-Generated Health Data (PGHD) Interoperability: An Integrative Perspective. *Stud Health Technol Inform*. 2021 May 27;281:228-232. doi: 10.3233/SHTI210154. PMID: 34042739.

<sup>66</sup> The European Alliance for Cardiovascular Health (EACH) revealed its Cardiovascular Health (CVH) Plan for Europe: <https://www.cardiovascular-alliance.eu/each-plan-for-cardiovascular-health-launched/>

affecting factors: like environment and its relation to performing physical activity. This richness of data (mainly live data), would require relevant interoperability standards and artificial intelligence tools for real-time analysis<sup>67</sup>.

- From the **CR clinical perspective**, there is a strong need to **adopt out-patient and fully home-based CR programs<sup>68</sup> and launch national self-referral CR tools<sup>69</sup>**. In this way, patients will be more motivated to be enrolled and complete their CR programs successfully.

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<sup>67</sup> Vaidyam A, Halamka J, Torous J. Enabling Research and Clinical Use of Patient-Generated Health Data (the mindLAMP Platform): Digital Phenotyping Study. JMIR Mhealth Uhealth 2022;10(1):e30557. URL: <https://mhealth.jmir.org/2022/1/e30557>. DOI: 10.2196/30557

<sup>68</sup> Epstein E, Patel N, Maysent K, Taub PR. Cardiac Rehab in the COVID Era and Beyond: mHealth and Other Novel Opportunities. Curr Cardiol Rep. 2021 Mar 11;23(5):42. doi: 10.1007/s11886-021-01482-7. PMID: 33704611; PMCID: PMC7947942.

<sup>69</sup> Million Hearts® national initiative: <https://millionhearts.hhs.gov/tools-protocols/action-guides/cardiac-change-package/referrals.html>

## Patient Journey D: Wilma, Self-tracking for Long COVID diagnosis

Wilma is a 22-year-old Indigenous woman and an enrolled citizen of her federally recognized tribe who lived on the reservation until college and returns to stay with family regularly. She is currently employed part-time as a grocery store clerk and is enrolled full-time as a university student. Wilma was diagnosed with Lupus (an autoimmune disease) as a teenager and has developed a trusting relationship with her primary care provider (PCP) who has helped her find and maintain a reliable, stable treatment for several years, even as she goes back and forth from university. She was recently sick, likely with COVID-19, but never received a formal diagnosis. Subsequently, she started experiencing a new host of distressing symptoms that she worries started from that acute illness. She is seeking a diagnosis of Long COVID, so that she can document her accommodation needs at work and school and access specialized care. She also wants to contribute her data to science so that care can be improved for others but wants to protect her community and advance knowledge discovery in line with tribal values and priorities.

Wilma has been seeing the same PCP, a family doctor at her local Indian Health Services (IHS) clinic on the reservation since childhood. Wilma was diagnosed with Lupus when she was 16, and her PCP helped to find and maintain a stable treatment regimen that works. The provider also addresses barriers to accessing care (e.g., organizing transport) and health-related resources (e.g., healthy foods). Wilma has maintained this care relationship even as she goes back and forth to university. Although her condition does require her to manage her health and different symptoms related to Lupus, she has been able to maintain and enjoy an active lifestyle and fully engages with family and friends, school and work, and hobbies.

Earlier this year, she was ill for about two weeks with “flu-like symptoms” including congestion and coughing, lost sense of smell, and mild GI distress (cramping and diarrhea). She was not hospitalized, and, although she was unable to be tested with a COVID-19 PCR test since she didn’t want to leave isolation from her dorm, it is clear that she was infected with the novel coronavirus. After her cough and congestion improved, she began noticing episodes where her heart started racing for no reason and began feeling weaker over time and started noticing that she didn’t have enough energy for simple activities like washing dishes. On her first gentle hike about six weeks after her illness, her heart started racing, then her knees buckled, and then she passed out and needed to be carried back to the car. After this episode, she started experiencing fatigue so severe that she could barely get off the couch, and she felt like she was having trouble focusing and concentrating on simple tasks. She has also experienced more episodes of dizziness and fainting. All of the symptoms she was tracking typically worsened 12 to 48 hours after activity and lasted for days or weeks, indicating post-exertional malaise (PEM). She has been keeping track of her symptoms and wants to seek a formal diagnosis of Long COVID in order to document her accommodation needs at work and school and get access to enhanced, comprehensive care. Without a formal diagnosis, her accommodation requests have not been approved.

Wilma hopes to use her health data, self-tracking logs, and the reflection and insights they prompted, to advocate for a clinical diagnosis of Long COVID, which will allow her to access care and justify accommodations at school and work. The doctor that she saw at the university clinic dismissed her reports of symptoms, refused to look at her tracking logs documenting post-exertional malaise, and did not believe that her experiences could be related to COVID, due to a lack of an initial PCR test. Without a diagnosis and referral by this provider at the student health clinic, she cannot get on the waitlist for the Long COVID clinic and will not be able to access accommodations (e.g., sitting on a stool when working the register). She shared her data with her trusted PCP at her next visit to the IHS tribal clinic, who believed her and will support her in seeking a formal clinical diagnosis and accessing care.

Wilma has tracked her own personal health data that has given her insight on her condition, which she hopes to use to seek a Long COVID diagnosis. Full detail into the PCD used and shared with providers can be found in Table 9. A summary of the PCD she collects and uses is below.

- Wilma has used her **personal health data** to understand her own body and health since being diagnosed with Lupus and has recently been using it to monitor her illness and recovery. She started noticing patterns of episodes where her heart would race after resolution of her initial COVID-like symptoms, which led her to suspect that something may be wrong with her recovery. Her activity data shows erratic measurements of vital signs especially after physical activity, which confirms her struggles with post-exertional malaise. Her GPS location data adds contextual information to the full picture by documenting the time she spends in different locations, including trends (e.g., less time spent at work and hiking, more time spent at home and at the clinic). Additionally, with GPS location data, she has observed less frequent symptoms at home compared to school, likely because of the support of her family and acceptance by her tribe.
- While trying to figure out what has been going on with her health status, Wilma began connecting with **online health communities** that provide peer support and discussions around health experiences. Wilma found others suffering from similar symptoms through a Facebook group. These communities illuminated the likelihood that Wilma has been experiencing Long COVID and that her many seemingly unrelated symptoms may all tie back to this one cause. She has also become aware that her dizziness post-COVID may be associated with development of COVID-induced Postural Orthostatic tachycardia syndrome (POTS). Group members even shared self-tracked data with each other to analyze and seek insights together, which is how she conducted her own preliminary testing for POTS. They are eager to share their data broadly to help fill gaps in medical knowledge, but the healthcare system and the technical EHR systems are not set up to accept these data.

- Wilma is also interested in **contributing her data to research**, to help promote scientific discovery around the emerging condition. She wants to help generate knowledge around Long COVID, particularly from the patient perspective, so that care can be improved for others. At the same time, she wants to protect her community and is aware of tensions, particularly with mistrust of the healthcare system and medical research, especially around genetic data and tribal sovereignty. She is worried about the data collected, research questions pursued, and limits around security and ownership of existing options, so she is trying to create a partnership between her tribe and her university to potentially start a repository and conduct research on Long COVID. She is interested in the long-term experience and trajectories of recovery or long-term disability, and how the availability of social services and access to tribal healthcare services impact health outcomes.

Type of Data	Description	How captured (incl active/pass) & stored	How used (incl solicited/unsolicited)	Benefits & Drawbacks	Issues & Challenges to Highlight
Self-tracking logs	The patient keeps a detailed spreadsheet of her symptoms and notes about her health experiences and the contexts in which they occur	Spreadsheet, stored in the cloud and accessed from smartphone	<p><i>Solicited</i> Her PCP encourages her to continue to track and share her data</p> <p><i>Unsolicited</i> Despite the fact that not all of her doctors are willing to take time with her data, Wilma continues to track and share it in the hopes that insights and collaboration will occur</p>	<p><i>Benefits</i> Low-cost</p> <p><i>Drawbacks</i> Very detailed and difficult to interpret</p> <p>Requires active data collection</p>	Not standardized
Activity data	Smartwatch sensors capture physical activity data and physiological measurements (e.g., heart rate)	Passive tracking with smartwatch and smartphone	<p><i>Unsolicited</i> She shows this to her providers as evidence for POTS and PEM, to advocate for further evaluation and testing</p>	<p><i>Benefits</i> Low-cost</p> <p>Passive data collection</p> <p><i>Drawbacks</i> Difficult to interpret</p>	
Photos & other	The patient	Captured with	<i>Unsolicited</i>	<i>Benefits</i>	

digital media	<p>compiles photos, videos, and voice memos related to her illness</p> <p>Photos can be used to capture context</p> <p>Video and voice memo journals can fill in details</p> <p>Voice data could be used as a biometric to infer health status</p>	<p>smartphone camera and microphone</p> <p>Stored in a folder on the patient's phone</p>	<p>This information is not requested or used by the patient's providers, but does help her to figure out what to tell providers and what may link different experiences and symptoms</p>	<p>Captures context from day-to-day life</p> <p><i>Drawbacks</i> Hard to organize and incorporate into patient care</p>	
GPS location	<p>Location tracking (e.g., home vs school/work vs hiking/socializing vs healthcare vs errands)</p>	<p>Passively tracked via smartphone app that uses geofences to automatically track time in locations, which the patient reviews and revises occasionally</p>	<p><i>Unsolicited</i> The patient noticed patterns of less severe symptoms in specific locations, and sought this data herself, which she will sometimes bring as aggregated summaries and trends to show providers</p>	<p><i>Benefits</i> Adds useful information for context</p> <p>Can help get picture of impacts on ADLs, day-to-day disruption from illness</p> <p><i>Drawbacks</i> Challenging to integrate</p>	<p>Potential privacy issues and concern around surveillance</p>
Environmental data	<p>e.g., living conditions, green spaces</p>	<p>Mapped by hand</p>	<p><i>Unsolicited</i> The patient tracks this information because she thinks it is relevant, but doesn't generally share it with providers</p> <p>When she showed her primary care provider, she emphasized that the information does seem important for research</p>	<p><i>Benefits</i> Captures SDoH, could be helpful for population-level analysis, and potentially a future learning health system</p> <p><i>Drawbacks</i> Difficult to capture and integrate into caring for a patient</p>	<p>Not directly related to illness, but could still be important for providing access to social services or tailored interventions and for future public health research</p>



			and for future interventions to address equity		
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**Table 9. Wilma's PCD records and how they were used for care**

There are a lot of barriers that impede Wilma's ability to access effective, culturally competent care.

- Poorly understood scientifically** - Long COVID is characterized by diffuse symptoms and is not well-established. However, other post-viral illnesses and chronic manifestations of disease have been documented in the past and provide some background to rely on<sup>70</sup> (e.g., fatigue that may be classified as ME/CFS along with cognitive impairments and a range of other systemic body responses following Lyme disease, Epstein-Barr/mononucleosis, prior influenza and SARS outbreaks, Ebolavirus, Giardia, and dengue fever), although research on these chronic manifestations were largely under-funded. Increasing reports of the development of POTS post-COVID are lending support to this diagnosis as well. It is generally difficult for chronically ill patients to access care for novel or contested illnesses, but these challenges have been compounded during the COVID-19 pandemic because of the additional burden on the healthcare system to respond to the needs of patients globally. PCD is the best tool available when it comes to poorly understood medical issues and meets the needs of patients and providers in this context, ultimately supporting the medical sciences in generating important knowledge around these conditions.
- Stigmatization and lacking validation** - Illnesses that are not well understood scientifically, particularly those with non-specific symptoms and broad, diffuse impacts across body systems, often result in environments where patients are not believed. Patients discuss this pattern of not being believed or having their complaints wrongly blamed on psychological factors. This sometimes leaves patients questioning their own experiences and mistrusting the healthcare system, which leaves them disconnected from care and often self-treating their symptoms. This worry could be somewhat mitigated by using PCD for patient self-advocacy and building trust.
- Healthcare access** - Wilma sometimes has issues with timely access to care through the IHS on the reservation due to a chronically under-funded healthcare system that makes appointments challenging to schedule and barriers to transit (Wilma shares a single car with her family). While the care she receives at her university clinic is more easily accessible, it is less culturally congruous and does not always align with her preferences for care.

<sup>70</sup> Islam MF, Cotler J, Jason LA. (2020) Post-viral fatigue and COVID-19: lessons from past epidemics, Fatigue: Biomedicine, Health & Behavior, 8:2, 61-69, DOI: [10.1080/21641846.2020.1778227](https://doi.org/10.1080/21641846.2020.1778227)

- **Tribal ethics around research** - When she went into the clinic to inquire about a diagnosis and care for her condition, she was approached for recruitment for research into Long COVID that involved both biological samples and PCD. She felt uneasy about the informed consent process, including the research questions guiding the study and the provision for keeping and using samples for future research. Historically, Indigenous people have been exploited and sometimes harmed by research. With the emergence of so much health data, including PCD and also multi-omic data collected for repositories and research, worries about who owns the data and the discoveries or innovations that result from the research, control over the research questions and methods applied, and inadequate informed community and individual consent around how the data will be used and for what purpose have become more prominent. To address some of these concerns, Wilma plans to form a partnership between her tribe and researchers from her university, with the support of her advisor who is tenured faculty at the university and also an active member of her tribe and has already established research networks from prior projects. Together they plan to meaningfully collaborate among stakeholders to formulate research questions and methodologies, seek approvals from the tribal IRB as well as the university IRB, and ensure adequate informed consent at the community and individual levels for each project following a DNA-on-loan type approach for approving any subsequent research (where the tribe maintains ownership over the biospecimens and requires new research agreements for new projects).<sup>71</sup>

Future efforts could mitigate the lack of evidence around emerging public health concerns.

- It would be ideal for emerging conditions like Long COVID to be a priority for generating and integrating evidence into healthcare. A **Learning Health System** has the potential to facilitate this knowledge generation and implement interventions and care that is likely to help patients get timely, personalized care. For Wilma, it is important that research and clinical efforts around Long COVID are patient-led, and in particular is invested in work that is Indigenous-led and focused on those issues of access, equity, community value, and tribal sovereignty.
- Research projects initiated and led by patients have already contributed to the understanding of Long COVID,<sup>72</sup> but these projects could be more readily integrated into the medical community, as many clinicians are unaware they exist.
- Teaching clinicians about the value of PCD as part of ongoing medical education could reduce the likelihood that insights like those Wilma brought would be met with dismissal and mistrust.

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<sup>71</sup> TallBear K. Native American DNA: Tribal belonging and the false promise of genetic science. U of Minnesota Press; 2013.

<sup>72</sup> <https://patientresearchcovid19.com/research/>

## **Patient Journey E: Marcella, Diagnosis and pathway to care for a complex, poorly understood chronic illness**

Marcella is a 34-year-old Black Caribbean-American woman who is employed as a middle school science teacher. She has a long history of problematic health symptoms related to digestion, pain, and inflammation, which fluctuate, especially around parts of her menstrual cycle. Marcella has been frustrated by how often doctors dismissed her symptoms and her account of her health. She began to collect and organize her own health data as a way of providing concrete data to discuss with doctors. She also conducted independent research, which helped her understand her health experiences and investigate whether different self-management strategies work to reduce the chronic and progressive pain she has been experiencing. After seeing a series of providers over several years, she was able to successfully use her PCD to advocate for and secure an endometriosis diagnosis. Now she wants to use what she has learned from her data and research collaboratively with her care team to inform care of her chronic illness and figure out a treatment plan and management regimen that works for her and meets her main goal to reduce her chronic and progressive pain.

Marcella's symptoms started around 14 years of age with painful periods and gastrointestinal (GI) distress; she was diagnosed with irritable bowel syndrome (IBS) at age 18 and began a medication treatment regimen that has helped somewhat (e.g., with emptying bowels). At 24, she was diagnosed with Hashimoto's disease (autoimmune disorder of the thyroid) and began treatment, which addressed several additional symptoms (e.g., constipation and dry skin). But some of her symptoms persisted (e.g., painful periods, GI distress during menstruation), and progressively over the past 6 years, new symptoms causing increasing distress have started (e.g., pain with sitting, pain with tight clothing, pain associated with sex, tingling and numbness in legs). Her mother and grandmother, who both had debilitating periods when they were younger, with the grandmother needing an emergency hysterectomy at 35 due to uncontrollable bleeding, assured her that painful periods are normal for their family and that she might be exaggerating her discomfort.

As her symptoms intensified around age 28, Marcella began to suspect endometriosis as the cause of her symptoms. She started conducting independent research, engaging with online health communities, and tracking her own health experiences, which all pointed to endometriosis as the likely cause of her symptoms. She talked to both her primary care provider and general gynecologist about her concerns, but neither gave much weight to the patient's report of symptoms or her ideas about what was causing them. Following a trip last year to the emergency department (ED) due to pelvic pain, she received a diagnosis of polycystic ovary syndrome (PCOS) that was later determined to be incorrect because she doesn't have the associated features of the disease (i.e., she has painful, heavy periods and bloating that are features of both PCOS and endometriosis, but not long, irregular, anovular cycles, symptoms of hyperandrogenism such as excessive hair growth, or indications of polycystic ovaries). Unbeknownst to

Marcella, doctors also recorded a general anxiety diagnosis in her record, probably due to unresolving symptoms and documented it in her chart, but failed to mention this diagnosis to her. These incorrect diagnoses documented in her record make accessing care more difficult, and there is no mechanism for her to correct the record or accurately narrate her own story. Recently, her debilitating pain and GI symptoms have been progressing more rapidly, resulting in 3 trips to the ED in the last 6 months. In an attempt to mitigate her symptoms, her independent research and community discussions helped her decide to try various things, such as, over-the-counter pain medications, hormonal contraception, and various self-management approaches (e.g., cutting dairy out of her diet, hip stretches, tens machine), which were only somewhat effective.

Marcella first collected and used PCD to understand and monitor her health status, then started using her data to support her self-experimentation with treatments and management strategies. Ultimately, Marcella sought to use her PCD to advocate for a diagnosis that aligned with her lived experience of illness. Marcella's frustrating six-year process of seeking a diagnosis involved seeing at least six clinicians before a new gynecologist finally attended to her concerns and thought she might be right after looking at her data summaries, leading her to provide a referral to a specialist who was able to order the necessary tests. Marcella's PCD was critical in advocating for and securing a diagnosis that fit her experience of illness – endometriosis. Now she plans to use her PCD to help establish an approach to treatment and navigate the patient-provider relationship. She is also always wary of being labeled as a difficult patient, since she has developed independent expertise, follows a self-directed, personalized management plan, and engages in extensive self-tracking. In a recent ED visit, one of the doctors treated her as a drug-seeker, which deepened her distrust of the formal healthcare system. Full detail into the PCD used and shared with providers can be found in Table 10. A summary of the PCD she has used to understand and manage her condition, both independently and together with her providers, is presented below.

- For a few years when her symptoms started getting worse around her periods, Marcella was using a **period tracking app** to log her menstrual cycle, but the general menstrual tracker did not offer symptom domains that she needed to track, beyond general cramping. Seeking something to better suit her needs, she downloaded an **endometriosis-specific self-tracking app** to log her experiences of illness and contribute to research on endometriosis from the patient perspective to fill in gaps in medical knowledge.

During visits for reproductive health, doctors always ask the date of the last menstrual cycle. Using an application that provides this information and recalls it easily helps Marcella take part in her own care and provide that necessary information to doctors when asked. As Marcella's symptoms continued to worsen, using the endometriosis tracking app proved useful to track the gamut of symptoms she experiences and advocated for a diagnosis to explain. While unsolicited, tracking these

symptoms and treatment regimens that she tried independently at home ultimately aided in identifying and securing a diagnosis with her doctor.

- Successful **diagnosis** came only after the patient used her curated personal health records to persuade a new provider, a general gynecologist, to refer her to a specialist, who was then willing to order the appropriate tests (i.e., laparoscopy to view endometrial lesions in the pelvis and sample the tissue for pathology). Beyond using the data to document and share her symptoms and health experiences, the data were useful to empower Marcella as an active and valued participant in the care team. PCD enabled her to assert her perspectives and facilitate transparent two-way communication. The delay in diagnosis was not resolved due to PCD on its own, but PCD was useful as a tool to facilitate this process within clinical encounters when providers were willing to use them. And while PCD is valuable and enables patients to self-advocate, it also places burdens on patients to engage in these tasks and coordinate their own care.
- After her diagnosis, supported by PCD and independent research, the patient tracks and shares PCD with her specialist and care team to aid in communication and guide **care and treatment** of the condition. She is currently preparing for excision surgery to address her symptoms and is working on a management plan to complement this treatment. She has started pelvic physical therapy to both ease her symptoms and prepare for surgery, which is supported by her detailed data tracking.

The patient considers her self-tracked data to be a valuable resource in her care and **wants to share her PCD meaningfully with her care team**. However, she has different reasons for sharing with each care provider and wants to have the ability to tailor sharing to different providers. With her surgeon, she only wants to share high-level data such as aggregated weekly summaries of symptoms and functional impairments, across only high-level domains. She does not want to share details about the domains of painful sex and associated mental health concerns. On the other hand, with her pelvic physical therapist, she wants to share detailed data (granular daily level data) across all domains, including painful sex and mental health details.

Type of Data	Description	How captured (incl active/pass) & stored	How used (incl solicited/unsolicited)	Benefits & Drawbacks	Issues & Challenges to Highlight
Personal health history records	The patient has collected a large file of health records	Most of these records are paper or PDF summaries	<i>Solicited</i> Sometimes this information is solicited by	<i>Benefits</i> Useful for accuracy	Lacking a simple way to show health data on a longitudinal timeline or

	over the course of seeking care for her symptoms	The compiled documents are stored in a paper file folder at home and digital files on the patient's laptop	new providers  <i>Unsolicited</i> With each new provider, she requests previous clinicians send copies of her health data and shares that with her new providers, regardless of if they ask for it	<i>Drawbacks</i> Too much historical information can get in the way of conveying important information in a clinical visit without a way to synthesize, summarize, and navigate the large volume of heterogeneous data	tools for patients to annotate such a timeline with relevant facts
"At-a-glance" health history	The patient has compiled a single page health history for doctors to see "at-a-glance"	The patient has constructed this document on her own, which functions as the patient's story	<i>Unsolicited</i> The patient has created this data resource on her own and brings it to visits, particularly new visits	<i>Benefits</i> Short, synthesized, and aligns with patient perspective  <i>Drawbacks</i> Few providers engage with the document or data  Clinical workflow and resource limitations (e.g., provider time) impact interactions around the health history	Nowhere to upload to chart, other than as a general PDF
Period tracker app	The patient has 5 years of historical menstrual cycle data, including start dates, days of menstruation with heaviness of flow, and cramping	Captured on smartphone app	<i>Solicited</i> Providers often ask for the date of last menstrual period	<i>Benefits</i> Consistently available and simple to understand  <i>Drawbacks</i> Limited data domains and customizability based on app used	Can only share with provider verbally or by showing them the app
Self-tracking app for endometriosis	The patient has been self-tracking her symptoms for about 2 years with an endometriosis-	Data are collected and stored in the app as raw, granular data  The data can be exported	<i>Unsolicited</i> The patient provides this information at every appointment, even if the provider does not ask for	<i>Benefits</i> Captures details about patient's illness experience, from their perspective in an app	Nowhere to upload to the patient chart, other than as PDF or in notes/text field

	<p>specific app; the data provide a detailed representation of recent illness experiences</p> <p>Domains include:</p> <ul style="list-style-type: none"> <li>• overall daily indicator</li> <li>• menstrual cycle data</li> <li>• endometriosis symptoms (such as: pain, GI/urinary symptoms, fatigue, skin rashes, headache)</li> <li>• positive/negative mood</li> <li>• activities of daily living that were hard to do</li> <li>• self-management strategies</li> <li>• treatments/medications</li> <li>• foods that may hurt/help</li> <li>• physical activity that may hurt/help</li> </ul>	<p>as a long, detailed pdf printout</p> <p>The raw data can be requested in a spreadsheet</p> <p>Before visits, the patient reviews her data and creates aggregations and text summaries to be shared with the doctor alongside the “at-a-glance” page</p>	it	<p>specifically designed for this disease</p> <p><i>Drawbacks</i> Hard to make sense of without support for visualization or analysis in the app</p> <p>Hard to share with providers, especially because granular data is overwhelming</p>	
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**Table 10. Marcella’s PCD records and how they were used for care**

There are several barriers and concerns that impact Marcella’s access to effective care.



- **Enigmatic disease** - Uncertainty in the illness context and individualized experiences of illness means complexity and uncertainty for both providers and patients. This impacts both care and the patient-provider relationship. It also often leads to patients who develop expertise around their condition based on their own experiences, often supported through PCD, and existing medical research and literature. There are benefits to active patient engagement and expertise in managing their care, but may also burden patients.
- **Stigmatizing health context** - Marcella has been navigating a healthcare system that ignores her independent research (which is seen as problematic, despite the quality of her sources), self-tracking detailed, rich detailed accounts of her personal experiences of illness (which is seen as a symptom of anxiety), and self-reports of pain and symptoms (which is seen as exaggerating the magnitude of her distress, especially around menstrual-related pain). She has often felt stigmatized for being a complex patient with unresolved complaints. Social determinants of health are also important in this context, where racism in medicine results in disparities in pain management.
- **Family history** - Family history of painful periods, but family members assured her that painful periods are normal. Marcella never shared her family history with providers because she didn't realize it was relevant.
- **Use of data** - PCD were valuable to tell an accurate story and map the patient's narrative to data, which enabled Marcella to assert her experiences and perspectives. Providers value the quantified, measurable data points that PCD affords, but it is a concern that providers may value discrete and quantifiable documentation as more "objective" than the patient's verbal self-reports of symptom experience. Further, the PCD were valuable in seeking and securing a diagnosis, but the actual data were not critical in securing a referral or diagnostic testing.
- **Transparent communication** - To be successful, PCD should include two-way communication between the care team and the patient. However, the care team diagnosed Marcella with anxiety, without her knowledge. Beyond making care more difficult, this misstep can cause distrust, something that takes time to rebuild for a successful care team and patient relationship.
- **Patient corrections** - Errors in patient data are a persistent problem, and current mechanisms for patient requests for corrections are insufficient. As patients gain more access to their health data, errors that need correction are more likely to be found. Errors can originate from historical records, from machine errors, from data entry, from clinician error, from new information that requires corrected diagnoses or updated meds list. Further, errors can arise when PCD and system or clinician generated data are discordant.

Technology in the future could mitigate some of the burdens Marcella experienced and improve her experience and the success of care.

- Because of her challenging illness journey, Marcella is invested in contributing her data to **citizen-science research** that may advance medical understanding of her conditions and that could further support other patients like her to access quality care in a timely manner and avoid the barriers and negative experiences that inhibited her own care. She participates in endometriosis-specific research through the self-tracking app. In the future, PCD like this could be shared with either general repositories or those specific to reproductive health (with informed consent for this purpose). Ultimately, the data could ideally be integrated into a **Learning Health System** that could enable more immediate, real-time insights to improve the healthcare system.
- A **clinical decision support (CDS) tool** for the ED could facilitate early detection of enigmatic conditions such as endometriosis and help in connecting patients to relevant care.
- Adding **intelligent decision support** to Marcella's tracking tool could help detect patterns in her data and to help with early detection, symptom monitoring, guiding treatment and management decisions, and communication and shared-decision making with her clinicians.
- Widespread adoption of **patient requests for correction** tools could alleviate Marcella's problem with an incorrect diagnosis remaining on her record. This would improve the quality of care and also the quality of data for observational research in the future.

## Recommendations

- Incorporate PCD and patient perspectives into community, citizen-science, and observational research to help advance medical understanding of certain conditions, such as Long COVID and endometriosis.
- Develop and implement Learning Health Systems to collect PCD and use them to produce more immediate, real-time insights for improving delivery of personalized care within healthcare systems. Address sociotechnical and organizational factors.
- Add intelligent decision support functionalities to patient tracking apps that can help with detection and communication to clinicians about symptoms and treatments, and include PCD in CDS tools deployed in formal healthcare environments. Leverage patient-focused methods like participatory design.
- Include clinician training on the usefulness of PCD to reduce the likelihood of dismissal and mistrust when a patient brings in their own data to assist them in clinical care. Also address workflow issues when designing tools, so that providers are willing and able to incorporate the tools into their day-to-day clinical visits.
- Create a national certification body established for accrediting the digital tools, apps, sensors, etc., (for instance, the ISO/TS 82304-2:2021 Health software — Part 2: Health and wellness apps—Quality and reliability) as well as introducing a regulatory framework for digital health reimbursement and coverage models in health insurance plans (for instance, the German Digital Healthcare Act – DVG on November 7, 2019 (DiGA) and mHealth Validation Pyramid to assess the quality and effectiveness of digital health applications).
- Include a specific area where PCD can be collected and stored within the EHR, making the data more user-friendly and accessible to care teams.
- Introduce the universal device identifier (UDI) for each device as well as the unique mobile health app identifier (UMHAI) for identification of system apps to support PCD interoperability.
- Leverage smart home technology and sensors for remote monitoring of patients that can automatically detect falls and infer ADLs. Incorporate both high-tech and low-tech wearables and devices.
- A broad range of domains can be valuable for gaining a rich, holistic view of a person's life, but current tools do not make it easy to construct such a view. New tools should facilitate crafting these rich illness representations with a wide variety of PCD. There is value in both active and passive tracking sources.
- Build features to surface insights about PCD, analyze to identify trends, and mechanisms to track these insights, communicate about them with providers, and then incorporate them into the EHR.
- Enable viewing and sharing PCD at different granularities, and for particular domains.
- Enable control over sharing PCD, with the ability to specify particular providers to see different types of data or different details, and allowing consent to be granted and revoked easily.

- Track at-home medical supplies via an app to simplify re-ordering monthly supplies and improve cost effectiveness for insurers
- Organizations should enable proxy accounts within their EHRs to simplify communication and better protect patient privacy.
- Add virtual voice assistant skills to help with routine tracking and better integrate the tracking into day-to-day activities. Deploy these systems to prevent and respond to crises.
- Address issues of access to healthcare and also technology, and work to mitigate systemic barriers and health disparities using PCD. Incorporate social determinants of health.
- Address ethics related to individuals and communities related to research with PCD, and also security and privacy of health-related data.

## Chapter 9: Descriptors of PCD

In the introduction of this white paper we provided an overview of what, in our view, constitutes patient contributed data (PCD). The Venn diagram made clear that it includes much more than just patient generated health data (PGHD), as other types of data, such as electronic health record extracts from other healthcare providers and more extensive personal and family history, are part of PCD. Given the types of data included in PCD, as mentioned in the JAMIA paper and extended in the chart in Chapter 4: History, we felt the need to come up with a set of descriptors to truly understand the breadth and depth of PCD.

Not only will this set of descriptors help us to better understand the concept of PCD, it also can serve both the person(s) and the professional(s) that produce, collect, and share PCD. We envision the use of these descriptors as follows:

- An individual person may use a Personal Health Environment (PHE) to organize their collection of health data. Such a PHE could make use of a set of descriptors that clarifies the origin and purpose of the data being collected; this makes it easier to share this data with future health care professionals they are engaged with;
- A healthcare professional typically uses an Electronic Health Record System (EHR-S) to keep track of a patient's health status and to communicate actions and results with the care team. Such an EHR-S may use the descriptors to aid the healthcare professional in assessing the value or impact that PCD may have in delivering care. When storing such information in an EHR-S, healthcare professionals may review it for clinical relevance before incorporating it into the professional health record.<sup>73</sup> Even without this clinical assessment, this information may be important to understanding and collaboration with the patient.

In the long run, we recognize the need to include PCD in a complete record of a person's health. This need is served in part by a common system of describing PCD that differentiates it from other types and categories of health data. Only with clarity about the nature and type of PCD will we be able to create appropriate structures for storing and managing it as a component of a complete history of someone's health.

In this chapter we first introduce a proposed set of descriptors at a fairly high level. Next we apply the descriptors to a few of the patient journeys detailed in previous chapters. This illustrates the use of the proposed descriptors and how they inform both the patient and the healthcare professional about the nature of the PCD being shared. A first elaboration of each of

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<sup>73</sup> See the definition of "healthcare information for import" in the EN ISO standard 13940 on a system of concepts for the continuity of care (ContSys): "healthcare information that is a candidate for import into a professional health record after a healthcare professional has confirmed its clinical relevance to that professional health record." - [https://contsys.org/concept/healthcare\\_information\\_for\\_import](https://contsys.org/concept/healthcare_information_for_import)

the descriptors, including suggestions for the value sets to be used when providing concrete instances of PCD, is included in the Annex to this white paper.

## Proposed descriptors for PCD at a high level

Based on our internal discussions and testing initial versions of the descriptors on a variety of examples, we have come up with a first list of high-level descriptors to characterize PCD.

We suggest the following five descriptors to be used in relation to PCD:

- Topic - what is the data about. The “topic” data may be extensive, as it addresses the various data types enumerated in Table 1 in Chapter 4: History. Some of these data types contributed by patients overlap with data that is collected in medical settings, highlighting the importance of provenance for understanding and managing it.
- Type - what is the nature of the data
  - For a set of data, this might be a nested descriptor, describing both the set of data and the individual elements the set consists of
- Provenance - which person(s), entities, and processes were involved in producing, delivering or otherwise influencing the data from point of creation
  - For any data, or a document consisting of multiple data elements, provenance might be nested
  - Provenance also provides the chain of custody of the data from its origin to the current holder (the patient in case of PCD)
  - The origin of the data could be a person making an observation, the location or instrument that performed a diagnostic test or procedure, a device and/or sensor registering biometric measurement data, or consumer devices and apps including wearable sensors that the person may use to track their health (fitness, wellness, etc.) or interact with individuals or organizations such as to update personal information or in response to request for information (e.g., surveys).
- Method - what was the means of data capture and/or analysis of the data
  - For a set of data, it is expected that the method is described at the level of the set (i.e., how was this set put together and what conclusions are attached to the content of the full set), as well as at the level of the individual elements the set consists of
- Intent - why was the data created or collected and/or shared, with whom, and in which context
  - If the data was created or collected with a different intent than with which it is currently shared, at least the original intent and the current intent should be mentioned; there is no need to provide a full history of the different uses of the data, each possibly with their own intent
  - For a set of data, it may be helpful to describe the original intent for each of the individual elements the set consists of
  - Intent can be constructed with the following components in mind:
  - Why: *purpose* - for what purpose was the data created or collected

- With whom: *target* - which entities and processes were targeted to use the data (the next step in the chain of provenance)
- In which *context* - what is the context in which the data is to be used

Both provenance and intent provide a critical foundation for assessing the data's authenticity and applicability, thus enabling trust in the patient contributed data. In both instances there could be multiple entries, reflecting the origin and changes to data.

The importance of metadata such as provenance will only increase as information used to identify, assess, treat, coordinate, and measure care increasingly relies on patient contributed information. Representing the most granular metadata associated with its creation and lifecycle is essential for information contributed by patients to be recognized, trusted, integrated in EHRs and other Health IT systems, and used for collaboration with the patient and overall care team.

## The PCD descriptors applied to selected Patient Journeys

This section applies the descriptors to elements of the patient journeys in the prior section of the paper. We present a brief summary here but many additional details are available in Chapter 8: Patient Journeys. We have chosen a few of the key PCD examples to illustrate the use of the descriptors, using the proposed value sets for each of the descriptors as detailed in Appendix A.

### *Patient Journey A: Ann, Moving and setting up a new patient-centered care team*

Ann is moving and trying to establish a new care team with clinicians who will collaborate with her around her self-tracked asthma and allergy data. She tracks and graphs her peak flows, overlays episodes of oral prednisone use, and also shows trends in air quality, pollen count, ambient temperatures, and ambient humidity to understand correlations and triggers. The graph with overlaid data highlights the fact that asthma episodes are correlated with episodes of below zero cold as well as with high humidity.

Peak flow tracking could be characterized as:

- Topic: Physiological metrics / biometrics
- Type: Granular single topic data, specifically a time series of singular data
- Provenance:
  - Patient
  - Device
- Method: Standalone device with direct electronic reporting
  - Consumer grade home health device
- Intent:
  - Purpose:
    - Immediate: Self-knowledge and self-management;
    - Over time: Evaluating a treatment
  - Target:
    - Immediate: Patient;



- Over time: Medical doctor / Nurse practitioner
- Context:
  - Immediate: Individual (self) care;
  - Over time: collaboration with a care team

When the peak flow data is put in a graph, when prednisone doses are overlaid, and when weather data is added, the characterization using the descriptors is modified to include other components noted below. While the base is still granular single topic data in a time series, the characterization now has additional features:

- Topic: Physiological metrics / biometrics
- Type: Graphs based on combined and summarized data
- Provenance: Patient (and personal device(s)?)
- Method - personal analysis of multiple data streams, using some form of correlation determination of the following:
  - Air quality - meteorological institute (downloaded [copied] from an external source)
  - Ambient temperature - personal weather station (standalone device with direct electronic reporting)
  - Humidity - personal weather station (standalone device with direct electronic reporting)
  - Peak flow - home medical device (standalone device with direct electronic reporting)

When Ann finds an appropriate care team, she will share her full health history with the care team. This set of data has the following characteristics:

- Topic: Health history
- Type: Combination of structured and unstructured data
- Provenance:
  - Patient
  - Health care provider
- Method: Downloaded (copied) from an external source
- Intent:
  - Purpose: Continuity of care
  - Target: Health care provider
  - Context: Collaboration with a care team

*Patient Journey C: Markus, Sports medicine and home-based Cardiac Rehabilitation (CR) with rich data capture*

Markus is a 57-year-old Austrian man who recently had a heart attack. His rehab program offers him the ability to complete cardiac rehab at home using a program supplied by the clinic. In addition, on the advice of his rehab team, he is tracking his exercise using his smartphone, tracking his food intake using an app, tracking his weight using a connected scale, and tracking his blood pressure using another app recommended by the rehab team.

## Exercise

- Topic: Lifestyle data - Exercise
- Type: Granular single topic data
- Provenance:
  - Patient
  - Device
- Method: Standalone device with direct electronic reporting
- Intent:
  - Purpose: Evaluating a treatment
  - Target: Medical doctor
  - Context: Collaboration with a care team

Weight - this data only differs on the following descriptors

- Topic: Physiological / biometric data
- Method: Device with manual read-out and reporting

Blood pressure - this data only differs on the following descriptors

- Topic: Physiological / biometric data
- Method: Standalone device with direct electronic reporting

Diet - this data only differs on the following descriptors

- Topic: Lifestyle data/behaviors
- Provenance: Patient
- Method: Simple personal observation

## *Patient Journey E: Marcella, Diagnosis and pathway to care for a complex, poorly understood chronic illness*

Marcella is a 34-year-old Black Caribbean-American woman with a long history of problematic health symptoms related to digestion, pain, and inflammation, which fluctuate, especially around her menstrual cycle. She has collected and organized her own health data, alongside information from research she conducted independently, which has helped her understand her health and suspect a diagnosis of endometriosis. She is still hoping for a formal clinical diagnosis that would help her get appropriate care. Marcella tracks her menstrual cycle, her symptoms, and treatments she has tried in an endometriosis-specific app.

Menstrual cycle:

- Topic: Physiological/biometric data
- Type: Granular single topic data
- Provenance: Patient
- Method: Simple personal observation
- Intent:
  - Purpose:
    - Immediate: Self-knowledge and self-management

- Over time: Getting to a diagnosis
- Target:
  - Immediate: Patient
  - Over time: Medical care provider
- Context:
  - Immediate: Individual self care
  - Over time: Collaboration with a care team

## Recommendations

1. Align PCD descriptors with existing implementations of “descriptors” of electronic health record data - hopefully descriptors can travel across the health system, irrespective of whether it is PCD or not.
2. Align the proposed elaboration of PCD descriptors with the value sets from other standards and application areas.
3. Extend the USCDI definition of Provenance to be more aligned with the W3C and HL7 FHIR definitions of Provenance.
4. Develop a FHIR implementation guide for PCD descriptors, to have an implementable specification of PCD descriptors to be used by the developers of systems on both the patient and the healthcare provider side.

## Chapter 10: Recommendations

### Overarching recommendations

- Create a framework to support the development of Personal Health Environments that engage and empower individuals to aggregate health information from multiple sources so as to provide a rich storyboard of health history drawn from both their formal medical encounters (via APIs from various sources) as well as PCD the individual has created and accessed within an array of diverse tools and environments.
- Create a policy infrastructure that extends USCDI data standards to PCD as it is collected, stored, and transmitted by devices, wearables, and apps.
- Create a policy infrastructure that explicitly supports privacy protections for PCD created from or stored in devices, wearables, and apps. This valuable data is at significant risk for misuse without such protections.
- Incorporate education about PCD into medical training and continuing medical education in order to increase awareness by healthcare professionals as to the value that can be gained by collaborating with patients using PCD. Note that physicians need to be mindful that patients may begin tracking PCD on their own to better understand their health conditions as part of bringing concrete information to their medical team to overcome implicit or explicit biases in treatment.

### Recommendations for standards

- Expand healthcare's definition of provenance to incorporate PCD, reflect the authoring person or personal health device, and to add "chain of custody" information. We believe that a more robust provenance capability would address many of the issues of including PCD in health records. This includes extending the USCDI definition of Provenance to be more aligned with the W3C and HL7 FHIR definitions of Provenance.
- Create a subset of USCDI that explicitly identifies PCD that is not currently documented by clinicians as medical information, or indicate self-reported or contributed data for data classes containing information provided by patients (e.g. Patient Demographics). Note that not all PCD need to be included in the individual's chart information scattered across multiple EHRs, but when clinical systems evolve to incorporate PCD, it should be able to be integrated into the EHR as something more than unstructured blob text.
- Consider adding "write" capabilities to USCDI so that data that is retrieved from a provider's clinical record by a consumer via an API can be written to another provider's EHR or the individual's PHR as discrete data. Most of the work around USCDI to date has focused on "pulling" data rather than "pushing" it; our recommendation is to enable patients themselves to aggregate data across providers or, if they prefer, into a single source personal health environment. This will necessitate that we provide guide rails and structure regarding principles for pushing patient contributed data to systems or records.

- Encourage organizations to test and pilot the HL7 Patient Request for Corrections IG to allow patients to identify and request an update to their record when incorrect diagnosis or information is contained within.
- Encourage testing and adoption of the HL7 Advance Directives on FHIR IG that recently went to ballot to provide an interoperable way for patients to share their treatment goals and wishes.
- Open a broader dialogue with other organizations working on recognizing the value of PCD to health information, such as the AHIMA white paper on broadening what is considered EHI.<sup>74</sup>
- The team had a great deal of difficulty determining what standards were active and what their state of maturity is. We recommend HL7 create a framework for tracking standards development and implementation guides (IGs), identifying the standards that are current, gaps and known areas of the existing standards that are in need of update, and which standards have been superseded and which are retired. It would also be useful to understand the state of adoption and maturity of each standard and IG.

## Recommendations for workflow

- Current medical workflows require healthcare professionals to “validate” an individual’s PCD before incorporating it, in some manner, into the medical record. While this process ensures that the data is reviewed and not just blindly integrated, we strongly suggest that framing the review as “validation” implies that the professional is also making a judgment about accuracy, completeness, and validity, which diminishes the perceived value of the PCD to the individual who has taken the steps to record or capture this important information. Instead of requiring a clinician “validate” the PCD as a gatekeeper to the information, the introduction of PCD should be viewed as an occasion to discuss why the individual is collecting data on their health or condition, what the data reveals that enriches the known information about that individual, and how it can be used collaboratively by the individual’s complete care team even if across providers.
- From a workflow perspective, we also need to consider how to simplify and streamline the process of obtaining and exchanging PCD, whether it is encounter-based clinical data harvested from previous health system encounters or data from apps, trackers, sensors, and wearables. The process of communicating PCD to health systems is difficult and should be both streamlined and simple to facilitate.
- Reconciliation of data from multiple EHRs and medical encounters is currently complex and fraught with issues related to identifying the source of truth or how to reconcile duplicate data, or importantly data that is discordant between sources. Similarly, medical errors in the data can be widely distributed and difficult for patients to correct, despite progress on a standards project working on FHIR-based patient Request for Corrections. Systemically, we need to invest in tools that make it easier to reconcile disparate medical records to help patients pull together, understand and tell their stories more effectively while also enabling physicians to access and learn from a comprehensive, composite view of the patient’s health history. This may require a new class of professionals and software to support the process.

<sup>74</sup> <https://www.linkedin.com/posts/activity-6900448095726100480-5TrD>

- We should develop new strategies for better patient engagement and empowerment to use PCD (including human factors, trust, and interpersonal relationships with technology).

## Recommendations for consent

- We support the goal of allowing patients to consent to sharing their data at a granular level and believe they should be able to approve, and subsequently deny, who their data is shared with and for how long.
- Patients should also have the ability to consent to sharing (or not) data harvested from implanted devices and apps.
- It is critical to address community and group-level consent considerations, such as tribal ethics in the U.S.

## Recommendations for health data ecosystem

- We recommend extending functionalities of the HL7 PHR-S FM to include additional components and patient-friendly tools for data curation, health storytelling, visual analytics, and assessment of temporal and cross-correlation trends between clinical data and PCD.
- Enable de-duplication and harmonization of clinical data when pulled from various sources using APIs.
- Support patient-mediated data exchange where an individual selects which data to share and with whom to share it.
- Ensure effective health information management privacy and security safeguards.
- Incorporate PCD into research and prioritize patient and community perspectives and leadership.

## Recommendations for principles

- We believe that public endorsement of the Health Data Governance Principles by all PCD stakeholders will focus attention on prioritizing equity, protecting people, and promoting health value through creating a robust PCD national/regional PCD governance strategy (see Table 2 in Chapter 6: Principles).
- In the European Union (EU), PCD protection, interoperability, governance, and sharing should be compliant with the current proposal for a Regulation for the European Health Data Space (EHDS).

**Note:** the EHDS regulation is based on a patchwork of relevant EU legislation, such as the General Data Protection Regulation, the security of Network and Information Systems (NIS) Directive, and, specifically for the medical sector, the Medical Devices Regulation, the In Vitro Diagnostics Regulation and the Cross-Border Health Care Directive. Moreover, the proposal will consider the proposed Data Governance Act, the proposed Data Act, and the proposed Artificial Intelligence Act. The EHDS proposal

Data would make Data Governance Act and Data Act principles more concrete for health data.

### **Recommendations for further work on descriptors**

- Align PCD descriptors with existing implementations of “descriptors” of electronic health record data - hopefully descriptors can travel across the health system, irrespective of whether it is PCD or not.
- Align the proposed elaboration of PCD descriptors with the value sets from other standards and application areas.
- Develop a FHIR implementation guide for PCD descriptors, to have an implementable specification of PCD descriptors to be used by the developers of systems on both the patient and the healthcare provider side.

### **Recommendations for future work**

- Charter a team to create an IG for extensions to the USCDI that incorporate PCD and write functionality.
- Charter a case study of collaboration between medical team members and patients to raise awareness of the benefits of collaboration that includes PCD.
- Clarify what data should be included in EHRs vs Personal Health Environments and the relationship between them.
- Leverage the role of PCD in realizing the connected health model in compliance with the current worldwide initiatives, such as, the European Health Data Space (EHDS) in the European Union.



## Appendix - Elaboration of PCD Descriptors

For each of the descriptors we have detailed an initial proposed set of values to be used in describing PCD. As multiple descriptors may refer to persons or organizations, we first provide general value sets for these types of values to be used across the descriptors. We then elaborate each of the individual descriptors, referencing the Patient value set or Organization value set, where appropriate. Please note that these value sets started out from our common understanding of PCD, but have evolved by applying the descriptors to a variety of use cases. They will need to evolve and be aligned with standards and application areas other than PCD.

### *General value sets across descriptors*

Some of the descriptors refer to a person, which might be detailed as follows

- Person (as related to PCD)
  - None
  - Patient
  - Relative or informal care provider
  - Medical care provider
    - Medical doctor
    - Registered nurse
    - Nurse practitioner
    - Allied healthcare professional
    - Healthcare support staff
    - Qualified medical technician

Open question: when the organization is more important than the individual person, do we infer the organization through an employment relationship or do we substitute the person with the organization?

- Organization (as related to PCD)
  - None
  - Health data management organization
  - Health care provider
  - Health insurance provider
  - Medical device manufacturer/operator
  - App developer/operator

### *Further elaboration of Topic*

- Topic - what is the data about<sup>75</sup>

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<sup>75</sup> The Topic descriptor is a further elaboration of the Data Categories and Types described in Chapter 4: History.

- Personal and family history
  - Health history
    - Medications
    - Immunizations
    - Allergies
    - Symptoms
    - Interventions
    - Diagnostic results
    - Conditions/Diagnoses
    - Personal health narrative
    - Outcomes
  - Family history
    - Father
    - Mother
    - Siblings
    - Children
- Physiological metrics / biometrics
- Health assessments such as health risk appraisals or condition screenings
- Patient reported outcomes and symptoms
- Personal experiences of care
- Patient goals and treatment preferences
  - Health/life goals
  - Treatment goals and preferences
  - Personal development goals
  - Personal plan to meet goals
  - General Physical Preparedness (GPP) for future medical care
  - Health care proxy
- Social history (social determinants of health)
  - assessments
  - risk factors
  - social needs
  - interventions
- Lifestyle data/behaviors
  - Exercise
  - Activities of daily living
  - Stress management
  - Diet/nutrition
  - Substance Use (tobacco, alcohol, etc.)
  - Digital dust (social media or interactional footprints)

*Further elaboration of Type*

- Type - what is the nature and/or purpose of the data
  - Granular single topic data

- Point measurement
  - Time series
- Narrative - unstructured data
- Combination of structured and unstructured data
- Annotations to existing data
- Corrections to existing data
- Analysis based on combined and summarized data
  - Graphs based on combined and summarized data
  - Alerts and insights generated on the basis of combined and summarized data
  - Hypotheses generated on the basis of combined and summarized data
- Procedures/activities
  - Schedule of procedures/activities
  - Report of procedures/activities

#### *Further elaboration of Provenance*

For now, we limit this elaboration of provenance to the agents to be recognized and leave out any details on activities and timestamps.

- Provenance - which person(s), entities, and processes were involved in producing, delivering or otherwise influencing the data from point of creation
  - Person (to be detailed according to the Person value set)
  - Organization (to be detailed according to the Organization value set)
  - System (if a system performs activities on data without human interaction)
  - Device (if a device has generated data directly)

#### *Further elaboration of Method*

- Method - what was the means of data capture and/or analysis of the data
  - Standalone device with direct electronic reporting
  - Implanted device with direct electronic reporting
  - Device with manual read-out and reporting
    - information about the device may be useful (UDI, make, model, age, supplied by)
  - Personal observation using a validated questionnaire
  - Simple personal observation
  - Linked to an external source (real-time)
  - Downloaded (copied) from an external source
  - Analysis
    - Personal analysis
    - Professional analysis
    - Care team analysis
    - Multidisciplinary assessment

- Algorithmic analysis

*Further elaboration of Purpose*

- Purpose- for what purpose is (or was originally) collected
  - Self-knowledge and self-management
    - Alleviation of symptoms
    - Preventing exacerbations
  - Getting to a diagnosis
  - Evaluating a treatment
  - Continuity of care
  - Patient safety
  - Sharing of insights

*Further elaboration of Target*

- Target - which person, system or device is (or was originally) supposed to use the data
  - Person (to be detailed according to the Person value set)
  - Organization (to be detailed according to the Organization value set)
  - System (if a system does substantial processing before alerting a person or activating a device)
  - Device (if a device acts directly upon the data received)

*Further elaboration of Context*

- Context - what is the context in which the data is (or was originally) to be used
  - Individual knowledge or (self) care
  - Collaboration with a care team
  - Reporting to a medical doctor
  - Research
  - Pharmacovigilance (reporting to pharma industry and/or medicines authority)
  - Post-marketing surveillance of a device or app