Open-Source Computerized Patient-Reported Outcomes: Case Studies Illustrating Fifteen Years of Evolution

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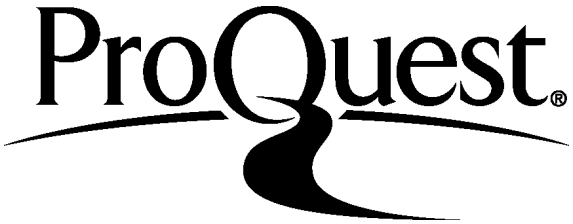

University of Washington

Abstract

Open-Source Computerized Patient-Reported Outcomes:
Case Studies Illustrating Fifteen Years of Evolution

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Over a fifteen year period, Patient Reported Outcomes ("PRO") applications to support over forty clinical and research projects have driven the evolution of an open-source computerized PRO system ("cPRO", http://cprohealth.org). The projects varied widely in PRO content, clinical domain, and workflows. Detailed case studies of six major implementations of the cPRO system offer a framework to understand the socio-technical challenges and opportunities in collecting computerized PROs and incorporating PROs into clinical care, patient-centered tools, and research.

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LIST OF ACRONYMS

ADT	Admissions, Discharge, and Transfer system
AJAX	asynchronous JavaScript and XML
API	application programming interface
BIT	Behavioral Intervention Technology
BSD	Berkeley Software Distribution
BYOD	"bring your own device"
CAT	computerized adaptive testing
CCDA	Consolidated-Clinical Document Architecture
CEHRT	certified electronic health record technology
CFAR	Centers for AIDS Research
CHARN	Community Health Applied Research Network
CIRG	Clinical Informatics Research Group
CMS	Centers for Medicare & Medicaid Services
CNICS	Centers for AIDS Research Network of Integrated Clinical Systems
CPR	Center for Pain Relief at the University of Washington
cPRO	Computerized Patient Reported Outcomes
CSS	cascading style sheets
DOM	document object model
EHR	electronic health record
EMA	ecological momentary assessment
ESRA-C	Electronic Symptom Report and Assessment for Cancer
FAQ	frequently asked questions
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HL7	Health Level 7 International
HTML	hypertext markup language

HTTPS	Hypertext Transfer Protocol Secure
ICD	International Classification of Disease
IRB	institutional review board
IRT	item-response theory
IT	information technology
ITS	UW Medicine Information Technology Services
LAMP	Linux-Apache-MySQL-PHP
LGBT	lesbian, gay, bisexual, transgender
MB	megabyte
MED	morphine equivalent dose
MRN	medical record number
MU	Meaningful Use
NCI	National Cancer Institute
NIH	National Institutes of Health
NINR	National Institute of Nursing Research
P3P	Personal Patient Profile-Prostate
PCORI	Patient-Centered Outcomes Research Institute
PGHD	patient-generated health data
PRO	patient-reported outcome
PROMIS	Patient Reported Outcomes Measurement Information System
PSIP	Patient Safety Innovations Program
PTSD	post-traumatic stress disorder
QI	quality improvement
REDCap	Research Electronic Data Capture
REST	representational state transfer
SaaS	software as a service
SMART	Substitutable Medical Applications and Reusable Technologies
SMS	short message service
SSI	surgical site infection
SxQOL	symptoms and quality of life

UMA	OAuth 2.0 User Managed Access
URL	uniform resource locator
UW	University of Washington
UWHIS	University of Washington HIV Information System
UWMC	University of Washington Medical Center

Chapter 1. INTRODUCTION

Patient-Reported Outcome (PRO) collection has proven value across a variety of clinical domains. However, computerized implementations have revealed many socio-technical challenges. There are numerous parties involved, each with potential for improving PRO collection: patients, providers, organizations, and implementers. These parties can have conflicting interests, however. Patients face a burden in assessment, but benefit from improved communication and patient-centered tools based on PROs. Clinicians can capitalize on PRO assessment across the continuum of care, but doing so requires changes throughout workflows, and protocols in one practice or domain of care may not apply to another. Institutions can use PROs for measuring quality improvement and meeting regulatory and payer requirements, but need to weigh PRO collection against other clinical and technical initiatives competing for resources and attention. Researchers have long used standardized instruments for comparative effectiveness research, but may face competition for patient screen time as PROs are increasingly collected for other purposes.

Over a fifteen year period, PRO applications to support over forty clinical and research projects have driven the evolution of an open-source computerized PRO system ("cPRO" (1)). The projects varied widely in PRO content, clinical domain, and workflows. A socio-technical model is used to place detailed case studies of six major implementations of the cPRO system in context, and to understand the socio-technical aspects in collecting computerized PROs and incorporating PROs into clinical care, patient-centered tools, and research. The objective is to answer this question: What does the fifteen year evolution of an open-source software system tell us about the

socio-technical aspects of collecting computerized PROs, and incorporation of PROs into clinical care, patient-centered tools, and research?

Chapter 2. BACKGROUND AND SIGNFICANCE

2.1 PROs DEFINED

Patient-Reported Outcomes, aka Patient-Reported Measures, aka Patient-Generated Health Data...

Patient-Reported Outcomes (PROs) refer to patient self-assessment of symptoms, function, behaviors, and feelings, via a structured format. Self-assessment means direct reporting by the patient, without interpretation by a provider (2). The word "outcome" implies a post-treatment measurement, but in common usage, PRO refers to assessment before, during and after courses of treatment, or episodes of care; “patient-reported measure" is used synonymously. The Food and Drug Administration (FDA) distinguishes PROs from other sources of clinical outcome assessment including clinician- or observer-reported outcomes, and performance outcomes (e.g., patient performance in cognitive testing) (2). Key attributes that differentiate PROs from one another include: 1) the extent to which an assessment utilizes a standardized measure (3), 2) whether assessment is initiated by the provider, 3) the conditions under which collection takes place (e.g., in time and location) and 4) the extent to which the patient has control over collection (e.g., in clinic, vs. ad lib via a mobile device). An example of one PRO subtype's position in these dimensions is the "Ecological Momentary Assessment" ("EMA"), which is characterized by measurement in natural settings (sometimes with precise timing and location) where the settings are crucial to the measure, and by the patient exerting little control over the conditions of collection

(4). PROs are a type of "Patient-Generated Health Data" (PGHD), a term that also includes more passive, frequent, and objective collection of data (e.g., biomarker data) (5).

The FDA characterizes PROs as the only way to measure unobservable qualities and symptoms, such as pain severity and depression (2); PROs are considered the gold standard for assessing symptoms in clinical trials (6). There is strong evidence that routine collection of PROs with timely feedback improves patient-provider communication (7,8), patient satisfaction with care (9), and the management of chronic conditions (10). PROs offer standardized collection of information that is otherwise often collected conversationally, and less consistently and comprehensively by providers (11,12). Computerized administration of PROs alleviates patient concern with provider perceptions (reducing social desirability bias) of sensitive topics such as sexual risk behaviors (13–16) and hazardous alcohol use (17), and is preferred over paper by patients (18). Computerized collection also enables compilation of multiple instrument scores into prioritized reports for clinicians for immediate integration of results into care (19), longitudinal interpretation, reporting of discrete data into the electronic health record (EHR), analysis for quality improvement (QI) (3), and comparative effectiveness research towards a learning healthcare system (20–22). It should be noted that there is a lack of design research into modern presentation of PRO data to providers, but evidence does show a need for interactive, dynamic user interfaces (23,24).

2.2 Interventions Based on PROs

A primary use case for clinical PROs is collection and feedback of patient reported health information to providers, but there is also opportunity to increase patient engagement beyond collection of measures, via timely interventions tailored on PRO data (25). A 2013 systematic review of PROs in oncology found that routine feedback of PROs alone may not improve patient

management and outcomes, but that other interventions may be needed in concert, such as education, referral services and patient management plans based on the PROs (7). Evidence suggests that patients value PRO collection systems that directly support patient education (26), and patient-powered research networks that offer self-management approaches (27). Examples of computerized interventions include education for symptom management (28), self-management of chronic conditions (29), decision support (7,25,30), and smoking cessation (31). It should be noted that many such interventions are one-offs for research purposes, and that there is little implementation evidence in this area (32).

The age of pervasive mobile computing has enabled health interventions that are highly interactive and capable of evolving over iterations of data collection, inference, and feedback ("eHealth" and "mHealth"), but there is a lack of **health behavior theory** applicable to these dynamic and iterative interactions (33). Riley et al. proposed applying process engineering approaches such as dynamical system models; Mohr et al. built on that with their hybrid conceptual and technical "Behavioral Intervention Technology" (BIT) model; the technological framework includes components for measurement, intervention planning (via workflow implemented as a finite state machine), and an intervention repository (34). Gee et al. proposed an "eHealth Enhanced" version of the well-established Chronic Care Model for chronic care self-management (35). There is very limited evidence in the literature of the aforementioned models being used. In contrast, the approach advocated by Heron et al. for integrating Ecological Momentary Intervention with the aforementioned EMA (4) is cited in several dozen intervention studies.

2.3 FORCES PROMOTING PRO ADOPTION

2.3.1 *Regulators, Payers, Research Funding Agencies*

There is increasing demand by regulators, payers, and research funding agencies for integration of PROs into clinical care. PROs have been included with other PGHD as being required for collection for 15% of patients in Meaningful Use (MU) Stage 3, in effect for 2018 (36). The MU program's longevity is in question by many, including Andy Slavitt, the acting head of Medicare & Medicare Services, who has reported that CMS may propose a replacement of the Meaningful Use program. However, the policies that replace it are likely to include PROs, as Slavitt's list of goals includes reducing the burden of data entry on physicians, and the need to move to a system based on outcomes quality measurement (37). The current shift in payer models from fee-for-service to accountable care and capitation results in increased need for quality of care metrics. Finally, with the establishment of the Patient-Centered Outcomes Research Institute (PCORI) in 2010, the federal government began a program of funding patient-centered research, supporting research of PRO approaches and infrastructure (38,39).

Meaningful Use also includes an objective in support of patient interventions which might be tailored based on EHR data (including, PROs, potentially), namely MU Stage 2's sixth objective for 2015 is to "use clinically relevant information from certified electronic health record technology (CEHRT) to identify patient-specific education resources and provide those resources to the patient." (40) The objective statement clarifies that the education resources do not need to be stored within or generated by the CEHRT, ancillary intervention systems are not excluded.

2.3.2 *Technology*

Modern software applications are distinguished by the interactivity and adaptability of the user experience, and by utilization of computing- and data-intense services on the internet (the "cloud"). Their evolution has been supported by the sheer volume of consumer and professional uptake of pervasive mobile devices, a maturity in software engineering practices and programming technologies (e.g., app frameworks), and internet standards and open-source software libraries (manifested in web service protocols, and cross- operating system and browser standardization, for example). This pervasive consumer computing infrastructure has the potential to support computerized PRO collection both in and out of the clinic setting; initiation of interactions by patients, providers, and algorithm; presentation of PRO instruments based on automated logic; and rich interventions built on PRO feedback.

Electronic health information systems do not have a history of patient-centeredness, however; most were developed to meet healthcare organization–centered requirements. EHRs are siloed by medical institution and vendors, and interoperability beyond low-level data exchange standardization has been extremely limited. These systems have long been oriented towards the needs of reimbursement and compliance, less so towards clinical utility and usability (41), and much less towards patient empowerment (42–44). They continue to evolve, however, and clinical trends towards patient-centered care, and consumer-initiated mHealth innovations (e.g., patient self-tracking / Quantified Self movements, and clinician BYOD ("bring your own device")) are pressuring clinical organizations to implement patient-facing systems such as tethered patient portals and PROs, and third-party interoperability from low-level data exchange on up through application integration at the graphical user interface level. Open standards initiatives supporting this (e.g., Fast Healthcare Interoperability Resources (FHIR) (45), SMART on FHIR (46) and

openmhealth.org (47)) are gaining traction, and there is strong commercial interest this area (e.g., Epic MyChart (48) and Apple CareKit (49)). However, clinical IT system adoption can be hampered by implementation teams' backlogs of competing tasks, which need to be carefully synchronized with organization-wide goals (50).

When considering how to collect PROs, providers and clinical institutions are inclined to look to tethered patient portals (11,50); however, recent literature indicates that patients face significant obstacles with these systems. Many portals fail to deliver information at patients' health literacy levels (51,52), and that patients' unfamiliarity with portal features (43,53) and overall poor usability (54) are significant impediments to patients' use of portals. Krist et al. proposed a five-level model for shifting patient portals to more patient-centeredness: accommodating lower levels of health literacy; improving usability; collecting patient reported measures, behaviors and symptoms; providing individualized clinical recommendations to the patient; and providing personalized vetted information resources, decision aids, and self-management tools (43). Integrating PROs with EHRs and tethered patient portals at this level may eventually allow for coordination of PROs with clinic visits, real-time delivery of results and alerts to providers, and storage of discrete data and summary reports to the EHR. There are examples of operational PRO integration into patient portals and EHR's in recent literature. Wagner et al. described administration of a computerized adaptive testing (CAT) -based system to patients seen at an outpatient oncology clinic, wherein the MyChart patient portal's user interface was customized to embed the PROMIS (55) assessment center website, which administered the PRO (56). Kummerow et al. described a postoperative system administered at a single clinic with REDCap (57) and a locally developed patient portal (58). Carberry et al. describe a pediatric surgical subspecialties PRO system wholly implemented within the Epic patient portal (50). PRO-based

interventions implemented in patient portals have been shown to improve outcomes in treatment of depression in the context of integrated health service networks (59,60). Free and public systems such as National Library of Medicine's "MedLine Plus Connect" are intended to support retrieval of diagnosis-specific information via the HL7 "infobutton" standard, but current portals do not have generalized mechanisms to use this accurately (61).

2.4 Forces Limiting PRO Adoption

The primary factors cited for limiting PRO adoption are requisite changes to clinical practice and workflows, and concern with increasing patient burden. Provider impacts are common to the introduction of health information technologies. Specific to PROs, physicians have cited limited time for collecting and utilizing results, and inadequate reimbursement (18). Few PRO systems automate collection outside of visits (62). Careful integration of computerized collection into clinic workflow (e.g., at moments where patients tend to be waiting) can reduce time impacts (63). Instrument selection is key to minimizing burden on both providers and patients (3,18); for example, instruments may introduce topics which providers are not fully prepared to cover. There are incongruities between patient and provider goals and expectations of PGHD (58,64), though PROs' reliance on the evidence base of standardized instruments distinguishes it from other PGHD, and provides greater context for providers. Patient burden can be minimized by collecting brief PRO assessments at tailored intervals, with flexibility in location and patient device, and with instruments sufficiently focused to avoid redundancy (3,65). One recent study in diabetes care demonstrated limited patient willingness and ability to access electronics systems to report outcomes from outside the clinic (66). In contrast, study of a cancer symptom management intervention found that 85% (319 / 374) of subjects elected to use the system outside of clinic, and 35% of these used the intervention voluntarily (outside of study requirements). This study found

that remote and voluntary use was correlated with education and work status (the latter with only borderline significance) (67), indicating the need to consider disparities in these areas when designing computerized PRO systems.

2.5 A Socio-Technical Approach to Understanding PROs

PRO systems are socially complex health information systems with direct use by many parties (e.g. patients, providers, researchers) in a variety of workflows, with interactions between these different roles and workflows. These systems are also technically complex, as they include interactions with EHRs, a wide range of consumer grade computing devices, and service providers across the internet. From an information standpoint, patient generated health data have complexity in the provenance of the data (the source of the data, and processing and transitions the data undergoes) (5). PROs' novel set of complexities indicate the need to study them both in fine granularity (e.g. patient usability of a longitudinal PRO dashboard (68)), and at the larger socio-technical scale.

Sittig and Singh have posited an 8-dimensional socio-technical model for studying systems at this larger scale (69). This model's concepts include 1) hardware and software, 2) clinical content, 3) the human computer interface, 4) people, 5) workflow and communications, 6) organizational features (policies, procedures and culture), 7) external rules and regulations, and 8) measurement and monitoring. These concepts are interdependent and interrelated, reflecting the complex and adaptive nature of health information systems. This model recognizes patients amongst the direct users of systems. It has been applied to retrospective analysis of clinical decision support systems (70,71), computerized provider order entry (69), radiology diagnostic errors (72), and EHR-based referral processes (73).

Chapter 3. STUDY DESIGN AND METHODS

3.1 CASE STUDIES APPROACH

This section is comprised both of a detailed description of the cPRO system itself, and a set of six descriptive case studies of individual projects and clusters of related projects implemented on this common software platform, and demonstrate the growth and trajectory of the software over that period of time. The cases exhibit a breadth of research and usual clinical care characteristics, and a variety of clinical service settings, and include applications developed both to perform assessments and to deliver interventions. The cases were selected based on project duration, number of PROs administered, and the applicability of the system to modern PRO collection. This author was involved with the engineering and design of the systems in all these cases.

The case study approach employed here uses elements of an approach put forth by Anderson, et al., which incorporates complexity theory to address adaptive systems (74); the elements used include a review of system history, observation of the coevolution of systems, a focus on process as well as events, and recognition that in any given situation different patterns might be successful. This descriptive case study research is comprised of: 1) first-hand experience and review of systems, 2) discussion with principal investigators, implementation team members, and other stakeholders, 3) review of project publications, and 4) project and system documentation. Each case study begins by reviewing the project's history and goals. Then the scope of Sittig and Singh's socio-technical model is applied in review of implementation details, and the innovations in cPRO prompted by the specific project.

3.2 cPRO System

cPRO ("computerized Patient Reported Outcomes") is an open-source software system for delivery of health assessments and interventions (1,75). The system has features for use by patients, clinicians, and research staff in both clinical and research settings. It is web-based, with a modular and extensible object-oriented architecture. Its design and implementation follow best practices for protecting HIPAA-governed data (76), featuring role-based access (e.g. only allowing the appropriate staff users to access patient records), auditing, and encryption.

3.2.1 *Purpose and History*

The system originated at the University of Washington (UW) School of Nursing in 2001-2002 under the direction of Drs. Donna Berry and William Lober (77). It has been used by approximately 47 projects ranging from clinical practice, to public health, to consumer-health oriented systems, and from basic research to implementation (Appendix A). The platform has evolved over a series of natural experiments, driven by the needs of each subsequent implementation. cPRO is maintained by the UW's Clinical Informatics Research Group (CIRG), which is led by Bill Lober and comprised of 6-8 software engineering staff with expertise in health information systems, and a regular rotation of graduate research assistants (78).

cPRO's core is a generalized survey architecture that, from its earliest implementations, has had the capability for 1) conditional logic for both branching and skipping questionnaires and pages, and 2) replacement of text within pages (79). This conditionality was initially based on previous responses, then on wider interaction with the system (e.g., demographic characteristics and study data entered by staff), and subsequently on clinical data, and clinic and study workflows. This scoring and evaluation logic capability was soon leveraged to build tailored interventions, for example, patient education for decision support and self-management.

Technically speaking, cPRO is a database-driven web-based platform, oriented to support collection via both touch-screen mobile devices and personal computers from its earliest beginnings. The platform had precursors at the UW School of Nursing in portable device collection of PROs in the cancer pain domain (80) and in combination with tailored interventions (81–83). cPRO distinguishes itself from these early systems via a generalized, extensible platform, and by harnessing the potential of the internet, which affords the ability to 1) collect data from widely distributed locations, 2) to process, store and deliver data from a central server, and 3) to deliver graphical user interfaces implemented via web languages interpretable by a range of web browsers, on a wide variety of client platform operating systems (84).

3.2.2 *Survey Architecture Details*

The core cPRO survey data schema is as follows:

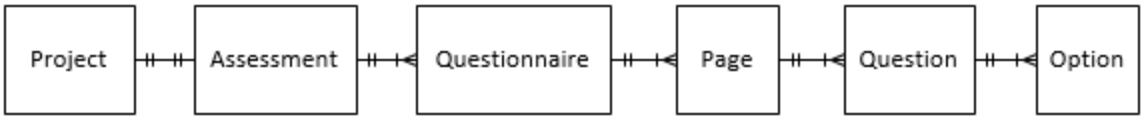

Figure 3.1. Core cPRO schema.

Each cPRO system defines a set of projects, with each project defining the content of an assessment (a set of questionnaires) and how it is to be administered, specifically: 1) the conditions required for an assessment to be available (e.g., user's preference, within two days of an appointment), 2) to whom it should be available (e.g., patients, treatment arm participants and/or clinic staff on behalf of a patient), 3) from which part of the user interface the assessment can be launched, and 4) verbiage around launching, continuing and completing the assessment. Each administration of an assessment to a subject is called a "session"; there can be many sessions per subject per assessment. Each assessment contains one or more questionnaires, which are often standardized instruments. Each questionnaire includes one or more pages; each page can have any

number of questions. Question types are defined by what the options that they contain; these include radio buttons (e.g., for Likert-type scales) and checkboxes (both with free-text "combo" variants), drop-down lists, free text boxes, dates, and visual analog slider. Later implementations include vector-based image maps, photo capture, events in time, and ranking questions. Pages, questions and options can include browser-interpretable code (HTML, JavaScript, and CSS).

cPRO has flexible mechanisms for **scoring instruments**, as dictated by the instrument definition or particular use case for the instrument. It has constructs for mapping individual responses to numerical values ("items"), and indicating the maximum and minimum range of reportable values at both the item and instrument levels. This mechanism allows for variably weighted items, and indexing based on arbitrary values (0- and 1- being most common). Individual items are aggregated into instrument scores by an extensible set of functions, for example, mean. Furthermore, these functions can apply criteria to only score the instrument if a minimum proportion of individual items have values.

3.2.3 *Palette of Extensible Features*

cPRO is highly configurable and extensible, in both functionality and appearance. For example, configuration allows for 1) selection of which website sections to include, 2) customization of navigation element labelling, 3) selection of which patient record fields to present to staff, and 4) choosing between system 'production', 'demo' or 'development' modes. Each system is assigned an "instance" identifier, which identifies a specific configuration "bundle" and facilitates automatic use of specific object-oriented class extensions, browser-rendered "view" code (HTML, JavaScript, and CSS), and logos and banners.

3.2.4 *The Patient Experience*

The features and navigation routes available to the patient are determined by the patient's current role (e.g., patient, treatment participant), the state of session collection (as dictated by project(s) rules), progression through interventions, clinical status, and demographic characteristics.

When a patient begins an assessment, a number of changes are made to the user interface to encourage focus on the currently rendered assessment. Most navigation elements are removed, banners are reduced in size, and questions are presented in large text with large graphical input elements (Figures 3.2, 3.3). This design facilitates rapid interactions via touch screens, which have been central to cPRO implementations since its inception, and remain critical with the extension of cPRO into mobile platforms.

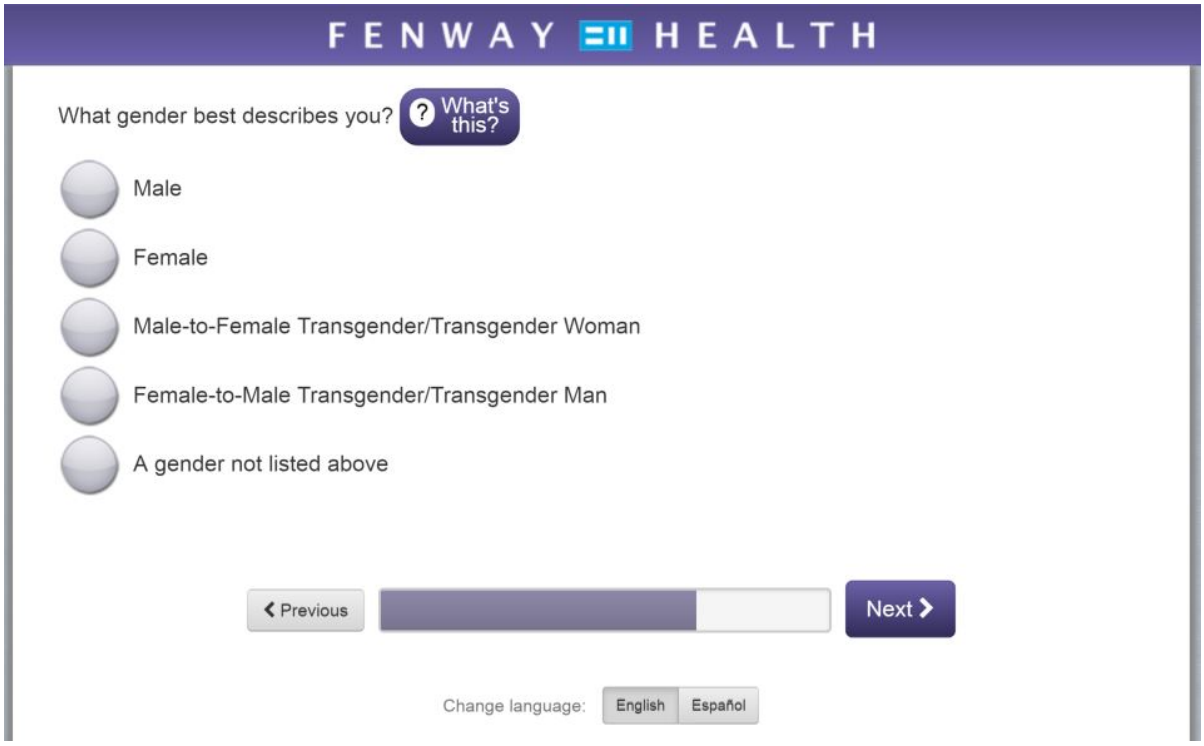

Figure 3.2. A typical cPRO assessment page, as viewed on a tablet computer.

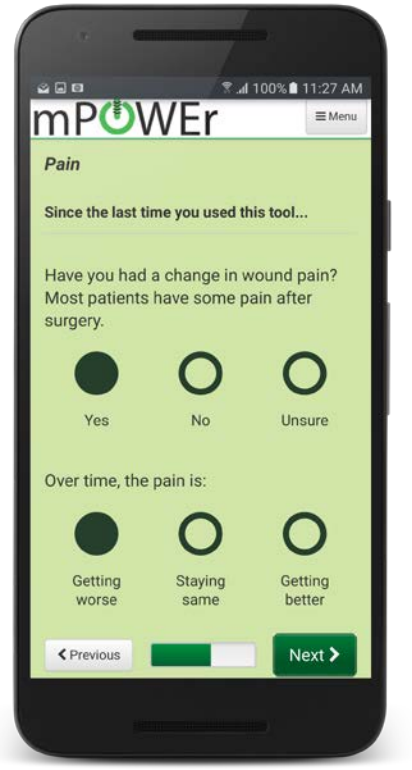

Figure 3.3. A typical cPRO assessment page, as viewed on a smartphone.

The patient's first interactions with the cPRO system can be enabled via a number of pathways: 1) the patient accesses a general URL and creates his or her own account, 2) staff create an account for the patient and send a unique URL to the patient via the system, 3) staff create an account and relay the site's URL, along with login ID and password via methods external to cPRO, and 4) staff create an account and give the patient access to the system via a kiosk system, obviating the need for patient system credentials. These pathways can be enabled by configuration.

3.2.5 *Language Support*

cPRO has multi-language support in the patient interface. All text and icons presented to the user are automatically delivered in the user's language of preference. The system currently has

full Spanish language content for two projects, and Amharic for one; past projects included a Cantonese system. Multi-language supported is implemented via the common GNU "gettext" library (85). Since 2013, cPRO projects have used a commercial cloud-based service to facilitate distributed, concurrent multi-user translation efforts (86).

3.2.6 *Staff Features*

A variety of features are available to staff to facilitate administration of research and clinical systems. The central component is a patient record manager, which includes a listing of all patients, and an individual patient record editor. The "all patients" list can be configured to specify which fields to include, and by which field the patients should be ordered. The list supports the user in sorting by any field, and searching across all fields. The individual patient record editor has functionality for editing a patient's demographic characteristics and login credentials, and viewing summary clinic reports (Figure 3.4). It is configurable to include a number of "submodules" including appointments, notes, patient preferred language, study subject management fields, and an email console. The email console supports staff sending emails to patients via the system, and displays a history of emails sent. Emails are customizable via templates; examples include reminders to register in the system, and to complete assessments. The appointments submodule can be populated by records imported from an external system, such as an EHR (see the Fenway and PainTracker/ActionTracker cases below). The patient record interface allows staff to complete an assessment (on the behalf of patient, or as a staff assessment of the patient's state), and to log in with the patient's account (typically used in-clinic, in cases where the patient is unable to log in to the system themselves). Staff can create patient accounts via the graphical interface. Depending on their cPRO roles (e.g., "Research Staff", "Clinic Admin" - see Authorization, below) staff can also create and edit other staff records.

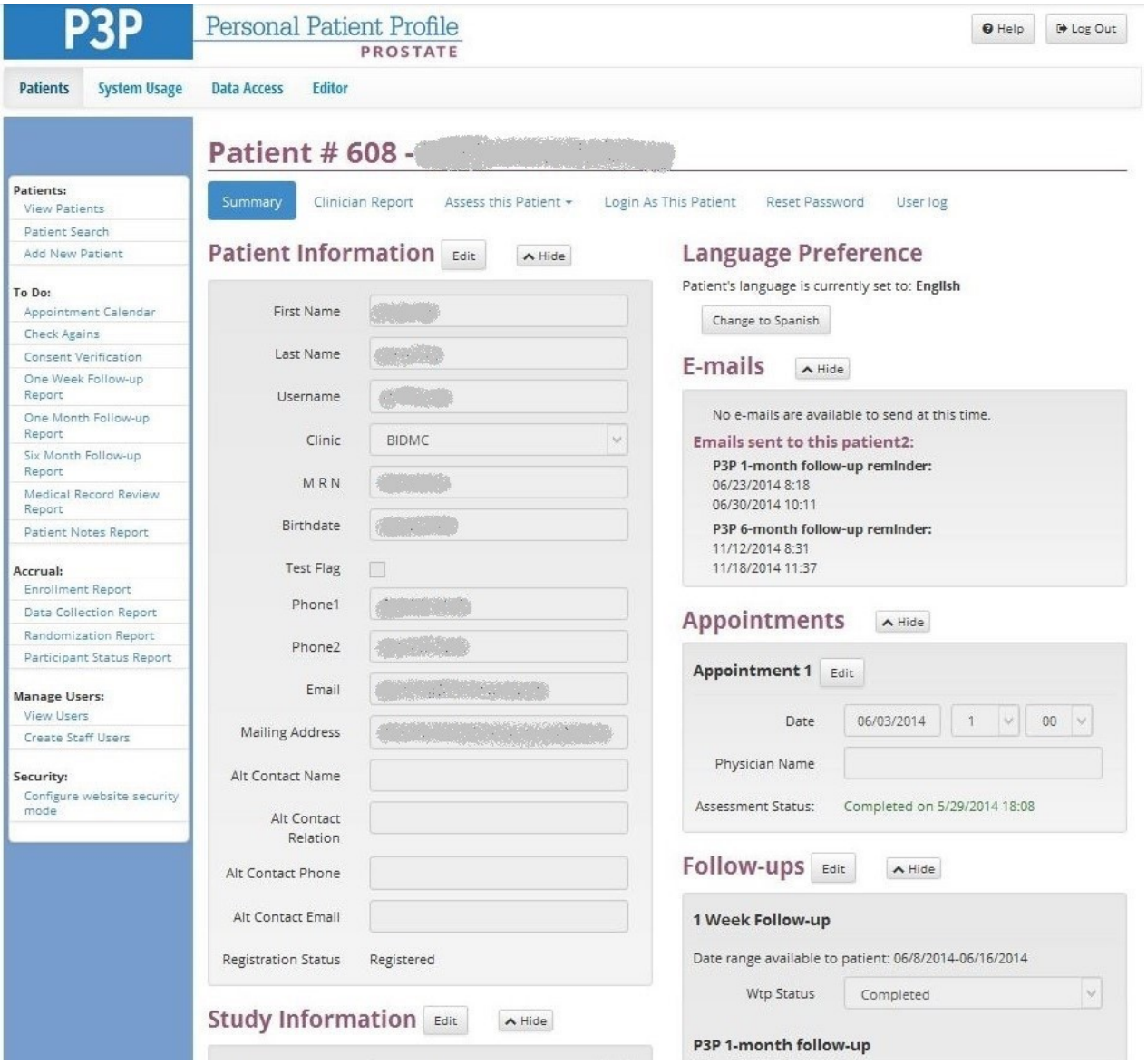

Figure 3.4. Patient record editor with optional e-mail, appointments, and "follow-ups" modules (1 of 2).

The study management module enables monitoring and management of the patient's status in a study, for example: assignment to study arms (several randomization schemes have been implemented), consent status, withdrawal from study (Figure 3.5).

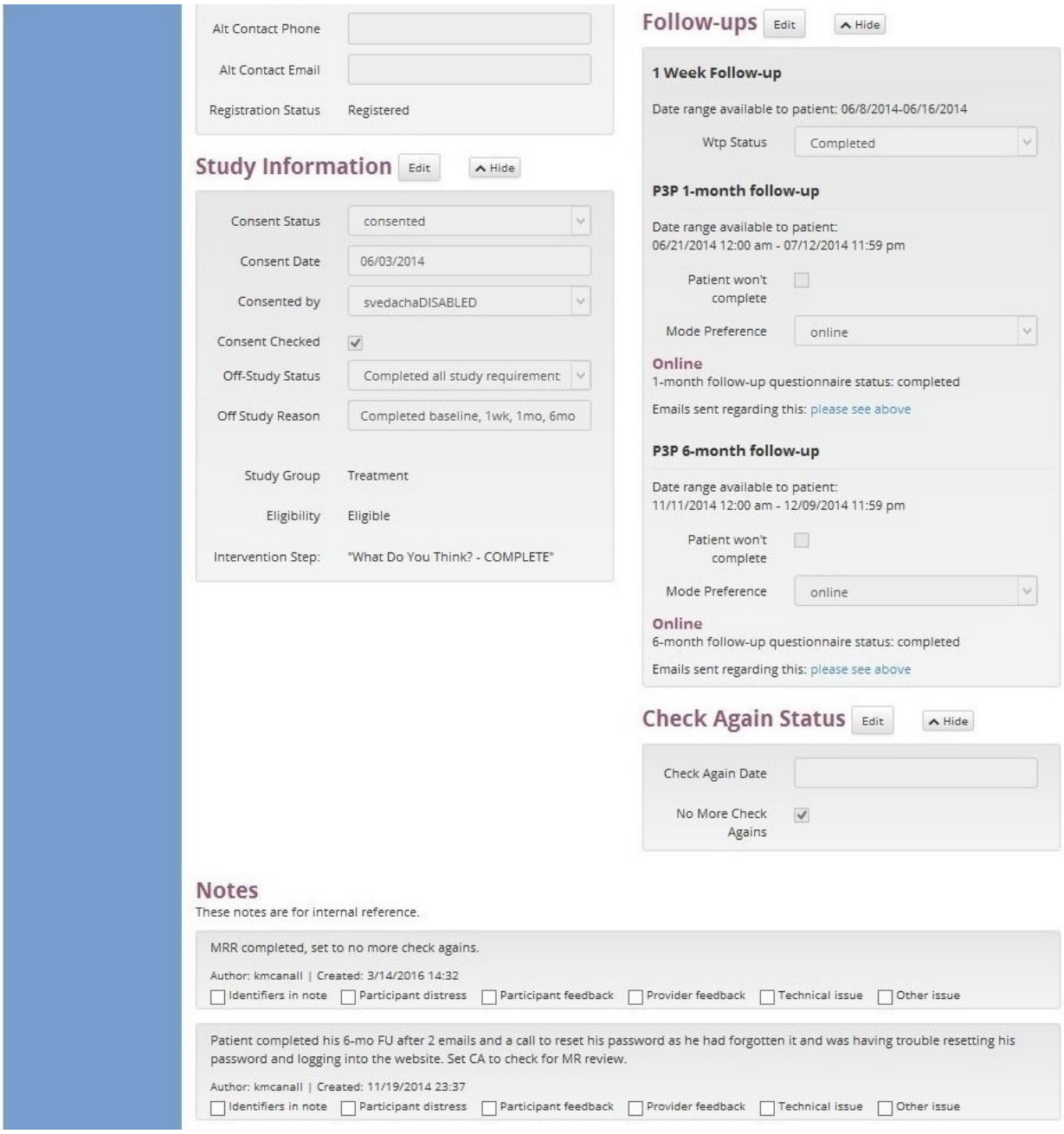

Figure 3.5. Patient record editor with optional study module (2 of 2).

The system allows staff with the "researcher" role to download de-identified data exports of each project. Staff can select exports of either response-level data, or calculated instrument scores. The system includes an assessment editor, which is primarily used for editing text and html, and adding translations for non-English languages.

3.2.7 *Technical Platform Description*

The system is implemented on an open-source LAMP foundation (87), namely, a Linux operating system (88), Apache web server (89), MySQL database server (90), and PHP software language (91). Early versions used a rather unstructured software codebase (as opposed to applying established software design patterns). In 2008-2009, to meet ESRA-C's evolving needs (see case below), the engineering team re-architected cPRO to leverage a web application framework layer built on top of standard PHP libraries (specifically, CakePHP version 2 (92)), which used the then-common "Model-View-Controller" architectural pattern for graphical user interface applications (93). This additional programmatic layer affords 1) improved separation of data, logic, and presentation layers, 2) improved data model bindings to schema, supporting richer data structures including enhancements to cPRO's instrument scoring abilities, 3) functional and utility libraries e.g. for authorization, authentication, and URL mapping, and 4) an abstraction layer allowing for the use of a variety of database, web server, and operating systems types. In addition to this server-side refactoring, the team leveraged nascent browser-interpreted language frameworks, primarily jQuery (94), a JavaScript framework that facilitates 1) cross-browser and -operating system development 2) AJAX (95), and 3) HTML DOM traversal and manipulation (96). cPRO leverages a variety of other open source libraries, including Bootstrap for "responsive" user interface styling (i.e., enabling dynamic multi-device formatting (97)), and Less, which extends the CSS styling language to make it more flexible (e.g., by supporting variables) (98). The cPRO engineering team uses a variety of open source software approaches (e.g., for compressing JavaScript libraries delivered to browsers (99)). Much of the functionality detailed in subsequent sections has been implemented by the engineering team from low-level programming libraries, for example, time-zone conversions, and user / clinic / parent institution relationship models.

3.2.7.1 Application Programming Interfaces (APIs)

Application Programming Interfaces (APIs) facilitate inter- and intra-application communication. The cPRO engineering team has pivoted towards a RESTful service / API - oriented architecture (100) over the past five years, in order to support: 1) integration into a variety of distributed system architectures, and 2) cPRO's own user interface / presentation layer becoming more like a small group of "single-page applications" (101). In 2014, the team began implementing services according to the HL7 FHIR specification (see Results and Discussion sections).

3.2.7.2 Security and Privacy

cPRO has been implemented to serve the five key security functions as defined in the National Research Council's 1997 "For the record: protecting electronic health information," namely: availability, accountability, perimeter identification, controlling access, and comprehensibility and control (76,102).

cPRO has always used encrypted HTTPS exclusively, and does not store or cache any personal health information in the browser. The system logs the user out after a duration of inactivity, as monitored by server and browser-side code. The default timeout is twenty minutes, but staff can configure it on a per-computer basis for 1) "kiosk" mode (five minutes), for use in clinic waiting rooms, for example, and 2) "private" mode (eight hours), for use at a staff members secured workstation.

3.2.7.3 Authorization (User Roles)

cPRO uses roles to govern users' access to functionality. Examples of roles include Patient, Participant, Treatment Participants, Clinic Staff, Clinic Administrator, and Survey Editor. A user can be assigned more than one role. Each role's access to resources is governed by an Access

Control List (103). In this model, roles are implemented as an "Access Request Object" tree, and resources in an "Access Controlled Object" tree.

When a user logs in to cPRO, the system enables user interface components based on whether the user's roles have access to the components. Authorization is also checked when services and functions are used within the code. For example, when a user with the "Survey Editor" role logs on cPRO displays the navigation tab to access the survey editing system, and if a user attempts to make a service call to edit a survey, the system checks to see that they have this role before allowing execution to take place.

3.2.7.4 Authentication

cPRO can be configured to use a number of authentication methods. Application-level authentication is self-contained within cPRO: it does not require interfacing with other services, but it does require that users maintain cPRO credentials. External authentication methods require more technical configuration, but can greatly facilitate the user experience. cPRO has client implementations for OAuth (104) and Shibboleth (105) external authentication services.

3.2.7.5 Auditing and Logging

A log entry is created for every patient interaction with the system, from page-level access to clicking on in-page dynamic elements. Uses for this level of logging include measurement of the extent to which the patient has used an intervention, and timing of user interaction with survey pages and navigation. Staff interactions are also logged, for auditing purposes.

3.2.7.6 Deployment Strategies

cPRO is most commonly implemented as a Software as a Service (SaaS) model administered by the UW's Clinical Informatics Research Group (CIRG), and run on either CIRG's server infrastructure or the owner's; selection of the host system is largely dependent on the

technical capacity of the owner's IT team, and the need to satisfy privacy and security requirements as dictated by the owner's IRB and operational oversight policies.

3.2.7.7 Open-Source Software Availability

The core cPRO platform is released as open source software under the BSD ("3-clause") license (106). Versions of the codebase are available at https://github.com/uwcirg/cpro. Some project-specific features are proprietary, for example: the P3P intervention, the mPOWEr-specific user interfaces, and the PainTracker body diagram. These are solely available by license; contact cirg@uw.edu for licensing terms.

Chapter 4. RESULTS (SIX CASE STUDIES)

4.1 ELECTRONIC SELF-REPORT ASSESSMENT PROGRAM FOR CANCER ("ESRA-C")

The Electronic Self-Report Assessment program for Cancer (ESRA-C) helps patients to identify and track cancer symptoms and quality of life concerns during treatment, to share these concerns with clinicians, and to engage in self-care. This was cPRO's first implementation of longitudinal PRO collection, a summary clinician report, and real-time screening alerts to staff and patients.

4.1.1 *Distinguishing Characteristics and History*

The Electronic Self-Report Assessment program for Cancer (ESRA-C) is a program that promotes the abilities of patients to identify and track cancer symptoms and quality of life (SxQOL) concerns during active treatment periods, to share these concerns with clinicians, and to engage in self-care activities. ESRA-C was the first electronic self-report application found to

significantly increase patient-clinician discussion of SxQOL issues and significantly reduce symptom distress in US randomized clinical trials (8,28).

Foundational work began in 2001 with implementation of the "Computerized Symptom and Quality-of-Life Assessment" (77,107). The technical infrastructure of this prototype informed many of cPRO's early characteristics, though it was not a generalized and extensible platform. In 2004-2007, a National Institute of Nursing Research R01 grant supported further development of ESRA-C and a randomized control trial to evaluate efficacy. By this time, the first generalized versions of cPRO had been developed and used by two other projects (including Personal Patient Profile – Prostate, described below), and the ESRA-C team was able to leverage and enhance the platform. In this first randomized trial, the intervention group patients' SxQOL were compiled by cPRO into a two-page graphical clinician report, with bar graph height indicating the instrument score, and color indicating whether the score met an a priori threshold.

In 2007-2011, an NINR grant supported development and evaluation of ESRA-C II. Where the first version queried the patient for SxQOL issues and reported to the clinician, this new version responded to the patient directly by letting them further rank the bothersome issues which standardized instruments highlighted, and offered tailored education and self-care strategies to deal with those issues (Figure 4.1).

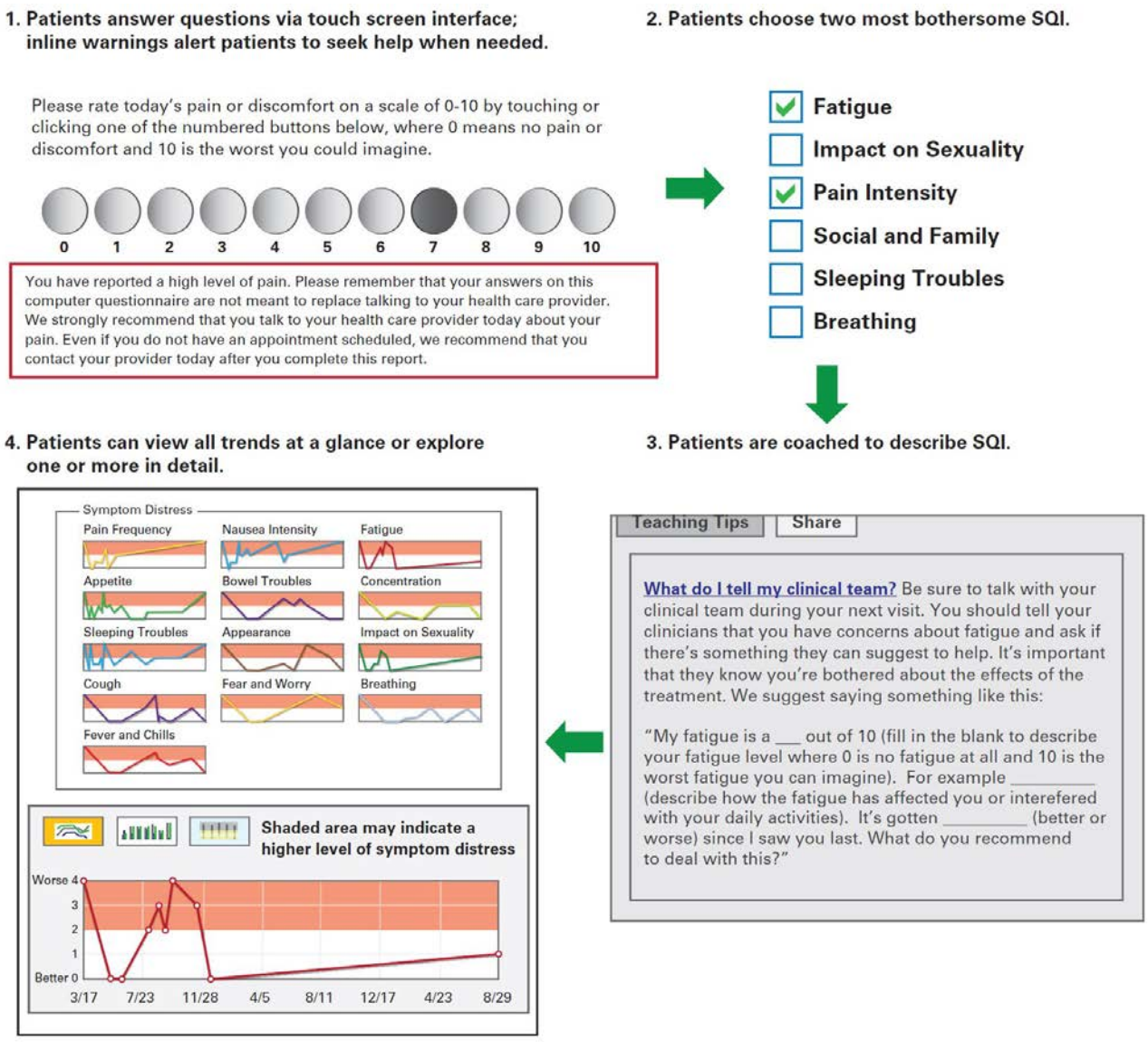

Figure 4.1. ESRA-C Assessment and Intervention. Berry et al., 2014 (28).

ESRA-C II leveraged P4's approaches to provide communication coaching (see Personal Patient Profile – Prostate, below). This study's findings established that ESRA-C was effective in reducing patients' symptom distress over the course of therapy (28), and that the more a patient voluntarily used the system, the greater the effect would be (67). The ESRA-C II assessment

included twelve validated questionnaires administered at various points throughout the course of assessment (28).

There have been a number of pilot variations on ESRA-C: A 2007 version focused on cognitive assessment; a 2008 pilot in Hong Kong; a Spanish-language version; a version focused on fatigue (a high priority symptom during treatment, as reported by patients (108)); and a 2008 adaptation that evaluated ESRA-C's feasibility with adolescents (109). Finally, the ESRA-C II system was used clinically at Seattle Cancer Care Alliance's Transplant clinic from 2011 through 2016, at which point the entire institution implemented universal screening for psycho-social distress.

4.1.2 *Implementation*

For ESRA-C I, assessments were administered to patients in clinical waiting rooms via touch-screen computers. The summary clinician report was printed and given to the clinician at the second on-treatment clinic visit, when treatment-related issues were expected.

ESRA-C II was available for the patient to access directly from their own personal computer or tablet, at their convenience (with clinic administration via touch-screen computers as a backup).

4.1.3 *Needs and cPRO Responses*

Along with its summary clinician report, ESRA-C I presented a screening report to research staff immediately following assessment of the patient; this highlighted the patient's report of any severe symptoms, pain, depression, and suicidal ideation; in situations of severe state, research staff would inform clinical staff. The system presented a form for research staff to indicate whether the clinical team had been alerted. This marks cPRO's first implementation of real-time actionable

alerts to staff based on time-critical patient state, and workflows and auditing in response to the alerts.

To meet ESRA-C's evolving needs, the engineering team re-architected cPRO in 2008-2009 (see Methods section). ESRA-C II development helped establish an iterative cPRO development model of patient-centric participatory design with end-users (110) and informed the use of eye-tracking systems in design studies (111). cPRO accessibility improvements were applied based on a usability session with a vision-impaired reviewer using a screen reader.

In ESRA-C II, when scored values of instruments and questions reached a preset level during the assessment, indicating the need for intervention, real-time guidance was presented to the patient. The system presented patient-customizable longitudinal graphical summaries, and allowed patients to share these with whomever they wished via email.

The 2008 pilot in Hong Kong informed internationalization and translation efforts in subsequent cPRO projects (112), as did a Spanish implementation that used iterative participatory design for improving readability and cultural sensitivity (113). The fatigue-oriented variant added a novel activity diary to the patient user interface plus expanded teaching tips for cancer-related fatigue (Figure 4.2) (114).

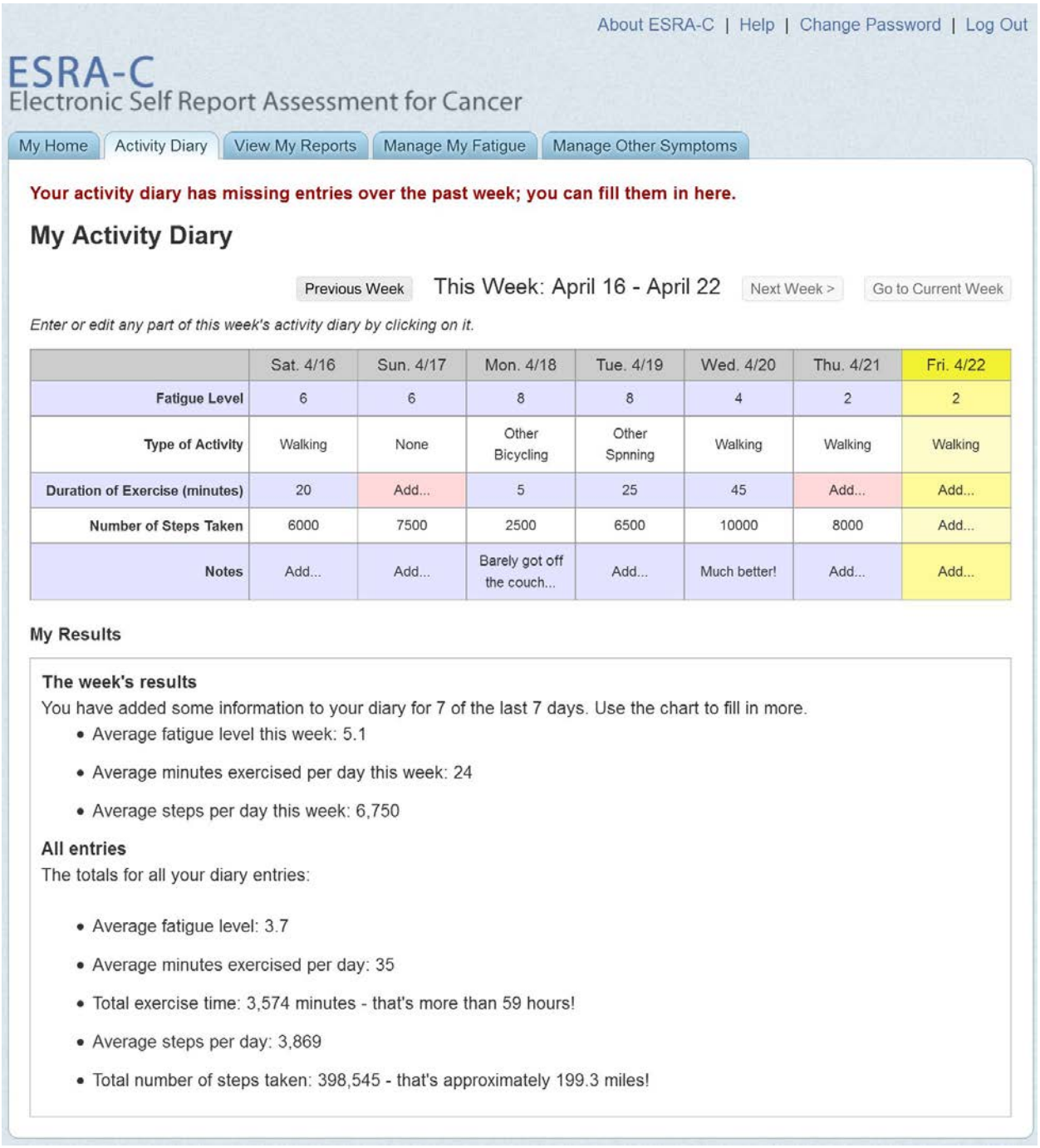

Figure 4.2. Activity diary from ESRA-C Symptom Management Excellence - Fatigue.

4.1.4 *Quantitative Results*

Table 4.1. ESRA-C Quantitative Results

Project	Research / Clinical	Patients	Sessions	Clinic / Remote	Sites
ESRA-C I	Research	660	1320	100% Clinic use	Seattle Cancer Alliance and the University of Washington Medical Center, across medical, radiation, and stem-cell transplant services
ESRA-C II	Research	752	3253	14.5% Clinic only / 85.5% remote to some extent	Seattle Cancer Care Alliance (stem cell transplant); Dana-Farber Cancer Institute in Boston, MA (medical oncology and radiation oncology services)
ESRA-C II Seattle Cancer Alliance	Clinical	2784	2345	100% Clinic use	Seattle Cancer Care Alliance (stem cell transplant)

4.2 PERSONAL PATIENT PROFILE-PROSTATE ("P3P")

The Personal Patient Profile-Prostate (P3P; aka "P4" in early versions) offers patient-centered decision support for men choosing between treatment options in a setting where there is no clear medical evidence for a choice, and therefore their decision rests on personal preferences and values. This was the first implementation of cPRO, and added tailored feedback, remote patient use, and multi-lingual features to cPRO capabilities.

4.2.1 *Distinguishing Characteristics and History*

P3P is a decision support tool for patients with localized prostate cancer that queries the patient for personal factors and characteristics: current symptoms, health and social outcomes of

interest, and influential people. Based on this information, the program presents tailored information and communication coaching to prepare the patient for discussing treatment options and sharing decisions with their consulting clinicians (Figure 4.3). This project had its beginnings in a 1998-2002 foundational study on the influence of personal factors in prostate cancer treatment decision making (115). A 2003-2005 NIH/NCI supported pilot was the first implementation of both P3P and cPRO (116), and demonstrated cPRO's assessment and tailored intervention abilities. In this first version, the intervention presented a summary of personal factors to the patient with a menu of web and printed resources, along with a tailored set of video vignettes modelling how a patient could communicate preferences and priorities with the physician (117). Men reported that they found the system useful, and there was a high rate of use amongst subjects (30).

A 2007-2009 NIH R01 supported the system's evolution and expansion to six clinics (including three Veteran Administration Clinics) in four US cities, introducing a greater diversity of patient demographic and health characteristics. The system now supported Spanish as well as English, and the intervention videos were tailored based on race, ethnicity, age, and language preference (specifically, the actors in the videos matched the patient's characteristics). Findings revealed that P3P significantly reduced decisional conflict over six months after enrollment as compared to usual care controls (25).

From 2010 through 2014 a number of "plan-do-study-act" iterations were made to improve the system's usability, and linguistic and cultural appropriateness for African American and Hispanic men. "Think-aloud" approaches were used to develop an inventory of issues (118). A study using an eye-tracking system suggested that among low literacy users, infographics may be of higher relative value than textual information (111). Simple translation to Spanish was found to not sufficiently address usability, linguistic or cultural appropriateness, so a process of forward

and back-translation of the system and subsequent cognitive interviews was used to further refine it (67).

A 2012-2016 R01 supported a two phase effectiveness / implementation study at three multi-clinic sites (Kaiser Permanente in southern California; Emory, Grady, and the VA clinic in Atlanta GA; and Beth Israel Deaconess in Boston MA). The first phase evaluated the revised P3P's efficacy with research staff coordination of administration for patients. The second phase removed the research staff support in a standard practice implementation project. This study refined P3P across all phases of patient involvement and clinic workflow (Figure: intervention screenshot at factors tab). Data collection and analysis is ongoing, including focus groups and surveys of staff.

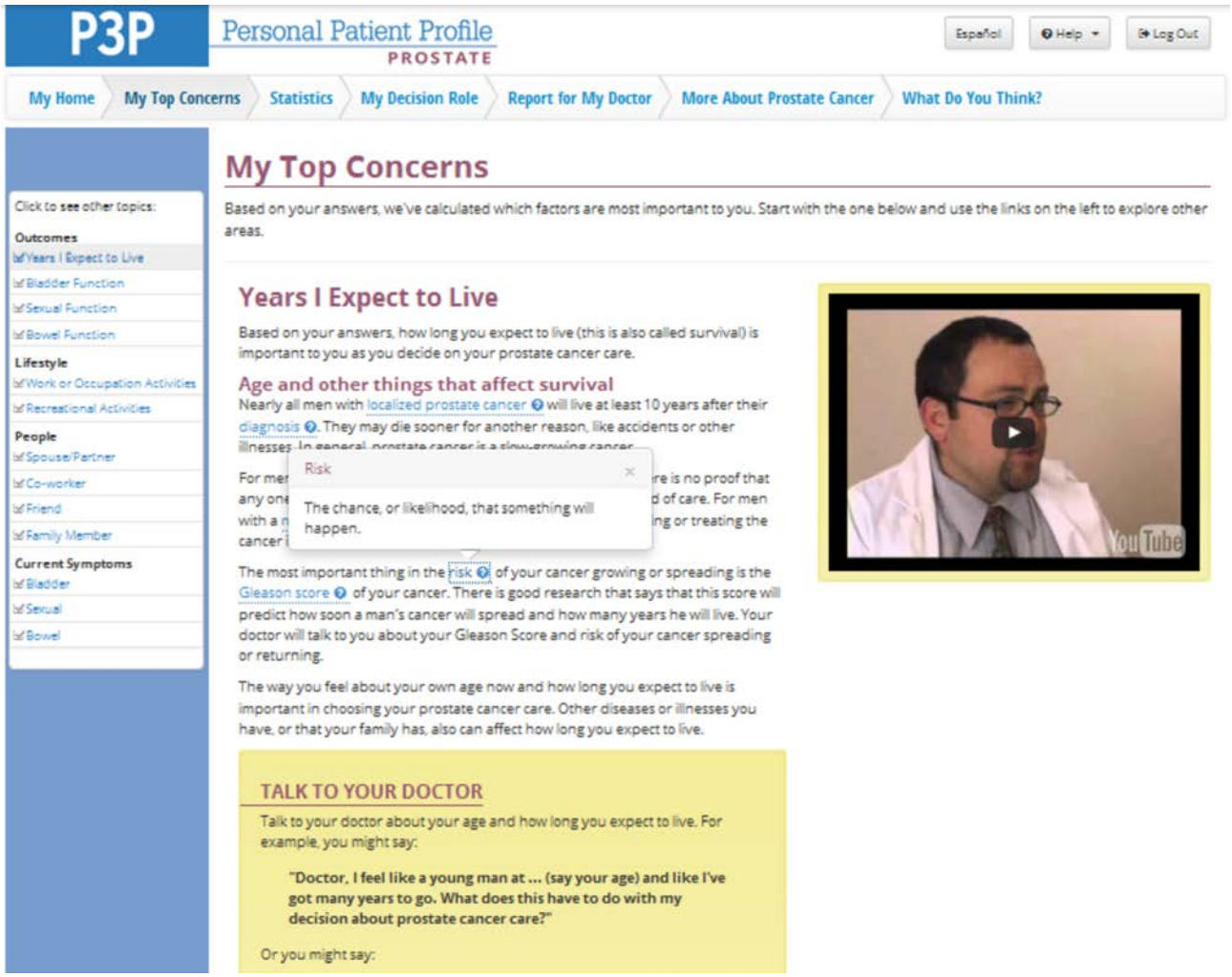

Figure 4.3. P3P Intervention.

In 2015 a pilot Hodgkin's Lymphoma survivorship website was deployed at Dana Farber Cancer Institute that used P3P's "guided intervention" framework (which promotes step-by-step navigation of the site), with intervention tailoring in this instance based on patient clinical history and demographic characteristics. As in P3P, this system presented videos to subjects, however more as informational tools versus P3P's vignettes demonstrating patient-provider communication.

P3P was adapted for use in the Movember Foundation -funded "TrueNTH-Australia" project (119) in 2015. This version leveraged cPRO's internationalization capabilities (described

above) to tailor linguistics to the Australian audience. As with all cPRO systems, style (colors) and branding (e.g., banner graphics) were customized. Videos were professionally re-produced in Australia. A future USA version of TrueNTH will also include P3P.

Table 4.2. P3P PRO Instruments

Instrument
1. Influential personal factors (30)
2. Information priorities (120)
3. Preferred role in the treatment decision (Control Preferences Scale (121)
4. Current symptoms (EPIC-26 or EPIC-CP (122)).
5. Decisional Conflict Scale (123)

4.2.2 *Implementation*

The pilot system (2003-2005) was presented on a desktop computer with a touch screen in a private patient education room at the University of Washington's Prostate Oncology Center. Patients were introduced to the system via a phone call from their physician. Starting with the first phase of the RCT (2007-2009) the system was offered for both clinic and home use via patient login, with the patient accounts created by staff.

The 2012-2016 hybrid effectiveness-implementation study system supported patient "self-registration" (details in the next section), and encouraged patient engagement with the system by sending a short series of reminder emails to patients who had begun but not yet completed the intervention. In the implementation (post-evaluation) phase, support for research staff was removed. Clinics engaged patients in P3P via various methods, some as minimal as simply providing the P3P URL in an after-visit summary and as extensive as a personal invitation by the urologist to visit the program followed by an emailed link from a patient care coordinator.

The TrueNTH Australia pilot system was deployed to Amazon Web Services virtual servers hosted in Sydney, Australia; this represented the first deployment of cPRO to an international cloud infrastructure.

4.2.3 *Needs and cPRO Responses*

Starting in 2007, P3P was offered for both clinic and home use via patient login (a first for cPRO), and 69% of users completed the initial assessment from home. The cPRO team's first designs and implementations of multilingual support for patients, and approaches to managing translation efforts also started during this time (details in methods).

During the hybrid effectiveness-implementation study (2012-2016), the P3P research and engineering teams implemented approaches and systems with the goal of building a more patient / consumer -guided system, and one that reduced clinic staff burden. A large part of this focus was on initial patient engagement and self-registration with the system. Clinic staff continued to introduce P3P to patients according to a protocol, but staff did not create accounts or otherwise enter the system. Patients created their own logins ("self-registered") on the website, consenting to terms of use that provided the characterization: "Information given by P3P is for educational purposes only and does not replace professional medical advice. Using information in P3P is at your sole risk and does not create a doctor-patient relationship." This process included the option for patients to indicate their clinic, which had two uses. First, the system's patient-management website for staff only displayed patients who self-identified as receiving care at the staff member's clinic, promoting privacy. Second, the patients' user interface offered the option to have the system send an email to a clinic-specific email address indicating when a summary report was available (for privacy reasons, the report itself was not emailed).

Several new features were added to cPRO to improve the patient's experience. A "guided tour" walked the patient through the basic features of pages that had new functionality or user interactions (such as the assessment, and survival statistics in the intervention). A new patient-triggered in-context glossary dialog addressed health literacy while limiting the amount of text on the page.

4.2.4 *Quantitative Results*

Table 4.3. P3P Quantitative Results

Project	Patients	Sessions	Clinic / Remote	Clinics
P3P RCT 2007-2009	494	1369	69% completed primary session from outside the clinic	6 clinics / 4 cities
P3P Efficacy Trial 2014-2016	413	766	51% remote	13 clinics / 7 sites
P3P Implementation Study 2016	99	98	95% remote	8 clinics / 4 sites

Table 4.4. P3P Efficacy trial: use in-clinic versus outside of clinic (home, mobile)

Clinic	Phase 1 in-clinic	Phase 1 outside clinic	Phase 1 outside clinic %
Beth Israel Deaconess	2	105	98%
Brigham Women's Hospital / Dana Farber Cancer Institute, MA	0	10	100%
Emory Healthcare: University & St. Joseph's, GA	143	3	2%
Emory Healthcare: Grady Hospital, GA	18	0	0%
Harris Health System, TX	2	0	0%
Kaiser Permanente Southern CA	3	63	95%

University of Virginia	2	~19	~90%
Veterans Administration Clinic, Atlanta, GA	32	0	0%
Total	202	210	51%

Table 4.5. P3P Implementation study: use in-clinic versus outside of clinic (home, mobile)

Clinic	Patients appropriate for P3P	Patients referred	Used P3P	Percent referred who used P3P	Used in clinic*	Used outside clinic*
Beth Israel Deaconess	155	82	44	54%	0 (0%)	44 (100%)
Emory Healthcare: University & St. Joseph's	140	67	24	36%	1 (1%)	23 (96%)
Emory Healthcare: Grady	(unknown)	4	4	100%	4 (100%)	0 (0%)
Kaiser Permanente So.Cal.	112	65	2	3%	0 (0%)	2 (100%)
Patient did not specify clinic	(not applicable)	(not applicable)	25	(not applicable)	(not applicable)	25
Total	407 known	218	99		5 (5%)	94 (95%)

* Per clinic workflow preferences. Patients were not offered a choice.

Table 4.6. P3P Implementation study: assessment completion and intervention usage

Registered	99 patients
Initiated assessment	99% (98)
Amongst those who initiated the assessment, percentage who completed it	95% (93)

Amongst those who started the intervention, percentage who completed it	53% (49)
Amongst those who viewed the clinician report (n = 66), percentage who sent to their provider	62% (41)
Amongst those who viewed the clinician report (n = 66), percentage who printed it	33% (22)
Assessment duration	10-15 min
Decision support intervention duration	15-45 min

4.3 CENTERS FOR AIDS RESEARCH (CFAR) NETWORK OF INTEGRATED CLINICAL SYSTEMS (CNICS)

The CNICS PRO is oriented towards routine clinical PRO data collection across a multi-center research network, providing evidence for HIV research and improving clinical care. cPRO innovations included enabling PRO collection in a variety of clinical workflows via roving tablet computer "kiosks", automatically advancing the assessment when the patient has answered all the questions on the page, real-time suicidal ideation alerts, and standardized instrument validation.

4.3.1 *Distinguishing Characteristics and History*

In 2005 cPRO was deployed at the University of Washington Harborview Medical Center HIV clinic for a study of the feasibility of routine computerized PRO collection during clinic visits, thus beginning the largest and longest running set of cPRO systems to date. Data were reported to the University of Washington HIV Information System (UWHIS), which captured longitudinal data on the UW HIV Cohort. The study saw much higher completion rates and lower assessment completion time relative to a previous paper assessment in the same clinic (124).

UW joined three other sites (University of Alabama, Birmingham, Case Western Reserve University, and University of California, San Francisco) to form the Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS), a clinic-based research network focused on building a comprehensive clinical data repository for HIV, orienting EHR data towards contributing to both point-of-care and research (125). Several more CFAR sites joined CNICS subsequently (University of California, San Diego, Harvard-affiliated Fenway Community Health Center, and University of North Carolina), and in 2008 CNICS sites began implementing variations on UW's model of routine PRO collection towards both clinical care and CNICS research, using cPRO. By early 2016 the CNICS cPRO systems had assessed over 16,000 patients, with a total of 55,000 sessions. Most of these sites had not collected computerized PROs previously, but implementation was facilitated by 1) UW's pioneering and evolving experience, 2) an overarching goal to keep assessments as short as possible in order to reduce patient burden, 3) shared interest in developing as common protocols as possible, and 4) CNICS-funded staffing at each site. cPRO quickly evolved in response to accommodating the large number of patients, enabled by commonalities in clinic workflows and research protocol.

The core CNICS PRO includes ten standardized instruments for depression and anxiety, symptoms, antiretroviral medication adherence, alcohol risk, tobacco use, illegal drug use, HIV-transmission risk behavior, health-related quality of life, physical activity, and body morphology abnormalities (124). In addition to providing research data directly towards the treatment, prevention, and improving the lives of those with HIV (126–130), the CNICS cPRO systems are also used for standardized instrument development and validation (131), identifying subjects for other research based on PRO data, and contributing data towards a national community health applied research network ("CHARN" (132)). A non-clinical version of cPRO was used for CNICS

researcher data collection in the field, in a study comparing telephone- and home visit-based monitoring of medication adherence (133).

4.3.2 *Implementation*

The system is administered on touch-screen tablet and laptop computers in clinic (to date there has been no use by patients outside the clinic). Early versions of the system used a dedicated Wi-Fi network (before clinics had an accessible wireless network). The general workflow is collection every 4-6 months. PROs are collected where patients tend to be passively waiting during visits; for some clinics this in the waiting room, in others, the exam room (134). A summary clinician report of the patient's PROs results is made available to the patient's provider in "real time" during the visit. In some clinics these reports are automatically printed out and delivered by PRO staff to providers; in other clinics reports are displayed to providers on workstations in the examination and provider rooms. In one case the summary report and discrete data are sent to the EHR (see Fenway, below). Most providers review the summary report prior to greeting the patient.

Patient-Based Measures Provider Feedback

Printed Mar. 22, 2016

Jack Foote **MRN: 114747** **DOB: 04/04/1984**

	3/20/2016 120 answers	**1/15/2016** 105 answers	**11/08/2015** 129 answers
Depression (PHQ-9)	9 Mild Depression	15 Moderate Depression	23 Severe Depression
Suicide Ideation (PHQ-9) In Last 2 Weeks	**3** **More than half the days**	2 Several Days	4 Nearly Every Day
Tobacco Use	1/2 - 1 pack a day	1/2 - 1 pack a day	Less than 1/2 pack a day
Alcohol Score	8 At-risk	5 At-risk	1 Not at-risk
Substance Use (Past 3 months)	Amphetamines, Cocaine/Crack, Marijuana	Amphetamines, Cocaine/Crack, Marijuana, Opiates	Amphetamines, Marijuana
Antiretroviral Adherence (Past 4 weeks) Last missed	**Poor** **Within the past week**	Good 1-2 weeks ago	Good 1-2 weeks ago
Concern for IPV	**Physical violence: yes** **Sexual violence: no**	None	None
Isolated/controlled	Most of the time	Some of the time	Some of the time
Fearful of harm	Most of the time	Some of the time	Some of the time
Sexual Risk Behavior (Past 3 months)			
Number of partners	6 Some female, some male-to-female	3 Some female, some male-to-female	1 Male HIV-negative partner not prescribed PrEP
Unprotected anal sex	Yes • HIV negative partners: some prescribed PrEP • HIV positive partners: all prescribed ARVs • 10% receptive partner	Unsure • HIV negative partners: all prescribed PrEP • HIV positive partners: all prescribed ARVs • 50% receptive partner	Yes 90% receptive partner
Unprotected oral sex	Yes, with all partners	Unsure, with all partners	Yes, with partner
Concerned for STI exposure	**Yes**	No	No

Figure 4.4. CNICS longitudinal clinician report.

The CNICS PRO Staff Guide is at http://tiny.cc/cnics-pro-staff-guide (135). CNICS PRO administration workflows continue to be refined, with some changes CNICS-wide, and some specific to individual sites. Fredericksen et al. describe a number of refinements applied at the UW clinic via "plan-do-study-act" cycles (19).

The CNICS PRO implementations offer a viewpoint on the variety of institutional health IT policies around security and privacy. Of the four sites using CIRG's server infrastructure, three

store fully identified records, while one uses patient initials only. Two sites use their own hosting infrastructure, but with remote server administration by CIRG (one of these systems interacts directly with the EHR, necessitating hosting on the sites' network).

4.3.3 *Needs and cPRO Responses*

Separate staff and patient/kiosk URLs are used, with patient and staff functionality further restricted via role-based access. The staff version of the website supports management of patient records and staff accounts, generation of "tickets" for patient access to the system (numerical codes, unique to a particular appointment & patient dyad; elaboration below), access to summary clinical reports, and downloads of unidentified bulk research data (for submission to CNICS, among other purposes). This site is never accessed by patients; staff access it via secured workstation computers, and login with individual staff credentials. In some cases, sites use institutional logins via InCommon and Shibboleth (136), thus avoiding the need for staff to manage a novel set of login credentials. A user interface and service were implemented for bulk patient registration & appointment entry, supporting both manual and automated entry of this data; facilitating this data transfer was key, as it is performed daily. Some sites use an entirely automated process, with nightly generation of reports from their EHR or ADT (Admissions, Discharge, and Transfer) systems, and server-side calls to upload this data to the cPRO service.

The patient website is used for PRO assessment. It is secured by login credentials which are only known to staff; this system is accessed via tablet computers (most commonly iPads), usually in exam rooms, directly by patients. Unlike most cPRO systems, patients do not access the CNICS PRO outside the clinic. The most common workflow is that patients receive the aforementioned ticket (unique numerical code) at check-in, printed on a piece of paper. Patients are then given access to a tablet, where they enter the code, at which point the PRO is launched.

Measures have been taken to restrict this "kiosk" system's access to data: along with cPRO's standard mechanisms to prevent caching of all data in the browser, the patient website avoids the browser writing to navigation history in a way that would allow return to previous patients' data, and the tablet computer is configured to prevent access to all apps except the browser. The patient site is available in English, Spanish and Amharic translations, with language options configurable by site. In 2015 the team implemented functionality to automatically advance the questionnaire when the patient has answered all the questions on the page; a study at UW found that this reduced assessment time by about 40 seconds (~5%), without significantly changing the rate of missing data (unpublished data, 2016).

All of the CNICS PRO systems use a real-time suicidal ideation alert, which is sent via text/SMS (and also email) to clinicians if the patient responds "nearly every day" to the final question of the PHQ-9 ("Thought that you would be better off dead or hurting yourself in some way… in the last 2 weeks") (134,137). Each clinic has established protocols in place to ensure that the text is received in real time and the patient is evaluated while they are in the clinic for safety if they indicate suicidal ideation.

The platform has been used to develop crosswalks and calibrations between legacy and new instruments (138,139), and fixed format and PROMIS Computer Adaptive Tests (CAT) (140), with one study using a cPRO implementation of CAT calibrated via item-response theory (IRT) (141).

4.3.4 *Quantitative Results*

Table 4.7. CNICS Quantitative Results, as of February 2016

Patients	16,000
Assessment sessions	55,000
Clinical Sites	6
Frequency of assessment	Every 4-6 months
Administration in clinic	100%

4.4 FENWAY HEALTH

The Fenway Health cPRO system features PRO collection across a community health care center, as part of usual care. This is cPRO's deepest integration with an EHR, including automated tailoring of assessments based on diagnoses.

4.4.1 *Distinguishing Characteristics and History*

Fenway Health is a Boston area provider affiliated with Beth Israel Deaconess and Harvard Medical School, focused on care for the LGBT (Lesbian, Gay, Bisexual, Transgender) community (Fenway Health, 2015); as mentioned above, it is also part of the CNICS cohort. When CNICS PRO collection began Fenway was using a commercial patient portal with some PRO capabilities as part of their EHR, and elected to not use cPRO; however in January of 2010 they switched to the CNICS PRO system hosted by CIRG, which had by then been used extensively by five of the other CNICS sites. In late 2012 Fenway worked with CIRG to develop a plan for using the system for all patients (i.e., beyond the CNICS HIV-infected population), and integrating cPRO data into Fenway's EHR. This version was brought online in February 2013; it is used with every visit and satisfies Meaningful Use, pay per performance, and patient-centered medical home requirements (142). The assessment includes standardized instruments for learning needs, smoking and tobacco

(oriented towards satisfying Meaningful Use criteria), fall risk, alcohol screening, drug screening, anxiety disorder, intimate partner violence, and depression. A behavioral health service -specific assessment and workflow was introduced in April 2016.

4.4.2 *Implementation*

The Fenway Health system currently shares the CNICS model of only collecting PROs in clinic, and there are no patient logins. Unlike CNICS, the system is used with every visit, and assessments are launched by staff via patient identifier lookup (instead of the unassisted ticket number entry used by CNICS). Clinical workflow is greatly facilitated by interfaces between cPRO and the EHR (details below).

4.4.3 *Needs and cPRO Responses*

In February of 2013 CIRG deployed a cPRO system on Fenway's server infrastructure for its general clinic population. This system became cPRO's deepest integration with an EHR system to date (Figure 4.5), enabled by close coordination between CIRG and Fenway leadership and technical teams. The first interface sent summary clinician reports in PDF format to the Centricity EHR's document store (143) via HL7 version 2.5 messages (144). Shortly thereafter, reporting of discrete PRO data (summary scores and/or individual responses, depending on clinical interest) was implemented. In 2015 an interface was deployed to receive messages from the Fenway Admissions-Discharge-Transfer (ADT) system (facilitated by the fact that it was already exporting to Fenway's radiology system). This automated the task of adding new patients to the cPRO system and updating demographic information, and thus was a high priority in order to reduce burden on Fenway PRO staff. In early 2016 an additional Centricity-to-cPRO interface was implemented for Consolidated-Clinical Document Architecture (CCDA) documents (also facilitated by an existing

outbound interface, this time with billing). This data is being used as a factor in determining which assessment instruments to prioritize; the first implementation looks for a depression diagnoses in the CCDA, and if found, cPRO places a higher priority on presenting the PHQ-9 instrument (see details below). Interfaces were implemented using the open-source Mirth Connect interface engine (145), with Mirth communicating to cPRO via FHIR messaging.

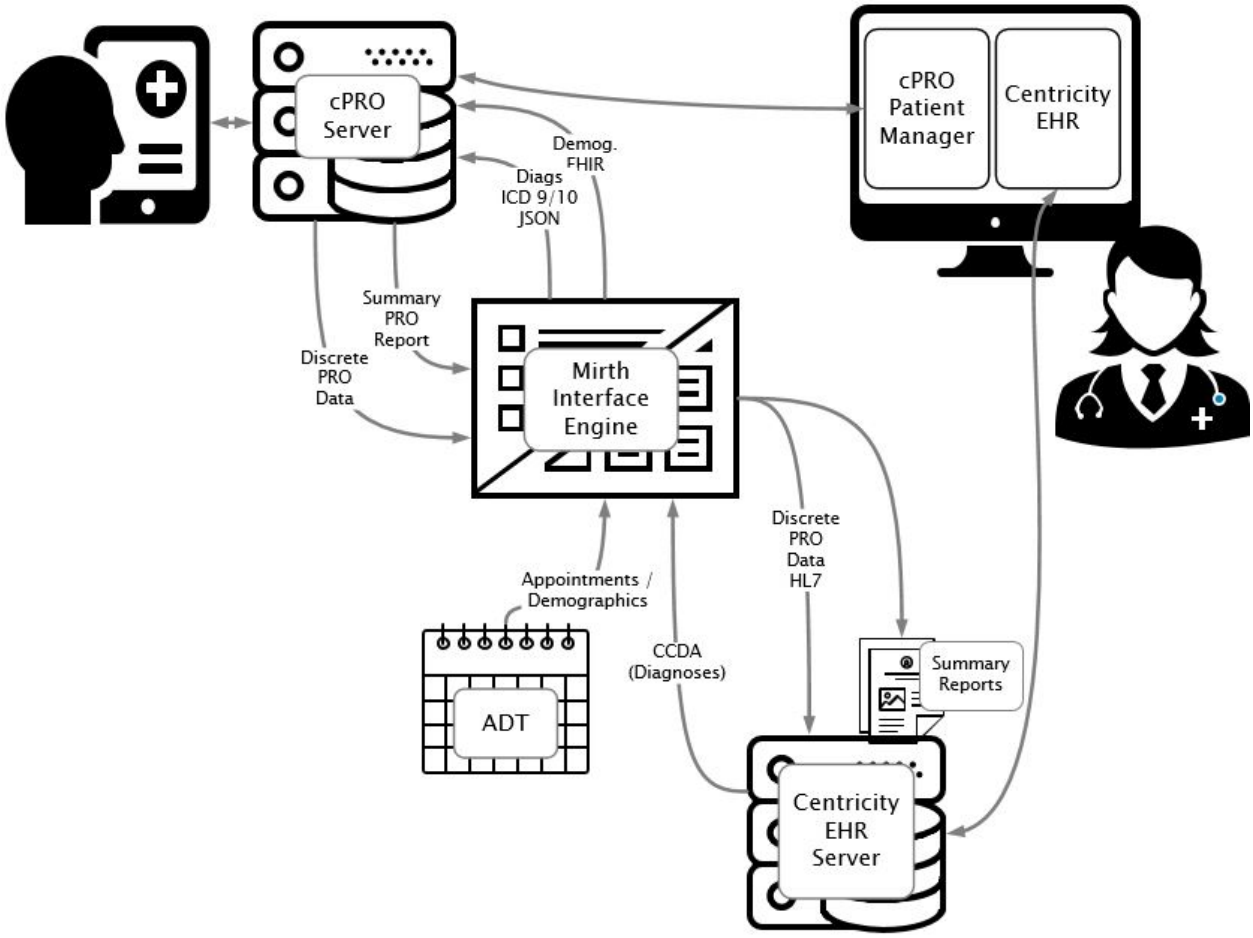

Figure 4.5. Fenway Health cPRO / EHR integrations.

Along with EMR integration and the advantages to workflow and information management it affords, Fenway PRO administration has a novel user interface for staff to select instruments

from a list which the system has populated, automatically prioritizing instruments based on how recently they have been completed, clinical diagnoses (e.g. depression, see above), clinical priority of the instrument, and estimated total time to administer the assessment (Figure 4.6) (146). This lets staff efficiently launch the presented sequence of instruments, or to add and remove individual instruments as they see appropriate (e.g. to remove instruments when short on time, or add instruments based on the patient or provider's voiced concerns).

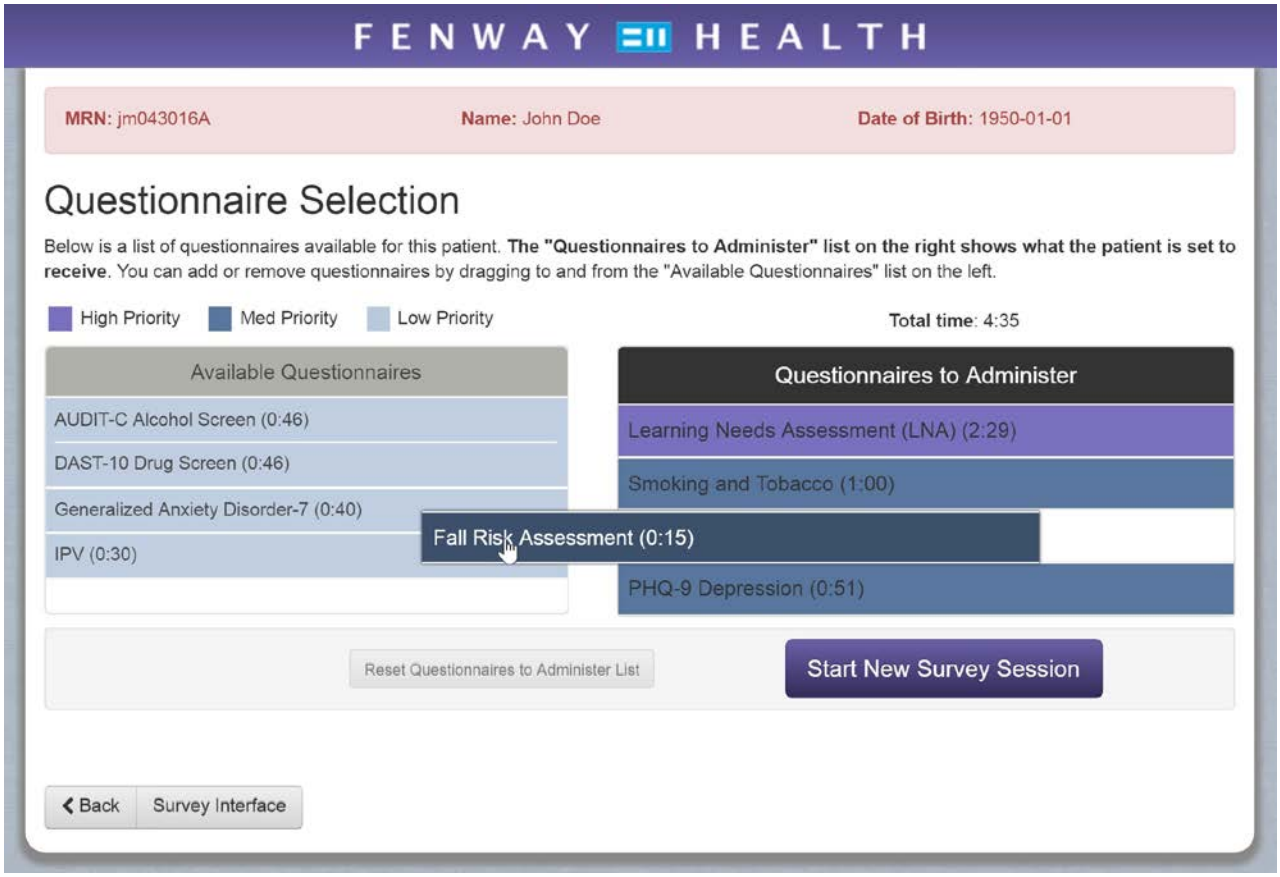

Figure 4.6. Fenway questionnaire selection.

4.4.4 *Quantitative Results*

Table 4.8. Fenway Health Quantitative Results

Patients who have completed at least one session	20,135
CNICS sessions	11,564
General care sessions	27,596
Behavioral health sessions	45
Frequency of assessment	Every visit
Percentage completed in-clinic	100%

4.5 PAINTRACKER™ / ACTIONTRACKER

The PainTracker and ActionTracker systems are used for chronic pain and orthopedic clinical care, as well as rural telehealth research and self-management research. cPRO innovations include patient-driven registration, automated reminder emails based on appointment data from the EHR, a body diagram question, and an extension into theory-based health behavior modifying intervention.

4.5.1 *Distinguishing Characteristics and History*

In late 2011 the CIRG team was approached by Mark Sullivan (UW Psychiatry, Anesthesiology and Pain Medicine) and Ardith Doorenbos (UW Nursing) to migrate the web-based chronic pain management system PainTracker™ from a vendor-implemented system. This previous implementation had limiting abilities in key areas including patient and institutional authentication, visualization of longitudinal results, user interface refinement, question format, and conditional branching. In early-mid 2012 the cPRO team implemented a proof-of-concept cPRO implementation of PainTracker (147). The PainTracker "core" assessment included standardized instruments for assessment of pain intensity and interference, activity difficulty, distress, difficulty falling asleep, and difficulty falling asleep.

Later that year the team launched a version to support a rural telehealth research system across the Northwestern U.S., "PainTracker Rural Symptom and Pain Management" (148). This system is also used for a UW videoconference-based consultative knowledge network ("TelePain" (149)) for care of rural and military patients.

The next PainTracker variants were non-research clinical implementations. These were not cPRO's first purely clinical systems (they were preceded by a 2005 mental health screen at the UW Hall Health clinic), but these implementations were the deepest integrations into combined clinic and patient/consumer workflows to date. "ActionTracker", an orthopedics system at UW's Sports Medicine clinic launched in April 2014. In July 2014 PainTracker was deployed at the UW Center for Pain Relief ("CPR"), a chronic pain clinic which previously used both paper and an alternative commercial product, C-PAIN.

Several research projects have been built around the CPR implementation, including an analysis of correlation between post-traumatic stress disorder (PTSD) and outcome measures (150), and a more general factor analysis of PainTracker instruments (151). A larger study, "PainTracker Self-Manager" (funded by Pfizer Independent Grants for Learning and Change), is ongoing. It expands PainTracker into a self-management tool that helps assess, engage, activate, and support patients' efforts to manage their chronic pain, in collaboration with their care team. The approach is based on a 4-phase patient engagement strategy derived from Acceptance and Commitment Therapy (152), using a visually engaging, storytelling-like approach based on previous smoking cessation "app" work (153).

4.5.2 *Implementation*

ActionTracker was the first PainTracker system for purely clinical use, and its implementation informed the later Center for Pain Relief (CPR) implementation. The cPRO /

ActionTracker team had approximately 10 weekly meetings with nursing and front-desk staff, with an emphasis on minimizing negative impacts on existing workflows. ActionTracker was launched within a few months of the clinic switching to EpicCare (48) and offering the Epic MyChart patient portal to patients; staff were still adjusting, but as most of that large-scale change was now in the rear-view mirror, there was some confidence that the general workflow framework around it was stable. The CPR deployment of cPRO used the same workflow approaches designed for ActionTracker, modified slightly (e.g. the schedule of email reminders to patients, due to differences in patterns of patients' appointments between the two clinics). For all PainTracker related systems, staff logged in with existing institutional credentials ("UWNetID") via Shibboleth, thus avoiding staff member's needing to remember a novel set of credentials.

Patients were introduced to the systems via a letter addressed from their physician, and directed by staff (both patient support specialists, and institution-wide contact center) to the websites, with instruction to create an account there and complete an assessment before their first appointment. Informational posters about the systems were displayed in the clinics' common areas and exam rooms to raise interest and awareness among patients.

A distinguishing characteristic of the clinical PainTracker assessments is the omission of free-text entry fields for the patients, which clinic staff viewed as a potential liability, for lack of established protocols around review and response to ad-hoc comments of potential concern.

4.5.3 *Needs and cPRO Responses*

ActionTracker & PainTracker CPR were not cPRO's first purely clinical (non-research) implementations (that was a 2005-2011 mental health screening at the UW Hall Health outpatient clinic), but they were the deepest integration into combined clinic and patient/consumer workflows to date. Patients interacted with the system independently, creating and managing their login

accounts (facilitated via automated password recovery), and completing assessments via their personal mobile devices, tablets and computers (enabled via modern "responsive" web page design). The system prompted patients to complete assessments one week prior to appointments; patients could also initiate assessments at-will. If patients did not complete an assessment before their appointment, they completed it at the clinic via kiosk tablet and PC's; if patients were unable to use the system independently, staff could either launch the patient's session (without the patient needing to create their own credentials), or enter assessment data on behalf of the patients. The morning of the appointment, staff used their system's patient management interface to 1) verify patient-created accounts by recording their medical record number in the system, and 2) print out the patient's longitudinal report (Figure 4.7). This "shared" report was developed via iterative participatory design sessions with clinicians. It included two pages for clinician use (including a section with flags for alerts), and a third page for the patient to keep and use at their discretion.

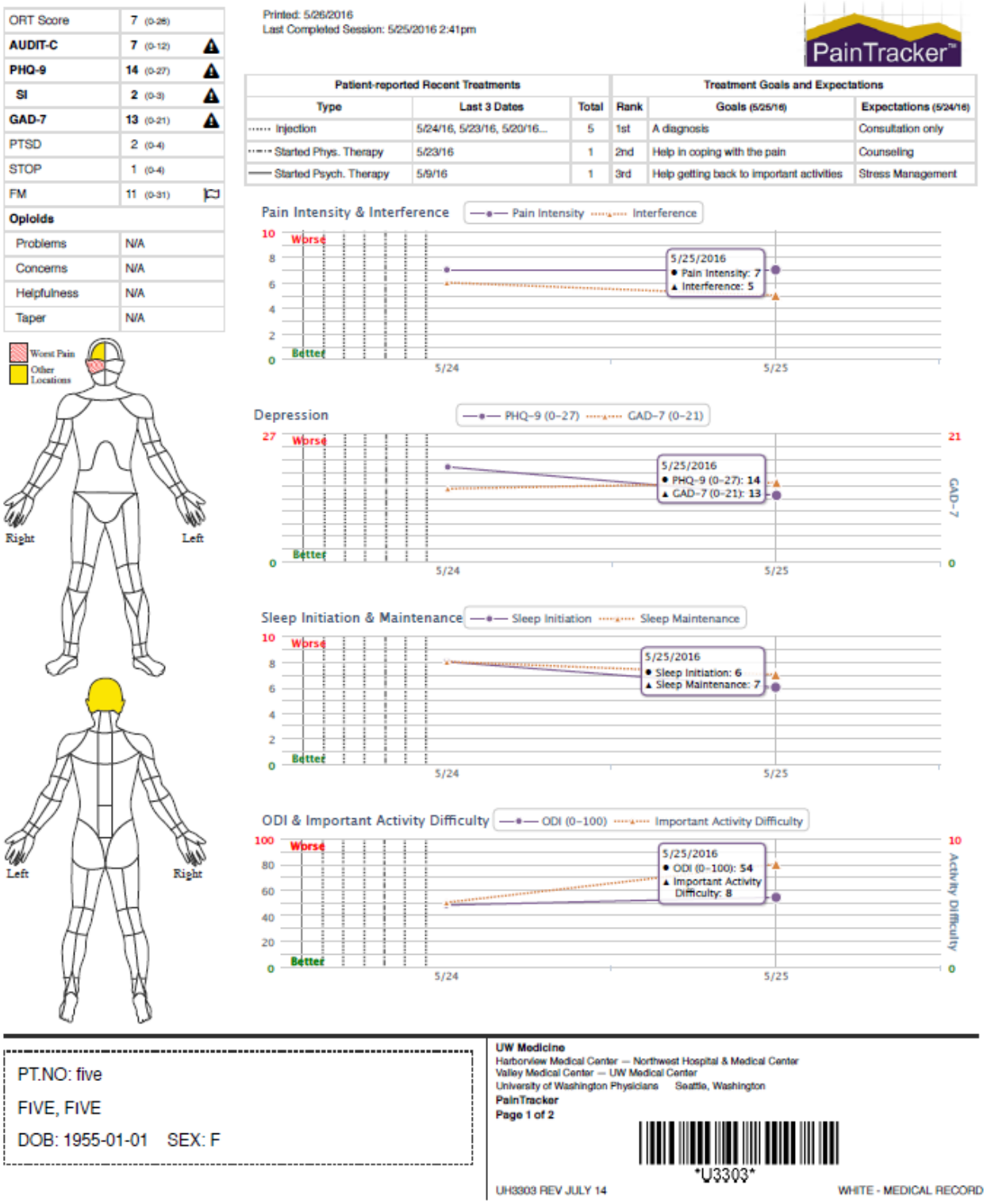

Figure 4.7. PainTracker shared report, page 1 of 3.

The institution's IT group did not have capacity to support integration into the EHR (EpicCare) or patient portal (MyChart), so several workarounds were put into place. On a daily basis the patient support specialist assigned to be ActionTracker lead copied Epic's "Department Appointments Report" data and pasted it into a custom form in ActionTracker. The ActionTracker system then automatically identified which patients among these who 1) had not completed an assessment in the past two days, and 2) had an appointment of an appropriate type in the next two days (e.g. for a procedure); it then sent an email reminder to those patients (it went through this process at the top of the hour throughout the day). On the reporting side, the aforementioned shared reports included a barcode indicating document type, as well as an institution standard format demographics and MRN section; these printouts were scanned for entry into EpicCare's document repository.

The assessments themselves featured innovative elements. A body diagram was presented to the patient, wherein they could select regions of pain; based on the locations selected, region-specific instruments were conditionally presented. PainTracker CPR leveraged this diagram further to calculate a fibromyalgia score. A form for procedures carried data across sessions, allowing patients to review and update it, without needing to enter it again. The PainTracker prototype and PainTracker Rural used a "Morphine Equivalent Dose" (MED) calculator, which presents a form for entry of opiate dosages, and automatic calculation of a morphine equivalent dose (154). The PainTracker team considered having subjects enter opioid dose data, but this was expected to yield insufficiently accurate data due to variances in medication branding, formularies, and subject interpretation of these variances (automatic population of med lists via RxNorm (155) was considered, but the gaps were still too wide). Therefore the Rural system's weekly patient assessments included a question as to whether the patient had a change in their medication intake,

with a positive response to this triggering a prompt for staff to fill out the MED form for that week. MED was included in the longitudinal summary report, displayed with color-coded alert levels (uncolored, yellow and red). The system also supported free-form entry of non-opioid pain medications.

Preliminary participatory design sessions for PainTracker Self-Manager have yielded storytelling visuals that have been brought to the current clinical system (Figure 4.8). This implementation is also fairly unique in the extent to which it incorporates an intervention into the cPRO assessment engine.

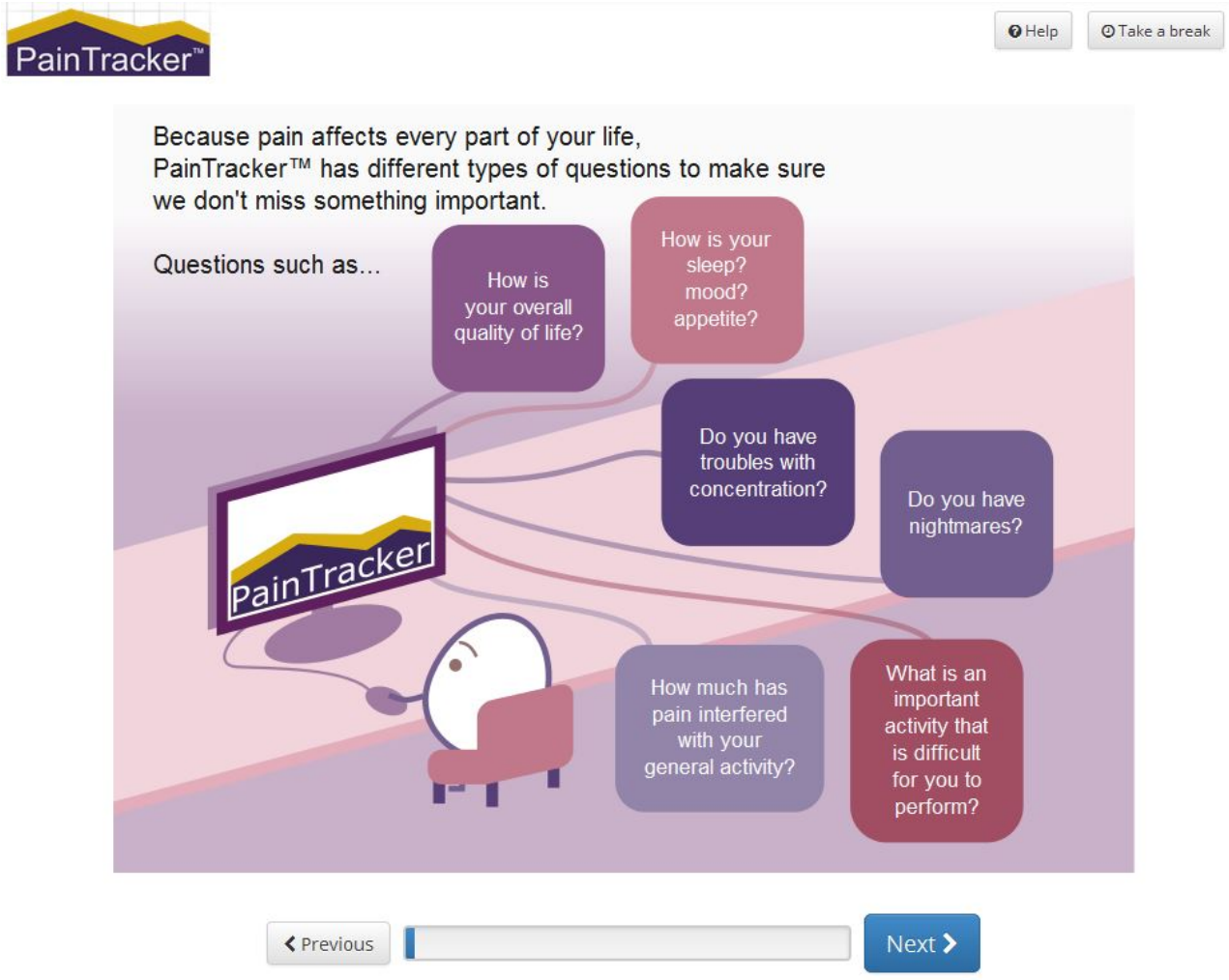

Figure 4.8. PainTracker Self-Manager storytelling visuals within assessment.

4.5.4 *Quantitative Results*

Table 4.9. PainTracker Quantitative Results

System	Patients	Sessions
PainTracker at the Center for Pain Relief	2,920	6,231
ActionTracker	5,406	8,239
PainTracker Rural	278	2,125

Table 4.10. PainTracker Center for Pain Relief Metrics

Baseline completion rate	66%
Baseline assessment duration	~45 minutes
Follow-up completion rate	50%
Follow-up assessment duration	15-30 minutes
Sessions completed outside of clinic, vs in-clinic	88%
Completion via personal computer	70%
Completion via smart phone	20%
Completion via tablet computer	10%
Number of physicians using the system	21

4.6 MPOWER

The mobile Post-Operative Wound Evaluator (mPOWEr) enables image-based communication for surgical recovery. mPOWEr is notable for incorporating smartphone-acquired images as "answers" within a cPRO instrument, shifting the development focus for cPRO to response design application frameworks, and enabling patients in engagement of care.

4.6.1 *Distinguishing Characteristics and History*

mPOWEr is an mHealth tool for monitoring post-discharge surgical site infection (SSI), the most common post-operative complication, and the leading cause of surgical readmissions (156). More than 50% of SSIs occur between discharge and the first post-operative visit (157), yet patients and providers lack tools to discover infections early (158). Patients have difficulty accessing providers post-discharge, and increasingly send wound photographs via email (159).

mPOWEr is a mobile-optimized web application for patients, and a web-based dashboard for providers. The patient app includes 1) a structured assessment of common signs and symptoms suggestive of SSI, 2) the ability to take photos using the smartphone's camera, and curate them serially, 3) a longitudinal review of signs, symptoms and photos, and 4) information on preparing and recovering from surgery, and how and when to communicate with providers. The user interface guides the patient through these processes according to a workflow which has surgery date, discharge dates, and assessment history as primary variables (Figure 4.9). mPOWEr is characterized to patients as a "wound diary", a framing that orients the patient towards self-monitoring.

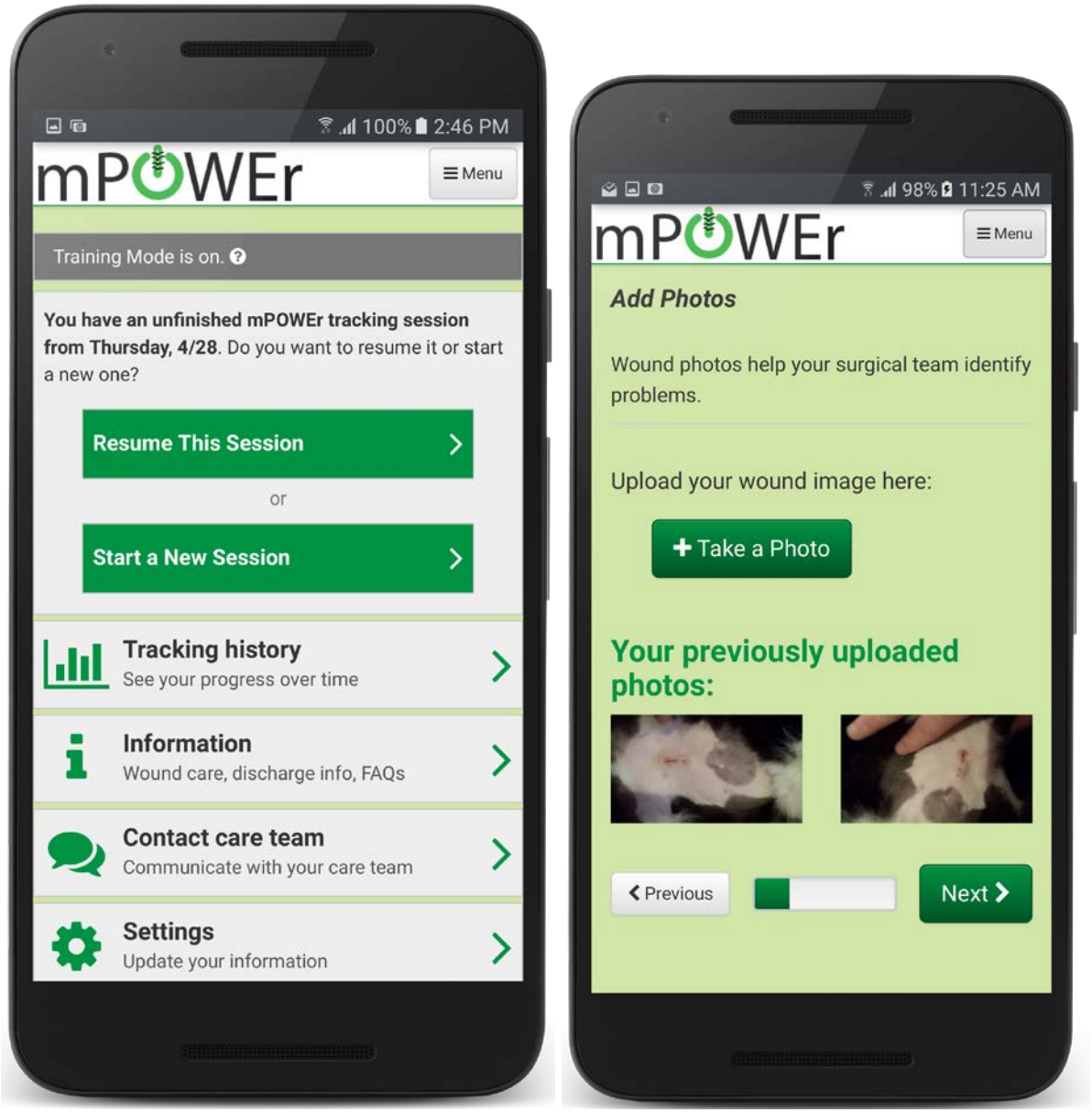

Figure 4.9. The mPOWEr patient app.

The application is depicted on an Android phone, but mPOWEr renders equally well on iPhone and Windows Phone platforms.

The provider dashboard launches with a list of all patients and their demographic characteristics, surgery type, surgeon, days post-discharge, and patient concerns, with patients sequenced by most recent assessment first. Clicking on a patient opens a detailed record view,

which presents the complete record including a longitudinal table of symptom measurements and "sparklines" (word/typographic-sized trendlines (160)), and photographs. From here staff can edit the patient record, launch an assessment of the patient, print or download the record, and view a version of the record formatted for pasting into an Epic note (Figure 4.10).

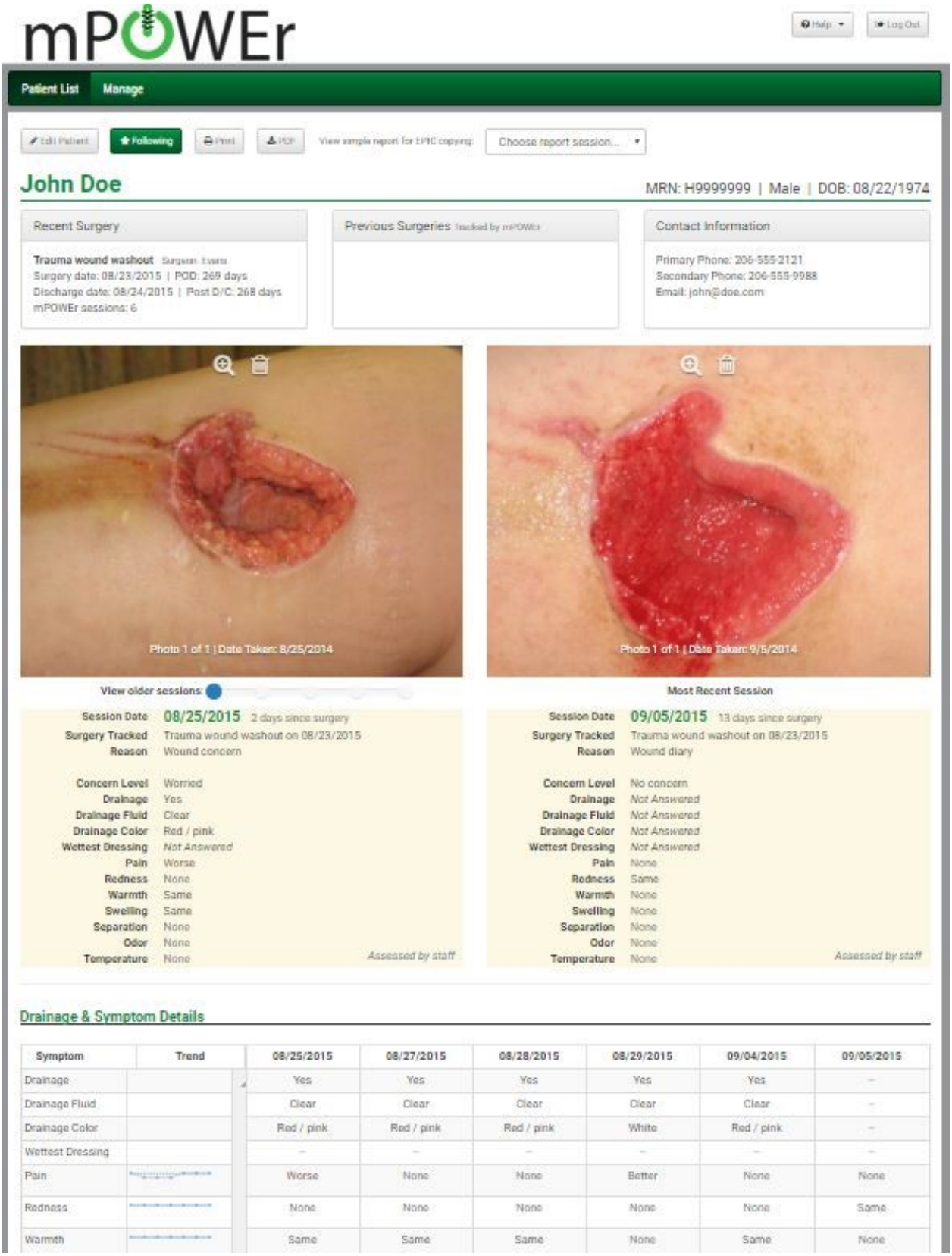

Figure 4.10. mPOWEr Provider view of the patient record.

The mPOWEr team is developing SSI predictive algorithms based on both self-reported wound characteristics and image analysis (159). Use of predictive algorithms may necessitate FDA approval as a regulated health app, depending on how the results of the algorithm are used by the patient or provider.

4.6.2 *mPOWEr Design*

A series of iterative design studies were conducted with providers and patients, before and during the cPRO implementation of mPOWEr (64,161–163). Additional interviews were conducted with clinic staff to identify workflow processes, formally documented with business process-modelling notation (164,165).

4.6.3 *Implementation*

In 2015 the mPOWEr team launched the system at UW Medicine's Center for Reconstructive Surgery as part of a quality improvement project to evaluate the effectiveness of its implementation. In preparation, the team conducted 6-8 iterations of application review, planning, and refinement with separate groups of nursing staff, nursing administration, and physicians before and during launch of the system. Time and resource constraints on nursing staff limited their engagement with the system. There were competing demands on clinic staff / patient interaction time, due to simultaneous patient portal enrollment. There was significant staff turnover and clinic reorganization during the launch period.

These factors resulted in a need for the mPOWEr team to orient the system for greater direction and initiation by patients. Providers did not have the time to monitor email alerts from the mPOWEr system, so the app instructed the patient to contact providers via normal clinic

communication channels if the patient had concerns about their wound, and to let the providers know that the patient had been using mPOWEr to record symptoms and wound photos. Clinician training was limited to ad hoc sessions during clinic hours, so an in-depth FAQ (including videos) was developed for staff, linked to from the login page. Patient orientation and registration sessions were generally conducted by the mPOWEr team; the team also developed a printed brochure for patients which provided context, orientation, registration instructions, and tips for taking wound photos (including a ruler printed on the brochure) (Figure 4.11).

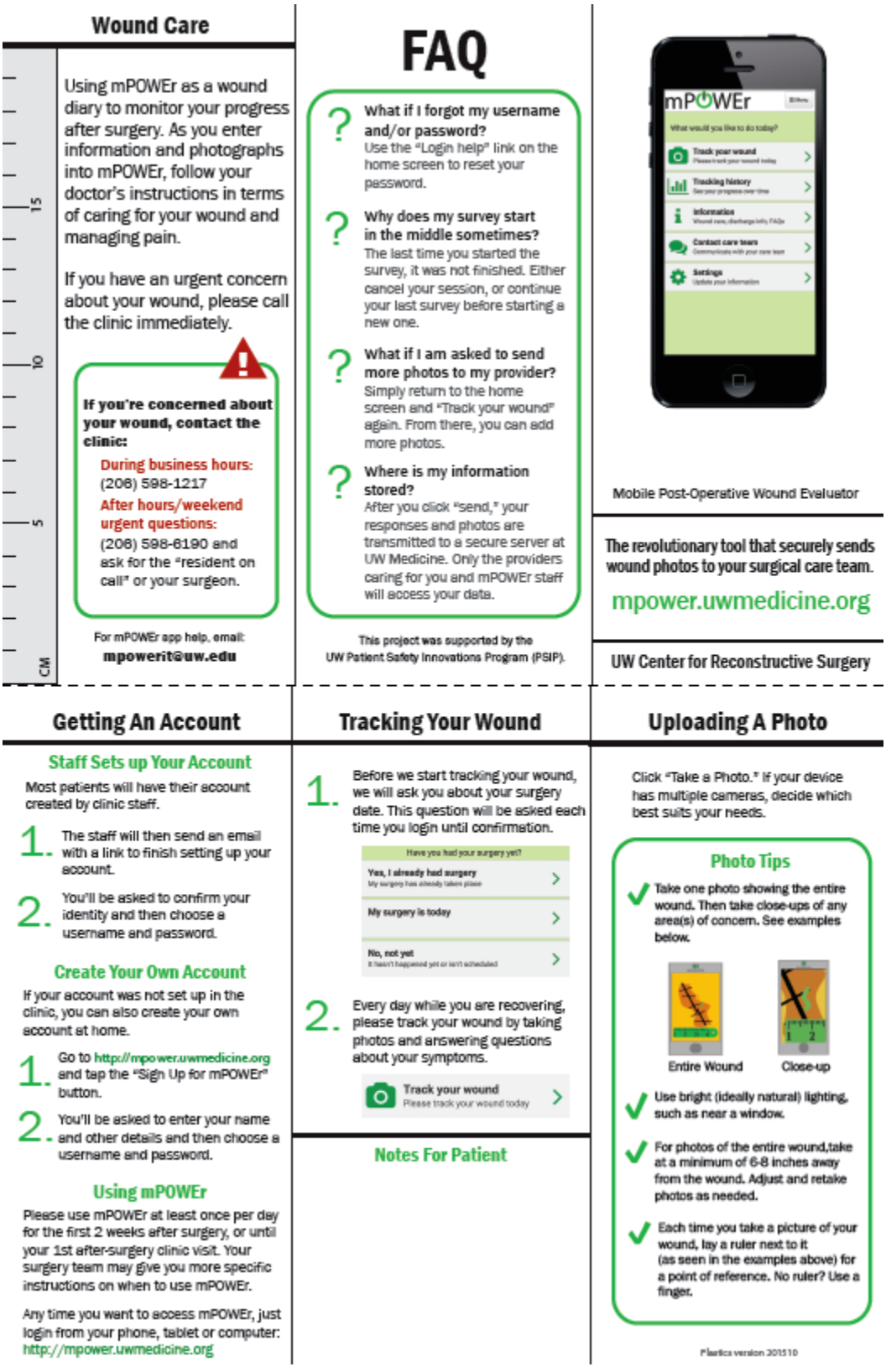

Figure 4.11. mPOWEr patient brochure.

Of 105 patients approached, 79 registered. Reasons for not registering included a) no smart phone / self-professed "low tech", b) not interested, c) surgery too far in the future, d) unknown.

A UW patient safety innovation program (PSIP) included support for a three-part security review of the mPOWEr cPRO system and infrastructure by the UW Medicine Information Technology Services (ITS) security team before launch. The first step involved configuring an ongoing vulnerability scan of the server (via a system hosted by the UW Medicine IT security) and approving initial results. The second step was an application-level vulnerability assessment. The third was an operational analysis to identify security gaps within the infrastructure, implementation, and operation.

4.6.4 *Needs and cPRO Responses*

mPOWEr has a "mobile first" approach to the design of its patient app, with an emphasis on leveraging the smartphone camera. It uses cPRO's "responsive" user interface capabilities (facilitating use with a variety of devices), but is optimized for a small form factor, more so than other cPRO systems to date. The need to capture photos brought new assessment capabilities. Images are implemented as a type of question (alongside e.g. radio buttons, checkboxes, free text, etc.), allowing their collection in a variety of assessment flows, and reporting alongside other results captured at the same session. mPOWEr is the latest cPRO implementation, and reflects evolution in its user interface: elements are displayed more dynamically than previous systems, based on user input; however, most of the rules governing the logic of user interface presentation continue to be implemented via cPRO's generalized state engine ruleset.

mPOWEr introduced the ability for patients to take "training" assessment sessions before their surgery date, to help orient the patient to the system outside of challenging post-discharge

conditions. A patient's surgery dates and other procedure information can be entered by both providers and patients; in the case that a provider enters a new procedure, the system will ask the patient to confirm its existence.

The provider dashboard adds the ability for each clinician to "follow" patients, and to optionally only display patients they are following in the dashboard. Staff can trigger emails from the system to invite new patients to register, remind them to register, and remind them to complete an assessment. To facilitate entry of data into the EHR, the provider's view on the patient record can 1) be switched to a version formatted to facilitate copying both text and images into the Epic Hyperspace (the application that providers use to access EpicCare (48)) user interface's notes section, with instructions for doing so, and 2) generate the structured summary report as a PDF file for upload as an external document.

mPOWEr is one of the most recent cPRO implementations, and reflects the project's orientation towards a set of "single-page applications" (see cPRO Methods section), with the UI/presentation layer making more use of backend services via in-page requests (AJAX). In 2014 the engineering team implemented cPRO's first HL7 FHIR services to support this, via FHIR "Media" (for images) and "Patient" resources. The image service saves the original image (up to 20 MB), and creates two downscaled versions in order to better present thumbnail and multi-image views in the user interface. Like all cPRO services, images are transmitted via encrypted means and stored on a HIPAA-compliant server (images shot via the mPOWEr app are not stored on the device).

4.6.5 *Quantitative Results*

Table 4.11. mPOWEr Quantitative Results from the Pilot Implementation, First 7 Months

Patients approached	105
Percentage who opted to register	75% (79)
Percentage who completed at least two tracking sessions	17% (18)
Total number of sessions	220
Average training time per patient	12 minutes

4.7 SOCIO-TECHNICAL ASPECTS OF CPRO SYSTEMS

Following Sittig's model, included below are the six case studies, and key aspects of each.

Table 4.12. cPRO Socio-Technical Aspects, 1 of 2

	ESRA-C	P3P	CNICS	Fenway Health	PainTracker	mPOWEr
Hardware and Software	Clinic-based touch screen computers; Personal computing devices used outside of clinic	Clinic-based touch screen computers; Personal computing devices used outside of clinic;	Clinic-based touch screen computers	Clinic-based touch screen computers; EHR	Clinic-based touch screen computers	Clinic-based touch screen computers; Personal computing devices used outside of clinic
Clinical Content	Patient input: SxQOL; Output to patient: symptom management guidance; Output: summary report to patient and provider	Patient input: symptoms, personal factors; Output: information in support of prostate cancer; Output: summary report to patient and provider	Patient input: symptoms, behavior; Output: summary report to provider	Patient input: symptoms, behavior; Output: summary report and discrete data to provider; Input from EHR: appointments, demographics & diagnoses	Patient input: SxQOL, behavior; Output: summary report to patient and provider	Patient input: images, wound characteristics; Output: summary report to patient and provider
Human-Computer Interface	Patient: assessment & intervention	Patient: assessment, intervention, glossary, videos, infographics, guided tour	Patient: assessment only	Patient: assessment, glossary	Patient: assessment only	Patient: assessment, image manager, report
People	Patients (autonomous); Providers; Research staff; Clinic staff	Patients (autonomous); Providers; Research staff; Clinic staff	Patients (clinic use only); Providers; Research staff; Clinic staff	Patients (clinic use only); Providers; Research staff; Clinic staff	Patients (autonomous); Providers; Clinic staff	Patients (autonomous); Providers; Research staff; Clinic staff

Table 4.13. cPRO Socio-Technical Aspects, 2 of 2

	ESRA-C	P3P	CNICS	Fenway Health	PainTracker	mPOWEr
Workflow and Communi-cations	Patient: longitudinal use; Patient: engaged by system per PROs; Provider: engaged by system per PROs (alerts)	Patient: episode of care; Patient: engaged by system per PROs; Provider: engaged by system per PROs (summary)	Patient: longitudinal use; Patient: not engaged by system per PROs; Provider: engaged by system per PROs (alerts)	Patient: longitudinal use; Patient: not engaged by system per PROs; Provider: engaged by system per PROs (alerts)	Patient: longitudinal use; Patient: engaged by system per PROs; Provider: not engaged by system per PROs	Patient: episode of care; Patient: engaged by system per PROs; Provider: not engaged by system per PROs
Organization Features (policies, procedures, and culture)	Support for research staff	Support for research staff; Minimal support for clinical staff	Support for research staff	Support for usual care & research staff	Support for staff	Minimal support for usual care staff
External Rules and Regulations				Used to meet Meaningful Use Criteria		
Measurement and Monitoring	Efficacy	Efficacy; Implementation	Risk identification	Clinical care; Clinical research; Quality of care metrics	Clinical care; Implementation	Efficacy; Implementation

Chapter 5. DISCUSSION

These case studies illustrate a diversity of uses for PROs, and approaches to implementing computerized PRO collection. Patient engagement, integration of data into clinical workflows, and interventions based on PROs are facilitated by a diverse palette of system capabilities.

5.1 Axes Differentiating cPRO Systems From One Another

There are a number of axes that differentiate these cPRO systems from on another: **1) the degree to which patients are given autonomy over the system** ("People" in Table 4.12). The CNICS and Fenway systems are used entirely in the context of the clinic: patients only engage with the system when in clinic, and do not have their own login credentials. The remaining systems described here are accessible for remote use; patients are directed to these websites by clinic staff, and it is up to the patient to create an account ("register") on the system. Part of the registration process is consent to terms, which generally state that staff at the clinic will be given access to the data entered into the system. This requires a subsequent verification step on the part of clinic staff, wherein the staff review patient records in the system and match the records to patients in the EHR. From the provider perspective, therefore, this axis might be considered **the degree to which patient interactions with the system need to be reconciled with clinic workflow needs**. Both ends of this spectrum have value propositions, much of which is dependent on **2) the extent to which the system engages patients based on their PROs** ("Clinical Content", "Human-Computer Interface" in Table 4.12, and "Workflow and Communications" in Table 4.13). In the CNICS and Fenway systems, patient interaction with the system ends at PRO collection. While the data collected therein are used for immediate care of the patient, that is external to the cPRO system, and dependent on individual clinics' practices (suicidal ideation alerts are an exception, see below). P3P is at the opposite end of this spectrum: it builds a shared decision support tool based on the patient's symptoms and preferences, and facilitates the patient's use of it before and during the initial decision visit. P3P illustrates the far end of another pole, namely, **3) the extent to which patients are engaged longitudinally** ("Workflow and Communications" in Table 4.13). P3P only collects the patient's symptoms and preferences for the purpose of preparing for a cancer

management decision. mPOWEr is similar in that it is oriented to an episode of care around surgery. The CNICS and PainTracker systems, in contrast, are used for chronic conditions, and administered for the duration of time the patient receives care at the clinic. **4) The extent to which the system engages clinicians** is key ("Workflow and Communications" in Table 4.13). The CNICS, Fenway, and early ESRA-C systems initiate a socio-technical response when the patient indicates suicidality via the PHQ-9 questionnaire: the system triggers email and SMS messages to clinic staff, who then engage the patient immediately (this is one reason these systems are restricted to clinic use). The current mPOWEr implementation at the Center for Reconstructive Surgery, in contrast, has prominent messaging to patients that the responsibility for real-time engagement lies with the patient. Finally, these systems illustrate differences in **5) the extent to which summaries are tailored for physicians, and the extent to which summaries are tailored for patients** ("Clinical Content" in Table 4.12). All of the systems in these use cases create an easily consumable printable summary report for clinicians, highlighted when scores reach standardized or a priori thresholds. All except CNICS and Fenway make this report available to patients; PainTracker refines this to a "shared report" concept, wherein a briefer summary is given to the patient during the visit, sans threshold alerts.

5.2 Patient Engagement and Reducing Burden

The patient's process of initial engagement with a PRO system can be burdensome. For the cases in this paper that were clinical but largely driven by the patient ("Patients (autonomous)" in "People", Table 4.12), the process includes:

1. Introduction to the purpose of the system, setting the patient's expectations as to what the PROs will be used for.
2. Patient self-evaluation of their interest and capacity to use the system

3. Agreement to terms of use.
4. Registration: creating an account on the system.
5. Instruction: orientation to using the system.
6. Troubleshooting: aid from the system and/or staff.
7. First entry of PROs into the system.
8. Interpretation of feedback.
9. Valuation of feedback: quality of information, responsiveness.

Each step in this process must be overcome for computerized PRO collection to succeed with the patient. This presents a large need for attention to the user experience in design, engineering and implementation throughout the system; however, PROs compete for patients' interest as consumers of a huge array of technical diversions including health apps that have little or no evidence of efficacy. To move forward, PROs will need to be more responsive in orienting towards dynamic and modern engagement, but still retain their evidence base; this points towards a need for rapid translation of evidence in consumer health informatics. These cPRO cases also illustrate that each step in this process can have several divergent variations, pointing to a delicate balance between generalized approaches, and those more customized to particular clinic and domain needs.

This set of processes also illustrates the potential incentive of high-quality feedback (e.g. provider response, and system-delivered education) specific enough for the patient to feel that PRO entry has value: a positive interplay between feedback and PRO entry ("Clinical Content" in Table 4.12, and "Workflow and Communications" in Table 4.13). The aforementioned "Behavioral Intervention Technology" model's technical framework utilizes these feedback mechanisms; cPRO was developed before that framework was proposed, but the approaches used in some cPRO implementations are similar. For example, the P3P implementation study offered clear context for data collection and what it supported, and automatically emailed a limited number of reminders to

those who had not completed the assessment and intervention. This project saw high rates of assessment completion among patients who initiated the assessment (95%), lending support to the value of these approaches.

The rate of use from outside the clinic for the P3P implementation study (95%) and PainTracker at the Center for Pain Relief (88%) suggest a strong willingness of patients to self-register with a computerized PRO system and engage with it independently. However, these two implementations have a critical difference that belies those percentages: the PainTracker clinic has robust staff-supported workflows to administer the assessment to patients in-clinic, whereas all but one of the P3P clinics did not have such workflows and elected to not provide point-of-service use ("Organization Features" in Table 4.13). Therefore patients without the capacity to use the system outside of clinic are underrepresented in the denominator for P3P. These patients are some of the most vulnerable to health disparities (166,167), raising a warning flag that computerized PRO capture can amplify such disparities without careful monitoring and accommodation of these patients during implementation.

There is a tradeoff between standardized PRO protocols and patient-centered assessments. Longitudinal collection of standardized instrument sets can be burdensome on the patient, which impacts adherence to assessment as well as patient satisfaction. Many standardized instruments have an evidence base built on non-automated administration of single instruments via paper, promoting a certain rigidity which can conflict with aggregating instruments into concise, modern "mHealth" apps that are appealing and non-repetitive to consumers, and available at their own pace and schedule. Achieving a balance that respects standardized instruments' validity, efficiency, and patient appeal (including the use of more ad-hoc sets of questions) is facilitated when PRO development teams have expertise in clinical care, psychometric and health behavior theory, and

health informatics and technology (indeed, the benefits of a cross-discipline team extend into most facets of computerized PRO collection, see below). cPRO systems have never required patients to answer assessment questions; reflecting the project's orientation as a patient-centric system.

5.3 Adjustment of Clinical Expectations

Two of these case studies illustrate that PRO implementation teams can underestimate the amount of workflow change required to support effective administration and integration of results into care, both during the visit and outside of it. The investment in time and resources can certainly seem to outweigh the benefits early in adoption, when change is greatest, clinicians may not yet have a gauge on the utility of the results, and there are insufficient data to show longitudinal trends. The degree to which stakeholders (clinicians, administration and payers) prioritize measuring outcomes can rapidly change due to the influence of organizational and governmental policy, and reimbursement models.

PRO collection does suit some clinical domains more readily than others, for example, treatment of chronic conditions, wherein both patients and clinicians may see that the cost of orientation towards PROs is outweighed by long-term benefits ("Workflow and Communication" in Table 4.13). The possibility that a clinical PRO system might also be leveraged for research use can also have a positive impact on clinician adoption (especially in academic medical centers), but research domains should be focused to minimize impact on clinical care.

5.3.1 *PainTracker and ActionTracker: Care of Chronic Conditions as a Strong Differentiator.*

Though novel approaches facilitated the ActionTracker deployment, it faced critical challenges in clinical adoption. Staff were still orienting to the recent EpicCare deployment, and

in the process of enrolling patients in the patient portal. There were several planning meetings with physician leads, and training materials developed for staff, but the majority of physicians only received training at a brief lunchtime session. The contact center's standardized protocol did not accurately distinguish those appointment types which merited ActionTracker (e.g., procedures) from those that did not (e.g., physical therapy); therefore, some patients were burdened with unnecessary prompts to complete ActionTracker, introducing uncertainty during the clinic visit as to ActionTracker protocols. Per a 2015 survey of physicians at the clinic, 44% of physicians were dissatisfied with ActionTracker overall, and 61% said it reduced their efficiency and that the time required to use the ActionTracker report during the patient visit was not worthwhile (168). In March 2016, with the recent departure of the clinician "champion" of the project, ActionTracker use was halted at the clinic.

There were several indications of misalignment in ActionTracker. This clinic was not oriented toward treatment of chronic conditions. The vast majority of ActionTracker patients only completed a single assessment (71%, with 5% completing none), so longitudinal reporting, one of the primary benefits of PROs, was not manifest in the system ("Workflow and Communications" in Table 4.13). Some physicians complained that ActionTracker introduced topics that they did not have a standard approach to discussing, such as distress and alcohol use risk, and that there were too many symptoms to address (also noted in other cPRO implementations (63)).

Relative to the acute care environment of ActionTracker, the Center for Pain Relief's chronic care environment lends itself to longitudinal data collection. At CPR, a higher percentage of patients in the system complete assessments for follow-up appointments (50%). A 2015 survey of clinicians found that 6% of physicians were dissatisfied with PainTracker CPR overall, and 12% said it reduced their efficiency and that the time required to use the PainTracker report during the

patient visit was not worthwhile; these numbers are marked improvements over ActionTracker (169).

5.3.2 *Patient Portal Considerations*

When considering how best to collect PROs, providers and clinical institutions are inclined to look to tethered patient portals (11). There is a long list of potential benefits: 1) PRO discrete and summary data entered into the EHR and thus available to providers (immediately in some cases, but not all (54)); 2) conditional PRO delivery based on EHR data e.g. diagnoses and upcoming appointments; 3) established patient-provider communication mechanisms; 4) facilitated tracking of PRO services for reimbursement; 5) no need for patients or providers to register with a new system; and 6) an integrated user experience with other portal features.

The case studies here point towards a need for this level of integration, but they also illustrate limitations to this approach. The PainTracker team has strongly considered implementation of the system in the Epic MyChart patient portal for several years. Some of the challenges are technical (e.g., conditional presentation of questionnaires based on the patient's selection of regions on a body diagram was not possible; inflexibility in graphing and alerts in a condensed summary), and some logistical (e.g., the institution had committed to collecting a different set of measures across the organization and did not want to further burden patients; an unwillingness to present research questions). Furthermore, the PainTracker team aims to use the system across institutions and EHR vendors, which would require reimplementation each time. The aforementioned studies by Wagner et al. and Kummerow et al. take a hybrid approach, by integrating existing survey systems into patient portals (PROMIS CAT and REDCap, respectively), though these systems were limited to single clinics. Possible architectures to support such interoperability are discussed in the "Integration with EHR Systems" section below.

5.4 COMPUTERIZED PRO IMPLEMENTATION TEAMS AND ORGANIZATIONAL IMPACT

The systems described here have been designed, engineered, and implemented by a variety of teams composed of specialists. The more technical members include systems engineers (systems administration, services and database development), and user interaction engineers (design, user interface, browser, and app technologies). Health informaticians, clinical scientists, and psychometricians with implementation experience form a bridge to clinical teams. Physician and nurses are engaged at points throughout the process; there is a strong need for clinical champions in each group. The Fenway case is an example of a system that benefits from the organization's leadership recognizing the potential in extending their well-established research-oriented PRO system to clinical use; the insight provided by this long-term experience has helped leadership envision features such as automated diagnosis-driven presentation of instruments.

5.5 TECHNICAL IMPLEMENTATION FACTORS AS ILLUSTRATED BY CPRO

5.5.1 *Integration with EHR systems*

The level to which an ancillary clinical information system can interact with institutions' EHRs has huge implications for the system's design and technical architecture. Potential integrations include data exchange, shared graphical user interfaces, and shared user state context. Factors include the sufficiency of standards for integration, vendor willingness to implement said standards, and clinical institutions' capacity for 1) vetting and approving third party application integrations, and 2) performing the technical work of deploying interfaces. Examples of ancillary applications with a history of EHR integration include clinical decision support tools and patient handoff systems (170). There is a realization that current clinical data integration standards are

insufficient, with one manifestation being that implementations use standards in ways that result in "one-off" solutions that can't be applied very generally (171).

Relative to other clinical data, there is a lack of integration standards applicable to PRO data and systems. PCORI has developed standards for the design and selection of PRO instruments, and their implementation in research and clinical care, but not in data or system integration (39). In 2015 the cPRO engineering team began implementing services using the emerging FHIR HL7 resources "Questionnaire" (for modelling assessment definitions) and "QuestionnaireResponse" (response data and scores); since that time others have reported using these same standards (specifically, for sending PROs from Apple ResearchKit to the i2b2 research data repository (172)). Standards such as HL7 Arden Syntax for Medical Logic Modules (173) has the potential to support logic around PRO assessment and interpretation; de Bruin et al. demonstrate using this standard to build decision support tools based on patient-generated data collected via mobile devices (174). Finally, there are nascent models for supporting patient authorization of movement of their own health data, including the OpenID HEART Working Group's refinement of the OAuth 2.0 User Managed Access (UMA) profile for obtaining consumer consent (175,176).

All six case studies here included summary reports ("Clinical Content" in Table 4.12), printed and used during the clinic visit, and in many of these cases this report was imported to the EHR. In some cases it is printed and then scanned via existing clinical processes, in others the digital file is uploaded manually to the EHR (specifically, to the Epic Hyperspace "Media Manager"), and in one case, automatically imported and made available immediately to providers using the General Electric Centricity EHR, where it can be retrieved for use during the patient

visit. These summary reports are often dense and context-providing, and managed as a single file; in contrast to discrete data, summary reports are the "low-hanging fruit" of data integration.

Several of the cases illustrate unsanctioned, or "workaround" approaches to EHR integration; for example, PainTracker's process of staff transferring text via "cut and paste" from an Epic Hyperspace appointment report into cPRO, and mPOWEr's detailed instructions for staff copying text and images from mPOWEr into the clinical notes section. Such unsanctioned approaches are inherently fragile in the long term, as changes in the EHR may cause them to become non-functional unexpectedly.

The Fenway case illustrates a cPRO capacity for robust data integration via sanctioned interfaces (Figure 4.5; "Hardware and Software" and "Clinical Content" in Table 4.12). These are described in that case's results section, and elaborated on here with a focus on the interface and standards. cPRO transmits summary reports and discrete data to the Centricity EHR via HL7 version 2.5 messages. Discrete data include summary scores and/or individual responses, depending on clinical interest; these are displayed in Centricity alongside laboratory results (Jensen et al. and Wagner et al. also reported displaying PRO responses as lab values, in EpicCare). cPRO receives messages from the Fenway ADT system (facilitated by pre-existing Fenway ADT exports to a radiology system), using this information to add and update patient records. cPRO also receives CCDA documents (facilitated by an existing outbound interface for ACO consumption), which are used as a factor in determining which assessment instruments to prioritize. The cPRO side of these interfaces were implemented using the open-source Mirth Connect interface engine, which benefits cPRO in acting as a single point of contact, buffering messages, logging, and offering a robust administration console. cPRO communicates with Mirth via services, some of which are RESTful; one service uses the HL7 FHIR "Patient" resource.

Import of CCDA records necessitated the development of a document repository to store a subset of those data; cPRO accesses this via a RESTful service, passing in a list of ICD-9 and ICD-10 codes for diagnoses of interest. The cPRO / Mirth interface layer has a configurable inactivity timeout (currently set to 5 minutes), wherein if the patient is not interacting with the system for that much time, Mirth requests the discrete data and the summary report from cPRO and sends it on to Centricity. There is a balance in this configuration: the higher the value is, the longer staff will need to wait to see the data in Centricity (to clarify, this timeout only acts on "stale" sessions; in contrast, when the patient explicitly finishes the assessment, the data are sent immediately).

There are several potential PRO integration points that have to date not been implemented in a cPRO system. For example, provider access to cPRO from the EHR, and patient access to cPRO from the patient portal. An optimum linking would avoid the need for the user to log in to cPRO. A first implementation of this might pass a minimal amount of patient context; a later version might be supported by more active two-way API calls. The aforementioned SMART on FHIR approach may be of value here, however it has a focus on using EHR data in external applications, as opposed to contributing data to the EHR.

5.6 Future Directions

The cPRO team's goals are for increased demonstration of interoperability via implementation of standardized health information system interfaces, and expanded engagement with patients in clinical, non-clinical, and research settings. To achieve these goals, the cPRO engineering team is undertaking a refactor of the architecture to better distinguish the following technical components: 1) a generalized assessment engine, 2) an HL7 FHIR service layer, 3) user interfaces, and 4) an OAuth authorization service. This work was initiated in part to support a web-based system (119) that will integrate two cPRO systems (P3P and a prostate cancer self-

management system), four systems each in support of a randomized control trial, and a commercial decision support system. Patient engagement will be 1) self-initiated via a public website, 2) initiated by one of 15 clinical sites across the country, or 3) via one of the randomized control trials.

5.7 LIMITATIONS

5.7.1 *Aspects Not Addressed In depth*

This study addresses neither the development, nor the selection of individual or combinations of standardized instruments; the author defers that to the robust community of researchers in psychometric methods and specific clinical domains. The advantages and disadvantages of Computer Adaptive Testing (CAT) and Item-Response Theory (IRT) are not explored. This study does not describe the financial costs of PRO development and implementation. The distribution, administration, and open-source collaborative development potential of cPRO are not covered, as the focus of this study is on PRO aspects, not this specific software. The vast commercial landscape of patient generated health data apps is not considered; a review of these may find novel user experience / design approaches. Patient- and consumer-initiated systems are not explored.

5.7.2 *Potential Biases*

This study focuses on a set of case studies rather than broader systematic review. As a case series, it is useful in exploring new hypotheses, but not in testing them. Selection bias must be considered in case series; in this study, cases were selected based on project duration, number of PROs administered, and the applicability of the system to modern PRO collection. The author has invested much time in cPRO, therefore publication bias may be manifest in the selection of cPRO

examples and of cPRO itself; however, the focus of this study is not on cPRO, but in the opportunities and challenges of computerized PRO collection found in its implementations. This study's focus on the implementation of PROs via a single open-source system ancillary to EHR and patient portal systems offers but one perspective of many.

Chapter 6. CONCLUSIONS

The implementation of cPRO across a large number of research and usual care systems offers an uncommon vantage point, and one that is of a scope suitable to the analysis of the socio-technical aspects of PRO implementation. Few generalized PRO platforms exist, and this author is not aware of any that have been implemented across such disparate domains and workflows.

PRO collection can be burdensome on patients. These case studies illustrate the process of engaging the patient in this effort, and suggest steps for improving the process. PROs cannot appear to patients to disappear into the same black hole that so much of paper-based intake forms do; patients need to sense some value or individualization based on the data they supply via PROs, whether that value comes from an information system or a clinician. PROs compete for patients' interest as consumers of a huge array of technical diversions including health apps that have little or no evidence of efficacy. PROs could stand for a profound modernization in design and patient engagement, with a re-orientation towards mobile device collection; however, steps need to be taken to ensure that PROs retain their base in evidence, and that health disparities are not amplified when relying on the patient's capacities outside of clinic.

These case studies suggest that it will be some time before PROs are systematically collected across clinical domains and enterprise medical records, and seamlessly and effectively integrated into both 1) clinical workflows for providers and 2) patients' clinical care experiences.

When collecting PROs for multiple purposes, in order to avoid the cumulative burden on patients, institutions need to prioritize collection, yet allow flexibility for specialized collection to accommodate novel research and clinical uses.

Computerized PRO collection is challenged by a lack of applicable data and system integration standards, and competing initiatives within clinical institutions health information systems teams. As it stands, many innovative PRO projects are isolated to being ancillary systems and small-scale research projects, challenged with overcoming EMR interfaces via novel workarounds.

Justifications to using cPRO include cross-institution and cross-EHR implementation, and assessments or interventions that are either too complicated for EHR and patient portal tools, or not prioritized by the clinical institution.

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APPENDIX A: CPRO SYSTEMS, PAST AND PRESENT

In approximate chronological order:

1. P4 R21: Personal Patient Profile-Prostate: A Customized Internet Decision Support Program
2. ESRAC-IP: Information Needs of Men with Prostate Cancer During Radiation
3. UCLA Symptoms
4. TTS: Improving Health Literacy: Feasibility and Evaluation of Virtual Surrogate Readers
5. Orange
6. Internet Diabetes Trial Survey - UWMC
7. Internet Diabetes Trial Survey - Harborview
8. ESRAC-1 SCCA (aka Clinical)
9. ESRAC-1 UWMC
10. ESRAC-1 OHMC
11. Dyspnea Self-Management: Internet or Face-to-Face
12. Colecta Palm Kenya
13. Colecta Palm
14. Cognitive
15. Active Options
16. KCCare IS
17. P4 in the Community ("CP4")
18. P4 Pilot at LBJ ("p4-lbj-pilot") aka P3P2 Spanish (2010)
19. P4 RCT
20. ESRAC-Adolescents
21. ESRAC-HK
22. P3P Mazzone
23. Mental Health Clinic at Hall Health - screening
24. CNICS Lypodystrophy pilot
25. CNICS UW
26. CNICS UAB
27. CNICS UCSF
28. CNICS UCSD
29. CNICS UNC
30. CNICS Fenway
31. CNICS Johns Hopkins
32. CNICS Case Western
33. ESRAC-II
34. ESRA-C Symptom Management Excellence - Fatigue
35. CNICS Adherence
36. ESRAC Pittsburgh
37. Fenway Health (General Clinic, Behavioral Health, and CNICS)
38. CHARN Beaufort-Jasper-Hampton Comprehensive Health Services
39. P3P 2nd RCT Phase I

40. TrueNTH Australia P3P
41. P3P 2nd RCT Phase II
42. Survivorship (Hodgkin's Lymphoma) DFCI
43. mPOWEr Plastics
44. mPOWEr SCCA
45. TrueNTH USA P3P
46. TrueNTH USA Self-Management
47. TrueNTH USA Assessment Engine