

A standard-based model for the sharing of patient-generated health information with electronic health records

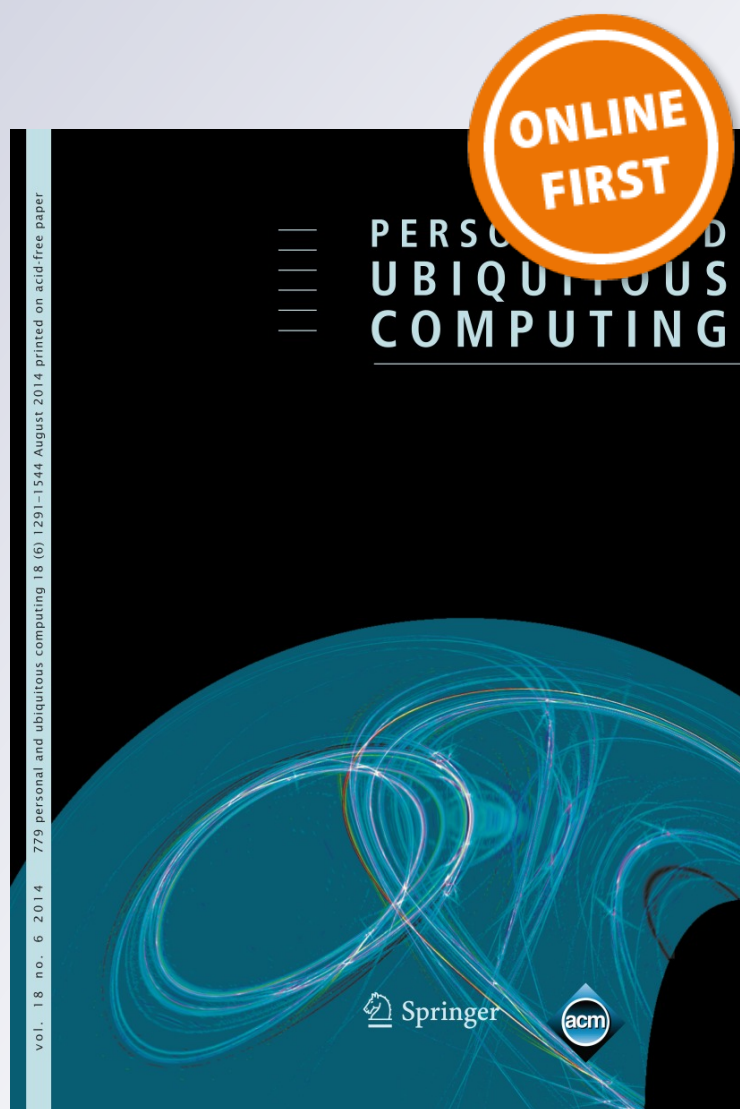
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A standard-based model for the sharing of patient-generated health information with electronic health records

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Abstract This paper proposes a standard-based model for the automated collection of patient data using personal health devices and the secure sharing of these data with authorized providers' electronic health records (EHRs). The model addresses a number of important requirements for the practical collection and exchange of such data between patients and providers. The technical elements of the model are based on the features of personal health devices, health data repositories, and interoperability standards that already exist. For the automated collection of data from patients' personal health devices (such as wireless glucometers or smartphone-based applications), the model suggests a set of content standards developed by the Continua Alliance and already implemented in a number of commercial products. For the sharing of collected data with providers' EHRs, the model specifies a secure transport layer based on the DIRECT Project's secure email standards and an application data layer based on HL7 v2.5.1 query-response messages combined with the clinical document architecture Release 2.0 personal healthcare monitoring report implementation guide. All of these standards have been implemented and are in current use, although they have not yet been combined to meet the specific use case of sharing patient-generated health information with providers' EHRs. The proposed standard-based model constitutes a "straw man" intended to foster thought, discussions, and refinement through pilot implementations and improvements.

Keywords Patient-generated health information (PGHI) · Personal health records (PHRs) · Electronic health records (EHRs) · Health information exchange · DIRECT project

1 Introduction and overview

In 2012, the Office of the National Coordinator for Health Information Technology (ONC) invited comments on a draft set of "Stage-3" criteria for the meaningful use of electronic health records (EHRs) [1]. This set included a proposed requirement that eligible providers and eligible hospitals enable patients to "(electronically) submit patient-generated health information (to their EHRs) that is most relevant for their patients and/or related to high priority health conditions they elect to focus on". ONC specifically sought comments on:

1. The types of information and data that may be of mutual interest for patients to share with their providers,
2. The types of data flows between patients and providers that would be mutually feasible, and
3. The readiness of standards that would enable patients to communicate data specifically from home medical devices to their providers' EHRs.

This paper proposes a standard-based model to communicate data from patients' personal health devices to providers' EHRs in a manner that is feasible for both patients and providers. The model addresses what we believe are important requirements for the practical exchange of such data. The technical elements of the model are based on the features of personal health devices, health data repositories, and interoperability standards that already exist.

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Patient-generated health information (PGHI) may comprise clinical parameters already familiar to medical providers (such as blood glucose measurements or pain-scale observations), as well as “Observations of Daily Living” (ODLs) [2] that are defined by patients and do not necessarily map directly to biomedical models of disease and illness (such as mood and sleep patterns). The model defined here applies to the sharing of both types of PGHI, to the extent that the patient-generated information can be referenced and represented in a standardized way. PGHI that is less well defined and standardized may also be valuable to patients and their providers, but it may not be amenable to sharing with EHRs as structured data.

The remainder of this section describes key requirements for exchanging data between patients’ personal health devices and providers’ EHRs and outlines the model we propose to address these requirements. The following sections describe the proposed model in further detail.

1.1 Desiderata

The vision of patient-generated data being available to providers via their EHRs and being useful for patients’ diagnosis and treatment is a compelling one. However, any system that fulfils this vision must meet a number of technical and logistical requirements:

- Patients must be able to trust that their personally generated data will be shared only with their authorized providers.
- A minimum of effort and complexity must be required for patients to collect data of interest to their providers, such as logs of blood glucose measurements, weight, and blood pressure.
- Providers must be able to control the flow of PGHI into their EHRs, because they may not wish to be medically and medico-legally responsible for monitoring patient-generated data that are automatically and continuously submitted to their EHRs.
- Providers must be able to distinguish patient-generated data imported into their EHRs from clinician-generated data, because providers may not trust the validity or accuracy of all data generated by patients.
- There must exist technical standards for uniformly representing patient-generated data in a manner that allows data generated by any home medical device or personal health application to be consumed by any provider EHR.
- There must exist technical standards for securely transmitting patient-generated data from any home medical device or personal health application to any provider EHR.

1.2 Overview of proposed model

The model we propose is based on several existing standards and technologies and entails patient and provider workflows that are consistent with these standards and technologies. The figure below illustrates the proposed model at a high level.

The initial model focuses on the communication of data from home medical devices to providers’ EHRs, either as raw data points or graphically summarized trends. This model is of interest because it pertains to a number of common chronic conditions that can result in significant patient morbidity and drive substantial healthcare spending, including diabetes, hypertension, and congestive heart failure. The model also pertains to the monitoring of subjective findings by patients through personal health applications, such as the Estrellita assistant for high-risk infants [3].

The proposed model entails the following technical and workflow processes:

1. Wireless devices that a patient uses at home automatically upload biometric measurements to the patient’s record in a secure repository of PGHI. For example, the Microsoft HealthVault system offers such a repository [4]. These uploads may take place via standard protocols (for example the protocols defined by the Continua Health Alliance—see Sect. 2.2.2) or via proprietary protocols specific to device manufacturers and data repositories. In either case, a data-upload interface associated with the data repository receives the data and stores them to the repository in a format that can be later retrieved and transmitted to EHRs via a standard query API.
2. Via her EHR, a clinician requests medical data for a specific patient by sending a DIRECT message to the DIRECT address of that patient’s record in the PGHI repository (see Sect. 3.1). The message identifies the patient, the requestor, and the type of data or report requested. A standard query API accepts such messages, accesses the repository, and formulates an appropriate response, per a standard set of request and response parameters. Depending on the specifications of the standard query API, clinicians may request individual data points in a standard structured format and/or aggregated data in a tabular or graphical report.
3. The standard query API sends a DIRECT message containing the requested data in a standard format (as a file attachment) to the requesting clinician’s DIRECT address. The standard format for this attachment may be either a binary Portable Document Format (PDF) file or a discretely structured document formatted per a set of standard specifications described in this

document (see Sect. 3.3). The clinician or the clinician's EHR receives the DIRECT message, opens and interprets the attached file, stores and processes the data in this file, and displays the resulting information.

This model is intended to address a number of the challenges inherent in the sharing of patient-generated medical information with providers' EHRs:

- Use of a trusted 3rd-party data repository that confers data ownership to the patient can enable patients to explicitly control who accesses their patient-generated data, while facilitating such access (when authorized) to clinicians practicing at various organizations and using various EHRs.
- The use of wireless home medical devices and other convenient data collection tools can obviate the need for patients to manually record data, increasing the convenience to them of collecting these data in a consistent and reliable way.
- Patient-generated data will be explicitly requested by clinicians to inform their care of the patients at the time the data are most useful, addressing clinicians' reservations about monitoring an automated and continuous feed of such data into their EHRs.¹
- The data-representation standards for retrieving patient-generated data from data repositories can include explicit denotations of the provenance of the data, addressing clinicians' need to evaluate the context and validity of medical information that may become part of the patient's official medical record.
- The use of DIRECT messaging as a secure transport protocol can increase adoption of the proposed model among commercial EHRs because support for DIRECT messaging will be a requirement for Stage-2 EHR certification by the fall of 2014 [5].
- The use of existing industry standards for collecting medical device data and for communicating such data to EHRs can leverage past standards work that is familiar to vendors of medical devices, data repositories, and EHRs, thereby accelerating widespread adoption of these standards to make the sharing of patient-generated data a practical reality.

¹ Because providers (and/or background processes acting on their behalf) initiate the retrieval of PGHI, providers can customize their data-retrieval patterns to match their organizational capabilities for evaluating and acting on the incoming data. As such, this model can accommodate a wide range of preferences regarding how often PGHI is retrieved and evaluated, from infrequent access (e.g., ad hoc querying of PGHI or retrieval of PGHI in preparation for a specific patient visit) to frequent automated "polling" for PGHI and rule-based processing of it such as an Accountable Care Organization might use for case management.

The remainder of this document describes in greater detail the standard-based models proposed for collecting and retrieving PGHI.

2 Collection and storage of patient-generated health information

Before PGHI can be available to providers' EHRs, it must obviously be captured at its source (the patient) and stored in a location that is accessible to other software systems. In practice, this process of collection and storage requires multiple steps involving several inter-communicating components. Until recently, inter-communication among the components required that they all be provided by the same manufacturer. Today, interoperability standards allow an increasing number of components from different manufacturers to exchange information.

2.1 Required components for data collection and storage

Figure 1 illustrates the components involved in the collection and storage of patient-generated data under the proposed model. As shown, the characteristics of these components may vary, as can the ways that data are transmitted from one component to another. In fact, there currently exist instances of applications and services that employ all of the types of components and communication mechanisms depicted in Fig. 1. The bold-faced selections in Fig. 1 indicate choices that we believe are most convenient for patients given the technologies and products currently available.

2.1.1 Data-collection tool

For physiologic parameters, such as blood glucose and blood pressure, the data-collection tools comprise home-monitoring devices that can collect physiologic values and related meta-data (such as time of observation). The devices transfer these data to a wide area network (WAN) gateway for ultimate storage in the cloud. Recently developed devices enable Bluetooth connectivity to WAN gateways, obviating the need for patients to physically dock a device to a separate piece of equipment or manually initiate the transfer of data. Such wireless devices include glucometers, blood pressure cuffs, weight scales, peak flow meters, and pulse oximeters [6].

For non-physiologic parameters (such as mood, diet, exercise patterns.), the data-collection tools typically comprise mobile health applications into which patients manually enter their data. The applications can also transmit the data to a WAN gateway for storage elsewhere.

In many cases, the WAN gateway is integrated with the data-collection device, which is typically a smart phone or cellular-enabled tablet computer, which obviates the need to connect to a separate device to upload data to the cloud.

2.1.2 Wide area network (WAN) gateway

The “WAN Gateway” is a general term for any hardware or software component that transmits patient-generated health information from a data-collection tool to a cloud-based data repository.

When the data-collection tool is a home-monitoring device, this component is typically a separate piece of hardware due to the limited size, battery life, and computing power of such devices. Commercial offerings for WAN gateways include dedicated appliances that can receive Bluetooth transmissions and forward the data to the cloud via the cellular network or via “plain old telephone service” (POTS). As alternatives to dedicated appliances, certain vendors offer smart phone applications that allow patients to relay data from medical devices to cloud-based repositories via the native Bluetooth and cellular communication capabilities of the phones they already own.

When the data-collection tool is a mobile health application, the WAN gateway may be a personal computer connected to the internet. The mobile application transmits data to the PC via a physical connection, a Wi-Fi LAN connection, or (less commonly) Bluetooth. An application running on the PC then forwards the data (automatically or when directed by the patient) over the internet to a storage site elsewhere. More conveniently, the WAN gateway for a mobile health application may be the cellular phone capabilities of the smart phone or tablet computer on which the application is running. This increasingly common approach obviates the need to configure a separate network connection to a PC or to physically connect a mobile device to a PC.

2.1.3 Data-upload interface

The “data-upload interface” is a general term for a network interface and related software application that exists in the internet “cloud” for the purpose of receiving patient-generated health information and ensuring its safe storage. The data-upload interface may receive transmissions from a WAN gateway via the internet (wired or wireless) or via a proprietary dial-up modem protocol. If information is received via the internet, the interface may support one or more internet transport protocols, including TCP/IP sockets, HTTP (web services), SMTP (email), and FTP.

The data-upload interface may support one or more structured formats for the representation of uploaded data,

including standard formats such as HL7 v2.x and IHE Technical Frameworks, or proprietary formats negotiated between specific WAN gateways and data-upload interfaces. In many cases today, the WAN gateway and the data-upload interface are part of the same product and employ a vendor-specific communication protocol and data-representation format. This is changing, however, as standards and products evolve to support “mixing and matching” between data-upload interfaces and PGHI repositories.

2.1.4 PGHI data repository

In the proposed model, patient-generated health information is stored in a data repository that is controlled by the patient, but available for authorized access by other persons or software applications. In certain cases, such repositories are simply the databases of specific personal health record (PHR) applications, which support the sharing of patient-generated data via their own user interfaces, web services APIs, authorization and access control mechanisms, etc. In these cases, the PGHI data repository is tightly coupled with and specific to a single vendor or application. An example is the proprietary data repository used by The-Carrot.com [7].

In other cases, PGHI data repositories are databases used by multiple software applications for the storage and sharing of patient-generated health information. In these cases, the PGHI data repository is loosely coupled with a variety of PHR vendors and applications through a set of APIs and access control mechanisms defined by the repository. A single patient record may be written to and read by a variety of independent applications, depending on the patient’s specified preferences. The most prominent example of this model is the Microsoft HealthVault repository [8].

Hybrid models also exist, in which a specific PHR product may have its own proprietary database (for use by its own applications via a proprietary API), but can also forward information to an independent shared data repository (for use by other applications via that repository’s open APIs). In these models, either or both of the repositories may provide a mechanism to share data with providers’ EHRs.

2.2 Standards for collecting and storing patient-generated health information

In the proposed model for sharing PGHI with providers’ EHRs, a standardized mechanism for collecting and storing patient-generated health information is not necessarily required. Health information may be collected and

transmitted to PGHI repositories in a variety of ways and still be available to providers' EHRs. What is most important in the proposed model is that a standardized mechanism exists for *accessing and retrieving* data from PGHI data repositories once the data reside there (depicted as steps 2 and 3 in Fig. 2). Such a mechanism, based on DIRECT messaging and a set of data-formatting standards, is described in Sect. 3.

However, there do exist certain minimum requirements for the collection and storage of PGHI to enable its retrieval via the standardized mechanisms specified in Sect. 3. There are also benefits to standardizing the collection and storage of PGHI, to the degree that it fosters a dynamic market of data-collection tools and data-storage resources.

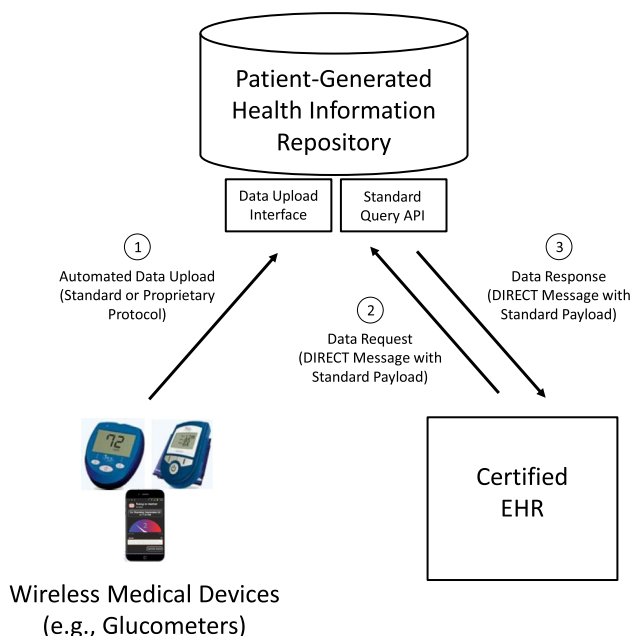


Fig. 2 High-level architecture of the proposed model

2.2.1 Minimal requirements for collection and storage of data

Several minimum requirements exist for the collection and storage of PGHI to enable its retrieval via the standardized mechanisms specified in Sect. 3:

1. Collection and storage of appropriate *provenance data*. The standard data-retrieval mechanism requires that certain minimal information be included regarding the sources of the patient-generated health information, including details about the person who collected the data and the context in which it was collected, as well as details about the specific physiologic monitoring device that was used to measure the data (if applicable). As data pass from the data collection tools to the PGHI data repository, this information must be retained in an appropriate format so that it may later be provided to requesting EHR applications.
2. Collection and storage of appropriate *clinical data values*. The standard data-retrieval mechanism described in Sect. 3 specifies the representation of retrieved clinical parameters, including the coding of parameters (e.g., SNOMED CT code 434912009 to depict Blood Glucose Concentration), the representation of the parameters' values (reporting Blood Glucose concentration as either millimoles/Liter or milligrams/deciliter), and certain meta-data that must accompany the parameter values (e.g., the date and time of the reported observation). To support the reporting of PGHI consistent with these requirements, the PGHI must be collected and stored in a manner that ensures the necessary data are available (for example, a date and time are collected for each blood glucose concentration) and the data can be converted to the required representation format (for example, proprietary codes for parameters and units of measure can be

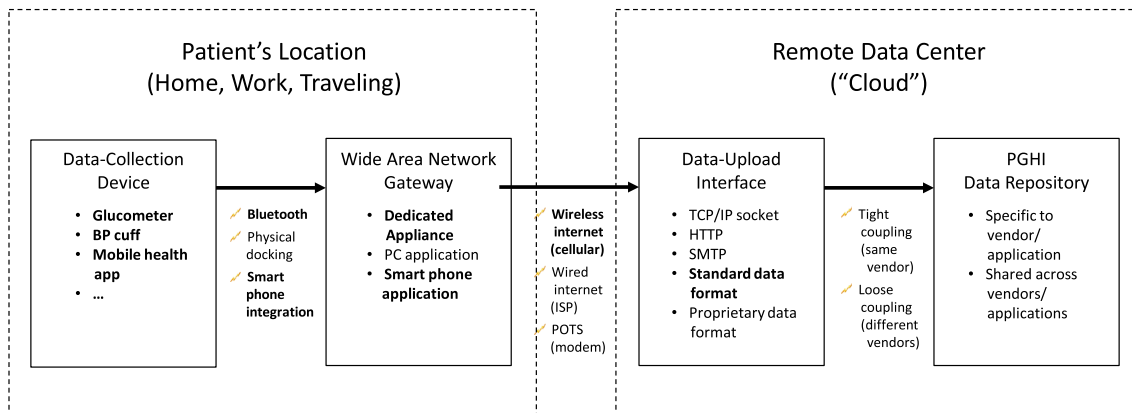


Fig. 1 Components for the collection and storage of PGHI, including their various features and methods for transferring data among them

converted to equivalent SNOMED codes). In practice, the collection and storage of appropriate clinical data values are relatively straightforward for common physiologic parameters, such as blood glucose concentration, blood pressure, and pulse oximetry readings, because these simple parameters have *de facto* standardization already. More difficult is the appropriate storage of clinical data values for observations such as mood, exercise patterns, and nutritional content of meals. As these parameters are incorporated into the set of standard reportable PGHI, there will be a requirement to further standardize the formatting and coding of their values and meta-data.

Table 7 in Sect. 3.3.1.3 lists the minimum set of data and appropriate data formatting for the parameters that may be reported per the standard mechanisms proposed here, to guide developers of data collection and storage systems that can support these mechanisms.

2.2.2 Continua standards for collection and storage of data

One potential source of applicable standards for the collection and storage of PGHI is the Continua Alliance, a consortium of medical device and healthcare software companies that is seeking to advance the collection and use of patient-generated data to improve fitness, aging-in-place and chronic disease management [9]. Within the past several years, Continua have designated a set of standards for the transmission of patient-generated health information, primarily from medical devices, to hosted data repositories [10]. The standards are specifically intended to foster interoperability among data-collection tools, WAN gateways, and data-upload interfaces from different vendors. It is hoped that such interoperability will expand the market for these components and facilitate the implementation of creative, multi-vendor solutions that leverage PGHI.

2.2.2.1 Interoperability standards between data-collection tools and WAN gateways Continua have designated a set of interoperability specifications based on the ISO/IEEE 11073 Personal Health Data standards [11]. These specifications define interactions between “agents” (data-collection tools) and “managers” (WAN gateways). The specifications include an object-oriented domain model for representing the structure and coding of transmitted medical data, as well as a communication model for defining the dynamics of message transmissions and acknowledgements. The specifications also require basic security and encryption capabilities.

Sub-specifications define interoperability profiles for specific types of devices, including glucometers, blood pressure monitors, and weighing scales. Notably, these Continua specifications are independent of any specific transport technologies and can be supported by common wired (e.g., USB) or wireless (e.g., Bluetooth) technologies, as well as specialized transport technologies specifically designed for wireless home-computing applications (e.g., Zigbee [12]).

To date, 29 data-collection devices have been certified as “agents” compliant with this Continua standard and 45 gateway devices have been certified as “managers” compliant with the standard [13].

2.2.2.2 Interoperability standards between WAN gateways and data-upload interfaces Continua have also designated a separate interoperability specification for the transmission of patient-generated data from WAN gateways to the data-upload interfaces used by PGHI repositories. This specification is based on the Device Enterprise Communication (DEC) integration profile of the IHE patient care device (PCD) Technical Framework [14]. The PCD-01 transaction defined by the DEC profile is, itself, based on the HL7 v2.6 message standard and the IEEE 11073 domain model for medical devices. Use of the IEEE 11073 domain model ensures a measure of compatibility with the Continua specifications designated for the transmission of data between data-collection devices and WAN gateways (as described in Sect. 2.2.2.1).

Similar to that specification, the specification for transmitting data between WAN gateways and data-upload interfaces is also independent of any specific transport technologies and can support wired WAN technologies (e.g., DSL, Ethernet, Fiber) as well as wireless (e.g., Cellular GPRS, EDGE, 3G/4G, WiMAX).

To date, three products have been certified as WAN gateways compliant with this Continua standard, and two products have been certified as compliant data-upload interfaces [13].

3 EHR access and retrieval of patient-generated health information

Although the collection and storage of PGHI is critical, the greater portion of the standard model proposed here addresses the manner in which patient data may be requested and retrieved from PGHI repositories. The model we propose uses the DIRECT Project’s secure email protocol as the transport mechanism, and a combination of HL7 v2.x messages and Continuity of Care Documents (CCDs) as the data-representation mechanism.

3.1 DIRECT messaging for standardized transport and access control

The DIRECT Project is an initiative sponsored by the Office of the National Coordinator for Health Information Technology (ONC) to develop a set of interoperability standards and policies for the electronic exchange of patient health information [15, 16]. In 2011, the DIRECT Project published the specifications for a model of secure point-to-point health information exchange based on standard internet email protocols (i.e., SMTP²) and widely used standards³ for securing email content [17]. The specifications included a standard mechanism to interface EHRs to secure email gateways, enabling EHRs to incorporate DIRECT messaging capabilities “natively” into their capabilities [18].

Although DIRECT messaging was intended and is primarily used today for communications among healthcare providers, it can also serve as a transport mechanism between healthcare providers and independent repositories of health information that is generated and controlled by patients. This contention is partially driven by the requirement in stage 2 meaningful use regulations that all certified EHR products must include the capability to exchange information via DIRECT messaging [5], which we feel will render DIRECT messaging a nearly ubiquitous capability of healthcare providers by 2015. It is also driven by the flexibility of DIRECT messaging and its simple but robust security model (as described below).

Figure 3 illustrates the proposed manner in which DIRECT messaging may be used to enable access by providers to patient-generated health information.

Note the following features of this model:

- The patient’s and provider’s identities are fully characterized by their DIRECT addresses. No patient-matching logic or provider identity verification is required on the part of the PGHI repository.
- The patient controls which providers may access his PGHI record by specifying the DIRECT addresses of those providers who are authorized to see his data. Depending on the policies and technical capabilities of the PGHI repository, this could be “all-or-nothing” access to the patient’s data, or potentially “fine-grained” access control that allows patients to grant access to specific parts of their record relevant to a particular provider.
- PGHI repositories accept requests from and send patient data to only those DIRECT addresses that have been authorized by the patient. Providers may authorize

staff members to access their DIRECT messaging accounts for purposes of sending requests or processing responses, but the providers are ultimately responsible for the appropriate handling of patient health information requested from and sent to their DIRECT addresses.

- Providers can access PGHI from any repository that supports the standard query API, provided that their patient has authorized them to access his record in that repository. Providers and their EHRs need not know anything about the PGHI repository except for the DIRECT address to which requests should be sent.
- PGHI repositories can respond to data requests from any provider whose information system supports the standard query API. The repositories need not know anything about the requesting provider except for her DIRECT address.

3.1.1 Leveraging the DIRECT identity and authentication model

The DIRECT messaging model incorporates certain technical and policy mechanisms that enable patients to securely share PGHI with their providers via the workflows depicted in Fig. 3.

- DIRECT messages are encrypted as S/MIME attachments as they pass over the public internet. DIRECT messages are also digitally signed by the sending entity to ensure that they are not tampered with in transit. The encryption and signing is performed using robust and mature protocols based on the public key infrastructure. These protocols are already used widely to secure internet communications in health care, finance, and other industries.
- A digital certificate created by a trusted certificate authority (CA) must be associated with each DIRECT address. The digital certificate may correspond to the *full DIRECT address* of the provider (e.g., “DrPat-Smith@direct.primarydocs.org”), in which case the identity of the provider is validated by the CA before the certificate is issued and the provider is relied upon to properly authenticate (via a password or stronger means) each time she uses that DIRECT address. Alternatively, the digital certificate may correspond to the *domain name* of the DIRECT address (e.g., “direct.primarydocs.org”), in which case the organization to which the certificate is issued is relied upon to validate the identity of all providers to whom it issues DIRECT addresses containing its domain name and to ensure that these providers authenticate properly each time they use their DIRECT addresses. In either case, it is the responsibility of the CA to ensure that providers’

² Simple Mail Transport Protocol.

³ Public Key Infrastructure (PKI) and S/MIME (Secure Multipurpose Internet Mail Extensions).

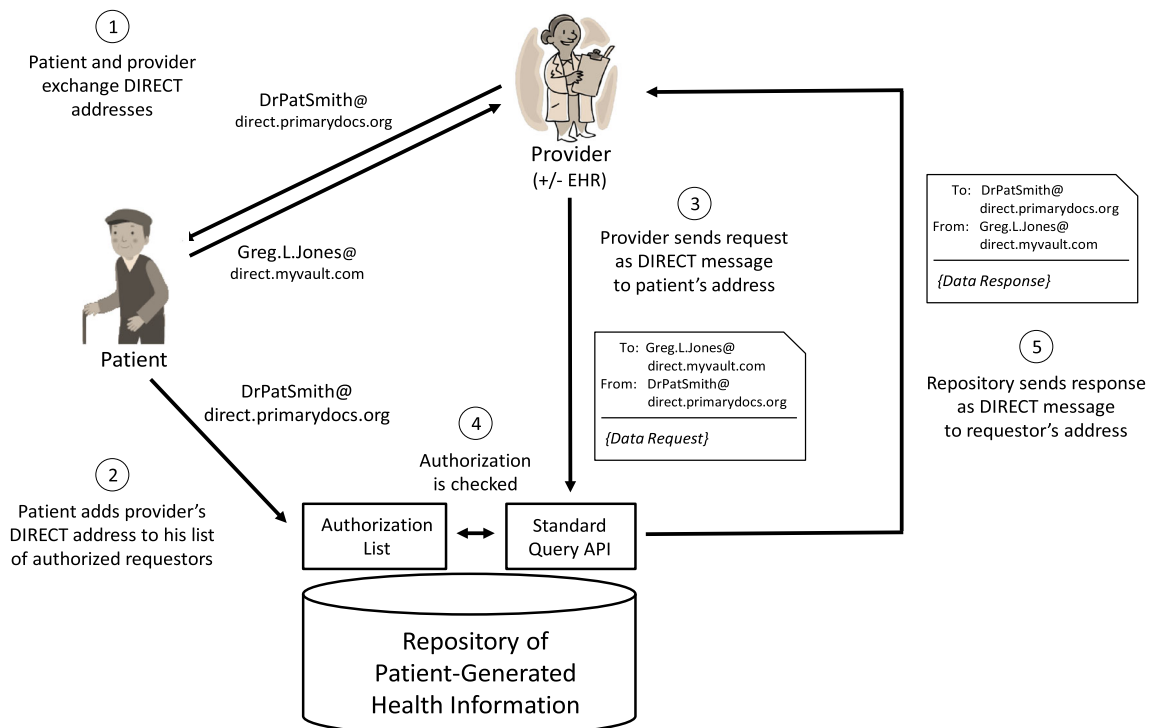


Fig. 3 The use of DIRECT messaging to enable secure exchange of patient data between providers and patients' PGHI repositories

identities are properly validated and their access is properly authenticated before they can use the DIRECT addresses that have been issued to them.

- Every DIRECT messaging system includes a technical mechanism to ensure that messages may only be sent to or received from DIRECT addresses that correspond to digital certificates created by trusted CAs (i.e., CAs trusted to dispatch the responsibilities described above responsibly). In the context of the model proposed here, if the DIRECT messaging systems used by the requesting provider and the responding PGHI repository trust each other's CAs, message exchange can take place between them. Although the DIRECT messaging specifications don't prescribe which CAs should or should not be trusted, other initiatives, such as DirectTrust.org [19], are working to define criteria by which the trustworthiness of CAs can be assessed and certified.

3.1.2 Duality of DIRECT messaging as a secure transport standard

Another favorable characteristic of DIRECT messaging is that it can be used as a secure transport mechanism both for "manual" messaging between users of DIRECT-enabled email clients, as well as automated messaging between DIRECT-enabled software applications.

In the manual mode, "conventional" email messages are formulated and addressed by human users and sent in a secure manner via the DIRECT specifications for digital signature and encryption. The security features of these systems are all but transparent to their users, who perceive the interactions as nearly identical to standard email.

In an automated mode, software applications formulate standard email messages programmatically and attach structured data to these messages as file attachments. The applications then send the messages securely over SMTP (per the DIRECT specifications) to end points specified as standard DIRECT addresses. At those end points, other software applications receive the messages and programmatically open and process the structured data files attached to them.

This duality of DIRECT messaging renders it a favorable technology for providers to request and receive PGHI from patients' data repositories, because it allows providers to request and receive such data even before they have EHRs that are DIRECT enabled. As long as a provider has a DIRECT address and some means of sending and receiving DIRECT messages,⁴ she can interact securely with a DIRECT-enabled data repository and receive authorized PGHI in a human-readable form (for example,

⁴ For example, a number of vendors now offer web-based email programs that can send and receive DIRECT messages and attachments.

Table 1 Standard contents of a DIRECT message requesting PGHI in “simple” model

To	Patient’s DIRECT address for requesting PGHI
From	Requesting provider’s DIRECT address
Subject	<i>None required</i> (DIRECT messaging does not encrypt the contents of the subject line, so no sensitive information should be sent here)
Body	Free text request containing: <parameter of interest> <date/time range> The specific wording of the request may vary—the standard query API of the PGHI repository must be able to process simple natural language expressions specifying the request Example requests: <i>Blood glucose 11/1/2012 – 11/5/2012</i> <i>Blood pressure November 2012</i> <i>Baby fussiness last 2 weeks</i> (Note: No patient demographic information is sent in the body, because the patient is identified through the DIRECT address in the “To” field of the DIRECT message)
Attachment	None

as PDF file attachments—see Sect. 3.2.2). For providers with DIRECT-enabled EHRs, the same transport mechanism enables them to request and receive PGHI from patients’ data repositories in a machine-readable form, which allows the information to be automatically incorporated into their EHRs as structured data (see Sect. 3.3.3).

The sections below specify in greater detail a model for standardizing both types of interactions between providers and PGHI data repositories.

3.2 Unstructured request/response messages: basic document retrieval

This section describes a simple model for providers to request and receive data from PGHI repositories via DIRECT messages. The simple model allows providers to specify only a limited amount of information about the data they are requesting, and it supports the delivery of the data only as PDF files attached to DIRECT message responses.

3.2.1 Standard unstructured request message

Table 1 describes the required contents of a DIRECT message for requesting PGHI via this simple mechanism. Note that only the standard set of patient parameters (as listed in Sect. 3.3.1.1.) may be requested in the body of the message, although the request may be formulated as a natural language expression (i.e., without the rigidly prescribed structure or terminology specified in Sect. 3.3.1.1.—see examples in Tables 1, 2).

Table 2 Example of a DIRECT message requesting PGHI in “simple” model

To	<i>Greg.L.Jones@direct.myvault.com</i>
From	<i>DrPatSmith@direct.primarydocs.org</i>
Subject	
Body	<i>Blood glucose 11/1 – 11/5</i>
Attachment	

Table 3 Standard contents of a DIRECT message responding to a request for PGHI in “simple” model

To	Requesting provider’s DIRECT address
From	Patient’s DIRECT address for requesting PGHI
Subject	General description of message (DIRECT messaging does not encrypt the contents of the subject line, so no sensitive information should be sent here)
Body	Summary of the information that is being provided
Attachment	PDF file containing graphical and tabular representations of the requested data, along with patient-identifying information and appropriate header information indicating the source of the data. This document should be suitable for including in the patient’s record as either a printed report in a paper chart or an imported document in an EHR chart. See Fig. 4 for an example.

Table 4 Example of a DIRECT message response to a request for PGHI in “simple” model

To	<i>DrPatSmith@direct.primarydocs.org</i>
From	<i>Greg.L.Jones@direct.myvault.com</i>
Subject	Your request for information from MyVault.com on 11/08/2012 10:41 AM EST
Body	<i>The attached file “myvault_report_5784958773.pdf” contains the following information you requested for Greg L. Jones (DOB: 04/23/1954):</i> <i>Blood Glucose Concentration in mg/dL (measured by patient at home)</i> <i>Date range: 11/1/2012 to 11/05/2012</i>
Attachment	<i>myvault_report_5784958773.pdf</i>

Example Table 2 shows an example of a DIRECT message requesting blood glucose measurements for Greg Jones during a specific date range.

3.2.2 Standard unstructured response message

Table 3 describes the contents of a DIRECT message response to a simple request for PGHI.

Example Table 4 shows an example of the DIRECT message sent in reply to the sample request message in Table 2.

Personal Health Monitoring Report

11/08/2012

Report ID: 5784958773

Source: MyVault Personal Health Repository (www.myvault.com)
(Data collected by patient via Roche Diastar glucometer)

Patient: Greg L. Jones (DOB: 04/23/1954)

Requested Data: Blood Glucose Concentration 11/02/2012 - 11/05/2012

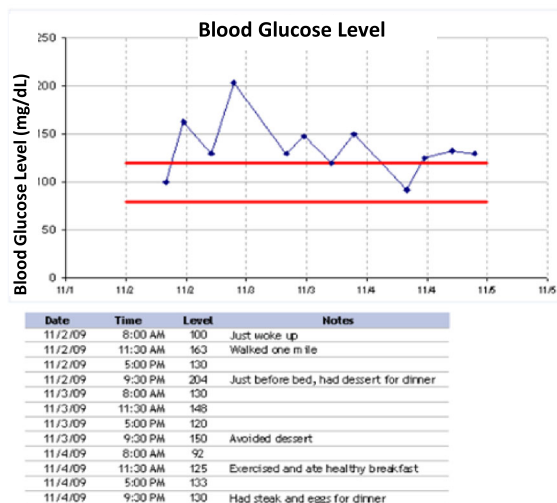


Fig. 4 Sample contents of a PDF file sent in response to a request for PGHI in simple model

Note that the specific contents and layout of the PDF file attachment that contains the patient data that are determined by the PGHI repository to which the request was sent. However, certain standard content must be included in these reports:

- A header containing the patient's name and date of birth, and the source of the document.
- A clear statement describing the origin of the data included in the document, specifically that the data was entered or collected by the patient via home-monitoring devices or a personal health application.
- The requested data points in both a graphical and tabular representation, with appropriate meta-data of clinical relevance (such as the date/time of each observation and whether blood glucose readings were taken during fasting or after meals).

Figure 4 shows an example of the contents of a PDF file sent in response to a request for PGHI following the "simple" model.

3.2.3 Error reporting

In cases where the provider's request for patient data cannot be fulfilled, the body of the response message must contain a suitable error message explaining the problem and suggesting steps to remediate it. For example:

- "The address DrPatSmith@direct.primarydocs.org is not authorized to access information from the account corresponding to the address Greg.L.Jones@direct.myvault.com. Please contact the holder of this account to arrange authorization. Further information is available at www.myvault.com/authorizing-access"⁵.
- "MyVault.com could not understand the following request you sent on 06/06/2013 10:41 AM EST for patient information from the account of Greg.L.Jones@direct.myvault.com: 'July's glucose' Please consult www.myvault.com/requesting-patient-data for information about the proper formatting of patient data requests".

3.3 Structured request/response messages: data and/or document retrieval

To provide greater expressiveness for requesting data from PGHI repositories and to enable data retrieved from PGHI repositories to be integrated into EHRs as discrete data objects, a more formalized standard is also required for representing data in requests and responses. The model we propose for this purpose specifies that standard data structures be sent as *attachments* to the DIRECT messages exchanged between providers and patients' PGHI repository.

The standard data structure sent in requests consists of an HL7 v2.5.1 "QBP" message [20] containing query parameters that formally describe the information to be retrieved. The standard data structure sent in responses consists of an HL7 v2.5.1 "RSP" message [20] that contains a CDA Release 2.0 document formatted per the personal healthcare monitoring report (PHMR) Implementation Guide Release 1.1 [21]. The CDA document contains individual PGHI observations collected by the patient, as well as (optionally) derived observations, such as graphs or calculated aggregates (average, min, max, etc.).

The next section describes the conceptual data model on which the first version of these data structures is based. The following two sections describe the data structures for requests and responses based on this conceptual data model.

⁵ Rather than immediately returning an error response when the patient has not already authorized the PGHI repository to respond to queries from the provider's DIRECT address, an alternative approach would be for the PGHI repository to prompt the patient about whether the request should be granted at the time the request is received. In this variation, the PGHI repository would wait a predetermined amount of time before rejecting the request if the patient does not authorize it.

Table 5 Observations that may be specified within structured requests for PGHI

Requested observation	Code	Coding system	Comment
Blood pressure	75367002	SNOMED CT	Both systolic and diastolic values
Systolic blood pressure	271649006	SNOMED CT	Systolic values only
Diastolic blood pressure	271650006	SNOMED CT	Diastolic values only
Blood glucose concentration	434912009	SNOMED CT	Blood and/or plasma glucose concentrations will be retrieved (whichever are available)
Plasma glucose concentration	434911002	SNOMED CT	Plasma glucose concentrations only will be retrieved
Body weight	27113001	SNOMED CT	
Infant fussiness	444951002	SNOMED CT	

Table 6 Formatting of retrieved observations that may be specified within structured requests for PGHI

Formatting Code	Coding System	Comment
Data	99onc ^a	Retrieve individual observations as discrete data elements only
Data-and-chart	99onc ^a	Retrieve individual observations as discrete data elements plus graphical depiction of the trend of observations
Chart	99onc ^a	Retrieve graphical depiction of trend of observations only
Data-and-chart-as-pdf	99onc ^a	Retrieve PDF file containing a graphical and tabular representation of the requested observations only (i.e., the same pdf file as would be returned in the Unstructured Response Message described in Sect. 3.2.2)

^a Placeholder only. Actual standard will specify a unique object ID (OID) to denote the coding system

3.3.1 Clinical data model for structured requests and responses

This section specifies a simple, initial data model for requesting and receiving PGHI via DIRECT messaging. The model specifies the set of PGHI observations that may be requested and the required representation of these observations within structured request messages (as specified in Sect. 3.3.2). The model also specifies the required structure of each observation returned within a structured response message (as specified in Sect. 3.3.3).

3.3.1.1 Request data model: observations Table 5 lists the types of observations that may be specified for retrieval within structured requests for PGHI.

3.3.1.2 Request data model: format Table 6 lists the formatting of retrieved observations that may be specified within structured requests for PGHI.

3.3.1.3 Response data model: data structure Table 7 specifies the data structures for the observations that may be returned in response to requests for PGHI.

3.3.2 Standard structured request message

Figure 5 illustrates the standard message structure for requesting information from PGHI repositories via

DIRECT messages. The structure requires that a HL7 v2.5.1 message be included as a file attachment to a DIRECT message sent from the requesting provider to the patient's address at the PGHI repository. The HL7 file specifies the information requested from that patient's record in the repository, as well as certain control information for uniquely identifying the query, specifying its urgency, etc.

3.3.2.1 HL7 v2.5.1 query message The standard model proposed here uses the "QBP/RSP" message pair specified in HL7 v2.5.1 [20] to communicate the query and response parameters. The query parameters are communicated in a "QBP_Q11" message structure. This structure contains a "QPD" message segment, in which the specific query parameters are expressed.

HL7 requires that the query parameters be communicated in the QPD segment within fields QPD-3 and greater. HL7, however, does not prescribe what the query parameters are or how many there may be for any specific use of a QBP/RSP message pair, so we have specified these parameters to correspond to the conceptual data model described in Sect. 3.3.1. Table 8 describes how the query parameters and other fields should be specified in the QPD segment.

Note: The prescribed content and formatting for the "MSH" and "RCP" segments are described in the HL7 v2.5.1 standard (Chapter 5) [20].

Table 7 Data structures for observations that may be retrieved within structured responses for PGHI

Returned Observation	Value type	Coding for units of measure	Date/time of observation	Description of collection instrument
Systolic blood pressure	Number	UCUM Code [=mm(Hg)]	Date and time + timezone	String
Diastolic blood pressure	Number	UCUM Code [=mm(Hg)]	Date and time + timezone	String
Blood glucose concentration	Number	UCUM Code (=mmol/L or mg/dL)	Date and time + timezone	String
Plasma glucose concentration	Number	UCUM Code (= mmol/L or mg/dL)	Date and time + timezone	String
Body weight	Number	UCUM Code [=kg or (lb_av)]	Date and time + timezone	String
Infant fussiness	Integer (1–10)	UCUM Code (=“1”)	Date and time + timezone	String = “Estrellita fussy-o-meter”

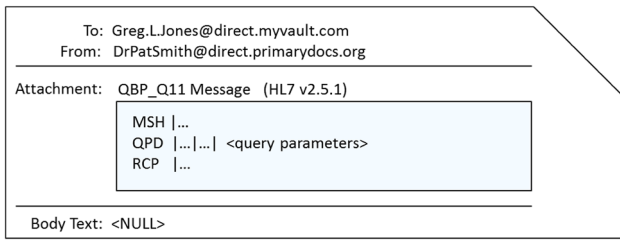


Fig. 5 Standard contents of a structured DIRECT message used to request data from a PGHI repository

Note that there is no patient identification (PID) segment included in the QBP message type defined here, because the patient’s identity is entirely specified by the DIRECT address to which the message is sent (the PID segment is optional in the QBP_Q11 message structure, and we have elected to omit it for our purposes).

3.3.3 QPD-3 requested observation(s)

This is a potentially repeating field containing the specific types of observation(s) to be retrieved from the PGHI repository. The types that may currently be retrieved are

listed in Sect. 3.3.1.1. One or more types of observations may be requested.

EXAMPLE Value of QPD-3 to request a patient’s blood glucose measurements and systolic/diastolic blood pressure readings:

```
434912009^Blood Glucose Concentration^SCT~75367002^Blood Pressure^SCT
```

3.3.4 QPD-4 requested format

This field contains a code indicating the format(s) in which the requestor would like the retrieved observations to be returned in the structured response message. The formats that may currently be requested are listed in Sect. 3.3.1.2. Only one format may be requested, which will apply to all of the observation types retrieved.

EXAMPLE Value of QPD-4 to request that the PGHI repository return individual observations as discrete data elements plus a graphical depiction of the trend of observations

```
data-and-chart^Discrete data and trend chart^99onc
```

Table 8 Specifications of the QPD segment in a structured QBP request

SEQ	Element name	LEN	Data type	Usage	Cardinality	Comment
1	Message query name	250	CE	R	[1..1]	Identifier of the type of query: - “Z100^PGHI DIRECT QRY^99onc”
2	Query tag	32	ST	R	[1..1]	Unique ID of the query instance (e.g., a GUID)
3	Requested observation(s)	227	CE	R	[1..*]	See Sect. 3.3.2.1.1
4	Requested format	227	CE	R	[1..1]	See Sect. 3.3.2.1.2
5	Lower datetime	227	DT	R	[1..1]	Lower time bound of requested observations, inclusive
6	Upper datetime	427	DT	R	[1..1]	Upper time bound of requested observations, inclusive

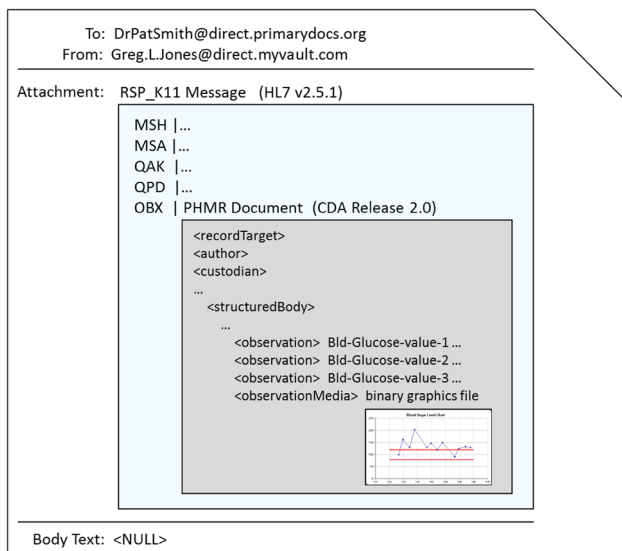


Fig. 6 Standard contents of a structured DIRECT message used to send patient data from a PGHI repository in response to a structured request

3.3.5 Standard Structured Response Message

Figure 6 illustrates the standard message structure for responding to requests from PGHI repositories via DIRECT messages. The structure requires that a HL7 v2.5.1 message be included as a file attachment to a DIRECT message that is sent from the patient's address at the PGHI repository to the requesting provider. The HL7 file contains the information that has been retrieved from that patient's record in the repository, including additional embedded structured documents.

3.3.5.1 HL7 v2.5.1 response envelope Data sent in response to a structured query are specified in an HL7 v2.5.1 "RSP_K11" message structure [20]. This structure contains an "OBX" message segment, in which the retrieved PGHI data are contained as an embedded PHMR Document (see Sect. 3.3.3.2). The other segments of this message structure ("MSH," "MSA," etc.) contain only "control" information, such as the unique identifier of the original request and relevant acknowledgement/error information.

The HL7 standard allows observations to be sent in OBX segments as "encapsulated data," which supports a variety of document types and encoding mechanisms. Using this feature, the model proposed here specifies that the PHMR document be encoded as a multi-part MIME attachment, with the first MIME part containing a Base-64 encoded representation of the PHMR document, and subsequent parts containing Base64 encoded representations of any binary image files embedded in the PHMR document (such as trend graphs of physiologic values).

The MIME-encoded data structure may be extracted from the HL7 message and de-coded upon receipt to reconstitute the original PHMR CDA document. This document may then be processed by any CDA-enabled software modules that recognize the document templates specifically defined by the PHMR implementation guide. If an XSL style sheet has been specified for the PHMR document, it may even be displayed directly in a web browser.

Table 9 describes how the fields of the OBX segment should be populated in an RSP_K11 message, as specified by the model proposed here. Figure 7 shows an example of an OBX segment that might appear in such a message.

Note that the prescribed content and formatting for the "MSH," "MSA," "QAK" and "QPD" segments are described in the HL7 v2.5.1 standard (Chapters 2 and 5) [20].

3.3.6 OBX-5 observation value

The PHMR document is represented as a MIME-encoded object of type "multipart" and sub-type "x-hl7-cda-level-one", per the specification in Table 10 and RFC 2557 [22].

Table 10 describes how the components of the OBX-5 field should be populated in an RSP_K11 message, as specified by the model proposed here. Lines 2–10 in Fig. 7 show an example of an OBX-5 value as it might appear in such a message.

3.3.6.1 PHMR structured data payload The "Implementation Guide for CDA Release 2.0 Personal Healthcare Monitoring Report" (PHMR) [21] was defined by an HL7 working group in 2008 for the purpose of communicating data collected by home-monitoring devices and personal health applications in a structured and coded fashion. This implementation guide further constrains the previously defined "HL7 Implementation Guide: CDA Release 2—Continuity of Care Document (CCD)" [23], which specifies a more general format for reporting clinical patient data as a CDA document. In fact, the PHMR specifications expressly follow the CCD implementation guide and re-apply most of its features:

"CONF-PHMR-44: Except where specifically noted in this [implementation guide], the structured body of a Personal Healthcare Monitoring Report SHALL conform to the constraints of HL7's Continuity of Care Document (CCD) specification (published April 1, 2007), and all references to CCD templateIds apply to that initial release of CCD".

The PHMR implementation guide (I.G.) is well-suited as a standard representation for PGHI due to a number of specific features:

Table 9 Specifications of the OBX segment in a structured RSP response

SEQ	Element name	LEN	Data type	Usage	Cardinality	Comment
1	Set ID – OBX	4	SI	R	[1..1]	“1”
2	Value type	2	ID	R	[1..1]	“ED”
3	Observation identifier	250	CE	R	[1..*]	“53576-5^Personal Health Monitoring Report Document^LN”
4	Observation Sub-ID	20	ST	O	[0..1]	Not used
5	Observation value	65,536	ED	R	[1..1]	See Sect. 3.3.3.1.1

Fig. 7 Example of an OBX segment in a RSP_K11 message used to transmit a personal health monitoring report

```

1  OBX|1|ED|53576-5^Personal Health Monitoring Report Document^LN|
2  ^multipart^x-hl7-cda-level-one^A^
3  MIME-Version: 1.0
4  Content-Type: multipart/mixed; boundary="HL7-CDA-boundary"
5  Content-Transfer-Encoding: Base64
6  --HL7-CDA-boundary
7  Content-Type: application/x-hl7-cda-level-one+xml
8  ... Base64-encoded CDA document ...
9  --HL7-CDA-boundary
10 ... Base64-encoded graphics file referenced within the CDA document...
    
```

Table 10 Specifications of the OBX-5 field in a structured RSP response

SEQ	Element name	LEN	DATA type	Usage	Cardinality	Comment
OBX-5.1	Source application	227	SI	O	[0..1]	Not used
OBX-5.2	Type of data	2	ID	R	[1..1]	“multipart”
OBX-5.3	Data subtype	250	CE	R	[1..1]	“x-hl7-cda-level-one”
OBX-5.4	Encoding	20	ST	R	[1..1]	“A” (displayable ASCII characters)
OBX-5.5	Data	65,536	ED	R	[1..1]	The MIME-encoded data. See Fig. 7 for an example

- The I.G. includes specific data elements for denoting the provenance of PGHI, including:
 - <recordTarget>: The patient to whom the data applies
 - <dataEnterer>: The source of the PGHI, if different than the patient (e.g., patient’s caregiver)
 - <assignedAuthoringDevice>: The application (PGHI data repository or client application) that generated the PHMR document
 - <custodian>: The steward of the data included in the document, i.e., the PGHI data repository
- The I.G. explicitly defines standard codes for representing common PGHI observations. These codes are drawn from widely accepted terminologies, including SNOMED CT, IEEE 11073, LOINC®, and UCUM. The specified observations include: blood glucose level, plasma glucose level, systolic BP, diastolic BP, pulse rate, body temperature, and oxygen saturation.
- The I.G. includes a “Medical Equipment” section, in which the specifications of the medical devices used by a patient to collect each PGHI observation may be

included. The I.G. specifies a standard mechanism for referencing entries in this section from the individual observations listed elsewhere in the document (because there is usually a many-to-one relationship between observations and medical devices in a PHMR document).

- The I.G. allows non-physiologic observations (such as infant fussiness) to be reported in an optional “Functional Status” section, per the templates for functional status observations prescribed by the CCD. The I.G. requires that either a set of physiologic observations or a set of functional status observations be included in every PHMR document (both types of observations may also appear in the same document).

3.3.6.2 Embedded binary files The PHMR I.G. also provides a mechanism for embedding binary files within the XML document content, using <observationMedia> entries. This capability (which is actually a feature of the

Fig. 8 Example of a PHMR document that contains individual data observations alongside a graphical summary of these observations. The structure and coding of the individual observations is omitted for brevity

```

<ClinicalDocument>
...
  <section>
    <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
    <title>Results</title>
    <entry><observation> ... blood glucose value 1 ... </observation></entry>
    <entry><observation> ... blood glucose value 2 ... </observation></entry>
    <entry><observation> ... blood glucose value 3 ... </observation></entry>
  <entry>
    <observationMedia classCode="OBX" moodCode="EVN" ID="BldGlucoseGraph">
      <id root="5d1ecb0d-a865-4fc1-bca2-a0e4693432ae">
        <value xsi:type="ED" mediaType="image/gif" representation="B64">
          4AAQsKzhRgACAO...*</value>
        </observationMedia>
      </entry>
    </vital signs>
  </section>
...
</ClinicalDocument>

```

* Base-64 encoded GIF file showing trend of blood glucose values 1-3

CDA specification rather than PHMR, *per se*) allows PHMR documents to include graphical contents suitable for direct human review, such as GIF or PDF files. This capability allows the PGHI data repository to summarize certain of the patient-generated data and provide this summary information in the form of a graphical file, in addition to sending the individual observations as structured data points for storage and further processing by the receiving system (e.g., an EHR).

Figure 8 contains an excerpt from a sample PHMR document, showing how individual observations may be reported (in `<observation>` elements) along with a graphical summary of the observations (in the `<observationMedia>` element).

4 Discussion of the model

The standard model proposed here constitutes a “straw man” intended to foster thought, discussions and refinement through pilot implementations and improvements. Although the model is based on existing technologies and standards, the specific combination proposed here has not yet been used (to our knowledge) in a production setting to request and retrieve PGHI for providers and EHRs. It is quite possible (and likely) that variations of this model will be necessary before it is suitable for designation as a required component of EHR certification under the meaningful use program. Potential variations may include:

- Replacement of the HL7 v2.5.1 QBP/RSP message attachments with an XML-based data structure, such as the HL7 v3 query message [24]. HL7 v3 messages are XML data structures that may confer less “impedance mismatch” between bar-delimited formatting of HL7 v2.5.1 messages and the XML formatting of PHMR

documents. Like HL7 v2.5.1, they also provide the ability to embed CDA documents within them [25]. On the other hand, HL7 v3 messaging standards are used very little in the United States to date and have not been included in any of the interoperability standards designated by the federal government. HL7 v2.5.1 is familiar to most EHR vendors and has been included in many of the government-designated interoperability standards.

- The PHMR implementation guide (v1.1) is not yet a normative HL7 standard. Since its development in 2008, it has been a “Draft Standard for Trial Use” (DSTU) only, available for testing and refinement in preparation for normative balloting by HL7. Such balloting is now scheduled for the fall of 2013, but the outcome of the ballot and any changes to the implementation guide that may result from it are as yet unknown.
- The PHMR implementation guide (v1.1) was developed for and has been largely tested in the international realm to date. As such and given the time elapsed since its development, PHMR may no longer conform to contemporary specifications designated for meaningful use in the United States. Specifically, PHMR may or may not conform to the specifications of the “Consolidated Clinical Document Architecture” (C/CDA) [26] that was incorporated in the meaningful use stage-2 EHR certification criteria [27], which will presumably also be a component of the stage-3 certification criteria. It is possible that a round of harmonization and further HL7 balloting will be required to bring the PHMR and C/CDA specifications into alignment.
- Widespread use of DIRECT messaging to communicate patient information between unaffiliated organizations (including providers and PGHI repositories) will

depend on the emergence of a uniform trust infrastructure. Such an infrastructure does not yet exist, and is being conceived and tested at this time. Depending on the outcome of this process, the model proposed here may need to change to include other security artifacts sent as attachments within DIRECT messages (such as the digital certificates of the requesting providers) or the model may need to adopt a different transport mechanism altogether.

Despite these potential challenges and required modifications, the standard-based model proposed here provides a viable and coherent mechanism for the sharing of patient-generated health information with electronic health records, fulfilling many of the technical and work flow requirements of this important use case.

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