Overview Chapter

HL7 EHR-System Public Health Functional Profile, Release 2 – US Realm

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1. Preface

1.1.   Publication of this document that has been registered as a Technical Report with ANSI has been approved by Health Level Seven International (HL7), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261. This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature. Comments on the content of this document should be sent to the HL7 <<Structured Documents>> Work Group, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261 or hq@hl7.org.

1.2.   *Notes to Readers: Introduction*

The current release of the Public Health Functional Profile (PHFP) of the HL7 Electronic Health Record System Functional Model and Standard (EHR-S FM), U.S. Realm, has been developed through The Task Force for Global Health, Inc. ("TFGH") and the Public Health Informatics Institute (PHII), and through the Public Health Data Standards Consortium (PHDSC) Electronic Health Record – Public Health (EHR-PH) Task Force. It is based on the HL7 EHR-S Functional Model and Standard Release 2.0, May 2013. It will be offered to the HL7 EHR Work Group and submitted for balloting at the committee level. The intention is for this functional profile to become an ANSI-approved Informative Standard.

The content of this document represents the views of the Task Group participants, not the views of the organizations of the participants.

1.3.   *History*
The initial PHFP was balloted in 2011 (PHFP Phase 1) as an Informative standard and covered three public health domains, namely:
- Early Hearing Detection and Intervention (EHDI)
- Vital Records (VR)
- Chronic Disease (Cancer Surveillance)

The next version (PHFP Phase 2) was balloted as a Comment-Only ballot in May 2013 and included the three domains of the PHFP Phase 1, plus five additional public health domains, namely:
- Public Health Laboratory Interactions (Orders/Reports) (PHLI)
- Health Statistics (HS)
- Occupational Disease, Injury and Fatality (ODIF)
- Birth Defects (BD)
- Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE)

The current version (PHFP Phase 3) contains a set of functional requirements identified for the eight public health domains from Phases 1 and 2, plus an Adverse Events health domain. The PHFP was also updated to meet the new requirements and format of the HL7 EHR System Functional Model Release 2.

1.4.   Changes from Previous Release

The Overview Chapter was restructured by rearranging the order of the topics to remove duplicated text and to better categorize certain topics. Additionally, the PHFP Function List was updated to include input from PH domain experts and to accommodate updates that were made to the EHR-S FM R2.

1.5.   Acknowledgements

1.6.   Sponsors

1.5.1. Public Health Data Standards Consortium (PHDSC)

(See: http://www.phdsc.org)

The PHDSC is a non-profit, membership-based organization of federal, state and local agencies, professional associations, academia, HIT vendors and individuals that collectively represent HIT standardization interests of public health stakeholders. To carry out project activities, the PHDSC has re-engaged the PHDSC Ad Hoc Task Force on Electronic Health Record-Public Health (EHR-PH) (http://www.phdsc.org/health_info/ehr-task-force.asp) which has been working on several initiatives related to EHR-S interoperability with public health information systems as explained below.

The U.S. Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) provided support for this project through the CDC Cooperative Agreement # 5U38HM000455-04 with the PHDSC. The goal of the NCHS is to provide statistical information that will guide actions and policies to improve the health of individuals and populations through national health-based programs. The NCHS provided subject matter expertise regarding individual and population health-related requirements and issues in order to promote the creation and use of more accurate, relevant, and timely data.

1.5.2. HL7 International

Founded in 1987, Health Level Seven International (HL7, http://www.HL7.org) is a not-for-profit healthcare standards development organization (SDO) accredited by the American National Standards Institute (ANSI). While traditionally involved in the development of messaging standards used by healthcare systems to exchange data, HL7 has begun to develop structured document standards related to healthcare information systems. In 2002, a newly formed HL7 EHR Special Interest Group began development of a functional model for EHR systems. Shortly thereafter, a number of organizations approached HL7 to develop a consensus standard to define the necessary functions for an EHR system. The EHR Special Interest Group was

promoted to a full technical committee (EHR-TC, later renamed to the EHR Work Group, EHR WG), and in 2004 published the *EHR-S Functional Model (EHR-S FM)* as a Draft Standard for Trial Use (DSTU).[1] The Functional Model underwent membership level ballot in September 2006 and January 2007, and it was approved as a standard in February 2007. In 2009-2010, the Functional Model was re-evaluated in preparation for the Release 2.0 standard. Public Health representatives participated in the re-evaluation under the PHDSC EHR-PH Task Force.

The HL7 EHR Work Group intends that unique functional profiles be developed by subject matter experts in various care settings to inform developers, purchasers, and other stakeholders of the functional requirements of systems developed for specific domains.

1.5.3. HL7 Vital Record Functional Profile Work Group

The Individual U.S. states/jurisdictions, the National Association for Public Health Statistics and Information Systems (NAPHSIS), and the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) have long collaborated to promote uniformity and consistency in vital records collection. In 2008, they again collaborated on the development of an HL7 EHR-S Vital Records Functional Profile (VRFP), a unified set of functional requirements for managing data collection and exchange across the vital records community that can be used by all the key stakeholders. The objective of the VRFP Project is to improve the timeliness and quality of vital records data through improved data gathering and standardization, and to reduce the workload of hospitals and states. In May 2010, the VRFP was balloted by HL7 to solicit broader vital records stakeholder review and comments. The VRFP received an affirmative vote. The VRFP was revised to include additional relevant functional requirements generated through the PHFP development process and was re-balloted in April/May 2011 to solicit further comments. Again receiving an affirmative vote, the VRFP was published as an informative standard in March 2012. It is intended that the VRFP will ultimately serve as the reference for the certification of EHR systems that include functionality to support vital records activities.

1.5.4. HL7 Public Health and Emergency Response (PHER) Work Group

The HL7 PHER Work Group was formed in 2005 to develop public health related standards at HL7. In 2011, PHER conducted ballot reconciliation of the PHFP Phase 1; it will continue to work with the PHDSC EHR-PH Task Force participants to finalize the current Functional Profile.

1.5.5. PHDSC EHR-PH Task Force

In 2003-2004, the PHDSC EHR-PH Task Force facilitated outreach with local, state and federal public health agencies, healthcare organizations, public health professional associations, schools of public health, health IT vendor organizations, private sector and individuals to conduct evaluation of the EHR-S Functional Model (URL: http://www.phdsc.org/health_info/adhoc-task-force.asp). The outcomes of the evaluation were summarized in the *White Paper on Electronic Health Record: Public Health Perspectives* (URL: http://www.phdsc.org/health_info/pdfs/PHDSC_EHRPH_WhitePaper2004.pdf).The White Paper, aimed to the public health community, described the need (1) for broader involvement in the national effort to standardize clinical and public health data and information systems; and (2) to express public health perspectives on the EHR-S FM.

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[1] Electronic Health Record Technical Committee: Electronic Health Record-System Functional Model, Release One. Health Level 7, 2007. (Available at: http://www.hl7.org/ehr/downloads/)

In 2007, the PHDSC EHR-PH Task Force members developed the White Paper on *Building the Roadmap for HIT Systems Interoperability for Public Health* at the Integrated healthcare Enterprise (IHE) (URL: http://www.ihe.net/Technical_Framework/upload/IHE-PHDSC_Public_Health_White_Paper_2008-07-29.pdf).The White Paper, aimed to the HIT community, described the organizational structure of public health, the use of HIT in various public health programs and approaches for developing interoperable clinical and public health information systems using examples of the cancer and immunization domains.

In May 2010, the PHDSC EHR-PH Task Force members completed the *Re-evaluation of HL7 EHR-S FM Release 1.1 from Public Health Perspectives* (URL: http://www.phdsc.org/health_info/ehr-task-force.asp). The Task Force identified 284 revisions for the HL7 EHR-S FM that were submitted to the HL7 EHR Workgroup for consideration for inclusion in the EHR-S FM Release 2.

The current PHFP project is the fifth activity of the PHDSC EHR-PH Task Force and is aimed at developing an approach for identifying public health criteria for certification of EHR systems based on the HL7 EHR-S FM.

2. PHFP: Objectives and Usage

2.1.   Need for the PHFP

The need for the PHFP is determined by the pressing necessity to incorporate information exchange between direct care and public health settings in the implementation of healthcare information technology solutions. Meeting this need will reduce the burden for direct care providers to report to public health stakeholders and will improve the completeness and quality of data that public health agencies have available for delivery of direct care, care coordination between providers and agencies, and population-based disease surveillance. The ultimate effect will be to improve the timeliness and effectiveness of public health interventions.

2.2.   Target Realm

The PHFP is aimed to serve as a U.S. Realm Functional Profile that articulates the functional requirements needed to support data exchange among care providers, patients, consumers, industry and public health stakeholders at all levels of government (local, state and federal public health agencies) in the various public health domains (programs)[2,3] including:

- Maternal and child health (e.g., early hearing detection and intervention (EHDI); vital records)
- Communicable diseases (e.g., public health laboratory (PH-Lab) data exchanges for public health case reporting and preparedness)
- Chronic disease (e.g., cancer, diabetes)
- Immunization
- Adverse event reporting (drugs, biologics, devices, tobacco, foods)
- Medical countermeasures and emergencies

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[2] Beitsch LM et al. Structure and functions of state public health agencies. APHA. 2006:96(1):167-72.
[3] Scutchfield, F.D., & Keck, C.W. Principles of public health practice, 2nd ed. 2003. Thomson/Delmar Learning: Clifton Park, NY.

- Other programmatic surveillance (e.g., syndromic surveillance, biosurveillance, surveillance administered by the U.S. Food and Drug Administration (FDA), and
- Other.

The current PHFP is limited to specifying functional requirements in eight public health domains. Those domains were selected because of their ongoing health information technology (HIT) standardization efforts[4,5,6] and the project team's ability to solicit the review of those domains' needs by the representatives from a broader community of stakeholders facilitated by each domain's Corresponding Center within the U.S. Centers for Disease Control and Prevention (CDC). There are currently other HIT standardization efforts relevant to Public Health and Meaningful Use of Health IT (MU) at the Office of the National Coordinator for Health Information Technology (ONC): ONC Standards and Interoperability (S&I) Framework activities (laboratory, pharmacy, allergy, public health reporting, transition of care, and others).[7]

2.3.   PHFP Uses

The PHFP serves as the overarching profile for public health functions relevant to an EHR-S from which other PHFPs may be derived. For example, this functional profile may be further expanded in the future to include additional public health domains, e.g., immunization, communicable diseases, biosurveillance / syndromic surveillance, behavioral health, environmental health, and others.

The PHFP may be used as a reference for certification of EHR systems that include functionality to support various public health domains (programs).

The PHFP may lay the foundation for developing a Public Health Information Systems (PH-IS) Functional Model that will specify common functions and conformance criteria for the interoperability of PH-ISs with clinical EHR-Ss and across public health agencies on all levels of government. In the future, the PH-IS FM may be used to establish certification process for PH-ISs.

2.4.   Authority and Conformance

The HL7 Public Health Functional Profile (PHFP) conforms to the HL7 EHR-S FM Release 2.0 and identifies functional requirements and conformance criteria for public health direct care information collection, management, and exchanges as they apply to the various public health programs (domains).

3. Definitions, Assumptions, and Environment

3.1.   Definitions

3.1.1. EHR-S Definitions and Standards

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[4] Integrating the Healthcare Enterprise (IHE).Early Hearing Detection and Intervention: Screening, Short-Term Care, and Clinical Surveillance for Hearing Loss (EHDI) - Published September 30, 2010
[5] Integrating the Healthcare Enterprise (IHE).Physician Reporting to a Public Health Repository-Cancer Registry (PRPH-Ca) - Revised 2010-11-04
[6] Integrating the Healthcare Enterprise (IHE).Mother and Child Health (MCH) - Revised 2010-10-15
[7] Office of National Coordinator for Health IT (ONC). Standards and Interoperability Framework Initiatives. URL: http://jira.siframework.org/wiki/pages/viewpage.action?pageId=4194700

The HL7-S EHR-S FM is based on the International Standards Organization (ISO) *ISO/TR-20514 Health Informatics – Electronic health record – Definition, scope and context* [8] and states:

> *"The primary purpose of the EHR is to provide a documented record of care that supports present and future care by the same or other clinicians…. Any other purpose for which the health record is used may be considered secondary."*

> *"The Core EHR contains principally clinical information; it is therefore chiefly focused on the primary purpose. The Core EHR is a subset of the Extended EHR. The Extended EHR includes the whole health information landscape; its focus therefore is not only on the primary purpose, but also on all of the secondary purposes as well. The Extended EHR is a superset of the Core EHR."*

In this respect, the PHFP may be regarded as a set of Extended (i.e., not Core) EHR functions.

3.1.2. Definition and Use of the term "Jurisdiction"

For the purposes of this document, the term "jurisdiction" is used as follows:

> A *jurisdiction* is an area, generally geo-political, in which a governmental agency or corporation has public health oversight and/or management responsibilities; a territorial range of authority or control. The jurisdiction could be a state, a metropolitan area (New York City, Chicago, etc.), a county within a state, or some other subdivision of a larger jurisdiction. A jurisdiction might encompass the entire country, as is the case with nationwide jurisdictions such as the jurisdictions of the Department of Veterans Affairs and the Federal Bureau of Investigation. A *subordinate jurisdiction* is a jurisdiction that is a subset of another jurisdiction.

3.2.   Assumptions

3.2.1. Publication Format

The PHFPs are designed to be modified by adapting them to local requirements. They are also designed to be merged with other Functional Profiles in order to fully specify system requirements. Since the PDF publication format is insufficient for editing and merging of sets of requirements, the PHFPs may be offered in other publication formats (e.g., spreadsheet format, free form text format, or database application -hosted document format).

3.2.2. EHR System Extensibility

The PHFPs are designed to extend the functionality of EHR system health care domains by offering well-formed, standards-based recommendations from Public Health domain experts. As such, one or more PHFPs can be merged in order to specify extensions to the EHR system of a given health care domain. Furthermore, the requirements specified by a given PHFP can be added incrementally to an EHR system. For example, an EHR system may initially be extended by including Vital Records and Health Statistics functionality. Later, Adverse Events functionality may be added. Thus, the EHR System stakeholders can use the set of PHFPs in order to

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[8] ISO/TR 20514: Health informatics -- Electronic health record -- Definition, scope and context. 2005-10-17 (Available at: http://www.iso.org)

develop a roadmap by which EHR Systems can be enhanced. In addition, the quality of an EHR might be validated by certifying each incremental Public Health system functionality improvement/extension.

3.2.3. Marketplace Improvements

Use of the PHFPs will likely expand the EHR system marketplace by increasing the number of stakeholders who interact with EHR systems, specifically, by enabling Public Health stakeholders to offer expert guidance and materials to healthcare providers and by enabling Public Health stakeholder to receive necessary public health –related information from EHR systems.

3.2.4. Implementation of Public Health Functional Profiles

A given PHFP could be implemented in an incremental fashion in order to better manage the impact of system changes/updates over time. For example, a small set of Health Statistics functions/reports may be implemented during the first year of system update, followed by larger sets of functions/reports in subsequent years.

3.2.5. Quantity of Public Health Functional Profiles

Public Health stakeholders are likely to develop PHFPs for other Public Health domains in the future.

3.2.6. Internationalization

Since Public Health requirements seem to be universal, it is likely that the entire set of PHFPs will need to be translated into various human languages. For example, all realms will likely desire to track and share Vital Records information.

3.2.7. Impact of Adoption

The adoption and use of PHFPs in EHR systems is likely to enhance system usability for the primary users of EHR systems (e.g., by improving the quality of the healthcare that they provide via input from Public Health domain experts) and enhance the usability of EHR systems by the Public Health stakeholders (e.g., by easing their access to EHR systems).

3.2.8. Next Steps

The PHFPs will need to be disseminated to EHR system stakeholders (including healthcare provider organizations, vendors, policy makers, academicians, public health stakeholders, and professional societies). Certification protocols will need to be developed by certifying bodies. Privacy, security, and confidentiality protocols will need to be developed to accommodate new information architectures and usages of public health data. Analytic techniques will need to be applied to the increasing volume of newly-accessible public health data repositories. A Public Health Functional Model could be developed that encompasses other, non-EHR system – related functions (e.g., water, air, food, or animals). Public Health systems will need to be enhanced to accommodate likely increases in the quantity and sophistication of public health - related functionality of EHR systems.

3.3.   Environment

3.3.1. Healthcare-related Forms and the Location of Forms

Healthcare-related forms are often used in the care-giving process to gather information in a cogent, well-disciplined manner. Forms can be specified locally (e.g., by an individual clinician or by a medical specialty) or can be specified across organizational boundaries (e.g., a form that gathers information regarding deaths). Functional Profiles can be used to define domain-specific requirements for these types of forms. Users of EHR systems might benefit from a "Forms Repository", perhaps with an associated "Forms Engine". This approach would enable an expert domain (e.g., a Public Health domain) to create and update a set of forms (based on new clinical knowledge or on new public health surveillance requirements) and supply those forms to EHR systems in real-time (perhaps through a Software Service).

3.3.2. Accommodation of Time Zones

The scope of practice, organizational policy, and/or jurisdictional law may require that a time zone is included within a timestamp. Furthermore, the Non-Repudiation section of the EHR-S FM states that a timestamp can be used to validate that a document existed at a certain date and time. Thus, date and time stamping implies the ability for the system to capture the time zone where certain data were recorded. Time zones are described in ISO 8601 Standard Time Reference.

3.3.3. Systems, Components, and Applications

An EHR system consists of a collection of systems, applications, modules, or components, developed on different architectures. For example, a provider might pair one vendor's clinical documentation system with another's tracking, discharge, or prescribing system. An EHR system may be provided by a single vendor, multiple vendors, or by one or more development teams.

A PH-IS also consists of a collection of systems, applications, modules, or components that may be developed on different architectures. For example, a public health agency might integrate one vendor's vital registration information system with another vendor's system that manages information regarding chronic diseases (e.g., cancer), EHDI, communicable diseases, environmental health, or immunizations. Similar to an EHR-S, a PH-IS may be provided by a single vendor, multiple vendors, or by one or more development teams.

3.3.4. Interoperability

All components, modules, or applications within an EHR system that manage care should operate in a well-integrated fashion. In addition, an EHR system should exchange data with a PH-IS in a manner consistent with the functional descriptions and conformance criteria specified in this profile. ISO 20514 states: The key to interoperability is through standardization of requirements for the EHR (record) architecture (e.g., ISO/TS 18308:2004) and ultimately the standardization of the EHR architecture itself (e.g., ENV 13606-1:2000).

The fact that an EHR system component, module, or application may send a notification, notice, alert, or request to an external system does not guarantee that the external system will perform an action that corresponds to the message that was sent. Thus, an EHR system is deemed to

have a set of capabilities and responsibilities and cannot control the actions of external systems or of external system actors.

4. Organization of the EHR-S Functional Model

4.1.   *Categorization of Sections of the HL7 EHR-S Functional Model*

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure, and Trust Infrastructure.

Overarching (OV)
Care Provision (CP)
Care Provision Support (CPS)
Population Health Support (POP)
Administrative Support (AS)
Record Infrastructure (RI)
Trust Infrastructure (TI)

Table 1: Function List Sections

Within the seven Sections of the Function List, the functions are grouped under header functions using a hierarchical structure (where each function may have one or more sub-functions).

4.2.   *Sections of the Function List*

The seven sections of the Function List reflect content of the Interoperability Model, now integrated in the Functional Model, and input from several profiles of the earlier versions of the Functional Model. Below is a summary description of each of the seven sections:

- Overarching: The Overarching Section contains Conformance Criteria that apply to all EHR Systems and consequently must be included in all EHR-S FM compliant profiles.
- Care Provision: The Care Provision Section contains those functions and supporting Conformance Criteria that are required to provide direct care to a specific patient and enable hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare offices, clinics, hospitals and specialty care centers.

- Care Provision Support: The Care Provision Support Section focuses on functions needed to enable the provision of care. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders).
- Population Health Support: The Population Health Support Section focuses on those functions required of the EHR to support the prevention and control of disease among a group of people (as opposed to the direct care of a single patient. This section includes functions to support input to systems that perform medical research, promote public health, & improve the quality of care at a multi-patient level.
- Administrative Support: The Administrative Support Section focuses on functions required in the EHR-S to enable the management of the clinical practice and to assist with the administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers.
- Record Infrastructure: The Record Infrastructure Chapter consists of functions common to EHR System record management, particularly those functions foundational to managing record lifecycle (origination, attestation, amendment, access/use, translation, transmittal/disclosure, receipt, de-identification, archive…) and record lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS).
- Trust Infrastructure: The Trust Infrastructure Chapter consists of functions common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS and RI).

The following table displays the categories (i.e., ID, Type, Name, Statement, Description, and Conformance Criteria) that comprise the functions of the EHR-S FM and offers examples of a few functions.

ID	Type	Name	Statement	Description	Conformance Criteria
CP.1	F	Manage Clinical History	Manage the patient's clinical history lists used to present summary or detailed information on patient health history.	Patient Clinical History lists are used to present succinct "snapshots" of critical health information including patient history; allergy intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/devices; and patient and family preferences.	
CP.1.4	F	Manage Problem List	Create and maintain patient-	A problem list may include, but is not limited to chronic	

			specific problem lists.	conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g., drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms…	
CP.1.4	C				1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.
CP.1.4	C				2. The system SHALL capture, maintain, and render a history of all problems associated with a patient.
CP.1.4	C				3. The system SHALL provide the ability to maintain the status of each problem (e.g., active, inactive, resolved).

Table 2: Example of Values of Functional Model Categories

Function ID
This is the unique identifier of a function in the Function List (e.g., CP.1.1) and should be used to uniquely identify the function when referencing functions. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is at the same level as CP.1.2, CP.1.1 is also a parent of CP.1.1.1 and child of CP.1. In many cases the parent is fully expressed by the children. NOTE: For a detailed discussion and graphic of the parent and child relationship, see 2.5.1 Hierarchical Structure in Chapter 2, Conformance Clause.)

Function Type
This is an indication of the line item as being a Header (H), Function (F) or Conformance Criteria (C). The Tag (T) is used to identify a new section in the spreadsheet and its related functions in the spreadsheet. A Tag has no directly associated Functions or Criteria.

Function Name
This is the name of the Function and while expected to be unique within the Function List; it is not recommended to be used to identify the Function without being accompanied by the Function ID.

Example: *Manage Medication List*

Function Statement
This is a brief statement of the purpose of this function. While not restricted to the use of structured language that is used in the Conformance Criteria (see below); the Statement should clearly identify the purpose and scope of the function.

Example: *Create and maintain patient-specific medication lists*

Description
This is a more detailed description of the function, including examples if needed.

Example: *Medication lists are managed over time, whether over the course of a visit or stay, or the lifetime of a patient. All pertinent dates, including medication start, modification, and end dates are stored. The entire medication history for any medication, including alternative supplements and herbal medications, is viewable. Medication lists are not limited to medication orders recorded by providers, but may include, for example, pharmacy dispense/supply records, patient-reported medications and additional information such as age specific dosage.*

Conformance Criteria
Each function in the Function List includes one or more Conformance Criteria. A Conformance Criteria, which exists as normative language in this standard, defines the requirements for conforming to the function. The language used to express a conformance criterion is highly structured with standardized components with set meanings. The structured language used to define Conformance Clauses in the Function List is defined in the Conformance Chapter.

Example: *1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.*

5. Conformance Clause

5.1.   Need for a Conformance Clause

The PHFP profiles conform to the HL7 EHR-S Functional Model, Release 2.

Key to the Functional Model and derived profiles is the concept of *conformance,* which is defined as *"verification that an implementation faithfully meets the requirements of a standard or specification".* [9] In the Functional Model and in derived profiles, the general concept of conformance may be expressed in a number of forms. For instance, a profile can be said to conform to the Functional Model if it adheres to the defined rules specified by the Functional Model specification. Similarly, to exchange data with a PH-IS an EHR system may claim conformance to one of these profiles if it meets all the requirements outlined in the profile.

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[9] HL7. Electronic Health Record-System Functional Model, Release 1.1. 2009. URL:
http://www.hl7.org/ehr/downloads/

5.2.   Conformance Criteria

Each function defined in the Functional Model or profiles is associated with specific *conformance criteria,* which are statements used to determine if a particular function is met (i.e., "the system SHALL capture, display and report all hearing tests associated with a patient"). Conformance criteria have been developed in accordance with the standards set forth by the EHR Work Group. In order to ensure consistent, unambiguous understanding and application of the Functional Profile, a consistent set of keywords (normative verbs) has been employed to describe conformance requirements.

The key words SHALL, SHALL NOT, SHOULD, and MAY in this document are to be interpreted as described in HL7 EHR-S Functional Model, Release 2, May 2013 Conformance Clause:

SHALL	Indicates a mandatory requirement to be followed (implemented) in order to conform. Synonymous with 'is required to' and 'must'.
SHALL NOT	Indicates a prohibited action. Synonymous with 'prohibited' and 'must not'.
SHOULD	Indicates an optional recommended action, one that is particularly suitable, without mentioning or excluding others. Synonymous with 'is permitted and recommended'.
MAY	Indicates an optional, permissible action. Synonymous with 'is permitted'.

Table 3: Optionality key words

5.3.   Functional Profiles

The EHR-S FM is a list of all functions that COULD be present in EHR systems and criteria for achieving that function. Any given EHR-S will perform one or more functions (i.e., a subset) from the FM list (i.e., the superset), depending on the purpose of the system. The selected subset of functions and the criteria for conforming to these functions characterize the EHR-S capabilities and are referred to as a "functional profile". The functions and conformance criteria will vary across functional profiles, depending on the operational needs of the system, i.e., what the system is in place to accomplish.

A "Functional Profile" is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. Functional Profiles help to manage the master list of functions. It is not anticipated that the full Functional Model will apply to any single EHR-S implementation. As such, an EHR system does not conform directly to the Functional Model; rather, it conforms to one or more Functional Profiles.

Functional Profiles are the expression of usable subsets of functions from the EHR-S Functional Model. The act of creating a Functional Profile is to support a business case for EHR-S use by selecting an applicable subset of functions from the EHR-S Functional Model list of functions, in effect constraining the model to meet specific requirements. For example, a Functional Profile may be created by a purchaser, to indicate requirements; by a vendor, to indicate the capability of specific products; or by any person/entity wishing to stipulate a desired subset of functions for a particular purpose, including a care setting within a specific realm. The Public Health Functional Profiles reflect EHR-S functions and criteria for the EHR-S to share data with specific public health programs.

5.4.   Conformance of EHR Systems to Exchange Data with PH-ISs

To claim conformance to a domain's PHFP, an EHR system (or systems) SHALL satisfy every conformance criterion designated in the functional profile as SHALL.

5.5.   Conformance of Derived Functional Profiles

The PHFP Phase 3 claims conformance to the public health program-related functions via the following functional profiles:

- HL7 Vital Records Functional Profile
- HL7 Early Hearing Detection and Intervention (EHDI) Functional Profile
- HL7 Chronic Disease (Cancer Surveillance) Functional Profile
- HL7 Public Health Laboratory Interactions (Orders/Reports) (PHLI) Functional Profile
- HL7 Health Statistics (HS) Functional Profile
- HL7 Occupational Disease, Injury, and Fatality (ODIF) Functional Profile
- HL7 Birth Defects (BD) Functional Profile
- HL7 Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Functional Profile
- HL7 Adverse Events (AE) Functional Profile

Derived profiles may prove valuable for:
- specifying certain subsets of EHR systems used to care for specific groups of population, e.g., children, adults, women, or geriatrics; and/or specific care settings, e.g., acute care, ambulatory care, specialty care, pharmacy, laboratory, or radiology.
- supporting information exchanges between clinical care and public health information systems.

In order for a derived functional profile to claim conformance with one or more domain's listed in the PHFP, the derived profile **SHALL** adhere to the principles and methods detailed in the Conformance Clause of the EHR-S FM.

5.6.   Normative Language

Additional clarification is necessary to understand the standardized nomenclature used to describe the actions performed by a system. The following excerpt from the EHR-S FM R2 Glossary, illustrates the hierarchical nature of the nomenclature. For example, the term "Capture" is used to describe a function that includes both direct data entry ("Enter") and indirect data entry (e.g., "Import" from another system. Similarly, "Maintain" is used to describe a function that entails storing, updating, and/or removing data.

Manage (Data)										
Capture	**Maintain**			**Render**			**Exchange**	**Determine**		**Manage-Data-Visibility**
Auto-Populate Enter Import Receive	Store	Update	Remove	Extract	Present	Transmit	Export Import Receive Transmit	Analyze	Decide	De-Identify Hide Mask Re-Identify Unhide Unmask
	Archive Backup Decrypt Encrypt Recover Restore	Annotate Attest Edit Harmonize Integrate Link	Delete Purge							

	Save	Tag									

Table 4: "Manage Data" Action-Verbs

6. PHFP Domains

Sections that follow describe the following public health domains:

- Early Hearing Detection and Intervention (EHDI)
- Vital Records (VR)
- Chronic Disease (Cancer Surveillance)
- Public Health Laboratory Interactions (Orders/Reports) (PHLI)
- Health Statistics (HS)
- Occupational Disease, Injury and Fatality (ODIF)
- Birth Defects (BD)
- Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE)
- Adverse Events (AE)

6.1.   Early Hearing Detection and Intervention (EHDI) Domain

Overview Congenital and delayed onset hearing loss in infants is linked with speech and language delay and lifelong social-emotional and cognitive challenges.[10],[11] In the United States (US) despite the widespread implementation of newborn hearing screening programs by public health agencies, annual data from US States reported to the Centers for Disease Control and Prevention (CDC) reveal that nearly 50% of infants needing additional care may not receive it.[12] For the estimated 5,000 children born each year in the US who have moderate to profound bilateral hearing loss without other disabilities, the CDC calculated the year 2007 value of the lifetime educational cost of hearing loss at $115,600 per child. School districts spend 2.4 times more for each student enrolled in a program for the deaf and hard of hearing than for a child who does not receive special education services. The identification of infants with permanent hearing loss through newborn hearing screening (diagnosed and intervened) reduces special education costs by an estimated 36% or a reduction of $44,200 per child, suggesting EHDI programs can save at least $200 million in additional U.S. educational costs per year.[13]

These problems exist because information flows among providers (birthing facilities, pediatricians and specialists) and public health agencies concerning EHDI have been

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[10] Joint Committee on Infant Hearing (JCIH). Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. Pediatrics. 2007; 120 (4): 898-921. URL: http://pediatrics.aappublications.org/cgi/content/full/120/4/898?ijkey=oj9BAleq21OlA&keytype=ref&siteid=aapjournals

[11] Joint Committee on Infant Hearing (JCIH). URL: www.jcih.org

[12] Centers for Disease Control and Prevention (CDC). Summary of 2007 National CDC Early Hearing Detection and Intervention (EHDI) Data URL: http://www.cdc.gov/ncbddd/ehdi/documents/DataSource2007.pdf

[13] Grosse SD. Education Cost Savings from Early Detection of Hearing Loss: New findings. Volta Voices 2007;14(6):38-40.

inconsistent and unreliable. Few state public health programs have web-based EHDI information systems (EHDI-ISs). None are yet fully interoperable with clinical electronic health records systems (EHR-Ss) at the birthing facility or at the provider's (pediatrician's or sub-specialty provider's) practice as well as with the baby's Personal Health Record System (PHR-S). Communicating hearing screening and follow-up information including important next steps for an infant is not done electronically leading to data errors, missed information and missed services. Varying data formats from non-standardized hearing screening devices and customized software applications in clinical care and public health agencies further hinder such efforts.

To provide better care, pediatric providers need to know more than screening results. They need a Care Plan for each infant which includes next steps such as who requires additional screening or direct referral for audiology diagnosis; who requires ongoing developmentally appropriate hearing screening because of risk factors for delayed or progressive hearing loss; and who should be referred to early intervention services.

To assure more effective care for all children, especially those with special needs, CDC has been working with the U.S. National Quality Forum to establish EHDI Quality Measures (EHDI-QM).[14]

Goal The PHFP-EHDI is aimed to enable electronic communication between participants of care to reduce the likelihood of procedural failures at birthing facilities, primary care settings, public health EHDI programs, and families with children with hearing loss thus advancing public health's ability to assure that all newborns receive recommended care. The electronic communication between participants of care will reduce the lifetime impact of hearing loss including the loss of communication skills.

While addressing these unique needs of a population of children with hearing loss, this Profile establishes one of the first meaningful interoperability opportunities in an individual's entire lifetime, laying the foundation of information exchanges between clinical care and public health. The exchange of the Early Hearing Care Plan (EHCP) is particularly suited to document sharing which enables the multiple care providers engaged in the early care and intervention for hearing to better manage the ongoing care plan actions. The responsibility to create and manage the EHCP is jurisdictionally defined (e.g., in the US, this is done by the public health authority).

The exchange of EHDI-QM is the first example of how quality measures can be electronically generated and exchanged between EHR-S and PHISs.

Scope The PHFP-EHDI specifies EHR-S functions and conformance criteria as well as information exchange content for Newborn Hearing Screening, Short-Term Follow-up and Clinical Surveillance. Newborn hearing screening occurs commonly during the birth admission (twenty-four to seventy-two hours of age) or before thirty days of age. Short-Term Follow-up includes audiologic diagnosis and early intervention up to the third birthday for those children who did not pass the initial hearing screening. Clinical surveillance conducted by primary care providers promotes recognizing children at risk for delayed onset or progressive loss. So, the scope of this Profile encompasses hearing healthcare scenarios from birth to three years.

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[14] Buz Harlor AD, Jr, Bower C. Hearing Assessment in Infants and Children: Recommendations Beyond Neonatal Screening. Pediatrics. 2009; 124 (4): 1252-1263. URL: www.pediatrics.org/cgi/doi/10.1542/peds.2009-1997

Please note that Hearing Screening is often viewed as part of Newborn Screening that, in addition to hearing, also includes newborn bloodspot screening. As Hearing Screening has information and workflow requirements that differ from those of newborn bloodspot screening, the latter is out of scope for this profile.

Settings (Actors) The PHFP-EHDI describes EHR-S functionality that is necessary to care for a child age 0-3 who receives routine wellness, preventive and specialty care supported by public health interventions that take place in:
- the birthing facility (newborn nursery)
- the inpatient hospital setting, e.g., neonatal intensive care unit (NICU)
- the primary care provider's office
- the specialty care clinic (audiology provider clinic)
- the state health department EHDI program
- the CDC EHDI program
- the child's home

Data Content The PHFP-EHDI specifies EHR-S functionality that is necessary to exchange the following data content:
- Notification of Birth
- Hearing Screening Standing Order
- Hearing Screening Consent
- Hearing Screening Test Results
- Hearing Screening Risk Factors
- Early Hearing Care Plan (EHCP)
- EHDI Quality Measures (EHDI-QM)
- Jurisdictional guidelines for clinicians on
    - Hearing screening
    - routine well-child care on hearing
    - care for children with hearing loss
- Educational materials for caregivers
    - routine well-child care on hearing
    - care for children with hearing loss

6.2.   *Vital Records Domain*

The National Center for Health Statistics (NCHS) in collaboration with the National Association for Public Health Statistics and Information Systems (NAPHSIS) and other vital statistics stakeholders initiated the development of the Vital Records Functional Profile (VRFP) in May 2008. The VRFP was a precursor to the development of the Public Health Functional Profile for which NCHS is also providing support. The initial VRFP ballot package was completed in May 2010 and submitted to HL7 for balloting in September 2010. The VRFP received an affirmative vote; however, several comments needed reconciliation as part of the HL7 ballot process. The VRFP was also revised to include additional relevant functional requirements generated through the PHFP development process and was re-balloted in April/May 2011 to solicit further comments from the initial ballot pool. The VRFP was published as an Informative Standard in March 2012. NCHS has included the VRFP in the PHFP as one of the domains represented in the profile to facilitate comparison with other public health domains. The VRFP is described in

more detail in the VRFP Overview Chapter that completes the VRFP Functional Profile documents.

Overview The individual U.S. states/jurisdictions, the National Association for Public Health Statistics and Information Systems (NAPHSIS), and the Centers for Disease Control and Prevention/National Center for Health Statistics (CDC/NCHS) have long collaborated to promote uniformity and consistency in vital records collection. State and jurisdictional laws require reporting of all births, deaths, and reportable fetal deaths to the jurisdiction where the event took place. Federal law obligates CDC/NCHS to produce national multipurpose statistics based on the state vital records information. CDC/NCHS closely collaborates with the states to develop standard certificates and reports for data collection and administrative purposes, as well as standardized procedures for data preparation and processing to promote a uniform national database[15].

The National Vital Statistics System has a long and enduring history that serves to provide essential data on births and deaths within the United States and is the oldest and most successful example of inter-governmental data sharing in Public Health[16]. Over 6 million vital event records annually, including statistical information (demographic, medical, health and geographic) are derived from over four million birth certificates and from about 2.4 million death certificates and fetal death reports. These events are registered by fifty-seven registration areas: 50 states, two cities (New York and Washington DC), and 5 U.S. Territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands). Detailed data on all events are transmitted to the CDC/NCHS for processing and dissemination.

The main goals of the Vital Records community are to:
- Efficiently create certificates of birth and death, and reports of fetal deaths that are accurate and available quickly to meet the needs of families experiencing these vital events
- Produce timely, accurate, high quality data based on birth and death certificates, and fetal death reports to inform public health at the local, state and national levels.

Many data items required by birth and death certificates and fetal death reports are captured in medical records. For example, the mother's and infant's medical records are recommended by CDC/NCHS and NAPHSIS to serve as the source for more than ½ of all data items collected on the 2003 U.S. Standard Certificate of Live Birth and the U.S. Standard Report of Fetal Death. Currently, these data typically are gathered by hospital personnel from the hospital's medical records using paper worksheets. (Functional Model standard worksheets are available; each jurisdiction (hereafter referred to as "state") develops state-specific worksheets to meet individual state's needs; these worksheets are provided to the hospitals for their use in gathering birth certificate and fetal death report information.) The information collected on the paper worksheets is then manually entered into the Electronic Birth Registration System (EBRS), or the Electronic Fetal Death Report System (EFDRS) located within the hospital. The EBRS/Electronic Death Registration System (EDRS) and EFDRS are provided by the state.

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[15] Centers for Disease Control and Prevention/National Center for Health Statistics/National Vital Statistics System. HHS Secretary notice of approval. Retrieved March 11, 2010 from http://www.cdc.gov.nchs/nvss.htm

[16] Centers for Disease Control and Prevention/National Center for Health Statistics/National Vital Statistics System. About the National Vital Statistics System. Retrieved March 11, 2010 from http://www.cdc.gov.nchs/nvss.htm

__Goals__ The VRFP is intended to be used by any EHR system domain of application that handles births and deaths of individuals, and fetal death reporting. The objective of the VRFP Project is to improve the timeliness and quality of vital records data through improved data gathering and standardization, and to reduce the workload of the hospital and states. The VRFP is intended to ultimately serve as the reference for the certification of EHR systems that include functionality to support vital records activities. The following are reasonable principles that support the certification of EHR-S that includes vital records functionality:

- The development of a unified set of functional requirements for managing data collection and exchange across the vital records community that can be used by all the key stakeholders
- The development of processes and formats for sharing data that promote the development of easier and timelier communication among the local data sources that provide the data, state and territorial agencies that receive and process the data, and the internal and external organizations that make use of the data
- The development of standards based solutions that utilize industry standards and best practices.

__Scope__ The scope of the VRFP Project is to create a VRFP that conforms to the HL7 EHR-S FM. The VRFP will facilitate the point-of-contact or point-of-care capture of selected vital records data via EHR systems. The VRFP project is U.S. focused and will initially specify the functional requirements needed to support messaging of selected U.S. vital records data among providers, states, local registrars and Federal agencies.

At this time, the CDC/NCHS/Division of Vital Statistics plans to limit the scope to a subset (See Appendices 2, 3, and 4 of the VRFP documents) of the vital records data items for the first iteration of the developing Health Level Seven (HL7) Electronic Health Record System (EHR-S) Vital Records Functional Profile (VRFP). CDC/NCHS and the jurisdictions legally responsible for the registration of vital events must be assured that the data received from the EHR-S are accurate and of high quality. Also, it is paramount to ensure that the source of the data for each data item is consistent with the requirements as defined in the CDC/NCHS Edit Specifications. Therefore, the initial goal will be to monitor and assess the quality of the data that will be exchanged between electronic health record and vital records systems and the quality of the process of information exchange through the implementation of demonstration projects utilizing this initial set of functional requirements. Future iterations of the VRFP may include additional data items as determined.

The primary focus of functional requirements for the death certificate is to provide the necessary information in the EHR to assist the certifier in accurately determining the cause of death. The following resources available at http://www.cdc.gov/nchs/about/major/dvs/handbk.htm are to be included in the EHR-S as references to assist the certifier in documenting cause of death:

__Setting (Actors)__ The list of primary EHR-centric Vital Records stakeholders and downstream users may include:

- Hospitals that provide birthing services
- Prenatal care providers
- Free-standing birthing facilities
- Certifying Physicians
- Midwives (home and hospital births)
- Primary Care Offices
- Emergency Departments

- Long Term Care facilities / Nursing Homes
- Care Providers
- Clinics
- Doctor's offices

Data Content VRFP data elements are specified by the *Birth Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Birth,* the *Death Edit Specifications for the 2003 Revision of the U.S. Standard Certificate of Death* and the *Fetal Death Edit Specifications for the 2003 Revision of the U.S. Standard Report of Fetal Death* developed by the CDC/NCHS and NAPHSIS. The Edit Specifications are available from the CDC/NCHS website at: http://www.cdc.gov/nchs/vital_certs_rev.htm.

Domain-Specific Description of the use of Data-Collection Instruments

- **Data-Collection Instruments (e.g., Forms / Templates / Assessments)**
Vital Records stakeholders have created forms (also called "worksheets") to help promote and support the collection of accurate and complete vital records' event information that meets the national standards for Birth and Death Certificates, and Reports of Fetal Death.

- **Creation / Management / Ownership / Governance of the Data-Collection Instruments**
These forms can be accessed online from a website, organization, web service, directory, repository, clinical expert, or third-party forms management software.

The forms and their content are the responsibility of each state, territory, and jurisdiction's Vital Records' Office to update and adjudicate. The forms typically do not change more often than once every ten years. The forms should not be tailored by an EHR stakeholder without discussion and consensus with the Vital Records' State Registrar.

The specific forms (worksheets) that are currently available are as follows:
  - Mother's Worksheet for the Birth Certificate   (version 1.28.04)
  - Facility Worksheet for the Birth Certificate   (version 2.5.04)
  - Patient's Worksheet for the Report of Fetal Death   (version 4.21.04)
  - Facility Worksheet for the Report of Fetal Death (version 2.5.04)

- **Data-Collection Methods**
The forms are completed within a 24-to-48 hour time period and not submitted to Vital Records organizations until the forms have been completed. For example, both the mother's worksheet and facility worksheet for Birth Certificates are completed and their data are submitted together to the Vital Records' Office. If some of the information is missing or erroneous, the forms are not resubmitted; instead, the reporting source contacts the Registrar directly to submit a change.

The data is typically extracted from the forms and stored in a central database. The data are validated based on an established set of rules (called "Edit Specifications") built into the receiving software and database. These edits are specified by the National Center for Health Statistics (NCHS) and a reference document containing the edits is updated and maintained on the NCHS' web site.

- **Other Uses of the Collected Data**

The completed forms are typically not shared with downstream users of the data. Many jurisdictions require that the completed forms are destroyed within a specified time.

The downstream users of information collected via the forms include:
- o Health Department programs (e.g., maternal child health)
- o Birth defects stakeholders
- o Public health or other registries
- o Non-profit organizations (e.g., March-of-Dimes; Robert Wood-Johnson Foundation)
- o Federal agencies (e.g., CDC)
- o Researchers / universities
- o State and local planning offices

All jurisdictions have policies on the access and release of the data, including cell suppression statistical disclosures rules and content-of-data-use agreements. In some cases, a jurisdiction's access and release regulations are more restrictive than the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations. Rules and policies are typically available on the jurisdiction's web site or by request to the Vital Records' Office.

- **Other Processing of the Data (e.g., Coding)**

The data collected on the forms is normally coded at time of entry into the database. A small portion of the data may be coded upon further review by in-house experts, such as the patient's cause-of-death.

- **Implementation Guides and/or Education Materials**

Vital Records stakeholders have created guidance documents that serve as instructional sources regarding the definitions and procedures for collecting vital records' event information. The guidance documents are maintained by NCHS and include:
- o Guide to Completing the Facility Worksheets for the Certificate of Live Birth and Report of Fetal Death (version 2003 with March 2012 update)
- o Physician's Handbook on Medical Certification of Death (version 2003)
- o Funeral Directors Handbook on Death Registration and Fetal Death Reporting (version 2003)
- o Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting (version 2003)

6.3.   *Chronic Disease (Cancer Surveillance) Domain*

Overview Established by Congress through the Cancer Registries Amendment Act in 1992, and administered by the Centers for Disease Control and Prevention (CDC), the National Program of Cancer Registries (NPCR) collects data on the occurrence of cancer; the type, extent, and location of the cancer; and the type of initial treatment.

State-based cancer registries are data systems that collect, manage, and analyze data about cancer cases and cancer deaths. In each state, medical facilities (including hospitals, physicians' offices, therapeutic radiation facilities, freestanding surgical centers, and pathology laboratories) report these data to a central cancer registry.

Before NPCR was established, 10 states had no registry, and most states with registries lacked the resources and legislative support they needed to gather complete data. Today, NPCR supports central cancer registries in 45 states, the District of Columbia, Puerto Rico, and the

U.S. Pacific Island Jurisdictions. These data represent 96% of the U.S. population. Together, NPCR and the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program collect data for the entire U.S. population.

State cancer registries are designed to:
- Monitor cancer trends over time.
- Determine cancer patterns in various populations.
- Guide planning and evaluation of cancer control programs (i.e., determine whether prevention, screening, and treatment efforts are making a difference).
- Help set priorities for allocating health resources.
- Advance clinical, epidemiologic and health services research.
- Provide information for a national database of cancer incidence.

Data collected by state cancer registries help public health professionals understand and address the nation's cancer burden. Vital information about cancer cases and cancer deaths is necessary for health agencies to report on cancer trends, assess the impact of cancer prevention and control efforts, participate in research, and respond to reports of suspected increases in cancer occurrence.

Until recently, complete and high quality cancer reporting has been achieved primarily through hospital cancer registries. Traditionally cancer patients receive diagnostic testing or work-up and/or treatment in hospitals. Hospital cancer registries use the North American Association of Central Cancer Registries (NAACCR) Volume II reporting guidelines[17] to routinely report clinical information on cancer patients that are diagnosed and/or treated within their facilities to the appropriate state cancer registry. The NAACCR Volume II Data Standard describes the data content and standard terminologies for reporting to state cancer registries from hospitals. This reporting standard is well established and has been utilized across the country for more than ten years.

However, advances in medicine now allow patients to obtain their care outside the acute care hospital setting. Data collection systems from other sources such as physician offices are not as consistent with reporting. This leads to under-reporting of certain types of cancers, typically those now diagnosed and treated outside the acute care hospital setting. Both melanomas and prostate cancers, for example, have been shown to be under-reported when central registries rely only on hospital reporting.

In many states, these non-hospital data sources are only minimally involved in reporting to the central cancer registry although the numbers are increasing each year. When reporting does occur, it may be through a manual process of identifying reportable cases and submitting copies of the medical record, or the central registry may send certified tumor registrars (CTR) to clinics or physician offices to manually abstract the information from the paper-based medical records. These processes are very resource-intensive, time-consuming, and vulnerable to errors in transcription.

The need to access the data contained in clinics/physician offices with only limited resources is driving the effort to develop an automated electronic process to identify and report cancer cases

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[17] North American Association of Central Cancer Registries (NAACCR) Standards for Cancer Registries. Volume II. Data Standards and Data Dictionary Sixteenth Edition Record Layout Version 12.2, Implemented January 1, 2012. URL: http://www.naaccr.org/LinkClick.aspx?fileticket=IFkNo_Dr1Vk%3d&tabid=133&mid=473

using the clinic/physician office electronic medical record (EMR). Through work with the Integrating the Healthcare Enterprise (IHE), the CDC has developed a content profile that defines the clinical information on cancer patients that are required for clinics/physician offices to report to state cancer registries. This IHE content profile, Physician Reporting to Public Health – Cancer Registry, has been implemented, tested and demonstrated by CDC and several EHR vendors at the 2011 Healthcare Information and Management Systems Society (HIMSS) Annual Conference.

Cancer registries also depend on anatomic pathology reports to obtain information on newly diagnosed cancer patients. The pathology report is one of the most critical sources of information for cancer registries to identify definitive cancer cases. For this reason, real-time reporting of electronic pathology reports has become a key component for cancer registries to ensure that all cancer cases have been reported. Until 2007, there was no standard defined for pathology laboratories to report cancer cases to state cancer registries. State cancer registries received pathology reports from laboratories on paper or in any format they could get the data. In September 2007, the NAACCR Volume V reporting guidelines document was developed to clearly describe the specification that all laboratories should use when reporting cancer pathology reports to state cancer registries. The NAACCR Volume II Data Standard describes the data content and standard terminologies required for laboratory information systems (LIS) to report to state cancer registries. This standard has been adopted by all state cancer registries, which reduces the burden on laboratories to modify the format based on each individual state request.

Goals The Public Health Functional Profile (PHFP)-Cancer is aimed to enable electronic communication between participants of care to enable public health professionals to report on cancer trends, assess the impact of cancer prevention and control efforts, participate in research, and respond to reports of suspected increases in cancer occurrence. Electronic communication between clinical care participants and public health will improve reporting of cancer cases that will allow public health and clinical care professionals to make the best decision based on the cancer burden in more real-time to positively impact the quality of care provided to patients.

Scope The PHFP-Cancer specifies EHR-S functions and conformance criteria as well as information exchange content for the diagnosis of cancer; the type, extent, and location of the cancer; and the type of initial treatment. The American Society of Clinical Oncologists (ASCO) has published Clinical Oncology Requirements for the EHR (CORE) which public health cancer registries are using to develop their profiles and reporting criteria. The scope of this Profile begins with patient diagnosis of cancer and follows patient through treatment.

Setting (Actors) Participants in the Cancer domain's EHR-S-based information exchange include:
- Clinic/Physician Offices (Dermatology, Urology, Hematology, Oncology, etc.)
- Laboratories (Anatomic, Clinical, Molecular)
- Freestanding Radiation/Treatment Centers
- Hospitals
- State/Territorial (Public Health) Cancer Registries
- CDC National Program of Cancer Registries (NPCR)
- USFDA, Office of Oncology Drug Products (OODP)

Data Content The PHFP-Cancer specifies EHR-S functionality that is necessary to exchange

the following data content:
- Patient Demographics
- Patient Risk Factor information (e.g., occupation, tobacco history)
- Provider/Facility information
- Pathology Laboratory information
- Diagnosis information, including tumor characteristics
- Stage/prognostic factors
- Comorbidities/Complications
- Cancer Treatment
- Follow-up/recurrence/death
- Cancer Treatment Plan
- Cancer Control information (e.g., screening)
- Cancer drugs-therapy-diagnostics(surveillance, AEs, patient safety)

6.4.   *Public Health Laboratory Interactions (Orders/Reports) (PHLI) Domain*

Overview Public Health Laboratories provide specialized testing for clinical care, surveillance and surge capacity during public health incidents of national significance. Laboratory information management and business practices form the backbone of public health surveillance and healthcare delivery. As stated by Zarcone, et al: "Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats."[18]

Health information technology standards are the key to enabling interoperability between senders and receivers of laboratory information. However, the survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability in the correct implementation of HIT standards, which compromises data sharing.[19] Impediments to HIT implementation stem from the frequent use of proprietary data, variability in the underlying data standards and business practices within the Public Health Laboratory Information Management Systems (LIMS), as well as multiple choices of information exchange standards, security protocols, and network infrastructure in the U.S.[20]

In 2006, members of the APHL Informatics Committee reviewed the need for, and obstacles to, building national interoperability.[21] They identified, among many others, the need to:
- harmonize the adoption of standards to support PHLI electronic data exchange
- reduce the expense of transmitting laboratory test orders and results
- increase the effectiveness of propagating the adoption of new methodologies and technologies.

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[18] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[19] 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011

[20] Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/

[21] Same.

General barriers to effective electronic laboratory information exchange are:

Barrier I - The <u>incomplete and inconsistent adoption of existing standards</u> by the wide array of laboratories, the EHRs and the public health information systems.

Barrier II - The <u>lack of adoption of Electronic Health Records Systems (EHR-S)</u>[22] in clinical settings (i.e., test order senders and result receivers) preventing electronic communication between providers and LIMS.

Barrier III - The <u>use of proprietary, non-standardized information systems</u> in public health preventing electronic communication between LIMS and public health programs (i.e., receivers of test results on public health threat conditions).

Barrier IV - The <u>absence of a sustainable approach and funding</u> to support the development and testing of laboratory standards; and of certification and adoption of standards-based IT products in clinical, laboratory and public health settings.

Goal The PHFP-PHLI is aimed to enable electronic communication between participants of care in a standardized way so that information can be quickly, reliably and economically shared, analyzed, and acted upon to improve clinical care, prevention, surveillance and management of communicable and chronic diseases.

The EHR system needs to possess the ability to construct Orders for Laboratory Tests and to receive the Results of those Tests. Those Orders and Results can be considered "data content". Additional functionality may exist that provides decision support services. The decision support functionality also requires data in the form of guidelines or rules (that are used by the decision support engine). Those guidelines or rules can be considered "data content".

Thus, the information that is exchanged between an EHR system and a Public Health Laboratory System consists of any and all types of information that might arrive from a PHL or be sent to an EHR system. Sometimes that information regards a single patient's test results (for example); other information might be regarding educational materials for the clinician or jurisdictional guidelines.

Scope The PHFP-PHLI specifies EHR-S functions and conformance criteria that enable information to be exchanged among EHR systems and PHLs. The information that is exchanged includes diagnostic information, reference information, newborn bloodspot screening information, environmental testing information, and other surveillance test orders and results information.

Settings (Actors) The PHFP-PHLI describes EHR-S functionality that is necessary to care for a patient who receives testing by a PHL. Participants in the PHL's EHR-S-based information exchange include:

- Provider Offices
- Clinics
- Laboratories
- Hospitals
- Local/State/Territorial Public Health Agencies
- CDC.

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[22] Office of National Coordinator for Health IT. DHHS, Health IT Adoption. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1152&parentname=CommunityPage&parentid=28&mode=2&in_hi_userid= 11113&cached=true

An example of the facilities that might be involved with a newborn bloodspot screening test could include:
- a birthing facility (newborn nursery)
- an inpatient hospital setting, e.g., a neonatal intensive care unit (NICU)
- a hospital.

Data Content The PHFP-PHLI specifies EHR-S functionality that is necessary to exchange the following data content:
- Laboratory Reference Test Order and related information
- Laboratory Reference Test Result
- Jurisdictional guidelines for clinicians on PHL Test Results reporting, e.g., newborn screening, infectious diseases, chronic diseases and other
- Educational materials for providers regarding PHL testing, e.g., infectious diseases

6.5.   Health Statistics (HS) Domain

Overview The Health Care Statistics domain is proposed to meet the needs and demands for statistical information about monitoring health and the provision of health care in the United States, including hospital inpatient, ambulatory and long-term care. Inpatient care is provided in settings such as hospitals and skilled nursing facilities. Ambulatory care is provided in a wide variety of settings, including physician offices, community health centers and hospital outpatient and emergency departments. Long-term care (LTC) includes institutional care, such as skilled nursing facilities and other residential care such as assisted living. LTC also includes adult day services, home health, and hospice services.

The National Center for Health Statistics (NCHS) is part of the Centers for Disease Control and Prevention (CDC). The National Center of Health Statistics' (NCHS) mission is to provide statistical information that will guide actions and policies to improve the health of the American people. As the Nation's principal health statistics agency, NCHS accomplishes its mission by collecting, analyzing and disseminating accurate, relevant, and timely data, including data on the use, access, quality, and cost of health care provided in the United States and on health-care organizations and professionals who deliver that care. Data collection is authorized under Section 306 of the Public Health Service Act (42 U.S.C. 242k).

The need for more complete data on health care provision, utilization, and characteristics of the users has been driven by changes in the health care system which in turn are influenced by factors such as increasing efforts to contain costs and improve access and health care quality; the rapidly aging population; the introduction of new medical technologies; the adoption of electronic health records; and the expansion of health care coverage to the growing number of persons without health insurance. As a result of these societal, technological, and policy changes, there has been considerable diversification in the financing, organization, and delivery of health care, especially in ambulatory care and in long-term care, as manifested by the proliferation of managed care, insurance, and benefit alternatives for individuals; the development of new forms of physician group practices and practice arrangements; the development of new options for provision of long-term care, and growth in the number of emerging fields of medicine, such as pain management and ambulatory surgery. The data needed to evaluate the performance of the U.S. health care system in terms of the way in which hospital, long-term care, and ambulatory health care is organized, financed, and delivered and to track health care trends can be provided by electronic health data.

Users of these data include, but are not limited to, Congressional offices, Federal agencies, state and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, health care providers, payers, health planners, and of course, consumers and patients.

In summary, the provision for monitoring the health of the nation, through electronic health data capture, can help fulfill the Public Health Service Act need to collect data to monitor and evaluate the performance of the U.S. health care system.

Goals The overall goal is to answer key questions of interest to health care policy makers, public health professionals, and researchers about the status of health care delivery in the United States. These issues can include the factors that influence the access to – and use of – health care resources, the quality of health care, including safety, and disparities in health care services provided to population subgroups in the United States. This is accomplished through surveys that are nationally representative, provider-based, and cover a broad spectrum of health care settings. Within each setting, data are collected from a sample of organizations that provide care (such as home health care agencies, inpatient hospital units, or physician offices) and from samples of patient (or discharge) encounters within the sampled organizations. These surveys have the following objectives:

- to monitor health by collecting data on patient visits to hospital facilities, office-based physicians, emergency departments (EDs), outpatient departments (OPDs), ambulatory surgery locations (ASLs) of general and short-stay hospitals, as well as freestanding ambulatory surgery centers (FS-ASCs) and the continuum of long-term care providers from nursing homes to home health care.
- to monitor health and functional status and identifying issues within access (e.g., under-insured, uninsured); exposures to health risks (including events that may or may not be relevant or irrelevant events (such as flooding)).
- to collect core information about health care setting which remains stable over time so that trends in the types of care delivered in each setting can be monitored in an objective and reliable manner and can be examined in relation to characteristics of providers, patients, and clinical management of patients' care.
- to provide surveys flexible enough to accommodate special data collection modules and to sample new provider organizations as new information is needed.

The goal of the PHFP-HS is to increase the point-of-care / point-of-collection stakeholders' ability to capture Health Statistics data that are complete, uniform, timely, and of high quality, and to better accommodate downstream users of that information.

To meet the needs represented by the Work Group members' organizations, the volunteers endeavored to address the needs of unrepresented stakeholders and to consider the needs of future stakeholders. It is hoped that today's standards-based Health Statistics data collection efforts may be expanded to meet the future needs of the international community and other broad stakeholder groups.

The PHFP-HS is intended to be used by any EHR system domain by the application reporting on the delivery of health services and for reporting health care statistics.

Scope The PHFP-HS will assist in monitoring the health of the United States health care system. The PHFP-HS specifies functions and conformance criteria as well as information

exchange content for health delivery. Additionally, information will also be collected on patients and on physician and facility characteristics that impact the US health care system.

Health Statistics surveys are conducted under the auspices of the CDC and are governed by the Public Health Service act. All information collected is held in the strictest confidence according to section 308(d) of the Public Health Service act [42 United States Code 242m (d) and Section 513 of the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (PL-107-347)]. NCHS:

- Maintains facility and patient confidentiality
- Restricts data access
- Physically protects records by keeping them on secure servers
- Conducts a disclosure review analysis to be sure that no provider or patient in a Health Statistics Survey sample could be identified in a public-use data set.

In order to meet health statistics survey requirement regarding certain patients or populations, the NCHS may use PHI to link patient data that resides in various hospital units with data that resides in other systems.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 privacy rule permits disclosure of PHI without patient authorization for public health purposes and for research that has been approved by an Institutional Review Board (IRB).

There are two types of functional profiles. A "Functional Domain Profile" describes an EHR system that may be used in one or more care settings, or may be used in a selected realm (and which meets the rules, regulations and standards applicable to that realm). A "Functional Companion Profile" is designed to be combined with one or more Functional Domain Profiles. The purpose of a Companion Profile is to list the features of an EHR System that are common to many domains, such as research, records management, or evidentiary support. The PHFP HS is likely to be viewed by many EHR system stakeholders as a Functional Companion Profile, because those stakeholders recognize the benefits of providing certain information to Health Statistics professionals – and the costs/risks of not providing that information. Furthermore, it is expected that EHR systems will be able to collect and share health statistics information securely and transparently (namely, with minimal impact on the user).

Because the PHFP-HS consists of a collection of functions and conformance criteria, it is likely that an electronic health statics data-collection framework can be incrementally defined, prioritized, and then incrementally developed and deployed.

Certain risks may be associated with the development and use of Health Statistics functionality, including:

- Possible high cost of developing an information collection and sharing engine.
- Possible high cost of deploying and managing the engine.
- Possible incompatibility of the engine's information demands against the EHR system's information structures.
- Possible lack of interoperability between the EHR system and the Health Statistics stakeholder's system.
- Dependency on the successful deployment and operation of the core EHR system application or of an EHR subsystem that applies to a given domain.

Certain benefits may be associated with the development and use of Health Statistics functionality, including:

- Automated, timely, transparent, efficient, import into Health Statistics systems (including specialized analytical systems) of high quality Health Statistics information for analysis.
- Reduction of human resources in completing paper or oral –based health statistics information requests.
- Increased uniformity and integrity of exported raw data.
- Possibility that health statistics experts could develop analytical reports that might benefit various, targeted stakeholder groups (such as physician offices, or large integrated hospital groups).
- In-house analysis of Health Statistics Survey Data (that has been collected and summarized) may prove to be useful to Administrative and the Quality-Review Staff, Policy Experts, Researchers, Academics, etc.

Various issues remain regarding EHR systems that may implement PHFP HS functionality, including:
- Economic resources to develop, maintain, and adjust to the import of electronic data.
- Training (or retraining) that will accommodate the new (electronic) approaches to data analysis.
- Vendor incentives to understand and incorporate the health statistics functional profiles.
- Need for cooperative agreements that permits data transport across state and jurisdictional boundaries.
- Stewardship and governance of electronic data received from EHR systems.
- Need to accommodate privacy and security expectations.
- Need to be sensitive when publishing results regarding poorly performing EHR systems.
- It would be good for the Health Statistics experts to propose a balance that would minimize the number of pop-up windows that appear which require user input for completing Health Statistics Survey –related items. Also, it would be good to provide pointers to external instructions regarding any Survey-items.
- Many EHR systems do not adequately collect information according to the nuance that is desired by the Health Statistics community. That is, EHR systems often capture a patient's complaints and/or presenting problems during a healthcare encounter, but they do not capture the reason, cause, or context for the complaint and or problem. For example, a patient may complain of belly pain that is the result of poison – but other information must be gathered: Was it intentional or accidental? Was it due to occupational exposure (such as a paint shop)? Was it due to military conditions (such as war)? Did it result from conflict with another person?
- Many EHR systems do not adequately collect information to the level of granularity that is desired by the Health Statistics community. Visualize: "The system SHOULD manage a set of information that describes the type of care offered by a given care provider (e.g., cardiologist or general practitioner), health care setting (e.g., long term care facility or hospital), and categories of patient (e.g., children or geriatric patients). For example, Dr. Jones provides care for ambulatory patients, but not for children)."
- It would be good for Health Statistics experts to propose the creation of a standard Health Statistics information collection method (an engine) that can be inserted into certified EHR systems. The specifications for this engine should be managed and governed by an expert third party who understands Health Statistics community's needs. If such an engine were subject to certification requirements, it could become part of future Meaningful Use requirements and incentives.
- It may be useful for the EHR system to monitor the behavior or level-of-service of ancillary systems (such as a Hospital Information System, Laboratory system, or pharmacy system) that may impact the EHR system.

Setting (Actors)
The list of primary EHR-centric Health Statistics information creators include:
- Physician Offices
- Community Health Centers
    - Federally Qualified Health Centers
    - Lookalike Health Centers
    - Urban Indian Health Centers
- Hospital Emergency and Outpatient Departments
- Large, integrated health care delivery networks
- Ambulatory Surgery Centers (hospital-based and free-standing)
- Hospital Inpatient Care
- Physicians, mid-level providers (Nurse Practitioners, Physician Assistants), Nurses, Medical Assistants, Midwives (home and hospital births),
- Nursing Homes
- Home and Hospice Care Agencies
- Long Term Care Facilities including nursing homes, residential care facilities and continuing care retirement communities
- Adult day services providers

The list of primary downstream users of the PHFP-HS may include:
- Local, State and Federal Public Health Agencies
- Researchers, including
    - Academic
    - Policy and Legislative
    - Marketing
- Users of the PHFP-HS in domains such as:
    - Public Health Reporting organizations
    - Public Health Care Providing organizations
    - Financial and Administrative organizations (including payers, employers, estate managers, financial managers, and benefits managers)
- Developers of derived Functional Profiles
- Users who may wish to merge Functional Profiles from various domains

The list of other downstream users of the PHFP-HS may include:
- Associated domains, such as:
    - Epidemiological Research
    - Surveillance Research
    - Clinical Research
    - Population Reporting, Planning, and Research
    - Disaster Reporting, Prevention, and Research
    - Fraud and Abuse Reporting and Research
    - Legal uses
    - Military uses
    - Genomics / Genetics / Cloning / Fertility
    - Veterinary Medicine
    - Personal Health Records, Personal History, Family History, and genealogical research
    - Health industry businesses, including:
        - Product and service providers

- ▪ Marketers
- ▪ Investors
  - o Consumers

Data Content
The Health Statistics community is interested in a broad array of information. These information categories are identified by the plethora of Conformance Criteria that are tagged within the PHFP-HS. Some of these information categories include:

- Encounter-specific information
  - o Demographic information
  - o Current diagnoses
  - o Medications
  - o Laboratory tests
  - o Radiological tests
  - o Other ordered test and/or services
  - o Scheduling
- Provider-related information
- Facility-related information
- Care team organization and coordination
- Decision support
- Finance and Administration
- Health Interview Survey Information

The National Health Interview Survey, as a major source of information and statistics on the health of the general U.S. population, has an interest in the interaction of the general public with the health care system, specifically regarding information that is exchanged electronically. The National Health Interview Survey experts are generally interested in analyzing the differing kinds of information that respondents/patients can get from their medical records and the means by which they can enter information into the system or correct data that is already present in their record.

Also, National Health Interview Survey experts are interested in analyzing the ease by which patients may correspond with their primary and other doctors or clinics, including exchanging messages, accessing information about their conditions and tests (printed, relevant websites, etc.), making appointments, getting prescriptions renewed, getting reminders about needed care, and transferring information from records to other medical sources like specialists.

Data Use for Public Health Surveillance and Research Information required for public health
assessment would most likely consist of provider information, patient information including admitting diagnosis, reason for visit, problem list, primary and secondary diagnoses, medical treatments, functional and cognitive status, the presence of health care acquired infections and health insurance and facility information.

Domain-Specific Description of the use of Data-Collection Instruments
Health Statistics-Public-Health-Domain stakeholders have created health statistics data collections forms that can be used as guides by EHR system administrators to help promote the collection of health statistics information in a standards-based manner.

- **Data-Collection Instruments (e.g., Forms / Templates / Assessments)**
  - o The data is typically extracted from the form and stored in a database.

- **Creation / Management / Ownership / Governance of the Data-Collection Instruments**
  - The form(s) could be tailored by health statistics EHR stakeholders.
- **Other Uses of the Collected Data**
  - The downstream users of the information collected via the form include Congress, health policy analysts, health services researchers and educators.
- **Other Processing of the Data (e.g., Coding)**
  - The forms are typically completed monthly.
  - The data collected by the form is typically coded afterwards.
  - The completed forms are typically validated by NCHS.
- **Implementation Guides and/or Education Materials**
  - Guidance on using the form(s) to collect data is available from http://www.cdc.gov/nchs/dhcs/dhcs_questionnaires.htm .

6.6.   Occupational Disease, Injury, and Fatality (ODIF) Domain

Overview As outlined in the 2011 Institute of Medicine letter report "*Incorporating occupational information in electronic health records*," work has an enormous impact on the health of the workers and their families, with employed Americans spending approximately 50% of waking hours at work.[23] Work may pose substantial risks – physical, biological, chemical, radiological and psychological – which can result in injury or illness that significantly interferes with productivity and quality of life. Failure by clinicians to recognize the risks and impact of work at the point of care may lead to poor outcomes and no prevention. Knowledge of conditions at work can also support successful management of chronic conditions.[24]

In the United States, mortality, morbidity, and economic burden associated with work-related illness and injury are high. In 2011, the Bureau of Labor Statistics (BLS) reported an estimated 3.1 million private-sector workers had a nonfatal work-related injury or illness, with 4,547 deaths from injuries sustained at work.[25][26] Annually, approximately 49,000 deaths in the U.S. are due to occupational diseases. Occupational illness and injury together are the 8th leading cause of death.[27] Approximately 9,000 workers are treated in emergency departments each day because of occupational injuries, and approximately 200 of these workers are hospitalized.[28] Work-related disease and injury account for a considerable fraction of total direct and indirect costs related to health outcomes. Among U.S. civilians, costs for occupational fatal and non-fatal injuries and illnesses in 2007 were estimated to be $250 billion.[29]

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[23] IOM (Institute of Medicine). 2011. *Incorporating occupational information in electronic health records: Letter report.* Washington, DC: The National Academies Press.

[24] American College of Occupational and Environmental Medicine. Workplace Health Protection and Promotion: A New Pathway for a Healthier—and Safer—Workforce. Guidance Statement. J Occup Environ Med 2011;53(6):695-702.

[25] Bureau of Labor Statistics. 2010. *Workplace Injuries and Illnesses — 2009.* Washington, DC: US Department of Labor. Available at http://www.bls.gov/news.release/osh.nr0.htm

[26] Bureau of Labor Statistics. 2011. *National Census of Fatal Occupational Injuries in 2010 (preliminary results*). Available at http://www.bls.gov/news.release/cfoi.nr0.htm.

[27] Steenland K, Burnett C, Lalich N, Ward E, Hurrell J. Dying for Work: the Magnitude of U.S. Mortality from Selected Causes of Death Associated with Occupation. Am J Ind Med 2003;43:461–82.

[28] CDC. Nonfatal Occupational Injuries and Illnesses—United States, 2004. MMWR 2007:56:393–397. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5616a3.htm.

[29] Leigh JP. Economic Burden of Occupational Injury and Illness in the United States. The Milbank Quarterly. 2011. 89(4):728-772.

To target effective interventions for work-related fatalities, injuries, and illnesses, information about employment (occupation, industry or type of business, employer name and address, and reported worksite exposures) must be captured and available to the clinician at the point of care. The benefits of collecting information about work range over numerous domains, e.g., vital records, maternal and child health, and a wide spectrum of acute and chronic diseases, including cancer, chronic lung disease, asthma, skin diseases, communicable diseases, as well as a variety of acute and chronic injuries. Not only does work have a role in the causation of certain diseases, but the workplace may also provide a means for transmission, e.g., TB, SARS, or influenza.

The U.S. National Institute of Safety and Health (NIOSH) and its partners have a long history of successfully using information about employment (industry and occupation) data to conduct surveillance and research to assess risk factors and to answer the questions of who is affected, where, and how, and to use that information to direct intervention efforts for prevention. Industry and occupation are relatively easy to acquire from workers or their next-of-kin. Industry and occupation may be present on death certificates, and is collected on many surveys and databases such as the National Health Interview Survey (NHIS) and tumor and trauma registries; its utility has been widely demonstrated.

Goals The overall goal of the occupational health community is the **r**outine collection and display of employment information data (industry, occupation, employer name and address, reported worksite exposures) to providers to improve patient care. Specifically to:
- facilitate the detection, diagnosis, and appropriate treatment by providing information when there is the possibility that the underlying condition may be work-related;
- improve the management, treatment, and return to work of patients, regardless of the etiology of their health condition.

Secondarily, other goals are to:
- facilitate state mandated public health reporting of occupational disease and injury; and
- provide data to guide prevention and research.

Scope The initial goal is to create an ODIF-FP that conforms to the HL7 EHR-S FM. The ODIF-FP will facilitate the capture of employment data via EHR systems. The scope of the FP may or may not be restricted: workplace hazards are ubiquitous and cross numerous domains. Further, settings and actors vary with condition. Given the wide range of illnesses and injuries that can arise from or be affected by work, the scope may or may not be restricted by condition.

Setting (Actors)
Settings and Actors vary with condition, e.g., acute traumatic injury, cancer, and asthma have different settings. For example:

	Conditions		
	Acute Traumatic Injury	Cancer	Adult Asthma
Settings (Actors)	EMS Emergency Room Urgent Care Community Clinic Radiology Hospitals	Clinic/physician offices- oncology, dermatology, urology, etc. Laboratories Hospitals Cancer Registries	Allergist Pulmonologist Pulmonary Function Lab Lung Disease Registries

	Primary Care Provider Trauma Registries	Freestanding Treatment Centers Radiology	

Table 5: Settings and Actors that vary based on Condition

Additional Settings (Actors) that would apply for all conditions include:
- Local, State and Federal Public Health Agencies
- Local and State Labor Departments
- State and Federal Workers' Compensation Programs
- Industry Groups
- Labor Unions
- Employers
- Researchers

Data Content A FP will be developed that specifies EHR-S functionality necessary to exchange the following data content:
- Current occupation (job)
- Usual occupation – occupation worked in for most of the working life up to the time of encounter
- Current industry (type of business)
- Usual industry – industry worked in for most of the working life up to the time of the encounter
- Employer name
- Employer address
- Worksite exposures

The standard code set/vocabulary for Current and Usual Occupation is the Standard Occupational Classification (SOC) (http://www.bls.gov/soc/), and the standard code set/vocabulary for Current and Usual Industry is the North American Industry Classification System (NAICS) (http://www.census.gov/eos/www/naics/).

6.7.   Birth Defects Domain

Overview Major birth defects are conditions that: 1) result from a malformation, deformation, or disruption in one or more parts of the body; 2) are present at birth; and 3) have serious, adverse effects on the affected person's health, development, or functioning. Of the more than 4 million infants born each year in the United States, approximately 120,000 have birth defects, or about 3% of all births.[30] Birth defects are a leading cause of morbidity and infant death accounting for more than 20% of infant deaths.[31] These conditions can have lifelong and life-limiting effects on children; in 2004, hospital costs for birth defects totaled $2.6 billion.[32]

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[30] CDC. Update on Overall Prevalence of Major Birth Defects --- Atlanta, Georgia, 1978—2005. MMWR 2008; 57 (01): 1-5.
[31] Heron MP, Hoyert DL, Murphy SL, Xu JQ, Kochanek KD, Tejada-Vera B. Deaths: Final data for 2006. National vital statistics reports; vol 57 no 14. Hyattsville, MD: National Center for Health Statistics. 2009
[32] Russo, C. A. (Thomson Medstat) and Elixhauser, A. (AHRQ). Hospitalizations for Birth Defects, 2004. HCUP Statistical Brief #24. January 2007. U.S. Agency for Healthcare Research and Quality, Rockville, MD.

Surveillance of birth defects in a population Is vital for quantifying the public health impact of birth defects, monitoring trends, forming the basis for etiologic and clinical studies, evaluating prevention strategies and interventions, planning for services, and making informed policy decisions. In most states, a birth defect is a health outcome that is reportable by state law.[33] In the United States, more than 40 states have, or are planning, population-based birth defect surveillance programs. The Centers for Disease Control and Prevention (CDC) supports many of these state surveillance programs.

In addition, the National Birth Defects Prevention Network (NBDPN) was created in 1997 to establish and maintain a national network of state and population-based programs for birth defects surveillance and research. NBDPN assesses the impact of birth defects upon children, families, and health care; identifies factors that can be used to develop primary prevention strategies; and assists families and their providers in secondary disabilities prevention. In 2004, NBDPN published the *Guidelines for Conducting Birth Defects Surveillance*[34] to improve data quality and utility, and encourage and promote the use of birth defects surveillance data for the purposes of linking affected children with services. NBDPN also has established a workgroup to address issues regarding utilization of electronic health record systems (EHR-S) for birth defects surveillance.

Case ascertainment of birth defects ranges along a continuum from passive to active methodology. Birth defect surveillance programs vary in objectives, the age at which children are included, the types of birth outcomes included (live births, still births, pregnancy terminations), the geographic scope of their activities, and case ascertainment methods. They also vary in the utilization of EHR-S for public health activities. In some systems, birth defects cases are reported from one or more ascertainment sources, while in others, staff conduct case-finding, review, and abstract information directly at the source(s). Other programs combine aspects of both active and passive systems, such as receiving case reports from sources and then reviewing a subset of them at the reporting site. In all of these systems, case ascertainment is improved when multiple sources are used for case identification and when clinical review of the cases is completed.

While birth defects surveillance programs provide important data on the occurrence of defects among newborns and infants in the U.S., there is little longitudinal tracking data on children, adolescents and adults with birth defects.

Goal The goal of birth defects surveillance programs is to collect quality data for use in improving the public's health.

EHR-S could improve the capacity of state and regional programs to: 1) conduct birth defects surveillance and follow cases longitudinally across the lifespan; 2) conduct epidemiologic and outcomes research through analysis of EHR data; and 3) improve the delivery of health services for affected individuals. EHR-S with birth defects functional requirements could enable a birth defects surveillance system to collect data in a more cost-effective and efficient manner. For example, a surveillance system may currently receive information from reporting sources in

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[33] National Birth Defects Prevention Network (NBDPN), 2010, State Birth Defects Surveillance Program Directory, Birth Defects Research Part A Volume 88;12:(1126-1174).

[34] National Birth Defects Prevention Network (NBDPN). Guidelines for Conducting Birth Defects Surveillance. Sever LE, ed. Atlanta, GA: National Birth Defects Prevention Network, Inc., June 2004. (http://www.nbdpn.org/birth_defects_surveillance_gui.php

varying formats (e.g., paper, scanned, electronic). In addition, reporting facilities may be required to send the same information to multiple state or local agencies or other entities, increasing the likelihood of data errors or delays. Surveillance staff have to process the received reports and standardize the format. Information captured via paper forms need to be entered into an electronic system. Duplicates need to be identified. Variability will exist in the information provided, as well as the quality of the data. EHR-S would provide the needed information in a consistent and more efficient and timely manner.

Thus, birth defects -specific EHR-S standards would enable public health surveillance to streamline existing processes and procedures for case ascertainment and data collection, and improve cost-effectiveness of surveillance and timeliness of data reporting. Furthermore, the use of standard birth defect-specific EHR-S conformance criteria could improve the comparability and feasibility of pooling of data among states, increase epidemiologic capacity, and guide primary and secondary prevention activities. The use of EHR-S and data standards would improve the quantity and quality of data collected, thereby enhancing the national public health capacity to monitor, understand, and prevent birth defects.

Scope The development of the Public Health Functional Profile – Birth Defect Domain (PHFP-BD) of the Health Level Seven (HL7) EHR-S Functional Model was primarily focused on conformance criteria and standards related to traditional case ascertainment of birth defects among infants. Birth defects specifications were included across all functional categories and sections since an EHR-S collects comprehensive information. The comprehensive data from an EHR-S could be useful for a variety of birth defects activities.

Settings (Actors The PHFP-BD domain describes EHR-S functionality needed to document the prevalence of birth defects and the occurrence of co-morbidities for patients of all ages who receive health care in:
- Hospital settings,
- Primary care provider's office,
- Outpatient surgical centers,
- Long term care facilities,
- Ambulatory care centers,
- Specialty care clinics

Data Content The PHFP-BD domain specifies EHR-S functionality needed to exchange the following data content on birth defects for public health surveillance and prevention activities:
- Diagnosis of birth defects and associated disorders
- Diagnostic methods (i.e., genetic testing, imaging studies, surgery, autopsy)
- Results of diagnostic methods/laboratory tests
- Demographic and geographic information
- Risk factors and prognostic factors
- Family history of birth defects
- Complications of birth defects
- Treatment for birth defects and co-morbidities
- Quality measures
- Jurisdictional guidelines for clinicians on prevention and diagnosis
- Prevention activities, including educational materials for caregivers

6.8.   *Deep Vein Thrombosis and Pulmonary Embolism (DVT/PE) Domain*

Overview Venous thromboembolism (VTE) encompasses both deep vein thrombosis (DVT), clots in the deep veins of the body, most commonly those of the legs; and pulmonary embolism (PE), which occurs when a clot breaks free and enters the arteries of the lungs. DVT and PE are both major public health issues. They affect all races and ethnicities, ages, and genders and are associated with severe morbidity and mortality.

Presently, there is no national surveillance for DVT and PE, and thus the precise number of people affected by DVT/PE is unknown. Studies have estimated the annual incidence to be between 1-2 per thousand of the population, or 300,000 to 600,000 cases.[35,36,37] However, since these studies have focused mainly on patients of white race, the risks – and more importantly – the true burden of DVT and PE on other populations are unknown and unaccounted for in current estimates. In addition, because DVT has many presentations and is diagnosed and cared for by multiple providers and in multiple settings (inpatient and outpatient); the overall burden of DVT is likely to be underestimated. Similarly, given that autopsy rates in the United States are low, and PE may be misdiagnosed as heart failure, current estimates of the actual number of PE events are probably inaccurate and underreported as well.

VTE is associated with significant mortality with about 25% of PE events presenting as sudden death.[38,39] Other serious complications include DVT/PE recurrence, and chronic, and sometimes, disabling morbidity. Patients at high risk of DVT/PE recurrence require long-term anticoagulation treatment to prevent future clots which decreases quality of life and places them at increased risk for adverse bleeding episodes.

Much of the morbidity and mortality associated with DVT/PE is preventable with early and accurate diagnosis and management. Surveillance data are needed not only to quantify the burden but also to help better understand where to focus research and target prevention measures. Surveillance data are also needed to provide while also providing a much-needed baseline rates of DVT/PE occurrence and for monitoring the effectiveness of prevention efforts.

Goals The goal of Public Health Functional Profile-Deep Vein Thrombosis and Pulmonary Embolism (PHFP-DVT/PE) is to develop standard clinical data elements to be collected in electronic health record systems (EHR-S) that can be used to document, monitor, and assess DVT and PE occurrence and prevention activities in the US population. This important activity will greatly enhance Public Health's ability to more accurately define and monitor the public health burden associated with these disorders as well as provide an avenue for assessing the effectiveness of prevention activities.

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[35] Silverstein MD, Heit JA, Mohr DN et.al. Trends in the incidence of deep vein thrombosis and pulmonary embolism: A 25-year population based study. Arch Intern Med 1998; 158:585-593.

[36] White R, Zhou H, Murin S, Harvey D. Effect of ethnicity and gender on the incidence of venous thromboembolism in a diverse population in California in 1996. Thrombosis and Haemostasis 2005;93(2):298-305.

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[38] Heit JA, Silverstein MD, Mohr DN, Petterson TM, Lohse CM, O'Fallon WM, et al. The epidemiology of venous thromboembolism in the community. Thrombosis and Haemostasis 2001;86(1):452-63.

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Scope The PHFP-DVT/PE will aid in patient care and public health practice activities including surveillance and prevention. Documenting DVT/PE diagnosis, care, presentation, and prevention will require the ability to link, evaluate, and collect many types of health care related data from multiple sources. DVT is increasingly being diagnosed and treated in outpatient or ambulatory care settings which will require case ascertainment from multiple types of providers and access points. Diagnosis for both DVT and PE is complex and requires radiological imaging (ultrasound, CT, etc) to confirm the event. To properly document the burden of DVT/ PE, additional data beyond diagnosis will be needed such as medical history data to distinguish recurrent events from incident events, data on symptoms to distinguish between symptomatic and asymptomatic events, and data on known risk factors to identify events that may, or may not, have been prevented. Finally, an estimated 25% of PE results in sudden death, requiring the link to vital records and autopsy data for case ascertainment.

Setting (Actors) The PHFP-DVT/PE describes EHR-S functionality that is necessary to document and by extension, prevent occurrence of DVT or PE for patients of all ages who receive health care in:
- hospital settings,
- primary care provider's office,
- outpatient surgical centers,
- long term care facilities,
- ambulatory care centers,
- the specialty care clinics

Data Content The PHFP-DVT/PE specifies EHR-S functionality that is necessary to exchange the following data content for public health surveillance and prevention activities of DVT and PE:
- Diagnosis of DVT/PE
- Radiologic Imaging for DVT/PE
- Symptoms of DVT/PE
- Laboratory Test Results
- DVT/PE Risk Factors
- Medical History of DVT/PE
- Complications of DVT/PE
- Prophylaxis and Treatment for DVT/PE
- Quality Measures
- Jurisdictional guidelines for clinicians on prevention and diagnosis
- Prevention activities (including educational materials for caregivers)

6.9.   *Adverse Events (AE) Domain*

Overview The EHR PHFP-Adverse Events (AE) stakeholders collect and examine information from EHR systems regarding Adverse Events. AE stakeholders may also share regulatory guidance, best practice guidance, or reference/training materials with EHR system stakeholders.

Adverse Events may consist of:
- an untoward medical occurrence or injury to a patient which occurs in a hospital or other setting (e.g., a physician may discover that a AE occurred at a patient's home – such as a drug overdose, product use error, or a serious event that required treatment)

- an untoward occurrence to a patient that arises from a drug effect, wound infection, technical complication, negligence, diagnostic mishap, or therapeutic mishap.

Examples of Adverse Events include, but are not limited to:
- a hospital-acquired infection
- a surgical procedure being performed on the wrong patient
- a drug-dispensing robot delivering the wrong drug to a patient
- medical device problem or failure
- birth defect associated with the use of a medical product by the mother
- severe liver toxicity due to prolonged use of a prescription drug product

AE information may be augmented by other PH domain stakeholders (e.g., Vital Records, Birth Defects, and Health Statistics). AE information included by these PH domain stakeholders help support a wide variety of reporting scenarios. For example, a birth defect resulting from the use of an incorrect drug taken by the mother must be reported.

AE surveillance and reporting requirements are provided by AE experts such as the FDA and AHRQ (Agency for Healthcare Quality and Research).

The AE domain helps address data quality issues (e.g., incomplete or missing data; misspelling a patient's name; or erroneous medication information). The AE FP specifies best practices regarding the kinds of data that should be collected and the report format that should be used.

AE reports include patient information found in EHR systems such as patient demographics, medical history, medication use, medical device use, and laboratory tests/results. Auto-population of AE report content (using EHR structured data capture template technologies) helps to reduce the healthcare provider's reporting burden by streamlining the data collection and validation processes required to integrate information contained in other clinical documents such as clinical notes or laboratory reports. This approach helps reduce errors that may be introduced via manual data entry and/or transcription from written notes or reports.

AE domain experts often differentiate between Adverse Events and "Serious Adverse Events" (SAE). SAE reports are associated with the use of human (and veterinary) regulated drugs, biologics (e.g., human cells, tissues, and cellular and tissue-based products), medical devices, dietary supplements, cosmetics, foods, and infant formula. Typical SAE reports include:
- product quality problems;
- product use errors;
- unplanned events that did not result in injury, illness, or damage or "near-miss" events;
- therapeutic inequivalence / therapeutic failure associated with the use of an FDA-regulated product, and
- suspected counterfeit products.

Health authorities and regulators desire information related to medical product safety. For example, an electronic medical device can export or record signals regarding the device's operations or calibration. Once submitted to regulators for analysis and review, this device information could result- in a product safety alert, product recall, product withdrawal, or a product labeling change. Regulators may also desire information regarding evidence of product tampering or product security violations.

The EHR System should contain functionality that enables configuration of the AE reporting detail, timeliness, target audience, and necessity.

Goals The goal of the Public Health Functional Profile (PHFP) Adverse Events is to enable electronic data capture and submission of adverse event (AE) reports from healthcare providers. Auto-populating AE reports with EHR information will significantly reduce the amount of time required to manually prepare AE reports, resulting in improved data quality. Auto-population of AE reports also helps reduce costs and the risk of errors by eliminating manual data entry into report collection systems.

Automated report-generation functionality (as part of the EHR system) will provide more timely access to an AE report, as opposed to the delay that occurs via manual data entry and coding of paper-based reports.

Adverse Events stakeholders demand AE reports in a timely fashion in order to detect possible Adverse Events (e.g., problems with medical products or the presence of a possible patient safety issue). Those stakeholders also require that EHR systems contain effective channels for receiving and sharing public health threats or efficacy alerts offered by Adverse Events analysts.

Manual, paper-based data entry by healthcare providers has often resulted in a lower-than-desired reporting stream to the Adverse Events analysts; electronic reporting and automated/assisted data entry of web-based forms may help mitigate that bottleneck as well as provide more accurate data from EHR systems. Examples of data that could be automatically gleaned from an EHR system include: patient history, care provision information, medical product usage information, and relevant laboratory information. The EHR system should also provide functionality that enables the caregiver to complete any remaining information that could not be automatically gleaned from the EHR system.

The ultimate goal of the PHFP-Adverse Event is to enhance EHR Systems with AE capabilities.

Scope The PHFP-Adverse Event specifies EHR-S functions and conformance criteria for the submission of adverse event reports to various organizations per scope of practice, organizational policy, and/or jurisdictional law. The scope of the PHFP-Adverse Event envisions:
- The collection, measurement, and analysis of AE-related information;
- Alerts, notifications, and recommendations from AE stakeholders;
- EHR System updates regarding AE –related materials;
- Information that is exported to AE stakeholders.

Use Cases that are within the scope of the PHFP-Adverse Event includes:
- Death events
- Life-threatening events
- Prolongation hospitalizations
- AE-caused hospitalizations
- Clinical Guidelines that help reduce or eliminate AEs (e.g., clinical interventions that prevent permanent impairment, disability, or damage to the patient)
- Congenital Anomalies or Birth Defects
- Other Serious Adverse Events

Though the PHFP-Adverse Event is focused on the arena of human health care, there is no structural reason that it could not be used (and/or adapted) for the veterinary medicine arena.

Setting (Actors) Participants in the Adverse Event domain's EHR-S-based information exchange include:

- Healthcare facilities (e.g., Clinic/Physician Offices; Hospitals; Skilled Nursing Facilities)
- Regulators (e.g., FDA Medical Officers, Safety Evaluators)
- Researchers (e.g.,
  - Adverse Event Patient Safety analysts;
  - CDC (Centers for Disease Control) (for Vaccine Reporting);
  - AHRQ (Agency for Healthcare Research and Quality);
  - Epidemiologists;
  - FDA (Food and Drug Administration) (Safety Reporting Programs))
- Product manufacturers (e.g., manufacturers of medicines, medical devices, dietary supplements, and/or food)Local/state/federal public health surveillance programs
- Patients (e.g., notifications sent to the patient regarding possible product recalls/problems or notifications received from patients regarding possible adverse events or side effects)
- External Systems (e.g., Incident Reporting or Risk Management systems)

Data Content The PHFP-Adverse Event specifies EHR-S functionality that is necessary to exchange the following data content:

- Patient Demographics
- Patient Risk Factor information (e.g., pregnancy, tobacco and/or alcohol use)
- Medical History
- Pre-existing conditions (e.g., allergies, hepatic/renal dysfunction)
- Medications History and Medical Device History and Use
- Provider/Facility information
- Laboratory tests and results
- Diagnosis and Medical Procedure information
- Description of Adverse Event(s), including date/time, actions taken
- Adverse Event Outcome Information (seriousness criteria) and resolution
- Concomitant Medications and/or Devices that could/may be involved in a possible AE (e.g., date/time of administration and/or use, indication, route of administration, dosage form, strength, dose, lot number, serial number, unique device Identifier, or unique product identifier).

7. Public Health Functional Requirements and Conformance Criteria for EHR Systems

Functional requirements and conformance criteria of EHR systems to exchange information with PH-ISs by domain are presented in the Function List (i.e., the domain comparison spreadsheet) document that is part of the set of PHFP documents.

Note: Each Public Health Functional Profile has been tailored from the EHR System Functional Model, Release 2. The Record Infrastructure and Trust Infrastructure Sections were incorporated almost universally in the Functional Profiles. Of the remaining Sections, approximately ten percent of the EHR-S FM items were incorporated in the Functional Profile *verbatim*; approximately ninety percent were modified in some way by the domain experts.

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