Mapping EHR Data to a Research Case Report Form:
How a Metadata Repository, CDISC's SHARE, can improve the IHE profile Clinical Research Data (CRD)

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The Problem: EHR enabled research

EHRs can help to

1. Evaluate study feasibility
2. Identify subjects based on inclusion/ exclusion criteria
3. Capture specific data during the course of the study

Not a data-mining exercise, but a workflow development

1. Data are needed ‘just in time’.
2. Subject must be identified, with pseudonym
3. The EHR cannot be expected to provide all data

Use Case

Study Data Manager is working with a clinical development team to **design the data collection for a new trial**. The data manager has a draft list of variables that the team dee… appropriate according to the protocol. Th… es out to a public data elemen… d searches for m… pr…

…and r… system receives the d… and imports / makes them av… system's screen building facility. In this way, th… availability of standard data elements streamlines creation of the study data collection system. (Source: Meredith Nahm, PhD, Duke Translational Research Instititue)

And the data element registry can point to the matching data element in an EHR-generated standard document so that the data capture form can be properly pre-populated at the point of care.

Why can't researchers merely access data directly from the EHR's database?

1. Security – direct access to an EHR database carries risk

2. Mapping – each EHR codes data in its proprietary format

By creating a standard XML document the problems with direct database access are solved.

1. The document buffers the EHR database from direct exposure
2. The document has know structure and coding to allow for searching and access.

So which document shall we use?

A New Published Paper from U. Texas

“The Promise of the CCD: Challenges and Opportunity for Quality Improvement and Population Health” D'Amore et al.

The Promise of the CCD: Challenges and Opportunity for Quality Improvement and Population Health

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Abstract

Interoperability is a requirement of recent ... such potential, this ... a computer program to parse and aggregate them. ... were parsed yielding 680 data in the core content modules of problems, medications, allergies and results. Challenges to interoperability were catalogued and potential quality metrics evaluated based on available content. This research highlights the promise of CCDs for population health and recommends changes for future interoperability standards.

Introduction

Recent incentives and policy decisions are promoting the rapid adoption of electronic health records (EHRs) in the United States. The American Reinvestment and Recovery Act of 2009 commits up to $27 billion in payments, beginning in 2011, to eligible professionals and hospitals that meaningfully use EHRs[1]. Those reimbursements will come in three stages and are expected to propel ambulatory and hospital EHR adoption to over 70% by 2020[2]. The rapid timeline for uptake, however, will lead to a heterogeneous environment of technology. With over 400 EHRs certified for the first stage of 'Meaningful Use,' interoperability will remain a concern[3]. As providers seek to improve quality and population health, technology standards advanced by this federal legislation will enable new methods for data aggregation.

Background

In July 2010, the Department of Health and Human Services adopted the Continuity of Care Document (CCD) as an option to meet the goals of clinical data exchange for 'Meaningful Use'[4]. Using an extensible markup language (XML) based structure, the CCD was collaboratively developed in 2006 by harmonizing standards from the American Society for Testing and Materials and Health Level 7 (HL7)[5]. The CCD provides a flexible format for the communication of free-text and codified data. Given the recent emergence of the standard, most health information exchanges are not routinely using CCDs today, although select institutions have launched pilots to explore their potential[6, 7]. The lack of widespread use means that EHR developers must rely on guidance from standards organizations, such as the Health Information Technology Standards Panel (HITSP), Integrating the Healthcare Enterprise (IHE) and HL7, on how to create and exchange CCDs.

HITSP released for implementation its first CCD patient summary construct, named C32, in 2007[8]. That construct is directly referenced in the final federal rule for Stage 1 of 'Meaningful Use'[4]. The most recent C32 specification references two other constructs developed by HITSP as well as technical frameworks previously released by IHE and HL7[9, 10]. Naturally, documents and specifications from different organizations and developed at different times may lead to varying interpretations about requirements. For Stage 1 of 'Meaningful Use,' the National Institute for Standards and Technology (NIST) has released the definitive testing procedures to determine whether an EHR-generated CCD meets the standards for 'Meaningful Use' certification[11]. These procedures focus on the ability of EHRs to generate, receive and display four categories of coded patient data with specific vocabularies: problem lists,

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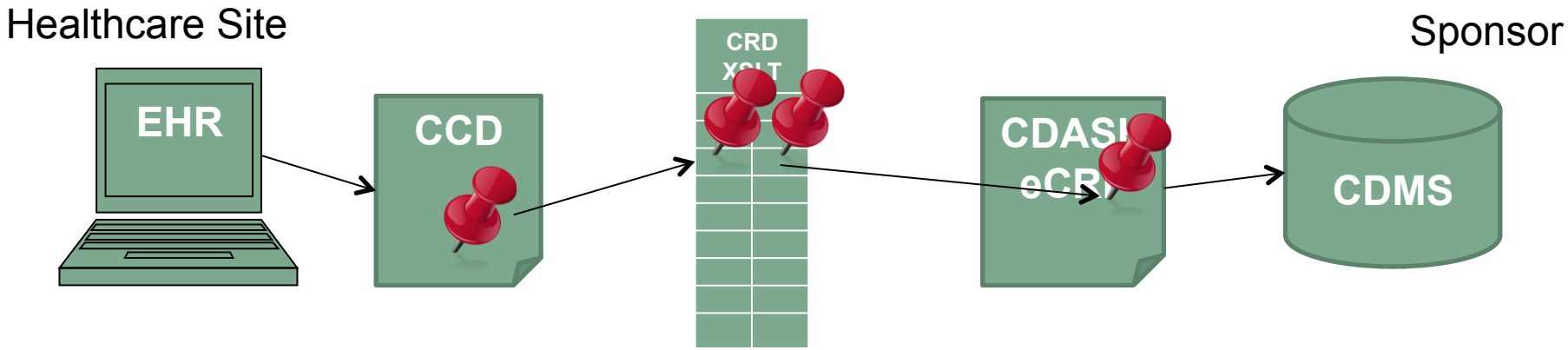
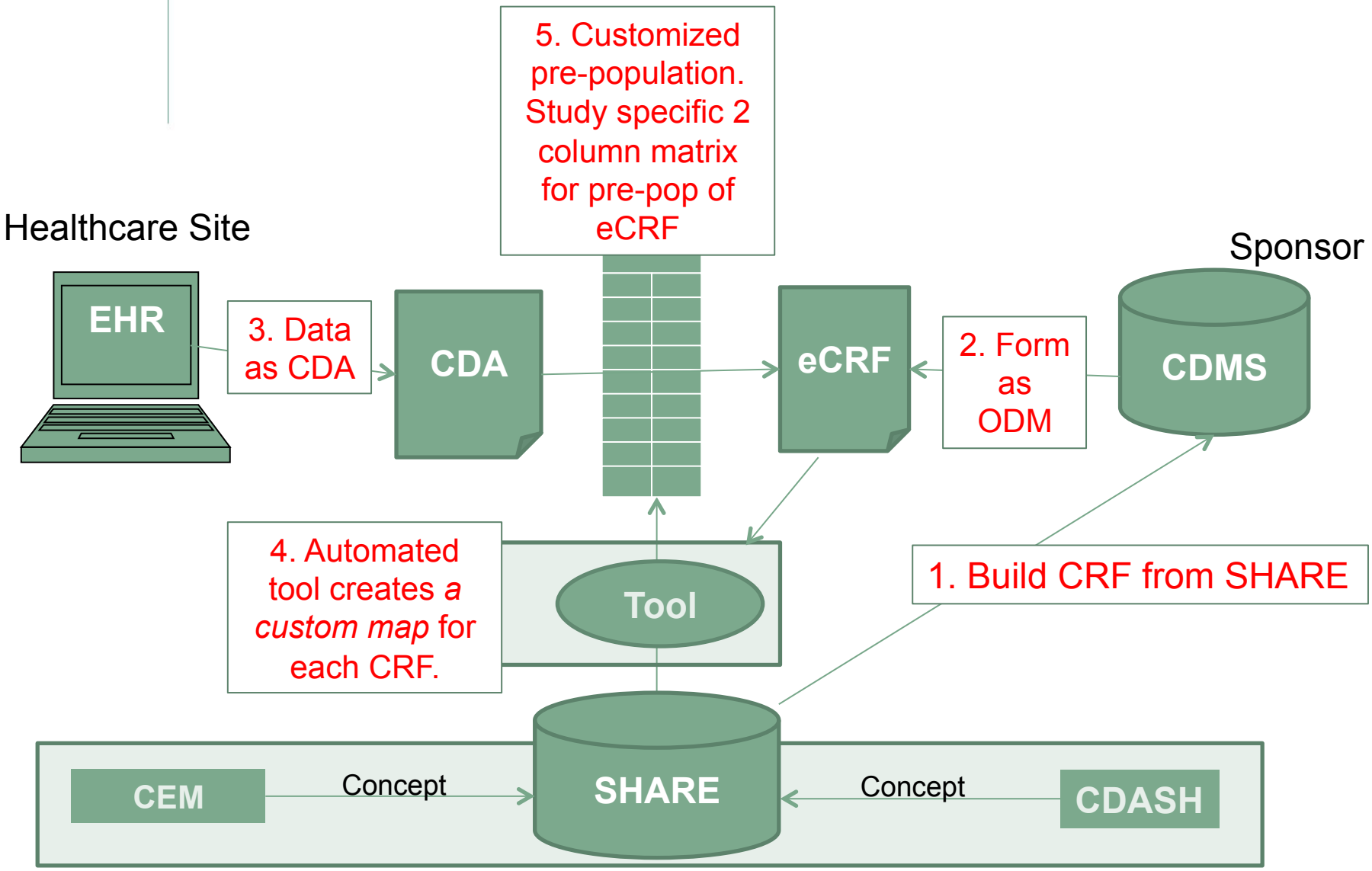
the CCD can be re-used to aggregate data from different EHRs.

A XML transform can render the HL7 document into useful research format



Document Export is useful, but brings its own problems

1. The XSLT is ‘one size fits all’.
    1. exports everything,
    2. maps some of everything
2. The form designer has no control over pre-population


5. Customized pre-population. Study specific 2 column matrix for pre-pop of eCRF
Healthcare Site
Sponsor
EHR
3. Data as CDA
CDA
eCRF
2. Form as ODM
CDMS
4. Automated tool creates *a custom map* for each CRF.
Tool
1. Build CRF from SHARE
CEM
Concept
SHARE
Concept
CDASH

Glossary

- CRD – Clinical Research Data, an IHE profile that maps CCD to CDASH/ODM.
- eCRD – electronic case report form, the basic data capture tool of clinical research.
- CCD – Continuity of Care Document, a type of CDA which summarizes a patient's status at a particular moment in time
- CDASH – a CDISC standard which defines the data elements common to Case Report Forms
- SHARE – CDISC's Metadata Repository
- CEM – Clinical Element Model
- RFD – Retrieve Form for Data-capture, an IHE infrastructure profile that enables web-service connection between EHRs and research systems.