FEATURE DOCUMENTATION

# Clinical Summaries and Meaningful Use

## A Primer

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### ABSTRACT

This paper will provide a solid foundation of the history, nature and context of clinical summaries. First, the author will discuss why clinical documents are important, including the business case for their use and the specific meaningful use requirements for clinical summaries. Next, the author will review the current context for using clinical summaries, including basic attributes of the two major clinical summary standards (CCD and CCR), as well as their roles in NHIN Exchange and NHIN Direct. Finally, the author will review barriers to using clinical documents effectively and will offer some steps to help overcome these barriers.

### KEYWORDS

Clinical documents, CCD, CCR, NHIN.

CLINICAL CARE summaries have become a key strategy in promoting and using electronic information to support patient care. They have also become a key component in meeting the requirements of meaningful use of electronic health records under the Centers for Medicare and Medicaid Services (CMS) EHR Incentive Program.

A subset of the meaningful use requirements focus on interoperability: the reliable and secure movement of health information *between* systems while leaving the meaning of that data intact. Clinical summaries are one of the primary means of organizing clinical information for interoperability, as well as formatting clinical data for easy viewing or reading.

However, from an information-processing standpoint, generating and using clinical summaries within information systems differs from traditional data extracts in critical ways.

Clinical summaries have many practical uses to clinicians. They are useful for assembling relevant data about a patient at key events, such as the transfer of care between providers (e.g., referral from a primary care physician to a specialist), discharge from a hospital or other facility and keeping patients informed about their treatment and care.

This paper will discuss aspects of clinical summaries and the underlying technology that they use—clinical documents. First, the paper will discuss why clinical summaries are important. What functions do they perform? Why would clinicians want to use them? What is their specific role in meaningful use? How are state-level health information exchange (HIE) programs using clinical summaries?

Next, the paper will address clinical summaries in context. How do clinical summaries fit into the larger data interoperability scheme? How are they constructed? What do they contain? How does building them and using them differ from traditional data processing extracts? How are they used by federal data interoperability initiatives, like NHIN Exchange and NHIN Direct? Finally, the paper will consider some common barriers to effective employment of clinical summaries, and suggest some mitigating strategies.

**Figure 1: Data-Centered Approach**

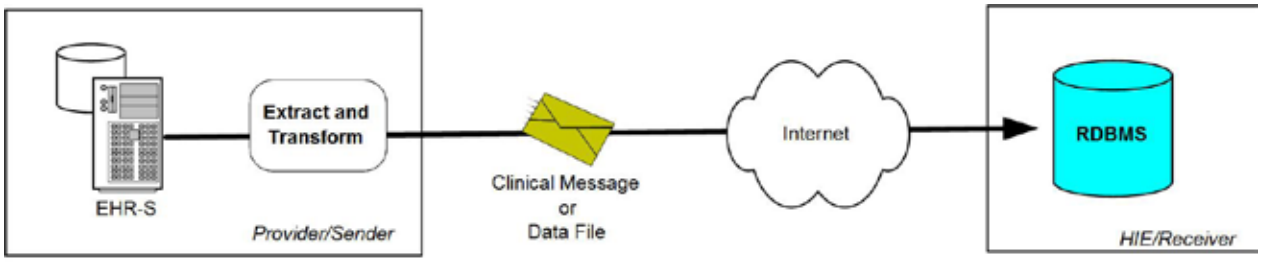
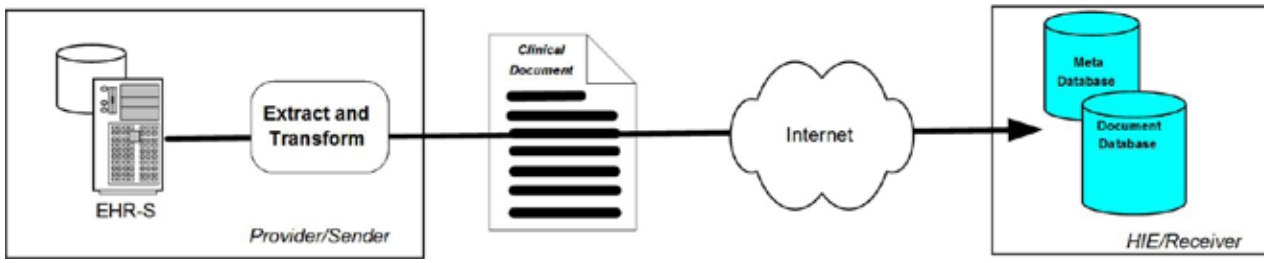



**Figure 2: Document-Centered Approach**




## WHY USE CLINICAL SUMMARIES?

There are a number of reasons why clinicians might want to use clinical summaries. Together they represent a strong business case for their use in support of clinical activities.

**Allows physicians to receive critical health data at transfer of care.** Clinical summaries contain critical patient health data that practitioners need, particularly at moments of transfer of care—between facilities and between individual caregivers. Standards development organizations (SDO) have worked for years with clinical input to define an appropriate set of data and an effective form of representing that data.

Most transfer-of-care documentation is idiosyncratically produced and inconsistent, often missing critical components and relying on the patient to transport information between providers. Failure to transfer this information can be significantly detrimental to patient care.

**Reduces cost in reproducing and transporting paper records.** Once an EHR system is configured to produce and transmit clinical summaries, the cost measured in both time and effort to generate and transport these records is significantly reduced over manual forms of reproduction and transportation.

**Reduces hassle to patient in completing new provider registration materials.** As patients move between providers, clinical summaries can reduce the time and trouble to the *receiving* clinician and to the *patient* by providing basic demographic data and clinical history that ordinarily would need to be provided by the patient manually. While paper records transferred with a patient may also contain this data, in practical terms patients are usually asked to transcribe this data—over and over again—onto paper forms used by the new clinician or facility.

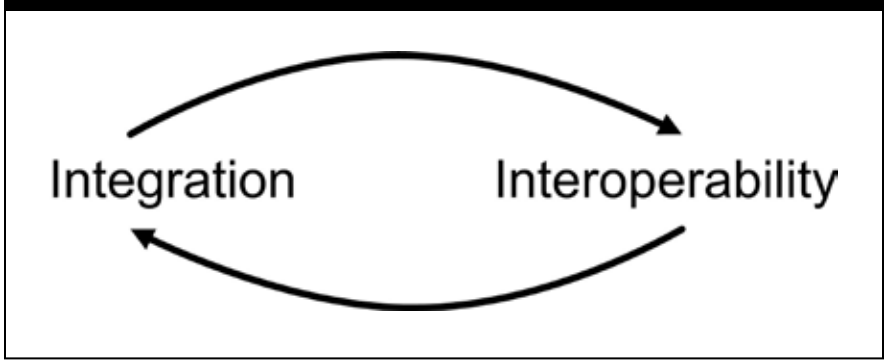
**Improves speed and accuracy of data absorption into the EHR.** A properly-configured and capable EHR system can absorb the electronic data in a clinical summary and can initialize a new patient record, or supplement an existing record, more quickly than manual data entry.

**Improves quality of care through complete and timely information.** As EHR systems are deployed more fully, and as they are brought into the clinical business process at the point of care, the data they contain will become more complete and will be available closer to the point of care in a more timely way. Clinical summaries will then be able to quickly provide summaries of care as they are extracted from these systems.

**Can provide patient with an accurate, readable record of a visit or encounter.** In addition to their use as a communications vehicle *between* clinicians, clinical summaries also provide an excellent summary of care for *patients* to receive. The nature of the technologies used to generate clinical summaries ensures that they are readable by machines and humans.

**Required by some measures of meaningful use.** As we will see below, clinical summaries are a key component in satisfying several important measures within meaningful use. For this reason alone, they

**Figure 3: Integration-Interoperability Cycle**




will increase in importance and EHR systems will adopt methods to both produce them and absorb their data.

**Easier to generate than other forms of e-data.** Given the broad range of health data they potentially contain, and the standards-based technologies used to represent this data, clinical summaries are relatively easy to generate, given the relative complexity of other forms of interoperable health data, like Health Level 7 (HL7) messages.

**Clinical summaries are extensible.** New types of data can be added to clinical summaries as the needs of the medical community change. Similarly, sections of clinical data can be left off a particular summary if they are not relevant to the care being offered a patient (for example, immunizations are provided in one section of a clinical summary, but their inclusion may not be necessary for, say, a healthy adult who may not be suffering from an infectious disease).

As we will see below, major standards development and harmonization organizations and vendor associations, have embraced clinical summaries as the preferred way of generating and exchanging health data, including HL7, the Health Information Technology Standards Panel (HITSP), Integrating the Healthcare Enterprise (IHE), the HIMSS Electronic Health Record Association (EHRA) and the Nationwide Health Information Network (NHIN) Initiative.

## CLINICAL SUMMARIES AND MEANINGFUL USE

The Medicare and Medicaid Programs Electronic Health Record Incentive Program Final Rule (July 2010) contains a number of objectives which are fulfilled using a clinical summary of some kind within the initial set of measures (Stage 1) of meaningful use, including:

- Provide patients with an electronic copy of their health information upon request.

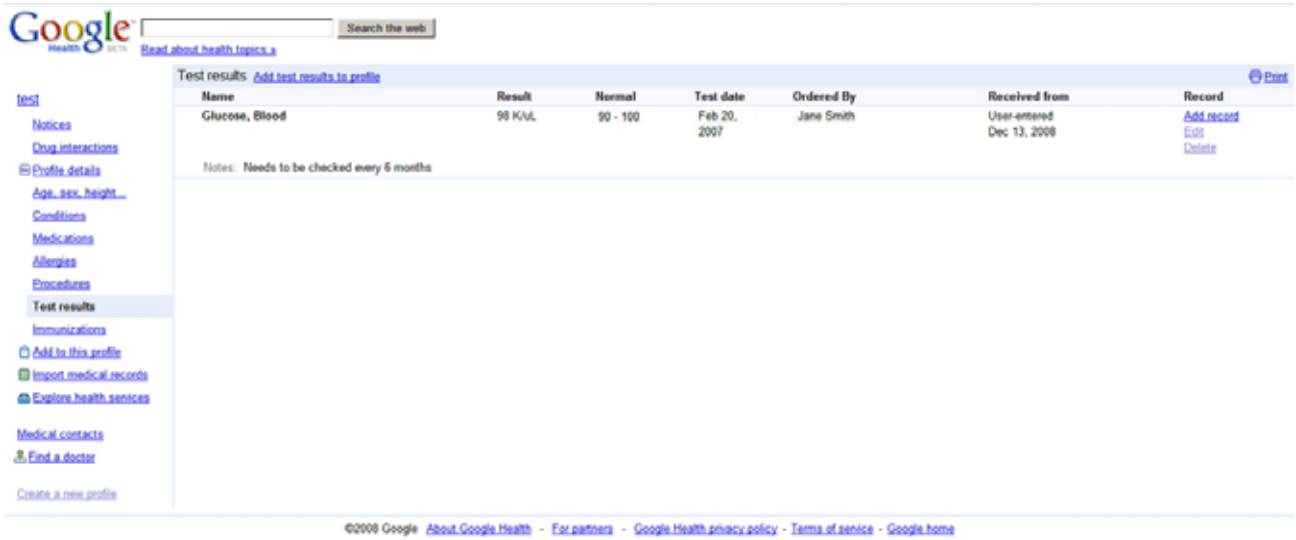
Provide a clinical summary for each visit.

- Exchange clinical information electronically with providers and patient-authorized entities.
- Provide summary care record for each transition of care and referral.
- Provide patients with an electronic copy of their discharge instructions and procedures.

In addition, several objectives could use clinical documents to fulfill their requirements, including:

- Incorporate clinical lab results into certified EHR technology as structured data.
- Various public health reporting objec-

**Fugure 4: CCR Representation in Google Health**



tives (immunization reporting, lab results reporting for communicable diseases, syndromic surveillance), though public health has been slow to implement clinical documents with its systems and processes.

This inclusion of clinical summaries in the Final Rule ensures that both EHR system vendors and clinicians will expect this capability relatively quickly. In addition, the *Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology* (July, 2010) states:

> *Clinical summaries. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:*
> *Provided in human readable format; and*
> *Provided on electronic media or through some other electronic means in accordance with...* (p. 44631)

This dual-purpose standard supports the measures identified above. Why did ONC adopt a dual standard rather than choose only one format? The Final Rule provides the following explanation:

> *We adopted both standards for a few reasons. First, we are aware, contrary to some commenters' statements, that a significant segment of the HIT industry still uses the CCR patient summary record standard and that some health care providers prefer the CCR over the CCD. For this reason, we did not want to mandate, at such an early stage, that all of these early adopters adopt a different summary record standard for the purposes of meaningful use Stage 1, given that electronic health information exchange is not required. Second, we understand that in some circumstances the CCR is easier, faster, and requires fewer resources to implement than the CCD. We have therefore concluded that it was appropriate to adopt the CCR standard for patient summary records in this initial set of standards. Finally, we believe that at the present time, each standard could equally be used to satisfy the requirements of meaningful use Stage 1.* (p. 44633)

**Table 1: Basic CCR Facts**

- An outgrowth of the Patient Care Referral Form (PCRF) designed and mandated by the Massachusetts Department of Public Health for use primarily in inpatient settings, but designed for all clinical settings.
- Core data set of the most relevant administrative, demographic and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
- Data set includes a summary of the patient's health status (for example, problems, medications, allergies) and basic information about insurance, advanced directives, care documentation and the patient's care plan.
- Primary use case is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.
- Specification specifies XML coding that is required when the CCR is created in a structured electronic format; permits users to display the fields of the CCR in multiple formats

**Table 2: Basic CCD Facts**

- Standard intended to specify the encoding, structure and semantics of a patient summary clinical document for exchange.
- Constraint on the HL7 Clinical Document Architecture (CDA) standard based on the HL7 Reference Information Model (RIM).
- Core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
- Primary use case is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.
- Developed as a collaborative effort between ASTM and HL7 as an alternate to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 CDA.
- Basis of many IHE profiles and HITSP constructs.

CLINICAL SUMMARIES are one of the primary means of organizing clinical information for interoperability, as well as formatting clinical data for easy viewing or reading.

## CLINICAL SUMMARIES AND THE STATE-LEVEL HIE PROJECT

As part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the Office of the National Coordinator for Health Information Technology (ONC) entered into cooperative agreements with each of the states and US territories to coordinate and support health information exchange activities within their jurisdictions. Nearly $550 million has been awarded under this program. The Funding Opportunity Announcement (FOA) instructs state applicants to:

> *Develop or facilitate the creation of a statewide technical infrastructure that supports statewide HIE. While states may prioritize among these HIE services according to its needs, HIE services to be developed include:*
> *Clinical summary exchange for care coordination and patient engagement (p. 13)*
> *A subsequent Program Information Notice (PIN) further states that,*
> *... states and SDEs shall outline in their Strategic and Operational Plans (state plans) a concrete and operationally feasible plan to address and enable these three HIE capabilities in the next year:*
> *Sharing patient care summaries across unaffiliated organizations (p. 3)*

Based on these instructions, the state-level HIE projects in each state and territory are required to plan for inclusion of clinical summary exchange in the strategic and operational plans for their projects. These plans are being developed first and foremost to support meaningful use within the states. The prominence of clinical summary exchange in their plans may result in states taking a stronger leadership role in the development of this capability, by encouraging things like:

- Focus on just one clinical summary standard to make it easier for EHR systems to interoperate (see below).
- Stronger insistence on more consistent terminology and semantics, which will make interoperability more reliable.
- Providing services, such as directory services, master patient index (MPI), and record locator services (RLS) to enable and facilitate health information exchange.
- Coordinate among other funded activities, like Regional Extension Centers and Beacon Communities, which are promoting HIE within states.

## CLINICAL SUMMARIES IN CONTEXT

Before we look at the structure and contents of clinical summaries themselves, we will examine the context of clinical summaries, and the underlying clinical document architectures, within health IT implementation. For years health IT professionals have been enabling interoperability between systems, both within organizations and between organizations. There are two approaches to preparing and processing information that originates in one system and is destined for another.

The first approach is data-centered. In this approach (see Figure 1) data is extracted from an EHR system (or any participating system), transformed into a data file (e.g., fixed length or delimited file) and sent to the recipient who processes the data into a database.

This has been a common mode of data interoperability for many years. Data-centered files can contain information about just one patient or about many patients depending on the use cases and systems involved. Examples of data centered files are HL7 version 2 messages and X12 messages.

The second approach is document-centered. In this case, data extracted from an EHR system (or any participating system)

**Figure 5: XML Code for CCR Lab Result**

```
<Results>
  <Result>
    <Test>
      <DateTime>
        <Type>
          <Text>Collection start date</Text>
        </Type>
        <ExactDateTime>2007-02-21T07:00:00Z</
      </DateTime>
      <Description>
        <Code>
          <Value>2339-0</Value>
          <CodingSystem>LOINC</CodingSystem>
        </Code>
      </Description>
      <TestResult>
        <Value>98</Value>
        <Units>
          <Unit>K/uL</Unit>
        </Units>
      </TestResult>
      <NormalResult>
        <Normal>
          <Description>
            <Text>90 - 100</Text>
          </Description>
        </Normal>
      </NormalResult>
      <Source>
        <Actor>
          <ActorID>Jane Smith</ActorID>
          <ActorRole>
            <Text>Ordering clinician</Text>
          </ActorRole>
        </Actor>
      </Source>
    </Test>
  </Result>
</Results>
```

is formed into a clinical document—usually expressed as an XML file (more on that below)—and sent to the recipient. But rather than process the data into a database, the clinical document is usually stored intact in a document repository (like an electronic filing cabinet). An additional "meta" database is maintained which has entries *about* each document to facilitate their retrieval (like information about the patient whose clinical data is in the document, but not the clinical data itself). Clinical documents typically contain data about just *one* patient at a time.

In many ways, the movement from data-centered to document-centered interoperability is seen by many as a progression. A data-centered approach supports discreet messages of data which are collected, processed, and interpreted by the receiving system. This supports the *integration* of data into the receiving system fairly well through well-defined transactions as data is absorbed into the receiving system's database and displayed as native data (though usually tagged with its system of origin).

A document-centered approach brings with it additional context, an easier ability to view the information received, and often a broader longitudinal snapshot of data within a single transaction. This exchange supports the *interoperability* of data between systems better than a data-centered approach as the data is potentially better able to support a clinician's needs within a single transaction (depending on how complete it was).

However, the "end game" we are striving for is one which supports a much richer, data-on-demand capability, which allows systems to query each other in a more dynamic, real-time way, and provide information back and forth that supports the clinical business processes required by their organizations. To do this well, systems will need to show the clinician data from multiple sources *integrated* into the system being viewed representing clinical *knowledge* that can be useful to the viewer. So with this vision we have come full-circle (see Figure 3) as we have increased the sophistication of the data exchange activity.

**Figure 6: Sample CCD**

**Good Health Clinic Continuity of Care Document**

**Created On:** April 7, 2000

| | | | |
|---|---|---|---|
| **Patient:** | Henry Levin , the 7th | **MRN:** 996-756-495 | |
| **Birthdate:** | September 24, 1932 | **Sex:** Male | |
| **Guardian:** | Kenneth Ross<br>17 Daws Rd.<br>Blue Bell, MA, 02368<br>tel:(888)555-1212 | **Next of Kin:** | Henrietta Levin<br>tel:(999)555-1212 |

**Results**

| | March 23, 2000 | April 06, 2000 |
|---|---|---|
| ***Hematology*** | | |
| HGB (M 13-18 g/dl; F 12-16 g/dl) | 13.2 | |
| WBC (4.3-10.8 10+3/ul) | 6.7 | |
| PLT (135-145 meq/l) | 123* | |
| ***Chemistry*** | | |
| NA (135-145meq/l) | | 140 |
| K (3.5-5.0 meq/l) | | 4.0 |
| CL (98-106 meq/l) | | 102 |
| HCO3 (18-23 meq/l) | | 35* |

What types of clinical summaries exist today, and what technologies and standards are used to create them? The *Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology* (July, 2010) provides the following dual-standard which is consistent with current software implementations:

> **"§170.205 Content exchange standards and implementation specifications for exchanging electronic health information**
> *(a) Patient summary record. (1) Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). Implementation specifications. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).*
> *(2) Standard. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in §170.299)."(p. 44649-50)*

So, one of these standards is based on the HL7 continuity of care document (CCD), and one is based on the older ASTM International continuity of care record (CCR). Let's look at each of these standards in a little detail.

The CCR is the older of the two standards. Basic facts about the CCR are found in Table 1.

Note that the primary use case is a point in time snapshot of a single patient. The detailed specification documents are available for a fee from ASTM International, but unless you are a software developer there is little need to consult them. Figure 4 shows an example of a CCR as it might appear on Google Health, in this case a lab test result.

Figure 5 shows the underlying XML code for that lab result. Note how much it looks like Hypertext Markup Language (HTML), which is why a Web browser can usually display these documents easily as long as an appropriate style sheet is available.

The CCD evolved out of the ASTM CCR based on a desire to represent similar information with a more flexible set of standards underneath. Basic facts about the CCR are found in Table 2.

**Figure 7: XML Code for CCD Lab Result**

```
<templateId root="2.16.840.1.113883.10.20.1.14"/>
<!-- Results section template -->
<code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
<title>Results</title>
<text>
    <table border="1" width="100%">
        <thead>
            <tr>
                <th> </th>
                <th>March 23, 2000</th>
                <th>April 06, 2000</th>
            </tr>
        </thead>
        <tbody>
            <tr>
                <td colspan="3">
                    <content styleCode="BoldItalics">Hema
                </td>
            </tr>
            <tr>
                <td>HGB (M 13-18 g/dl; F 12-16 g/dl)</td>
                <td>13.2</td>
                <td> </td>
            </tr>
            <tr>
                <td>WBC (4.3-10.8 10+3/ul)</td>
                <td>6.7</td>
                <td> </td>
            </tr>
            <tr>
                <td>PLT (135-145 meq/l)</td>
                <td>123*</td>
                <td> </td>
            </tr>
```

Note the similarity between the basic attributes of CCR and CCD. CCD information is available on HL7's Web site, but it is a little harder to find (embedded within the CDA standard) and usually requires paid membership to view the detailed specification documents. Figure 6 shows a sample CCD as it might be displayed in a Web browser.

Figure 7 shows the underlying XML code for the first lab result.

So what are the implications of these two approaches? Data-centered approaches (e.g., HL7 v2) which were introduced when computers were first applied to healthcare still dominate intra-organization interoperability (i.e., data exchange between applications within a hospital or other organization).

This affects an organization's technical capacity to shift to clinical summaries for external interoperability, so much of the installed base of *existing* inter-organizational interfaces is also data-centered (e.g., laboratory orders and results). HIEs seem to be moving to a document-centered approach (see next section), largely spurred on by the work of IHE.

## CLINICAL SUMMARIES AND NHIN

"The Nationwide Health Information Network (NHIN) is a set of standards, services and policies that enable secure health information exchange over the Internet." It is made up of a number of initiatives. NHIN Exchange, a demonstration project involving selected federal agencies and a number of partner organizations, relies on more sophisticated technology and is most suitable when participants do not necessarily know each other personally.

NHIN Direct is an initiative to create a simpler set of data exchange protocol specifications (and corresponding reference implementation software) to support point-to-point, secure exchange between known parties. Several key NHIN Exchange specifications rely on clinical documents, including query for documents, retrieve documents and document submission. These specifications rely on constructs developed earlier by HITSP (including TP13, C80, T31, and C32), which themselves rely on technical frameworks from IHE. Because of this heritage, NHIN Exchange specifications assume and expect, but do not require, CCDs. The current trial implementation network is primarily CCD-based.

NHIN Direct is developing specifications and software to fulfill a number of user stories, six to eight of which can be accomplished using clinical summaries. While NHIN Direct does not require any particular content format, it does recommend zipped IHE XDM files which are usually CCDs. There may be even more specific requirements if an NHIN Direct participant is communicating with an NHIN Exchange (or other HIE) participant who is not using NHIN Direct.

## CHALLENGES TO IMPLEMENTING CLINICAL SUMMARIES

A number of challenges exist to successfully implementing clinical summaries—and their underlying clinical documents—today, including:

**Hype vs. Reality.** Even though the HIE world seems to be moving quickly to document-centered standards, EHR systems have been slow to implement the capability to create or absorb a standards-based clinical summary, though most major products can *demonstrate* the capability in newer versions of their products. Additional work needs to be done to ensure that clinical data sources are compatible with clinical

DATA-CENTERED APPROACHES still dominate most data interoperability implementations, but clinical summaries are gaining ground due to the richness of their data representation and their pre-eminence within both federal HIE interoperability standards and vendor product development.

document technologies, and that EHR-S vendors fulfill their obligations to their clients to provide this capability. It is also critically important to understand that data alone does not fulfill any useful objectives: systems need to use data to provide useful *information* for its users.

**Extra Effort to Support Multiple Formats.** Though the Initial Set of Standards, Implementation Specifications, and Certification Criteria for EHR Technology (July 2010) recognizes both CCD and CCR as compliant document-centered formats, most EHR system vendors seem to be moving to CCD; personal health record (PHR) systems seem to be supporting CCR. Supporting both is far from ideal and will place an added burden on vendors and clinicians trying to use this technology. Over time, one format should emerge as dominant, most likely the CCD.

**Data Aggregation Assues.** It is often useful to create a "summary of summaries" in a document-centered approach, since it may be difficult for a clinician or patient to weed through a growing collection of clinical document effectively. But combining information from multiple clinical summaries into one document may be problematic, including the need to eliminate duplicate (and even harder, near-duplicate) information, and preserving the clarity of the information's source(s). In addition, clinical summaries do not easily support data aggregation and reporting *across patients* unless they are further processed and their data integrated into a more traditional database management system.

**Data Content Issues.** Some types of data that might be included may have additional privacy/security restrictions (e.g., mental health, adolescent health, some communicable diseases such as HIV/AIDS). Additional parsing—and scrutiny—may be required before clinical summaries are exchanged; policy development may also be required to ensure compliance with law which varies across the country to prevent that transport of clinical summaries that inadvertently contain data segments (which can be as subtle as a lab result, progress note or medication) that reveals something about a patient that is protected.

**Semantic Interoperability Issues.** Different providers and EHR systems may use different coding and semantic standards, making exchange with retention of clinical meaning more challenging. Data exchange partners will need to develop policy, negotiate with stakeholders to converge on a single set of standards and access translation services if available. State-level HIE projects may assist in providing some of these policies and services.

## CONCLUSION

Clinical care summaries have become a key strategy in promoting and using electronic information to support patient care. They provide clinicians with a critical tool for quickly and accurately moving data between parties to support a wide variety of clinical needs and information-sharing requirements.

Data-centered approaches still dominate most data interoperability implementations, but clinical summaries are gaining ground due to the richness of their data representation and their pre-eminence within both federal HIE interoperability standards (best exemplified by NHIN specifications) and vendor product development (best exemplified by the Integrating the Healthcare Enterprise initiative). Additional work still needs to be done to minimize and overcome some of the challenges identified in this article. Perhaps more pervasive use of document-centered technologies will provide the incentives necessary to address these issues. **JHIM**

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