

# Putting It All Together: EHRs and Integrating Data For Clinical Trials

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# Arguments for using patient care data for clinical research

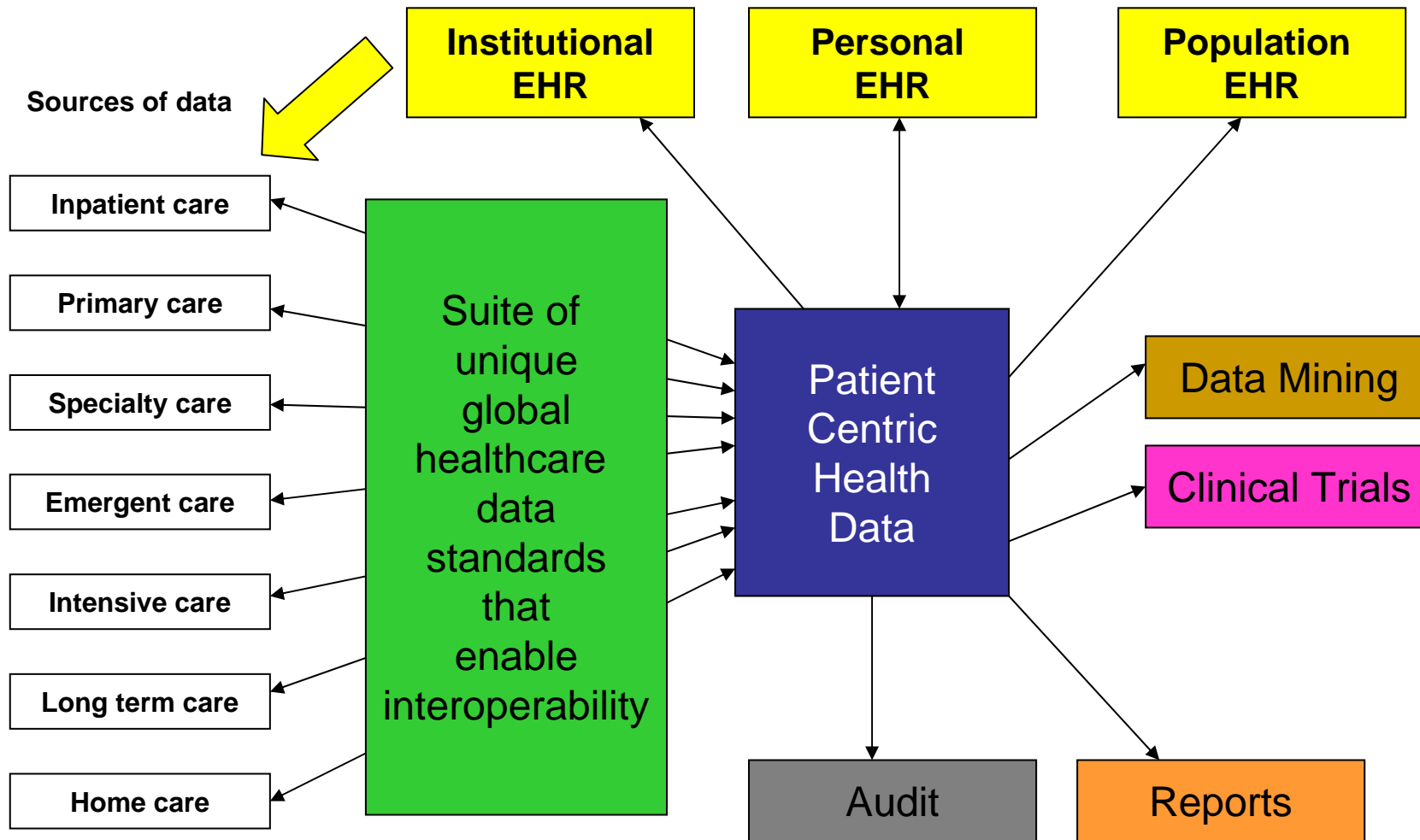
- Cost: separated EDC and EHR systems are redundant and are overly expensive.
- Interoperability: both patient care and research would benefit through structured data collection through consistent and precisely defined data elements that are semantically interoperable.
- Volumetric: All persons, with their permission, would be able to contribute to clinical trials and the extraction of knowledge for evidence-based medicine.
- Speed: Research results would be available more quickly and the time frame from bench to bedside would be significantly reduced.
- Accuracy: Data collected for both patient care and research would be more accurate as a result of computer algorithms and expanded use of data.
- Completeness: Structured data, structured clinical statements, structured documents and structured EHRs with result in more complete and more meaningful documentation.

# Arguments against using patient care data for clinical research

- Not the same data collected for patient care as for clinical research
  - Some experts say as little as 50% overlap
- Providers don't have time to collect additional data
- Data collected for patient care
  - Will always be of lower quality because of lack of motivation, lack of time, interruptions
  - Will be inconsistently collected
  - Will be incomplete, unstructured and uncontrolled

# Additional Issues

- Patient care data needs to be what actually is measured rather than an interpretation
  - Record actual temperature rather than elevated temperature
  - Record actual cholesterol rather than elevated cholesterol
  - Record actual dates of occurrence rather than sore throat within the last 6 months
- Identification of candidates for clinical trials will be automatic. Studies on rare diseases will become easier as candidate patients will be identified world-wide.
- Global Clinical Trials Registries (such as the AMIA GTB) will be updated and maintained automatically



# Standards for interoperability

- Data Elements
  - A single term for each element
  - Single data type
  - Expert-defined, precise definition
  - Units
  - Value set of possible values (function of data type)
- Structures built from data elements
  - Templates or archetypes
    - Compound elements, complex structures
  - Clinical Statements
- Structured Clinical Documents (CDA, CCD)
- Transport Standards (data, audio, images, waveforms)
- Communication Standards
- Security and Confidentiality Standards
- EHR Architecture and Functional Requirements
- Decision Support including Research protocols and guideline specifications

# The Future Clinical research

-Case report form data

## Concept

-Basic science and pre-clinical data

## Guidelines

-Data-driven decision  
support

### Data standards

Data elements

Terminology

Data interchange

## Outcomes

-Patient registries

## Quality indicators

-Patient care data

## Performance measures

-Aggregated reporting and metrics

# Admission Sx Presentation

## Row 4 of the spreadsheet

Data Element Name: Permissible Value Set Name Or Format 1	Data Element Definition 1	Data Element Definition or Permissible Value Set 2	Data Element Definition or Permissible Value Set 3	Data Element Definition or Permissible Value Set 4	Data Element Definition or Permissible Value Set 5
Template for color coding of Number of studies per Definition	1	2	3	4	5 or more
<b>Admission Sx Presentation</b>	<p>Changeable: Heart Failure, Coronary Artery Disease, Unstable Angina, Syncope, Cerebral Vascular Disease, peripheral vascular disease, Acute MI</p> <p>Stable = Angina that is controlled by oral and/or transcutaneous medication. Patients that are painless with or without medication but with a history of angina are captured here.</p> <p>Unstable = Angina which necessitates the initiation, continuation or increase of angina control therapies that may include: nitroglycerin drip, heparin drip, or IV BP placement. The type of angina may include, but is not limited to: rest angina, new onset exertional angina of at least I New York Heart Association (NYHA) Class III in severity, recent acceleration in pattern and increase of one NYHA class to at least NYHA Class III, variant angina, non-Q wave myocardial infarction, or post-infarction angina.</p>	<p>1. <b>BT MI</b> is defined as an ACS in which there is cardiac marker evidence of myocardial necrosis (e.g., positive CK-MB) and new (or presumably new if no prior ECG is available) ST-segment elevation on the admission ECG. (For a complete definition, please refer to "MI" in the "Outcomes" section.)</p> <p>2. <b>UBT MI</b> is defined as an ACS in which there is cardiac marker evidence of myocardial necrosis (e.g., positive CK-MB or Troponin) without new ST-segment elevation. (For a complete definition, please refer to "MI" in the "Outcomes" section.)</p> <p>3. <b>BBU/Unstable type</b>. For a complete definition, please refer to "MI" in the "Outcomes" section.</p> <p>4. <b>Unstable angina</b> is defined as angina pectoris (or equivalent type of ischemic discomfort) with any 1 of the 3 following features:</p> <ol style="list-style-type: none"> <li>Angina occurring at rest and prolonged, usually greater than 20 minutes</li> <li>New-onset angina of at least I CCS classification, II severity</li> <li>Recent acceleration of angina reflected by an increase in severity of at least 1 CCS class, b) at least CCS class III</li> </ol> <p>The patient must also not have any biochemical evidence of necrosis.</p> <p>5. <b>Stable CAD</b>: The patient has a clinical diagnosis or prior history of CAD, but after evaluation in the hospital, the episode of discomfort was not thought to have represented unstable angina</p> <p>6. <b>Noncardiac chest pain</b>: Pain in the chest, neck, or arms or abdomen (or other clinical manifestations) not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin</p>	<p>1. MI as defined in endpoint section</p> <p>2. <b>Unstable Angina</b> is defined as angina that occurred at rest and was prolonged, usually lasting more than 20 minutes - or - new onset angina of at least I CCS III severity - or - recent acceleration of angina reflected by an increase in severity of at least 1 CCS class to at least CCS III class.</p> <p>3. <b>Stable Angina</b> angina without a change in frequency or pattern for the six weeks before this procedure. Angina is controlled by rest and/or sublingual/oral/transcutaneous medications.</p> <p>4. <b>Atypical Chest pain</b>: pain pressure or discomfort in the neck, chest or arms, not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin.</p>	<p>Asymptomatic, chest pain, dyspnea, fatigue, syncope, cardiac arrest / labor or sudden death, other symptoms, unknown</p>	<p>ST Depression, transient ST elevation for less than 10 minutes, positive cardiac markers, new LBBB, persistent ST Elevation</p>

**Admission symptoms are described using many contributing data elements**

# Breaking down a data element to its pieces

Data Element Name	Permissible Value Set Name Or Form	Data Element Definition				
Template for outloading of Number of studies per Definition	1					
Admission or Presentation	<p>Typical angina present prior to this surgical intervention.</p> <p>Stable = Angina that is controlled by oral and/or transcutaneous medication . Patients that are pain free with or without medication but with a history of angina are captured here.</p> <p>Unstable = Angina which necessitates the initiation, continuation or increase of angina control therapies that may include: nitroglycerin drip, heparin drip, or IABP placement. The type of angina may include, but is not limited to: rest angina, new onset exertional angina of at least New York Heart Association (NYHA) Class III in severity, recent acceleration in pattern and increase of one NYHA class to at least NYHA Class III, variant angina, non-Q wave myocardial infarction, or post-infarction angina.</p>	Congestive Heart Failure, Coronary Artery Disease, Unstable Angina, Myocardial Infarction, Cerebral Vascular Disease, Peripheral Vascular Disease, Acute MI				
	Valid Response Values	<table border="1"> <tr> <td data-bbox="1008 734 1612 1101">Stable</td> <td data-bbox="1612 734 2072 1101">Angina that is controlled by oral and/or transcutaneous medication . Patients that are pain free with or without medication but with a history of angina are captured here.</td> </tr> <tr> <td data-bbox="1008 1101 1612 1524">Unstable</td> <td data-bbox="1612 1101 2072 1524">Angina which necessitates the initiation, continuation or increase of angina control therapies that may include: nitroglycerin drip, heparin drip, or IABP placement.</td> </tr> </table>	Stable	Angina that is controlled by oral and/or transcutaneous medication . Patients that are pain free with or without medication but with a history of angina are captured here.	Unstable	Angina which necessitates the initiation, continuation or increase of angina control therapies that may include: nitroglycerin drip, heparin drip, or IABP placement.
Stable	Angina that is controlled by oral and/or transcutaneous medication . Patients that are pain free with or without medication but with a history of angina are captured here.					
Unstable	Angina which necessitates the initiation, continuation or increase of angina control therapies that may include: nitroglycerin drip, heparin drip, or IABP placement.					



# Challenges

- Engaging the international clinical community in creating therapeutic domain content
- Defining a structure to develop domain content as well as cross domain content
- Defining a process in which research requirements can easily be integrated into patient care systems
- Identifying an acceptable organization to be the repository for the master set of data elements plus terminology and other attributes
- Identifying and developing tools to support the entire process
- Funding demonstration projects for proof of concept
- Identifying one standard for one purpose