Clinical and Research Use of PHR Data

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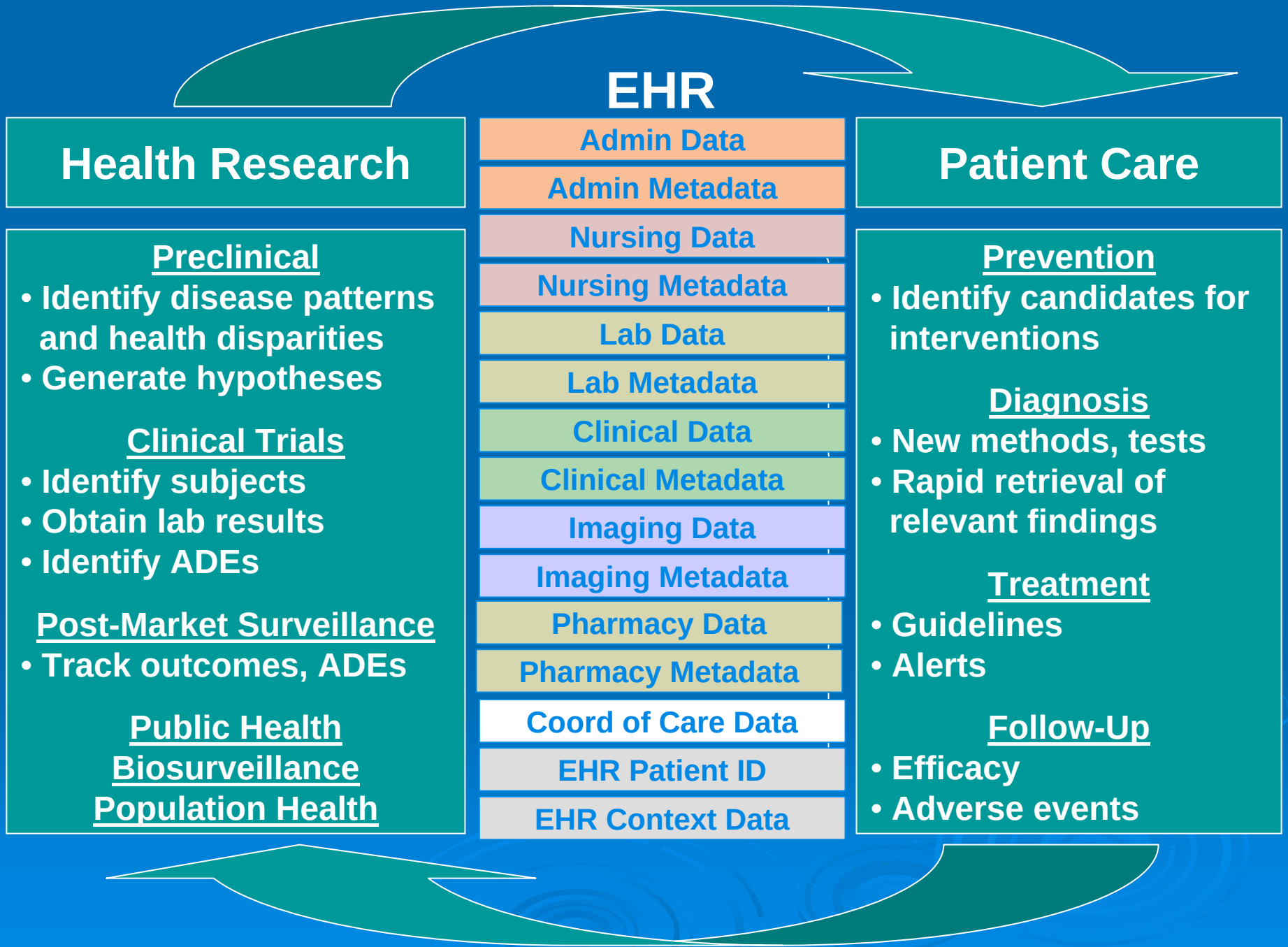
What Does Biomedical Research Have To Do With PCHRI?

- Research needs patient information for
  - Clinical trials
  - Outcomes research
  - Detection of adverse events
  - Phenotype information
  - Clinical research
- Properly structured and managed personally controlled health records (PCHRs) can be used to provide information to benefit patients and biomedical research.


EHR
Admin Data
Admin Metadata
Nursing Data
Nursing Metadata
Lab Data
Lab Metadata
Clinical Data
Clinical Metadata
Imaging Data
Imaging Metadata
Pharmacy Data
Pharmacy Metadata
Coord of Care Data
EHR Patient ID
EHR Context Data
Health Research
Preclinical
• Identify disease patterns and health disparities
• Generate hypotheses
Clinical Trials
• Identify subjects
• Obtain lab results
• Identify ADEs
Post-Market Surveillance
• Track outcomes, ADEs
Public Health
Biosurveillance
Population Health
Patient Care
Prevention
• Identify candidates for interventions
Diagnosis
• New methods, tests
• Rapid retrieval of relevant findings
Treatment
• Guidelines
• Alerts
Follow-Up
• Efficacy
• Adverse events

Personally Controlled – A Key Factor

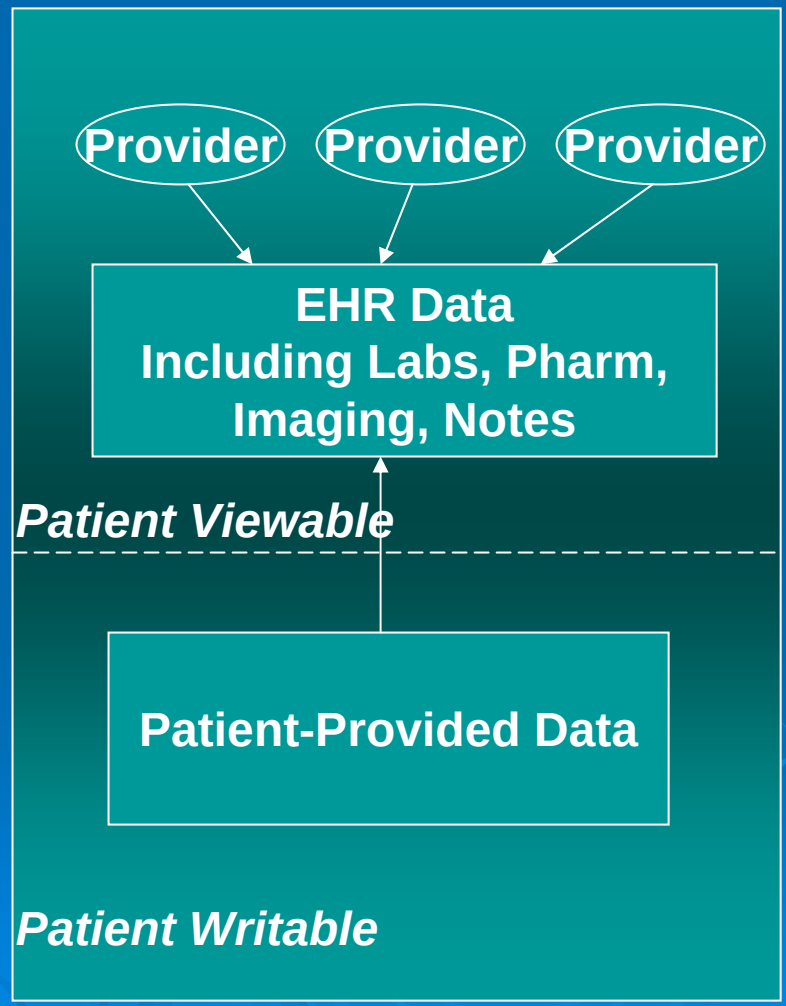
- If clinical data are ***personally*** controlled, they will not be useful for most research purposes, but
  - **Anecdotal or patient-self report data can be useful for some types of research**
  - **Using the PCHR system as a means to communicate with patients can be valuable.**

Patient-Provided Data

•Patient questionnaires for clinical research
•Diaries of symptoms, etc. can be useful for understanding the patient's progress with a given therapy, quality of life, etc.
•Allergy reports
•Patient perceptions of possible adverse events
•Family histories
•Use of supplements and alternative medicine

A Longitudinal ***Personal*** Health Record Is Something Else

- Would contain EHR data that is NOT under patient control
- Would allow the patients to add to the data, annotate, provide histories, etc., in a separate work space.
- Would have to clearly partition the data provided by the patient versus that provided by EHR systems.



Other Uses for PCHR Systems

- **Communicate with patients for clinical research**
  - **Build awareness, with targeted information tailored to age, location, health problems**
  - **Request participation in clinical research**
  - **Provide a support environment for research participants**
    - **Calendar for appointments, FAQs, ADE reporting, etc.**
- **Allow the PIs to communicate with the patients at the end of the research programs**
    - **Notify when results are published**
    - **Provide a permanent record for patient and their physicians, in case questions arise later concerning the research interventions.**
    - **Allow long-term follow up, especially for reporting of ADEs.**
- **A permanent, longitudinal record system could be very valuable for follow up**

What Can Be Done To Improve Information Exchange?

- Use standardized EHR data to feed the PHR and *maintain* standardization
- Provide mechanisms to extract data from PHRs for clinical research, with appropriate patient consents and approval
- Provide means for clinical researchers to reach patients with research-related news and requests for participation
- Follow up at the conclusion of a trial and provide a way for patient to remain in touch with the investigators

Use the Same Standards

- The same standards should be used by biomedical researchers and clinicians to the extent possible
- Standards being developed by biomedical researchers need to be integrated with clinical data and the EHR as new technologies mature
  - Imaging standards evolving for MRI annotation
  - Standards for new tests like DNA microarrays and proteomics need to be developed and incorporated before these tools move into the clinic
  - PHR standards, to capture patient-provided information in a structured form

Work Together To Improve Standards

- Ensure that metadata requirements adopted by the EHR community include the specificity needed for biomedical research, and work with all stakeholders to achieve inclusion of standardized metadata in the EHR
- Work with the research community as new terminologies evolve so they can be mapped to existing terminologies to allow interoperability and integration into the EHR
- Work with the PHR community to ensure that evolving PHR systems capture data in a standardized way

Work Together To Gain Patient Trust

- Explain the value of the records for biomedical research
- Show patients how they can participate
  - Population-based research
  - Clinical trials, clinical research in community settings
- Show them what self-provided information would be really useful
  - ADEs, family histories, outcomes, etc.
- Build trust in the clinical research process early on

Research results drive advances in medical care.

- ***Prevention***
- ***Detection***
- ***Intervention***
- ***Outcomes analysis***

Patient care outcomes shape the medical research agenda.

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