BUILDING PRIMARY CARE RESEARCH INFRASTRUCTURE AT YOUR COMMUNITY HEALTH CENTER

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First Edition
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Toolkit Overview

• This toolkit is designed to provide Community Health Centers with the elements needed to build a primary care research infrastructure.

• The toolkit is organized in eight easily-navigated, interactive, stand-alone modules.
Contents

Module 1: Quality Improvement and Research
Module 2: Building Primary Care Research Infrastructure
Module 3: Data
Module 4: Study Design and Methods Overview
Module 5: Dissemination and Action
Module 6: Funding your Research
Module 7: Partnerships for Research
Module 8: Ethics and the Institutional Review Board
Module 3
Data
Module 3 Learning Objectives

After completing this module, participants will be able to:

1. Describe the benefits and limitations of utilizing electronic medical records for research and quality improvement efforts.
2. Identify infrastructure to address analytic needs.
3. Identify elements of data storage security and maintenance (e.g. databases, HIPAA compliance).
4. Identify components of a data use agreement.
“A patient record system is a type of clinical information system, which is dedicated to collecting, storing, manipulating, and making available clinical information important to the delivery of patient care. The central focus of such systems is clinical data and not financial or billing information.”

EMRs are Designed for Clinical Care *Not* Research
Benefits of EMR for Research

- Provides easy access to patient data
- Allows examination of large and longitudinal cohorts/datasets and patient-level diagnosis and treatment data
- Integrates billing, pharmacy, radiology and laboratory information in a central location
- Facilitates queries to identify patients by diagnosis, procedures, medications, etc.
Using EMR for Quality Improvement

- Increased adherence to guidelines through computerized provider order-entry (CPOE) systems or decision support tools
- Enhanced surveillance and monitoring can facilitate novel methods of delivering care
- Reduction in medication errors
- Improvement in preventative care (e.g. vaccination and screening rates)

What is in the EMR for Research/QI?

• Health information from clinical encounters
• Lab and procedure results
• Orders (e.g. pharmacy)
• Billing information
• Administrative processes (e.g. appointments)
• Health management registries

What Does Research/QI Require?

• Searchable system
• Discrete data elements
• Ability to facilitate prospective and retrospective research
• Standard language
• Consistent definitions
Limitation of the EMR for Research/QI

- Providers decide where to put information
- Information may be entered as free text
- Images are scanned
- Flexibility in terminology
- Minimal number of required fields (i.e. data that is not important to clinical care is missing)

Limitation of the EMR for Research/QI

• Quality of data (e.g. missingness)
  – Evaluate the extent of missing data and discuss reasons for missingness
    • Delete records with missing data prior to analysis
    • Use analytic strategies (e.g. imputation) to address missingness

• Observational data (i.e. non-experimental)
  – No inclusion/exclusion criteria
  – No data on what happens outside the system (e.g. other medical visits)
Maximizing EMR Research Capabilities

• Train providers on how to reliably and completely enter data
• Develop consistent definitions and vocabulary
• Develop online informed consent procedures
• Hire onsite data manager to ensure data quality
EMR Example

• Dr. Jones wants to conduct a study with obese patients. He is interested in learning about disparities in his patient population compared to another site. So after getting an IRB approval, he requests a data pull from the EMR to identify the patients who might meet criteria in 2 clinics.

How many patients in my clinic fit BMI obesity criteria?
• Dr. Jones asked for the following:
  – BMI data by category on all patients seen for primary care in clinic A and clinic B over a 6 month period
  – “seen in primary care” was defined as having at least one visit with a provider at the clinic (acute and preventive). This excluded nursing visits and telephone encounters
  – Patients > 18 years of age
EMR data showed large number of patients without BMI data in the chart. In addition, there were large differences between the amount of missing data by clinic.
Data Raised New Questions

- Was data missing because it was never actually collected? Or was it just not entered?
- Why did one clinic have higher rates of collection and recording than the other?
- Were patients who had BMI in their charts different than those that did not?
- Were the clinics different from one another (systems, staffing, etc)?
Take home messages

• Data requests need to be clear
  – What’s in the EMR, where is the report being pulled from, what are the limitations of those sources?

• Evaluate missing data and discuss strategies to address this

• Garbage in garbage out

• Look before you leap (into research)
Building Analytic Infrastructure

• What is ideally needed:
  – Designated analytic expertise: individuals with expertise in data pulls, knowledge of current data, basic statistical analysis, etc.
  – Request system: a system for collecting data requests (e.g. online form)
  – Request process: a process for fulfilling data requests

Please see Appendix D for a sample Data Consultation Request Form.
Building Analytic Infrastructure

• What if you don’t have the resources:
  – Find outside contractors with analytic expertise
  – Utilize trainees or students from local universities to support analysis
  – Partner with academics and their teams
Sample Analytic Request Process

Investigator has research question

Investigator meets with analyst leadership to define research question

Initial simple data pull is free

Further information requires additional analytic support

Analyst assigned

Data pulled from Data Warehouse
- Claims
- EMR
Data Storage and Maintenance

• Multiple ways to store data
  – Microsoft Access, Microsoft Excel, Text file, SAS data set

• Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191
  • Mandates that all covered entities fulfill certain requirements for data backup, data storage, and data recovery
Data Storage and Maintenance

**Data Backup**
Ability to maintain and access retrievable, exact copies of data

**Disaster Recovery**
Ability to restore data in the event of a data loss resulting from fire, vandalism, natural disaster, or system failure

**Data Storage Retention**
Retention of data in a secure location
Reducing Risk for Inadvertent Disclosure

- When possible, use anonymous data
- Create formal, written plan for data security
- Use confidentiality agreements with all individuals accessing the data
- Limit data access only to key staff
- Do not share raw data electronically (e.g. via email)
- Create password protected data storage system
Data Use Agreement

• Establish a written Data Use Agreement in advance, including:
  – Agreement between whom? (e.g. organization and researcher, collaborator and researcher, etc.)
  – Ownership of information
    • Who will own the documents and data?
    • Who will keep the original data and who will have a copy?
Data Use Agreement

– Term and termination
  • Who will have access to the data during and after termination of study?
– Data storage and usage
  • How will data be stored?
  • How and who will use the data?
– Liability
– Compensation
Discussion Questions

• If you currently have an EMR at your organization, how do providers and staff utilize the EMR system? What are providers’ perceptions around EMR and EMR use?
• If you do not currently have an EMR at your organization, how might adopting an EMR change the way in which providers and staff provide care to patients at your organization? How might providers and staff use the EMR for research/quality improvement efforts?
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