Brookings Webinar on Medical Countermeasures Surveillance

Findings from a Mini-Sentinel Medical Countermeasures Surveillance Field Test

Engelberg Center for Health Care Reform
The Brookings Institution
July 29, 2014

Linking Data from Public Health Medical Countermeasure Campaigns with Electronic Health Records

The Mini-Sentinel Medical Countermeasure Post-marketing Surveillance Project

Rationale

Marsha E Reichman, PhD
Senior Advisor & Scientific Lead for Surveillance Programs
CDER Sentinel Initiative Lead
OPE/OSE/CDER/FDA

KAISER PERMANENTE®

DENVER HEALTH
Level One Care for ALL

Denver Public Health
Promotion • Preparedness • Prevention • Protection

NACCHO
National Association of County & City Health Officials

Issues in Safety/Efficacy Surveillance During & After MCM Events

- Dispensing of MCM interventions in non-traditional medical settings – "PODS" –points of dispensing
  - Without identifying/contact information cannot follow for adverse outcomes or contact for follow-up doses, further treatment
  - Do not generate medical claims or administrative data
  - One person may obtain intervention for multiple others
- Some MCM interventions may not be previously approved, may be approved for other indications, may lack sufficient safety and/or efficacy data
  - Need for during and post MCM event follow-up for adverse health outcomes.

Project Goals

- Implement a field test of mobile device capable of capturing identifying information in an MCM setting
  - Primary public health goal is to get the MCM to the impacted population as rapidly as possible; data collection must not disrupt distribution of MCM interventions
  - Without undo burden on participants
  - Making use of existing documents (driver licenses, health insurance cards, etc.) from those that have them
  - Facilitating linkage to safety/efficacy databases such as the Mini-Sentinel Distributed Database (MSDD)
- Assess the successes of the field test and indicate areas for enhancement to be fully effective in an MCM event

Brookings Webinar on Medical Countermeasures Surveillance

Findings from a Mini-Sentinel Medical Countermeasures Surveillance Field Test

Engelberg Center for Health Care Reform
The Brookings Institution
July 29, 2014

Linking Data from Public Health Medical Countermeasure Campaigns with Electronic Health Records

The Mini-Sentinel Medical Countermeasure Post-marketing Surveillance Project

Arthur J. Davidson, MD, MSPH

Matthew F. Daley, MD

Outline

- Mini-Sentinel
- Medical countermeasures (MCM)
- “HANDI” device: a tool for rapid collection of standardized patient data
- Kaiser Colorado field exercise: pilot use of HANDI for external collection of MCM data; link to clinical data
- Conclusions

Mini-Sentinel Pilot Project

- FDA-sponsored Sentinel Initiative, launched in response to Congressional mandate (2007 FDA Amendments Act)
- ***Perform active surveillance of the safety of approved drugs through use of routinely collected electronic health information***
- Goal – national, integrated, electronic system for monitoring medical product safety using a distributed dataset
- Mini-Sentinel is a pilot program charged with developing the framework, data resources, analytic capabilities, policies, and procedures to satisfy the 2007 Congressional mandate

Mini-Sentinel

- Uses pre-existing healthcare data from normal business activities; multiple sources (i.e., Data Partners)
- Uses a distributed data approach, Data Partners retain control over data in their possession
- Depends on distributed dataset; relies on Common Data Model at each partner site
- Data Partners execute standardized computer programs or queries within their own institutions and share aggregated results with the Mini-Sentinel Operations Center
- Medical countermeasures (MCM) surveillance is an area of focus within Mini-Sentinel

Medical Countermeasures (MCMs)

- Pharmaceutical (e.g., vaccine, antimicrobials, antidotes and antibody preparations)
- Non-pharmaceutical (e.g. ventilators, devices, and personal protective equipment)
- Used to prevent, mitigate, or treat adverse health effects of an intentional or naturally occurring public health emergency
- Lack a comprehensive and integrated approach to monitoring and assessing the safety of MCM drugs and vaccines administered

MCM Surveillance

- Despite availability of several voluntary surveillance systems (FAERS, VAERS), capabilities to monitor and assess adverse events associated with MCMs delivered during a public health emergency remain limited.
- Unique challenges associated with MCMs:
  - Dispensing occurs during a public health emergency
  - Capturing individual identifiers for those receiving MCM
  - Linking MCM exposure data to various adverse event surveillance systems

FAERS: FDA Adverse Event Reporting System; ***VAERS:*** Vaccine Adverse Event Reporting System

MCM Dispensing

- Involves participation from all levels of government, as well as non-governmental and civilian partners
- Local governments, in particular health departments (LHD), play a lead role in public health emergency response
- Centers for Disease Control and Prevention (CDC) works with local and state public health systems to ensure preparedness and response during public health emergencies, including plans for MCM distribution and dispensing
- Planning is guided by CDC's Public Health Preparedness Capabilities: National Standards for State and Local Planning

MCM Dispensing

- In limited cases, MCMs may be managed, dispensed and documented within traditional health care systems
- In large-scale cases, alternative methods are required to rapidly dispense MCMs to a broad population
  - Use of local, state, and/or regional caches of drugs and vaccines or the CDC's Strategic National Stockpile (SNS)
  - Points of Dispensing (PODs)
- PODs can be structured in a variety of ways:
  - "Pull" and "push" mechanisms
  - Medical, non-medical, open, and closed

Data Collection during MCM Dispensing

- Jurisdictional plans include data recording protocols to report data on those receiving MCMs
- Currently, most data collection is paper-based and does not support linkage of MCM exposure data to electronic healthcare data (e.g., adverse events)
- To improve safety surveillance for MCMs delivered via PODs, policies, processes, and guidance for collecting data on individuals exposed to the MCM will need to be developed, enhanced, and/or modernized

Mobile Data Collection Tool

- DPH's Hand-held Automated Notification for Drugs and Immunizations (HANDI)
  - iOS mobile app
  - Web-based administration tool (HANDIMan)
  - Server-based database
  - Health Level 7 (HL7) compliant

- Utilizes barcode/magnetic stripe scanning technology through use of "sled"
- Captures images of health insurance cards

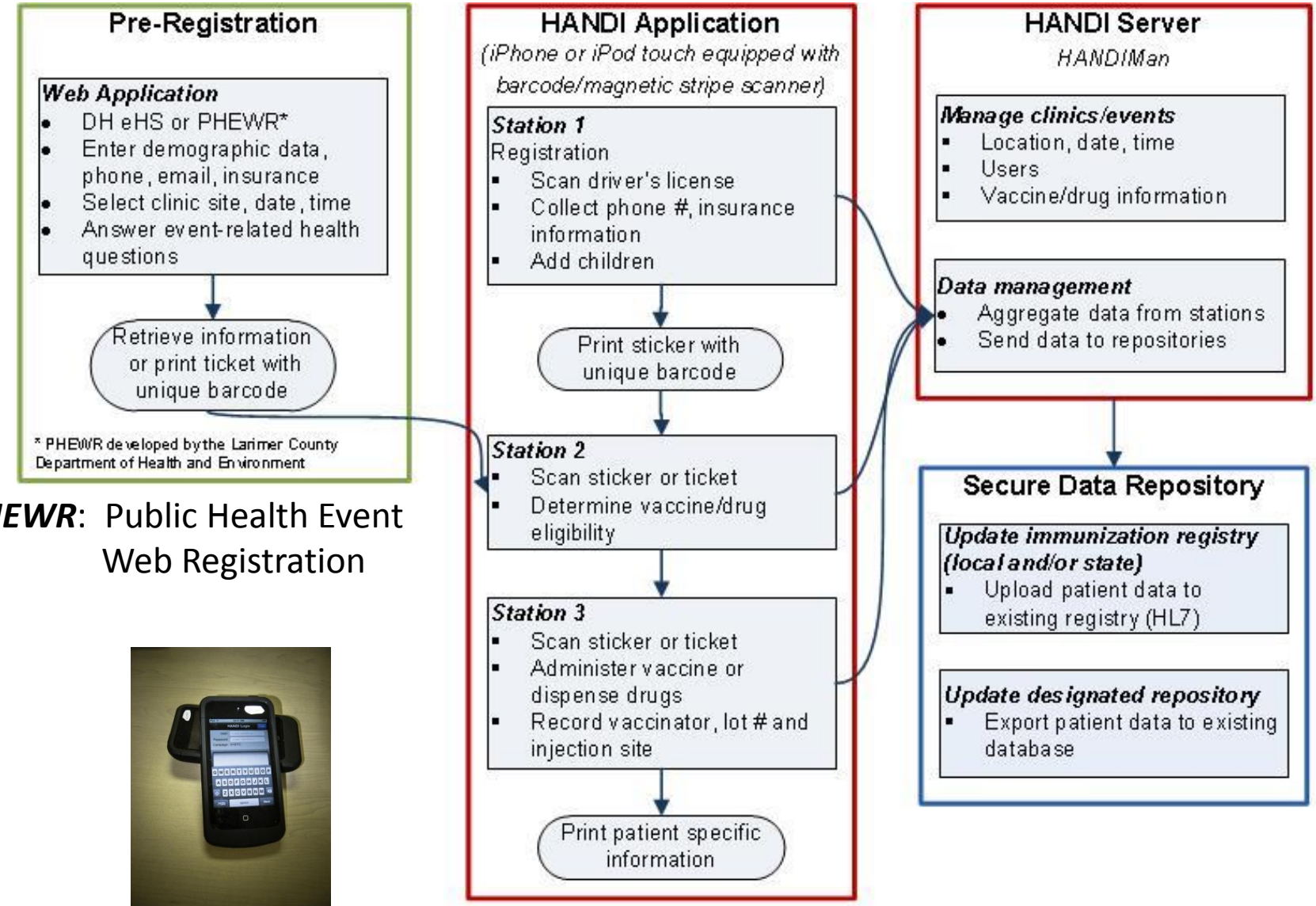
HANDI – Background and Objective

- In 2009-2010, many LHDs had to mount major H1N1 vaccine campaigns. Challenges included:
  - Tracking vaccine and who was vaccinated
  - Time consuming patient registration
  - Data entry afterwards - resource intensive, often incomplete and inaccurate
- ***Objective:***
  - ***to support efficient public health immunization and prophylaxis activities through rapid collection and transfer of standardized data***

HANDI - Flexible 3 Station Workflow

- Station 1 – Demographic/Insurance
- Station 2 – Eligibility/Contraindications
- Station 3 – Administration/Documentation
- If stations used separately, unique patient barcode generated and printed at Station 1 for scanning at Stations 2 and 3
- Optional pre-event web registration

HANDI - Workflow and Interfaces

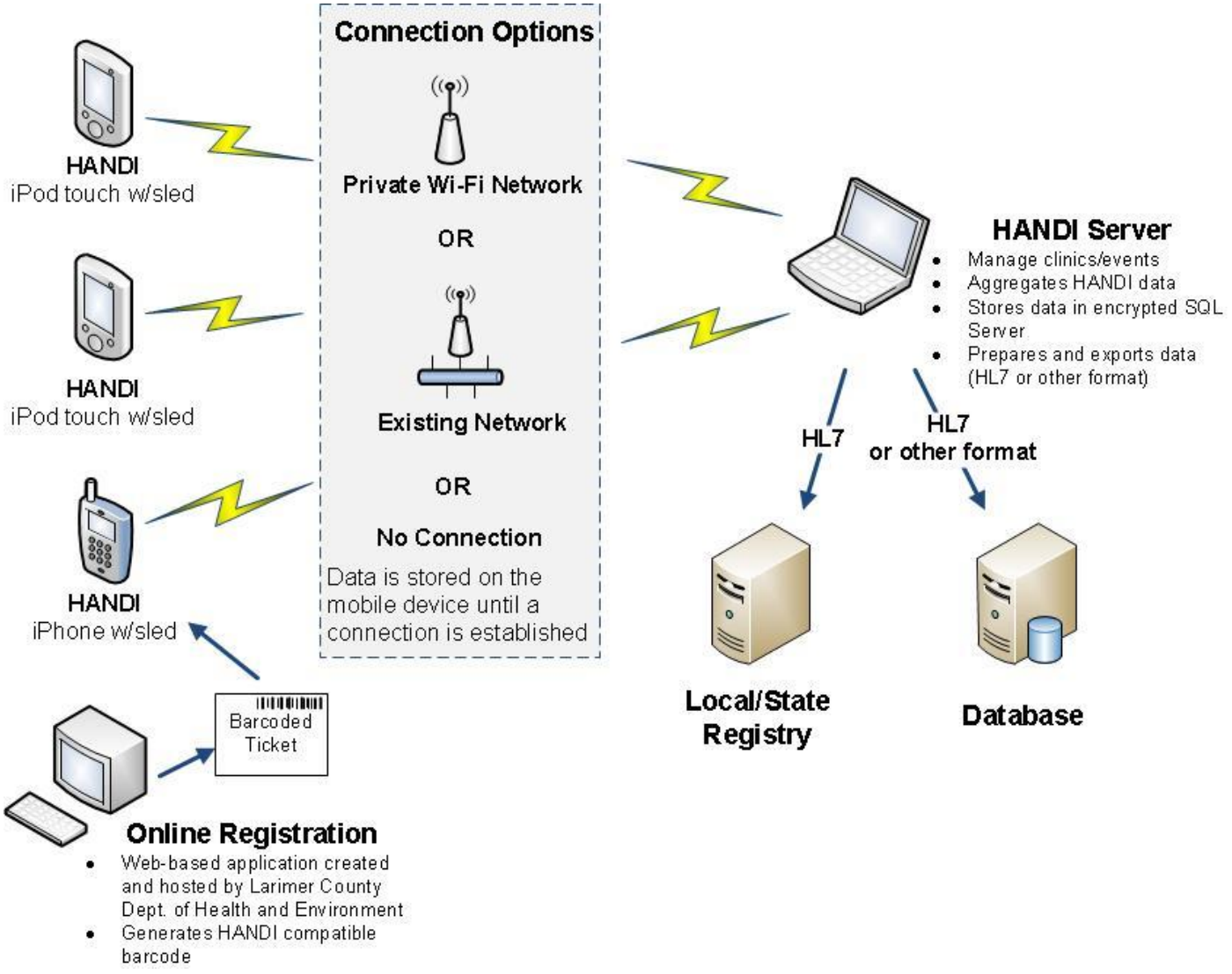


**** PHEWR***: Public Health Event Web Registration

HANDI - Network Environment/Security

- Network Topologies
  - HANDI dedicated network
    - HANDI Server
    - Wi-Fi access point
  - Existing network
  - No connection during data collection
    - Data is stored on device until a connection is established
- Data encrypted with Advanced Encryption Standard (AES-256)
- Mobile Device Manager - Good

HANDI Network Environments



Denver Health Employee Flu Vaccine Campaign

- HANDI used during the 2012, 2013 employee campaigns
  - Employees pre-registered on DH intranet
  - At vaccination, HANDI users scanned employee badges, recorded vaccinator and injection site
- 2012 – vaccinated ~3,000 employees during week of mass clinics
- 2013 – vaccinated ~5,700 employees at mass clinics, community clinics, other DH divisions
- Made process significantly more efficient

Additional HANDI Applications

- Tdap (pertussis) Vaccination
  - Childcare worker outreach – Winter 2013, n ~ 400
  - 9News Health Fair – May 2014, n=54
- Emergency Preparedness POD Exercises
  - DPH staff retreat lunch dispensing, conference registration
  - NACCHO Preparedness Summit, April 2014
- HANDI users report that data entry is easy, straightforward, intuitive, and fast

HANDI - Next Steps

- Expanded data model to accommodate a wider range of services
  - PPD (tuberculosis) testing
  - DH ED patient ID/insurance card retention
  - Healthcare outreach
- Health Level 7 (HL7) messaging
  - Triage of message and linkage to EHRs
  - Direct transfer from device to data repository
- Streamline hardware - test use of device camera to replace expensive scanner; locate HANDI server in secure cloud
- Improve mobile device management

Field Test Objectives

- Primary: among patients presenting for routine care at Kaiser Permanente Colorado (KPCO), determine whether patient identifying information could be gathered using external mobile device, linked to KPCO's information systems and the local KPCO Mini-Sentinel Database (KPCO MSD)
- Secondary: determine whether same process could be used at influenza vaccination clinics, with additional collection of vaccine information

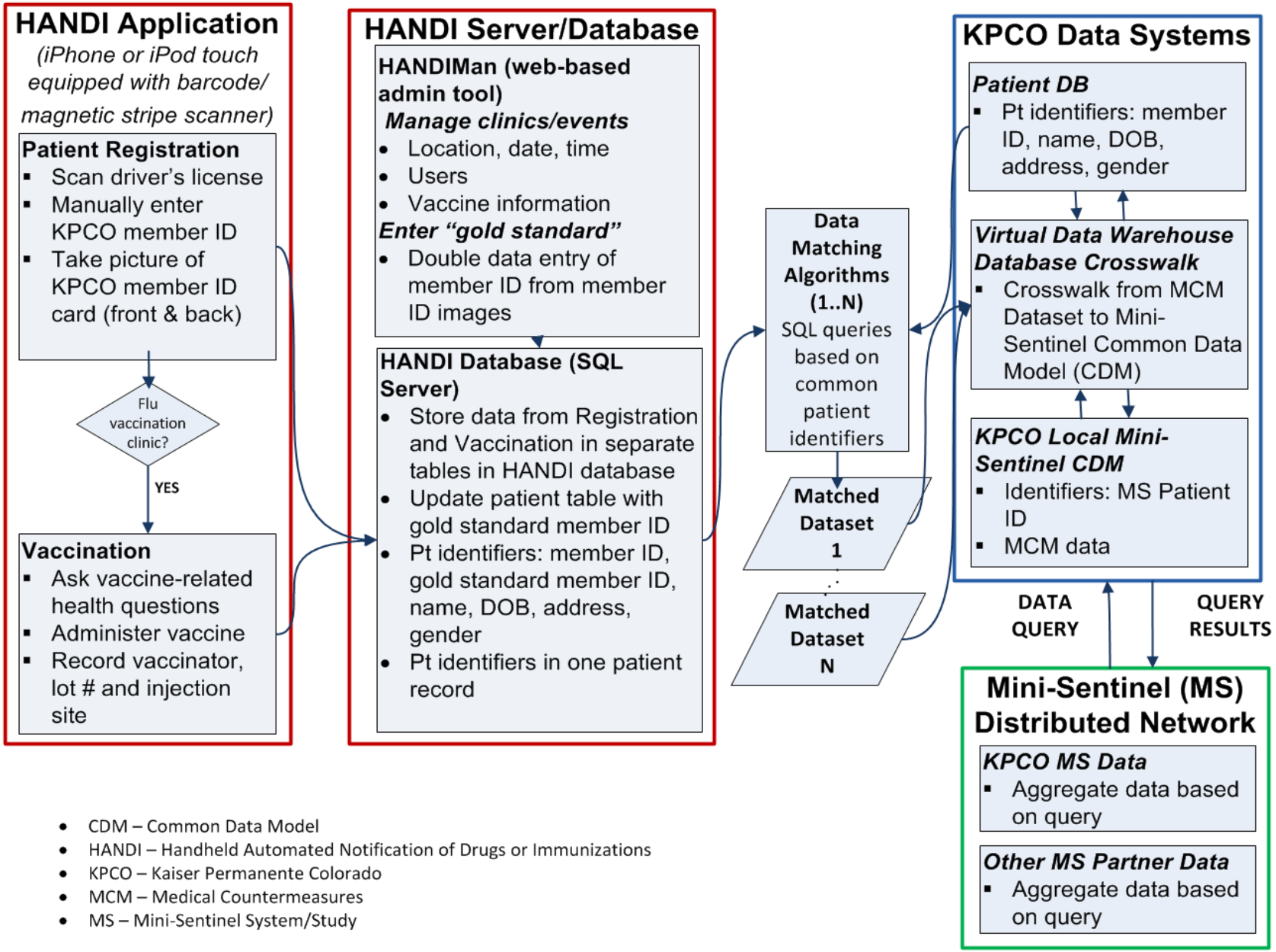
Methods – Field Exercise

- Project team: Mini-Sentinel, FDA, Denver Public Health (DPH), Kaiser Permanente Colorado (KPCO) and the National Association of County and City Health Officials (NACCHO)
- Setting:
  - KPCO primary care clinic site between 11/2013 -1/2014
  - KPCO influenza vaccination clinic in 11/2013
- Population: convenience sample of adults checking in for routine care

Methods – Data Collected

- Scan of the patient's driver's license magnetic stripe or 2-D barcode: first and last name; address; date of birth; gender
- Manually entered KPCO member ID number (e.g. health record number) by touch pad
- Photograph of KPCO member ID card (captured as "gold standard" for matching to KPCO member database)
- Influenza clinics only: detailed vaccine information (e.g. type, lot, expiration date, site)

Data Flow



- CDM – Common Data Model
- HANDI – Handheld Automated Notification of Drugs or Immunizations
- KPCO – Kaiser Permanente Colorado
- MCM – Medical Countermeasures
- MS – Mini-Sentinel System/Study

Methods – Data Matching

- Matching algorithms applied to link HANDI data to the KPCO patient information system and then to the local KPCO Mini-Sentinel database
  - **Driver's license data to KPCO enrollment data -** used exact first name, last name, and date of birth stored in HANDI to match to KPCO member enrollment data
  - **Hand-entered member ID to enrollment data -** used hand-entered member IDs from HANDI data to match to KPCO member enrollment data
  - **"Gold standard" member ID to enrollment data**- used the double-entered member ID from the member ID card image to match to KPCO member enrollment data

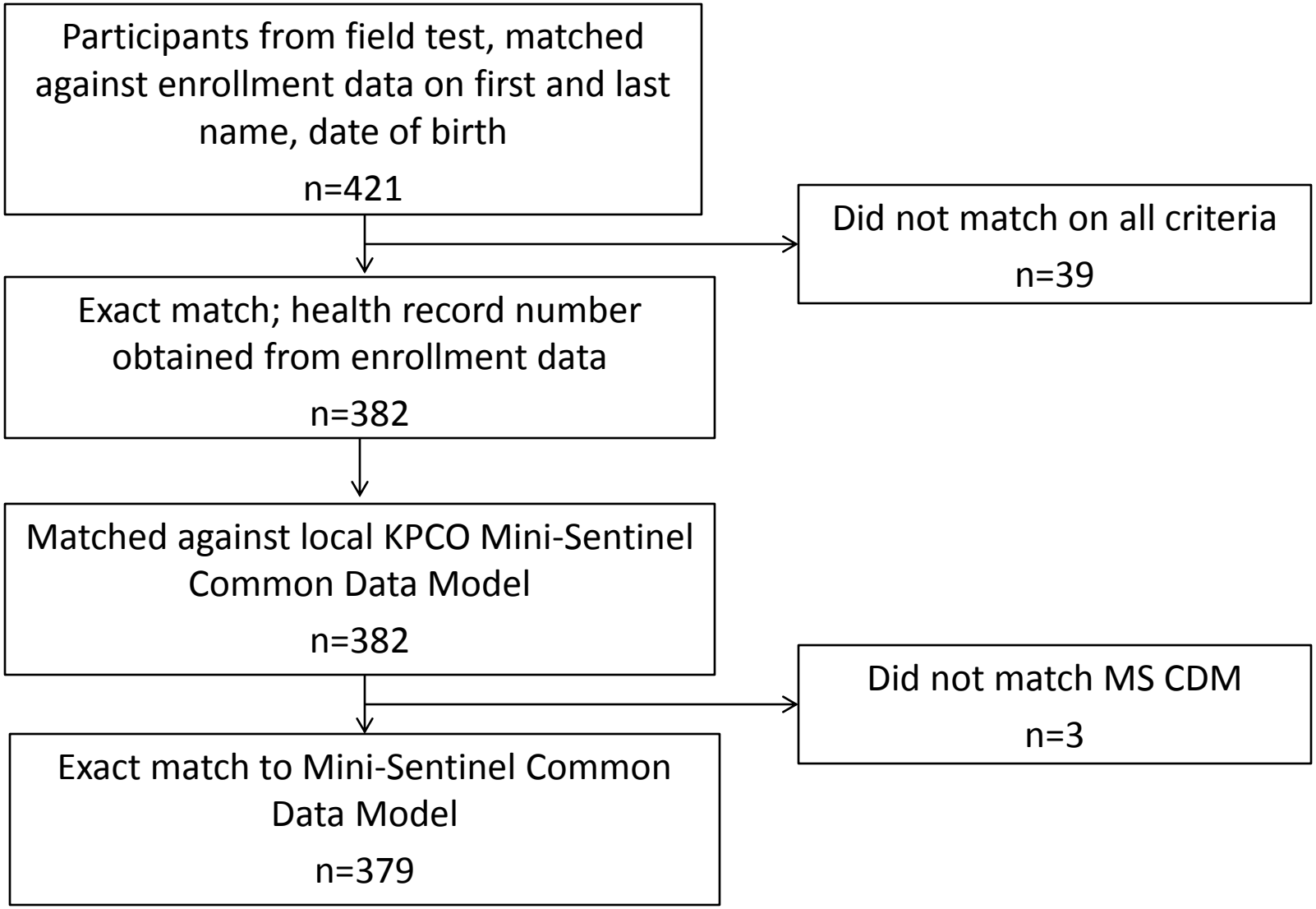
Results-Deployment

- HANDI successfully deployed at KPCO
- KPCO staff found HANDI easy to use and non-disruptive to patient flow
- Data collected in non-connected environment – data stored on device and 'synched' with server following data collection event

Results-Driver's License

- n=464 approached for participation
- n=431 (93%) agreed to participate
- n=10 did not have readable photograph of their KPCO health insurance card, and therefore did not have a "gold standard" of their true identity; excluded from all analyses
- Sample for matching analyses, n=421

Results-Driver's License



Additional Results

- Reasons for non-match from driver's licenses: hyphenated names; formal versus nick-names (Jim versus James); family members; name changes
- Matching hand-entered health record number to health plan enrollment: 417 of 421 matched (99%)
- Influenza vaccination clinic pilot:
  - 21 patients participated; all matched to MS CDM
  - All data elements (vaccine type, lot number, dose, manufacturer) exact match with electronic health record except site (right versus left deltoid, 88% match)

Discussion

- A mobile device was successfully used to capture patient data and MCM information
- High match rate (90%) achieved using name and DOB from driver's license
- Reasons for non-matches: subtle name differences, name changes, data update lags
- Relational database model used; subsequent data integration will leverage HL7
- Linkage to MS distributed dataset builds capacity to link adverse events treated in the course of regular medical care

Limitations

- Used routine patient care instead of real or simulated MCM dissemination
- Conducted within a single healthcare system among patients seeking care
- Matching accuracy may not be generalizable to other events where public receives a MCM
  - Could not assess "true negatives:" individuals who did not match with KPCO, but should not have matched
  - Less likelihood for "false positives:" individuals wrongly matched to KPCO members based on name, DOB

Beyond the Field Test

- Field test offers proof of concept for linking externally collected MCM exposure data to a Data Partner's information system and its local MS CDM
- As efforts to improve MCM safety surveillance continue, additional consideration will need to be given to the following:
  - Data access authorization, ownership, and use
  - Data sharing/transfer and interoperability among a number of partners and systems and across jurisdictions
  - Increased implementation of electronic data collection, electronic health records, and health information exchanges
  - Improved electronic data collection capabilities
  - Timeliness/freshness of the data (for assessment)
  - Additional guidance, funding, and support for health departments and MCM distribution and dispensing planning

Acknowledgements

- Kaiser Permanente Colorado – Matthew Daley, Kristin Goddard, Carsie Nyirenda, Ted Palen
- Denver Public Health – Art Davidson, Melissa McClung
- NACCHO – Gretchen Weiss, Paul Etkind
- Mini-Sentinel/Harvard Pilgrim – Richard Platt, Susan Forrow
- FDA – Marsha Reichman, Brooke Courtney

Brookings Webinar on Medical Countermeasures Surveillance

Findings from a Mini-Sentinel Medical Countermeasures Surveillance Field Test

Engelberg Center for Health Care Reform
The Brookings Institution
July 29, 2014