MINI-SENTINEL DATA ACTIVITIES

MEDICAL COUNTERMEASURES SURVEILLANCE

FIELD TEST REPORT

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October 7, 2014

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Mini-Sentinel is one piece of the Sentinel Initiative, a multi-faceted effort by the FDA to develop a national electronic system that will complement existing methods of safety surveillance. Mini-Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Mini-Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223200910006I. This specific project was funded by the Center for Drug Evaluation and Research (CDER) Task Order 7 (Contract number HHSF22301007T).

Mini-Sentinel Data Activities

Medical Countermeasures Surveillance Field Test Report

Table of Contents

I. EXECUTIVE SUMMARY

During public health emergencies, such as a severe influenza pandemic or an anthrax attack, medical countermeasures (MCMs) (e.g., drugs and vaccines) may be needed to prevent or treat the health impacts of a particular threat. While a number of medical product surveillance systems exist, collecting, analyzing, and using information about MCM use during emergencies present unique challenges. The goal of the Mini-Sentinel Medical Countermeasure Surveillance Field Test was to determine whether patients presenting for care at a primary care clinic within the Kaiser Permanente Colorado (KPCO) health care system could be uniquely identified using an external mobile data collection system, accurately linked to their individual medical record within KPCO, and subsequently linked to the local KPCO database used for Mini-Sentinel public health surveillance. The broader purpose of the field test was to develop capacity to assess safety outcomes of exposures to drugs and vaccines administered as medical countermeasures, especially in non-traditional settings, in response to a public health emergency.

A project team comprised of representatives from Mini-Sentinel (MS), the U.S. Food and Drug Administration (FDA), Denver Public Health (DPH), KPCO, and the National Association of County and City Health Officials (NACCHO) developed a protocol to link externally collected MCM data for KPCO members to KPCO's information systems and subsequently to the local KPCO Mini-Sentinel Distributed Database (KPCO MSDD). In this context, "externally collected" means that information was gathered from KPCO members using a process that was outside of the KPCO electronic health record and patient registration system. The team conducted a field test from November 2013 through January 2014 at KPCO routine patient registration and at an influenza immunization clinic at a single primary care facility within the KPCO system. DPH's Hand-held Automated Notification for Drugs and Immunizations (HANDI) mobile data collection tool was used to capture standardized, encrypted patient demographic and vaccination information. When patients presented for care, the HANDI device equipped with a barcode/magnetic stripe scanner was used to scan the patient's driver license, photograph the KPCO member ID card, manually enter the KPCO member ID and capture influenza vaccination information. Matching algorithms were applied to link the HANDI collected data to the KPCO electronic health record and then to the local KPCO MSD.

For the patient registration component, a total of 464 individuals were approached while checking in for routine care; of these, 431 (93%) agreed to participate, and 33 (7%) declined participation. Among the 431 who agreed to participate, 10 subjects did not have a readable photograph of their KPCO health insurance card, and therefore did not have a "gold standard" of their true identity. These 10 subjects were excluded from all analyses. All 421 subjects included in analyses had a first name, last name, and plausible date of birth extracted from their driver license.

When using the exact last name, first name, and date of birth from the driver license, 382 of 421 (91%) were matched with a patient from the KPCO enrollment database, while 39 of 421 (9%) were not matched. Among the 382 individuals with a match, the health record for 5 individuals (1%) did not match the health record number (HRN) from the gold standard. Among the 377 individuals with a match of HRN to the gold standard, 374 (99%) were matched to the Mini-Sentinel Common Data Model used for surveillance. Taking these matching steps in aggregate, among the 421 individuals participating in the field test, 374 (89%) were correctly matched to a record within the Mini-Sentinel surveillance system.

During the field test, the HANDI device was also piloted during the annual fall influenza vaccination campaign at KPCO to determine whether the device could accurately collect detailed information about influenza vaccines administered to KPCO members. In addition to the driver license and KPCO member ID card information the following additional data points were collected about the vaccination: specific antigen (e.g. influenza), lot number, manufacturer, expiration date, dose, site (e.g. right deltoid), administrator, and administration date. A total of 21 individuals participated in this part of the overall pilot. Of these 21 participants, all were accurately matched to the "gold standard" HRN. Among data elements on vaccination that were captured by both HANDI and the KPCO electronic health record, only vaccination site (i.e. right deltoid versus left deltoid) was not matched with 100% accuracy.

It is important to recognize certain limitations of the field test, particularly because it was not conducted in the context of an actual MCM event. The field test was conducted among KPCO members presenting for care at KPCO, and the matching was to a database including all active KPCO members. KPCO members presenting for care at KPCO may be more likely to participate in sharing their driver license information than the public would be to share this information in a true MCM event. In addition, while the KPCO population is generally representative of the population of Colorado, these results may not generalize to specific populations, such as the uninsured. Additionally, in an MCM event, with participants from multiple health care organizations, sophisticated methods for data query and response would be needed to either "push" or "pull" data from the MCM event to the correct health care organization for each individual. Such mechanisms for data query and response would need to be established, multiple organizations would need to be involved, and technical challenges could be encountered.

Overall, the field test conducted at KPCO demonstrated the feasibility of using a hand-held mobile device to collect patient information from driver licenses and health plan cards, and that this information could uniquely and accurately link individuals to their health record and the Mini-Sentinel Distributed Database in the large majority (89%) of cases. It was also demonstrated that the HANDI device was capable of capturing detailed and accurate information about administration of influenza vaccine, a capacity that is analogous to what may be needed to capture information about a medical countermeasure during a public health emergency.

II. BACKGROUND

A. FOOD AND DRUG ADMINISTRATION'S MINI-SENTINEL PILOT

Begun in September 2009, Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system - the Sentinel System - to monitor the safety of FDA-regulated medical products. The Sentinel System is part of the larger Sentinel Initiative, which is the FDA's response to the Food and Drug Administration Amendments Act of 2007 (FDAAA) requirement that the FDA work with public, academic, and private entities to develop a system to obtain information from existing electronic healthcare data from multiple sources to assess the safety of approved medical products.

Mini-Sentinel uses electronic healthcare data obtained in the normal course of business by institutions such as health insurance providers and health maintenance organizations. These data partners, in concert with academic institutions such as medical centers and schools of public health, provide

scientific and organizational expertise to the pilot. Mini-Sentinel's collaborating institutions currently include 18 data partners and over a dozen academic organizations.[1]

Mini-Sentinel uses a distributed data approach in which data partners maintain physical and operational control over electronic data in their existing environments. This distributed approach is achieved by using a standardized data structure referred to as the Mini-Sentinel Common Data Model.[2] The Common Data Model relies on existing standardized coding schema (e.g., ICD-9-CM, HCPCS/CPT and NDC) to minimize the need for mapping and enable interoperability with appropriate evolving healthcare coding standards. Data Partners transform their data locally according to the Common Data Model, which enables them to execute standardized computer programs that run identically at each Data Partner site behind their own firewalls. Data partners then share the output of these programs with the Operations Center and project workgroups, typically in aggregated form. A key benefit of the distributed approach is that it minimizes the need to share identifiable patient information. The combined collection of datasets across all Data Partner sites is known as the Mini-Sentinel Distributed Database (MSDD).[3]

B. MEDICAL COUNTERMEASURES

Natural disasters, terrorist attacks, and disease outbreaks can provoke large-scale public health emergencies. The public health system's ability to save lives may depend on its capacity to develop and dispense medical countermeasures, or MCMs, very quickly to a large number of people. Medical countermeasures include drugs (e.g., antibiotics, antivirals), biologics (e.g., vaccines), and other medical products (e.g., devices) for the response to public health emergencies involving chemical, biological, radiological or nuclear (CBRN), or emerging infectious disease, threats. Current plans for stockpiling, distributing, and dispensing MCMs during or in anticipation of public health emergencies are largely coordinated by the Centers for Disease Control and Prevention (CDC), which oversees the Strategic National Stockpile, and by state and local public health agencies. Depending on the emergency and patient care needs, MCMs may be dispensed or administered under a non-medical model (e.g., at points of dispensing (PODs), such as schools, managed by local public health agencies) or through the traditional health care system (e.g., hospitals).

Medical countermeasures dispensed in response to a CBRN or naturally occurring event may already be FDA-approved medical products, such as ciprofloxacin or doxycycline for post-exposure prophylaxis of inhalational anthrax. Conversely, some MCMs may be unapproved medical products, or approved products used in unapproved ways, that may be authorized for emergency use in relation to a particular MCM event, such as a rapidly emerging influenza pandemic. Also, some MCMs might have been approved using animal models and limited human efficacy testing if broader human efficacy testing was not ethical or feasible. Therefore, timely data on the safety and efficacy of an MCM may be needed to help inform decision-makers and health care professionals about continued use of the MCM during the emergency response and in the future.

[1] http://mini-sentinel.org/about_us/collaborators.aspx
[2] http://mini-sentinel.org/data_activities/distributed_db_and_data/details.aspx?ID=105
[3] http://mini-sentinel.org/data_activities/distributed_db_and_data/default.aspx

C. MEDICAL COUNTERMEASURES SURVEILLANCE

Past public health emergencies (e.g., the H1N1 influenza pandemic) have demonstrated that data on MCM use in impacted populations can be critical to informing clinical decision making and public health risk communications. While a number of important surveillance systems (e.g., CDC-FDA Vaccine Adverse Event Reporting Monitoring System (VAERS) and FDA Adverse Event Reporting System (FAERS)) exist for the post-marketing monitoring of medical products, collecting, analyzing, and having actionable information to use about adverse events and relevant health outcomes associated with MCM use (e.g., safety, compliance, and clinical benefit) *during* and even immediately following emergency responses presents unique challenges. Some examples of these challenges could include:

- possibility of underreporting due to operational challenges of the response
- barriers obtaining complete data from a large number and different types of clinical sites
- lack of pre-established procedures to collect and analyze data
- potential barriers linking MCM use with clinical benefit outcomes of interest
- reliance on current passive adverse event monitoring systems

Efforts are underway to contribute to addressing the need for a national capability for monitoring and assessing MCM use during public health emergencies.
Surveillance of MCM safety during public health emergencies requires linking MCM exposure information (e.g. that an individual received a particular MCM) with health outcome information (e.g. subsequent diagnoses for that same individual, from their regular source of care). Currently, the FDA's Mini-Sentinel pilot has medical product exposure and health outcome information for individuals who are insured by, and in some cases also receive care from, participating Data Partners. This data is used to assess the safety of regulated medical products. However, in the case of an MCM event, information concerning exposure to the MCM product may not be readily available in a timely fashion in the data routinely held by Mini-Sentinel's Data Partners as a result of normal course of business operations. This may occur when the dispensing or administration of the medical product takes place in a non-traditional location (e.g., a POD or an alternate care site). Administration at a non- traditional location outside the patient's regular source of care is particularly possible when the public health emergency necessitates rapid MCM dispensing to the impacted population.

D. MINI-SENTINEL MEDICAL COUNTERMEASURES FIELD TEST

Using KPCO patient registration and an influenza vaccination clinic as study environments, this field test examined whether patients presenting for care within KPCO could be uniquely identified using an external mobile data collection system, accurately linked to their individual medical record within KPCO, and subsequently linked to the KPCO MSDD. Gathering patient information at registration was chosen primarily as a means of testing our ability to link individuals to the MSDD, because showing a driver license or other identification is similar to what might occur at an MCM event. Conducting a smaller pilot at an influenza vaccination clinic was done as a means of testing our capacity to capture data on a specific MCM administered, given that influenza vaccine data could serve as a proxy for the types of data (e.g. medication name, dosage, and route of administration) that may be captured on MCMs administered.

This field test involved collaboration among the FDA, Mini-Sentinel Operations Center (MSOC), Denver Public Health (DPH), Kaiser Permanente Colorado (KPCO), and the National Association of County and City Health Officials (NACCHO). Its goal was to develop and execute a field test using KPCO patient

registration (front desk check in) and an influenza immunization clinic to evaluate a mechanism for capturing patient identification and exposure information, and linking the information obtained with the MSDD.

III. OBJECTIVES

The objectives of this field test were to assess whether patients presenting for medical care could be uniquely identified using an external mobile data collection system, accurately linked to their administrative data record, and subsequently linked to the KPCO MSDD. This was accomplished by:

- Testing the ability of a mobile data collection device to:
    - Capture unique identifying information from individuals presenting for care from:
        - scanning a driver license
        - manual data entry
        - photograph of medical insurance card
    - Capture MCM information (receipt of seasonal influenza vaccination was chosen as a model for receipt of an MCM)
- Matching device-collected information accurately to correct administrative record:
    - Verify match as compared to a "gold standard"

IV. DETAILS AND METHODS

A. HUMAN SUBJECT PROTECTION

As the field test was conducted as part of the Mini-Sentinel pilot of the Sentinel Initiative, which has been determined by federal authorities to be public health surveillance, it was consequently not subject to the human subjects review required for research activities. In addition, KPCO considered the project to be a quality improvement initiative, because KPCO was seeking innovative ways to identify patients at check-in, in order to facilitate the check-in process and prevent identity fraud. Because of these public health and quality improvement determinations, the pilot was not reviewed by the human subjects review board at KPCO, and written informed consent was not required. However, verbal permission was obtained from each patient during patient check in, and patients were given the opportunity to decline if they had any concerns about the field test.

B. LOCATION

Both components of the field test (i.e., front desk check in and the influenza immunization clinic) were conducted during November 2013 through January 2014 in Denver, Colorado, at one primary care clinic within KPCO, a large integrated care delivery organization.

C. STUDY PARTICIPANTS

Participants were all KPCO members. In the front desk check-in portion of the field test, participants were presenting for scheduled appointments at a single primary care clinic in Denver, Colorado. In the

influenza vaccination portion of the field test KPCO members could walk-in without appointment to the vaccination clinic. All adults 18 years of age or older presenting for care were eligible for participation in the field test.

D. DEMOGRAPHICS

Of the 421 members with a readable KPCO member card image in the front desk check-in portion of the field test 57% were female and 43 % were male. Ages of participating members ranged from 18 years to 94 years with a mean age of 55.4 years and a median age of 58 years. 58.2% of participating members were identified as white or Caucasian, 10.3% as African American, 1.2% as Native American, 0.96% as Asian American and 0.48% as Native Hawaiian/Pacific Islander. Race as listed as unknown for 28.5% of participants. Additionally, 15.6% indicated Hispanic ethnicity.

E. DATA COLLECTION TOOL

Denver Public Health's Hand-held Automated Notification for Drugs and Immunizations (HANDI) data collection tool was used to capture patient information during the field test. Developed by DPH, HANDI is a mobile app that runs on an iPod touch equipped with a barcode and magnetic stripe scanner and is supported by server and database components. DPH uses HANDI during both emergent and routine intervention delivery events to electronically collect patient demographic, eligibility and intervention information. HANDI has been used during Denver Health's fall employee influenza campaigns; in 2012 HANDI captured vaccination data for approximately 3,000 employees, and its use was expanded to record 5,700 vaccinations in 2013. DPH also uses HANDI to support community pertussis vaccination through childcare worker outreach and health fairs. The HANDI server converts the Tdap vaccination data into HL7 messages which are then sent to the Colorado Immunization Information System providing timely documentation. DPH also deploys HANDI on an ongoing basis during emergency preparedness exercises such as PODs to train new HANDI users and keep established users familiar with the app.

For the field test, the HANDI app was enhanced to capture images of health plan member identification cards, and the HANDI administration tool, HANDIMan, was enhanced to display the images and allow for double data entry of the member health record number. Kaiser Permanente Colorado personnel were trained by Denver Public Health staff on usage of the HANDI devices prior to the field test. KPCO used HANDI to scan patient driver licenses, photograph the KPCO insurance card, manually enter the KPCO member ID and capture vaccination information. When the data were transferred to the HANDI server, KCPO staff used the HANDIMan functionality to enter the member health record number to be used as the gold standard for member matching (described in Section F).

HANDI was developed to operate in three network environments: a HANDI dedicated network where all application components communicate in real-time via a HANDI Wi-Fi access point, a network where all components communicate via an existing network, and a disconnected environment where data are securely stored on the devices until a connection to the server is established. For the KPCO field exercise, data were stored on the HANDI device until the devices were connected to the HANDI server using a HANDI dedicated network. Thus, while KPCO used the HANDI system, it was never installed on the KPCO network and therefore simulated externally collected data.

F. TIMING

For a subset of the participants, data collection was timed from the approach for participation through the completion of participant/ data collector interaction.

G. HEALTH RECORD NUMBER CONFIRMATION

The gold standard for a patient's health record number (HRN) was a double verified member ID obtained from the photograph of the KPCO member ID card. After the field test data collection was completed, the HRN from the photograph of the KPCO member ID card was entered twice (i.e. double data entry) into a database for verification (the two entries had to match for the record to be saved into the database). This verified HRN was considered the gold standard for the field test, meaning this represented the "true" HRN and the "true" identity of the patient.

H. MATCHING

Matching algorithms were applied to link the HANDI collected data to the KPCO patient information system and then to the KPCO MSDD.
Three datasets were used for matching to the KPCO health plan enrollment database and subsequently linked to the KPCO MSDD:

- Data set 1: HANDI collected driver license information
- Data set 2: Manually entered KPCO member ID number collected on HANDI device
- Data set 3: The gold standard – HANDI photo of healthcare member ID card presented at clinic and double verified by research staff in the HANDI database.

There were 4 possible matching outcomes:

- True positive: a match with the HANDI data to the correct person in the Kaiser system
- False positive: a match, but with the incorrect person in the Kaiser system
- True negative: no match, but the person is not a current KPCO member
- False negative: no match, but the person is a current KPCO member

Table 1. Possible matching outcomes

	KAISER PERMANENTE COLORADO Records	
HANDI Data	**True Positive** - a match with the HANDI data to the correct person in the Kaiser system	**False Positive** - a match, but with the incorrect person in the Kaiser system
	False Negative - no match, but the person is a current KPCO member	**True Negative** - no match, but the person is not a current KPCO member

V. DATA COLLECTION

A. FRONT DESK CHECK-IN

Data was collected at a single primary care clinic within the Kaiser Permanente Colorado health care system. Individuals were approached to participate in the field test during the check-in process for scheduled appointments. At check-in, patients are asked to provide their KPCO insurance card and picture identification. For the field test, research staff approached patients during check-in, and explained the purpose of the field test. Those approached represented a convenience sample, as patients were skipped if patient flow would have been impeded due to high check-in volume.

During the field test, all patient data was collected using the portable, hand-held HANDI device, described in the section above. Once a patient verbally agreed to participate, the research staff swiped the patient's driver license magnetic strip with the HANDI device. If the license was not readable on the first attempt, a second attempt was made to swipe the license. If the license was still not readable, the research staff attempted to use the license 2-d bar code if one was available (a 2-d barcode is available on Colorado driver licenses, which made up a majority of state IDs presented at check-in as the field test was conducted in Colorado). Next, the research staff manually entered the patient's KPCO HRN visualized from their KPCO member ID card, into a touch keypad on the HANDI device. Finally, using the built-in camera within HANDI, the research staff photographed the front and back of the patient's KPCO member ID card.

The check-in process was able to continue as data collection was occurring. At the end of each day, the information contained within the HANDI device was downloaded to a secure server at the KPCO Institute for Health Research, and deleted from the HANDI device.

For each individual willing to participate in the field test at the front desk check in process, the following data points were collected on the HANDI device:

1. Scan of the patient's driver license magnetic stripe or 2-D barcode
    - Name (first name, last name)
    - Address
    - Date of birth
    - Gender
2. Manually entered KPCO member ID number (from the KPCO member card presented)
3. Photograph of the front and back of KPCO member ID card. This was considered the gold standard for HRN identification.

B. INFLUENZA VACCINATION CLINIC

Each fall at KPCO, influenza vaccination is given to KPCO patients in the lobby of its medical office buildings. Data was collected on one day during KPCO's influenza vaccination campaign inside the same Kaiser primary care facility as the check-in exercise. The objective was to determine whether the device could accurately collect detailed information about influenza vaccines administered to KPCO members. The influenza vaccination station in the lobby is a walk-up service, no appointment or check-in is needed. KPCO patients simply present the nurse staffing the influenza vaccination station with their driver ID and KPCO ID card. After verbal permission was obtained from each patient, research staff

gathered information from the patient's driver license and KPCO member ID card prior to vaccination, in exactly the same manner as described above for the front desk check-in component.

In addition, research staff entered information about influenza vaccination into the HANDI device. Research staff loaded vaccine information (lot numbers, expiration dates, doses, manufacturer) obtained from the KPCO pharmacy records into the HANDI database prior to data collection. At the time of data collection variables were selected within a pre-populated drop-down menu on HANDI to minimize data entry error.

The following influenza vaccine-related data points were collected:

- Antigen – specific vaccine (e.g. influenza)
- Lot Number
- Expiration Date
- Dose
- Manufacturer
- Site (e.g. right vs. left deltoid)
- Administered By
- Administration Date

C. DATA FLOW

Figure 1 shows how KPCO member data was collected and linked during the field test. Data was collected using the mobile HANDI device and transferred to the HANDI server. Matching algorithms were applied to the HANDI and KPCO data systems to produce the matched datasets which were then linked to the KPCO MSDD. Once incorporated into the KCPO MSDD, the data could be queried as part of the MSDD by an analytic program written by the Mini-Sentinel Operations Center and distributed to all Mini-Sentinel Data Partners.

Figure 1. Diagram of KPCO member data flow

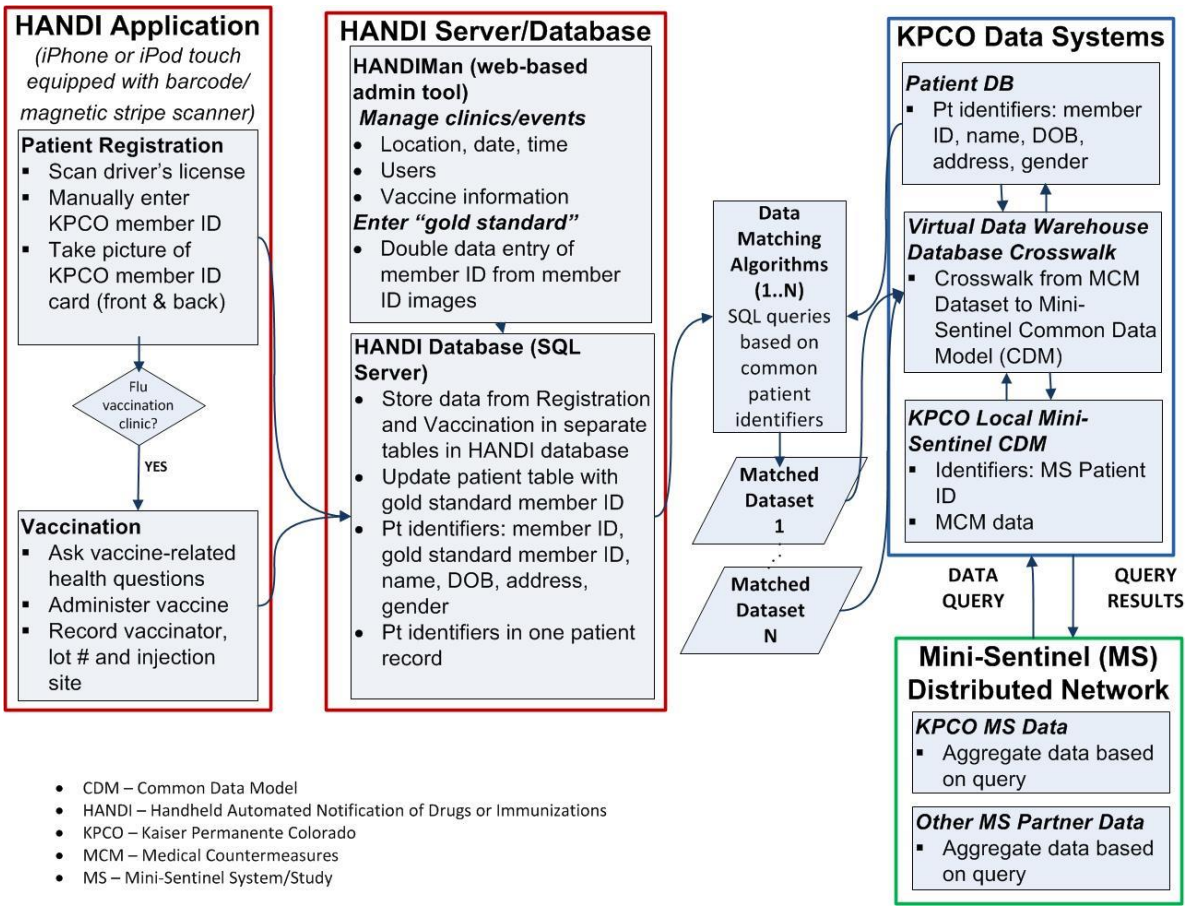
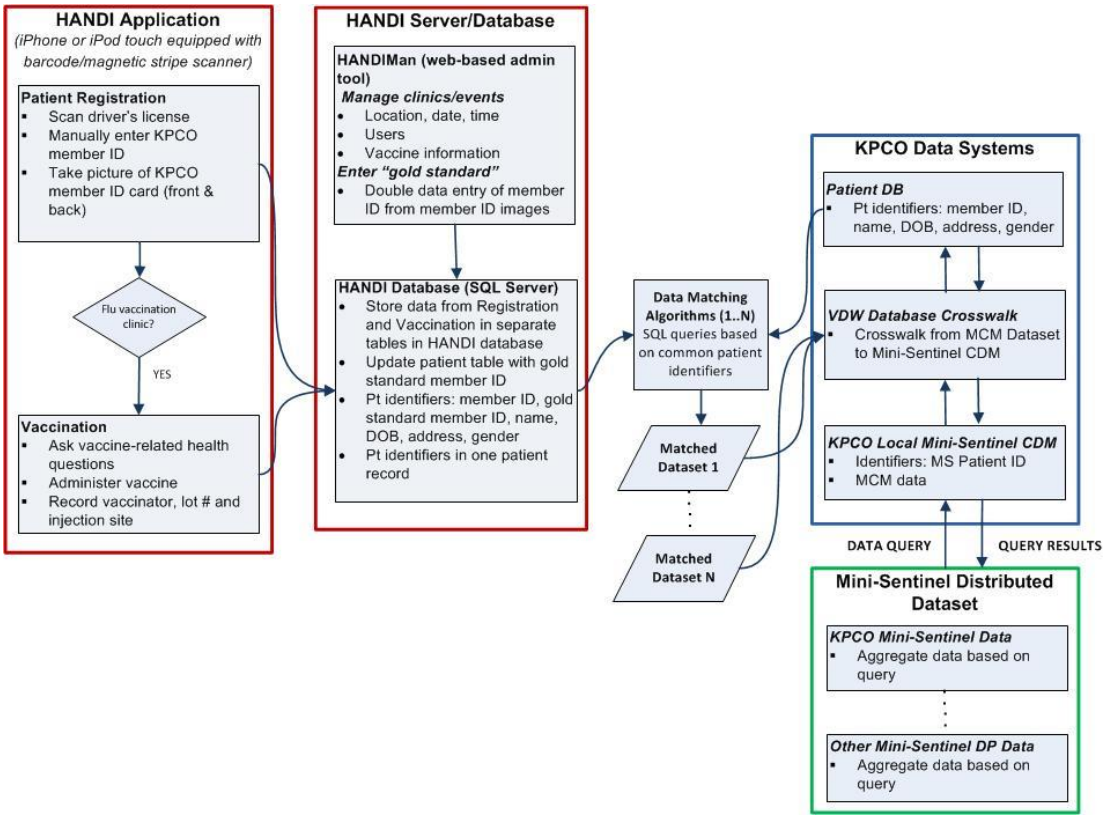


Figure continued on following page.


HANDI Application
(iPhone or iPod touch equipped with barcode/magnetic stripe scanner)
Patient Registration
Scan driver's license
Manually enter KPCO member ID
Take picture of KPCO member ID card (front & back)
Flu vaccination clinic?
YES
Vaccination
Ask vaccine-related health questions
Administer vaccine
Record vaccinator, lot # and injection site
HANDI Server/Database
HANDIMan (web-based admin tool)
Manage clinics/events
Location, date, time
Users
Vaccine information
Enter "gold standard"
Double data entry of member ID from member ID images
HANDI Database (SQL Server)
Store data from Registration and Vaccination in separate tables in HANDI database
Update patient table with gold standard member ID
Pt identifiers: member ID, gold standard member ID, name, DOB, address, gender
Pt identifiers in one patient record
Data Matching Algorithms (1..N)
SQL queries based on common patient identifiers
Matched Dataset 1
Matched Dataset N
KPCO Data Systems
Patient DB
Pt identifiers: member ID, name, DOB, address, gender
VDW Database Crosswalk
Crosswalk from MCM Dataset to Mini-Sentinel CDM
KPCO Local Mini-Sentinel CDM
Identifiers: MS Patient ID
MCM data
DATA QUERY
QUERY RESULTS
Mini-Sentinel Distributed Dataset
KPCO Mini-Sentinel Data
Aggregate data based on query
Other Mini-Sentinel DP Data
Aggregate data based on query

VI. RESULTS

A. FRONT DESK CHECK-IN

Of the 464 members approached to participate in the field test, 431 (93%) agreed to participate and 33 members (7%) declined. Of the 431 members who agreed to participate, 421 (98%) had a readable KPCO member card image (gold standard). Of the 421 individuals with a verifiable gold standard image, 382 (89%) had an exact match in the KPCO membership database using the matching criteria of exact first name, exact last name, and exact date of birth -as taken from the individual's driver license.

Thirty-nine individuals did not have an exact match in the KPCO membership database. After all matching scenarios were completed further investigation was done to elucidate the reasons for these non-matches. The main causes for non-matches were found to be discrepancies between datasets due to: hyphenated names and names with spaces, formal versus nick-names (Jim versus James), name changes, and differing birthdates. Four of the 39 non-matching individuals had multiple discrepancies between datasets.

Of individuals whose gold standard HRN did not have an exact match in the Kaiser enrollment database (n=5 in Figure 1) all were subsequently identified as having multiple HRNs in the Kaiser system. All five were matched within the Kaiser system using the multiple HRN table (a crosswalk linking an individual to all HRNs they have in the Kaiser system). Although uncommon, multiple HRNs per individual can occur when an individual leaves and returns to Kaiser and is issued a new HRN.

Figure 2. Matching driver license data to KPCO enrollment data

Figure 2 shows results from the matching of driver license information to the Kaiser Permanente Colorado health plan database, for subjects participating in the field test during front desk check-in.

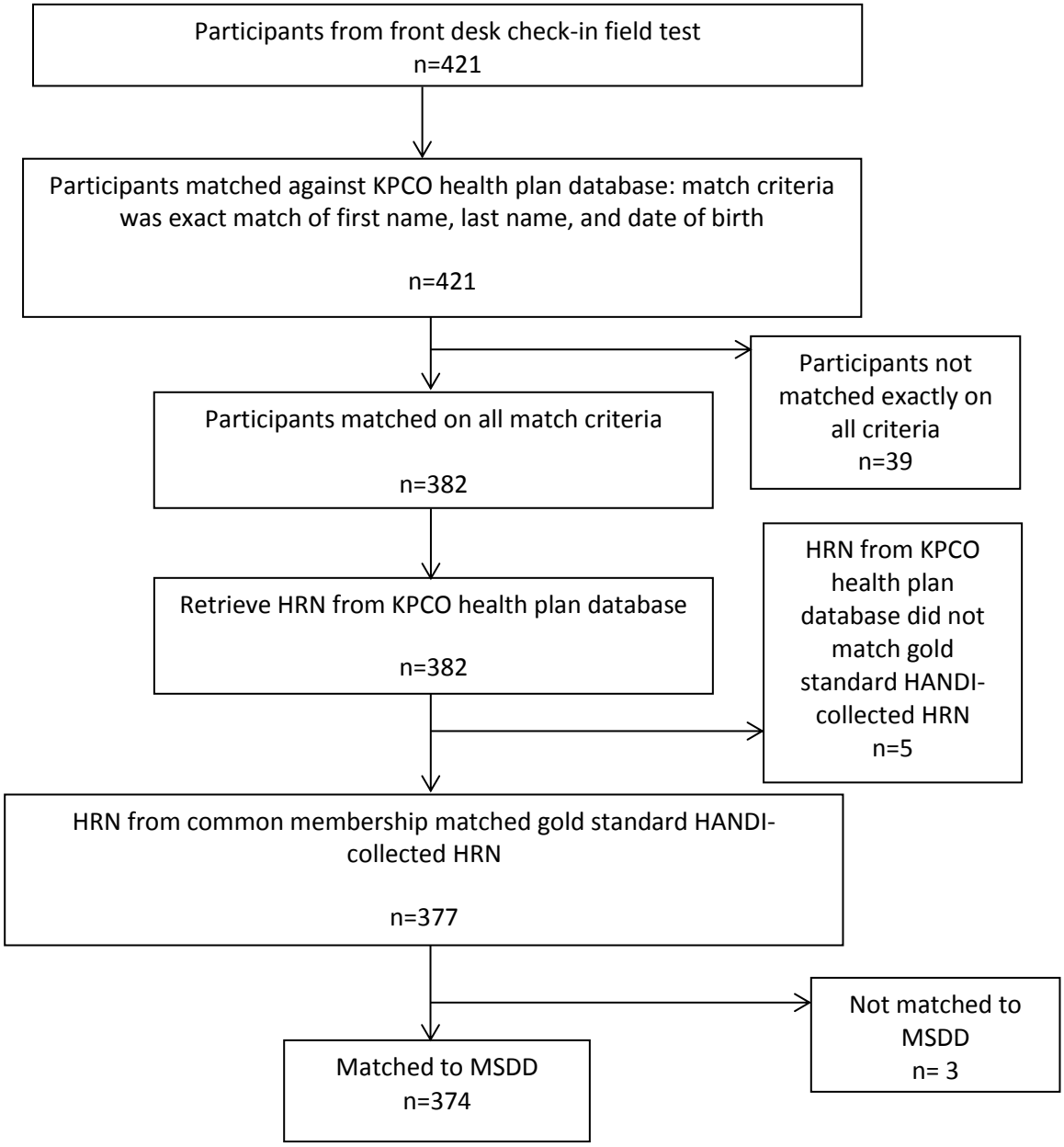
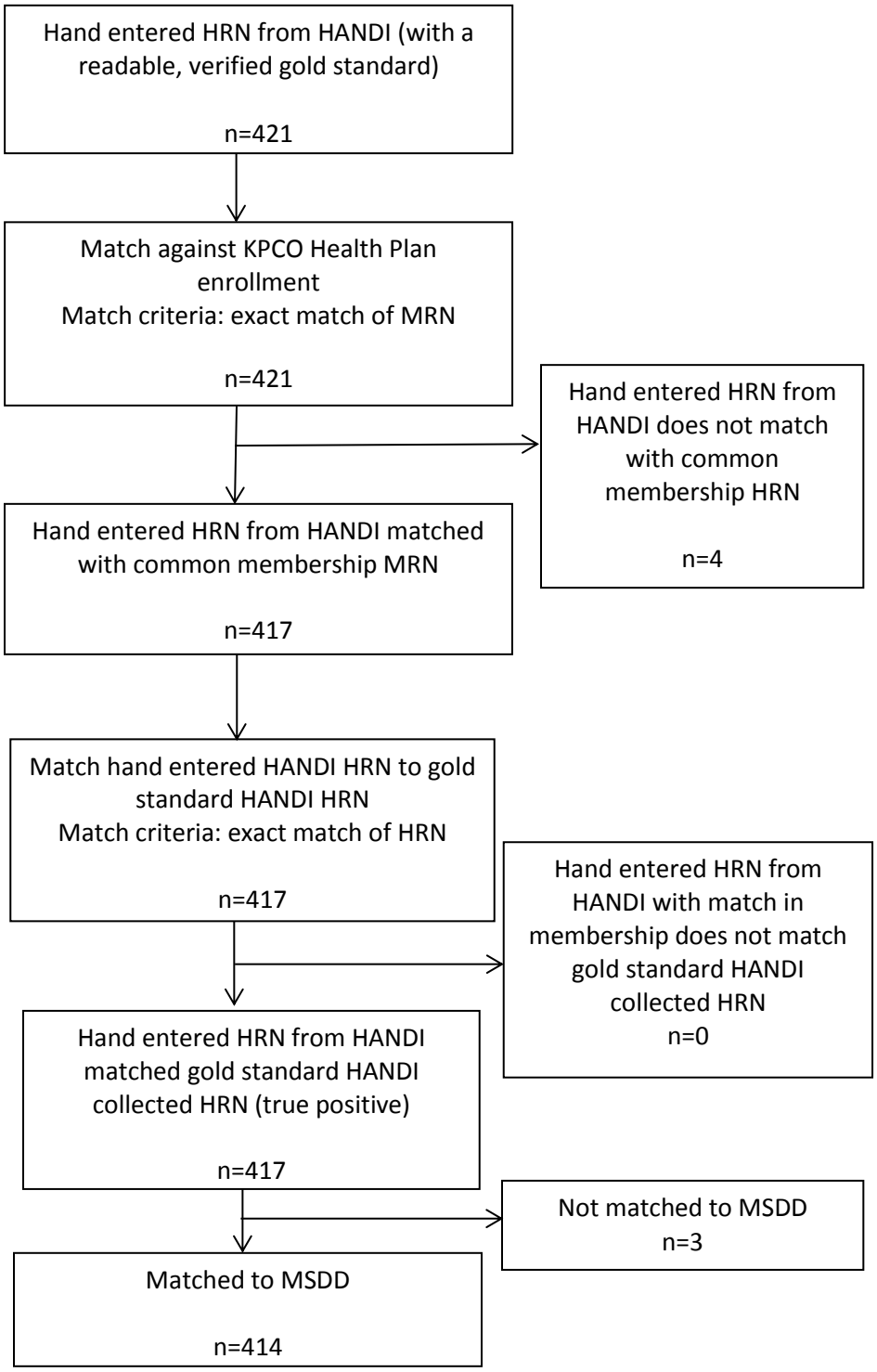


Figure 3 shows rates for matching of the HANDI hand-entered HRN data to the Kaiser enrollment data. Of the 421 participants with a verified, readable gold standard image, 417 (99%) of hand-entered HRNs from HANDI device data collection matched correctly to HRNs in the KPCO enrollment database. Of the 417 members matched to the correct electronic health record at KPCO (by HRN), 408 (98%) matched correctly to the KPCO MSDD.

Figure 3. Matching HANDI hand-entered HRN to Kaiser enrollment data



B. QUALITATIVE ASSESSMENT

Following training of KPCO staff, HANDI devices were deployed in KPCO during the field test without assistance from DPH staff. Field test data collection did not impede front desk check-in at Kaiser primary care clinic. Based on observation of the process for n=25 individuals, the average time for data collection on an individual was one minute and two seconds; the average time for routine front desk check-in was not captured. Overall, patients were willing to have their information collected electronically using a mobile device. Thirty-three (7%) patients who were asked to participate declined due to time restrictions (n=11), lack of comfort with the collection of their personnel information (n=21), or for no explicit reason (n=1).

C. INFLUENZA VACCINATION CLINIC

The goal of this component of the field test was to determine if the HANDI device could accurately collect detailed information about influenza vaccines given to KPCO members. Due to timing of the KPCO annual influenza vaccination clinics and the timeline of this project data was collected from the influenza vaccination clinic on one day. A total of 21 individuals participated in this part of the overall field test. Of these 21 participants, all were accurately matched to the "gold standard" HRN. Results of the collection of influenza vaccine data are shown below, in **Table 2**.

Table 2. Influenza clinic results - The extent to which data on influenza vaccination, captured by the HANDI device during the field test, matched with data available within the electronic health record

Data element	Data type within HANDI	Matched to KPCO EHR data, n (%)
Vaccine type (e.g. influenza vaccine)	Preselected, not editable	21 of 21 (100%)
Lot number	Preselected, prepopulated	21 of 21 (100%)
Dose (e.g. 0.5 mL)	Preselected, prepopulated	21 of 21 (100%)
Site (e.g. right deltoid)	Preselected	18 of 21 (88%)
Manufacturer	Preselected, prepopulated	21 of 21 (100%)
Route	Not recorded within HANDI	All indicated as intramuscular

Prepopulated – loaded into the HANDI manager as drop down options during data collection (e.g. lot numbers KPCO pharmacy dispensed to the study clinic were preloaded into the HANDI database for selection during data collection).

Preselected – During data collection, after the first person's vaccine information was collected the application prepopulated the fields to the last used selection (i.e. right arm, if the last person received the immunization in the right arm). The data collector could change the selection for each individual.

As can be seen in **Table 2**, the influenza vaccination data collected by the HANDI device closely matched the data available in the KPCO electronic health record. Among data elements that were captured by both HANDI and the KPCO electronic health record, only site (i.e. right deltoid versus left deltoid) was not matched with 100% accuracy.

VII. DISCUSSION

This field test demonstrated that patient identifying information from driver licenses could be successfully and efficiently captured using a mobile hand-held device. It also demonstrated that using this information, a high proportion (89%) of patients could be uniquely and accurately linked to their health record and the Mini-Sentinel public surveillance databases. The vast majority of patients (93%) were willing to provide their driver license and health insurance card as part of this field test. Additionally, the mobile hand-held device successfully captured seasonal influenza vaccination data, which is similar to the type of data that, depending on the circumstance and the MCM, may be needed for MCM administration during a public health emergency.

However, it is important to recognize certain limitations of the field test. It was not conducted in the context of a true MCM event, but among KPCO members presenting for care at KPCO, with matching to a database including all active KPCO members. Therefore, the likelihood of "true positive" matches from driver license information would be expected to be high, and "false positive" matches relatively low. In addition, the field test was not designed to quantify the "true negative" match rate (i.e. the number of individuals who did not match KPCO health plan data, but should not have matched, because they were not KPCO members). Thus results may not be generalizable to a situation where the general public, including those with many different types of insurance, and also uninsured individuals, and/or those without driver licenses, receive a MCM in a true CBRN or emerging infectious disease event.

Also, KPCO members presenting for care at KPCO may be more likely to participate in sharing their driver license information than the general public in an actual MCM event. KPCO members may view KPCO as a "trusted entity" that has a justifiable need to verify their identity. It is possible that in a true MCM event occurring in the community, fewer individuals would be willing to have their driver license data scanned by responders using the HANDI device due to privacy concerns. Finally, it is likely that in a true MCM event, the mechanism of data transfer used in the field test would need to be enhanced to account for multiple insurers, those without insurance and/or identification, and multiple geographic locations of varying types (e.g. PODs, hospitals, schools, pharmacies, etc.) Sophisticated methods would need to be established to either "push" or "pull" data from the MCM event to the correct health care organization for each individual. Such a system would need cooperation from multiple agencies and organizations and would benefit by advance planning, both technical and logistic. The scale of a potential MCM event will also impact the type of planning needed and the likelihood of success.

In conclusion, during a true MCM event, it may be necessary to capture data on individuals who receive an MCM and link this data with individual patient health records to assess the safety of the MCM. The potential ability to quickly determine who has received the MCM, especially in situations where dissemination of the MCM is through non-traditional medical environments, is critical to monitor both the efficacy and safety of the intervention. This is especially true if the MCM intervention used involves unapproved drugs or those that are approved but being applied in unapproved ways. This field test has demonstrated that it is feasible to capture patient identification information from driver licenses and from health insurance cards, and to additionally capture information on a vaccine dispensed, using a mobile device and subsequently link these data to existing Mini-Sentinel data with a high degree of accuracy.

VIII. APPENDICES

A. APPENDIX A. FIELD TEST PROTOCOL

Mini-Sentinel
Medical Countermeasure Surveillance

Kaiser Permanente Colorado Data Linkage Exercise Plan

Exercise Dates: November 2013 – January 2014

Revision Date: October 1, 2013

PURPOSE

An Exercise Plan (EXPLAN) gives planners from participating organizations the information necessary to plan, design, conduct and evaluate an exercise. It is provided to familiarize appropriate stakeholders with the planning group's intent to conduct an exercise, and the roles, responsibilities and resources involved in planning and execution.

This EXPLAN provides planning guidance for the Mini-Sentinel Medical Countermeasure Surveillance Kaiser Permanente Colorado Data Linkage exercise. This EXPLAN is based on planning factors and estimates available at the time of preparation, and it is subject to modification during final exercise planning and preparation. This EXPLAN was produced in collaboration with Kaiser Permanente Colorado (KPCO) and Denver Public Health (DPH) with additional input from the Mini-Sentinel Medical Countermeasures Surveillance team.

ADMINISTRATIVE HANDLING INSTRUCTIONS

1. The title of this document is the *Mini-Sentinel Medical Countermeasures Surveillance Kaiser Permanente Colorado Data Linkage Exercise Plan*.
2. This document should be safeguarded, handled, transmitted, and stored in accordance with appropriate security directives. Reproduction of this document, in whole or in part, without prior approval from Kaiser Permanente is prohibited.
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EXERCISE OVERVIEW

BACKGROUND

The goal of the Mini-Sentinel Medical Countermeasure Surveillance project is to assess a proof of concept regarding the ability of the Mini-Sentinel pilot to obtain information on individuals receiving a medical product in the context of a Medical Countermeasures (MCM) event, to structure this information into a data file that can be linked with electronic health data, and to demonstrate whether the linkage within the Mini-Sentinel Distributed Database is feasible. The purpose of the linkage will be to identify adverse events/safety issues after the MCM event, and also potentially during the MCM event.

EXERCISE OBJECTIVES

The overall goal of the exercise is to test the ability to link patient data collected by an external data collection system to a KPCO patient record. Specific objectives include:

- Test the ability of HANDI to capture Kaiser Permanente Colorado (KPCO) health plan membership information through scanning of KPCO member driver's licenses, manual data entry, and a photo image taken by the HANDI device camera of KPCO membership cards.
- Develop a data linking algorithm that utilizes the HANDI collected data fields to link a HANDI patient record to a Kaiser patient record.

- Determine which data fields from the driver's license, member ID card, and manually entered fields achieve an acceptable linkage rate.

EXERCISE SUMMARY

Exercise Name

Kaiser Permanente Colorado Data Linkage Exercise

Type of Exercise

Functional

Exercise Start Date

November 2013

Exercise End Date

January 2014

Location

Kaiser Permanente Colorado
Institute for Health Research
10065 E Harvard Ave
Denver, CO 80231

Program

Kaiser Permanente Colorado, Institute for Health Research

Sponsor

Kaiser Permanente Colorado

Scope

This exercise is intended to test the ability to collect demographic and Kaiser health plan membership information using HANDI, a mobile data collection tool, in order to link the data to Kaiser's information systems.

Capabilities

The exercise will test the capability of the Mini-Sentinel project and KPCO to successfully link data collected during healthcare delivery outside of the KPCO system to internal KPCO data systems and individual patient records. To support this, the capability of the HANDI device to collect and store health insurance information will also be tested.

Scenario Type

Two existing KPCO patient flows will be used to collect data:

1. Routine patient registration

2. Seasonal influenza vaccination clinics

Resources

- Target number of patient participants: 500
- HANDI users: KPCO check-in clerks, KPCO research assistants
- Evaluators: Art Davidson, Melissa McClung, Matthew Daley, Ted E. Palen, NACCHO and/or FDA representatives (TBD)
- IT: Mike Bodily
- Project Manager: Kristin Goddard
- Facilitators: Research assistant(s), TBD

EXERCISE DESIGN

Exercise Concept and Scope

Scope

The exercise is designed to collect patient information for 500-1000 KPCO members and will be complete when the target number of records is reached. The duration of the exercise will be determined during the exercise and is dependent on patient registration congestion and patient willingness to participate. Exercise data collection may be suspended if patient wait times are considered too long,

Assumptions:

- Demographic and Kaiser health plan membership data will be voluntarily collected from actual Kaiser patients. Patients may decline participation.
- Data collection efforts during the exercise will not significantly impact normal patient registration and care.
- The gold standard for data linkage between HANDI collected data and KPCO data systems will be a double entered member ID. The linking process may test several different algorithms using the driver's license, member ID card, and manually entered fields to determine the best set of data to achieve an acceptable linkage rate.

Artificialities

Although this exercise is being conducted as a means to test medical countermeasure delivery capabilities, medical countermeasures will not actually be delivered during the exercise conducted during the patient registration workflow. KPCO patients will receive flu vaccinations at the flu clinics, and the data collected by HANDI during these clinics may include vaccination data.

Exercise Scenario

Two existing KPCO patient flows will be used to conduct the exercise:

1. Conduct the exercise as part of the patient registration workflow at one or more of KPCO's major hub clinics. Currently registration clerks ask the patient for their KPCO health plan membership card (the card may not be presented if the patient knows their member ID) and their driver's license (or approved picture identification) as proof of identity. HANDI would be used either by the clerk or a KPCO research staff member to photograph the KPCO's member health plan ID card, scan the magnetic stripe on their driver's license, and manually enter the member's health plan ID number during the usual process of collecting health visit co-payment,

printing the receipt and patient specific information (patient visit record, PVR)

2. Conduct the exercise as part of KPCO's annual influenza vaccination campaign. Influenza clinics are held in the main reception area of some KPCO facilities and patients may choose to receive a flu vaccination in conjunction with a visit. The HANDI device would be used by a KPCO research staff member to photograph the KPCO's member health plan ID card, scan the magnetic stripe on their driver's license, and manually enter the member's health plan ID number during the course of registering for and waiting to receive their influenza vaccination. HANDI could also be used to capture the vaccination information associated with the patient such as vaccine manufacturer, lot number, vaccinator and site of injection. Vaccine manufacturer, lot numbers and vaccinator name and titles would be prepopulated prior to the event using the HANDI administration tool in order to minimize the amount of data entry required during the vaccination process.
   This option requires the exercise to occur during the influenza vaccination events in October through early December of 2013. Ideally being scheduled for late October, or early November.

Patient Notification

KPCO members will be notified of the exercise in two ways.

1. A poster with the following information will be placed at the beginning of the check-in line for registration and flu vaccination:

> Kaiser Colorado is looking into new ways to identify our members during check-in.
>
> As part of this, we will use a hand-held device to:
> - Scan your driver's license
> - Photograph of your Kaiser insurance card
> - Type in your Kaiser health record number
>
> This information will be kept confidentially within Kaiser, but you don't have to participate in this process if you do not want to.

2. The exercise will also be explained to patients verbally using the script below before using the HANDI device to collect their data, and patients will be given the option to decline participation.

"Kaiser Colorado is looking into new ways to identify our members during the check-in process. This will help us make sure we accurately identify our members during check-in, and will help us make the process as efficient as possible.

As part of this, we would like to use a hand-held device to do three things:

- *Scan your driver's license, which will give us information such as your name and birthdate*
- *Take a photograph of your Kaiser insurance card, and*
- *Type in your Kaiser health record number*

Doing this exercise also helps us plan for future emergencies. For example, public health officials could use this hand-held device to track patients who receive vaccines at mass immunization clinics.

The information you provide will be kept confidential within Kaiser Colorado, and won't be shared outside Kaiser. You don't need to participate in this process if you do not want to. Simply let us know if you don't want to participate, and you can skip this process and go straight through for your appointment/vaccination."

Exercise Tools

Denver Public Health has developed a mobile app, HANDI (Hand-held Automated Notification for Drugs and Immunizations), as a data collection tool for mass immunization and prophylaxis events. Using mobile devices (e.g., iPhone, iPod touch) equipped with barcode and magnetic stripe scanners, HANDI facilitates data collection by healthcare workers to register individuals, monitor contraindications and track prophylaxis/immunizations administered during routine and mass intervention events. HANDI will be used during the KPCO exercise to scan the magnetic stripe on patient driver's licenses, photograph KPCO health plan ID cards and allow for manually data entry of additional fields. The data will be encrypted and securely transferred from each device to the HANDI database onsite at KPCO.

The HANDI administration tool (HANDIMan) will be used to collect the member ID as the data linkage gold standard. A KPCO research staff member will view the images of the member ID cards and enter the member ID displayed on the card twice. The member IDs must match before the data are saved to the patient's HANDI record which will include both the member ID initially captured during registration and the gold standard member ID for comparison.

Patient Confidentiality and Data Security

Kaiser plans to deploy a full HANDI install (the mobile devices and a virtual machine (VM) which contains the HANDI server and database) that operates on their internal network. This approach maintains Kaiser ownership of the data and therefore no transfer is necessary, and Denver Public Health would play a supportive role. The linking process would use the data from the HANDI SQL Server database. The Kaiser IT department is involved well in advance of the exercise to ensure network connectivity and adherence to Kaiser data security standards.

HANDI Scanner Data Security

The iPod touches and the HANDI app provide data security through several methods. All devices use Good, a mobile device manager required by Denver Health IT Security, which is an application that forces device passcodes and provides the ability to remotely wipe the device of all data and applications if it were to become lost or stolen. The HANDI app itself also requires a username and password to access the app, and all data are encrypted using the industry standard AES-256 algorithm (Advanced Encryption Algorithm 256-bit) during storage and transport to the HANDI server. Health plan member ID card images are stored as encrypted text on the device in the HANDI database and not as actual images. Once the card images are saved through the HANDI app, they cannot be reviewed by the HANDI user and are not accessible through the Photos app on the iPod touch. Once the images are transferred to the HANDI server, they are unencrypted, decoded and stored as images (.jpg) and are able to be reviewed through the password protected HANDI administration tool (HANDIMan).

Exercise Control and Evaluation

This section describes the exercise control concept and delineates associated responsibilities for the management and span of control for Kaiser Permanente Colorado Data Linkage Exercise.

Implementation Rules

The following rules apply to exercise implementation:

1. Real emergency actions take priority over exercise actions.
2. **"Real-World Emergency"** is the designated phrase that indicates there is a real emergency in the exercise area requiring immediate attention that may or may not stop the exercise.
3. **"Timeout"** is the designated phrase to temporarily stop the exercise.

Exercise Participants

Patients

Patients are actual KPCO members who agree to study participation and allow their

driver's license and member ID card to be scanned and or photographed and health plan ID membership numbers manually inputted into the HANDI device.

HANDI Users

HANDI users are KPCO research staff and potentially KPCO registration clerks who will operate the HANDI devices to collect KPCO member information. These individuals will receive training on HANDI prior to the exercise and will be asked to provide feedback during the post exercise evaluation discussion.

Exercise Commander and Facilitators

The Exercise Commander and facilitators will be responsible for the overall control of the Kaiser Permanente Colorado Data Linkage Exercise. Together they will ensure the exercise moves forward and operates smoothly. They will also ensure proper data and information are collected during and at the end of the exercise. The Exercise Commander and facilitators will evaluate patient flow throughout the exercise to determine if the exercise needs to be suspended at any time to maintain normal patient flow through the KPCO registration process.

Evaluators and Observers

DPH: Art Davidson, MD, MSPH

Melissa McClung, MSPH

KPCO: Ted E. Palen, PhD, MD, MSPH

Matthew Daley, MD

Kristin Goddard, MPH

Mike Bodily, MBA, PMP

Safety

Participant safety takes priority over exercise events. All Kaiser Permanente employees share the basic concept of ensuring a safe and healthful workplace for each other. In addition, aspects of emergency response are dangerous. Professional health and safety ethics should guide all participants to operate in their assigned roles in the safest manner possible. The following general requirements apply to the exercise:

1. All exercise controller/evaluators will serve as safety observers while exercise activities are under way.
2. Participants will be responsible to look out for their own and each other's safety during the exercise. It is the responsibility of every person associated

with the exercise to stop play if, in his or her opinion, a real safety problem exists. Once the problem is corrected, exercise play can then be restarted.

3. Kaiser Permanente will comply with their environmental, health, and safety plans and procedures, as well as all appropriate Federal, State, and local environmental health and safety regulations.

Code of Conduct

1. If an actual emergency occurs during the exercise, controller/evaluators will immediately suspend exercise play and evaluate the situation. The Exercise Commander and facilitators will then decide if the exercise can be safely resumed.
2. Act in a professional manner at all times.
3. Understand the scope of the exercise. If you are unsure about a certain aspect of participation in the exercise, ask the Exercise Commander or a facilitator.

Exercise Evaluation

Metrics for evaluating the exercise:

- Number of KPCO members with HANDI collected data
- Number of KPCO members who decline participation
- Duration of each data collection event (random sample of participants)
- Average time to collect data from each member (will require an evaluator to record times)
- Number of matched individuals for each linkage algorithm

Gold Standard for Data Linkage

The gold standard for data linkage between HANDI collected data and KPCO data systems will be a double entered member ID. The linking process may test several different algorithms using the information from scanning the magnetic stripe on driver's license, information from the photographic image of the KPCO health plan membership ID card, and manually entered information in HANDI to calculate the rate of linkage to the gold standard.

Optional: A survey tool (or qualitative interview) will be used to collect information from patients, clerks, and or research assistants to evaluate the impact using the HANDI device had on normal clinic workflow.

After Action Report

An After Action Report (AAR) will be prepared after the exercise by KPCO and DPH to describe the outcome of the exercise and if the objectives were met. Results,

limitations, lessons learned and recommendations will be included in the report. This report will be in the form of the Mini-Sentinel Project Report and serve as a report on the field test as a whole.

Logistics

Location

Exercise will be held at one or more KPCO Hub clinics:

- Kaiser Franklin Clinic
- Kaiser Skyline Clinic
- Kaiser East Clinic
- Kaiser Lakewood Clinic

Parking

Staff will park in their normal areas. Exercise participants from partner agencies will park in general clinic parking. .

Breaks

Breaks will be taken by KPCO research staff members as needed.

Restroom Facilities

Restroom facilities will be located on site during the exercise.

Appendices

1. Acronym List

Appendix 1: Acronym List

Acronym	Definition
AAR	After Action Report
DPH	Denver Public Health
EOP	Emergency Operations Plan
EXPLAN	Exercise Plan
HANDI	Handheld Automated Notification for Drugs and Immunizations
JIT	Just-In-Time Training
KPCO	Kaiser Permanente Colorado
MSEL	Master Scenario Exercise List
POD	Point of Dispensing
TCL	Target Capabilities List
UTL	Universal Task List

B. APPENDIX B. HANDI USER GUIDE

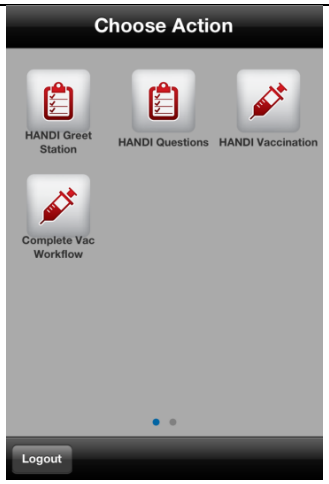
Mini-Sentinel Medical Countermeasures
Kaiser Permanente Colorado Data Linkage Exercise
HANDI User Guide

Device Passcode = "kpco"

Launch the HANDI app 1. Tap the HANDI icon on the Home Screen.	
HANDI Login HANDI user logins: • User: first initial last name • Password: first initial last name 123 • Example: Jane Doe – User: jdoe, Password jdoe123 • OR you can log in using "user", "user123" 1. Tap the "User" text box. A keyboard at the bottom of the screen will appear. 2. Enter your user name and password. 3. Tap the "Password" text box. 4. Enter your password. 5. Select the Location. 6. Tap the blue "Login" button.	

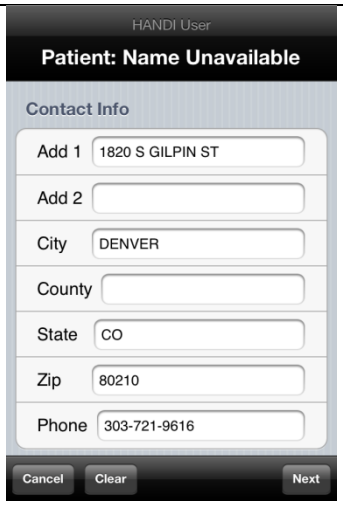
Choose Action

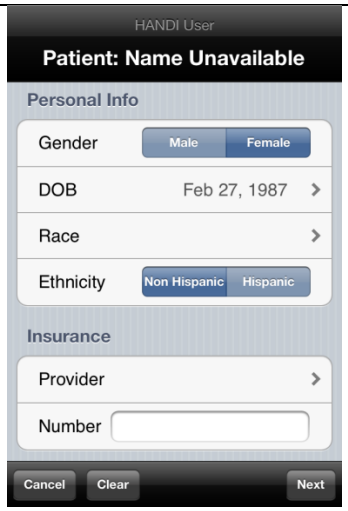
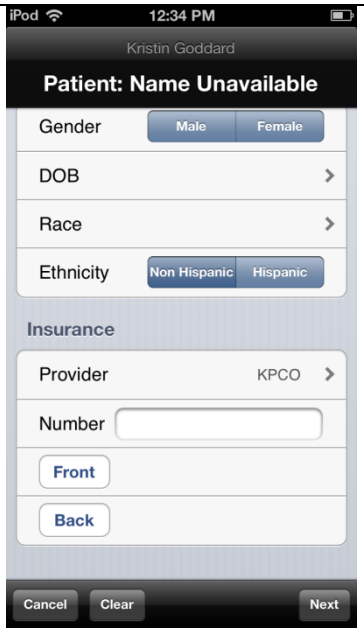
1. Select Complete Vac Workflow.



Screen 1 – Patient Demographics

1. Scan the patient's driver's license.
   a. Holding license picture side down, swipe magnetic stripe through slot in the back of the device OR use the 2-D scanner and aim the light beam at the 2-D barcode on the back of the license.
   b. If the swipe/scan is successful, the name, address, gender and DOB text boxes will be populated.
   c. If the swipe or scan was unsuccessful or only partially successful, retry the scan or use the keypad to enter the data manually.
2. Enter the patient's phone number using the format 123-456-7890.



	
1. Patient Insurance Information a. The Provider will default to “KPCO”. b. Enter the patient’s member ID in the Number field. c. Take a picture of the front of the KPCO member ID card by pressing the “Front” button. Focus the camera on the front of the card and press the camera button. d. Take a picture of the back of the KPCO member ID card by pressing the “Back” button. Focus the camera on the back	

of the card and press the camera button.

e. The images can be reviewed by pressing the images.

f. Once the patient's record has been saved, the images cannot be reviewed on the device.

2. Tap the "Next" button.

Screen 2 – HANDI Vaccination

1. The patient's first name, last name initial and birth month and day will appear at the top of the screen.
2. Select the Lot No, Manufacturer, Dosage, Site, Admin By fields. Once these fields have been set the first time, the only field to be entered for subsequent patients is Site (during your current session).
3. **Tap the "Save" button**.

Troubleshooting and FAQs

1. **You cannot log into HANDI**.
    a. Check that you correctly spelled your user name and password.
    b. Confirm with ? that you are registered as a HANDI user.
    c. Login using “user”, “user123”.
2. **HANDI seems sluggish and slow to respond** (e.g., typed letters have a delayed appearance)
    a. Close HANDI and start it again.
    b. To close HANDI (or any app):
        i. Logout of HANDI if you are logged in.
        ii. Press the Home Screen button on the bottom of the front of the device (below the display screen) to return to the Home Screen.
        iii. Double press the Home Screen button to display the apps currently open.
        iv. Press and hold the HANDI app until it wiggles and displays a minus sign in the upper left corner.
        v. Press the minus sign to close the app.
        vi. Press the Home Screen button to return to the Home Screen where you can restart the app.
        vii. NOTE: if an app is pressed and held on the Home Screen, it will start to wiggle and display an “x” in the upper left corner. Pressing this “x” will **delete** the app from the device.
3. **The sled is not scanning**.
    a. Close HANDI and start it again.
    b. If the sled is still not scanning, perform a hard shut down by pressing and holding the button on the top of the device. The device will prompt you to “slide to power off”. Restart the device by pressing and holding the top button until you see an apple icon on the screen.
4. **You saved more than one record for one patient**. Each subsequent save overwrites the previous record for the same patient, so the last record saved represents the vaccination record.
5. **The Good app prompts you for a password**. You do not need to be logged into Good to use HANDI. Return to the Home Screen and open HANDI. You should close Good in order to reduce battery usage.