

SENTINEL METHODS

SENTINEL MEDICAL CHART REVIEW GAP ANALYSIS PUBLIC REPORT

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April 18, 2018

The Sentinel System is sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to proactively monitor the safety of FDA-regulated medical products and complements other existing FDA safety surveillance capabilities. The Sentinel System is one piece of FDA's [Sentinel Initiative](#), a long-term, multi-faceted effort to develop a national electronic system. Sentinel Collaborators include Data and Academic Partners that provide access to healthcare data and ongoing scientific, technical, methodological, and organizational expertise. The Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223201400030I. This project was funded by the FDA through HHS Mini-Sentinel contract number HHSF22301007T.

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I. EXECUTIVE SUMMARY

Background: The Food and Drug Administration (FDA)'s Sentinel Initiative captures and curates electronic healthcare data from health insurers and re-purposes these data to answer regulatory questions. Selective medical chart review is important to assess the performance of claims-based algorithms for identifying conditions of interest, and to validate specific individuals' exposures and/or health outcomes of interest. Medical chart review has historically been led by *ad hoc* investigator teams that have created project-specific policies and procedures to support individual studies' needs. More standardization is needed to scale chart review activities for future projects.

Objectives: Assess the Sentinel Initiative's chart review processes to: 1) identify the major drivers of time and cost needed for completion, 2) describe improvements that have been implemented, and 3) propose recommendations to re-engineer the process to reduce the overall cost, time, and effort needed to complete medical chart reviews.

Methods: Five medical chart review projects were evaluated using internal documents, tracking reports, and budgets. Interviews and surveys were conducted with Sentinel Operations Center staff and Data Partners to identify the major cost drivers and recommendations for improving and standardizing the chart review process. Four stages of medical chart review were assessed: initiation, facility identification, chart retrieval, and chart abstraction and adjudication.

Results: Major cost drivers included: time and effort for compliance with Data Partners' privacy, legal, and regulatory policies; uncertainties about the scope of work at the time of contracting; available flexibility in selecting cases for review; the effort required to link patients with providers; the number and length of charts required; the number of chart components requested per case; the cost of redacting Protected Health Information (PHI), and the complexity of case definitions requiring abstraction and adjudication.

Conclusion: The Sentinel Operations Center staff identified several areas for improvement. Activities underway include switching to lower cost vendors for retrieving charts and initiating the use of standardized modular programs for chart selection. Potential future changes include standardizing and simplifying the current contracting structure and compliance policies, and exploring modifications to the Sentinel Common Data Model to provide better patient and provider linkage information. The Sentinel Operations Center staff will also work with Data Partners, their vendors, and the FDA to optimize the number of chart components and/or source records required per patient.

II. MEDICAL CHART REVIEW PROCESS OVERVIEW

Sentinel medical chart review involves four major steps¹: 1) initiation, 2) facility identification, 3) chart retrieval, and 4) chart abstraction and adjudication.

STEP 1: INITIATION

Sentinel medical chart review initiation includes development of a Scope of Work including project objectives, deliverables and timeline; budgeting and contracting with the Data Partners and other external collaborators; contracting between Data Partners and chart retrieval vendors; and development of project-specific Standard Operating Procedure to govern chart retrieval procedures and requirements.

STEP 2: FACILITY IDENTIFICATION

Facility identification involves identification of the provider facility from which to request charts. Historically, each chart review project has developed and implemented *ad hoc* chart selection program(s) to identify individuals whose charts will be requested (Step 3). Multiple charts are often needed for a single patient, particularly if one must confirm both an exposure and outcome. When several charts are required, these charts are ranked to prioritize the most relevant charts to pursue.

STEP 3: CHART RETRIEVAL

Chart retrieval includes execution of the Standard Operating Procedure to retrieve charts from provider sites, redaction of PHI, and centralization of the charts for abstraction and adjudication (Step 4). National claims-based Data Partners must formally request each chart from a provider or facility and typically contract with an external vendor to perform this service. Data Partners that are integrated healthcare delivery systems often have direct access to charts. A given chart review project can include Data Partners from both types of systems. Once charts are obtained, PHI is redacted, to create Limited Data Sets under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), typically via a manual process. Charts are uploaded for review by abstractors and adjudicators via a Federal Information Security Management Act (FISMA)-compliant secure portal, along with tracking information to enable continual monitoring of the status of each request.

STEP 4: CHART ABSTRACTION AND ADJUDICATION

Abstraction involves populating a structured case report form from the chart information. Information captured can include demographics, case outcomes, exposure and clinical information, and is typically entered into a chart abstraction database. Either a single (one abstractor per chart) or double (two abstractors per chart) abstraction process is utilized based upon project complexity.

Chart adjudication further captures information requiring medical expertise. Clinician adjudicators review and extract data pertinent to the case determination. Certain adjudication data, such as dates, are quality-checked using abstraction data, and discrepancies are investigated. Projects with more complex health outcomes of interest typically employ double adjudication, rather than single adjudication.

¹ In addition to the four major steps outlined, Sentinel medical chart review projects include activities prior to the initiation, such as workgroup start up, protocol development, and a abstraction and adjudication form development.

III. METHODS

Five Sentinel medical chart review projects were selected for evaluation including, but not limited to, the following criteria: 1) availability of first hand narrative information; 2) inclusion of both integrated delivery systems and national claims-based insurers; and 3) validations that examined outcomes only and exposure-outcome pairs. Data were collected using meeting minutes, project databases, Standard Operating Procedures, Chart Extraction Trackers, staff interviews, and a Sentinel Operations Center survey. Data reviewed included length of charts, tracked issues, timeliness during each phase of chart review, costs, and assessment of communication to Data Partners and vendors. Additionally, the Sentinel Operations Center conducted semi-structured surveys with Data Partners to review processes for contracting, chart selection and retrieval preparation, chart extraction tracking, and chart retrieval.

IV. RESULTS

A. PRIMARY FINDINGS

The average number of charts requested per project was 401 (range: 143-442). The average number of pages per chart was 80 (range: 49-1,942). Medical chart review steps 1-3 together accounted for 65-81% of the total cost of medical chart review. Abstraction and adjudication (Step 4) accounted for the remaining 19-35% of costs.

Resource requirements varied across projects (**Table 1**). The following elements increased resource intensity: 1) complexity of the case definition (e.g., the number of clinical elements required to review to make a determination), 2) requirements for “specific patient” charts, 3) greater number of Data Partner participants, 4) greater number of charts or chart components requested, and 5) greater length of charts. Activities aiming to validate both exposure and outcome, or multiple exposures and/or outcomes and/or settings were more resource intensive than validating a single exposure or outcome. Selection of particular patient charts, i.e., to validate a risk estimate, involved less flexibility in chart selection and were more resource intensive than chart selection from a large class of eligible patients (“any patient”), which could be required for a general validation project.

B. FINDINGS BY PHASE

Step 1. Initiation

There were two major cost drivers in the initiation phase: budgeting for uncertainty at the time of contracting, and compliance with Data Partners’ privacy, legal, and other regulatory requirements. Budgets for scopes of work were prepared using estimations for chart numbers and chart components. Initiation costs also included the time and effort required to comply with each Data Partner’s privacy, legal, and other regulatory requirements and processes, which varied greatly by Data Partner.

Step 2. Facility Identification

Lack of standardization was a primary cost driver for identification of providers and facilities from whom to request charts. Each medical chart review project employed custom coding for chart selection and retrieval. One key issue is that the Sentinel Common Data Model is built around the unit of the encounter, which often does not uniquely identify the facility of interest. Data Partner source systems are built around the unit of a claim, and many claims, and thus providers, can be rolled up into a single patient healthcare encounter in the Sentinel Common Data Model.

Additionally, Data Partners reported difficulty retrieving charts when the encounters of interest occurred several years in the past due to changes in patient and provider name and address information over time. Obtaining these charts required manual reconciliation.

Step 3. Chart Retrieval and Redaction of Potentially Identifiable Data

While a majority of charts were received within 10 weeks, Data Partners used up to twelve weeks for chart retrieval. Data Partners' Sentinel teams typically paid premium vendor rates, compared with Data Partner clinical service teams, due to Sentinel project needs being relatively small and unpredictable. There were fixed vendor costs per chart review activity, plus variable costs that increased with the number and length of charts, and the intensity of redaction requirements. Sentinel Operations Center staff performed additional PHI redaction that was missed in the first round of Data Partner and vendor redaction, or to further blind adjudicators to exposure status. Data Partner interviews revealed the lack of standardization in operational processes, such data requested and received for the Chart Extraction Tracker, used to monitor chart retrieval progress.

Step 4. Abstraction and Adjudication

Typically, projects used either double abstraction, which improves data accuracy, and single or double adjudication. Projects that employed double adjudication required a longer timeline due primarily to achieving consensus for discordant responses, and accommodating clinicians' schedules.

Table 1. Projects' Resource Intensity Drivers in Addition to Number and Length of Charts

Activity	Type of Verification	No. of Charts Requested	No. of Clinical Elements Required for Outcome Verification	No. of Chart Components Requested	No. of Variables Abstracted	Setting(s)	Flexibility in Selecting Patients	Abstraction and Adjudication Process	Resource Intensity ¹
1	Outcome Only (2)	225	Up to 3	6	18	Inpatient	Yes	Single abstraction, Double adjudication	Low
2	Outcome Only	143	Up to 5	Up to 7 depending on setting	36	Inpatient, Ambulatory Care, Emergency Department	Yes	Single abstraction, Double adjudication	Low
3	Exposure, Outcome (4), and Timing of Outcome	442	Up to 6	Up to 15	Up to 75	Inpatient, Ambulatory Care	Yes	Single abstraction, Single adjudication	High
4	Exposure, Outcome and Timing of Exposure	618	3	18	100+	Inpatient, Ambulatory Care, Emergency Department	No	Double abstraction, Single adjudication	High
5	Exposure, Outcome, and Timing of Outcome	356	Up to 8	9	265	Inpatient, Ambulatory Care, Emergency Department	No	Double abstraction, Single adjudication	Moderate

¹Resource intensity increases under the following circumstances: 1) complexity of the case definition (e.g., the number of clinical elements required to review to make a determination), 2) requirements for "specific patient" charts (*inflexibility* in selecting patients), 3) greater number of Data Partner participants, 4) greater number of charts or chart components requested, and 5) greater length of charts, 6) double adjudication and double abstraction.

V. RE-ENGINEERING THE PROCESS

STEP 1: INITIATION

Improvements Underway: The Sentinel Operations Center is working with select Data Partners to switch to lower cost vendors.

Next Steps: A Chart Review Resource Intensity score is under development at the Sentinel Operations Center. The goal of this score is to signal when the case definition may result in more expensive or resource-intensive medical chart review activities. Further, the Sentinel Operations Center will investigate changes, such as establishing standard budgets within the current Sentinel Operations Center-Data Partner contracting structure, and will increase standardization across Scopes of Work and Standard Operating Procedures, in order to improve timeliness.

Due to increasing Data Partner concern around data sharing and the privacy of patient information, the Sentinel Operations Center will move forward to establish more systematic and clearer data sharing guidance that meets federal and other requirements, in order to minimize the need for extensive Data Partner compliance review for each chart review activity.

STEP 2: FACILITY IDENTIFICATION

Improvements Underway: The Sentinel Operations Center has worked to standardize the format of Data Partner chart requests through development of a standardized modular program. The Sentinel Operations Center has provided training to all the national claims-based insurers on its use, and plans to deploy this new program in upcoming validation projects with the specific aim of standardizing facility identification.

Next Steps: The inconsistency of the provider and facility code fields in the Sentinel Distributed Database remains a hurdle. The Sentinel Operations Center and the FDA have committed to funding a more thorough assessment of these fields' present "fitness for purpose" with respect to medical chart review, which may lead to changes in the Sentinel Common Data Model. This assessment will be a component of a greater technical infrastructure assessment of Data Partners' readiness to participate in large-scale non-traditional health outcome of interest validation activities such as machine learning procedures aimed at outcome detection algorithm improvement.

STEP 3: CHART RETRIEVAL

Improvements Underway: The Sentinel Operations Center has improved routine communication with Data Partners and their vendors to ensure timeliness and prompt responses to issues during the chart review process.

Next Steps: The Sentinel Operations Center will adopt greater standardization of Standard Operating Procedures, including clearer guidelines for communication. Additional guidance will be available to optimize the number of chart components per patient and to clarify redaction requirements.

STEP 4: ABSTRACTION AND ADJUDICATION

Improvements Underway: The Sentinel Operations Center has worked to standardize abstraction and adjudication supporting infrastructure. Several medical chart review projects have used the online survey tool, REDCap, to collect adjudication data.

Next Steps: The Sentinel Operations Center will work with FDA to establish criteria for the use of single vs double abstraction and adjudication. Candidates for single abstraction or adjudication may include projects with uncomplicated case definitions, or ones for which the penalty for error in an individual case is not high.

VI. ACKNOWLEDGEMENTS

The authors would like to gratefully acknowledge the contributions of Sentinel Data Partners who participated in this project, and would like to acknowledge the expertise and contributions of the following individuals: Claudia Coronel-Moreno, Alison Kawai, Megan Reidy, and Lauren Zichittella.