



Aurora Health Care: Using Electronic Medical Records for a Randomized Evaluation of Clinical Decision Support

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- I. Background: Case Study & Data
- II. Data Sharing Challenges
- III. Making Data Usable
- IV. Data Security & Data Publication
- V. Key Factors for Success



Case Study: Evaluation of Clinical Decision Support

In 2014, CMS announced an impending mandate: Starting January (2022)*, CMS will require providers to consult Appropriate Use Criteria through a Clinical Decision Support (CDS) tool prior to ordering advanced imaging (CT, MR, PET, NM) for Medicare patients [1-2]

- Medicare spent over \$4 billion on high cost imaging in 2014 [1]
- CDS tools provide information about the appropriateness of images at the time orders are placed, via a pop-up alert

* Originally scheduled for January 2017

[1] Medicare Payment Advisory Commission, 2014; [1] [42 CFR 414.94](#), [2] <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program> accessed 22 October 2020

Randomized Evaluation with Aurora Health Care

Aurora Health Care: largest health care system in Wisconsin, comprising fifteen hospitals and more than 150 clinics in thirty communities, and the Aurora Research Institute.

- Was planning to implement CDS to prepare for CMS mandate
- Dr. Reimer—radiologist and researcher—interested in understanding impact of CDS

RCT:

- December 2016 – December 2017
- 3,511 Aurora health care providers. Randomly assigned $\frac{1}{2}$ to receive CDS and $\frac{1}{2}$ to order scans as usual.

Example of Pop-up Alert

Appropriateness rankings for a 35 year old Female

Indication(s): Headache, chronic, neuro deficit ✕

Appropriateness	Service	Display Evidence...
4	CT ANGIOGRAM HEAD	Select this service
8	MRI BRAIN	Select this service
7	CT HEAD BRAIN	Select this service

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Additional portion at the bottom of the BPA allows the provider to continue with or remove original order, and/or place an alternative order

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Data

Quiet Period: Apr 22-Dec 14, 2016 (8 months)

Study Period: Dec 15, 2016 – Dec 15, 2017 (12 months)

Hospital data (from Aurora)

- Provider demographic information
- EMR data from Epic (patient demographic information, encounter and scan order data)

CDS data (from NDSC)

- Scan order data (scan id, scan, indication, score, alternatives)

I. Background: Case Study & Data

II. Data Sharing Challenges

A. Cost

B. HIPAA Privacy Rule

C. Approvals

III. Making Data Usable

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Data Sharing Challenges – Cost

Leadership at Aurora recognized the value of their data and were concerned about giving it away without compensation.

- Advocated for value of the research knowledge gains
- Cost-reimbursable sub-award to support Aurora's data teams



Data Sharing Challenges – HIPAA

In the United States, the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) regulates the sharing of health-related data generated by health care entities such as Aurora Health Care. It allows, but does not require, sharing data for research.



The HIPAA Privacy Rule (45 Code of Federal Regulations (CFR) Part 160 and Subparts A and E of Part 164, accessed at https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr160_main_02.tpl on 06-23-2020.

Data Sharing Challenges – HIPAA

The Privacy Rule defines three levels of data:

- **Research identifiable data**
- **Limited data sets**
 - No direct identifiers
 - Requires a Data Use Agreement with specific terms
- **De-identified data**
 - Dates must be excluded



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Data Sharing Challenges – HIPAA

Solution: Use only de-identified data.

- Relatively simple DUA that did not need to meet HIPAA requirements
- Used HIPAA [Safe Harbor method](#) (45 CFR 164.514(b)) to de-identify data
 - Remove 18 identifiers enumerated by HIPAA

Data Sharing Challenges – Approvals

- Research Administrative Preauthorization (RAP) required before proceeding to IRB review.
 - Reviewed for quality, alignment with Aurora's values
 - Assessment for whether adequate resources exist for the project
- IRB review
- Research sub-award contract outlined additional terms
 - e.g., allowing the publication of an aggregated public-use data set



I. Background: Case Study & Data

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III. Making Data Usable

A. Identify & extract data

B. Understand and interpret data

C. Create a linked panel dataset while complying with HIPAA

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Identifying Relevant Data

Epic EMR system: The most common in the US, and includes an industry standard radiology information and order entry system.

- ACR Select, which is a third-party software designed by NDSC, integrates with Epic to generate the alerts
- Epic and integrated programs generate and store data in a relational database (SQL at Aurora). → tables are easy to link
- 18,000 tables → data can be hard to find

Understand and Interpret Data

Documentation, but mostly:

- Site visits
- Observation
- Interviews



Creating a Panel Data Set: Linking de-Identified Data

- Monthly extracts
- Need to create an anonymous patient and provider ID to link records
- Process must be stable and replicable each month
- Ran checks to ensure the process was replicable



Simplified Illustration: Surrogate ID Generation

Original - Jan		
Provider Name	Provider ID	T/C
Laura Feeney	543	T
Amy Finkelstein	319	C
Joe Doyle	359	T

Master List as of Jan			
Provider Name	Provider ID	T/C	Anon ID
Laura Feeney	543	T	2
Amy Finkelstein	319	C	11
Joe Doyle	359	T	9

MIT - Jan	
Anon ID	T/C
2	T
11	C
9	T

Original - Feb		
Provider Name	Provider ID	T/C
Laura Feeney	543	T
Amy Finkelstein	319	C
Sarah Abraham	621	T

Master List as of Feb			
Provider Name	Provider ID	T/C	Anon ID
Laura Feeney	543	T	2
Amy Finkelstein	319	C	11
Joe Doyle	359	T	9
Sarah Abraham	621	T	1

MIT - Feb	
Anon ID	T/C
2	T
11	C
9	T
1	T

Creating a Panel Dataset: Relative Dates

- HIPAA de-identified data must exclude dates.
- Solution:
 - Generate a patient-specific reference date
 - Convert each date variable to a relative reference to the number of days difference from the reference date



Making Data Usable Requires Time & Effort

- High time & mental effort requirements from Aurora analysts: Locating data, interpreting data, and creating a linked panel data set
- MIT research team offered and provided as much support as we could: pseudo code, templates, guidance, discussion
- Success hinged on:
 - Strong communication between analysts
 - Trust
 - Shared incentive

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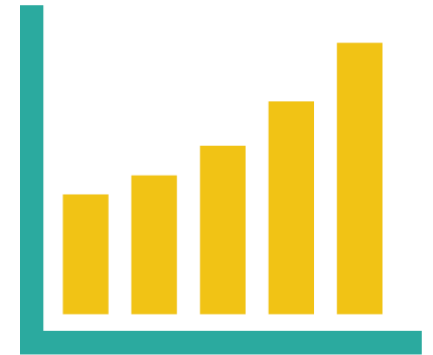
Data storage & transfer

- MIT only had access to de-identified data
- Data shared via Secure File Transfer Protocol (SFTP)
- Stored on a secure, encrypted server maintained by IT professionals at the MIT Department of Economics.
- Access to server through an encrypted Secure Shell (SSH) protocol after connecting to the MIT network or MIT VPN, which utilizes an independent authentication system.



Data Publication

- The agreements between Aurora and MIT explicitly acknowledged and permitted the publication of scholarly work that would include analytic results.
- Sub-award permitted a public data set to enable replication
 - aggregated to the provider rather than scan-order level
- 30-day review period for disclosure



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Key Factors for Success

We attribute much of the success of this data sharing and research collaboration to clear communication, strong relationships, and patience.

- Frequent in-person meetings → trust, a shared vision, commitment

Interest from Aurora in continued collaboration on research



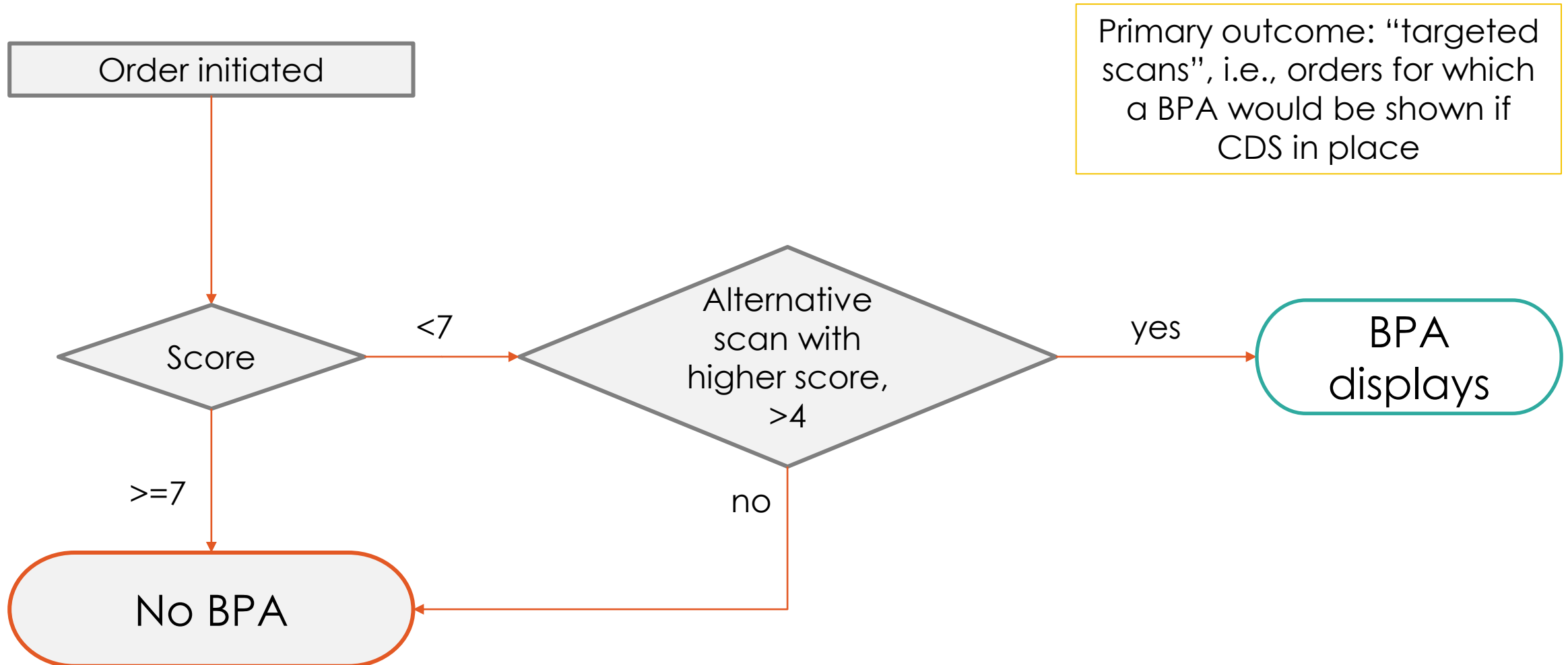
Thank you!

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Intervention Flowchart: Logic for showing Best Practice Alerts (BPAs)



Overview of 5 Safes

- Several steps are taken in the process of sharing data. Aurora had an established process for some steps; others were developed to meet the specific needs of the clinical decision support evaluation. Overall, assessments and approvals for the project as a whole took several months, during which researchers were cautious about devoting additional resources to a project that might not be approved.



Preservation and Reproducibility of Researcher-Accessible Files

- Aurora Health Care does not actively maintain the researcher-accessible de-identified files made available for this research study. The files sent to MIT were snapshots of a data warehouse, which is periodically updated, with the potential for certain values to be overwritten.
- Within the study period, the MIT team received data in regular updates, typically every two to four weeks.

6.2-Preservation of Researcher-Generated Files

- Research-generated data files and code are preserved on MIT's secure servers. Researchers do not have permission to share the raw de-identified data nor the intermediate or final disaggregated data sets. The data use agreements require that MIT return or destroy confidential data upon request by Aurora; however, to date no such request has been made.
- The Public Use Files are sufficient to replicate all published results. However, due to the aggregation and limited fields of the data set, the possibilities for further analysis may be limited.

Sustainability and Continued Success: Revenue

- The research on clinical decision support received funding from the Laura and John Arnold Foundation (now Arnold Ventures). Through a sub-award from MIT to Aurora Health Care, the research team provided funding on a cost-reimbursable basis for data extraction and preparation as well as support for interpreting the data. While this award seemed to garner goodwill for the project, the sub-award would have accounted for an extremely small fraction of Aurora's annual operating budget.