

Data Quality and Clinician Burden

Overview, Examples, and Basic Recommendations (Part 1 of 2)

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Assignment:

DQ and RCB Overview and Recommendations

“This week Dr Reed Gelzer will offer a presentation on Clinician Burden related to Data Quality, Integrity and Reliability.”

Hypothesis: Uncertainties Create Clinician Burdens

Who's telling me that this system is fit to do its job?

Can I trust the way it captures information?

- When it's made easy, is there harm? Risk?
- When it's difficult, is there any good reason for that or am I simply solving someone else's problem, all burden/zero bedside care quality value?

Can I rely on the information this system presents for my use, others use in:

- My patients' care?
- In business operations?
- In care improvement?
- In community health promotion? In pandemic harms mitigation?

Data Quality = Data's Fitness for Use

“DQ checks are generally utilized for determining whether or not the data available is appropriate for particular tasks, also described as “fit-for-use”².

²Kahn, MG, Raebel, MA, Glanz, JM, Riedlinger, K and Steiner, JF. A Pragmatic Framework for Single-site and Multisite Data Quality Assessment in Electronic Health Record-based Clinical Research. *Med Care*. 2012; 50. DOI: <https://doi.org/10.1097/MLR.0b013e318257dd67> as cited in Rogers, JR, et al. 2019 A Data Element-Function Conceptual Model for Data Quality Checks. *eGEMs (Generating Evidence & Methods to improve patient outcomes)*, 7(1): 17, pp. 1-14. DOI: <https://doi.org/10.5334/egems.289>, p. 9 of 14.

Data Quality Is Context/End-Use Dependent

- Accurate = End-Use Dependent = Accurate for the purpose of _____
- Timely
- Relevant
- Complete
- Understood
- Trusted

Today's focus: "Accurate for the purpose of _____"

¹Olsen, Jack E., Data Quality: The Accuracy Dimension, Morgan Kaufmann Publishers, San Francisco, CA, 2003, p. 24

Side-Brief on “Reliability” and “Integrity”

Reliability: The EHR is **CAPABLE** for producing accurate data and authentic records.

Ex: 2013 HHS-OIG Survey-88% of 864 sampled hospitals can corrupt audit functions and records. (Mitigation remains incomplete today.)

Integrity: (here a subcategory of Reliability): The EHR is **CAPABLE** of preserving, protecting, and auditably verifying the uncorrupted state of data and records outputs.

NOTE: Other authoritative professional domains (ex: Judges, lawyers, CPAs)

Data Quality Specifications Are Context/End-Use Dependent

Example: State Records Requirements (Generally, States have first-standing) EHR-sourced data and records have overarching end-use requirements as intra-state business records.

Purpose: Anyone doing business must be assured that an enterprise keeps its records at least to the same “minimum necessary” as everyone else in that State.

Thus: EHRs are *not designed to be* **accurate for the purpose of supporting intra-State business records requirements.**

Therefore: The burden falls on the clinician to verify fitness for intra-State business records requirement OR accept the burden of non-conformance

Clinician Burden Sources: The 50K' View

Challenge 1: EHRs aren't designed as Clinical Records Systems.

- External POV
- Internal POV
- Professional POV

Challenge 2: Non-transparency of the EHR marketplace

In both challenges, the burden falls to the clinician to test and verify or accept the risks and costs of errors, harms, uncertainty, including safety and security.

Most enterprises and clinicians try to do right, but with extraordinary variance (ex: 2 physicals).

Recommendations = Address Due-Diligence Gaps, Reproduce/Scale Successes, Solve specific end-use data quality requirements.

Challenge 1:

EHRs Aren't Designed As Clinical Records Systems
Therefore the “fitness” burden is on the end-user

A: External POV

B: Internal POV

C: Professional POV

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

A: External POV- Clinical Records' Requirements as defined by U.S. context Many examples

First Example :

Records requirements are primarily defined at the State level and apply to all business entities operating in that State. (Partial exceptions: MHS, VA)

Derived from accumulated real-world experience (including science-informed experience) with differentiating false records from true records in matters of law. (Ex: Remington case, Illinois BH case)

Clinical records in most States are a subtype of business records. They enjoy special treatment as long as they don't violate basic rules

EHRs were not designed to support conformance with State records rules

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

A: External POV- Clinical Records' Requirements as defined by U.S. context

Second Example: Nationally, publicly traded hospital entities like HCA, Tenet, Quorum, (11 more on NYSE) are required under SEC rules to assure the accuracy of records insofar as it has impact on stock value (such as the value of the Accounts Receivable).

<https://topforeignstocks.com/stock-lists/the-full-list-of-hospitals-stocks-trading-on-the-nyse/>

Charitable organizations also have unique obligations to assure conformance with records laws.

EHRs were not designed to support conformance with SEC records or applicable Federal or State Charitable org rules (Ex: Rigorous Internal Controls)

Therefore clinicians are burdened with the requirement of proving that records are accurate for the purpose of meeting applicable SEC rules or charitable organization rules.

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

Resulting Clinicians Burden 1A:

Clinicians are responsible for testing EHRs for records law conformance or accept the risk if conformance fails. (Ex: “Learned User” principle)

This is currently a relatively low risk area unless audited in a State context (Medicaid, malpractice, or etc.) It does greatly simplify investigations, prosecutions

Examples: Authoring “convenience” functions that mis-represent or falsify author, date, time of data creation. Records aggregation/reports functions

In some states falsifying business records is a felony, esp. if \$\$.

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

B: Internal POV- Clinical Records' Requirements as defined by applicable formal Enterprise Documentation P&P

Examples:

Commonly include general requirements for authoring and amending plus detail for key record and report types, especially in high-risk or high volume areas (Operative Reports, Discharge Summaries)

EHRs are not required to assure conformance with stated enterprise records policies and procedures = Clinician burden

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

Resulting Clinician Burden 1-B:

Clinicians are responsible for testing EHRs for conformance with their facility P&P or, in the absence of proof, to accept the risk if conformance fails. (Ex: “Learned User” principle)

Note: In many clinical settings

- Records Management professionals were not part of the EHR vetting or selection team.
- Nobody explained to clinicians why some apparent burdens aren't burdens, but protections. Why some “conveniences” are wrong, how come can be made OK.

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

C: Professional POV- Clinical Records' Requirements as defined by Professional duties and obligations as sovereign professionals.

Examples:

Clinical professionals are generally required to consider “all readily available information” In an EHR system there can be terabytes of “readily available”, know it all? (Ex: E.D.)

EHRs are not required to assure conformance clinicians professional obligations and duties = Clinician burden

Challenge 1:

EHRs Aren't Designed For Clinical Records Data Quality

Resulting Clinician Burden 1-C:

Clinicians are responsible for testing EHRs for conformance with the professional duties and obligations, or, in the absence of proof, to accept the risk if conformance fails. (Ex: “Learned User” principle)

Ex: EHR “defaults” in allergies, meds, prompts

NOTE: Paused Here May 4

Further discussion tentatively scheduled for June 1, 2020

Additional content, if any, TBD.

Regards and thanks for today's discussion. RDGelzer, MD, MPH

Challenge 2:

Markets Require Transparency = No EHR Market

EHR Accuracy Attributes and End-Use “Fitness” information is unavailable to the public.

- **No “Consumer Reports” for EHRs**
- **No reliable data on EHR-mediated harms**
- **No reliable data on EHR settlements**
- **Investigations of EHR defects are settled without public trial**

Challenge 2:

Markets Require Transparency = No EHR Market

Challenge 2 Resulting Clinician Burden

No means (no marketplace) for comparing/contrasting EHRs based on

- **Harms and errors history**
- **Consumer/customer reports of harms events, near-misses, legal settlements**
- **Accuracy, authenticity attributes support demonstrations**
- **No “Consumer Reports” for EHRs**
- **EHR vendor fraud investigations’ findings and settlement records (no public trial)**

Therefore: Clinicians are required to evaluate (or accept) risk and burdens blind, without market transparency

Sample Recommendations

Identify domains where Data Quality principles operationalized in practice, celebrate, replicate, and scale them. Facilitate a success marketplace

- CLIA
- Anesthesiology Information Management Systems
- 1814 Clinic at University of Alabama-Birmingham (scaling state-wide HIV extraordinary care)

Facilitate and publish bedside care value projects with defined, measurable, end-use requirements

Create resource library of Due-Diligence tools (ex: Joint Commission Information Management Requirements' Conformance Testing including Harms and Errors reporting)

Facilitate projects to define and verify conformance with end-use requirements (Ex: HL7 EHR WG LE-SWA) <https://build.fhir.org/ig/HL7/fhir-skin-wound-ig/branches/master/index.html>

Consider

Adapting, improving the draft, proposed Burden Typology here to better fit your work

Contact Information

Dr. Gelzer consults for Trustworthy EHR, LLC, supporting data quality, records authenticity, and compliance initiatives for public, private, and military health facilities as well as health policy, program integrity, and EHR Standards organizations.

- Co-Facilitator of the HL7 EHR Systems “Data Quality” initiative thru the Lower Extremity Skin Wound Assessment project.
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- Co-author of “Diagnosing and Treating Legal Ailment of the Electronic Health Record: Toward an Efficient and Trustworthy Process for Information Discovery and Release”, The Sedona Conference Journal, Summer 2017.
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Out of the box

EHR Requirements Summary

	Law (State and Federal)	Programs	Regulatory	Data Science	Clinical Science
<u>Records</u> originated in EHRs	No	No	No	No	No
<u>Systems</u> capturing, managing records	No	No	Yes (minimum, below law thresholds)	No	No
<u>Reports</u> Outputs produced by EHRs	No	No	No	No	Variable

<http://www.fiercehealthpayer.com/antifraud/story/despite-repeated-warnings-pervasive-ehr-fraud-vulnerabilities-remain/2016-01-25>

“A 2013 survey conducted by (HHS) OIG of 864 hospital providers found that 44 percent of respondents reported they could delete their audit logs. Another 33 percent of hospitals said they could disable audits and 11 percent indicated they had the ability to edit audit logs.”

Current state as of May 4, 2020: Mitigation agreement never fulfilled