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Towards a Regulatory Framework for Electronic Medical Record Interoperability in Canada

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Abstract. All complex systems are potentially predisposed to failure. Healthcare systems are complex systems that are prone to many errors that can result in dire consequences for patients and healthcare providers. The healthcare system in Canada is under unprecedented strain due to shortages of healthcare providers, provider burnout, inefficient workflows, and a lack of appropriate digital infrastructure. We used failure mode and effects analysis (FMEA) to identify the failure modes for care provided in primary care settings. We identified failure modes in appointment scheduling, patient-provider communications, referrals, laboratory and diagnostic procedures, and medication prescriptions as the main failure modes. To mitigate the detected risks, we recommend solutions to 'close the loop' on failure modes to prevent patients from falling through the cracks, as vulnerable patients who cannot advocate for themselves are most likely to do so. We provide preliminary requirements for a regulatory regime for electronic health records that can reduce provider burnout, improve regulatory compliance, and improve system efficiency, all while improving patient safety, experience, and outcomes.

Keywords. Electronic health record, failure mode and effects analysis, healthcare system efficiency, interoperability, patient safety

1. Introduction

All systems have the potential for failure. In the case of the healthcare system, failures in primary care lead to downstream impacts such as increased healthcare utilization, healthcare provider burnout, failure to comply with regulatory requirements, and increased health system costs. To reduce errors, improve quality, reduce workload, and decrease costs, systems must become more proactive [1].

Healthcare systems are extremely complex because of the many interest holders (including patients/care providers, health care providers (HCP), payers, pharmaceutical

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companies, health technology vendors, administrators, researchers, policy-makers and decision-makers), rapidly evolving knowledge and practice and the complexity of how care is delivered in a modern healthcare system [2]. Healthcare is delivered through a diverse group of facilities including but not limited to private clinics, hospitals, community health clinics, long-term care facilities, pharmacies, laboratories, radiology, and diagnostic imaging facilities. This diversity and a lack of coordination between them adds to the complexity of the healthcare system, which consequently increases the risk of errors in the system and reduces its safety and efficiency.

The Canadian healthcare system is under significant strain and is experiencing several serious problems including but not limited to a shortage of family physicians, registered nurses, and nurse practitioners; burnout of HCPs; rising and unmanageable costs; and an explosion in advanced health technologies [3]. In addition, the digitalization of healthcare in Canada has evolved slowly in comparison with other developed countries including the US, the UK, and Continental European countries [4].

An evolution of Electronic Medical Record (EMR) systems to encompass new interoperability features is required to tackle the complexity of day-to-day care of patients in our healthcare system. Introducing a "safety-first" regulatory regime for interoperability with EMRs in Canada could reduce the risks of patients falling through the cracks. Sound interoperability principles could improve patient access, optimize clinic and system efficiency by decreasing time spent on documentation and reviewing them; reduce inequity and patients falling through the cracks; enhance the simplicity of knowledge use and thereby reducing HCP burnout; and improve compliance with regulatory requirements.

Failure Modes and Effects Analysis (FMEA) is a reliability management tool that can proactively detect potential failures of a system and help identify promising methods to prevent them from occurring by assessing their causes and evaluating their effects. [5]. FMEA has been used extensively to identify and analyze the risk of failures in different fields of healthcare over the past decade [5, 6].

2. Methods

We used the Institute of Healthcare Improvement's FMEA tool [5-7]. We focused on five main potential points of failure that frequently occur in the continuity of care based on our team's observations and documents from Canada Health Infoway, eHealth Ontario, the College of Physicians and Surgeons of Ontario, and the CommonWealth Fund healthcare performance indicators [3,7-9]. We performed a risk analysis on the causes and effects and obtained probability and severity rankings for them. We calculated the Risk Profile Number (RPN) for each failure mode. To calculate RPNs we estimated Occurrence (O) –the probability of failure of a process, Severity (S) –the severity of a failure, and Detection (D) –the probability of NOT detecting a failure. O, S, and D were measured on a scale of 1 to 10, and RPNs were calculated as O*S*D. RPNs range from 1 to 1000. Ethics approval was not sought. Our team of clinicians, health informaticians, and engineer-mathematicians brainstormed potential solutions for failure modes and effects.

3. Results

We grouped identified requirements into the following categories: efficiency of clinical and administrative processes, regulatory compliance, patient safety, patient experience, data for operational effectiveness, ease of knowledge use, and last but not least equity. For example, for patient safety requirements, we identified laboratory tests not done, patient did not attend a referral, and prescriptions not filled. From the provider's lens, regulatory compliance and patient safety requirements could be viewed as an increased liability and reputational risk; e.g., license suspension or being sued.

Overall, we identified five high-level potential failure modes in an outpatient clinic: scheduling, communications, referrals, laboratory and diagnostic imaging testing, and prescriptions (Figure 1). We determined the causes and effects and assigned scores to O, S, and D according to our observations and literature search (Table 1).

Table 1. Selected FMEA analysis of an outpatient flow started with their intention to book an appointment to receive the proper care. Causes, effects, occurrence (O), severity(S), probability of not detecting the failure (D), and Risk Profile Numbers (RPNs).

Process	Cause(s)	Effect(s)	O	S	D	RPN
Scheduling	Phone busy, appointment too far in the future	Diagnostic delay, treatment delay	4	5	9	180
Communications	Message not sent, message not received, telephone tag	Diagnostic delay, treatment delay	3	5	10	150
Referrals	Message not sent, message not received, wrong specialist, specialist rejects referral	Diagnostic delay, treatment delay, downstream complications	3	8	10	240
Laboratory and diagnostic imaging testing	Patient does not complete, results lost in filing	Diagnostic delay, treatment delay, regulatory non-compliance	3	5	10	150
Prescriptions	Patient doesn't fill, patient doesn't pick up	Medication not taken, potential complications, increased system utilization	6	6	10	360

Table 1 demonstrates that the inability to detect patients falling through the cracks in key areas can lead to significant diagnostic and treatment delays, leading to worsened disease and increased health system utilization. Although not explicit in the table above, vulnerable patients are more likely to fall through the cracks, leading to worse outcomes for this subpopulation.

Siloed information limits the ability of HCPs to make the best clinical decisions, but unplanned interoperability could potentially increase the noise ratio significantly, adding to burnout and system inefficiency. We recommend that interoperability requirements focus on helping clinicians better detect when patients are falling through the cracks and follow up on them. Given that the number of 'defects' in the process is likely to be astronomically high, we also recommend that interoperability include

robust risk profiling to ensure that those patients who are at the highest risk of complications and health system utilization are targeted first and that priority cases are no buried under an avalanche of missed visits, diagnostic testing, prescription abandonment, etc.

4. Discussion

An efficient booking and scheduling system is essential to facilitate timely patient access to physicians. A scheduling system that is interoperable with HCP EMRs could help detect the failure of appointment booking or referral completion, thereby preventing treatment delay.

A secure and robust communications system could enable clinics to identify when patients are not attending and provide appropriate follow-up. Since the risk of this happening is large, we recommend that clinics use this system with a risk profiling system to identify high-risk patients who need follow-up.

The process of ordering laboratory and diagnostic imaging testing is susceptible to the same potential errors. The College of Physicians and Surgeons of Ontario (CPSO) recommends that "physicians have an effective test results management system that enables them to effectively communicate test results to patients and take clinically appropriate actions" [11]. Clinicians need to decide on the importance of the results of diagnostic tests and procedures for the patient and decide on prioritizing communication. An interoperable EMR system with risk profiling can help clinicians track and follow up on high-risk laboratory results.

Medication prescription and dispensing is one of the processes that is frequently considered a failure mode in health systems [5]. The causes are diverse and can range from errors in prescription including drug interactions, not sending and delayed sending of the prescription and refill confirmations, wrong medication being given by the pharmacy, the patient not going to the pharmacy to get their drugs or delivery has not been arranged are just a few common causes. An interoperable EMR with risk profiling for high-risk patients (e.g., at-risk of developing kidney disease, blindness or stroke) could potentially help 'close the loop' on patients who fail to take their medications or who take too many because of prescriptions from multiple providers.

Despite improvements in implementing digital health solutions in Canada including the adoption of EMRs by more than 90% of physicians, these solutions and their functionalities could be used more efficiently [3]. Our proposed recommendations focus interoperability on improving quality of care, reducing cognitive workload, reducing administrative burden, improving system efficiency, reducing patient risk, improving compliance with regulations, and reducing health system utilization.

Limitations of our study include the narrow scope of the study for feasibility and reporting purposes. We focused on very simple but very common scenarios of encounter and care flow of a patient with their primary care physician, specialist, diagnostic laboratory and imaging facilities, and pharmacy. We only discuss the most common causes and significant effects in this paper. We also did not discuss technical aspects of interoperability.

5. Conclusions

We found several failure modes in outpatient care in the Canadian primary healthcare system that can and do result in significant effects such as increased risk to patients, HCP liability, and health system inefficiency and cost. Focused interoperability with EMRs can address most failure mode causes related to scheduling, communications, referrals, laboratory tests and diagnostic imaging procedures, and medication prescription and drug dispensing.

A regulatory regime for interoperable EMR needs the involvement of all interest holders and support from all three levels of government. This regime should encourage innovation and allow effective use of emerging technologies like artificial intelligence and machine learning.

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