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Understanding diagnostic processes in emergency departments: a mixed methods case study protocol

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ABSTRACT

Introduction Diagnostic processes in the emergency department (ED) involve multiple interactions among individuals who interface with information systems to access and record information. A better understanding of diagnostic processes is needed to mitigate errors. This paper describes a study protocol to map diagnostic processes in the ED as a foundation for developing future error mitigation strategies.

Methods and analysis This study of an adult and a paediatric academic ED uses a prospective mixed methods case study design informed by an ED-specific diagnostic decision-making model (the modified ED-National Academies of Sciences, Engineering and Medicine (NASEM) model) and two cognitive theories (dual process theory and distributed cognition). Data sources include audio recordings of patient and care team interactions, electronic health record data, observer field notes and stakeholder interviews. Multiple qualitative analysis methods will be used to explore diagnostic processes in situ, including systems information flow, human–human and human–system interactions and contextual factors influencing cognition. The study has three parts. Part 1 involves prospective field observations of patients with undifferentiated symptoms at high risk for diagnostic error, where each patient is followed throughout the entire care delivery process. Part 2 involves observing individual care team providers over a 4-hour window to capture their diagnostic workflow, team coordination and communication across multiple patients. Part 3 uses interviews with key stakeholders to understand different perspectives on the diagnostic process, as well as perceived strengths and vulnerabilities, in order to enrich the ED-NASEM diagnostic model.

Ethics and dissemination The University of Michigan Institutional Review Board approved this study, HUM00156261. This foundational work will help identify strengths and vulnerabilities in diagnostic processes. Further, it will inform the future development and testing of patient, provider and systems-level interventions for mitigating error and improving patient safety in these and other EDs. The work will be disseminated through journal publications and presentations at national and international meetings.

INTRODUCTION

Diagnosis and management of patients in emergency departments (EDs) involves highly complex cognitive processes under time pressure that are susceptible to errors,

Strengths and limitations of this study

► Prospective, observational studies informed by theory which explore diagnostic processes in situ are uncommon, yet urgently needed to improve understanding of emergency department (ED) diagnosis.

► Study findings will provide critical, contextualised knowledge of how ED diagnosis and management is accomplished through interactions of patients, providers and tools, informing the design of interventions to mitigate error.

► A transdisciplinary team including safety experts, data scientists, systems engineers, cognitive psychologists and emergency physicians contributed to this mixed methods study design.

► The focus on one adult and one paediatric academic ED is methodologically critical to achieve a deep understanding of cognition in context, but may limit transferability to other settings.

which we define as missed opportunities for improving diagnosis, regardless of patient outcomes.[1] While precise error rates are unknown, a conservative estimate of 5% of the 139 million ED visits annually suggests ~6.9 million errors per year.[2] Errors typically result from a complex interplay of factors arising from patients (eg, presenting symptoms, health literacy, disease complexity, behaviours), provider/care-team performance (eg, cognitive load, information gathering and synthesis, coordination) and systems (eg, health information technology, overcrowding, interruptions).[3] Current methods to study errors are suboptimal as they largely focus on retrospective analyses of what went wrong rather than understanding and contextualising diagnostic processes as they occur in the ED. Novel prospective studies are urgently needed to improve the understanding of ED diagnostic processes and to facilitate the development of interventions to improve patient safety.
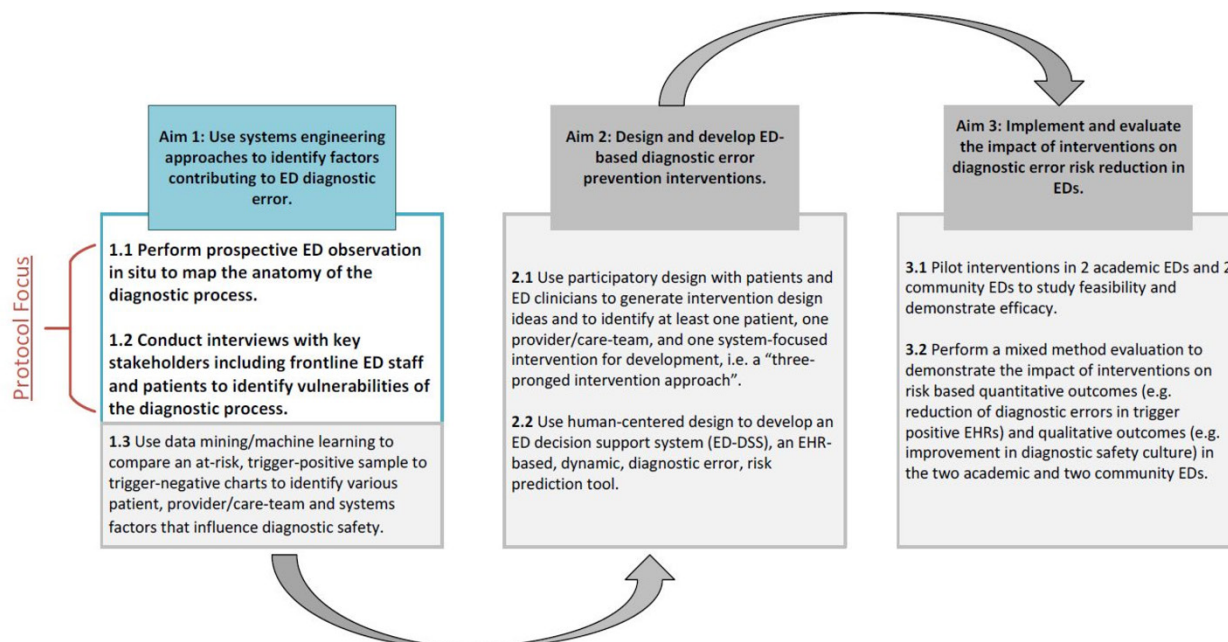
Figure 1 Improving Diagnosis in Emergency and Acute Care—Learning Laboratory (IDEA-LL) Aims. ED, emergency department; EHR, electronic health record.

We assembled a transdisciplinary team with expertise in emergency medicine, cognitive psychology, informatics, systems engineering, human–computer interaction (HCI) and design, anthropology, public health, mixed methods research and data science to address this gap. With support from the Agency for Healthcare Research and Quality, we are creating an Improving Diagnosis in Emergency and Acute Care—Learning Laboratory (IDEA-LL) to investigate ED diagnostic processes, study systems vulnerabilities and develop and iteratively test patient, provider and system-oriented interventions to mitigate diagnostic error. The three aims of the parent project (IDEA-LL) are shown in figure 1.

Patients that present to the ED often have complex and ambiguous problems that may not result in a 'diagnosis' if diagnosis is narrowly conceived of as a 'label' or solution to a problem. For the purposes of this study, we will operationalise diagnosis as an ongoing, sense-making process with inherent uncertainty as described by Ilgen *et al*.[4] Furthermore, we will use the term 'diagnostic processes' to encompass both diagnosis and related management processes.

Conceptual models of diagnostic and management reasoning typically break the process down into multiple components (eg, information gathering, hypothesis formation, differential diagnosis generation, development of a treatment plan).[5] A model recently proposed by the National Academies of Sciences, Engineering and Medicine (NASEM) incorporates these dynamic components and links diagnosis and management by healthcare teams to patient and system outcomes in a feedback loop.[3] This model, recently adapted by ED experts into the modified ED-NASEM model,[6] provides an overarching framework for exploring diagnostic processes in the current study.

Two complementary theories of human cognition also inform this work: *dual process theory*[7] and *distributed cognition theory*.[8] Dual process theory characterises information processing as it occurs 'in the head' of an individual. This theory holds that clinicians process information via two primary pathways: system 1 (pattern recognition) and system 2 (analytical thinking), and that experts switch back and forth between these two systems.[9 10] Inappropriate reliance on either system can result in errors.[11 12] Distributed cognition theory views information processing as occurring 'out in the world'.[8] Cognitive tasks such as diagnosis are accomplished through their distribution across multiple individuals (eg, patients, nurses, physicians), external tools (eg, electronic health record (EHR), computer-based searches, medical devices), spatial arrangements and time.[13] Many of these tasks occur outside of the diagnosing clinician's purview, including the prehospital setting and after patient disposition. Collaborative systems of people and tools (also known as 'artefacts') implement dynamic processes constituting a shared cognitive system to create a diagnosis, with breakdowns anywhere in the system potentially leading to error.[14–18] Individual cognitive processes 'in the head' are difficult to access in real time and must be inferred through observation or questioning; however, information processing in a distributed cognition system is more readily accessible through observation of interactions 'out in the world', which informs our study design.

This paper describes our three-part approach for sub-aims 1.1 and 1.2 in IDEA-LL, which focuses on *using*

systems engineering and cognitive theories to explore ED diagnostic processes, as well as vulnerabilities that may lead to error. The purpose of parts 1 and 2 is to prospectively explore ED diagnostic processes and to understand the distributed cognitive system supporting diagnosis in everyday ED practice. The purpose of part 3 is to elaborate on and enrich the modified ED-NASEM model and to examine perceived strengths and vulnerabilities in emergency care diagnostic processes.

METHODS
Design
This work will use a prospective mixed methods case study design[19 20] to collect quantitative and qualitative data in an adult and a paediatric ED. We will use both process measures (ie, tracking specific steps leading to diagnosis including interactions with tools, communications between people and monitoring elapsed time), and multiple qualitative methods (eg, field observations, cognitive ethnography,[21] interviews) to map information capture, transfer and sharing among patients and providers leading to diagnosis. Data collection will occur December 2020–December 2021. An overview of the proposed studies appears in table 1.

Our data collection procedures, in accordance with distributed cognition theory,[8 13] will primarily focus on direct observations 'out in the world' as diagnosis unfolds within the sociocultural settings of two EDs. We will record how cognitive work is distributed across people and tools in context by recording interactions and documenting its organisation across physical space and time. In addition, we will elucidate individual cognition by obtaining provider responses to brief mini-interviews during clinical work. As interruptions can add to provider cognitive load and potentially alter diagnostic performance, we will conduct interviews opportunistically to minimise interruptions in patient care.

Setting
Parts 1, 2 and 3 will be conducted in a single academic tertiary care setting with an adult and a paediatric ED. These EDs serve an urban area (population ~120 000), in addition to a large suburban and rural catchment area. Both EDs are level I trauma centres, with a total annual census of 106 470 visits (74 034 adult and 32 436 paediatric). The EDs have 110 beds (88 adult and 22 paediatric), augmented by hallway and recliner space. The EDs are staffed by ~65 attending physicians, ~64 residents, ~40 advanced practice providers and ~380 nurses. Resident trainees include postgraduate years (PGY) 1–4 with 16 residents per class, and ~170 medical students rotate through the department annually on a 1-month required clerkship. According to health system policy, patients up to age 21 may be seen in the paediatric ED, however, patients ages 18–21 account for a small percentage of the total paediatric population (ie, ~5%).

Sampling, eligibility, recruitment, informed consent and data collection
Part 1: individual patient case as the unit of observation
Sampling
We will use purposive sampling of patients presenting to the ED who are at higher risk for diagnostic mishaps such as those with undifferentiated symptoms of abdominal pain, fever, chest pain or shortness of breath.[22–27] While data has linked chest pain symptoms with a wide range of never-miss conditions,[23 27] limited research has explored shortness of breath and never-miss conditions. Both symptoms will be included as they represent undifferentiated symptoms commonly seen in the ED that have been associated with missed diagnosis. We anticipate a minimum sample size of 24 patients based on previous observational studies in medicine.[28] The final sample size will be determined when adequate conceptual depth has been achieved in the findings.[29]

Eligibility
Eligible adult patients will be 21 or older and capable of giving informed consent. Eligible paediatric patients will be between 0 and 21 years of age and their legally authorised representative must be capable of giving informed consent. For paediatric patients 13 years of age or older, assent will also be required. We will exclude non-English speaking patients and those with altered mental status due to limitations of obtaining informed consent.

Recruitment of patients
We will enrol patients with three types of undifferentiated presenting symptoms associated with a 'high-risk' for diagnostic errors, namely chest pain, shortness of breath and abdominal pain. Working in collaboration with the triage nurse as patients register, research personnel will identify potentially eligible patients at triage. We have a waiver for screening patients for eligibility and capturing initial information exchange prior to approaching for informed consent and enrolment. Informed consent will be conducted once triage is complete. After the patient is roomed, the researcher will notify the care team that the patient has been enrolled in the study. Enrolment will occur during varied ED clinical shifts over a period of 6 months. Participation will be completely voluntary and uncompensated.

Informed consent
Eligibility will be assessed by study personnel. Once determined eligible, patients (and any family or visitors present) will be asked for written informed consent. All primary providers associated with the patient will also be asked for informed consent. Consent from providers will largely be obtained prior to field observations via email, to minimise disruption.

Data collection
A small team of trained observers comprised of qualitative researchers and healthcare engineers will collect the qualitative data. These individuals do not have a background

Table 1 Overview of the proposed studies for sub-aims 1.1 and 1.2

	Aim 1.1		Aim 1.2
	Part 1 Individual patient case as the unit of observation, ie, the focus is on diagnostic processing of a single case across the ED care team.	**Part 2** ED provider as the unit of observation, ie, the focus is on diagnostic processing of multiple cases by an ED provider and the care team.	**Part 3** Interviews with key stakeholders.
Purpose	To prospectively explore ED diagnostic processes and to understand the distributed cognitive system in everyday practice.		To elaborate on and enrich the ED diagnostic map, and to examine perceived strengths and vulnerabilities in diagnostic processes.
Research questions	How does the diagnostic process unfold for an individual patient case across the care team?	How does the diagnostic process unfold for multiple patient cases managed by a provider on a care team?	How do patients and providers describe ED diagnostic processes? What do they perceive as strengths and vulnerabilities? What might the ideal diagnostic process look like?
Approach	Field observations, mini-interviews, artefact analysis.		Semi-structured interviews.
Theories	Distributed cognition (observations focus on detailed information flow through interactions between people and tools across space and time). Dual process theory (Questions probe what is happening 'in the head' as patient care evolves—What initial diagnoses were considered? How is new information integrated into thinking about the patient over time?)	Distributed cognition (observations focus on team performance, contributions to collective cognition, communication patterns, activities that generate divergent or convergent thinking, use of tools and contextual factors). Dual process theory (questions probe what is happening 'in the head' —What initial diagnoses were considered? How is new information integrated into thinking about the patient over time?)	Modified ED-NASEM model (for elaboration and validation). Distributed cognition. (What are strengths / vulnerabilities in how information flows through the system? How do interactions between people and tools contribute to / detract from ED diagnosis? How do aspects of the physical plant / culture / ED environment positively or negatively affect diagnosis?)
Description	A individual patient as the unit of observation.	A provider workflow over a complete shift as the unit of observation.	Interviews with key stakeholders (patients, care team and administrators).
Data collection procedures	Observers will shadow specific 'high risk' patients from arrival to disposition. Patient-provider, and provider-care team interactions will be audio recorded and transcribed verbatim to document information flow; field notes, structured data recording forms, mini-interviews and reflexive journals will be collected.	Observers will shadow core providers that impact diagnostic processes (attending physician, residents, bedside nurse, triage nurse) for an observation period. Interactions inside patient rooms will be scribed. Interactions (with other providers and systems artefacts) outside patient care areas will be audio recorded. Observers will take field notes, keep a reflexive journal, use standardised reporting forms and record mini-interviews.	Diagrams of the ED diagnostic process with points of strength and vulnerabilities will be generated. Video or audio recordings of the interviews will be transcribed verbatim.
Expected outcomes	The patient and provider maps of the diagnostic process will be overlaid to construct a rich picture of distributed diagnostic processes, including interactions between people and systems artefacts, processes (eg, information flow), sociotechnical and sociocultural context across space and time.		The map of ED diagnostic processes will be enriched and elaborated on, incorporating participants' suggestions of points to focus on and their identification of strengths and weaknesses.

Table 1 Continued

	Aim 1.1	Aim 1.2
Points of integration	All three studies will contribute to the development and refinement of ED diagnostic process maps that describe ED cognitive processes. This will be used to inform design interventions to reduce errors in aim 2 of the parent project.	

ED, emergency department; NASEM, National Academies of Sciences, Engineering and Medicine .

in emergency medicine, and thus no association with a particular professional role that might introduce bias into data collection.

Patient care trajectory assessment

Two observers will work together to follow the diagnostic processing of a patient case from triage to disposition. Since distributed cognition theory focuses on how information flows in interactions, one observer will follow the patient to capture interactions that occur at or near the patient's bedside. The second observer will follow the ED provider(s) (typically a resident or physician assistant) to capture events related to the care that occurs away from the patient's bedside. Both observers will use audio recording devices to capture verbatim information exchange. Phone calls are not recorded, so observers will directly query providers about the content of calls. We will capture patient–provider and provider–care team interactions to examine relationships between information input, output and the representation of information in various artefacts, to assess gaps in information exchange among patient, provider and care team members.

Observational data

Observers will use data collection forms developed through pilot observations. These forms will track approximate timing of events to allow for quantification of interactions (eg, communication between care providers and the patient or other providers, estimated duration of events, time spent using tools). Observers will also take extensive field notes first as jottings in the field, then expanded afterwards to full field observations. They will record their inferences and reflections in memos focused on context, content and concepts.[30]

Time in care measures

Observational data will be supplemented by information available through the time-stamped EHR (eg, total time in ED, time from arrival to triage, time to room, time to provider, time to intervention (eg, medications, fluids), time to test performance, time from when results are available to when they are reviewed, time when patient data and diagnoses are recorded in the EHR and viewed by care team members).

Mini-interviews

Observers will briefly probe care team members to capture their thought processes during diagnostic work. At the end of the patient observation, the observers will ask patients and providers their perspectives on the complete

diagnostic process and any strengths and vulnerabilities from their perspectives.

Part 2: ED provider as the unit of observation

Sampling

Different contexts and team configurations can influence how cognition is distributed across ED providers and artefacts.[8 10] Thus, we will intentionally sample across different shifts (eg, day, evening, night) and work areas in the EDs to capture a range of patient volumes and staffing models. We will recruit attending physicians, residents, physician assistants and nurses to explore how different roles engage in the ED diagnostic process. These roles represent the core members of ED patient care teams, and intentional sampling by role will help us construct a 360-degree view of distributed cognition. This will allow us to discern how information flows and is processed in the system through interactions with people and artefacts. We anticipate a minimum of 24 provider observations. As in part 1, the final sample size will be determined by attainment of adequate conceptual depth.[29]

Eligibility

Eligible providers will be directly involved in patient care. Attending physicians, physician assistants and nurses will have a minimum of 1 year's experience working in the ED setting. Residents may be PGY 1–4.

Recruitment of providers

Providers will be recruited via email in advance of a shift or in person on the day of a shift by study personnel.

Informed consent

We will obtain informed consent of providers. Providers that refuse participation will not be observed. We anticipate these providers will come into contact with multiple patients and other providers as part of their routine work practices. We will provide an Institutional Review Board (IRB) approved information sheet to 'incidental contacts' notifying individuals that the information and communication will be recorded and collected for the purposes of research.

Data collection

Observations

In part 2, we will shadow ED providers caring for multiple patients over a 4-hour time frame, ensuring capture of either beginning-of-shift or end-of-shift handovers. The provider observations will occur on different days than the patient case observations. Observers will follow a

provider as they go about their work routine, communicating with other providers, accessing medical records, sending or answering pages, dictating or writing notes, accessing resources outside the ED, providing instruction to other care team members and so on. Audio recordings will supplement observer field notes to capture the detailed content of information-dense interactions. When providers are interacting with patients, only handwritten notes will be collected. Patients may decline the presence of the observer at any time.

In part 2, the focus is the interactions of people and tools within the sociocultural and sociotechnical context of the ED. In line with distributed cognition theory, observations will document exchanges between primary clinicians with patients, family or visitors, care team members and consultants and others over the 4-hour time frame. Additionally, we will collect details on how clinicians organise their patient cases and digital tools.[31] This study of interactions will capture the questions, orders, instruction, information sharing and recording, corrections, interruptions, workload demands, team dynamics and communication patterns over several hours of a shift.[11] In addition to audio recording, observers will use data collection forms, open-ended field notes and reflexive memos. Notations will be made of contextual factors such as overall ED volume and the number of patients a provider is concurrently managing. We will also capture use of artefacts such as paper or electronic notes used by providers.

Mini-interviews
During our observations, we will prompt providers to verbalise their thinking at key moments. At the end of the shift, the handover process between providers will be observed, and then individual providers will be briefly interviewed about their impressions of the diagnostic process over that shift.

Potential impact of mini-interviews and observations
In both parts 1 and 2 of this study, we acknowledge that the presence of researchers in the EDs could impact both thinking, that is, cognition and behaviour. By conducting mini-interviews, we could inadvertently alter participants thinking (by promoting synthesis), or at the very least make thinking more conscious. By having observers present, we could alter participant reactions per the 'Hawthorne effect', however, such alterations in behaviour have largely been shown to be insignificant.[32]

Part 3: interviews with key stakeholders
Sampling
We plan to conduct semi-structured interviews with attending physicians, residents/advanced practice providers, nurses, prehospital providers and patients. Groups will be purposively sampled based on roles and their experience with diagnostic processes. We anticipate a minimum of 20 interviews.

Eligibility
Eligible providers will be those involved in patient care with a minimum of 1 year's experience working in or consulting in the ED. Eligible patients or legally authorised representatives will be English-speaking, capable of providing informed consent and have visited the ED within 2–3 weeks preceding the interview.

Recruitment of patients and providers
Patients will be recruited by a study coordinator prior to discharge or admission during their index ED visit. We will also use the patient recruitment portal (https:// umhealthresearch.org/). Providers will be recruited through email. A US$25 gift card will be provided to patients/caregivers as compensation for their time.

Informed consent
We will obtain informed consent from all patients, legally authorised representatives and provider participants.

Data collection instrument
An interview guide will be developed using distributed cognition theory and guided by the modified ED-NASEM model[6] of diagnosis. (Please see online supplemental appendix 1 for details of the interview guide.) Questions will direct participants to reflect on their own experiences with ED diagnostic processes. Probes will focus on elucidating key points of interaction among people, artefacts and systems for diagnosis, depicting how information flows through the system, emphasising activities that contribute to or inhibit timely diagnosis and highlighting perceptions of key points that lead to breakdowns and errors.

Data collection process
At the beginning of each session, we will brief participants on the nature of the study, explain the format of the session and establish a safe environment for information disclosure. Each interview will be recorded and last approximately 60 min.

Qualitative data entry and cleaning
Recordings from observations and interviews will be transcribed verbatim and stored in a secure location in accordance with IRB procedures. Only de-identified data will be made available to the broader research team. All qualitative data, including field observation notes and transcriptions, will be entered into and analysed using MaxQDA. Time stamped data and other quantitative measures will be entered first into excel, and then exported into SPSS.

Data analysis
Based on the research questions for each part, we will use both inductive and deductive analysis methods, with the latter shaped by the theories previously mentioned. The mixed data analysis will be qualitatively driven; that is, the quantitative measures will play a supportive role relative to an overarching qualitative analysis.[33 34] These mixed data will be merged in response to emerging findings

where timing could frame and enhance understanding of qualitatively elucidated information. We will begin iterative data analysis during the data collection process. We will employ both qualitative and quantitative codes for the transcripts, field observation notes and mini-interviews from parts 1 and 2. Quantitative codes will characterise observed behaviours by counting the number and duration of interactions between people or artefacts, event occurrences (eg, pages, consults), dialogue analyses and other behaviours through the calculation of descriptive statistics.

Emergent themes will be identified and added as codes using an open coding method[35] to look for recurring themes. In the open coding method, two to three researchers from different professional backgrounds will analyse the transcripts and participant observation data following techniques described by Marshall and Rossman.[36] Since inductive analysis values the subjectivity of researchers as they make meaning from data, the backgrounds of the study team members conducting the analysis are important: MD and PM are emergency physicians who work in the adult and paediatric EDs under study; CMS is a cognitive psychologist who has a strong background in distributed cognition theory; PPC and MDF are experts in qualitative methodology; and SYP is an expert in HCI, design and complex systems. Each researcher will review a set of initial transcripts independently and code the content of each transcript. Each analyst will independently and continuously compare each incident, event, quote and instance to look for similarities and differences. The researchers will discuss, compare and reconcile differences in coding and create a consensus code template, which will then be used to code the remainder of transcripts. Weekly discussions will be held to interpret the meanings and themes from the beginning of the analysis.

During the data analysis, we will discuss emerging findings or questions with participants through a series of informal conversations to clarify any misconceptions and verify the validity of the themes identified in this study as another form of member checking.[37] To increase the reliability of our findings, we will then triangulate by comparing and contrasting data obtained via interviews and observations. Data collection will end when reasonable conceptual depth[29] has been achieved in the findings. Code reliability will be examined through independent coder comparisons, and differences resolved to consensus.

Integration of the quantitative findings into the analyses will occur through the use of joint display analysis where the quantitative data will be linked with related qualitative findings.[38 39] Additional targeted inquiries will be made of these data based on the emerging themes from the quantitative analysis. We will use multiple diagramming methods[40] (eg, communication, shared spaces, information flow, timelines) to map the process of ED diagnostic work practices. These descriptive data analyses will help develop a comprehensive map of the diagnostic process,

identify factors that lead to potential breakdowns and design requirements that will guide our intervention design phase in aim 2 of the larger IDEA-LL study.

Comparison of the adult and the paediatric EDs within the same institutional context will allow the examination of differences such as patient age, illness, interactions, sociocultural context or physical layout that lead to differences in diagnostic processes. These analyses will help us construct a detailed map of the distributed diagnostic processes in the two EDs by identifying when and how key information is introduced, gathered, assembled, communicated, transferred and applied.

Patient and public involvement

To ensure our research focuses on issues relevant to patients and the public, patients will be involved at multiple stages. Part 1 focuses on individual patients with undifferentiated symptoms as they experience the diagnostic process. In part 2, although our focus is on providers treating multiple patients simultaneously, patients will again be invited to participate. Part 3 will include interviews with patients and caregivers so that we may learn from their experiences and solicit their insights on challenges and vulnerabilities in ED diagnostic processes. Thus, parts 1–3 ensure the patient experience will inform the development of future interventions to improve diagnosis.

DISCUSSION

Many aspects of the ED diagnostic process unfold within an increasingly information-rich environment that is poorly understood, resulting in limited knowledge about how to improve patient safety. Our study findings will shed new light on strengths and vulnerabilities in ED diagnostic processes.[31]

A strength of this protocol is the interdisciplinary team that contributed to its development. Team members brought diverse perspectives on conceptual and theoretical models to guide data collection and analysis. Multiple study designs were considered to elucidate facets of cognition and sociotechnical/sociocultural work, and we chose to emphasise interaction processes, allowing us to prospectively learn from 'what went wrong' as well as 'what went right'.[41] This shift in safety perspective has been recently highlighted as critical to understanding and reducing errors. Multilevel qualitative and semi-quantitative data analysis will enable a comprehensive and deep understanding of a distributed system, providing opportunities to examine how information is gathered and interpreted in the diagnostic process.

Another strength of this protocol is the integration of complementary models and theories to guide our data collection and analyses. An exclusive focus on dual process theory or distributed cognition (as is the case with many studies) misses out on the opportunity to appreciate simultaneously occurring processes (ie, what's 'in the head' *and* 'out in the world'). These theories will

be leveraged to enrich the current modified ED-NASEM model of the diagnostic process, which currently implicitly incorporates some aspects of these theories, but does not do so explicitly.

To our knowledge, there have been few studies that use intensive, qualitatively driven mixed method approaches to examine ED diagnostic processes. Conducting in situ observations of the entire ED care delivery process, focused on individual patients and provider workflow, including physical workflow, documentation workflow, communication workflow and cognitive processes is particularly unique. This study will be one of the first to offer empirical data about how information is gathered, exchanged, recorded and used at the individual, team and system level, highlighting challenges and breakdowns that potentially lead to diagnostic errors in real-world emergency care settings.

This study design with two EDs in the same institutional setting holds constant the impact of certain system and community factors on ED diagnostic processes. Due to the many social and cultural factors influencing ED performance, focusing on two similarly situated EDs can improve our ability to observe system factors (eg, providers' workflow, system workflow, interruptions, impacts of triage policies and ED care procedures). Additionally, a comparison between two EDs within the adult and paediatric settings allows differences in their diagnostic approaches to become salient.

As case study research, we will examine in great depth an adult and a paediatric ED in a single hospital system. While methodologically critical to achieve deep understanding of cognition in context, this may limit transferability. Further studies under the larger IDEA-LL study will compare ED systems in other settings.

Our findings will provide critical knowledge regarding how diagnostic processes occur across interactions of adult and paediatric patients, providers, care teams and tools in EDs. Findings will help identify opportunities for improving diagnostic processes, particularly those at risk of error in ED work systems. Finally, the results will inform intervention design for mitigating errors in the subsequent aims of IDEA-LL. This is the first step in our study to develop safer diagnostic processes in the ED that prevent patient harm.

ETHICS AND DISSEMINATION

Ethical approval for this study has been granted by the University of Michigan IRB (HUM00156261). We plan to share our results in peer-reviewed publications and national/international research platforms, however, we will not share identifying patient/provider information with anyone who is not approved by the IRB.

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REFERENCES

1 Singh H. Editorial: helping health care organizations to define diagnostic errors as missed opportunities in diagnosis. *Jt Comm J Qual Patient Saf* 2014;40:99–AP1.
2 Centers for Disease Control and Prevention. Emergency department visits, 2017. Available: https://www.cdc.gov/nchs/fastats/emergency-department.htm [Accessed 27 Jul 2020].
3 Ball J, Balogh E, Miller BT, eds. *National Academies of Sciences, Engineering, and Medicine Improving Diagnosis in Health Care (2015) Consensus Study Report*. Washington, DC: The National Academies Press, 2015.

4 Ilgen JS, Eva KW, Regehr G. What's in a label? Is diagnosis the start or the end of clinical reasoning? *J Gen Intern Med* 2016;31:435–7.
5 Daniel M, Rencic J, Durning SJ, *et al*. Clinical reasoning assessment methods: a scoping review and practical guidance. *Acad Med* 2019;94:902–12.
6 Mahajan P, Mollen C, Alpern ER, *et al*. An operational framework to study diagnostic errors in emergency departments: findings from a consensus panel. *J Patient Saf* 2019. doi:10.1097/PTS.0000000000000624. [Epub ahead of print: 25 Nov 2019].
7 Evans JSBT, Stanovich KE. Dual-Process theories of higher cognition: advancing the debate. *Perspect Psychol Sci* 2013;8:223–41.
8 Hutchins EL. *Cognition in the wild*. Cambridge: MIT Press, 1995.
9 Daniel M, Khandelwal S, Santen SA, *et al*. Cognitive debiasing strategies for the emergency department. *AEM Educ Train* 2017;1:41–2.
10 Croskerry P, Singhal G, Mamede S. Cognitive debiasing 1: origins of bias and theory of debiasing. *BMJ Qual Saf* 2013;22 Suppl 2:ii58–64.
11 Croskerry P, Singhal G, Mamede S. Cognitive debiasing 2: impediments to and strategies for change. *BMJ Qual Saf* 2013;22 Suppl 2:ii65–72.
12 Norman GR, Monteiro SD, Sherbino J, *et al*. The causes of errors in clinical reasoning: cognitive biases, knowledge deficits, and dual process thinking. *Acad Med* 2017;92:23–30.
13 Wilson E, Seifert C, Durning SJ, *et al*. Distributed cognition: interactions between individuals and artifacts. *Diagnosis* 2020;7:343–4.
14 Wears RL, Perry SJ. Status boards in accident & emergency departments: support for shared cognition. *Theoretical Issues in Ergonomics Science* 2007;8:371–80.
15 Seifert C, Hutchins E. Error as opportunity: learning in a cooperative task. *Human-Comp. Interaction* 1992;7:409–35.
16 Hutchins E. How a Cockpit Remembers its speeds. *Cogn Sci* 1995;19:265–88.
17 Cohen T, Blatter B, Almeida C, *et al*. A cognitive blueprint of collaboration in context: distributed cognition in the psychiatric emergency department. *Artif Intell Med* 2006;37:73–83.
18 Custer JW, White E, Fackler JC, *et al*. A qualitative study of expert and team cognition on complex patients in the pediatric intensive care unit. *Pediatr Crit Care Med* 2012;13:278–84.
19 Guetterman TC, Babchuk WA, Howell Smith MC, *et al*. Contemporary approaches to mixed Methods–Grounded theory research: a Field-Based analysis. *J Mix Methods Res* 2019;13:179–95.
20 Guetterman TC, Fetters MD. Two methodological approaches to the integration of mixed methods and case study designs: a systematic review. *Am Behav Sci* 2018;62:900–18.
21 Ball LJ, Ormerod TC. Putting ethnography to work: the case for a cognitive ethnography of design. *Int J Hum Comput Stud* 2000;53:147–68.
22 Naiditch JA, Lautz TB, Daley S, *et al*. The implications of missed opportunities to diagnose appendicitis in children. *Acad Emerg Med* 2013;20:592–6.
23 Pai CW, Banerjee T, Kamdar NS. Utility of 72-hour emergency department return visits among children with undifferentiated symptoms. SAEM 18 Abstracts. Available: https://onlinelibrary.wiley.com/doi/pdf/10.1111/acem.13424 [Accessed 27 July 2020].
24 Medford-Davis L, Park E, Shlamovitz G, *et al*. Diagnostic errors related to acute abdominal pain in the emergency department. *Emerg Med J* 2016;33:253–9.
25 Mahajan P, Basu T, Pai C-W, *et al*. Factors associated with potentially missed diagnosis of appendicitis in the emergency department. *JAMA Netw Open* 2020;3:e200612.
26 Sundberg M, Perron CO, Kimia A, *et al*. A method to identify pediatric high-risk diagnoses missed in the emergency department. *Diagnosis* 2018;5:63–9.
27 Waxman DA, Kanzaria HK, Schriger DL. Unrecognized cardiovascular emergencies among Medicare patients. *JAMA Intern Med* 2018;178:477–84.
28 Vasileiou K, Barnett J, Thorpe S, *et al*. Characterising and justifying sample size sufficiency in Interview-Based studies: systematic analysis of qualitative health research over a 15-year period. *BMC Med Res Methodol* 2018;18:148.
29 Nelson J. Using conceptual depth criteria: addressing the challenge of reaching saturation in qualitative research. *Qualitative Research* 2017;17:554–70.
30 Fetters MD, Rubinstein EB. The 3 Cs of content, context, and concepts: a practical approach to recording unstructured field observations. *Ann Fam Med* 2019;17:554–60.
31 Singh H, Sittig DF. Advancing the science of measurement of diagnostic errors in healthcare: the safer DX framework. *BMJ Qual Saf* 2015;24:103–10.
32 Paradis E, Sutkin G. Beyond a good story: from Hawthorne effect to reactivity in health professions education research. *Med Educ* 2017;51:31–9.
33 Kelly C. Postmodernist Approaches to Mixed Methods Research. In: Hesse-Biber S, ed. *Mixed methods research: Merging theory and practice*. New York: Guilford Press, 2010: 154–73.
34 Hesse-Biber S, Rodriguez D. Frost NA qualitatively driven approach to multimethod and mixed methods research. In: Hesse-Biber S, Johnson B, eds. *The Oxford Handbook of multimethod and mixed methods research inquiry*. New York: Oxford University Press, 2015: 3–20.
35 Glaser BG, Strauss AL. *The discovery of Grounded theory: strategies for qualitative research*. New Brunswick: Transaction Publishers, 1967.
36 Marshall C, Rossman GB. *Designing qualitative research*. 6th ed. Los Angeles: SAGE Publications, 2015.
37 Klein HK, Myers MD. A set of principles for conducting and evaluating interpretive field studies in information systems. *MIS Quarterly* 1999;23:67–93.
38 Guetterman TC, Creswell JW, Kuckartz U. Using joint displays and MAXQDA software to represent the results of mixed methods research. In: McCrudden M, Schraw G, Buckendahl C, eds. *Use of visual displays in research and testing: coding, interpreting, and reporting data*. Charlotte: Information Age Publishing, 2015: 145–75.
39 Guetterman TC, Fetters MD, Creswell JW. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Ann Fam Med* 2015;13:554–61.
40 Beyer H, Holtzblatt K. *Contextual design: defining Customer-Centered systems*. San Francisco: Morgan Kaufmann Publishers, 1997.
41 Hollnagel E, Wears RL, Braithwaite J. From Safety-I to Safety-II: a white paper. The resilient health care net: published simultaneously by the University of southern Denmark, University of Florida, USA, and Macquarie University, Australia, 2015. Available: https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/10/safety-1-safety-2-whte-papr.pdf [Accessed 27 Jul 2020].