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Understanding Diagnostic Decision-Making in Emergency Departments: A Mixed Methods Case Study Protocol

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TITLE PAGE

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Understanding Diagnostic Decision-Making in Emergency Departments: A Mixed Methods Case Study Protocol

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ABSTRACT

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

Methods and Analysis: This study of an adult and a pediatric academic ED uses a prospective mixed-methods case study design informed by an ED-specific diagnostic decision-making model (the modified ED-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, mini-interviews, and focus groups. Multiple qualitative analysis methods will be used to explore diagnostic decision-making 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 four-hour window to capture their diagnostic workflow, team coordination, and communication across multiple patients; Part 3 uses role-based focus groups 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 to identify strengths and vulnerabilities in diagnostic processes and 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.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- Prospective, observational studies informed by theory which explore diagnostic decision making and error *in situ* are uncommon, yet urgently needed to improve understanding of ED diagnosis.
- Study findings will provide critical, contextualized knowledge of how ED diagnosis 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 pediatric academic ED is methodologically critical to achieve a deep understanding of cognition in context, however, limits transferability to other settings.

INTRODUCTION

Diagnostic decision-making in Emergency Departments (EDs) involves highly complex cognitive processes under time pressure that are susceptible to errors, which we define as missed opportunities to make a correct or timely diagnosis, regardless of patient outcomes.[1] While precise error rates are unknown, a conservative estimate of 5 percent of the 139 million ED visits annually suggests ~6.9 million errors per year.[2] Diagnostic errors typically result from a complex interplay of factors arising from patients (e.g., presenting symptoms, health literacy, disease complexity, behaviors), provider/care-team performance (e.g., cognitive load, information gathering and synthesis, coordination) and systems (e.g., health information technology, overcrowding, interruptions).[3] Current methods to study diagnostic errors are suboptimal as they largely focus on retrospective analyses of what went wrong rather than understanding and contextualizing diagnostic decision-making as it occurs in the ED. Novel prospective studies are urgently needed to improve our understanding of ED diagnostic processes and to facilitate the development of interventions to improve patient safety.

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**.

Several important conceptual models and theories inform this work. Conceptual models of diagnostic decision-making typically break the process down into multiple components (e.g., information gathering, hypothesis generation, differential diagnosis, etc.).[4] A model proposed by the National Academies of Sciences, Engineering, and Medicine (NASEM) incorporates these dynamic components and links accurate and timely diagnoses to patient and system outcomes in a feedback loop.[3] This model, recently adapted by ED experts into the modified ED-NASEM model,[5] provides an overarching framework for diagnosis in the current study. Two complementary theories of human cognition also inform this project: *dual process theory*[6] and *distributed cognition (DCog)*[7] *theory. Dual process theory* describes information processing as it occurs "in the head" of an individual. Clinicians process information via two primary pathways: system 1 (pattern recognition) and system 2 (analytic thinking), and experts switch back and forth between these two systems.[8,9] Inappropriate reliance on either system can result in errors, or cognitive biases.[10,11] *DCog theory* views information processing as occurring "out in the world".[7] Cognitive tasks such as diagnosis are accomplished through their distribution across multiple individuals (e.g., patients, nurses, physicians), external tools (e.g., electronic health record (EHR), computer-based searches, medical devices), spatial arrangements, and time.[12] Many of these tasks occur outside of the diagnosing clinician's purview, including the pre-hospital setting and after patient disposition. Collaborative systems of people and tools (also known as "artifacts") implement dynamic processes constituting a "shared cognitive system" to create a diagnosis, with breakdowns anywhere in the system leading to error.[13-17] 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 3-part approach for sub-aims 1.1 and 1.2 in IDEA-LL, which focuses on *using systems engineering and cognitive theory to explore ED diagnostic decision-making and factors contributing to ED diagnostic 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 upon 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[18-19] to collect quantitative and qualitative data in an adult and a pediatric ED. We will utilize both process measures (i.e., tracking specific steps leading to diagnosis including interactions with tools, communications between people, and monitoring elapsed time), and multiple qualitative methods (e.g., field observations, cognitive ethnography,[20] interviews, focus groups) to map information capture, transfer and sharing among patients and providers leading to diagnosis. Data collection will occur August 2020 – December 2021. An overview of the proposed studies appears in **Table 1**.

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 as the unit of observation	**Part 2** ED provider as the unit of observation	**Part 3** Focus groups 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 diagnostic decision-making take place for an individual patient?		What do patients and providers perceive as strengths and vulnerabilities in ED diagnostic processes? What might the ideal diagnostic process look like?
Approach	Field observations, mini-interviews, artifact analysis		Focus groups
Theories	Distributed Cognition (Observations focus on detailed information flow through interactions between people and tools across space and time) Dual Processing Theory (Questions probe what is happening "in the head" as patient care evolves – What initial patterns (illness scripts) 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 Processing Theory (Questions probe what is happening "in the head" – What features of patients lead to rapid recognition of patterns versus what triggered more analytic thinking?)	Modified ED-NASEM model (initial map for elaboration) 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?) Dual Processing Theory (What biases arise and how are they mitigated?)
Description	A individual patient as the unit of observation	A provider workflow over a complete shift as the unit of observation	Focus group reflections 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 decision-making (attending physician, residents, bedside nurse, triage nurse) for an observation period. Interactions inside patient rooms will be scribed. Interactions (with other providers and systems artifacts) outside patient care areas will be audio recorded. Observers will take field notes, keep a reflexive journal, use standardized reporting	Diagrams of the ED diagnostic process with points of strength and vulnerabilities will be generated. Audio recordings of the focus groups will be transcribed verbatim.

	forms, and record mini-interviews.	
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 artifacts, processes (information flow), sociotechnical and sociocultural context) across space and time. Points of error mitigation or course correction will be identified.	The map of ED diagnostic processes will be enriched and elaborated on, incorporating participants' suggestions of points to focus on and identification of strengths and weaknesses.
Points of integration	All three studies will contribute to the development and refinement of ED diagnostic maps that describe ED cognitive processes. This will be used to inform design interventions to reduce errors in Aim 2.	

Our data collection procedures, in accordance with DCog theory,[7,12] will primarily focus on direct observations "out in the world" as diagnosis unfolds within the socio-cultural settings of two EDs. We will record how cognitive work is distributed across people and tools in context by recording interactions and documenting its organization across physical space and time. In addition, we will observe individual cognition (informed by dual process theory[9]) 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 minimize interruptions in patient care.

Setting

Parts 1, 2, and 3 will be conducted in two tertiary, community care settings: an adult and a pediatric academic ED. Both EDs are Level I trauma centers, with a total annual census of 106,470 visits (74,034 adult and 32,436 pediatric). The EDs have 110 beds (88 adult and 22 pediatric), 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 post-graduate years (PGY) 1-4 with 16 residents per class, and ~170 medical students rotate through the department annually on a one-month required clerkship.

Sampling, eligibility, recruitment, informed consent and data collection

Part 1: Individual patient 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.[21-26] While data has linked chest pain symptoms with a wide range of never-miss conditions,[22,26] 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.[27] The final sample size will be determined by the criterion of data saturation, the point when no substantively new information about the diagnostic process emerges[28] or 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 pediatric patients will be between 0 and 21 years of age and their legally authorized representative must be capable of giving informed consent. For pediatric 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 enroll patients with three types of undifferentiated presenting symptoms associated with a "high-risk" for diagnostic errors. Research personnel will identify potential eligible patients at triage and approach them about enrollment. Enrollment will occur during varied ED clinical shifts over a period of six 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 minimize disruption.

Data collection: A multi-disciplinary team of trained observers, consisting of both medical (e.g., physicians or other practitioners with knowledge of diagnostic and therapeutic decision- making) and non-medical personnel (e.g., qualitative researchers, healthcare engineers) will conduct the field observations so that observations are informed by diverse expertise.

Patient care trajectory assessment: Two observers will work together to follow a patient from triage to disposition. We have a waiver for screening patients for eligibility prior to approaching for informed consent and enrollment. Since DCog 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 decision-making about the case occurring away

from the patient's bedside. Both observers will utilize 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 artifacts, 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, allowing for quantification of interactions (e.g., communication between care providers and the patient or other providers, estimated duration of events, time spent using tools, etc.). Observers will also take extensive field notes and 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 (e.g., total time in ED, time from arrival to triage, time to room, time to provider, time to intervention (e.g., 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 conduct mini-interviews with care team members to examine their thought processes during diagnostic work. Several brief questions will ask about patterns emerging from the data (attempting to get at dual-processing functions) and explore how the

differential evolves as new information is presented and integrated. 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 weaknesses observed.

Part 2: ED provider as the unit of observation

Sampling: Different contexts and team configurations can influence how cognition is distributed.[7,9] We will sample across different shifts (e.g., day, evening, night) and work areas in the EDs. We will recruit attending physicians, residents, physician assistants, and nurses to capture different providers involved in the ED diagnostic decision-making process. We anticipate a minimum of 24 provider observations. As in Part 1, the final sample size will be determined by data saturation[28] or 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 one 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

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 four-hour time frame, ensuring capture of either beginning-of-shift or end-of-shift handovers. 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, etc. Audio recordings will supplement observer field notes to allow capturing the detailed content of information-dense interactions. When providers are interacting with patients, only hand-written 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 DCog theory, observations will document exchanges between primary clinicians with patients, family or visitors, care team members and consultants, and others over the four-hour time frame. Additionally, we will collect details on how clinicians organize 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.[10] In addition to audio recording, observers will utilize 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 artifacts such as paper or electronic notes used by providers.

Focused interview queries: During our observations, in accordance with dual process theory, we will again conduct mini-interviews to prompt providers to verbalize what is going on "in the provider's head." At the end of the shift, the handover process between providers may be observed, and then individual providers will be briefly interviewed about their impressions of the diagnostic process over that shift.

Part 3: Focus groups with key stakeholders

Sampling: We plan to conduct 10-12 focus groups based on *roles* in the diagnostic process (e.g., attending physicians, residents / advanced practice providers, patients, nurses, and others (consultants, radiologists, pharmacists, technicians, paramedics, and key administrators). This will provide opportunities to sample providers beyond the core care team to complement Parts 1 and 2. Groups will be purposively sampled and consist of 3-6 representatives from the adult and pediatric EDs.

Eligibility: Eligible patients or legally authorized representatives will be English-speaking, capable of providing informed consent, and have visited the ED within 2-3 weeks preceding the focus group. Eligible providers will be those involved in patient care with a minimum of one year's experience working in or consulting in the ED, with the exception of residents (PGY 1-4).

Recruitment of patients and providers: Patients will be recruited by a study coordinator prior to discharge or admission during their index ED visit. Providers and other stakeholders will be recruited through email. A $25 gift card will be provided as compensation for participation.

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

Data collection instrument: An interview guide will be developed based on preliminary findings of Parts 1 and 2 and guided by the modified ED-NASEM model[5] of diagnosis. Questions will direct participants to reflect on their own experiences with ED diagnostic work. Probes will focus on elucidating key points of interaction among people, artifacts, and systems for diagnosis, depicting how information flows through the system, emphasizing activities that contribute to or inhibit timely diagnosis, and highlighting perceptions of key points that lead to breakdowns and errors. Probes will address experiences with diagnostic success or failure. Building consensus, strengths and vulnerabilities in current diagnostic processes will be explored for intervention opportunities in Aim 2.

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 focus group will be recorded and last approximately 90 minutes.

Data Entry and Cleaning

Recordings from observations and focus groups will be transcribed verbatim and stored in a secure location in accordance with Institutional Review Board 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 analyzed 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. Our data analyses will be guided by the theories previously outlined. The mixed data analysis will be qualitatively driven; that is, the quantitative measures will play a supportive role relative to an overarching qualitative analysis.[32-33] 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 characterize observed behaviors by counting the number and duration of interactions between people or artifacts, event occurrences (e.g., pages, consults), dialogue analyses, and other behaviors through the calculation of descriptive statistics.

For deductive coding, we will use a series of *a priori* codes from previous studies about factors contributing to error (patient, provider, system factors),[3] conceptual models of decision-making,[3-5] and theories of cognition (dual process theory[8-9] and distributed cognition[12-14]) as sensitizing concepts (**Table 2**).[34]

Table 2: Sensitizing concepts for analysis drawn from different conceptual models and theories of cognition

Models or theories	Sensitizing Concepts
Contributors to error[3]	Patient factors Provider factors System factors
Components of medical decision-making[4]	Information gathering Hypothesis generation Problem representation Differential diagnosis Leading or working diagnosis Diagnostic justification Management and treatment plan
National Academies of Sciences, Engineering, and Medicine of the diagnostic process modified for acute care in the ED[5]	Communication Intervention Outcomes
Dual Processing Theory[6,8-10]	Pattern Recognition Analytic Thinking Cognitive Bias (premature closure, anchoring, diagnostic momentum, triage cueing, visceral bias, etc.)
Distributed Cognition[7,12,14-17]	Interactions (people-people / people-artifacts or tools) Processes (information flow) Sociotechnical and sociocultural context of the ED (interruptions, workload, team dynamics, communication patterns, EHR, etc.) Course corrections / error mitigation

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, 2-3 researchers from different professional backgrounds (medical experts and qualitative researchers) will analyze the transcripts and participant observation data following techniques described by Marshall and Rossman.[36] 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 initial 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 focus groups and observations. Data collection will end when saturation is reached[28] or 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] (e.g., communication, shared spaces, information flow, timelines) to map the process of ED diagnostic work practices from multiple theoretical perspectives. 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 pediatric 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 decision-making 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 to diagnostic decision-making.

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 who will be invited to participate after they provide informed consent. In Part 2 although our focus is on providers treating multiple patients simultaneously, patients will again be invited to participate after we obtain their informed consent. Part 3 will include focus groups consisting of patients and caregivers where we anticipate active engagement of patients/caregivers as we learn from their diagnostic journey experiences and solicit their insights on challenges and vulnerabilities of ED diagnostic decision making. Thus, parts 1-3 ensure the patient experience will inform the development of future interventions to improve diagnosis.

Ethics and dissemination: Ethical approval for this study has been granted by the University of Michigan Institutional Review Board (HUM00156261). We will obtain informed consent from all patients, legally authorized representatives, and provider participants. We will perform this study to investigate the diagnostic journey of patients and the decision-making processes employed by the providers as observers. Thus, patient safety is not impacted and we will ensure confidentiality by ensuring all identifying data is removed as soon as feasible. We will 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 Institutional Review Board.

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 emphasize 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 (i.e., 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, qualitative 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 utilized 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 (e.g., providers' workflow, system workflow, interruptions, impacts of triage policies and ED care procedures). Additionally, a comparison between two EDs within the adult and pediatric settings allows differences in their diagnostic approaches to become salient.

As case study research, we will examine in great depth an adult and a pediatric 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.

CONCLUSIONS

Our findings will provide critical knowledge regarding how diagnostic processes occur across interactions of adult and pediatric 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.

Figure 1: Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

DECLARATIONS

Author contributions: All authors participated in multiple team discussions to conceptualize the manuscript and to refine the methodologies. MD was the primary author of the manuscript with significant text refinement provided by SYP, CMS, ABC, PPC, MDF, and PM. In particular, MD, HS and CMS provided the theoretical framing, and CMS, SYP, PPC, and MDF contributed methodological expertise. All authors read and approved the final manuscript.

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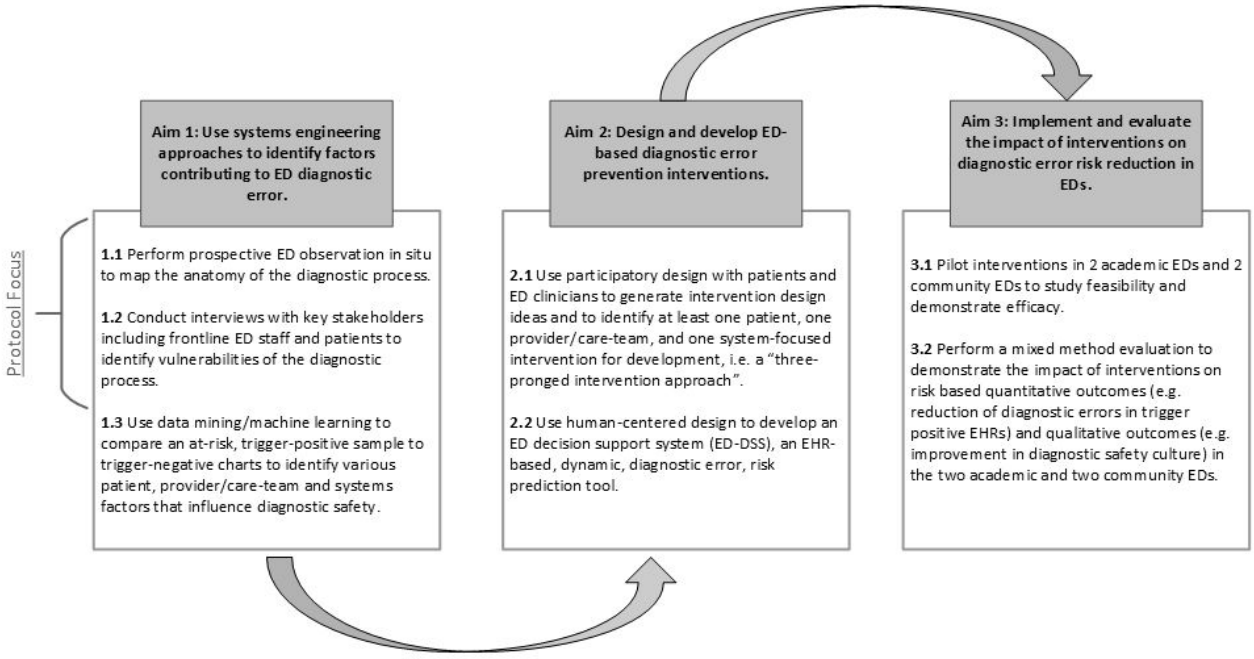
Figure 1: Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims



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TITLE PAGE

Title:

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 pediatric academic ED uses a prospective mixed methods case study design informed by an ED-specific diagnostic decision-making model (the modified ED-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 four-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.

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 ED diagnosis.
- Study findings will provide critical, contextualized 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 pediatric academic ED is methodologically critical to achieve a deep understanding of cognition in context, but may limit transferability to other settings.

INTRODUCTION

Diagnosis and management of patients in Emergency Departments (EDs) involves highly complex cognitive processes under time pressure that are susceptible to errors, 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 percent 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 (e.g., presenting symptoms, health literacy, disease complexity, behaviors), provider/care-team performance (e.g., cognitive load, information gathering and synthesis, coordination) and systems (e.g., 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 contextualizing 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.

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 operationalize 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 (e.g., information gathering, hypothesis formation, differential diagnosis generation, development of a treatment plan, etc.).[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 characterizes 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 (analytic 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 (e.g., patients, nurses, physicians), external tools (e.g.,

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 pre-hospital setting and after patient disposition. Collaborative systems of people and tools (also known as "artifacts") 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 3-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 upon 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 pediatric ED. We will utilize both process measures (i.e., tracking specific steps leading to diagnosis including interactions with tools, communications

between people, and monitoring elapsed time), and multiple qualitative methods (e.g., 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**.

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 i.e., the focus is on diagnostic processing of a single case across the ED care team	**Part 2** ED provider as the unit of observation i.e., 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, artifact 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 artifacts) outside patient care areas will be audio recorded. Observers will take field notes, keep a reflexive journal, use standardized 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 artifacts, processes (e.g., 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.
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.		

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 socio-cultural settings of two EDs. We will record how cognitive work is distributed across people and tools in context by recording interactions and documenting its organization 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 minimize 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 pediatric 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 centers, with a total annual census of 106,470 visits (74,034 adult and 32,436 pediatric). The EDs have 110 beds (88 adult and 22 pediatric), 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 post-graduate years (PGY) 1-4 with 16 residents per class, and ~170 medical students rotate through the department annually on a one-month required clerkship. According to health system policy, patients up to age 21 may be seen in the pediatric ED, however, patients ages 18-21 account for a small percentage of the total pediatric population (i.e., ~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 pediatric patients will be between 0 and 21 years of age and their legally authorized representative must be capable of giving informed consent. For pediatric 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 enroll 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 enrollment. Informed consent which 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. Enrollment will occur during varied ED clinical shifts over a period of six 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 minimize 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 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 utilize 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 artifacts, 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 (e.g., communication between care providers and the patient or other providers, estimated duration of events, time spent using tools, etc.). 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 (e.g., total time in ED, time from arrival to triage, time to room, time to provider, time to intervention (e.g., 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 artifacts.[8,10] Thus, we will intentionally sample across different shifts (e.g., 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 artifacts. 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 one 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 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 four-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, etc. Audio recordings will supplement observer field notes to capture the detailed content of information-

dense interactions. When providers are interacting with patients, only hand-written 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 four-hour time frame. Additionally, we will collect details on how clinicians organize 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 utilize 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 artifacts such as paper or electronic notes used by providers.

Mini-interviews: During our observations, we will prompt providers to verbalize 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, i.e., cognition, and behavior. 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 behavior 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, pre-hospital 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 one year's experience working in or consulting in the ED. Eligible patients or legally authorized 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 $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 authorized 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 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, artifacts, and systems for diagnosis, depicting how information flows through the system, emphasizing 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 minutes.

Qualitative Data Entry and Cleaning

Recordings from observations and interviews will be transcribed verbatim and stored in a secure location in accordance with Institutional Review Board 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 analyzed 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 characterize observed behaviors by counting the number and duration of interactions between people or artifacts, event occurrences (e.g., pages, consults), dialogue analyses, and other behaviors 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, 2-3 researchers from different professional backgrounds will analyze 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 pediatric emergency departments under study; CS is a cognitive psychologist who has a strong background in distributed cognition theory; PC and MF are experts in qualitative methodology; and SYP is an expert in human computer interaction, 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] (e.g., 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 pediatric 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 who will be invited to participate after they provide informed consent. In Part 2 although our focus is on providers treating multiple patients simultaneously, patients will again be invited to participate after we obtain their informed consent. 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.

Ethics and dissemination: Ethical approval for this study has been granted by the University of Michigan Institutional Review Board (HUM00156261). We will obtain informed consent from all patients, legally authorized representatives, and provider participants. We will perform this study to investigate the diagnostic journey of patients and the decision-making processes employed by the healthcare team. Thus, patient safety is not impacted and we will ensure confidentiality by ensuring all identifying data is removed as soon as feasible. We will 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 Institutional Review Board.

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 emphasize 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 (i.e., 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 utilized 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 (e.g., providers' workflow, system workflow, interruptions, impacts of triage policies and ED care procedures). Additionally, a comparison between two EDs within the adult and pediatric settings allows differences in their diagnostic approaches to become salient.

As case study research, we will examine in great depth an adult and a pediatric 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.

CONCLUSIONS

Our findings will provide critical knowledge regarding how diagnostic processes occur across interactions of adult and pediatric 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.

Figure 1: Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

DECLARATIONS

Author contributions: All authors participated in multiple team discussions to conceptualize the manuscript and to refine the methodologies. MD was the primary author of the manuscript with significant text refinement provided by SYP, EW, KP, CMS, PPC, MDF, and PM. In particular, MD, HS, EW and CMS provided the theoretical framing, and CMS, SYP, PPC, KP and MDF contributed methodological expertise. Data analysis will be conducted by MD, CMS, HS, SYP, PPC, MDF and PM, with all authors contributing to interpretation of the findings. All authors read and approved the final manuscript.

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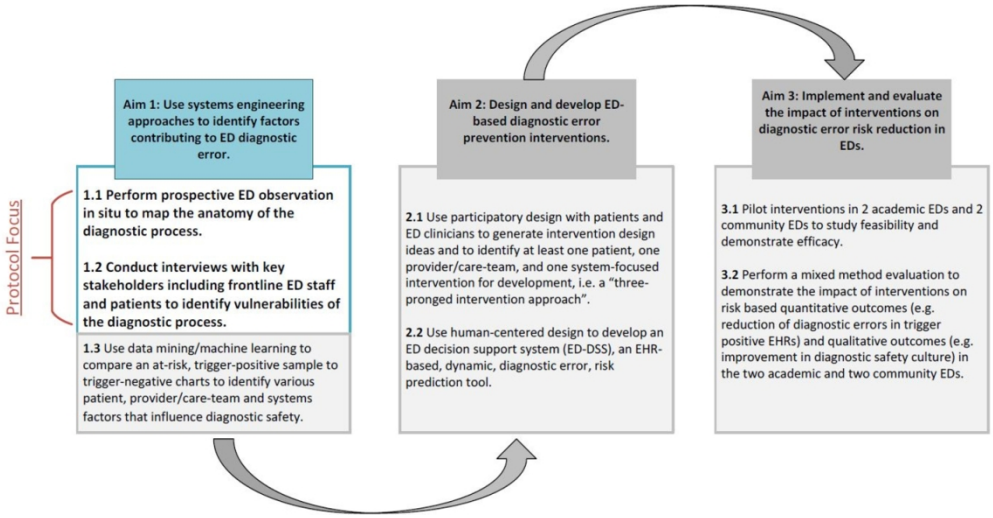


Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

Appendix 1: Interview Guide

Topic 1 (15 minutes)

Patient ED experience. What are typical points of interaction among people, technology, and systems for diagnosis?

Activity: Creating an ED diagnostic process/journey map

Elucidate key points of interaction among people, technology/tools, and systems for diagnosis. Through a process map activity, participants will be asked to:

1. Identify typical points of interaction and opportunities for communication amongst people and system technology/tools (pagers, computer, ECG printouts, etc),
2. Depict how information flows through the system (across space and time), through direct interactions or indirectly (i.e., through technology/tools), emphasizing activities contributing to diagnosis, and
3. Highlight what they perceive to be key decision points

Questions and Probes:

1. *Time allotted, 5 minutes* [Moderator]: Think about a patient case where there was difficulty in the diagnostic process, such as an undifferentiated chief complaint. Based on your ED work practice, we would like for you to review this simplified timeline of a diagnostic process. We will give you a couple of minutes to look it over, first: react to it/discuss if steps are missing or out of order (< 5 minutes), and then have you walk us through the process for a patient presentation. Any questions?

   After reviewing timeline: We would now like for you to present your work processes. In addition to your activities, try to include all of the elements or information you use that contribute to diagnosis or management decisions or that affect diagnostic processes (e.g., interactions with people, any physical or electronic tools you use, how the physical space impacts the process, etc.).
      1. You may choose to point out areas where problems/potential breakdowns/issues arise as well as areas where things are helpful in the process and work well
      2. You may choose to point out points where key decisions are made

   As you walk through the timeline, we will jump in to ask additional questions or for you to provide more detail to help our understanding.

2. *Presentation;* Participant will then present work process using timeline with discussion.
   1. Moderator probes
      i. What specific work practices do you use individually?
         1. Probe: How is information captured, recorded, organized, and documented at various points in the diagnostic process?
      ii. Where is the most important part in the process?
      iii. Where is the most challenging part in the process?
      iv. How do you cope with the challenges?
         1. Probe: What strategies do you use?

v. What are barriers/facilitators leading to a diagnosis? Where were the points things were delayed or you didn't understand or get the information you needed?
    1. Probe: What patient related factors do you feel contribute to or detract from the diagnostic process?
    2. What clinician related factors do you feel contribute to or detract from the diagnostic process?
    3. What system-related factors do you feel contribute to or detract from the diagnostic process?
vi. Can you think of a case where the diagnostic process could have been improved? How?

2. Moderator should note whether certain domains are excluded from timeline presentation to provide foundation for discussion in Topic 2

Optional Break (5-10 Minutes)

We are going to take a quick 5-10 *(depending on if running behin*d) minute break. When we get back, we will explore the different domains involved in the diagnostic process in more detail. Please be back to your computer at XX:XX.

Topic 2 (30-40 minutes)

Elaborate on diagnostic experiences and brainstorm possible interventions.

Reflect on specific ED diagnostic experiences, exploring the strengths and vulnerabilities in diagnostic successes or failures. Participants will be encouraged to elaborate on their stories through follow up questions.

Domain specific Questions and Probes

1. **Information Gathering (Collection & Organization)** We are interested in hearing how you arrive at a diagnosis and what steps do you take to get there.
    1. As a [interview participant's role], *what type* of information do you collect during the diagnostic process and *how* do you collect it?
        i. Where does the information come from?
        ii. What information do you gather from other clinicians such as nurses?
        iii. What information do you gather from patients or family members?
    2. Describe the diagnostic timeline - How does this information flow through the system?
        i. Probe: Who knows information at any point in time?
        ii. Probe: How do others gain access to that information?
    3. How do you organize this information once it is collected?
        i. Differential diagnosis list / working diagnosis
            1. When do you make an initial diagnosis?

2. What are you using (resources – medical tools, other roles) to make that diagnosis?

4. What do you perceive as a strength / weakness / area of opportunity concerning information flow and organization through the system?
    i. Probe: What are the strengths?
    ii. Probe: What are the weaknesses?
    iii. Probe: What are areas of opportunity?
5. Physician: How do you deal with diagnostic uncertainty? What causes/influences you to place more orders? Describe how you navigate diagnostic uncertainty.

2. **Interpersonal Factors**: Describe the people you interact with during the ED encounter, and how you interact with them (in-person, using technology). How do these people contribute to the diagnostic process? Consider the following examples of who you may interact with during the ED encounter: Patients, patient surrogates or caregivers, nursing team, patient techs, consultants, security, social work, residents, fellows, medical students, or other stakeholders.
    1. What are strengths / weaknesses / areas of opportunity as it relates to these interactions?
    2. What strategies do you use to come to shared understanding with patients/caregivers? Nurses? Consultants? Etc.

3. **Technological Factors**: How do interactions between people and tools/technology facilitate and/or detract from ED diagnosis and management? (i.e., in what ways do you think people and tools interact in ED diagnosis)
    1. How does the EMR affect diagnosis? Consider the use of prior records, outside data, sticky notes/chat, comments, track board, etc.
    2. What changes to EMR or other tools within the system do you think could improve the diagnostic process or help with diagnostic decision-making?

4. **Environmental/Systems Factors**: How do environmental aspects of the ED affect diagnosis and decision-making? Consider the following examples of environmental aspects of the ED that may affect diagnosis and decision-making: Layout (space, time), noise, lighting, patient volume, seating/positioning of staff and patients, or other factors.
    1. Describe the burden of interruptions, high cognitive workload, workflow, clinical activities.
    2. Are there specific institution protocols or policies in place that aid or detract from your diagnostic processes?
        i. Are these situations related to any particular groups of patients – e.g., those requiring imaging, or of a certain age?

5. Optional: Thinking back to the patient timeline we displayed earlier, would you think the 'ideal' diagnostic process is similar or different than that diagnostic process?
    1. How so?
    2. Are there opportunities for interventions? – creating a new tool/system/physical space, role, policy, etc.

With remaining 15-20 minutes. Now that you have explored a patient case using this simplified timeline, we are going to show you an ED diagnostic Framework [Moderator: scroll to ED Acute Care Framework on Miro board].

1. We are first going to walk you through this framework and will again ask you to react to it – is anything missing or anything that can be eliminated from this model?
2. Where commonly are the gaps in the diagnostic process? Where do you think breakdowns leading to errors are happening?
3. Where do you see opportunities to improve diagnostic decision making? How can we make these improvements?

End, Debriefing (5 Minutes)

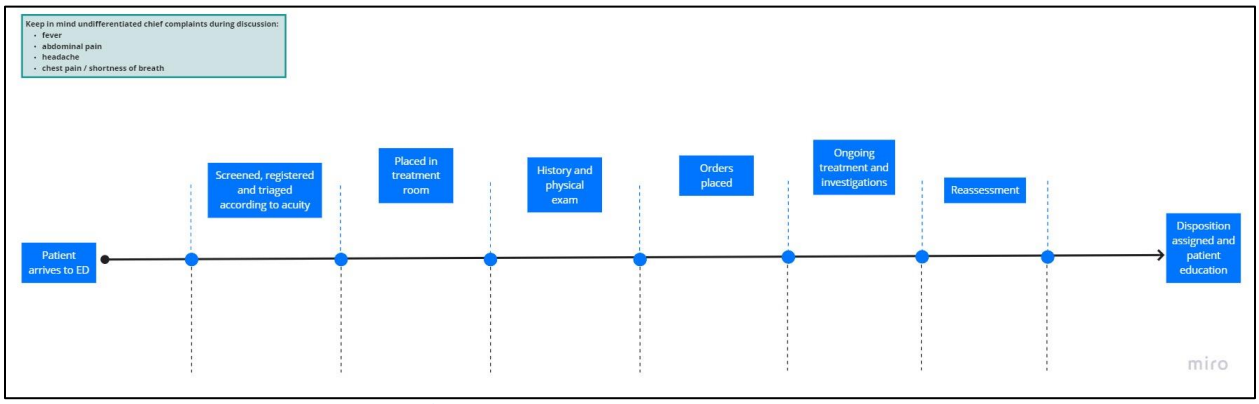
Are there any other factors that haven't been discussed that affect the diagnostic process?

Is there anything else we should have asked to help us understand your experience better?

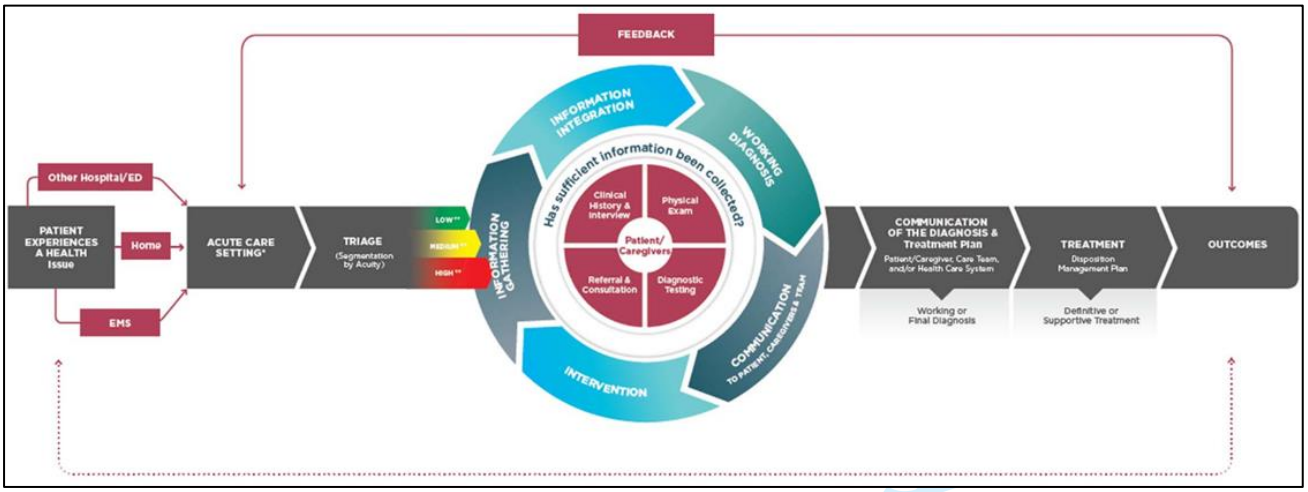
1. Moderator will debrief participant and notify the participant that the patient timeline will be used as summary of the discussion. The timeline with discussion points will be sent via email to the participant for brief review to ensure it captures an accurate understanding of what was discussed. Offer points of contact for further information on involvement and next steps.
2. Participants will be thanked for taking part in the study and released.

Zoom Screen Share Images

Miro ED Patient Timeline



ED Acute Care Framework (Modified-NASEM)



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Understanding Diagnostic Processes in Emergency Departments: A Mixed Methods Case Study Protocol

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TITLE PAGE

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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 pediatric academic ED uses a prospective mixed methods case study design informed by an ED-specific diagnostic decision-making model (the modified ED-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 four-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.

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 ED diagnosis.
- Study findings will provide critical, contextualized 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 pediatric academic ED is methodologically critical to achieve a deep understanding of cognition in context, but may limit transferability to other settings.

INTRODUCTION

Diagnosis and management of patients in Emergency Departments (EDs) involves highly complex cognitive processes under time pressure that are susceptible to errors, 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 percent 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 (e.g., presenting symptoms, health literacy, disease complexity, behaviors), provider/care-team performance (e.g., cognitive load, information gathering and synthesis, coordination) and systems (e.g., 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 contextualizing 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.

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 operationalize 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 (e.g., information gathering, hypothesis formation, differential diagnosis generation, development of a treatment plan, etc.).[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 characterizes 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 (analytic 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 (e.g., patients, nurses, physicians), external tools (e.g.,

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 pre-hospital setting and after patient disposition. Collaborative systems of people and tools (also known as "artifacts") 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 3-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 upon 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 pediatric ED. We will utilize both process measures (i.e., tracking specific steps leading to diagnosis including interactions with tools, communications

between people, and monitoring elapsed time), and multiple qualitative methods (e.g., 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**.

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 i.e., the focus is on diagnostic processing of a single case across the ED care team	**Part 2** ED provider as the unit of observation i.e., 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, artifact 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 artifacts) outside patient care areas will be audio recorded. Observers will take field notes, keep a reflexive journal, use standardized 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 artifacts, processes (e.g., 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.
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.		

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 socio-cultural settings of two EDs. We will record how cognitive work is distributed across people and tools in context by recording interactions and documenting its organization 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 minimize 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 pediatric 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 centers, with a total annual census of 106,470 visits (74,034 adult and 32,436 pediatric). The EDs have 110 beds (88 adult and 22 pediatric), 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 post-graduate years (PGY) 1-4 with 16 residents per class, and ~170 medical students rotate through the department annually on a one-month required clerkship. According to health system policy, patients up to age 21 may be seen in the pediatric ED, however, patients ages 18-21 account for a small percentage of the total pediatric population (i.e., ~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 pediatric patients will be between 0 and 21 years of age and their legally authorized representative must be capable of giving informed consent. For pediatric 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 enroll 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 enrollment. Informed consent which 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. Enrollment will occur during varied ED clinical shifts over a period of six 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 minimize 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 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 utilize 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 artifacts, 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 (e.g., communication between care providers and the patient or other providers, estimated duration of events, time spent using tools, etc.). 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 (e.g., total time in ED, time from arrival to triage, time to room, time to provider, time to intervention (e.g., 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 artifacts.[8,10] Thus, we will intentionally sample across different shifts (e.g., 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 artifacts. 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 one 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 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 four-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, etc. Audio recordings will supplement observer field notes to capture the detailed content of information-

dense interactions. When providers are interacting with patients, only hand-written 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 four-hour time frame. Additionally, we will collect details on how clinicians organize 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 utilize 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 artifacts such as paper or electronic notes used by providers.

Mini-interviews: During our observations, we will prompt providers to verbalize 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, i.e., cognition, and behavior. 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 behavior 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, pre-hospital 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 one year's experience working in or consulting in the ED. Eligible patients or legally authorized 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 $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 authorized 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 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, artifacts, and systems for diagnosis, depicting how information flows through the system, emphasizing 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 minutes.

Qualitative Data Entry and Cleaning

Recordings from observations and interviews will be transcribed verbatim and stored in a secure location in accordance with Institutional Review Board 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 analyzed 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 characterize observed behaviors by counting the number and duration of interactions between people or artifacts, event occurrences (e.g., pages, consults), dialogue analyses, and other behaviors 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, 2-3 researchers from different professional backgrounds will analyze 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 pediatric emergency departments under study; CS is a cognitive psychologist who has a strong background in distributed cognition theory; PC and MF are experts in qualitative methodology; and SYP is an expert in human computer interaction, 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] (e.g., 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 pediatric 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 who will be invited to participate after they provide informed consent. In Part 2 although our focus is on providers treating multiple patients simultaneously, patients will again be invited to participate after we obtain their informed consent. 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.

Ethics and dissemination: Ethical approval for this study has been granted by the University of Michigan Institutional Review Board (HUM00156261). We will obtain informed consent from all patients, legally authorized representatives, and provider participants. We will perform this study to investigate the diagnostic journey of patients and the decision-making processes employed by the healthcare team. Thus, patient safety is not impacted and we will ensure confidentiality by ensuring all identifying data is removed as soon as feasible. We will 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 Institutional Review Board.

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 emphasize 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 (i.e., 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 utilized 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 (e.g., providers' workflow, system workflow, interruptions, impacts of triage policies and ED care procedures). Additionally, a comparison between two EDs within the adult and pediatric settings allows differences in their diagnostic approaches to become salient.

As case study research, we will examine in great depth an adult and a pediatric 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 pediatric 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.

Figure 1: Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

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.

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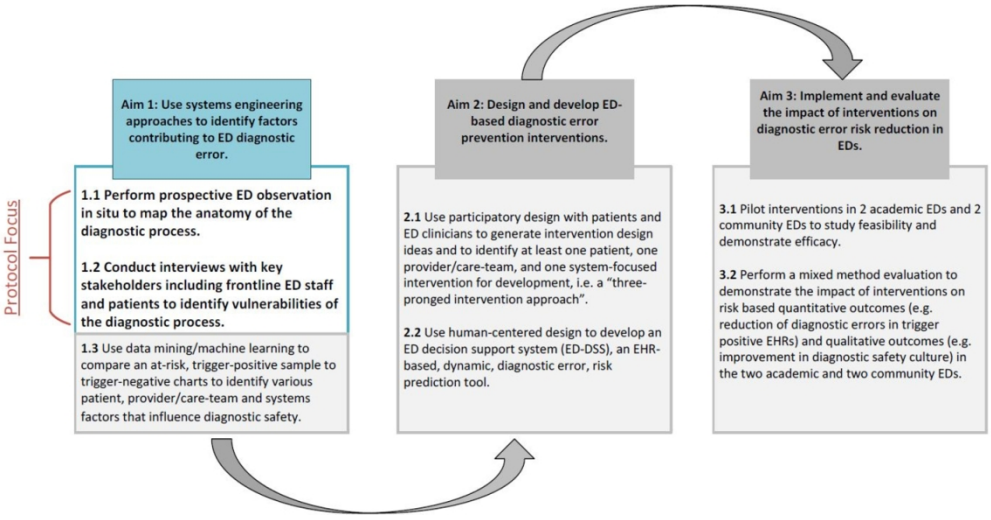


Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

Appendix 1: Interview Guide

Topic 1 (15 minutes)

Patient ED experience. What are typical points of interaction among people, technology, and systems for diagnosis?

Activity: Creating an ED diagnostic process/journey map

Elucidate key points of interaction among people, technology/tools, and systems for diagnosis. Through a process map activity, participants will be asked to: 1. Identify typical points of interaction and opportunities for communication amongst people and system technology/tools (pagers, computer, ECG printouts, etc), 2. Depict how information flows through the system (across space and time), through direct interactions or indirectly (i.e., through technology/tools), emphasizing activities contributing to diagnosis, and 3. Highlight what they perceive to be key decision points

Questions and Probes:

1. *Time allotted, 5 minutes* [Moderator]: Think about a patient case where there was difficulty in the diagnostic process, such as an undifferentiated chief complaint. Based on your ED work practice, we would like for you to review this simplified timeline of a diagnostic process. We will give you a couple of minutes to look it over, first: react to it/discuss if steps are missing or out of order (< 5 minutes), and then have you walk us through the process for a patient presentation. Any questions?

   After reviewing timeline: We would now like for you to present your work processes. In addition to your activities, try to include all of the elements or information you use that contribute to diagnosis or management decisions or that affect diagnostic processes (e.g., interactions with people, any physical or electronic tools you use, how the physical space impacts the process, etc.).
      1. You may choose to point out areas where problems/potential breakdowns/issues arise as well as areas where things are helpful in the process and work well
      2. You may choose to point out points where key decisions are made

   As you walk through the timeline, we will jump in to ask additional questions or for you to provide more detail to help our understanding.

2. *Presentation;* Participant will then present work process using timeline with discussion.
   1. Moderator probes
      i. What specific work practices do you use individually?
         1. Probe: How is information captured, recorded, organized, and documented at various points in the diagnostic process?
      ii. Where is the most important part in the process?
      iii. Where is the most challenging part in the process?
      iv. How do you cope with the challenges?
         1. Probe: What strategies do you use?

v. What are barriers/facilitators leading to a diagnosis? Where were the points things were delayed or you didn't understand or get the information you needed?
    1. Probe: What patient related factors do you feel contribute to or detract from the diagnostic process?
    2. What clinician related factors do you feel contribute to or detract from the diagnostic process?
    3. What system-related factors do you feel contribute to or detract from the diagnostic process?
vi. Can you think of a case where the diagnostic process could have been improved? How?

2. Moderator should note whether certain domains are excluded from timeline presentation to provide foundation for discussion in Topic 2

Optional Break (5-10 Minutes)

We are going to take a quick 5-10 *(depending on if running behin*d) minute break. When we get back, we will explore the different domains involved in the diagnostic process in more detail. Please be back to your computer at XX:XX.

Topic 2 (30-40 minutes)

Elaborate on diagnostic experiences and brainstorm possible interventions.

Reflect on specific ED diagnostic experiences, exploring the strengths and vulnerabilities in diagnostic successes or failures. Participants will be encouraged to elaborate on their stories through follow up questions.

Domain specific Questions and Probes

1. **Information Gathering (Collection & Organization)** We are interested in hearing how you arrive at a diagnosis and what steps do you take to get there.
    1. As a [interview participant's role], *what type* of information do you collect during the diagnostic process and *how* do you collect it?
        i. Where does the information come from?
        ii. What information do you gather from other clinicians such as nurses?
        iii. What information do you gather from patients or family members?
    2. Describe the diagnostic timeline - How does this information flow through the system?
        i. Probe: Who knows information at any point in time?
        ii. Probe: How do others gain access to that information?
    3. How do you organize this information once it is collected?
        i. Differential diagnosis list / working diagnosis
            1. When do you make an initial diagnosis?

2. What are you using (resources – medical tools, other roles) to make that diagnosis?

4. What do you perceive as a strength / weakness / area of opportunity concerning information flow and organization through the system?
    i. Probe: What are the strengths?
    ii. Probe: What are the weaknesses?
    iii. Probe: What are areas of opportunity?
5. Physician: How do you deal with diagnostic uncertainty? What causes/influences you to place more orders? Describe how you navigate diagnostic uncertainty.

2. **Interpersonal Factors**: Describe the people you interact with during the ED encounter, and how you interact with them (in-person, using technology). How do these people contribute to the diagnostic process? Consider the following examples of who you may interact with during the ED encounter: Patients, patient surrogates or caregivers, nursing team, patient techs, consultants, security, social work, residents, fellows, medical students, or other stakeholders.
    1. What are strengths / weaknesses / areas of opportunity as it relates to these interactions?
    2. What strategies do you use to come to shared understanding with patients/caregivers? Nurses? Consultants? Etc.

3. **Technological Factors**: How do interactions between people and tools/technology facilitate and/or detract from ED diagnosis and management? (i.e., in what ways do you think people and tools interact in ED diagnosis)
    1. How does the EMR affect diagnosis? Consider the use of prior records, outside data, sticky notes/chat, comments, track board, etc.
    2. What changes to EMR or other tools within the system do you think could improve the diagnostic process or help with diagnostic decision-making?

4. **Environmental/Systems Factors**: How do environmental aspects of the ED affect diagnosis and decision-making? Consider the following examples of environmental aspects of the ED that may affect diagnosis and decision-making: Layout (space, time), noise, lighting, patient volume, seating/positioning of staff and patients, or other factors.
    1. Describe the burden of interruptions, high cognitive workload, workflow, clinical activities.
    2. Are there specific institution protocols or policies in place that aid or detract from your diagnostic processes?
        i. Are these situations related to any particular groups of patients – e.g., those requiring imaging, or of a certain age?

5. Optional: Thinking back to the patient timeline we displayed earlier, would you think the 'ideal' diagnostic process is similar or different than that diagnostic process?
    1. How so?
    2. Are there opportunities for interventions? – creating a new tool/system/physical space, role, policy, etc.

With remaining 15-20 minutes. Now that you have explored a patient case using this simplified timeline, we are going to show you an ED diagnostic Framework [Moderator: scroll to ED Acute Care Framework on Miro board].

1. We are first going to walk you through this framework and will again ask you to react to it – is anything missing or anything that can be eliminated from this model?
2. Where commonly are the gaps in the diagnostic process? Where do you think breakdowns leading to errors are happening?
3. Where do you see opportunities to improve diagnostic decision making? How can we make these improvements?

End, Debriefing (5 Minutes)

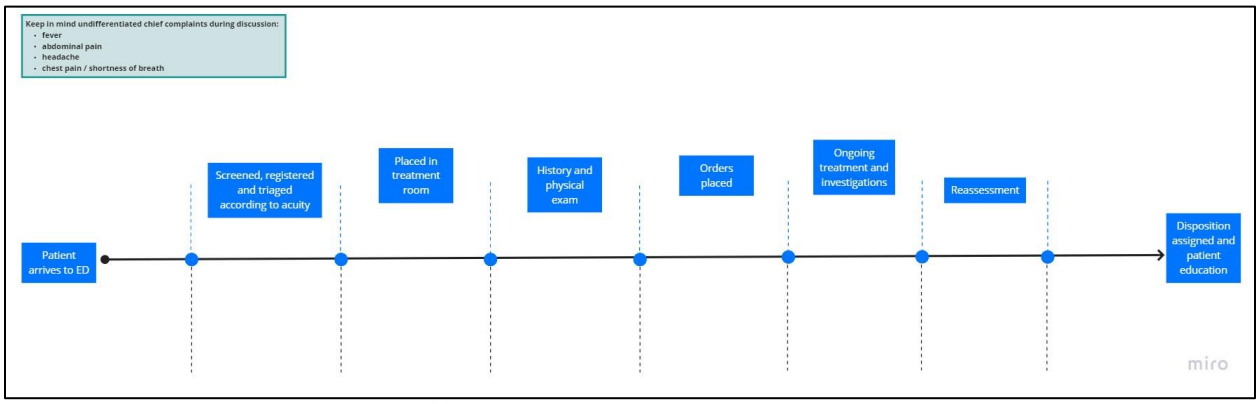
Are there any other factors that haven't been discussed that affect the diagnostic process?

Is there anything else we should have asked to help us understand your experience better?

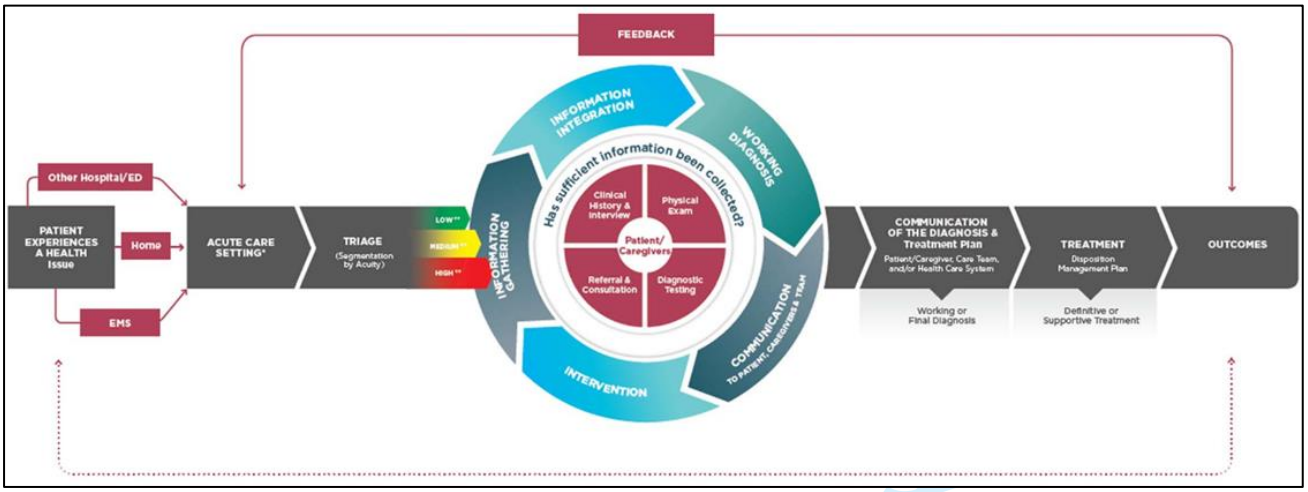
1. Moderator will debrief participant and notify the participant that the patient timeline will be used as summary of the discussion. The timeline with discussion points will be sent via email to the participant for brief review to ensure it captures an accurate understanding of what was discussed. Offer points of contact for further information on involvement and next steps.
2. Participants will be thanked for taking part in the study and released.

Zoom Screen Share Images

Miro ED Patient Timeline



ED Acute Care Framework (Modified-NASEM)



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Understanding Diagnostic Processes in Emergency Departments: A Mixed Methods Case Study Protocol

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TITLE PAGE

Title:

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 pediatric academic ED uses a prospective mixed methods case study design informed by an ED-specific diagnostic decision-making model (the modified ED-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 four-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.

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 ED diagnosis.
- Study findings will provide critical, contextualized 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 pediatric academic ED is methodologically critical to achieve a deep understanding of cognition in context, but may limit transferability to other settings.

INTRODUCTION

Diagnosis and management of patients in Emergency Departments (EDs) involves highly complex cognitive processes under time pressure that are susceptible to errors, 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 percent 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 (e.g., presenting symptoms, health literacy, disease complexity, behaviors), provider/care-team performance (e.g., cognitive load, information gathering and synthesis, coordination) and systems (e.g., 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 contextualizing 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.

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 operationalize 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 (e.g., information gathering, hypothesis formation, differential diagnosis generation, development of a treatment plan, etc.).[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 characterizes 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 (analytic 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 (e.g., patients, nurses, physicians), external tools (e.g.,

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 pre-hospital setting and after patient disposition. Collaborative systems of people and tools (also known as "artifacts") 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 3-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 upon 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 pediatric ED. We will utilize both process measures (i.e., tracking specific steps leading to diagnosis including interactions with tools, communications

between people, and monitoring elapsed time), and multiple qualitative methods (e.g., 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**.

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 i.e., the focus is on diagnostic processing of a single case across the ED care team	**Part 2** ED provider as the unit of observation i.e., 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, artifact 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 artifacts) outside patient care areas will be audio recorded. Observers will take field notes, keep a reflexive journal, use standardized 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 artifacts, processes (e.g., 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.
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.		

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 socio-cultural settings of two EDs. We will record how cognitive work is distributed across people and tools in context by recording interactions and documenting its organization 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 minimize 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 pediatric 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 centers, with a total annual census of 106,470 visits (74,034 adult and 32,436 pediatric). The EDs have 110 beds (88 adult and 22 pediatric), 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 post-graduate years (PGY) 1-4 with 16 residents per class, and ~170 medical students rotate through the department annually on a one-month required clerkship. According to health system policy, patients up to age 21 may be seen in the pediatric ED, however, patients ages 18-21 account for a small percentage of the total pediatric population (i.e., ~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 pediatric patients will be between 0 and 21 years of age and their legally authorized representative must be capable of giving informed consent. For pediatric 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 enroll 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 enrollment. Informed consent which 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. Enrollment will occur during varied ED clinical shifts over a period of six 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 minimize 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 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 utilize 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 artifacts, 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 (e.g., communication between care providers and the patient or other providers, estimated duration of events, time spent using tools, etc.). 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 (e.g., total time in ED, time from arrival to triage, time to room, time to provider, time to intervention (e.g., 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 artifacts.[8,10] Thus, we will intentionally sample across different shifts (e.g., 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 artifacts. 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 one 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 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 four-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, etc. Audio recordings will supplement observer field notes to capture the detailed content of information-

dense interactions. When providers are interacting with patients, only hand-written 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 four-hour time frame. Additionally, we will collect details on how clinicians organize 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 utilize 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 artifacts such as paper or electronic notes used by providers.

Mini-interviews: During our observations, we will prompt providers to verbalize 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, i.e., cognition, and behavior. 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 behavior 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, pre-hospital 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 one year's experience working in or consulting in the ED. Eligible patients or legally authorized 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 $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 authorized 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 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, artifacts, and systems for diagnosis, depicting how information flows through the system, emphasizing 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 minutes.

Qualitative Data Entry and Cleaning

Recordings from observations and interviews will be transcribed verbatim and stored in a secure location in accordance with Institutional Review Board 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 analyzed 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 characterize observed behaviors by counting the number and duration of interactions between people or artifacts, event occurrences (e.g., pages, consults), dialogue analyses, and other behaviors 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, 2-3 researchers from different professional backgrounds will analyze 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 pediatric emergency departments under study; CS is a cognitive psychologist who has a strong background in distributed cognition theory; PC and MF are experts in qualitative methodology; and SYP is an expert in human computer interaction, 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] (e.g., 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 pediatric 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 emphasize 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 (i.e., 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 utilized 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 (e.g., providers' workflow, system workflow, interruptions, impacts of triage policies and ED care procedures). Additionally, a comparison between two EDs within the adult and pediatric settings allows differences in their diagnostic approaches to become salient.

As case study research, we will examine in great depth an adult and a pediatric 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 pediatric 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.

Figure 1: Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

Ethics and dissemination: Ethical approval for this study has been granted by the University of Michigan Institutional Review Board (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 Institutional Review Board.

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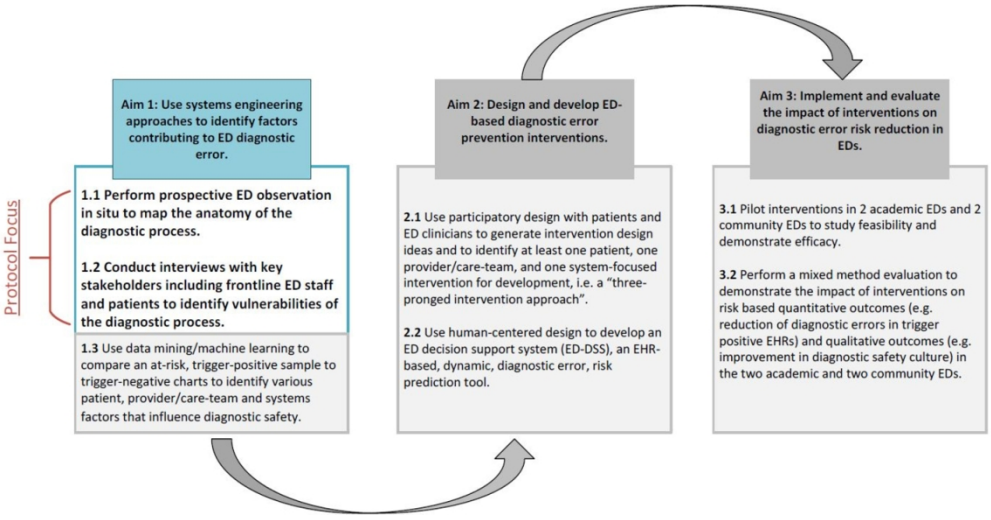


Improving Diagnosis in Emergency and Acute Care – Learning Laboratory (IDEA-LL) Aims

Appendix 1: Interview Guide

Topic 1 (15 minutes)

Patient ED experience. What are typical points of interaction among people, technology, and systems for diagnosis?

Activity: Creating an ED diagnostic process/journey map

Elucidate key points of interaction among people, technology/tools, and systems for diagnosis. Through a process map activity, participants will be asked to: 1. Identify typical points of interaction and opportunities for communication amongst people and system technology/tools (pagers, computer, ECG printouts, etc), 2. Depict how information flows through the system (across space and time), through direct interactions or indirectly (i.e., through technology/tools), emphasizing activities contributing to diagnosis, and 3. Highlight what they perceive to be key decision points

Questions and Probes:

1. *Time allotted, 5 minutes* [Moderator]: Think about a patient case where there was difficulty in the diagnostic process, such as an undifferentiated chief complaint. Based on your ED work practice, we would like for you to review this simplified timeline of a diagnostic process. We will give you a couple of minutes to look it over, first: react to it/discuss if steps are missing or out of order (< 5 minutes), and then have you walk us through the process for a patient presentation. Any questions?

   After reviewing timeline: We would now like for you to present your work processes. In addition to your activities, try to include all of the elements or information you use that contribute to diagnosis or management decisions or that affect diagnostic processes (e.g., interactions with people, any physical or electronic tools you use, how the physical space impacts the process, etc.).
      1. You may choose to point out areas where problems/potential breakdowns/issues arise as well as areas where things are helpful in the process and work well
      2. You may choose to point out points where key decisions are made

   As you walk through the timeline, we will jump in to ask additional questions or for you to provide more detail to help our understanding.

2. *Presentation;* Participant will then present work process using timeline with discussion.
   1. Moderator probes
      i. What specific work practices do you use individually?
         1. Probe: How is information captured, recorded, organized, and documented at various points in the diagnostic process?
      ii. Where is the most important part in the process?
      iii. Where is the most challenging part in the process?
      iv. How do you cope with the challenges?
         1. Probe: What strategies do you use?

v. What are barriers/facilitators leading to a diagnosis? Where were the points things were delayed or you didn't understand or get the information you needed?
    1. Probe: What patient related factors do you feel contribute to or detract from the diagnostic process?
    2. What clinician related factors do you feel contribute to or detract from the diagnostic process?
    3. What system-related factors do you feel contribute to or detract from the diagnostic process?
vi. Can you think of a case where the diagnostic process could have been improved? How?

2. Moderator should note whether certain domains are excluded from timeline presentation to provide foundation for discussion in Topic 2

Optional Break (5-10 Minutes)

We are going to take a quick 5-10 *(depending on if running behin*d) minute break. When we get back, we will explore the different domains involved in the diagnostic process in more detail. Please be back to your computer at XX:XX.

Topic 2 (30-40 minutes)

Elaborate on diagnostic experiences and brainstorm possible interventions.

Reflect on specific ED diagnostic experiences, exploring the strengths and vulnerabilities in diagnostic successes or failures. Participants will be encouraged to elaborate on their stories through follow up questions.

Domain specific Questions and Probes

1. **Information Gathering (Collection & Organization)** We are interested in hearing how you arrive at a diagnosis and what steps do you take to get there.
    1. As a [interview participant's role], *what type* of information do you collect during the diagnostic process and *how* do you collect it?
        i. Where does the information come from?
        ii. What information do you gather from other clinicians such as nurses?
        iii. What information do you gather from patients or family members?
    2. Describe the diagnostic timeline - How does this information flow through the system?
        i. Probe: Who knows information at any point in time?
        ii. Probe: How do others gain access to that information?
    3. How do you organize this information once it is collected?
        i. Differential diagnosis list / working diagnosis
            1. When do you make an initial diagnosis?

2. What are you using (resources – medical tools, other roles) to make that diagnosis?

4. What do you perceive as a strength / weakness / area of opportunity concerning information flow and organization through the system?
    i. Probe: What are the strengths?
    ii. Probe: What are the weaknesses?
    iii. Probe: What are areas of opportunity?
5. Physician: How do you deal with diagnostic uncertainty? What causes/influences you to place more orders? Describe how you navigate diagnostic uncertainty.

2. **Interpersonal Factors**: Describe the people you interact with during the ED encounter, and how you interact with them (in-person, using technology). How do these people contribute to the diagnostic process? Consider the following examples of who you may interact with during the ED encounter: Patients, patient surrogates or caregivers, nursing team, patient techs, consultants, security, social work, residents, fellows, medical students, or other stakeholders.
    1. What are strengths / weaknesses / areas of opportunity as it relates to these interactions?
    2. What strategies do you use to come to shared understanding with patients/caregivers? Nurses? Consultants? Etc.

3. **Technological Factors**: How do interactions between people and tools/technology facilitate and/or detract from ED diagnosis and management? (i.e., in what ways do you think people and tools interact in ED diagnosis)
    1. How does the EMR affect diagnosis? Consider the use of prior records, outside data, sticky notes/chat, comments, track board, etc.
    2. What changes to EMR or other tools within the system do you think could improve the diagnostic process or help with diagnostic decision-making?

4. **Environmental/Systems Factors**: How do environmental aspects of the ED affect diagnosis and decision-making? Consider the following examples of environmental aspects of the ED that may affect diagnosis and decision-making: Layout (space, time), noise, lighting, patient volume, seating/positioning of staff and patients, or other factors.
    1. Describe the burden of interruptions, high cognitive workload, workflow, clinical activities.
    2. Are there specific institution protocols or policies in place that aid or detract from your diagnostic processes?
        i. Are these situations related to any particular groups of patients – e.g., those requiring imaging, or of a certain age?

5. Optional: Thinking back to the patient timeline we displayed earlier, would you think the 'ideal' diagnostic process is similar or different than that diagnostic process?
    1. How so?
    2. Are there opportunities for interventions? – creating a new tool/system/physical space, role, policy, etc.

With remaining 15-20 minutes. Now that you have explored a patient case using this simplified timeline, we are going to show you an ED diagnostic Framework [Moderator: scroll to ED Acute Care Framework on Miro board].

1. We are first going to walk you through this framework and will again ask you to react to it – is anything missing or anything that can be eliminated from this model?
2. Where commonly are the gaps in the diagnostic process? Where do you think breakdowns leading to errors are happening?
3. Where do you see opportunities to improve diagnostic decision making? How can we make these improvements?

End, Debriefing (5 Minutes)

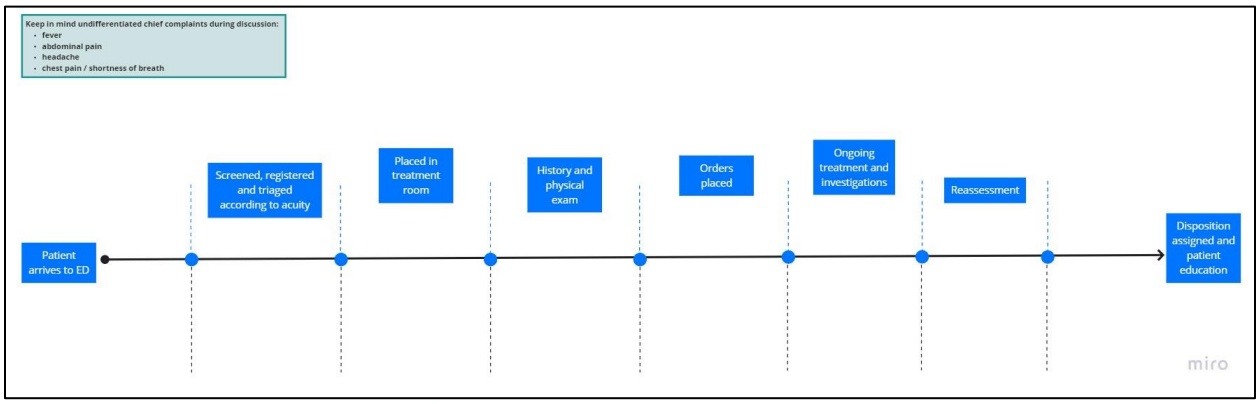
Are there any other factors that haven't been discussed that affect the diagnostic process?

Is there anything else we should have asked to help us understand your experience better?

1. Moderator will debrief participant and notify the participant that the patient timeline will be used as summary of the discussion. The timeline with discussion points will be sent via email to the participant for brief review to ensure it captures an accurate understanding of what was discussed. Offer points of contact for further information on involvement and next steps.
2. Participants will be thanked for taking part in the study and released.

Zoom Screen Share Images

Miro ED Patient Timeline



ED Acute Care Framework (Modified-NASEM)