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14. ABSTRACT
This project aims to better understand how physicians engage in clinical reasoning and how different types of contextual factors influence their clinical reasoning performance and self-regulation. In addition to asking participants about how they think about reasoning we will also examine several biometric indicators such as heart rate and blood pressure to examine how participants' physiologic responses might be influenced while they are engaging in clinical reasoning. Understanding how contextual factors influence clinical reasoning performance and its self-regulation will help inform new educational interventions to help faculty and physicians learn how to improve their clinical reasoning.

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INTRODUCTION

This project aims to better understand how physicians engage in clinical reasoning and how different types of contextual factors influence their clinical reasoning performance and self-regulation of clinical reasoning. In addition to asking participants about how they think about reasoning we also examined several biometric indicators such as heart rate variability and blood pressure to examine how participants' physiologic responses might be influenced while they are engaging in clinical reasoning. Understanding how contextual factors influence clinical reasoning performance and self-regulation of clinical reasoning will help inform new educational interventions to help faculty and physicians learn how to improve their clinical reasoning.

KEYWORDS

Clinical reasoning, Video-based simulation, Simulation-based learning, Cognitive load theory, Self-regulated learning microanalysis, Biometrics, Think-aloud, Burnout, Sleepiness, Situated cognition, Contextual factors

ACCOMPLISHMENTS[1]

3.1) What were the major goals of the project?

Aim 1: Video case development and validation (completed)
Aim 2: Scenario case development and validation (completed)
- *Milestone:* Scenario created (completed more scenarios than stated in proposal)
- *Deliverable 1:* Dissemination of case development process (ongoing)

Aim 3: IRB submission and approval (completed)
- *Milestone*: IRB Approvals (completed)

Aim 4: Enrollment and data collection (phase 2 completed; phase 3 planned)
- *Milestone:* Subjects enrolled and phase 2 data collection complete (exceeded minimum sample requirement of 80 participants)

*Aim 5: D*ata analysis (ongoing)
- *Milestone:* completion of data analysis for phase 2 (ongoing)
- *Deliverable 2:* Dissemination of findings (ongoing--several manuscripts for peer-review publication are underway, as are multiple conference presentations)

Aim 6: Development of educational intervention (ongoing)
- *Milestone*: educational intervention developed (ongoing) and IRB approved (completed)

3. 2) What was accomplished under these goals?

For Aim 2: **Scenario case development and validation**

[1] *See Appendix A for our progress on the JPC-approved statement of work in table format. Below we detail, for each aim and deliverable, progress made during *this period* (i.e., 2017-2018). Please refer to previous annual report for tasks accomplished in the fiscal year 2016 - 2017.

Construction and validation evidence for standardized patient team-based scenarios. Examine how theoretically derived variables are related to clinical reasoning performance in-vivo during inpatient scenario-based simulations.

Subtask 1: Writing and revising outpatient and inpatient scenarios

- Inpatient Scenario Condition: We developed and revised one inpatient scenario condition
    - The scenario was developed by Drs. Durning and Battista with input from Megan Ohmer, Dr. Jeffrey Mikita (Walter Reed Sim Center Department Head), Drs. Walter Kucera and Matthew Nealeigh (general surgery residents in their research year), and Drs. Sarah Ordway and Thomas Mellor (Internal Medicine Chief Residents). Anna Howle and Sarah Krajnik (of the Walter Reed Simulation Center) supported testing and revisions as well as casting a standardized patient to portray the patient.

Subtask 2: Pilot testing and formative assessment of individual and team scenario

- We conducted several meetings with designated subject matter experts to ensure that the scenario introduced an adequate amount of clinical ambiguity to stimulate clinical reasoning, while also presenting a patient and clinical situation that could plausibly be treated by our target physician sample (i.e., internal medicine, family medicine, general surgery). The inpatient case was pilot tested with four physicians to get review and feedback.
- We cast and trained one standardized patient to implement the inpatient scenario condition.

Milestone Achieved: Successfully developed and implemented the inpatient scenario condition with 20 participants.

Deliverable 1: Dissemination of case development process

- We developed and submitted a manuscript entitled, "Clinical Reasoning in the Primary Care Setting: Two Scenario-Based Simulations for Residents and Attendings" on May 10th, 2018 to *MedEdPortal*. This manuscript was accepted for publication on 12 Oct 2018.
    - The article describes the development, implementation, evaluation, and design improvements of two scenario-based simulations (i.e., diabetes, angina) and their use alongside our think-aloud reflection protocol and open-ended post-encounter form (PEF).
    - We reported on the implementation evaluation of these two scenarios for 12 physicians (a total of 24 scenarios) using data drawn from activity analysis of physician performance, qualitative analysis of think-alouds, and quantitative analysis of post encounter forms, the cognitive load measure, and authenticity scores.

For Aim 3: IRB submission and approval

IRB actions since the prior annual report:

- Received approval of modification (modification 3) for the addition of new study sites to enhance our recruitment efforts (Fort Belvoir Community Hospital, Naval Medical Center San Diego (NMCSD), and Brooke Army Medical Center) and addition of study personnel (Dr. Konopasky, Dr. Surry, Dr. Condos, and Sunny Yauger). [Feb, 22, 2018]
- Local site determination - NMCSD performed a facilitated review and acknowledged

USUHS as the IRB of record. (approved on April 26, 2018)
- Received approval of modification (Modification 4) for the addition of Brooke Army Medical Center (approved by USUHS April 12, 2018)
- Received approval of modification: addition of three additional research personnel (approved on May 14, 2018)
- Received approval (modification 6) for adding civilians and contractors to one part of the protocol (it was already added to the narrative portion of the protocol, creating an inconsistency in the paperwork) [approved on June 25, 2018]
- Received approval from USUHS IRB for conversion to multisite study protocol [Aug, 10,2018]
- Submitted continuing review to eIRB on 27th Sep 2018 (awaiting final determination).

Milestone Achieved: Received IRB approval for intervention phase of the study. [Sep, 18, 2018]

For Aim 4: Enrollment and data collection
Our aim was to meet the target of enrolling 80 participants for phase 2 of the study by the end of September 2018. We successfully met that target, enrolling and collecting data for **85** participants (attending and resident physicians) on 12th September 2018.

- We completed enrolling and collecting data for 20 participants in the inpatient trauma scenario condition and 65 participants in the outpatient condition (includes video and live scenario conditions)

Milestones Achieved: Completed data collection for video, outpatient and inpatient scenario conditions [September 12, 2018]

Information on Enrollment/Withdrawals and Completions as of September 12th, 2018.
- Projected enrollment: 85
- Enrollment (figures reflect the month in which participants enrolled in and started the protocol):
    - November 2017 - 0
    - December 2017 - 3
    - January 2018 - 4
    - February 2018 -1
    - March 2018 - 1
    - April 2018 - 2
    - May 2018 - 4
    - June 2018 - 16
    - July 2018 - 10
    - August 2018 - 20
    - September 2018 -1

- Withdrawals (reflects participants who completed the consent process but who withdrew from the study during the data collection):
    - August 2018- 2

- Enrollment/Completed and Withdrawal (to date):
    - Enrolled: 89
    - Competed: 85
    - In Process: 0

- Withdrawn: 4

For Aim 5: Data analysis

- We have completed the following analyses on the data collected. Analyzing data is a two-step process which involves: 1) managing and transforming data and 2) conducting the analysis. We continue to conduct a variety of analyses.

  - *Managing and transforming data*: We follow a data management system to ensure all data are retrieved and saved for analysis. The data saved is then transformed into a format on which we can run analysis. To date we have:
    - Retrieved and saved all video data to dual hard drives
    - Retrieved and saved all audio to dual hard drives
    - We have transcribed think-aloud interviews for 77 participants (154 think-alouds total)
    - We have also successfully transcribed 28 (including outpatient and inpatient) scenario conversations

  - *Analysis*: Since we have a diverse set of collected data (e.g. biologic data, self-report surveys, think alouds, video, self-regulation data, etc.), we have different teams of expert researchers analyzing these data.

    - *Holter data:* We have successfully retrieved the data of 43 participants and entered their Holter data into the Mortara software system to begin analysis of heart rate variability and QTc variability. The cardiology team is currently performing data analysis. We are submitting a manuscript using our planned methodology to *Perspectives on Medical Education*.

    - *Think-aloud and other transcribed language data:*

      - We have coded think alouds of 26 participants (52 think-alouds total) for reconsideration: instances of participants reflecting and changing their mind (indicative of depth and breadth of reflection).
      - We have coded 10 think-alouds for conditional and counterfactual thinking (i.e., all statements where participants posited causal connections, either in reality or hypothetically [e.g., “would have” or “could have”]).
      - We are running activity analysis on scenario videos and transcribed scenario conversations (28 outpatient and inpatient).
      - We have conducted comparative and descriptive analysis of 32 sets of post-encounter forms and self-report variables (cognitive load, expertise, self-regulation, clinical reasoning, and demographics)
      - Coded think-aloud interviews of 25 participants for linguistic features (e.g., cognitive processes, affective markers).
      - We created a coding scheme for semantic competence and discompetence, have coded 68 think-aloud transcripts, and have conducted interrater reliability on that coding.
      - We held several meetings with our two associate investigators at UTHSCSA and NMCSD and are refining a coding schema for clinical tasks in think-alouds (a measure of the variety of clinical reasoning tasks participants engage in).

- *Survey Analysis:*
  - We have done inter-rater reliability checks on 65 out of 65 of the outpatient post-encounter forms (PEFs).
  - We have assembled a team of 3 clinicians to code inpatient PEFs and have completed coding 4 of the 7 PEF items.

- *Self-Regulation Analysis:*
  - With the help of the team of researchers at Rutgers University, the self-regulated learning (SRL) data of 54 participants have been coded.
  - We will be running preliminary descriptive statistics to look at the initial trends.

Deliverable 2: Dissemination of findings

- Our abstract for a poster presentation entitled "Case Specificity in Clinical Reasoning: A Qualitative Case Study of Conditional Reasoning Processes" was accepted and presented at Uniformed Services University of Health Sciences' Research Days (presented on 17th May 2018).
  - This poster used qualitative research methods to examine how five physicians from the larger study reasoned through two video-based outpatient cases.
  - We analyzed these participants' think alouds for instances of *conditional reasoning*: causally connecting symptoms and diagnoses with supporting evidence. Results suggested differences reasoning patterns for our two different medical cases (i.e., diabetes and angina).

- We wrote and have submitted a manuscript entitled, "The heart may reveal the mind: An exploratory study of physiologic variables and their relationship with self-reported measures of cognitive load and performance in medical students."

  - The purposes of this exploratory study were twofold: (a) to gather biologic validity evidence for correlates of different types of self-reported cognitive load, and (b) to explore the association of self-reported cognitive load and physiologic measures with clinical reasoning performance.

- We submitted two abstracts and had both accepted (a workshop and a poster presentation) for presentation at the International Meeting on Simulation in Healthcare (IMSH) in January 2019, entitled "An introductory workshop for activity and linguistic analysis of video in healthcare simulation" and "Reflection in live and video simulation contexts: A comparison study" (accepted Oct 4, 2018).
  - The workshop focuses on teaching participants how to use some practical tools to analyze the content of video to enhance teaching, assessment, faculty development or research.
  - The poster reports on statistically significant differences in reconsideration and linguistic markers in the video versus live scenario conditions, partially answering our research question regarding the effects of authenticity of context on performance.

- We submitted and presented an abstract at the Military Health System Research Symposium (MHSRS) entitled, "The Effect of Contextual Factors on Clinical Reasoning:

A Mixed Methods Study Examining Outcome and Process (Accepted for presentation May 30, 2018; Presented on Aug 21, 2018; invited submission to an upcoming issue of *Military Medicine*).
    - Examined patterns in outcomes of clinical reasoning, PEF and cognitive load (mental effort) scores, comparing between the contextual and non-contextual factors conditions.
    - Both quantitative and qualitative findings were found to be consistent with expectations based on the theories of situated cognition and cognitive load. The presence of one or more contextual factors significantly and negatively impacted clinical reasoning performance and increased cognitive load.

- Our submission "Emergent Clinical Reasoning During Think Alouds: How physicians Reflect on their Own and Others' Practice in live and Video Simulation" detailing the results of our initial linguistic analysis of the clinical reasoning reflected in think-alouds was accepted to be presented at the American Association of Medical College (AAMC) annual meeting on November 5, 2018.

Additional tasks achieved:

In addition to the goals, tasks, subtasks and milestones achieved and reflected on above, we also achieved several additional infrastructure related tasks. They include the following:

- Recruitment and Personnel
    - We added new study sites to our study protocol via IRB to help us in recruiting participants for the study, which included NMCSD, BAMC, and UTHSCSA.
    - A new study team member joined us in April 2018. This new team member is a medical student who is helping with study implementation and data analysis. She has been a very strong addition to the study team.
    - We had two study team members travel to San Diego (NMCSD) for three days of data collection (video condition) for 15 participants.

- We continue to develop, update and improve the infrastructure necessary to implement various phases of the the study, including:
    - We purchased an Auris Stethoscope (simulated stethoscope with an accompanying iPad) for the inpatient scenario.
    - We also purchased other necessary study equipment to support continuation of the study (e.g. Holter patches, batteries, Holter pouches, makeup for moulage for inpatient scenario, etc.).
    - We acquired two Mifi wireless hotspot devices to overcome network connection issues that caused intermittent disruptions while participants filled out their online survey.
    - We successfully coordinated and worked with the Walter Reed Simulation Center to reserve rooms for scheduled participants.
    - After researching different software packages and gaining approval from the USUHS IT department, we purchased two additional software packages for data analysis (Dedoose qualitative analysis and Linguistic Inquiry and Word Count [LIWC] linguistic analysis).
    - We contracted with a transcription company, Accentance Inc., to help us with transcribing audio recording of think alouds and scenarios.

    - We hired and trained two new standardized patients to help us implement the outpatient and inpatient scenario conditions.
    - We continue to revise and improve our data management plan, which was approved by the USUHS IT and IRB teams to support data collection, analysis and development of new measures and assessment tools.
    - We developed and continue to revise and improve our recruitment strategies. This plan includes:
        - Working with designated "resident champions" in internal medicine and general surgery to help us recruit to residents and faculty.
        - Presenting at local department meetings and at a an internal medicine didactics conference to create awareness about the study and recruit participants.
        - Targeted emailing for recruitment through lists obtained from clinical directors.
        - Reached out to designated local site PIs at three additional sites (i.e., Naval Medical Center San Diego, University of Texas Health Science Center at San Antonio, and Brooke Army Medical Center) to complete the required local IRB processes to help increase study enrollment.
            - We sent out recruitment emails to 87 participants at NMCSD.
            - We successfully recruited 15 participants who completed the study in early August 2018.
        - Regularly attending monthly department meetings to present study details to potential candidates.
        - We offered flexible scheduling, both regarding time and location.
        - We also began using a "snowballing" strategy, reaching out to prior participants for suggestions of other potential participants to recruit.
        - We scheduled recruitment sessions during the intern orientation (beginning in June) and faculty onboarding (in July) when participant schedules are more predictable.
- We established a regular research team meeting schedule to support achievement of the aims and tasks related to this program of research. This includes large-group meetings held with all investigators, monthly team meetings for investigators located at USUHS, and meeting with our nine data analysis teams.

Methodology:

Sample:

- Phase 2 (comparative study): 85 primary care (internal medicine and family medicine) and surgical (residents and attending physicians). Our target was 80 participants based on power analysis. We have completed phase 2.
- Phase 3 (pilot intervention): ~15-20 primary care (internal medicine and family medicine residents and attending physicians) and surgical (residents and attending physicians). We anticipate beginning phase 3 recruitment in the near future.

Overall Design:

- Mixed-methods, experimental design. Use of qualitative and quantitative measures is complementary.
- Using video- and live scenario-based simulations to elicit physicians' reasoning in increasingly complex and authentic settings.

- Comparison of video-and live-scenario-based simulations.
- Adapting novel measures (e.g., biometric, think-aloud, self-regulated learning, linguistic measures) to assess physicians' reasoning.

Design and development of video- and live-scenario-based simulations.
Outpatient Videos and Scenarios:
We have completed developing, revising, and implementing four outpatient videos and two outpatient live simulations (all either diabetes or angina cases). Please refer to the previous annual report (2016-2017) for details regarding this process.

Inpatient Scenario:
We developed, revised and implemented one inpatient scenario (Tension pneumothorax) (May 2018).

- The scenario was primarily developed by Dr. Battista and Dr Durning, assisted by two surgical residents and two internal medicine residents to ensure the clinical authenticity.
- A medical student researcher also assisted in writing the scripts for various pieces of the scenario (e.g. leading nurse, rapid response team member, standardized patient).
- We met and consulted with the staff at the Walter Reed National Military Medical Center's Simulation Center to ensure accurate implementation, including all the necessary clinical artifacts and tools.
- The inpatient case was pilot tested with four physicians to get review and feedback prior to running actual participants, whereupon it was further revised.
- We cast and trained one standardized patient to implement the inpatient scenario condition and provided him with multiple rehearsal sessions, resulting in further revision.

Outpatient Scenario for Phase 3:

We are creating a new scenario to implement the intervention phase of the study (see Appendix B for preliminary intervention workflow).

3.3) What opportunities for training and professional development has the project provided?

The project involves several integrated processes of data collection at different levels of the study. To ensure that the data collection system is efficient the key personnel and the research assistants were trained on the following:

Research Protocol Implementation Training:

The study implementation entails a series of steps to be followed, for which each team member underwent training in learning to set up and conduct the study. The following are areas in which members received training:

a) sending initial recruitment emails to potential participants
b) consenting participants
c) arranging time and space to fit participants with watch and Holter monitor
d) setting up digital recording equipment prior to the day of study (e.g., SD cards, charging cameras, etc.)
f) setting up the simulation rooms including the video system
g) administering the pre-study survey

h) conducting post-study think aloud interviews and microanalysis protocols, and
i) removing data from digital devices and following designated data management protocols.

All of our core research team members also underwent training on the proper handling and use of biometric devices to collect data.

1) Actigraph Watch - The actigraphy watch helps us to collect data on participants' activity and sleep level. Members of the team were trained to configure the actigraphy watch using the actigraphy software and also on how to retrieve and save the data collected.
2) Holter Monitor - The Holter monitor helps us collect data on heart rate variability. Members of the team learned how to fit a 12-lead Holter monitor which involves 1) Instructing the participant on how to wear the Holter monitor 2) Prepping the participant prior to fitting them with 12-lead Holter b) Fitting the Holter monitor d) Retrieving the data and cleaning the Holter card.
3) Automatic blood pressure machine - training was provided so that research team members could efficiently use BP machine to collect blood pressure data of the participants.
4) Auris stethoscope - We used a simulation stethoscope for our inpatient scenario condition, for which members of the study team learned how to use the Auris software to create different breath sounds to represent worsening of the pneumothorax and deterioration of the patient. This helped increase the authenticity of the inpatient scenario. Participants were briefly oriented to the stethoscope by a team member prior to participation.

Apart from learning how to set up and conduct the study, members of the team also received training on data analysis:

Think aloud analysis: Our research assistants have learned how to qualitatively code participants' think alouds, identifying:

a) Reconsideration: We analyzed participants' think-aloud reflections and coded for instances of reconsideration: moments when practitioners questioned their own choices or thought processes. The think aloud was uploaded to Dedoose software wherein: 1) we entered the different index codes to be used, 2) we highlighted the reflections for reconsideration assigning specific index codes to them, 3) and, for inter-rater reliability, each researcher added comments attached to the coded reflection.

b) Semantic competence: We are analyzing think-aloud transcripts for the use of advanced medical terminology (semantic competence) as well as instances where participants could have used medical terminology and did not (semantic discompetence). It is hypothesized that participants use less medical terminology in the presence of contextual factors representing increased cognitive load.

Implementation Checklist: A checklist was developed to ensure we are efficiently implementing the scenario cases in terms of ensuring the standardized patients do not deviate from the character they are portraying for our live scenarios. Members of the team also received training on how to account for efficient implementation of the live scenario condition.

Standardized Patient Training: An important aspect of the simulation based cases involved training and educating standardized patients about the clinical cases to be portrayed (e.g., appropriate portrayal of symptomatology, responses to the questions posed by the study participants, knowledge about medical history/background). Our study team members and the simulation staff held meetings with all of the standardized patients in order to rehearse the case prior to the study. The simulation lab staff as well as the standardized patients were also educated on study aims, procedures, and processes which helped in ensuring that we have all the required resources in order to efficiently implement the study.

Data Management Training:

One of our research assistants enrolled and completed an online course on "Research Data Management and Sharing" to better aid in managing the diverse data collected for the study. The courses covered the following areas a) understanding data b) developing a data management plan c) working with ongoing data collection d) sharing data e) archiving data for future use. The course also highlighted some of common problems faced due to poor data management often leading to data loss along with ways of mitigating. (Appendix H: Certificate)

Software Training:

We use different software to help with data conversion as well as data analysis. In terms of linguistic and qualitative analysis, we purchased two types of software: LIWC2015 and Dedoose. We also have Video Pro software to help us convert video data files to audio files which can be later transcribed while preserving participant confidentiality.

- In order to understand key functions as well as optimal use of the software based on our research needs, a research team member thoroughly reviewed the video and handbook tutorials explaining how to use the software.
- Team members learned how to upload the think-aloud transcription data as well as run specific analyses using Dedoose and LIWC2015. This also entailed conversing with personnel at the software company, discussing our research needs, and troubleshooting problems.

Regulatory Training:

As per IRB regulations it is mandatory for all research personnel to undergo and complete research specific regulatory training. All research team members underwent several mandatory CITI training modules as per the IRB for research requirements to be eligible to be actively involved in undertaking research activities (e.g. human subjects protection biomedical and SBR Initial, conflict of interest in research, HIPAA for clinicians, training for research coordinators & research assistants). Two team members also went through several locally offered IRB workshops to learn to more efficiently use the electronic IRB system.

Presentation Opportunities for Junior Team Members:

Our research assistants have had the opportunity to both advertise the study to potential participants as well as share and present preliminary data analysis.

- An abstract of one of our research assistants was accepted for presentation at the Uniformed Services University of the Health Sciences' Research Days. It involved

running preliminary qualitative analysis on 10 think alouds identifying participants' conditional reasoning process and presenting that data in the form of a poster.

Manuscript Development for Junior Team Members:

One of our research assistants is developing a manuscript to submit to *MedEdPortal* describing the development of the inpatient scenario, preliminary content analysis of the Post Encounter Forms and Think Alouds, and providing a package of materials for other medical educators to use in the teaching and/or evaluation of physician learners.

The research assistant along with a physician colleague are also conducting data analysis in order to prepare a manuscript on the use semantic competence in participants' think alouds and how the use of semantic competence may be related to increased cognitive load in the presence of contextual factors.

Professional Development Beyond the Local Research Team:

In addition to providing internal team members with professional development opportunities, we have begun developing workshops to present and share with members of the larger professional community. For example, we have developed a workshop to present at the International Meeting on Simulation in Healthcare (IMSH) in January 2019 to provide attendees with an introductory practice session to learn how to conduct basic forms of video and linguistic analyses.

The study also provided opportunities for internal medicine residents as well as health professions education program students to contribute in developing and revising inpatient scenario medical cases.

In addition, annually in December, we also participate in and present our most current findings at the annual National Capital Region Simulation Consortium (NCRSC). This is a one-day local conference that supports simulation researchers from the organizations in the NCRSC (e.g., Walter Reed, Fort Belvoir, Portsmouth, Joint Base Andrews, etc.).

3.4) How were the results disseminated to communities of interest?

We have submitted two manuscripts for publication (two of them in *MedEdPortal*, which offers free educational resources to physicians). We have also presented at conferences and plan for future presentations at conferences, with more applications to come. Please refer to section 3.2 (Dissemination of findings) for further details on dissemination.

3.5) What do you plan to do during the next reporting period to accomplish the goals?

Intervention Phase:

- We have begun the third phase of our work, development of an educational intervention to assist physicians with clinical reasoning performance. This intervention will be similar in structure to our research (physicians either viewing a case video or participating in a live scenario accompanied by various surveys and reflections), but will involve some explicit training materials, including:

    - A planned video on the topic of clinical reasoning, contextual factors in reasoning, mental effort (i.e., cognitive load), and diagnostic error. (currently this has been outlined, but not completely developed)
    - An adaptation of our self-regulated learning questions for use in reflection
    - An adaptation of our "think-aloud" reflection.
    - An adaptation of a reflection tool believed to help reduce error (SAFER)
- We are currently in the design phase for this part of the project and we plan to enroll participants during the next quarter.

Manuscripts and Publications:

We are currently in the process of analyzing the data collected and are working on the following paper publications:

Peer Reviewed Empirical Manuscripts in Process:

1. "The Effect of Contextual Factors on Clinical Reasoning: A Mixed Methods Study Examining Outcome and Process" (based on Post Encounter Form data)
2. "Clinical Reasoning in Scenario-Based Simulations: A Descriptive Analysis" (based on simulation and think-aloud data)
3. "Emergent Clinical Reasoning During Think-Alouds: How Physicians Reflect on their Own and Others' Practices in Live and Video Simulation" (based on think-aloud data)
4. "'It totally possibly could be': How clinical language changes in the presence of contextual factors in a group of military physicians" (based on think-aloud data)
5. "First-year medical students' calibration bias and accuracy across clinical reasoning activities: An initial investigation" (based on previous data collection)

Media and Scenario Manuscripts in Process:

1. "Clinical Reasoning in the Inpatient Setting: A Scenario-Based Simulation for Residents and Attendings"
2. We are also working on manuscript discussing the development of outpatient video cases, to be submitted to *MedEdPortal*

IMPACT

Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

4.1) What was the impact on the development of the principal discipline(s) of the project?

We conducted qualitative and quantitative analysis on the data collected with aim of understanding how physicians clinically reason as well to examine if any difference between video versus live simulation condition. The following are the implications of our preliminary analysis:

Implications of results:

- Our results suggest that the study of and intervention into the effect of *context* on physician reasoning performance is important for understanding context specificity and reducing *errors* and should be continued and built upon.
- The findings also suggest new tools for *measuring* physician reasoning, indicating aspects of physician language we can study to see if their reasoning is being affected by contextual factors.
- In addition to the importance of context, our study indicates that the *content* of the clinical case (i.e., what type of medical problem) can affect physician reasoning as well (and is consistent with prior work in clinical reasoning).
- We also found that clinical reasoning differs according to level of *experience*, suggesting we might need to teach clinical reasoning differently depending upon how much experience physicians have.
- Our results also indicate that performance as well as learning opportunities in *live scenario cases* versus *video cases* are different. Participants seem to do a different kind of cognitive processing and reflection in each modality, perhaps thinking and reflecting a bit more *deeply* in the live scenario cases. Further study of the implications of and use of different genres of simulation (i.e., video, live) could be important based on the findings from our preliminary analyses.

4.2) What was the impact on other disciplines?

Nothing to report.

4.3) What was the impact on technology transfer?

Nothing to report.

4.4) What was the impact on society beyond science and technology?

Nothing to report.

CHANGES/PROBLEMS

5.1) Changes in approach and reasons for change?

We revised our statement of work which was approved by JPC (Dec 2017). The statement of work was revised for the following reasons: (a) to reflect the more specific subtasks that we have developed as we move through the grant, (b) to reflect the additional sites we are incorporating for data collection, and (c) to more clearly guide the study team and our supporting agencies (e.g., JPC review board) moving forward.

5.2) Actual or anticipated problems or delays and actions or plans to resolve them?

We were able to successfully mitigate several problems and implement the study efficiently. The following are the problems faced and the ways we mitigated them:

- We faced difficulties in data collection due to network connectivity issues, which made it difficult for participants to fill out the online survey.

- Therefore, we acquired two Mifi hotspot devices to overcome network connection issues.

- There were a few difficulties in terms of recruiting participants due to scheduling issues.
  - We developed and continue to revise and improve our recruitment strategies and we have met our recruitment targets to date. (Please refer to section 3.2, Additional task achieved)

- We also faced an increase in pass-back from eIRB in terms of modification submissions, which delayed our study implementation plan.
  - We identified a point of contact within the USU IRB to help us with our modification submissions, now we are able to discuss our plans prior to submission to ensure we have entered all the required information correctly.
  - Two of our research personnel went through in person training sessions set up by the eIRB as well as training videos and booklets. The training session helped get a better understanding of the eIRB system as well as the process of submitting modifications.

5.3) Changes that had a significant impact on expenditures?

Not applicable.

5.4) Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents?

Not applicable.

PRODUCTS

6.1) Publications, conference papers, and presentations:

See sections 6.2 - 6.8 below.

6.2) Journal publications

- We submitted a manuscript titled, "Clinical Reasoning in the Primary Care Setting: Two Scenario-Based Simulations for Residents and Attendings" to *MedEdPortal*. We received notification that the manuscript passed the initial screening on 30 May 2018 and a request to revise and resubmit on 10 September 2018. We submitted the revised manuscript on 20 September 2018. The manuscript was accepted for publication on 12 Oct 2018.

- The current JPC study results has informed the publication of a paper in the *Journal of the American Medical Association*, entitled, "Management reasoning: Beyond the diagnosis" (See open access link: https://jamanetwork.com/journals/jama/fullarticle/2681495)

6.3) Books or other non-periodical, one-time publications.
"Nothing to Report"

6.4) Other publications, conference papers, and presentations.
1) Our abstract for a poster presentation entitled "Case Specificity in Clinical Reasoning: A Qualitative

Case Study of Conditional Reasoning Processes" was accepted and presented at Uniformed Services University of Health Sciences' Research Days (presented on 17th May 2018)

2) We submitted and presented an abstract to the Military Health System Research Symposium (MHSRS) entitled, "The Effect of Contextual Factors on Clinical Reasoning: A Mixed Methods Study Examining Outcome and Process" (Accepted 30th May 2018 and Presented on 21st Aug 2018)

6.5) Website(s) or other Internet site(s)
Nothing to report.

6.6) Technologies or techniques
Nothing to report.

6.7) Inventions, patent applications, and/or licenses
Nothing to report.

6.8) **Other Products**

Live scenarios:
Ohmer M, Durning S, Kucera W, Nealeigh W, Mellor T, Ordway S, Mikita J, Howle A, Krajnick S Battista A, Konopasky A, Ramani D, Battista A. Clinical reasoning in the inpatient setting: A standardized patient case for residents and attendings. 2018

Battista A, Konopasky A, Ramani D, Ohmer M, Mikita J, Howle A, Krajnick S, Torre D, Durning S. Clinical reasoning in the primary care setting: Two standardized patient cases for residents and attendings. 2017

Videos:

Battista A, Hemmer P, McBee E, Ratcliffe T, LaRochelle J, Howle A, Durning S. Clinical Reasoning in the Primary Care Setting: Two video-based clinical vignettes. 2016

- Design and post-production for the adaptation of two control video-based scenarios for the JPC-1, CDMRP grant, Award # NH83382416

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

7.1) What individuals have worked on this project?

Name:	Steven J. Durning
Project Role:	*Principal Investigator*
Duration on project:	Jan 2016 - Present
Percent effort:	10%
Contribution to Project:	Supervision of all study personnel; direction of research design and study implementation; direction of data analysis and

	dissemination

Name:	Anthony R. Artino Jr.
Project Role:	*Co- Principal Investigator*
Duration on project:	Jan 2016 - Present
Percent effort:	5%
Contribution to Project:	Collaborates with PI on direction of research design and study implementation; direction of data analysis and dissemination

Name:	Alexis Battista
Project Role:	*Key Personnel*
Duration on project:	Jan 2016 - Present
Percent effort:	20%
Contribution to Project:	Helps direct study design and implementation; assists in recruitment and data collection; helps direct data analysis and dissemination; lead instructional designer of video and live scenario-based simulations; oversaw construction and validation of video and live-scenario-based simulations; developed data management plan.

Name:	Abigail Konopasky
Project Role:	*Key Personnel*
Duration on project:	2nd Oct 2017 - present
Percent effort:	100%
Contribution to Project:	Assists in recruitment and data collection; helps direct data analysis and dissemination

Name:	Divya Ramani
Project Role:	*Key Personnel*
Duration on project:	20th March 2017 - present
Percent effort:	100%

Contribution to Project:	Directs recruitment and outreach efforts including: establishing recruitment relationships and strategies, scheduling and coordinating study participants, direction and oversight of simulation lab scheduling and setup to established study quality standards. Oversees simulation lab coordination with the simulation lab operations staff, data collection (including think-aloud protocol), data management (e.g., capture, archival, data transformation, data auditing); engages in data analysis and dissemination (e.g., drafting of literature reviews and manuscripts).

7.2) **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report.

7.3) **What other organizations were involved as partners?**

Provide the following information for each partnership:

- **Organization Name:** Walter Reed National Military Medical Center
- **Location of Organization:** Bethesda, Maryland, 20814.
- **Partner's contribution to the projec**t: Research site for the study
- **Financial support** - "Not Applicable"
- **In-kind support** - "Not Applicable"
- **Facilities** *(e.g., project staff use the partner's facilities for project activities)*; Walter Reed provides their simulation laboratory space for study implementation
- **Collaboration** *(e.g., partner's staff work with project staff on the project)*; Walter Reed provides simulation laboratory staff for help with project when needed
- **Personnel exchanges** *(e.g., project staff and/or partner's staff use each other's facilities, work at each other's site)*; "Not Applicable"
- **Other.** "Not Applicable"
- **Organization Name:** Rutgers University
- **Location of Organization:** New Brunswick, New Jersey
- **Partner's contribution to the projec**t: Consulting related to the self-regulated microanalysis protocol (Dr Tim Cleary)
- **Financial support** - $124,698.00 (Y1 $37,811.00)
- **In-kind support** - "Not Applicable"
- **Facilities** *(e.g., project staff use the partner's facilities for project activities)*; Not Applicable
- **Collaboration** *(e.g., partner's staff work with project staff on the project)*; Project partner, Dr. Tim Cleary, provided guidance in developing the self-regulated learning microanalysis protocol and supported refining the fuller research protocol. Dr. Cleary is also engaged in supporting data analysis related to the microanalytic protocol.
- **Personnel exchanges** *(e.g., project staff and/or partner's staff use each other's facilities, work at each other's site)*; "Not Applicable"
- **Other.** "Not Applicable"

SPECIAL REPORTING REQUIREMENTS

- **Please find attached Quad Chart**

APPENDICES

Appendix A
Recent Progress on JPC-Approved Statement of Work

***We sent approved statement of work to HJF Personnel Ester Paul December 27 2018, and we received an acknowledgement on January 2 2018 (full SOW is attached separately)*

Specific Aim 2 Scenario case development and validation	Expected Date of Completion	Status
Subtask 1: Writing and revision of individual and team scenarios	December 2016	Phase 2 complete Phase 3 ongoing
Subtask 2: Pilot testing and formative assessment of individual and team scenarios	March 2017	Phase 2 complete Phase 3 ongoing
Milestone: completion of scenarios	March 2017	Phase 2 complete Phase 3 ongoing
Deliverable 1 Dissemination of case development process		
Subtask 1: Co-author manuscript on instrument development	October 2018	Completed
Milestone: submission of manuscript for publication	October 2018	Completed
Specific Aim 3 IRB Approval for video and scenario with human subjects		

Subtask 1: Seek local IRB/IACUC Approval	October 2018	Completed Modification for Phase 3 - Ongoing
Milestone: IRB approval for USUHS and WRNMMC	October 2018	Completed Modification for Phase 3 Ongoing
PHASE TWO Empirical research: experimental study		
Specific Aim 4 Enrollment and data collection		
Subtask 1: Recruit, consent, and enroll patients/human subjects (residents and staff physicians) to study	Oct 2018	Completed 12th Sep 2018
Subtask 2: Data collection for video, scenario, and group scenario conditions	Oct 2018	Completed 12th Sep 2018
Milestone: Subjects enrolled and phase 2 data collection complete	July 2018	Completed 12th Sep 2018
Specific Aim 5 Data Analysis		
Subtask 1: Theoretically grounded analysis of individual and trauma scenarios	Oct 2018	Ongoing
Subtask 2: Linguistic analysis of think-alouds	Oct 2018	Ongoing
Subtask 3: SRL analysis of micro-analytic data	Oct 2018	Ongoing
Subtask 4: Analysis of biometric data	Oct 2018	Ongoing
Milestone: completion of data analysis for phase 2	Oct 2018	Ongoing
Deliverable 2 Dissemination of findings		
Subtask 1: Co-author manuscript on biometric data and clinical reasoning assessment	April 2019	Ongoing
Subtask 2: Co-author manuscript on linguistic assessment of clinical	April 2019	Ongoing

reasoning (individual & team-based)		
Subtask 3: Co-author manuscript on self-regulation and microanalysis	April 2019	Ongoing
Subtask 4: Co-author manuscript theoretic assessment of clinical reasoning (individual and team-based)	April 2019	Ongoing
Subtask 5: Co-author manuscript on methodological innovations	April 2019	Ongoing
Milestone: submission of phase 2 manuscripts for publication	April 2019	Ongoing
PHASE 3 Construction and Piloting of Intervention	April 2019	Ongoing
Specific Aim 6 Educational intervention development		
Subtask 1: Write and revise intervention (from data from aims 1 and 2)	June 2018	Ongoing
Subtask 2: IRB approval of intervention	June 2018	Completed
Subtask 3: Pilot intervention	Aug 2018	Not started
Milestone: educational intervention developed and IRB approved	Aug 2018	
Specific Aim 7 Educational intervention		
Subtask 1: Enroll subjects for intervention	April 2019	Not started
Subtask 2: Data collection for intervention	April 2019	Not started
Subtask 3: Initial analysis of intervention data	April 2019	Not started
Subtask 4: Pilot intervention findings with unannounced SPs	Feb 2019	Not started
Subtask 5: Co-author manuscript(s) on use of intervention	April 2019	Not started
Milestone: completion of intervention pilot & accompanying manuscript	April 2019	Not started

Appendix B

Intervention Workflow

****Attached Separately**

Appendix C

MHSRS Presentation:The Effect of Contextual Factors on Clinical Reasoning: A Mixed Methods Study Examining Outcome and Process.

****Attached Separately**

Appendix D

Inpatient Scenario Case

****Attached Separately**

Appendix E

MedEdPortal Manuscript: Clinical Reasoning in the Primary Care Setting Two Standardized Patient Cases for Residents and attendings

****Attached Separately**

Appendix F

IRB Approval Letters

****Attached Separately**

Appendix G

IMSH Approved Abstract : The Use of Think-Aloud Reflections to Examine Learners Experiences in Live and Video-Based Simulation Contexts: A Comparison Study

**** Attached Separately**

Appendix H

Research data management and sharing

****Attached Separately**

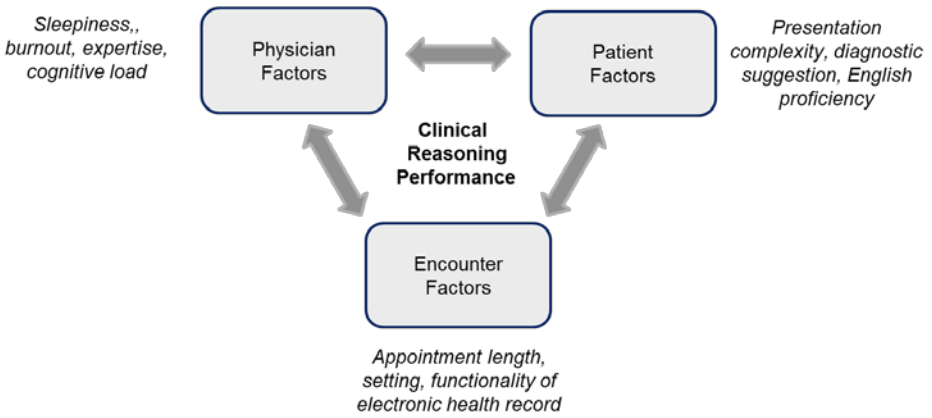
Quad Chart

Study Aims

- To examine how theoretically derived variables are related to clinical reasoning performance in vitro (using videotapes).
- To examine how theoretically derived variables are related to clinical reasoning performance in-vivo during 2 live scenario-based simulations.
- To evaluate whether a novel intervention based on the results of specific aims 1 and 2 improves clinical reasoning performance.

Approach

This is a 3-phase, prospective, mixed-methods study design, which involves: (1) developing video recorded clinical encounters and scenario-based simulations; (2) using video tapes and live, team-based trauma simulation scenarios to investigate relationships between clinical reasoning, cognitive load and contextual factors; and (3) developing an intervention and planning unannounced SP encounters at MTFs.



Timeline and Cost

Activities CY	16	17	18	19
Phase 1: Video development & validation				
Phase 2: Empirical studies (video and live)				
Phase 3: Intervention study				

Goals/Milestones:

CY18 Goal – Continue with empirical studies

☐ Intervention study to improve clinical reasoning

CY19 Goal – Data analysis, Manuscript development, etc.

Comments/Challenges/Issues/Concerns:

☐ Technical issues in the implementation of the data collection

☐ IRB process of conversion to multi site took longer than expected

☐ **Budget Expenditure to Date:**

- Projected Expenditure: $ 1,081,920
- Actual Expenditure: $ 688899

STATEMENT OF WORK

PERFORMANCE PERIOD Oct 1, 2016-April 1, 2019

Site 1: Uniformed Services University
4301 Jones Bridge Rd Bethesda MD
PI: Drs Durning & Artino

Site 2: Walter Reed National Military Medical Ctr
8901 Rockville Pike Bethesda
PI: Dr. Jeffery Mikita

Site3: Fort Belvoir Community Hospital
9300 DeWitt Loop
Fort Belvoir, VA 22060
PI: Sunny Yauger

Site 4: National Medical Center San Diego
34800 Bob Wilson Drive
San Diego, CA. 92134
PI: Dr. Elexis McBee

Site 5: UT Health San Antonio
7703 Floyd Curl Dr, San Antonio,
TX 78229
PI: Dr. Temple Ratcliff

Specific Aim 1 Video case development and validation	**Timeline**	**USU**	**WRNMMC**	**FBCH**	**NMCSD**	**UTHSC-SA**
Subtask 1: Construction of videotapes	1-2	SD&AA[1]	JM[1]	n/a	n/a	n/a
Subtask 2: Validation of videotapes	2-4	SD&AA	JM	n/a	n/a	n/a
Milestone: completion of videos	4					
Specific Aim 2 Scenario case development and validation						
Subtask 1: Writing and revision of individual and team scenarios	1-2	SD&AA	JM	n/a	n/a	n/a
Subtask 2: Pilot testing and formative assessment of individual and team scenarios	3-6	SD&AA	JM	n/a	n/a	n/a
Milestone: completion of scenarios	6					
Deliverable 1 Dissemination of case development process						
Subtask 1: Co-author manuscript on instrument development	24	SD&AA	JM	n/a	n/a	n/a
Milestone: submission of manuscript for publication	24					
Specific Aim 3 IRB Approval for video and scenario with human subjects						
Subtask 1: Seek local IRB/IACUC Approval	6	SD&AA	JM	SY[1]	EM[1]	TR[1]
Milestone: IRB approval for USUHS and WRNMMC	6					
PHASE TWO Empirical research: experimental study						
Specific Aim 4 Enrollment and data collection						
Subtask 1: Recruit, consent, and enroll patients/human subjects (residents and staff physicians) to study	6-24	SD&AA	JM	SY	EM	TR
Subtask 2: Data collection for video, scenario, and group scenario conditions	12-24	SD&AA	JM	SY	EM	TR
Milestone: Subjects enrolled and phase 2 data collection complete	21					

[1] Steven Durning (SD), Anthony Artino (AA), Jeffrey Mikita (JM), Sunny Yauger (SY), Elexis McBee (EM), Temple Ratcliffe (TR)

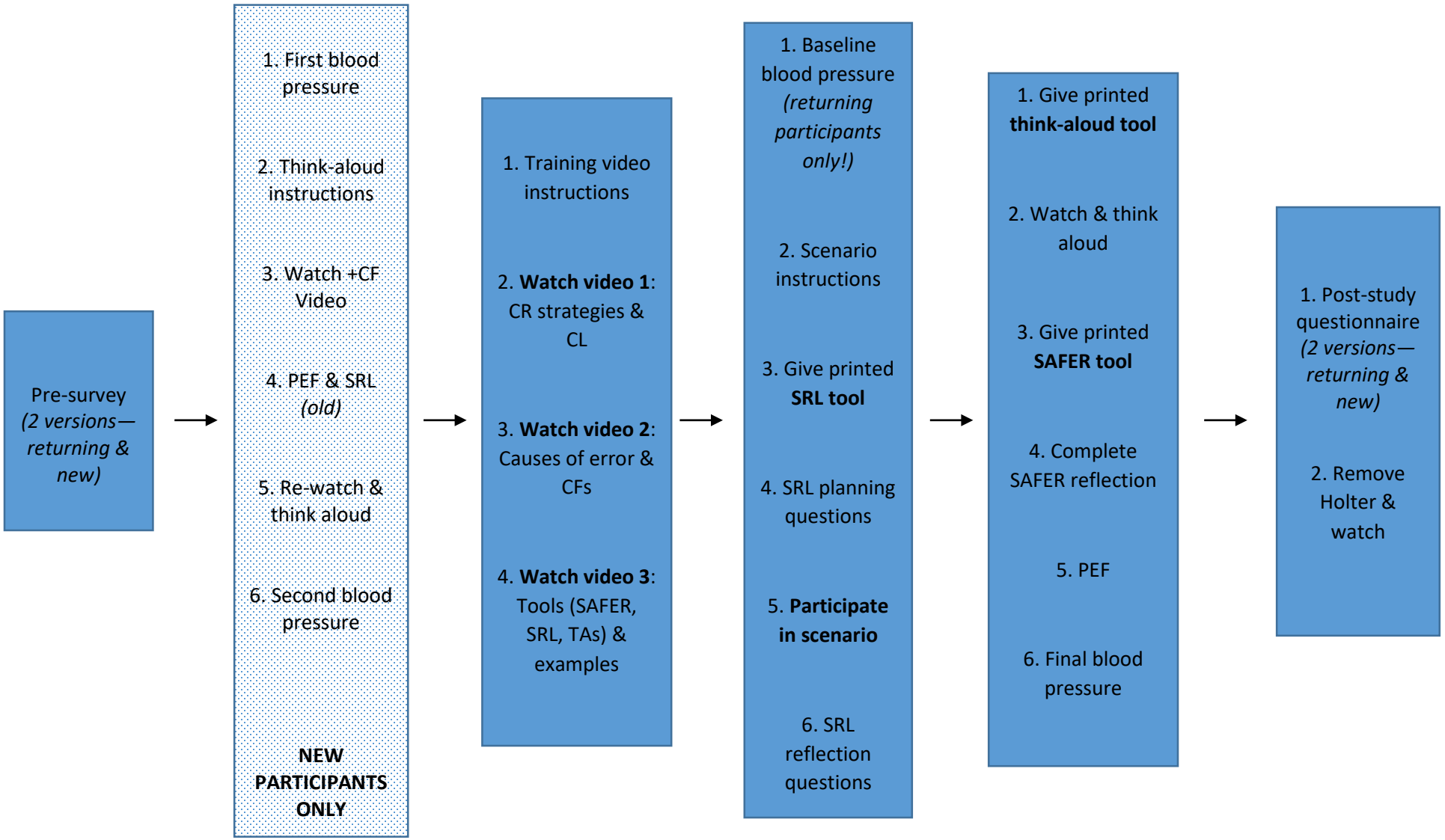
Specific Aim 5 Data analysis	**Timeline**	**USU**	**WRNMMC**	**FBCH**	**NMCSD**	**UTHSC-SA**
Subtask 1: Theoretically grounded analysis of individual and trauma scenarios	12-24	SD&AA	JM	SY	EM	TR
Subtask 2: Linguistic analysis of think-alouds	12-24	SD&AA	JM	SY	EM	TR
Subtask 3: SRL analysis of micro-analytic data	12-24	SD&AA	JM	SY	EM	TR
Subtask 4: Analysis of biometric data	12-24	SD&AA	JM	SY	EM	TR
Milestone: completion of data analysis for phase 2	24					
Deliverable 2 Dissemination of findings						
Subtask 1: Co-author manuscript on biometric data and clinical reasoning assessment	15-30	SD&AA	JM	SY	EM	TR
Subtask 2: Co-author manuscript on linguistic assessment of clinical reasoning (individual & team-based)	15-30	SD&AA	JM	SY	EM	TR
Subtask 3: Co-author manuscript on self-regulation and microanalysis	15-30	SD&AA	JM	SY	EM	TR
Subtask 4: Co-author manuscript theoretic assessment of clinical reasoning (individual and team-based)	15-30	SD&AA	JM	SY	EM	TR
Subtask 5: Co-author manuscript on methodological innovations	15-30	SD&AA	JM	SY	EM	TR
Milestone: submission of phase 2 manuscripts for publication	30					
PHASE 3 Construction and Piloting of Intervention						
Specific Aim 6 Educational intervention development						
Subtask 1: Write and revise intervention (from data from aims 1 and 2)	16-20	SD&AA	JM	SY	EM	TR
Subtask 2: IRB approval of intervention	16-20	SD&AA	JM	SY	EM	TR
Subtask 3: Pilot intervention	20-22	SD&AA	JM	SY	EM	TR
Milestone: educational intervention developed and IRB approved	22					

Specific Aim 7 Educational intervention	**Timeline**	**USU**	**WRNMMC**	**FBCH**	**NMCSD**	**UTHSC-SA**
Subtask 1: Enroll subjects for intervention	22-30	SD&AA	JM	SY	EM	TR
Subtask 2: Data collection for intervention	22-30	SD&AA	JM	SY	EM	TR
Subtask 3: Initial analysis of intervention data	28-30	SD&AA	JM	SY	EM	TR
Subtask 4: Pilot intervention findings with unannounced SPs	26-28	SD&AA	JM	SY	EM	TR
Subtask 5: Co-author manuscript(s) on use of intervention	28-30	SD&AA	JM	SY	EM	TR
Milestone: completion of intervention pilot & accompanying manuscript	30					

Projected Quarterly Enrollment (red & italicized = completed)

	Year 1				**Year 2**				**Year 3**	
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**
USUHS[1]			***1***	***3***	***1***	3	2	2[7]	3	3
WRNMMC[2]			***12***	***5***	***5***	5	10	5[7]	3	3
FBCH[3]						10	8	3[7]	3	3
NMCSD[4]							3	5[8]	3	3
UTHSCSA[5]							3	4[8]	3	3
Phase 2 Target Enrollment (cumulative)			***13***	***21***	***27***	45	71	**80 (phase 2 total)**		
Phase 3 Target Enrollment (cumulative)								10	25	**40[6] (phase 3 total)**

[1]Uniformed Services University of the Health Sciences
[2]Walter Reed National Military Medical Center
[3]Fort Belvoir Community Hospital
[4]Naval Medical Center San Diego
[5]University of Texas San Antonio
[6]This is an approximation: we are hoping to recruit between 30 and 40 for our intervention
[7]For phase 3
[8]For phase 2


Pre-survey *(2 versions—returning & new)*
1. First blood pressure
2. Think-aloud instructions
3. Watch +CF Video
4. PEF & SRL *(old)*
5. Re-watch & think aloud
6. Second blood pressure
NEW PARTICIPANTS ONLY
1. Training video instructions
2. **Watch video 1**: CR strategies & CL
3. **Watch video 2**: Causes of error & CFs
4. **Watch video 3**: Tools (SAFER, SRL, TAs) & examples
1. Baseline blood pressure *(returning participants only!)*
2. Scenario instructions
3. Give printed **SRL tool**
4. SRL planning questions
5. **Participate in scenario**
6. SRL reflection questions
1. Give printed **think-aloud tool**
2. Watch & think aloud
3. Give printed **SAFER tool**
4. Complete SAFER reflection
5. PEF
6. Final blood pressure
1. Post-study questionnaire *(2 versions—returning & new)*
2. Remove Holter & watch

The Effect of Contextual Factors on Clinical Reasoning: A Mixed Methods Study Examining Outcome and Process

Abigail Konopasky, PhD; Alexis Battista, PhD; Divya Ramani, MS; Megan Ohmer; Anthony Artino, PhD; Steven J Durning, MD, PhD

USU
Uniformed Services University

This work was funded by a Congressionally Directed Medical Research Programs' Joint Program Committee-1 grant.

Objectives

- To understand **context specificity**
- To understand how contextual factors impact **performance**
- To explore outcomes and processes of **clinical reasoning**

Image from http://inmyownterms.com/finding-the-right-context-for-a-term/

BACKGROUND

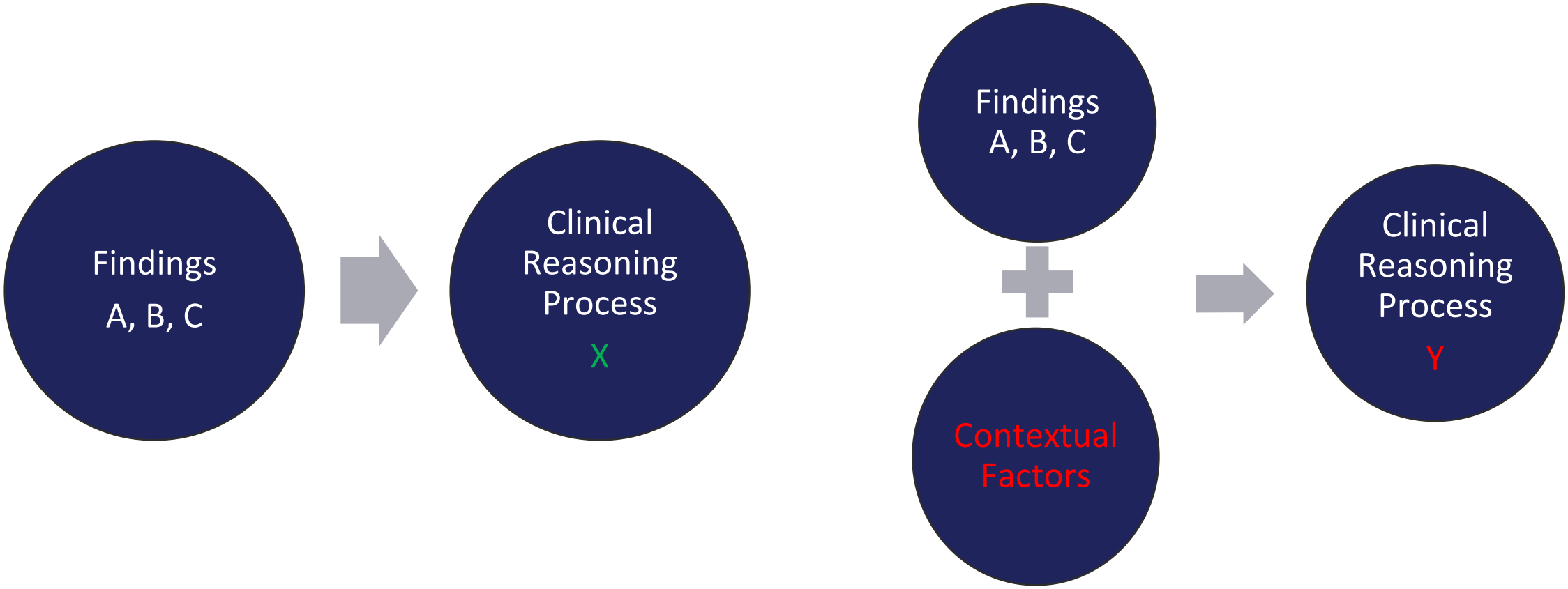
Diagnostic Error

- Recent Institute of Medicine report:
  - *"Most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences."*
  - Diagnostic error a leading cause of death in US

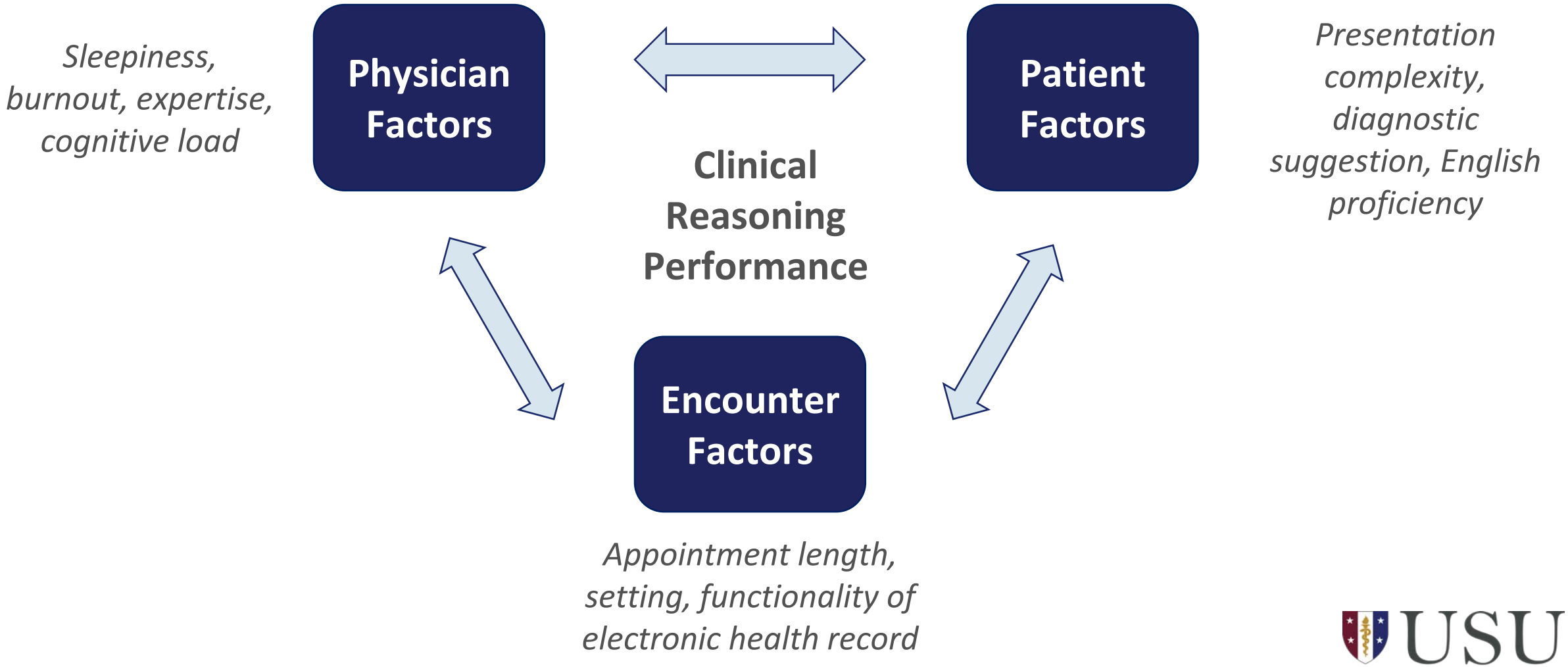
    -National Academies of Sciences, Engineering, and Medicine, 2015

- A major source of errors: contextual factors

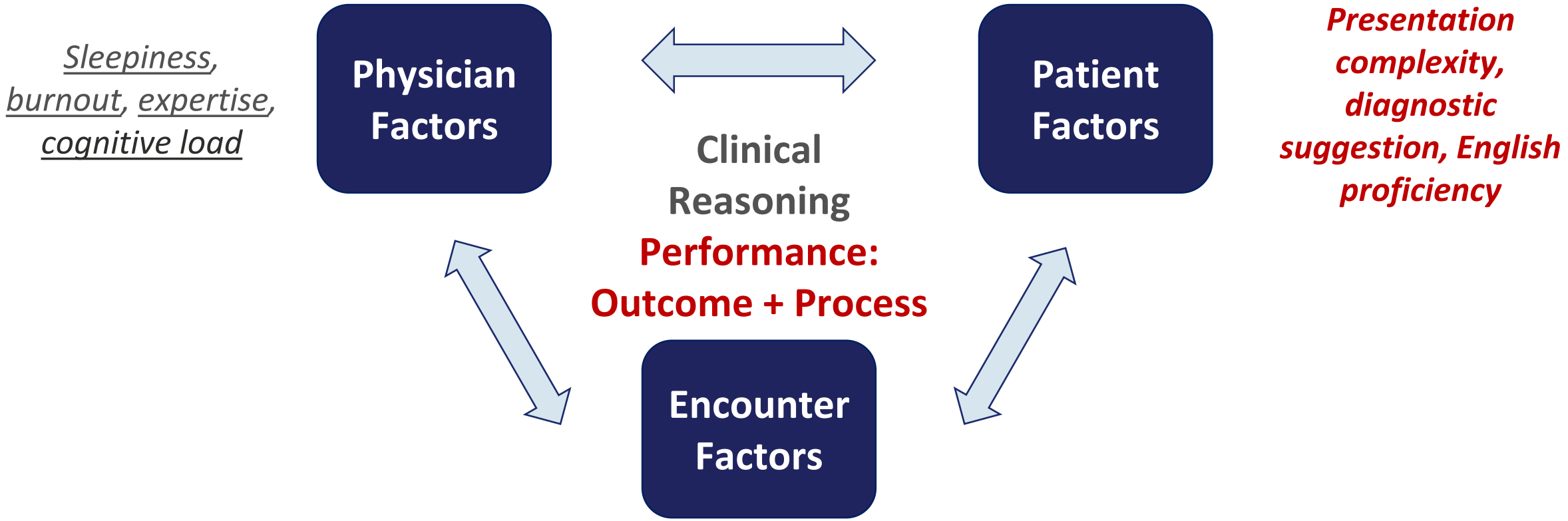
Context Specificity



A Situated Cognition Approach



Contextual Factors & Clinical Reasoning



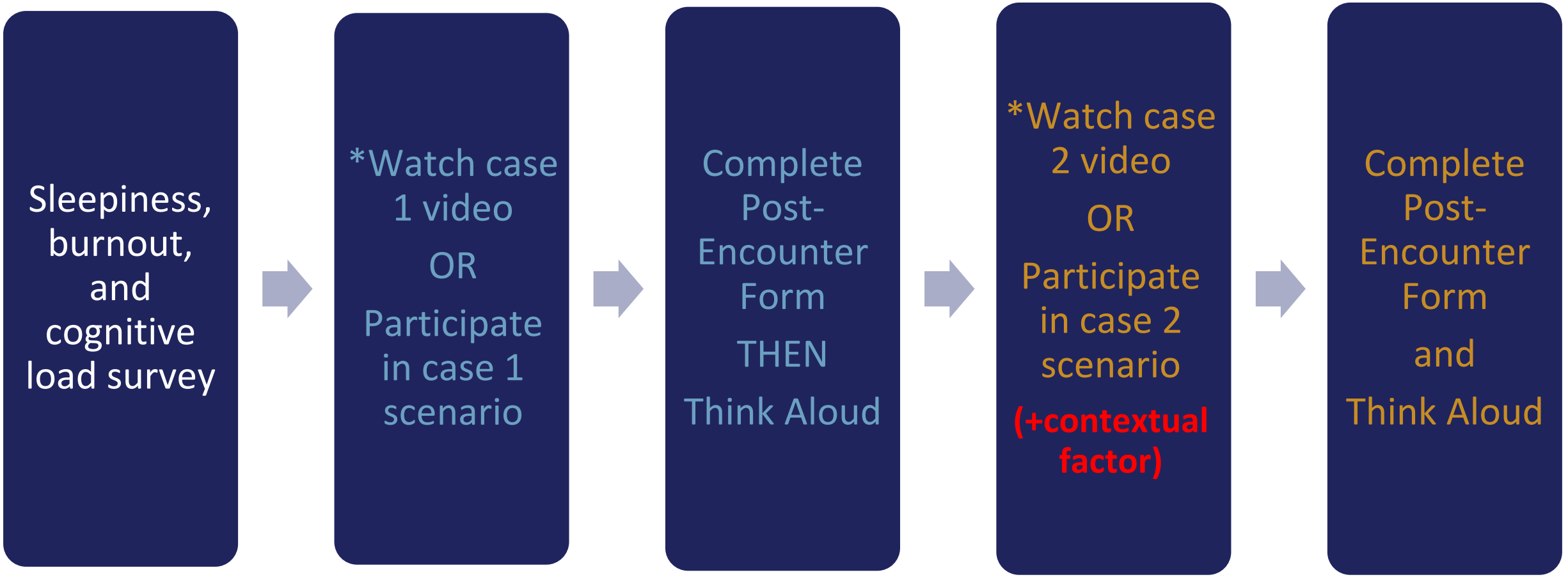
METHODS

Participant Details

29 participants in internal medicine, family medicine, and surgery

	Mean (SD)	Range
Age (8 female; 21 male)	36 years (11)	25-66 years
Years in practice	9.2 years (11.4)	1-39 years

Procedure



*Order of these is varied: half of participants have video/scenario with no contextual factors first and half receive it second

Study Design

PARTICIPANTS WERE ASSIGNED TO ONE OF THREE GROUPS:

Group A	Group B	Group C
Video	*Video*	*Live Scenario*
-Angina (-CF)	-Diabetes mellitus (-CF)	Diabetes mellitus (-CF)
-Diabetes mellitus (limited English)	-Angina (presentation complexity)	Angina (diagnostic suggestion)
N = 11	*N = 7*	*N = 11*

Hypotheses & Research Questions

Quantitative Hypotheses (data source: DPEF & mental effort ratings)

- Outcome scores (DPEF) will be **lower** in the presence of contextual factors.
- Mental effort ratings will be **higher** in the presence of contextual factors

Qualitative Research Questions (data source: think-aloud transcripts)

- Are there distinct patterns of language use (i.e., contextual factor mentions, hedgers, subject pronouns) across conditions?

RESULTS

Effect of Contextual Factors

1. **Mention of contextual factors**
    - “But yeah, I feel like this part goes on too long. But it was just because he was so excited that he fixed his medical problem!” (+CF)
2. **Emotional language and doubt**
    - “So this is really bothering her and he seems pretty callous about it” (+CF)
    - “He just says that he takes ‘pills’ for his blood pressure, he doesn't really know what they are, so it’s hard to say if he’s actually taking them.” (+CF)
3. **Comparison to participant’s practice**
    - [The doctor’s late and the patient’s upset] ”I’ve been there” (+CF)

Quantitative Results

	No Contextual Factors M (SD)	Contextual Factors M (SD)	*t*-test (significance)
Additional interview questions (0-10)	5 (2.6)	4.6 (3.2)	.8 (*d* = .14)
Additional exam items (0-10)	4.3 (2.2)	2.8 (2.1)	3.3** (*d* = .7)
Differential diagnosis (0-6)	4.2 (1.3)	4 (1.2)	.4 (*d* = .16)
Problem list (0-2)	1.5 (.3)	1.3 (.3)	2* (*d* = .67)
Leading diagnosis (0-2)	1.8 (.4)	1.4 (.4)	4.9*** (*d* = 1)
Supporting evidence (0-10)	9.4 (2.3)	6.8 (4)	2.7* (*d* = .8)
Mental effort (1-10)	5.7 (1.5)	6.3 (1.5)	-1.8 (*d* = .4)

*$p < .05$, **$p < .01$, ***$p < .001$

Qualitative Results: Saving “Face”

- **Hedging (qualifying statements): Contextual factor vs. diagnostic process**
  - “He brought up acid reflux. And it *seemed like* he was very excited that he had solved his problem and that this wasn’t something scary, and I was *trying to like*… validate this? Because, you know, it *totally possibly could be*, but at this point I was very concerned that it was cardiac.”(+CF)
  - So *I think* the first thing, is *kinda*, he’s talking about pain in the center of his chest.” (-CF)
- **Generic *you/we*: Not enough information**
  - “*You* just don't get the history from her, though, that this was going on that long, so it’s not necessarily consistent with the rest of her story, so it makes me wonder.” (+CF)

CONCLUSION

Conclusions

- Contextual factors significantly affect **performance**. We see this through:
  - Impaired diagnostic performance in presence of CF
  - Language markers (evaluatives, hedgers, generics, CF mention) in presence of CF
- Unique **theoretical** model (situated cognition) and **measures** (e.g., linguistics) to track effect of contextual factors
- Important step towards reducing **diagnostic error**
- Next steps:
  - Testing this hypothesis across full data set (~60 participants)
  - Exploring patterns in **heart rate variability** across conditions
  - Designing and testing an **intervention** based on results

Thank you!

- Feel free to contact me with thoughts and questions!
  - abigail.konopasky.ctr@usuhs.edu

BACKUP SLIDES

Data Sources

Quantitative

Diagnostic Post-Encounter Form (DPEF)

- Open-ended 6-item form asking about diagnosis & treatment

Mental Effort Score

- Single-item rating of mental effort on scale of 1-10

Qualitative

Think-Aloud Interview

- Rewatch video of case or rewatch self in scenario
- Asked to “think aloud” as to how reached diagnosis
- Minimal to no cuing from researcher

Live Scenario – Inpatient Trauma[1]

Summary:
This scenario is set in the inpatient setting where Mr. Carl Fisher, a 50-year-old male, was admitted the previous evening (around 0500) with a diagnosis of cellulitis. Today (time of the study) Mr. Fisher has tripped and fallen on the sink (right chest) in his bathroom which causes a rib fracture and subsequent pneumothorax. The fall was not witnessed, but he told the nurse that he got tangled up in the wires and feet of his IV pole and fell. After his fall, the nurse responded, helped him settle back to bed, asked the technician to check his vitals and called the physician to come check him out. At the beginning Mr. Fischer isn't in significant distress; however, as the scenario progresses the pneumothorax will progress to a tension pneumothorax that requires treatment with needle decompression or placement of a chest tube. Study participants are also expected to eventually call for a rapid response.

Leading Diagnosis	Differential Diagnoses	Contextual Factors
❖ Pneumothorax → Tension Pneumothorax	❖ Rib Fracture ❖ Hemothorax ❖ Pulmonary Contusion ❖ Pulmonary Embolism ❖ Syncope related to cardiac arrhythmia (e.g., a fib, Vtach) ❖ Hypovolemia (e.g., dehydration, sepsis) ❖ Anaphylaxis ❖ Stroke/CVA ❖ Pneumothorax ❖ Cardiac Contusion ❖ Splenic or liver laceration/hematoma	❖ *Limited knowledge of the patient* ❖ *Emotional volatility due to increasing hypoxia* ❖ *Increasing acuity of presentation* ❖ *Team-based clinical reasoning*

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<table>
<tr><th colspan="4">Scenario Storyboard</th></tr>
<tr><td>Scenario Start
 
0-3 min</td><td colspan="3">After the participant receives their instructions and expectations for participants and indicates they have no further questions (see participant hand off script below) they will receive a phone call (using a study team designated phone) from the participant portraying the patient’s primary nurse.
Opening Statement [Ideally read verbatim for continuity by SP Primary Nurse]:

“Hi, this is [name of nurse] up on 4 Center. I’m calling about Mr. Fisher – he was just admitted from the ED about 30 minutes ago with cellulitis. We got his antibiotics hung and he got up to go to the bathroom and fell. He says he got tangled up in his IV pole. He’s alert and oriented, denies any loss of consciousness and says he didn’t hit his head...but he’s got some pain on his chest where he hit the sink.”

His vital signs are:

Pulse: 98
BP: 130/80
Respirations: 18
SP02: 98% RA
Pain: 7/10 at the injury site
The study participant can ask further questions of the primary nurse, such as how is he doing now? What are his vital signs? Can you get a 12 lead so I can see it when I get there? If the participant asks for a 12 Lead let the participant know you will work on getting one. <u>See details for Primary Nurse for additional responses.</u>
Following the call - the study coordinator will direct the participant to the patient’s inpatient room.[2]</td></tr>
<tr><th>Time</th><th>Goals and monitor settings</th><th>Patient Responses/Cues</th><th>Potential Participant Actions</th></tr>
</table>

[2] The scenario will run in real time rather than speeding the time lapses up. We reason that by running the scenario in actual time will more accurately allow us to assess the participant's clinical reasoning processes. Speeding time up sets up a situation in which we could skew participant’s reasoning by making time move more quickly than typically experienced in the actual clinical setting. Participants will only have access to those diagnostic findings that they seek and perform. Diagnostic findings will not be volunteered without prompting because this will allow us to assess their reasoning processes, including, what they prioritize early in their assessment, what diagnostic evidence they use to make choices, and the order in which they ask for and use it.

Physician arrival at bedside.  **3-8 min**	Goal: During this segment the patient will compensate to give the participant an opportunity to assess the patient and consider potential differential diagnoses. Vital Signs: *Pulse: 106* *BP: 124/78* *Respirations: 20* *SP02: 97% RA* **For the primary nurse SP – for vital signs checks in this stage of the scenario please take the cuff and SPO2 probe off the patient.	1. Patient is in the patient bed with staff having already obtained a set of vital signs at the participants' arrival. 2. In pain, cooperative, appears uncomfortable – braces *(holds area with arm or hand type gesture*) his injured side and tries to minimize movement (*stiff - guarded movement*), respiratory effort is mildly elevated and not deep because it's painful to take in a full breath. - Pain without movement is achy and 4/10 -- but "*fears*" the sharper pain that comes with movement. - Pain worsens - sharp - with movement or deep breath (8/10). - Increased pain and tenderness to the right lateral chest with palpation (*SP will guard if palpation attempted*) (8/10).	1. Communication with the patient (introduction, diagnostic questions). 2. Conduct an initial physical exam (focused). 3. Reviews/analyzes initial set of vital signs. 4. May request repeat vital signs. 5. Request and review patient admission documents, diagnoses, prior dx, and medications. 6. May request supplemental Oxygen, 7. May request pain management (e.g., Tylenol, Tylenol with a narcotic PO or medication by IV). 8. May request an ultrasound machine.
Time	**Goals and monitor settings**	**SP Responses/Cues**	**Potential Participant Actions**
Continued assessment,	Goal: During this time	1. Pain may be decreased (5 or 6/10) if analgesia	1. Reviews/analyzes vital signs

patient deteriorates and rising acuity  **8 - 18 min**	frame the patient will start to deteriorate which will further introduce increased acuity and increase patient anxiety. Vitals (trending down to the following): Pulse: 130 BP: 86/60 Respirations: 26 SP02: 91% with supplemental Oxygen. *Decreased breath sounds on the right (injury site). * *For the primary nurse SP – for vital signs checks in this stage of the scenario please leave the cuff and SPO2 probe on the patient.	previously given (e.g., Morphine). 2. Difficulty breathing continues to worsen even with supplemental oxygen. 3. Anxiety continues to the point where the patient occasionally is frustrated with the medical providers, including the study participant. 4. If the participant doesn't recognize the changes in patient affect and vital signs, the SP can elevate their level of frustration with the study participant. 5. Near the end of this stage the patient will start to become somnolent. 6. At the point of somnolence and if no RRT team called yet the SP nurse will cue the participant to call an RRT.	2. Continues communication with the patient. 3. May request supplemental Oxygen (e.g., nasal cannula, ox mask, simple mask, NRB). 4. May request subsequent vital signs checks (at this stage of the scenario the primary nurse will leave the BP cuff on) 5. May request moving crash cart into the room along with continuous 3 - lead ECG monitoring with a monitor 6. May request a stat chest x ray 7. May request an ultrasound machine. 8. May request additional vascular access be started 9. May choose to call rapid response or senior resident. 10. May decide to treat the tension pneumothorax and perform a need decompression or a chest tube.
Time	**Goals and monitor settings**	**Patient Responses/Cues**	**Potential Participant Actions**
Option 1: Participant chooses to support & await RRT	Goal: During this time frame the first of the rapid response teams will arrive	1. In the event the participant does not know how or feel comfortable performing a needle	1. The participant will give handoff report to the arriving RRT team member.

Arrival  **XX - 20 min**	and seek an initial report on the patient's status. The goal will be to allow this reporting to be completed because it represents an opportunity to learn about their understanding of the situation. After report the study team will stop the scenario. Vitals (trending depends on actions): Pulse: 136 BP: 84/60 Respirations: 26 SP02: 90% with supplemental Oxygen.	decompression or placement of a chest tube (even after cueing) the patient's condition will continue to deteriorate. 2. The RRT team will focus on getting report.	
Time	**Goals and monitor settings**	**Patient Responses/Cues**	**Potential Participant Actions**
Option 2 & 3: Needle decompress/Chest tube & await RRT Arrival to Handoff to	Goal: During this time frame if the participant chooses to treat the tension pneumothorax the	1. If they request a chest tube tray or a needle for decompression the primary nurse in the scenario will respond: *"I'm going to call an RRT"* (if	1. The participant needle decompresses or places a chest tube. 2. The participant may request a RRT – the primary nurse will cue this if not called and

End the Scenario  **XX – 20ish min**	patient will begin to improve. Shortly thereafter, the first of the rapid response team members will arrive and seek an initial report. Following report, the study team will end the scenario. Vitals (trending upwards): *Pulse: 120* *BP: 94/70* *Respirations: 22* *SP02: 94% with supplemental Oxygen.*	they don't call one) *"Let me get the crash cart"* (if they call for a chest tube/needle) 2. If the participant decompresses or places a chest tube the patient will experience pain during the procedure but will experience relief after placement.	request to do a decompression/chest tube. 3. May request regular vital signs assessments/updates. 4. The participant will give handoff report to the arriving RRT team member to allow for an opportunity to learn about the participant's understanding of the situation.

Simulated Activity System Questionnaire

Tools and Structured Interventions

Question	Free Text Response
What are the typical physical tools (e.g., stethoscope, ultrasound device, etc.) that are needed or found in this type of scenario?	For the patient room: 1. Inpatient med/surg room (med/surg ward) 2. Inpatient bed (med/surg ward) 3. IV pole x 1 (the one he tripped on) 4. Bedside table 5. Headwall with air/oxygen ports -simulated 6. Clock 7. Fresh linens and 2 gowns for SP 8. BP Cuff/Sp02 probe with automated device that can assess pulse, pulse ox, blood pressure with pre-printed & laminated vital signs ready/stored for easy access. 9. Crash cart with chest tube tray and Needle decompression kits or 14G needles (longer length) [stored outside room in the hallway until called for]. 10. Traumaman on wheeled cart with fresh skin in place 11. PPE equipment (i.e., gloves, sink or alcohol gel, face shield, disposable gowns) 12. IV start kit including tape (modified for us on an SP) 13. IV tubing 14. IV fluids (1 liter bag of NS) 15. Antibiotic piggyback with tubing (Vancomycin) For the simulated patient (Call 1 hour prior to scenario start): 16. Simulated patient wearing a patient gown. 17. Patient ID band 18. Moulage of right chest area - abrasions and redness where he struck the sink. 19. Moulage right chest redness, abrasions and evidence of cellulitis (redness) on left lower leg. 20. Kerlex dressing around L foot as evidence of drained abscess on dorsal aspect of the left foot (no moulage underneath needed). For the primary nurse: 21. iAuris Stethoscope to support simulated differences in lung

	sounds. Will hand to participant during scenario. 22. Patient chart with appropriate admission documentation, labs, orders and nursing treatment. 23. 12 Lead ECG showing sinus tachycardia a. May be requested by participants to be ready at arrival to the patient room or made ready within 3-5 minutes after request by the SP portraying the tech. Other considerations: 24. Chest X Ray a. If requested, the primary nurse will leave to call and return and tell them they will be about 15-20 minutes -- they are currently in the SICU. 25. EFAST Ultrasound a. If requested, indicate to the participant that someone has gone to get the device. b. Ultrasound won't become available during the scenario. 26. Other Radiology Studies a. If requested, the primary nurse will ask them to put the order in CHCS -- "your going to have to put the order in CHCS" b. If the primary nurse needs to call down to radiology they can share that they've got a patient in the scanner right now or something to this effect. 27. Laboratory Studies a. If requested, the primary nurse or tech will simulate drawing blood and state they will send to the lab. b. When RRT team arrives they may bring an iStat with them; however, we will terminate the scenario after the participant gives the RRT nurse report. 28. ABG a. If requested, the tech can say they will call respiratory. b. If we make this available we will need to develop some pre-staged ABG readings at predetermined time markers (Time 0, 5 min, 10 min, 15 min,20 min)
What props would further support the clinical situation?	1. For needle decompression/chest tube insertion we will utilize a hybrid strategy using Trauma Man with skins for needle decompression or chest tube insertion.
What personal patient	1. Gloves

safety equipment should be available for the scenario?	2. Alcohol gel 3. Gowns 4. Face shield
What are the diagnostic findings that would be needed to support participants as they make or confirm a diagnosis in this scenario?	1. Narrative and injury that is plausible enough to cause a tension pneumothorax (see storyboard) 2. Simulated patient portraying an increasingly anxious and uncomfortable patient using verbal and gestural cues. 3. Vital signs showing a trending decline in blood pressure, rising heart rate, declining oxygen saturation and diminished breath sounds on the affected side. (See storyboard for trends) 4. Chest X Ray images showing rib fracture and pneumothorax. 5. Admission documents and labs
What diagnostic activities (e.g. auscultation, palpation, etc.) would normally be used in this type of scenario?	1. Visualization 2. Auscultation 3. Palpation 4. Review and interpret consecutive vital signs readings. 5. Request and interpret chest X Ray 6. Request and interpret a 12 Lead 7. Diagnostic questioning 8. Situational management
What types of therapies (fluid challenge, medications, etc.) would typically be offered in this type of scenario?	In place prior to scenario start: 1. Peripheral IV a. IV start kit including tape (modified for us on an SP) b. IV tubing c. IV fluids (1 liter bag of NS) d. Antibiotic piggyback with tubing (Vancomycin) e. Patient ID band Available for use as scenario progresses? 1. Additional peripheral IV a. IV start kit b. IV tubing c. IV fluids (type of fluid prefered?) 2. Needles or needle decompression kits 3. Chest Tube Kits 4. Chest Tubes 5. Pain management medication options. 6. Pleur Evac (only need 1 - can be reused)

Roles and Rules

Question	Free Text Response

What rules would normally guide or govern care or behavior in this scenario?
 	
<u>Rules</u> –are conventions or guidelines that regulate activities. For example, is there a standard that governs how all patients who present with trauma are assessed or treated? Are there standard order sets that govern care?
	Assessment and Practice Guidelines:
	1. WRNNMC assumptions of practice for medicine and surgical,
	  1. Interns
	  2. Residents
	  3. Attendings
	2. ACLS Guidelines
	3. ATLS Guidelines
	4. WRNNMC guidelines for assigning patients to surgical and medical teams for inpatient coverage.
	5. WRNNMC RRT Guidelines
	6. Simulation scenario guidelines
	  1. Run in real time (except the time frame from call to arrival at patient door due to close proximity & potential need to send RRT team sooner).
	  2. Participants will be advised to perform the actions they feel are necessary. The SP nurse can remind them if they only use words.
	  3. We will ask participants to work within their own limitations and capabilities.
	  4. Rather than allowing the patient to fully decline, we will speed up the RRT team for those who are not comfortable with needle decompression or chest tube placement.

Who is typically present during a scenario such as this, and what role do they play during the event? Please give a brief description of what the role entails. Please include all roles typically present. <u>Roles</u> – are the division of labor. For example, so you may have a physician stationed at the head of the bed whose role is airway. The person present is the physician and their role is airway management.	1. Standard participant to portray the patient. 2. Standard participant to portray the patient's primary nurse. 1. Assist the participant in caring for the patient and to help with unfamiliar material or issues that may arise during the scenario so the scenario narrative can continue to advance.

	3. Standard participant to portray a backup\ nurse or technician role 1. Assist with information gathering outside the room, bringing the patient chart, requesting additional resources (e.g., radiology) and helping set up for a needle decompression/chest tube placement (which uses a hybrid simulation strategy). 4. One individual to portray the attending or senior resident for participants to call and request help from. 5. One individual to portray the RRT ICU nurse (RRT team member arrival is often staggered as people arrive from different locations in the hospital) member - first to arrive to receive handoff. (Cameo role).

Simulated Participant (Patient)

Domain: Inpatient ward

Diagnosis: Pneumothorax →Tension Pneumothorax

Name: Carl Fisher

Gender: Male

Age: 50

Unique Findings/Characteristics: None

Compatible Characteristics: N/A

Setting: inpatient ward (admitted to 4 Center around 0500 the morning of the scenario)

Preadmission Backstory:
Presented to the ER last night with foot pain, erythema, and swelling for the past 5 days. Also reported fevers for the past 3 days. He may have scraped or injured the area while working in the yard, but is not sure. He has been having a lot of pain in his foot especially while walking and wearing shoes, he has been limping and stayed home from work yesterday (the day of ED presentation). Reports fevers at home up to 100.6 for the past 3 days and some chills. Mostly healthy, has a history of diabetes and hypertension. Normally exercises regularly, but has not since this foot pain started.

In the ER, I&D (incision and drainage) of the abscess was performed late last night. The wound was packed with gauze and wrapped in a bandage with your sock placed over it. You were given Tylenol in the ER for pain and fever.

General Appearance: At the outset the patient is sitting on the bed, in his patient gown, not yet wearing specific fall prevention socks (having only just arrived on the floor. He initially appears as if he is protecting his chest where he hit the sink because movement, palpation and deep breaths make the pain much worse. He's also just generally frustrated and tired after being sick for the last 5 days, 3 of them with a fever that didn't resolve and eventually led him to seek care in the ED. He didn't expect to need to be admitted.

Clothing/Gown: in a patient gown with SP belongings in a patient belongings bag either sitting on the chair in the room or hanging on the backdoor.

Moulage:

- Evidence of redness on his right lower chest where he struck the sink– mostly red with some purple present – this may vary some depending on the SP's skin tone. Slight abrasions also present.
- Redness related to cellulitis in the lower left leg and dressing (Kerlex wrapped around foot and taped in place) over a drained abscess on dorsum of foot (near space between the toes) – no moulage under the wound dressing.

Chief Complaint: Shortness of breath, chest pain with inspiration and movement that is worsening following trip and fall when exiting the bathroom. No loss of consciousness reported and did not hit his head.

Opening Statement: See opening stem on page 1.

History of Present Illness: See opening stem on page 1.

Affect and Behavioral Expectations: He's generally frustrated and tired after being sick for the last 5 days, 3 of them with a fever that didn't resolve and eventually led him to seek care in the ED. He didn't expect to need to be admitted.

As scenario progresses [about 5 minutes after the physician enters the room] his fatigue and frustration begin to make way to his feeling increasingly concerned and anxiousness as the tension pneumothorax develops. Towards minute 12 Mrs. Fischer is really struggling to breath and feels like no matter how hard he tries he can't get a good breath and likens it to feeling like he's breathing through a straw.

In the final phase of the scenario (starting around minute 15) the patient will begin to become less anxious and is "running out of steam." He's hypoxic (low oxygen and rising C02) at this stage, may feel a little dizzy and his verbal responses are slowed and not clear to others in the room. Participants may do a number of things at this stage, including:

- Focus on stabilizing him with oxygen and start another IV while awaiting help from the rapid response team. In this case the study team will not allow the scenario to run long enough to where the patient could develop cardiac arrest.
- Perform a needle decompression where we will ask the physician participants to do the procedure on a model but encourage to interact with the SP patient (hybrid). Should participants do this you will feel better very quickly as you "catch your breath" though you still have a lot of pain where you struck the sink.
- Place a chest tube where we will ask the physician participants to do the procedure on a model but encourage to interact with the SP patient (hybrid). Should participants do this you will feel better very quickly as you "catch your breath" though you still have a lot of pain where you struck the sink.

Onset of complaint: Approximately 5 - 10 minutes prior to the nurse calling the physician to assess the patient.

Location of Pain: Pain is on the right side of the chest where the patient struck the sink.

Character/Quality of Pain/Complaint: Feels sharp, especially when breathing in. Cannot raise his hands above his head.

Severity/Pain Scale:

- 7/10 (currently) sharp pain when he tries to take a deep breath or moves *(gesture should include shorter breaths - inspirations)*
- If the patient is able to sit still and minimize movement the pain is an achy 3/10 but he fears moving (gestures will include guarding this area and wince with any effort to palpate.
- The pain decreases some to 5/10 with pain management medication if given IV - if given by mouth pain will remain unchanged because it won't have time to take effect during the scenario time.

Frequency of Pain: Constant aching pain since the fall that gets much worse with breathing or movement because he fracture a couple of ribs (6/7/8 - lower ribs) when he hit the sink.

Aggravating Factors: worsens significantly with inspiration and exaggerated arm movement or movement in general. When the SP moves he should do so in a "guarded" manner (gestural cue) – bracing or holding (gestural cue) his chest where he struck the sink. If the physician tries to examine his chest the SP should be guarded as they pull back the gown and guard the site if the physician tries to palpate the injured area. Laying down makes it harder to breath and as the tension pneumothorax gets worse the SP should be resistant to lying back.

Alleviating Factors: Initially felt better by bracing with a pillow or his arm. The SP should brace and be protective of the right side which will help make the ribs more stable and move less, thus lessening the pain.

Associated Symptoms: Shortness of breath – initially at the scenario outset that he's feels pain where he struck his chest on the sink - but this eventually worsens to his feeling like it's getting harder to breathe.

Similar Episodes: No

Admission Medications:

- Vancomycin 1500 mg q6hr - first dose given 30 min prior to scenario start

Pre-Admission Medications:

- HCTZ 25 mg every morning once per day)
- Prilosec 20 mg every morning once per day)
- Metformin 500 mg in the morning and evening twice daily

Past Medical History: Diabetes (5 years), HTN (8 years), GERD

Surgical History: No prior surgical history.

Social History (Shx):

Occupation: Chaplain
Religion: Episcopal
Education: B.A. History, M. Divinity
Length of Military Service: [Need]

Habits:

Alcohol: 2-4 drinks per week (combination of wine or Scotch on occasion), CAGE = 0/4
Tobacco: 1/2 pack per day x 5 years but quit 25 years ago
Drug use: Denies
Sexual History: Not currently sexually active

Family History:

Father died of PE age 55 after gallbladder surgery
Mother died of Breast cancer age 75
No siblings
Widowed
3 children (aged 24, 22, 18) alive, all well

Physical Exam Results:

- **Central nervous System**: Alert, oriented, denies loss of consciousness, denies striking his head, anxious at the beginning - becomes increasingly anxious and frustrated.
- **Cardiovascular:** Tachycardia, regular rhythm
- **Pulmonary**: Tachypneic, Breath sounds on right chest diminished
- **Gastrointestinal**: some general diffuse abdominal pain 3/10
- **Musculoskeletal**: Pain @ injury site of right lateral thorax
- **Integumentary**: Intact, redness (recent bruising minor abrasions) noted at injury site of right thorax and right elbow/hand from the fall. Also, redness related to cellulitis in the lower left leg and dressing over a drained abscess on dorsum of left foot (near space between the toes).
- **Psychological**: Anxious and agitated due to worsening difficulty breathing and hypoxemia.

Simulated Participant (Primary Nurse)

Domain:
Inpatient medical or surgical ward

Gender:
Male or female

Age:
Can vary

Goals of this Character:
The primary nurse role serves to support the scenario by performing requests from the physician participant, answer questions from the physician participant regarding the patient in the scenario, and to help prompt the participant in drawing out certain types of information to help the study team in gaining a better understanding of the study participant's perceptions while the scenario is still active. The primary nurse places the initial phone call to the physician participant, enters the patient room with the participant, and is present in the room throughout the scenario. The primary nurse is helpful and may perform some tasks, such as administering oxygen, without being asked. The primary nurse may also draw attention to information that may indicate the correct diagnosis, such as noting that he or she could not hear breath sounds on the right side in the event the iAurus stethoscope malfunctions or if the participant struggles for and extended period of time.

For the purpose of this scenario and the JPC simulation study, the lines are scripted for uniformity among participants, but may be adjusted to each situation. Ideally, this role is portrayed by a carefully trained standardized participant or a study team member for consistency.

General Appearance & Clothing:
Active duty nurses on med/surg floors normally wear their respective camouflage uniform (sometimes with a matching scrub top instead of the normal blouse). Civilian nurses wear either personal scrubs or hospital scrubs.

Goals of the Primary Nurse:
Give participant background information about the patient. Cue the participant as needed in assessing the situation, performing interventions, and calling for help.

Relevant Clinical Background:
Holds a BSN. Has worked as a Med-Surg nurse for 3 years.

Opening Statement:
"Hi, this is [name of nurse] up on 4 Center.

"I'm calling about Mr. Fisher – he was just admitted from the ED about 30 minutes ago with cellulitis. We got his antibiotics hung and he got up to go to the bathroom and fell. He says he got tangled up in his IV pole. He's alert and oriented, denies any loss of consciousness and says he didn't hit his head...but he's got a lot of pain on his chest where he hit the sink."

Other Potential Opening Scene Statements:
"I just helped him get back into bed but he's in a lot of pain."

"I haven't had a chance to get them (vitals)*...He just came up from the ED."*

"I was just getting ready to go in and do my assessment on him when he fell."

"He was just admitted from the ED with cellulitis of the left lower leg and foot."

"I don't have one (an EKG) *and...it looks like they didn't do one in the ED. Do you want one?"*

Rapid Response Team Nurse - 1st to arrive

Domain:
Inpatient medical or surgical ward

Gender:
Male or female

Age:
Can vary

Primary Purpose:
The rapid response team nurse role serves to support the scenario by engaging the participant about what has transpired leading up to their arrival. The rapid response nurse arrives as the scenario time is up, at approximately minute 13-15 and will seek to gather certain key information from the participant and then end the scenario. This participant is helpful.

For the purpose of this scenario and the JPC simulation study, the lines are carefully scripted to deliberately draw out certain types of information to help the study team in gain a better understanding of the study participant's perceptions while the scenario is still active. For example, the participant in this role will ask about what has transpired, what the participant thinks the patient's problem is, and what is their reasoning for treatment thus far. Ideally this role is portrayed by a carefully trained standardized participant or a study team member for consistency.

Clothing:
Scrubs or related hospital attire

Opening Statement:
"Hi, I'm (insert your name) from the ICU. Someone called a rapid response for this patient? What's going on?"

Other Key Statements or Actions:
"What have you done for him so far?"

"What do you think is going on with him?"

"What are you thinking in terms of next steps?"

"Okay, sounds good. I can call the ICU to see about getting a bed assignment"

To End the Scenario:

"Okay, thanks. We're going to end the scenario here."

Clinical Reasoning in the Primary Care Setting: Two Scenario-Based Simulations for Residents and Attendings

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Structured Abstract

Introduction: This resource describes the development and implementation of resources medical educators or researchers can use for developing or analyzing resident through attending physicians' clinical reasoning in an outpatient clinic setting. The resource includes: a) two scenario-based simulations (i.e., diabetes, angina), implementation support materials, an open-ended post-encounter form, and a think-aloud reflection protocol.

Method: We designed two scenarios with potential case ambiguity and contextual factors to add complexity for studying clinical reasoning. They are designed to be used prior to an open-ended written exercise and a think-aloud reflection to elicit reasoning and reflection. We report on their use in a research context but developed them to be used in both educational and research settings.

Results: Twelve physicians (5 interns, 3 residents, and 4 attendings) considered between three and six differential diagnoses for the diabetes scenario (*m* = 4.0) and between three and nine (*m* = 4.3) differentials for angina. In think-aloud reflections, participants reconsidered their thinking between zero and 14 times (*m* = 3.5) for diabetes and zero and 11 (*m* = 3.3) times for angina. Cognitive load scores ranged from four to eight (out of ten; *m* = 6.2) for diabetes and five to eight (*m* = 6.6) for angina. Participants rated scenario authenticity between four and five (out of five).

Discussion: The potential case content ambiguity along with the contextual factors (e.g., patient suggesting alternative diagnoses) provide a complex environment in which to explore or teach clinical reasoning.

Educational Objectives:

As a result of participating in these scenarios, participants will:

1. Practice gathering and analyzing information and evidence and interpretation of that evidence to formulate differential diagnoses, and forming a problem list and a leading diagnosis with supporting evidence.
2. Practice planning and performing a focused physical exam to further support clinical reasoning.
3. Practice developing and communicating a management plan.
4. Reflect on their own clinical reasoning efforts and strategies by thinking aloud and observing their own video-recorded simulation.

Introduction and Background

Clinical reasoning includes the gathering and synthesizing of information, interpreting data (e.g., patient's responses to diagnostic questions, lab or radiologic findings), generating and refining hypotheses, and problem representation or the use of illness scripts[1-5]. Clinical reasoning is vital to making an accurate diagnosis, eliciting appropriate management and the development of efficient therapeutic plans[1,6,7]. Research examining clinical reasoning suggests it is a complex activity that relies on several factors, including the physician's cognitive processes, knowledge derived from formal and informal experiences, and prior practice experiences (e.g., prior exposure to similar patients)[5,7].

Efforts to assess clinical reasoning use a variety of strategies: among some of the most common are: multiple choice questions[8], case-based learning[9], the integration of think-aloud reflections with video-based scenarios[10] or virtual patient scenarios[11]. In many of these examples, participants are asked to imagine themselves as the hypothetical participant rather than engaging in their own clinical encounter. Live scenario-based simulations are also reported, however, less frequently[12-14]. Moreover, save one example, [Burbach[15]], none of these scenario-based approaches are paired with a free-text, open-ended approach to assessment and reflection, which can offer deeper understanding of the *process* of reasoning[16,17].

In addition, most of these efforts to support clinical reasoning are designed to support individuals still in their undergraduate training rather than health care professionals' learning and development *throughout* their career, something recommended by the recent National Academies of Science report on improving diagnostic efforts[6].

We aimed to create scenarios where we could examine how physicians with a range of experience levels organized their interview, physical exam, diagnostic ideas, and management choices when engaging with a single patient (portrayed by a standardized patient [SP]). We considered that scenario-based simulations, which use a narrative to guide participants' engagement as they address a problem that needs to be explored or resolved[18], would encourage physician performance that would be similar to the actual clinical setting while allowing us to control for the known leading and differential diagnoses. We also considered that these scenarios would provide physician participants with the opportunity to engage in many of the component activities associated with clinical reasoning (e.g., information gathering, interpretation of diagnostic information, hypothesis generation, management plans).

Several authors argue that scenario-based simulations like these are ideal for exploring the complexity of clinical practice, such as clinical reasoning[3,19,20]. For example, Elstein and colleagues describe how they utilized scenario-based simulations to conduct an in-depth descriptive analysis of physicians' behaviors while engaging a SP[3]. Furthermore, Dieckmann and colleagues argue that scenario-based simulations are complex social endeavors that support interactions among health professionals (e.g., medical doctors), simulated participants (e.g., SP) and other culturally relevant devices, such as diagnostic equipment[19]. Kneebone and colleagues suggest simulations present participants with contexts that support the development of skills and knowledge within a context that represents many of the elements of professional clinical practice[20]. And the findings of a more recent descriptive analysis of scenario-based simulations suggests that they provide participants with an opportunity to *make sense* of a clinical situation because they support activities such as information gathering (e.g., diagnostic questioning, interpreting diagnostic findings) as well as carrying out patient management activities[21].

The purpose of this article is to describe the development, testing, design improvements, and implementation of two *live* scenario-based simulations (i.e., new onset diabetes, coronary artery disease presenting with angina), together with an open-ended written exercise and a think-aloud reflection protocol. Here we report on a single study of their use in a research context but we developed them to be used in both educational and research settings. This suite of resources can be used to support researching or teaching resident *and* attending physicians' clinical reasoning in an outpatient clinic setting.

Audience and Contribution

This resource was designed to assess the clinical reasoning of physicians with a range of experience and ability (i.e., residents to attendings). This article describes the strategies we used to develop and test scenarios with the expressed intent of integrating diagnostic ambiguity (where a series of signs and symptoms could be attributed to more than one diagnosis)[14] and contextual factors (referring to factors that may interact, such as patient, physician, and setting factors)[10,22] as ways to increase scenario complexity. Furthermore, pairing the scenarios with two different reflective tools (the free-text clinical questions[23] and open-ended think-aloud reflection[16,17]) allows for a range of reflective experiences through which researchers, instructors, and learners can explore clinical reasoning.

This resource adds to the growing body of resources in MedEd Portal supporting the development of clinical reasoning and similar concepts (i.e., diagnostic reasoning, diagnostic decision making). For example, several current resources focus on teaching medical students explicit strategies to develop their clinical reasoning skills[24-28]. This suite of resources adds scenarios and a reflection protocols that are explicitly designed to support more experienced physicians by way of designing in increased complexity. Additionally, many of the resources currently available emphasize teaching strategies such as classroom-based case discussions[24] , case-vignettes supported by illness script worksheets[28] or case presentations of patients seen during a family medicine clerkship[25], to name a few. Others focus on strategies faculty or peers can use to assess clinical reasoning in the clinical setting[29]. Among simulation-based or SP-based scenarios, few focus explicitly on supporting everyday clinical decision making, rather, they frame clinical reasoning as an activity that supports diagnosing rarely occurring or high-risk/low frequency diagnoses[30,31]. Also, while other live scenario simulations offered in Med Ed Portal address either diabetes or angina[32-34], none offer a pairing of different cases, allowing learners to discuss the challenges brought about by the specifics of case content.
Lastly, this resource builds upon prior work in Med Ed Portal two ways: first, these scenarios take clinical reasoning skills out of the classroom or small group context and offer individual-level practice opportunities. Second, the think aloud protocol could be independently integrated with existing simulation or SP scenarios in addition to or in lieu of post-simulation debriefing. These cases and related tools offer much needed instructional material for the outpatient primary care setting (as opposed to, for instance, the emergency setting[34].

Method

This section reports on the participatory design procedures and instructional features used to develop the scenarios; the measures and reflection tools used; the procedures and logistics for scenario implementation; and the casting and training of SPs.

Participatory Design Procedures

Participatory instructional design is an approach to design that encourages the inclusion and integration of the perspectives of diverse stakeholders[35]. This approach allowed us to develop scenarios: that could be reliably implemented by the simulation lab, that represented common patient conditions, and that would support analysis of language and behavioral patterns. The scenario was developed in three phases: initial design, pilot testing, and an implementation evaluation with physician participants.

Initial design: This stage began by determining scenario goals and identifying stakeholders who could help develop scenarios to support the practice behaviors of physicians with diverse levels of expertise. Clinical stakeholders included resident and attending physicians practicing family medicine, internal medicine, and surgery. Among these individuals, most regularly taught or evaluated less experienced physicians and provided insight into common errors and practice behaviors. Simulation stakeholders included SP trainers, SPs, and operational specialists. Our stated goals were to:

a) adapt two video-based scenarios representing common patient presentations in primary care (i.e., diabetes, angina) to the live scenario-based context,

b) ensure that both adapted scenarios contained diagnostic ambiguity, which we argued would provide participants with an opportunity to consider more than a single diagnosis, and
c) embed contextual factors into one scenario to allow for more complex clinical reasoning and an opportunity to compare participant performance across these two cases.

We conducted design meetings with small groups of stakeholders to develop the scenario-based simulations (we refer the reader to the literature on Activity Theory for more information on our theoretical framework[21,36,37]). We adapted an existing context questionnaire[36] to determine what participants' *goals* or working hypotheses may be, what clinical *tools* and diagnostic *artifacts* they may request or rely upon, what clinical *guidelines* may influence their practice behaviors, and the *roles* and anticipated *activities* of other actors who may normally be present (e.g., patient care tech). In this way we developed: the simulation session workflow (Appendix A), participant expectations and instructions (Appendix B), door information (Appendices D for diabetes, I for angina), standardized patient cases (final cases in Appendices E for diabetes, J for angina) and scenario storyboards (final storyboards in Appendices G for diabetes, L for angina).

Preliminary testing: Following the initial design phase, we conducted a read-through followed by a rehearsal of each scenario. After read-throughs and discussions with two physicians, two cast SPs, and the SP educator, we further revised pertinent medical history and social and family history and identified a series of scripted key statements for each patient case (Appendices E for diabetes, J for angina). The revision history of each design change was preserved through Google documents.

Implementation evaluation: In this phase we examined scenario implementation of 12 physician participants who completed both scenarios, examining whether our design strategies resulted in physicians considering more than a single diagnosis, allowed participants to gather enough information to develop a management plan, and provided adequate complexity for interns, residents, and attendings. We conducted a content analysis of the post encounter forms (PEFs): free text questions about leading and differential diagnoses, problem list, and management decisions (Appendix N)[23]. We also analyzed the think-aloud transcriptions for the presence of reflection (in particular, reconsidering prior stances and indicating uncertainty) to better understand the broad quality of clinical reasoning. Finally, we asked participants to rate their perceptions of scenario authenticity after they completed the second think aloud-protocol (see Appendix A for workflow and Appendix R for authenticity item).

Instructional Design Features Used to Develop this Resource

We drew from Tschan and colleagues' strategy of creating scenarios that introduced an ambiguous diagnostic situation, which they define as a series of symptoms and findings which could suggest more than one diagnosis (of note, each scenario was written as a straightforward presentation of the correct diagnosis being portrayed, validated by a group of expert physicians)[14]. For example, they designed scenarios where the SP's signs and symptoms could have plausibly been attributed to anaphylaxis or tension pneumothorax, but also included information in the scenario to allow a physician participant to rule out the incorrect diagnosis[14]. We achieved this in our scenarios by incorporating a history of present illness, past medical history, and social and family history into the case where the SP presented with symptoms of the leading diagnosis (i.e., diabetes or angina) but where some of the signs and symptoms *could* also be consistent with other conditions (e.g., urinary tract infection, indigestion). We hypothesized that this diagnostic ambiguity would generate relatively complex and authentic scenarios that could be used to support the learning of physicians across their careers[6].

For one scenario (i.e., angina), in addition to diagnostic ambiguity, we introduced a contextual factor (diagnostic suggestion) to further increase complexity. Recent literature suggests that contextual factors like this may influence clinical reasoning performance, in novice and expert clinicians alike, potentially introducing significant unwanted variance (error) in patient care[10]. When contextual factors are introduced, a physician may see two patients with the same history, symptoms, and findings and yet come to two *different* diagnostic decisions[10]. We believed that the combination of ambiguity and a contextual factor in one of the cases would both be authentic and offer an opportunity to compare the two cases for relative complexity and challenge.

Selected Measures and Reflection Tools

The scenario development process described above was accompanied by a thoughtful selection of measures and reflection tools and included: an open-ended PEF eliciting clinical reasoning; a think-aloud protocol for reflection on reasoning; and a cognitive load question to check for appropriate difficulty across participants. We describe each below.

Post encounter form: To examine the clinical reasoning *process* (i.e., the steps to the diagnosis and management decisions), we used a previously published PEF that has been argued to be reliable and valid for assessing clinical reasoning (see Appendix P)[23]. This measure asks for leading and differential diagnoses, additional interview questions or exam actions participants would like to take, a problem list, supporting data for the leading diagnosis, and a management plan. We considered that this detailed open-ended measure would give us a good understanding of the process participants go through in coming to a diagnosis and treatment plan.

Think-aloud reflection: Asking someone to "think aloud" about a task, either concurrently or retrospectively, can provide insight into cognition and experience (see Appendix C for think-aloud warm-up and instructions)[16,17]. Moreover, thinking aloud has been used to great benefit in live simulation, offering a better understanding of reasoning and actions throughout the simulation[15]. Unlike some other forms of reflection (e.g., debriefing), thinking aloud involves little to no feedback during the exercise[15-17,38]. Instead, while watching the video of their own performance, participants are encouraged to provide almost a stream of consciousness reflection on their thoughts at the time of the scenario. The think-aloud literature advises the use of only minimal verbal prompting, such as "keep talking," "uh-huh," or "think aloud" if the participant pauses for more than 15-60 seconds[16,17,38]. This retrospective thinking aloud not only reveals reasoning patterns, but offers an opportunity for participants to strengthen their learning through this reflection[15].

Cognitive load: We also examined participants' cognitive load related to completing the post-encounter form using a single question provided on a separate from adapted from Brunken and colleagues[39]. We assessed participants' perceptions of their cognitive load after they completed each PEF (see Appendix A for workflow) asking participants to "please rate your invested mental effort after completing the post-encounter form" on a scale ranging from one (very low mental effort) to ten (very high mental effort). Due to the range of years of experience of participants, we included this question to check for adequate effort and engagement across participants.

Scenario Procedures and Logistics

Scheduling logistics: For each scheduled date we requested two rooms in the simulation center. The first room was used to allow participants to complete the think-aloud warm up and PEF and to re-watch their own video-recorded performance while thinking aloud. No special setup was required for the first room. The second room mimicked an outpatient clinic setting, including an exam table, a stool, a chair, a sink and a functioning headwall with an otoscope and ophthalmoscope. Participants were also provided with a stethoscope in the event they didn't bring their own. A complete supply list is included in the appendices (Appendices H for diabetes & M for angina).

Staffing requirements: We scheduled two team members, in addition to the designated SPs portraying patient roles, to support each session. The first team member was responsible for greeting each participant, ensuring that they were oriented to the simulation and think-aloud activities and that they completed all the steps of the session. The second team member was responsible for coordinating the SPs and simulation operations (e.g., giving door report, keeping time), managing the video recording and sitting with participants while they engaged in the think aloud (Appendix C). Both team members were trained to conduct the think-aloud protocol and were research associates, rather than a physician team member.

Video recording and video playback during think-alouds: To support the replaying of participant videos during their think alouds, we video recorded each scenario using two video cameras fitted with removable SD cards. In this way, one camera could act as a backup in case the primary camera failed.

Think-alouds: Following each scenario, while the participant was completing the PEF, a study team member removed the data card from the camera and inserted it into a designated computer for replaying. This same team member then read the instructions and sat with the participant during the think aloud process. During the think-aloud, the study team member was instructed to not ask questions and to limit verbal interactions to comments such as "uh huh" or "hmm" to minimize disruptions. In the event participants stopped thinking aloud for more than 15-60 seconds, the study team member gently nudged the participant by saying, "think aloud." Appendix C contains detailed warm-up and implementation instructions.

Participant procedures: On the scheduled scenario day, physician participants were oriented to the simulation rooms and the workflow of the day (Appendices A & B). They were then oriented to the think-aloud procedures they would use following the scenario (Appendix C). Instructions and practice think-aloud exercises were scripted for consistency and were implemented by study team members.

Next a study team member:

1. provided participants with the door information (Appendix D) for the first scenario and advised them to enter when ready,
2. provided participants with up to 15 minutes to complete their initial assessment, physical exam and post-assessment discussion with the SP (there was no penalty for finishing early or being stopped before completion and, depending upon time constraints, some participants were allowed to go a couple of minutes beyond 15), and
3. advised participants that the scenario would run in actual time (i.e., not sped up).

Following the scenario performance, a study team member guided participants to the designated debriefing room to:

4. complete the PEF (Appendix P),
5. complete the cognitive load question (Appendix Q)
6. review the instructions for thinking aloud (Appendix C), and
7. re-watch their own video-recorded performance while thinking aloud (this was audio recorded using a digital audio recorder [Appendix C]).

Following the first scenario, participants followed steps one through seven above for the second scenario. Participants' total time to complete these two scenarios, the related post encounter forms and think alouds, and the other informational questionnaires was approximately two hours.

Optional feedback: Because these scenarios and reflection protocols were initially used to support researching clinical reasoning processes we did not schedule time for immediate feedback. However, we recognized that participation in these scenarios could still be treated as learning experiences. Thus, following participation, we offered to scheduled time for participants to receive feedback from an attending physician on the study. These sessions were scheduled on an ad hoc basis.

Casting, Training and Quality Improvement

SP casting and training: We sought SPs similar to our designed role in age and body habitus (e.g., diabetes actress was moderately overweight). SPs were provided with the patient case (Appendices E for diabetes and J for angina) and then then rehearsed with an SP trainer as needed, drawing from a rehearsal guide (Appendices F for diabetes, K for angina). The use of a rehearsal guide was intended to support implementation fidelity because we occasionally had large breaks in time between study participants. SPs were instructed to provide information if prompted and minimize volunteering.

Quality improvement of SP performance: We developed and conducted a review of all SP portrayals to examine how consistently they implemented their roles (see Appendices N for diabetes and O for angina). This, in turn,

supported ongoing SP training needs and guided decisions about which performances were of high enough quality for analysis. For example, if an SP's performances were inconsistent with the case as written, we posited that clinical reasoning processes could be skewed. After implementation reviews, findings were shared with the SPs to improve future performance. Findings also supported ongoing scenario improvements (e.g., modifying a scripted SP response or gestural cue).

Results

Participants in this sample were 12 internal medicine, family medicine and surgery physicians, six (6) female and six (6) male. Eight (8) were resident physicians (five [5] from post graduate year 1 [PGY 1], three [3] from PGY 3) and four (4) attending. Age and gender of participants are given in Table 1.

Use of Scenario Time

For the diabetes scenario, participants' time ranged from 7:06 to 19:10 minutes (*m* = 14:38 minutes). In the stable angina scenario, participants' scenario time ranged from 11:10 to 17:15 minutes (*m* = 14:19 minutes). Two participants ran out of time and their scenarios were stopped by the study team between 17 and 19 minutes to protect participants' schedules and ensure completion of the PEF and think aloud.

Table 1. Participant Demographics (*N* =12)

Training Level	Age	Gender
Intern (PGY-1)	32	Female
	28	Male
	42	Female
	27	Female
	27	Male
Resident (PGY-3)	30	Female
	29	Male
	29	Female
Attending	55	Male
	60	Male
	38	Female
	49	Male

Differential Diagnoses and Supporting Data Listed by Participants

Diabetes: Participants considered a total of 17 independent differential diagnoses as measured by the PEF (Table 2). The most common differentials included diabetes (n = 12), hypothyroidism (n = 9), diabetes insipidus and urinary tract infection (n = 5 for the latter two). These appeared to differ by PGY: interns considered ten independent differential diagnoses, residents considered five and attendings (those having completed their initial residency) listed 12. The number of differential diagnoses listed by each participant ranged from three to six (m = 4.0). These also differed by PGY status (due to the small size of the sample, neither this nor any of the distinctions below are statistically significant): interns listed between three and six differentials (m = 4.0), residents (PGY -3) listed between three and four differentials (m = 3.3) and attendings listed between three and six differentials (m = 4.25). This range suggests that, despite the straightforwardness of the case in terms of leading diagnosis (all participants correctly listed diabetes as their leading diagnosis), there was adequate ambiguity to create other possibilities.

Content analysis of the PEF revealed that the most common supporting data participants listed included, polydipsia (*n* = 10), polyuria and fatigue (*n* = 9 for the latter two), polyphagia and recurrent yeast infections (*n* = 7 for the latter two), vision changes (*n* = 6) and obesity (*n* = 4). Participants also listed items related to past medical and family history. Among the most common were, hypertension and hypothyroid (*n* = 3) and smoking history and prior parathyroid surgery (*n* = 2). These differed by PGY status: interns listed between four and six items of supporting data (*m* = 4.8), residents listed between five and nine (*m* = 7.33) and attendings listed between four and ten *(m* = 7.5).

Table 2. Most Common Differential Diagnoses Considered for the Diabetes Scenario

Differential Diagnosis	**Frequency of listed differential diagnoses for interns (*n* = 5)**	**Frequency of listed differential diagnoses for residents (*n* = 3)**	**Frequency of listed differential diagnoses for attendings (*n* = 4)**
Type 2 Diabetes	5	3	4
Hypothyroidism	5	2	2
Diabetes Insipidus	1	3	1
Urinary Tract Infection	1	2	2
Hypercalcemia	2		
Psychogenic Polydipsia	1		1
SIADH	2		
Yeast Infection		1	1

Note: Additional diagnoses listed that received a single mention, included: anemia, bladder incontinence, glomuleronephritis, nephrotic syndrome, non-specific endocrine, non-specific autoimmune, MEN, potomania and sleep apnea.

Angina: The most common leading diagnoses were angina (*n* = 5), stable angina (*n* = 4), coronary artery disease (n = 2), and acute coronary syndrome (*n* = 1). We considered unstable angina as the correct leading diagnosis as it was the most specific, but offered near full credit for angina, angina pectoris, and stable angina.

Participants considered a total of 25 independent differential diagnoses (Table 3). The most common differentials included cardiac causes, like, coronary artery disease/acute coronary syndrome/unstable angina/stable angina (*n* = 17), followed by GERD (*n* = 9) musculoskeletal/costochondritis (*n* = 4), pulmonary embolism (*n* = 4), and peptic ulcer disease (*n* = 3). Notably, GERD was the most commonly mentioned diagnostic suggestion by SPs in the scenario. When taking into consideration PGY status, interns listed between three and nine (*m* = 4.4), residents between three and five *(m* = 3.6) and attendings between three and six (*m* = 4.75). These also appeared to differ by PGY status: interns considered 15 independent differential diagnoses, residents 10 and attendings 13.

The most common supporting data participants listed on the PEF included, chest pain (*n* = 12), which seven participants further qualified regarding onset with exertion; shortness of breath/dyspnea (*n* = 10), which six participants further qualified as also occurring with exertion, history of hypertension (*n* = 8); diabetes and smoking (*n* = 7 for the latter two), GERD (*n* = 5) and family history of cardiac disease (*n* = 3). When broken out by PGY status: interns listed between two and eight items of supporting data (*m* = 4.8), as did residents (*m* = 5) and attendings listed between two and 13 (*m* = 6.75).

Table 3. Most Common Angina Differential Diagnoses Considered

Differential Diagnosis	Frequency of listed differential diagnoses for interns (n = 5)	Frequency of listed differential diagnoses for residents (n = 3)	Frequency of listed differential diagnoses for attendings (n = 4)
Cardiac causes, like Coronary Artery Disease, Acute Coronary Syndrome, Angina/Angina Pectoris, Stable Angina, Unstable Angina[1]	8	4	5
GERD	3	2	4
Costochondritis/ Musculoskeletal Pain	2	1	1
Pulmonary Embolism		2	2
Peptic Ulcer Disease	1		2
Congestive Heart Failure	2		

Note: [1]Frequency counts exceed 12 because some participants listed more than one cardiac diagnosis. Additional diagnoses listed that received a single mention, included: anxiety, aortic dissection, arrhythmia, asthma, chronic cholelithiasis, COPD, deep vein thrombosis, enteritis, esophageal motility disorder, gastritis, myocardial infarction, non-cardiac chest pain, pancreatitis, prinzmetals angina and structural heart disease.

Management Considerations

We also examined participant PEFs for reasoning related to patient management.

Diabetes: Each suggested management, treatment, or testing option was individually scored by physician experts as correct, partially correct, or incorrect, resulting in a percentage of correct suggestions for each participant. For the diabetes case, attendings scored slightly better on the management item (*m* = 67.6%) compared to interns and residents (*m* = 56.9% for both). The most frequent lab tests requested included a blood glucose, AIC, thyroid levels/panel (*n* = 5 for each of these), a complete metabolic panel (CMP) (*n* = 4), urinalysis (*n* = 4) and urine culture (*n* = 4), and a CBC (*n* = 3). Other labs participants listed included: a urine glucose, ECG, KOH, an ABG, insulin antibodies, a cholesterol panel, a urine sodium and blood sodium. Three participants indicated they would request labs; however, they did not distinguish any specific tests.

In addition to obtaining labs, nine of twelve participants provided additional management choices that included, a) pharmacological management (e.g., use of antihyperglycemics like Metformin, an insulin trial), b) lifestyle management (e.g., nutrition, exercise) and c) referrals to other specialists (e.g., diabetes nurse educator, ophthalmologist).

Angina: For the angina case, management scores were similar, with the three residents scoring most highly (*m* = 81.9%), followed by interns (*m* = 77.8%) and attendings (*m* = 76.3%). The most frequent diagnostic test requested by participants was obtaining a stress test (*n* = 10) followed by obtaining an ECG (*n* = 9). Two participants considered requesting a chest x ray. Participants also considered obtaining additional laboratory testing, such as a CBC (*n* = 2), a CMP (*n* = 2) and cardiac enzymes (*n* = 2). Other labs mentioned included a lipid profile, A1C, and a urine glucose. Three participants indicated they would request labs; however, they did not provide further detail.

In addition to testing, four participants considered pharmaceutical management, the most common medications being a statin (*n* = 3), nitrates (*n* = 3) and aspirin (*n* = 3). Other medications listed included an ACE inhibitor, beta blockers and adjustments to the patient's current medications (i.e., HCTZ, Lisinopril). Four participants discussed whether to admit the patient or manage him in the outpatient setting and two indicated a cardiac catheterization might be necessary. These participants also prioritized administration of medications and stress testing using qualifiers, including "expedite," "ASAP" and "right away."

Think-Aloud Reflections

To explore participants' reasoning processes, we coded the think-alouds for (a) *reconsiderations*: indications that a participant would have done something differently, either in the scenario itself or the PEF and (b) *tentativeness:* words like *possibly, try, seem*, and *if* that tend to indicate uncertainty (the former were hand coded and the latter were automatically coded by Linguistic Inquiry and Word Count; LIWC)[40]. While detailed qualitative analysis is underway, we believe this initial pass offers some evidence that participants are actively reasoning by rethinking their decisions and hedging their beliefs.

Diabetes: As with PEF analysis above, we noted differences among the groups. Participants reconsidered their actions in the diabetes case between 0 and 14 times (*m* = 3.5). While significance testing was not possible (here or in any of these analyses), we noted that interns (*m* = 6.4) reconsidered actions more than residents (*m* = 2.7) who, in turn, reconsidered more than attendings (*m* = .5). Meanwhile, all participants used tentativeness markers (measured as a percentage out of the total word count), ranging from 4.5% of total words in a case to 10.1%. Interns (*m* = 7.1%) and residents (*m* = 7.5%) were more tentative in their diabetes think-alouds than attendings (*m* = 5.4%). Thus, while most participants reconsidered actions and were tentative in their phrasing to some degree in the diabetes case, attendings reconsidered less and were less tentative.

Angina: Participants reconsidered actions in the angina case between 0 and 11 times (*m* = 3.3). Interns (*m* = 4.8) and residents (*m* = 4.3) reconsidered actions more than attendings (*m* = .5). Tentativeness markers ranged from 4.2% of total words in a case to 8.9%. For the angina case, residents (*m* = 7%) were slightly more tentative than interns (*m* = 5.5%) and attendings (*m* = 5.6%). Thus, interns and residents reconsidered more actions than attendings, but residents were more tentative than either interns or attendings (again, with no statistical significance).

Cognitive Load

Diabetes: Participants' self-reported cognitive load for completing PEFs for this scenario ranged from four to eight on a scale of one to ten (*m* = 6.2; see Table 4). While the sample was too small for significance testing, we noted that PGY 1 interns found this scenario to be less complex (*m* = 5.8) than attendings (*m* = 6.8). PGY -3 residents rated it in between those groups (*m* = 6).

Angina: Participants rated the cognitive load of this scenario slightly higher than diabetes (*m* = 6.6; see Table 4), but not significantly so. Interns, residents, and attendings rated it relatively similarly (*m* = 6.6, *m* = 6.7, and *m* = 6.5 respectively).

Table 4. Self-Reported Cognitive Load by Level of Expertise (*N* =12)

Scenario	Level of Expertise	Minimum	Maximum	Mean
Diabetes	PGY 1 Interns (*n* = 5)	4	8	5.8
	PGY 2-4 Residents (*n* =3)	5	7	6
	Attendings (*n* = 4)	5	8	6.8
	Total	4	8	6.2
Angina	PGY 1 Interns (*n* = 5)	5	7	6.6
	PGY 2-4 Residents (*n* =3)	6	7	6.7
	Attendings (*n* = 4)	5	8	6.5
	Total	5	8	6.6

Participant Ratings of Scenario Authenticity

Participants rated both the diabetes and angina cases as being highly authentic, with a mean of 4.8 for diabetes and 4.6 for angina (both on a scale of one to five). While there was not enough power to test statistically, we noted that attendings rated the authenticity equal to or higher than interns or residents (see Table 5).

Table 5. Reported Scenario Authenticity by Level of Expertise (*N* =12)

Scenario	Level of Expertise	Minimum	Maximum	Mean
Diabetes	PGY 1 Interns (*n* = 5)	4	5	4.8
	PGY 2-4 Residents (*n* =3)	4	5	4.7
	Attendings (*n* = 4)	4	5	4.8
	Total	4	5	4.8
Angina	PGY 1 Interns (*n* = 5)	4	5	4.6
	PGY 2-4 Residents (*n* =3)	4	5	4.3
	Attendings (*n* = 4)	4	5	4.8
	Total	4	5	4.6

Discussion

This article describes the development and implementation of two scenarios used to formatively assess the clinical reasoning of physicians with a range of experience (i.e., interns, residents, and attendings). Findings from the implementation evaluation suggest that our strategies of including diagnostic ambiguity and contextual factors (i.e., diagnostic suggestions by the SP) may have increased complexity, possibly influencing physicians to consider a diverse range of differential diagnoses. Moreover, participants' reconsiderations, tentative language, moderate cognitive load ratings, and high authenticity ratings indicate that the design was challenging and engaging enough for interns through attendings. Of interest, we noted that while most participants selected the correct leading diagnosis, reported management choices displayed greater diversity.

These scenarios place a priority on *examining and practicing clinical reasoning behaviors.* This approach allows participants and instructors to focus not only on the outcome or solution to a diagnostic problem, but equally on the nuanced and iterative *meaning making process* leading to that solution[4,41,42]. Moreover, the inclusion of planned contextual factors provides opportunities to practice and reflect on the ways the meaning making process can shift across contexts[10]. For instance, the content analysis of the angina scenario PEF suggests that participants may have given added weight to GERD (the most frequent diagnostic suggestion) as a differential, and many participants reflected on this contextual factor in their think-alouds afterwards.

Opportunities for reflection were further supported by the think-alouds. Our brief analysis of these reflections indicates that the scenarios were complex enough for most participants, particularly newer clinicians, to reflect on possible changes to their practice through reconsiderations. Moreover, all participants used some tentativeness markers, which have been argued to indicate that an event has not been fully processed[40]. Thus, even when physicians reach a diagnosis and treatment plan, our preliminary results suggest that these cases may be complex enough to warrant some further processing.

Clinical reasoning likely differs according to level of expertise[43], as suggested by attendings' lower use of tentative language and reconsiderations compared to interns and residents. Nonetheless, the cognitive load and scenario authenticity findings reported here further support that these scenarios can provide interns, residents and attendings with a sufficiently challenging situation in which to engage. For example, two attendings had a relatively high cognitive load and the *highest* authenticity ratings when compared to residents, suggesting that these scenarios can be used across expertise levels. This approach potentially provides an alternative for those working to support the lifelong development and improvement of clinical reasoning in physicians of multiple levels of training[6,44].

Reflections on Development

Scenario-based simulation design is a complex task wherein designers attempt to plan many of the possible pathways scenario participants may take. In our experience, the result of incorporating diverse stakeholders' unique perspectives resulted in robust scenarios and being better prepared for addressing any unusual choices participants made.

For others considering participatory design approaches, we recommend that one individual be responsible for leading and coordinating the design effort, scheduling outreach to the different subject matter experts (SMEs) and supporting the occasional need to resolve conflicting team perspectives. While this coordination among multiple SMEs during the extended design and testing phases was sometimes time consuming, the process resulted in scenarios that required minimal revision during the implementation phase. This subsequently resulted in all 24 scenarios (12 diabetes and 12 angina) that we ran being of sufficient quality for inclusion in our larger study. Given the cost and scheduling constraints associated with scenarios, this added planning time seems worthwhile, minimizing the need to over-recruit study participants and preventing the disappointing loss of staff and laboratory time; funds; and participant data, time and effort.

Furthermore, incorporating diagnostic ambiguity proved to be a challenging task throughout all design phases. For example, writing detailed past, family and medical histories made it more difficult to predict which aspects participants might attend to. However, the participatory design approach made this process easier: our clinically oriented subject matter experts reviewed the SP cases multiple times to explore potential participant actions. Additionally, during the pilot phase, the SPs and SP educator highlighted the difficulty SPs might have in preparing to implement these scenarios. This helped us enhance our training and retraining strategies to include SP think alouds and the development of a rehearsal guide (Appendices F for diabetes, K for angina). During implementation the team noted the importance of tracking the variety of questions participants asked the SPs. This observation resulted in the development of the SP implementation checklist for each case (Appendices N for diabetes, O for angina). Subsequently these became an important part of our process for determining scenario implementation quality.

Through this careful design process, we were able to more consistently implement scenarios while still allowing for participant flexibility in the face of the ambiguity and contextual factors, resulting in the consideration of a variety of diagnoses and management strategies and the opportunities to reconsider these decisions.

Limitations

First, due to the difficulty recruiting participants for research, the sample size is small, only 12, making it difficult to generalize results beyond this group. Also, designing and refining these scenarios was challenging. Although our inclusion of multiple SMEs resulted in robust scenarios, taking an explicit participatory design approach was logistically challenging. For example, scheduling and coordinating meetings with SMEs required patience and there were occasional disagreements among SMEs about which aspects of the case were relevant and should be included. The lead instructional designer sought resolution through careful discussion. Additionally, during the implementation phase, we noted that a more complex scenario required more training and re-training for our SPs than initially expected. We addressed this by training SPs in pairs and providing detailed feedback using the implementation checklist (Appendices N, O). However, it should be noted that these scenarios were part of a research program, so some of these processes might be more rigorous than needed for other uses of these scenarios.

Lastly, the use of think alouds as a reflection strategy, as opposed to relying on brief faculty feedback, may be challenging for programs with time and space constraints because individual think alouds require scheduling the same amount of time as the participant's scenario and ideally a private room to complete the protocol uninterrupted. This, in fact, is one of the reasons we curtailed scenario times to approximately 15 minutes. Also, proper implementation of think alouds requires those sitting with the participant to be patient and wait until thinking aloud is complete. Most team members indicated early on that this was difficult because they often thought of questions for the participant as they listened. Yet they reported that it became easier with practice and was a valuable way to allow the participant space to reflect.

Future Directions

Developing and evaluating these scenarios highlighted the need to further examine the benefits of using scenario-based simulations for evaluating and teaching clinical reasoning, specifically focused on *management* choices. For example, the broad variation in the management choices participants considered and the effect of acuity (e.g., uncertainty about admitting or treating the angina patient in the outpatient setting) and resource availability on those plans suggest these kinds of scenarios could be important tools[45].

Additionally, since reflection is considered a vital component of simulation, the integration of open ended PEFs and think alouds could be used as a complementary reflection experience for simulation stakeholders that does not require recruiting large numbers of clinical faculty. Instead, this suite of resources is administered by trained research associates and simulation educators seeking to elicit what participants were thinking as they engaged. When used in conjunction with other simulation-based experiences relying on the support of clinical faculty or

trained debrief facilitators or standardized patients, this may offer learners a broader set of reflection experiences. Further research could be done to examine this combination of strategies.

Lastly, our strategy of integrating ambiguity did help create scenarios that were well received by diverse participants; however, because the process presented some challenges, developing systematic guidelines or a tool kit might be helpful to other simulation-based instructional designers.

References

1. Croskerry P. A Universal Model of Diagnostic Reasoning. *Academic Medicine.* 2009;84:1022-1028.
2. Heneghan C, Glasziou P, Thompson M, Bmj PR-, 2009 u. Diagnostic strategies used in primary care. *bmjcom.*
3. Elstein AS, Shulman LS, Sprafka SA. Medical Problem Solving an Analysis of Clinical Reasoning. 1978.
4. Juma S, Goldszmidt M. What physicians reason about during admission case review. *Advances in Health Sciences Education.* 2017;22:691-711.
5. Young M, Thomas A, Lubarsky S, … TB-mjo, 2018 u. Drawing Boundaries: The Difficulty in Defining Clinical Reasoning. *europepmcorg.*
6. Balogh EP, Miller BT, Ball JR. Improving Diagnosis in Health Care. 2015.
7. Norman GR, Eva KW. Diagnostic error and clinical reasoning. *Medical Education.* 2010;44:94-100.
8. Surry LT, Torre D, Durning SJ. Exploring examinee behaviours as validity evidence for multiple-choice question examinations. *Medical Education.* 2017;51:1075-1085.
9. Power A, Lemay J-F, Cooke S. Justify Your Answer: The Role of Written Think Aloud in Script Concordance Testing. *Teaching and Learning in Medicine.* 2017;29:59-67.
10. Durning SJ, Artino AR, Boulet JR, Dorrance K, van der Vleuten C, Schuwirth L. The impact of selected contextual factors on experts' clinical reasoning performance (does context impact clinical reasoning performance in experts?). *Advances in Health Sciences Education.* 2012;17:65-79.
11. Forsberg E, Ziegert K, Hult H, Fors U. Clinical reasoning in nursing, a think-aloud study using virtual patients - a base for an innovative assessment. *Nurse education today.* 2014;34:538-542.
12. Bucknall TK, Forbes H, Phillips NM, Hewitt NA, Cooper S, Bogossian F. An analysis of nursing students' decision-making in teams during simulations of acute patient deterioration. *Journal of Advanced Nursing.* 2016;72:2482-2494.
13. Prakash S, Bihari S, Need P, Sprick C, Schuwirth L. Immersive high fidelity simulation of critically ill patients to study cognitive errors: a pilot study. *BMC Medical Education.* 2017;17:36.
14. Tschan F, Semmer NK, Gurtner A, et al. Explicit Reasoning, Confirmation Bias, and Illusory Transactive Memory. *Small Group Research.* 2009;40:271-300.
15. Burbach B, Barnason S, Thompson SA. Using "Think Aloud" to Capture Clinical Reasoning during Patient Simulation. *International Journal of Nursing Education Scholarship.* 2015;12:1-7.
16. Durning SJ, Artino AR, Beckman TJ, et al. Does the think-aloud protocol reflect thinking? Exploring functional neuroimaging differences with thinking (answering multiple choice questions) versus thinking aloud. *Medical Teacher.* 2013;35:720-726.
17. Ericsson KA, Simon HA. How to Study Thinking in Everyday Life: Contrasting Think-Aloud Protocols With Descriptions and Explanations of Thinking. *Mind, Culture, and Activity.* 1998;5:178-186.
18. Alessi S. Fidelity in the design of instructional simulations. *Journal of Computer-Based Instruction.* 1988;15(2):40-47.
19. Dieckmann P, Gaba D, Rall M. Deepening the Theoretical Foundations of Patient Simulation as Social Practice. *Simulation In Healthcare: The Journal of the Society for Simulation in Healthcare.* 2007;2:183-193.
20. Kneebone RL, Scott W, Darzi A, Horrocks M. Simulation and clinical practice: strengthening the relationship. *Medical Education.* 2004;38:1095-1102.
21. Battista A. An activity theory perspective of how scenario-based simulations support learning: a descriptive analysis. *Advances in Simulation.* 2017;2:23.
22. Durning SJ, Artino AR, Pangaro LN, van der Vleuten C, Schuwirth L. Perspective: Redefining Context in the Clinical Encounter: Implications for Research and Training in Medical Education. *Academic Medicine.* 2010;85:894-901.
23. Durning SJ, Artino A, Boulet J, et al. The feasibility, reliability, and validity of a post-encounter form for evaluating clinical reasoning. *Medical Teacher.* 2012;34:30-37.
24. Weinstein A, Pinto-Powell R. Introductory Clinical Reasoning Curriculum. *MedEdPORTAL Publications.* 2016;12.
25. Felix T, Richard D, Faber F, Zimmermann J, Adams N. CoffeeTalks: An Innovative Approach to Teaching Clinical Reasoning and Information Mastery to Medical Students. *MedEdPORTAL Publications.* 2015.

26. Moroz A. Clinical Reasoning Workshop: Cervical Spine and Shoulder Disorders. *MedEdPORTAL Publications.* 2017;13.
27. Daniel M, Carney M, Khandelwal S, et al. Cognitive Debiasing Strategies: A Faculty Development Workshop for Clinical Teachers in Emergency Medicine. *MedEdPORTAL Publications.* 2017;13.
28. Levine M, Cennimo D, Chen S, Lamba S. Teaching Clinical Reasoning to Medical Students: A Case-Based Illness Script Worksheet Approach. *MedEd Portal.* 2016.
29. Weinstein A, Gupta S, Pinto-Powell R, et al. Diagnosing and Remediating Clinical Reasoning Difficulties: A Faculty Development Workshop. *MedEdPORTAL Publications.* 2017;13.
30. Beaver B, Wittler M. Toxic Ingestion/Acute Trycyclic Antidepressant (TCA) Ingestion. *MedEd Portal.* 2015.
31. Metzner J, Lombaard S, Au A, Kim S. Venous Air Embolism Curriculum. *MedEd Portal.* 2008.
32. Donegan D, Mader R, Weigel S, Kennel K. Newly Diagnosed Type 1 Diabetes Mellitus: A Resident Simulation. *MedEdPORTAL Publications.* 2013.
33. Glick S, Buchanan D, Rohr L, Kehoe L. Homeless Health Care Simulated Patient Case. *MedEdPORTAL Publications.* 2007.
34. Heitz C, Burton J, Fortuna T, Kuehl D, Perkins J, Prusakowski M. The Undifferentiated Chest Pain Patient - An Introduction to the ED Approach to the Patient. *MedEdPORTAL Publications.* 2013.
35. Könings KD, Brand-Gruwel S, Merriënboer JJG. Towards more powerful learning environments through combining the perspectives of designers, teachers, and students. *British Journal of Educational Psychology.* 2005;75:645-660.
36. Jonassen DH, Rohrer-Murphy L. Activity theory as a framework for designing constructivist learning environments. *Educational Technology Research and Development.* 1999;47:61-79.
37. Jonassen D. Revisiting activity theory as a framework for designing student-centered learning environments. *Theoretical Foundations of Learning Environments.* 2000:89-122.
38. Boren T, Ramey J. Thinking aloud: reconciling theory and practice. *IEEE Transactions on Professional Communication.* 2000;43:261-278.
39. Plass J, Moreno R, Brünken R. Measuring Cognitive Load. In: Plass JL MR, Brunken R eds, ed. *Cognitive load theory.* New York, New York: Cambridge University Press; 2010:pp 181-202.
40. Tausczik YR, Pennebaker JW. The Psychological Meaning of Words: LIWC and Computerized Text Analysis Methods. *Journal of Language and Social Psychology.* 2010;29:24-54.
41. Ilgen JS, Eva KW, Regehr G. What's in a Label? Is Diagnosis the Start or the End of Clinical Reasoning? *Journal of General Internal Medicine.* 2016;31:435-437.
42. *Understanding Clinical Reasoning from Multiple Perspectives: A Conceptual and Theoretical Overview,* 35-46(Springer, Cham 2018).
43. Schmidt HG, Mamede S. How to improve the teaching of clinical reasoning: a narrative review and a proposal. *Medical Education.* 2015;49:961-973.
44. Nestel D, Kelly M. Strategies for research in healthcare simulation. *Healthcare Simulation Education.* 2017:35-44.
45. Cook D, Sherbino J, Durning, SJ. Management reasoning: Beyond the diagnosis. *JAMA.* 2018.

Appendices

Scenario Implementation

A. Clinical Reasoning in the outpatient setting participant workflow diagram scenarios workflow diagram
B. Participant expectations and instructions script
C. Think-aloud instructions and warm up
D. Door information for diabetes
E. Diabetes standardized patient case
F. Standardized patient rehearsal guide for diabetes
G. Diabetes storyboard
H. Supplies list for diabetes
I. Door information for angina
J. Angina standardized patient case
K. Standardized patient rehearsal guide for angina
L. Angina storyboard
M. Supplies list for angina

Measures

N. Standardized patient implementation checklist for diabetes
O. Standardized patient implementation checklist for angina
P. Post encounter form (PEF)
Q. Cognitive load question
R. Scenario authenticity questionnaire

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September 18, 2018

MEMORANDUM FOR STEVEN DURNING, M.D., PH.D., DEPARTMENT OF MEDICINE

SUBJECT: USU Institutional Review Board (IRB) (FWA 00001628; DoD Assurance P60001) Approval of Amendment ref# 906950 to Protocol MED-83-3824 for Human Subjects Participation

Congratulations! The Amendment ref# 906950 for your No More Than Minimal Risk research protocol MED-83-3824, entitled "***Developing assessment tools to better understand the mechanisms of clinical reasoning in military medical simulation***," was reviewed and approved for execution on September 17, 2018 by Edmund G. Howe, M.D., J.D., Chair IRB under the provision of 32 CFR 219.110(b)(2). This approval will be reported to the USU IRB scheduled to meet on September 27, 2018.

The objectives of this study include a) use of existing, and novel measures to assess cognitive performance using simulation-based learning environments; b) to examine theoretical linkages in a proposed conceptual model with potential moderators; and c) to develop an intervention with the goal of enhancing our understanding of clinical reasoning and ultimately improving patient care.

The MODIFICATION submission proposes the following changes to the approved protocol:

1. Adding approximately 15 minutes of training video viewing to our protocol.
2. Moving the think-aloud reflection before the post-encounter form (PEF) for the last case.
3. Asking the self-regulation microanalysis questions before and after the scenario participation/video viewing rather than before and after filling out the PEF for the intervention portion.
4. Recruiting prior participants to view the videos and participate in another video viewing or scenario.

The following study documents were reviewed:

1. EIRB Modification Form - (Version 10.1)
2. EIRB Protocol Template - (Version 1.17)
3. Revised Intervention Consent (English)
4. Recruitment Email for Intervention for Brooke Army Medical Center - (Version 1.0)
5. JPC Recruitment Email _ UTHSCSA_Intervention - (Version 1.0)
6. JPC Recruitment Email _ NMCSD - (Version 1.0)
7. JPC Recruitment Email _ Walter Reed & USUHS - (Version 1.0)
8. JPC_Microanalysis_SRL Questionnaire - (Version 1.0)
9. JPC_Cognitive Load Questionnaire - (Version 1.0)

Authorization to conduct protocol MED-83-3824 will automatically terminate on December 05, 2018. If you plan to continue data collection or analysis beyond this date, IRB approval for continuation is required. Please submit an application for continuing approval to the IRB Office 60 days prior to your termination date.

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You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding this action or questions of a more general nature concerning human participation in research, Yaw Adomako-Ankomah, PhD at 301-295- 0428 or yaw.adomako-ankomah.ctr@usuhs.edu.

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USU Human Research Protection Program

The Use of Think-Aloud Reflections to Examine Learners Experiences in Live and Video-Based Simulation Contexts: A Comparison Study

Konopasky, Durning, Ramani, Ohmer, Artino, Battista

Introduction

The purpose of this study is to use "think-aloud" reflections to explore differences in learners' experiences between video and live scenario simulation contexts. Research indicates that learners' experiences differ across simulation modalities and designs: one study compared live scenarios to interactive video and workshop, finding the live scenarios were associated with significantly higher stress levels for gastroenterologists (1). In another study, students had different emotional responses to a narrative versus problem-solving design of a virtual patient (2). Reflection in simulation, primarily through debriefing, provides a window into learners' experiences of simulation, giving instructors and participants a deeper understanding of the learning process (3). We hypothesized that differences in simulation contexts would result in differences in learners' reflections. We asked:

1. How does reflection as a learning tool differ in each context?
2. What differences does reflection reveal in learner experience of each context?

Methods

Participants were 26 resident (PGY-1-4) and attending physicians in primary care or general surgery, assigned to a pre-recorded video (VI) or live scenario (LS) condition. All participants received one diabetes mellitus and one coronary artery disease scenario (52 cases total). Following Ericsson and Simon's protocol analysis approach to thinking as inner speech, participants were asked to "think aloud" while rewatching the pre-recorded video simulation or watching their own performance (4). To understand reflection as a learning tool, think-aloud transcriptions were coded for *reconsiderations*: moments when practitioners questioned their own or the video doctor's choices or thought processes (5). To explore learner experiences, transcripts were coded by the Linguistic Analysis and Word Count (LIWC) program for: first-person singular pronouns (attentional focus on the self; e.g., *I*), cognitive processing words (thinking styles; e.g. *consider, explain*) and affect (emotionality; e.g., *great, worry*) (5). LS and VI participants were compared for differences in reconsideration and LIWC variables using *t*-tests or chi-square tests as appropriate.

Results

Regarding reflection as a learning tool, LS participants were statistically significantly more likely to reconsider choices or thought processes (X^2 [1, N = 52] = 9.63, $p < .01$) compared to VI participants. Qualitatively, LS participants reflected more on their *own* choices compared to VI participants' focus on the video doctor's choices. LS participants were also the only ones to reflect on *management* decisions like follow-up tests or patient education.

Exploratory analyses of learner experience revealed that LS participants used statistically significantly more ($t = 3.5$, $p < .01$) first-person singular pronouns ($m = 5$ for LS; $m = 2.4$ for VI) and significantly more ($t = 2.5$, $p < .05$) cognitive processing words ($m = 19.2$ for LS; $m = 16$ for VI) than VI participants. However, there was no significant difference in affective markers ($t = .7$, $p = .5$). In sum, LS participants spoke more from an "I" perspective; spoke more about cognition (e.g., whether or not they were "sure" about something); and were similar to VI in both positive and negative emotions.

Conclusions

As a learning tool, there were both *more* and *different* kinds of reflections for LS participants, with a focus on the self's thoughts and choices. Learner experiences as measured by LIWC showed a similar contrast, with more of a focus for LS participants on the self (*I/me*) and on the cognitive process itself (e.g., talking about level of certainty with words like *sure* and weighing diagnostic differences with words like *but* and *if*). As one of the first inferential tests of varying simulation contexts (6), this study suggests a number of potentially important differences and the need for more detailed analysis of learning and reflection experiences in simulation. Moreover, through think-aloud methodology this study offers evidence that even without a faculty guide, participants demonstrate a range of reflective processes and experiences. Future research should examine whether think-aloud methodology could be used to augment guided reflection in various simulated learning environments.

References

1. Bong CL, Lightdale JR, Fredette ME, Weinstock P. Effects of simulation versus traditional tutorial-based training on physiologic stress levels among clinicians: a pilot study. Simulation in Healthcare. 2010;5(5):272-8.
2. Bearman M. Is virtual the same as real? Medical students' experiences of a virtual patient. Academic Medicine. 2003;78(5):538-45.
3. Palaganas JC, Fey M, Simon R. Structured debriefing in simulation-based education. AACN advanced critical care. 2016;27(1):78-85.
4. Ericsson KA, Simon HA. How to study thinking in everyday life: Contrasting think-aloud protocols with descriptions and explanations of thinking. Mind, Culture, and Activity. 1998;5(3):178-86.
5. Tausczik YR, Pennebaker JW. The psychological meaning of words: LIWC and computerized text analysis methods. Journal of language and social psychology. 2010;29(1):24-54.
6. Cook DA, Hatala R, Brydges R, Zendejas B, Szostek JH, Wang AT, Erwin PJ, Hamstra SJ. Technology-enhanced simulation for health professions education: a systematic review and meta-analysis. Jama. 2011;306(9):978-88.

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

We explored the phenomenon of context specificity. We ran a mixed methods study, wherein 65 participants were quasi-randomly assigned to either outpatient video or outpatient scenario condition. We conducted both qualitative and quantitative analysis on the data we had collected, to examine clinical reasoning in the presence of contextual factor. We also examined the difference between use of video versus live scenario condition in terms of participant performance. The findings revealed a significant difference between video versus live scenario condition in terms of participant reconsiderations and linguistic markers thereby signifying the effect of context on performance. Meanwhile comparing post encounter form (PEF) scores, we found a statistically significant difference in some items between contextual and non contextual factor conditions. The presence of one or more contextual factors significantly and negatively impacted clinical reasoning as measured by the PEF.

The study also involves 20 participants assigned to an inpatient scenario condition. We ran preliminary content analysis on the think aloud data collected. The analysis revealed an association between participants' expertise level and the diagnosis listed by them.

We are currently designing an intervention based on the above results.

15. SUBJECT TERMS

Clinical reasoning, Video-based simulation, Simulation-based learning, Cognitive load theory, Self-regulated learning microanalysis, Biometrics, Think-aloud, Burnout, Sleepiness, Situated cognition, Contextual factors

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