Empowering the Inexperienced Researcher: A Summary Report and Expert Recommendations

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Executive Summary:

This report summarizes the findings of the Society for Simulation in Healthcare (SSH) Research Committee Task Force on Research Integration and outlines a number of recommended strategies to improve the engagement and productivity of novice researchers. The task force identified a number of barriers to research engagement in the domains of Knowledge, Experience, and Mentoring/Collaboration. A number of strategies were developed to surmount these barriers. These included the creation of cognitive aids containing information specific to data collection, protocol development, program development, and initiation of multisite research studies, and the further implementation of an SSH research portal. On behalf of the SSH Research Committee, we offer these aids in the hope that they will facilitate entry of novice researchers into the field and improve the overall scholarly productivity of the community.

Key Points:

1. In 2012 The Society for Simulation in Healthcare Research Committee engaged in a modified Delphi process to uncover potential barriers to engagement in simulation research by novices.
2. The barriers uncovered can be broadly categorized as Barriers of Knowledge, Barriers of Experience, and Barriers of Mentoring/Collaboration.
3. Cognitive aids were developed to assist novices in overcoming knowledge and experience barriers, but the ultimate solution to these issues involves the facilitation of greater intra-programmatic collaboration and mentoring.

Introduction:

The past decades have seen tremendous growth in the use and acceptance of simulation as an educational and research methodology across the interprofessional spectrum, with a particular escalation in the professions of medicine and nursing. [1-8] The present state of simulation research has been synthesized in the reports of the 2011 International Meeting on Simulation in Healthcare (IMSH) Research Summit.[8-13] Yet despite this breadth of possibilities, comparatively few simulation programs are actively engaged in research. In a 2011 survey of 90 simulation centers performed by the Association of American Medical Colleges, only 40% of medical schools and 34% of teaching hospitals surveyed conducted research at their simulation centers[14]. This relatively lower level of research engagement is also mirrored among nurses, as a 2004 survey of 34 nursing schools using high-fidelity simulation revealed that only three (21%) university and three (19%) community nursing schools reported conducting simulation research[15]. This raises the question of how novice researchers, in the absence of active research occurring at their home institutions, can effectively engage in the research enterprise. In response to this issue, the Society for Simulation in Healthcare (SSH) Research Committee convened a Task Force on Research Integration in 2012 to identify possible barriers to research engagement and craft accessible solutions.

Methodology:

Consisting of physician educators, academic nurse educators, and specialists in education theory, this interprofessional task force conducted a modified multi-step Delphi Process during an iterative series of conference calls and electronic discussions.[16-18] These were initiated in early 2012, and concluded in 2013. Initial discussions attempted to delineate the most common reasons why, in the collective experiences of the task force members, simulation practitioners hesitated or refrained from engaging in research. Common issues encountered in existing simulation research were also explored as part of the discussions. Disagreement was encouraged to ensure each issue was addressed comprehensively, and an active email discussion continued between formal conference calls. After agreeing upon a comprehensive set of barriers, the task force divided into subgroups that examined the existing literature to further refine these barriers and develop possible solutions. Subgroup findings were presented

in a final round of conference calls, during which feedback was provided to each group and a joint position established.

Modified Delphi Process Results:

A number of barriers were identified through the modified Delphi process that can be classified into three domains: **Barriers of Knowledge**, **Barriers of Experience**, and **Barriers of Mentoring/Collaboration**.

Barriers of Knowledge: One common observation shared by our team was the propensity of new researchers to simply replicate earlier works with perhaps one or two alterations in methodology, a phenomenon frequently noted while reviewing conference abstracts. Based on this observation we postulated a lack of information regarding the current state of simulation research as it pertains to relevant research questions. Novice researchers, unaware of what has and has not been done and thus unaware of the contour of simulation's current frontier of knowledge, cannot appropriately assess the next best step to take in developing their research question, leading to unnecessary replication of previous work. The team also noted a general deficit in knowledge regarding development, implementation, analysis, and presentation of research questions and protocols (an observation spanning the domains of knowledge and experience). This knowledge component was deemed critical for the successful design and implementation of a research protocol, and naturally led to the question of how best to give format and give access to this knowledge.

*Barriers of Experience***:** It is perhaps a truism that inexperienced individuals lack experience, and yet this can be seen as a barrier that is more difficult to surmount than that of knowledge. After all, knowledge can be acquired from a number of sources, but experience is gained by doing. Considering this barrier, the task force observed that the entire flow of the research process, from protocol development through data gathering, is seen as quite daunting by inexperienced researchers, leading to protocols with inadequate methodology, difficulties describing their work in written form, and confusion when navigating the publication process.
The team also noted that inexperienced researchers are often burdened with inadequate or inappropriate data gathering mechanisms. Task force members observed that novice

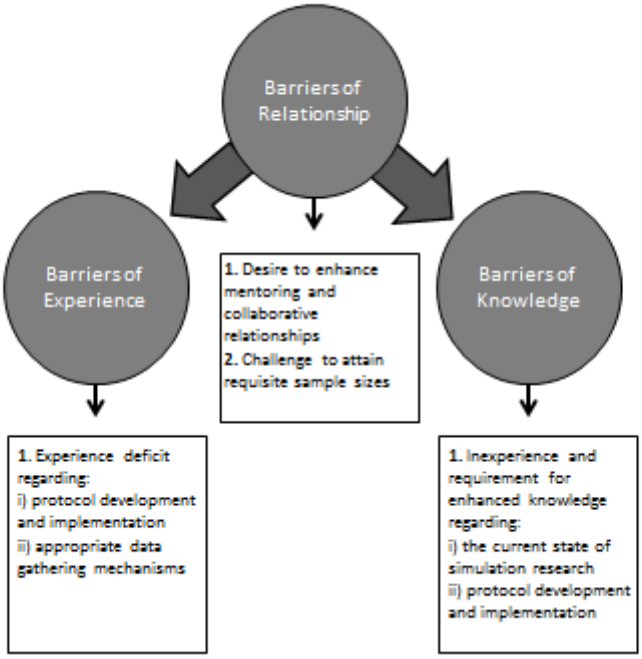
researchers entering the educational and simulation domain often default to self-scoring, comfort scores, and other low-level metrics (Kirkpatrick level 1-2) as the primary outcome measures of their research[19]. This level of evidence, while perhaps appropriate for the initial pilot phases of new curricula, often falls below the level of rigor needed for publication. Parallel with this, the task force noted a lack of thoroughness in the data gathered and archived as part of the normal educational process. These observations were seen as linked.

Barriers of Mentoring/Collaboration: Perhaps of greatest importance are the lack of needed mentoring and collaborative relationships often experienced by novice researchers. In a sense, the other barriers merge within this as an overall category, since it is traditionally these mentoring relationships that provide the boosts to knowledge and skill needed to experience initial success. In addition to the more global value derived from these relationships, the team observed that without these connections it can be particularly difficult to obtain adequate sample size to examine certain questions due to programmatic size constraints.

Consider the example of a pediatric simulation center that wishes to study the effect of a novel simulation-based educational intervention including defibrillation timing during an actual cardiac arrest. By making reasonable assumptions about clinically significant differences in time to defibrillation, sample size calculations (assuming an alpha of 0.05 and a power of 0.8) indicate the need for 166 intervention and 166 control patients. Given the relative infrequency of pediatric arrests due to ventricular tachycardia and ventricular fibrillation, it is virtually impossible to conduct this type of study at a single center within a reasonable amount of time.

Overall, what is needed here is a greater collaborative effort among institutions and disciplines accessible to novice researchers. A number of such collaborations currently exist, but, at present, these are limited to certain facets of the simulation community[20-22]. This lack of collaboration was seen as a magnifying factor for the other issues, as healthy inter-institutional and inter-disciplinary relationships have the potential assist new researchers in making needed mentoring connections. **Figure 1** illustrates these barriers and the relationships between them.

Figure 1: Barriers to Research Engagement



The above diagram depicts the three major domains under which barriers to research engagement fall, as well as outlining the specific content of each. Of note, both knowledge and experiential barriers can be corrected by appropriate collaboration and mentoring, the absence of which is often the overarching issue.

Potential Solutions:

The team arrived at two inclusive approaches for possible solutions to empower research centers and enhance research engagement. The first, development of cognitive aids, offers the possibility of swift solutions to many of the knowledge and experience issues noted. While valuable, however, the team recognized that this approach only partially addresses the majority of issues, and does not begin to address relationships. In order to completely address the barriers solutions fitting into the second category, facilitation of programmatic interaction are also required. Only by doing this can the needed mentoring relationships and collaboration to truly support the novice researcher be obtained. The remainder of this paper will sequentially explore these categories and their subdivisions, setting forth specific solutions and discussing salient exemplars.

Approach 1: Development of Cognitive Aids:

Given the multifaceted nature of the issues considered, it was clear to the task force that a single cognitive aid alone would not suffice. Further analysis revealed the need for these aids to achieve three distinct goals: providing novice researchers with needed briefing regarding the current state and active frontiers of simulation research, assisting them with navigation of the research process, and providing them with tools for rigorous data acquisition and management. The following subsections describe the ideal content and structure of these three suggested cognitive aids.

Cognitive Aid 1: Briefing the Novice Researcher

When embarking on a research program it is vital to have a working knowledge of constitutes the current state of the science. The importance of having this background information cannot be overstated, as without it the likelihood is high that a novice researcher's initial research questions and projects may be redundant with existing literature. Over the past several years, key articles and systematic reviews (articles which search and summarize the current "state of the literature" on a specific topic) have been published that amply summarize current research needs and directions. One notable example is the published proceedings of an Utstein-style meeting conducted in 2010 that set forth recommended research paths in the domains of Instructional Design, Outcome Measurement, and Translational Research[8]. Similar categories were also developed and discussed by the research summit referenced above and have been expanded upon by additional systematic reviews.[10,23,24]

Acquiring this up to date understanding knowledge requires a thorough understanding and review of the literature, but the diversity of the simulation literature base may make the review particularly difficult because it touches on an immense and diverse array of subject matter, academic disciplines, and educational methodologies[25]. Thus, while simulation-specific journals exist, important simulation-based research is frequently published in a wide array of subspecialty and discipline-specific journals. In addition, the simulation literature has been growing at a tremendous rate, making it difficult to keep up with new publications. Accordingly, simulation researchers are beginning to build taxonomies pertinent to simulation education[26-28]. Given the depth and breadth of simulation publications, the choice of database becomes

increasingly important. While certain research questions may be relatively database specific, many will span existing catalogues. For example, a research question that addresses the use of simulation to assess the quality of central line care may be well represented by a standard MEDLINE search, while a question dealing with more abstract pedagogical issues in clinical training may require a search of varied specialized clinical and educational databases. If the research question is something with a longer history of use in the field of psychology or educational training, then the search needs to widen, encompassing databases used by those fields. There are also challenges with search techniques themselves, such as how to combine search terms, how to limit the search, and most importantly, how to save and re-run an effective search. Many centers do not have the luxury of easy access to specialized librarian support and services.

Thus, the issue to be addressed here is not a lack of information, but rather the development of a *focused repository* where both general information regarding the state of simulation research as well as focused strategies for searching the existing databases can be easily accessed by those in need. After much thought our team concluded that such a repository should include…

- An easily accessible library of articles that systematically represents the state of simulation research
- Suggestions as to the optimal databases to search for various types of research question.[29-33]
- A basic simulation nomenclature.
- Templates of effective searches using a variety of accepted evidence-based formats;[34-36]

The first two components above have been addressed by the recent creation of an SSH Research Committee Portal, which contains links to relevant articles and databases. The third component had also been addressed by the recent publication of a simulation dictionary, which is easily accessible from SSH (http://www.ssih.org/dictionary).[37] Development of the suggested search templates is currently ongoing.

Cognitive Aid 2: Navigating the Research Process

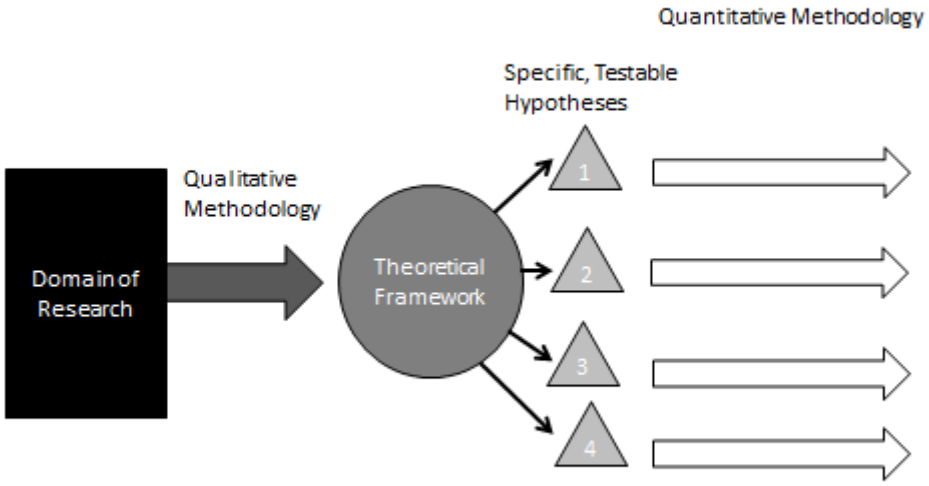
We now turn to the second suggested cognitive aid, which addresses the research process itself. When beginning a research project, it is easy to underestimate the importance of receiving

guidance from a mentor with experience in the field. A novice researcher, however, may not have enough local expertise to fill that need, and thus may benefit from a cognitive aid designed to anchor them in sound research practices and methodologies.

While such a cognitive aid cannot cover all possibilities, an appropriately constructed toolset could allow inexperienced researchers to chart a reasonable path forward and to avoid methodological problems commonly encountered by novice researchers. Although this approach does not replace expert consultation, some novices may be without easy access to such expertise and thus such a written outline could serve as a bridge to greater involvement and further the potential for initial success. Such a cognitive aid would be easiest to use if constructed in a stepwise format, allowing for a "checklist" approach to design[38,39].

First, such a document should address the process needed to take a general idea or concept through to an appropriately designed study, beginning with a discussion of the different types and taxonomies of simulation research. A number of ways exist to categorize research questions and their relationship to simulation in particular.[8-11,13,23,28,40] One such approach is included as an appendix to this document (**Categorization of Simulation Research Checklist).** Another distinction requiring specific clarification for the novice researcher is the difference between quantitative and qualitative designs and the meta-relationship between qualitative studies, theoretical frameworks, and subsequent quantitative research (**Figure 2**)[41-44]. While theoretical frameworks will not be germane to all possible research questions, the authors note that novice researchers may not necessarily think in these terms and thus it is invaluable to encourage them to consider how frameworks such as this might impact their study[45,46]. A number of frameworks have already been applied in the literature to simulation as an educational practice that can serve as a foundation.[28,47]

Figure 2: Schematic of the Relationship Between Quantitative and Qualitative Methodologies

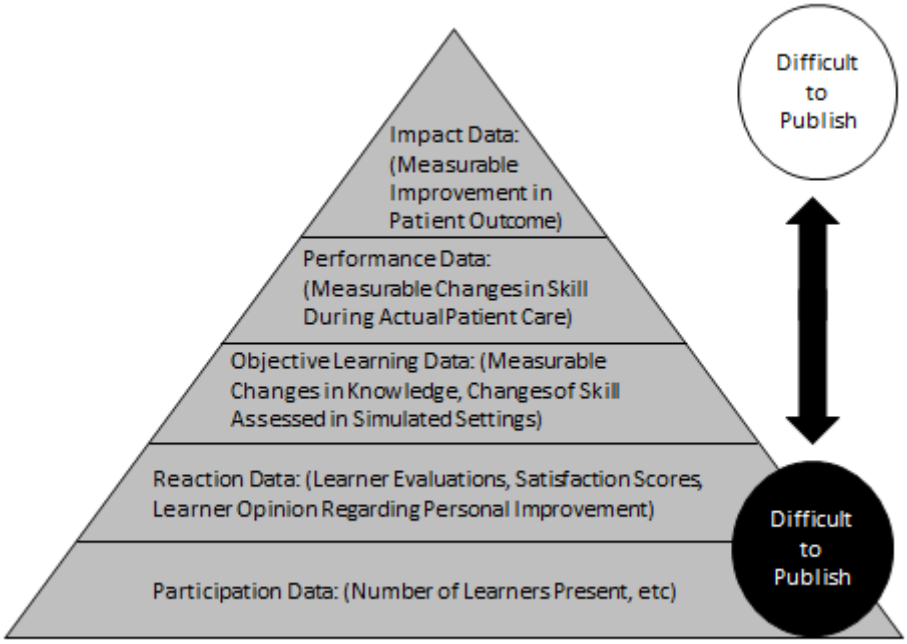


The above diagram depicts one of the means by which quantitative and qualitative research methodologies are related via theoretical frameworks. Note that not all research domains fit this general outline, and for some study types, qualitative methodology may be inappropriate. Nevertheless, novice researchers should understand this model as it pertains to many simulation-based medical education research questions.

Next, the suggested cognitive aid should walk the researcher through the steps needed to refine the research question. One such approach was defined by Hulley and Cummings in their book under the acronym of "FINER", referring to feasibility of the question, interest level to the researcher, novel nature with regard to the established literature, ethical status, and relevance to current and future practice.[48] By engaging these questions, researchers can gather a sense of the potential value of addressing the question at hand. An additional approach, the PICOT model, can then be used to further shape and give specificity to the nascent research question[13,49]. This approach has four elements: Participants, Intervention (independent variable), Comparison, and Outcome (dependent variable). These approaches are delineated in

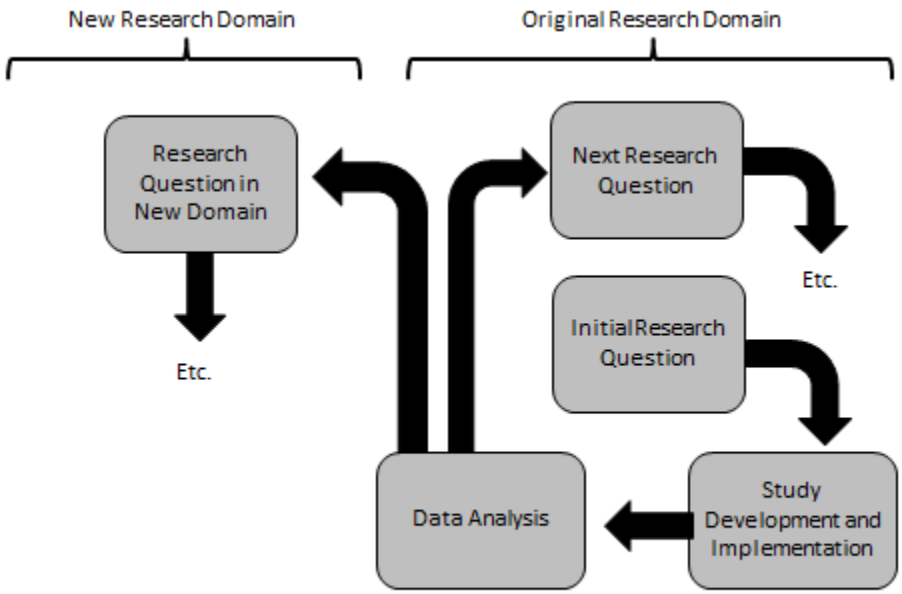
the appendix titled **Research Question Refinement Checklist**. Specific information should then be included regarding the design and execution of common qualitative and quantitative study designs, along with pertinent examples and instruction regarding the mitigation of validity issues.[39,42-44,48,50,51] A issue frequently encountered at this phase is the selection of an appropriate level of evidence for outcomes data. Here the modified Kirkpatrick Scale, depicted in **Figure 3,** can be a useful guide. [52] While minimal acceptable levels of evidence will vary between journals, at present few will accept studies using participation or reaction levels of evidence only. The **Basic Qualitative and Quantitative Study Design Checklist**, also included as an appendix, summarizes these issues. Please note that qualitative study design can be quite complex, and thus this checklist only addresses a relatively straightforward open coding process.

Figure 3: Modified Kirkpatrick Hierarchy of Evidence as Applied to Simulation



The modified Kirkpatrick Hierarchy begins with basic educational session participation data and culminates in improved patient outcomes.[52] While Participation or Reaction data can provide helpful context and feedback, researchers should be aware that studies relying solely on these outcomes are often difficult to publish in peer-reviewed journals.

Figure 4: Iterative Diagram of Research Program Development



This diagram shows the iterative nature of research program development. Programs of research are created as initial research questions are answered, leading to further related questions, and so on. It is important to recognize, however, that a given set of results might indicate the need to shift the focus of investigation to a different research domain altogether. Thus, a certain amount of flexibility is needed on the researcher's part.

In addition to this, the suggested cognitive aids must include a discussion of the transition between a single research study and the development of an overall research program. A recent article has noted that most simulation research is currently conducted on a "study-by-study basis," and advocates for a movement away from isolated small-scale studies addressing whether simulation-based interventions are effective toward more in-depth programs intended to explore the underlying foundations of simulation's effectiveness[53]. It is important, then, for novice researchers, even at the beginning of their investigations, to consider how their initial studies will build toward an overall program designed to address these issues. Key points include the iterative nature of the research process and the need for flexibility as new results

shape previous expectations as it is quite possible that unexpected observations could lead to significant programmatic shifts into unexpected fields of inquiry.[53-55] This possibility is illustrated in **Figure 4**. We have included a **Research Program Development Checklist** as an appendix to assist researchers in navigating this process. Finally, considerations of publication and dissemination must be addressed. While consideration of these issues are beyond the scope of this paper, we note a recent publication by Cheng et al that lays out guidelines for the reporting of healthcare simulation research and refer readers to this helpful resource.[56]

Cognitive Aid 3: Data Acquisition and Management

One factor recognized by the task force during the Delphi process is that many simulation centers not yet engaged in research may already possess portions of the infrastructure needed to gather quality research information. Examples may include programmatic databases for the archival of evaluative data and storage for videos recorded during simulation sessions. By increasing the robustness of these data archives, programs interested in developing a research program can thus enhance their ability to readily engage in research. Research using this data could be performed within many of the categories identified under the previous heading.

For example, consider a collection of video and written assessment data archived from a series of simulations in which a group of nursing students and medical students practice trauma management skills. This archive could well be used to retrospectively study the effectiveness of the simulation-based intervention employed as an inter-professional teaching tool.

This technique is often used in healthcare in the form of the retrospective chart review, which can shed light on specific clinical questions, and similar examples can be constructed for many of the other categories named above. While this approach will not be adequate for a more sophisticated research design, it could serve as an entry-point into the simulation research arena for novice researchers or programs, and has been successfully used to conduct and publish studies[57-63]. Data obtained from a retrospective “simulation chart review” thus represents an initial foray into a specific research domain that can subsequently lead to more intensive prospective investigation. Skills perfected by the rigorous archiving of quality simulation data on an ongoing basis can serve as a needed experience base for the developing researcher and, armed with this experience, new researchers may well find the data collection

and analysis components of a prospective trial less daunting. Suggestions regarding valuable data points to include in such an archive are included in **Table 1,** which explores data that could be potentially collected from individual sessions, and **Table 2,** which lists data that could be potentially collected on a less frequent recurring (or annual) basis**.**

Before leaving this topic it must be noted that the storage of videos in particular can carry with it a number of risks to the subjects. Unlike archived written scores, which are often already de-identified, video data can easily be used to identify individual learners. It is thus imperative that any program embarking on video archival does so in a manner that respects the informed consent of learners, practices rigorous confidentiality, and has been approved by the appropriate regulatory boards. This latter group included not only the local Institutional Review Board, but also hospital risk management and, in some cases, institutional legal counsel. By consulting with such agencies early, and by assuring that any data abstracted from video sources has had pertinent identifiers removed before presentation, these issues can be avoided.

Approach 2: Facilitation of Programmatic Interaction:

Despite the possible value of the above cognitive aids, the task force recognizes that these approaches would only lead to partial success and that a more comprehensive solution was needed. This solution, of necessity, must involve breaking down the current inter-disciplinary and inter-institutional barriers to multi-site simulation research and active encouragement of the formation of multi-site collaboratives. These goals invoke a host of other looming rhetorical questions, including but not limited to:

- How can appropriate mentorship be obtained?
- How can adequate funds for multisite collaboratives be obtained?
- How should such organizations be structured?[22,64]

Perhaps the best way to move forward is by an examination of current organizations that have already taken steps toward achieving this goal. To that end, we offer the International Network for Simulation-based Pediatric Innovation, Research, and Education (INSPIRE) network as an exemplar of how this can be addressed.

Table 1: Potential Data to Collect During Individual Simulation Sessions

Personal Demographics: What are the characteristics of the participant?	**Session Demographics:** What are the overall characteristics of the session itself?	**Individual Educator Assessment:** How did participants perceive each individual educators knowledge, skills, and attitude?	**Session Outcome:** How did learners perform within the session?	**Session Quality:** How did participants perceive the session?
• Participant identifier • Participant gender • Clinical discipline of participants • Experience level of participants • Amount of prior simulation training experienced by participants • Generation of participant (ie, what style of learning are they most likely to engage in)	• Session Content (ie, what is being simulated)* • Session Length • Mannequin model and age used-any modifications made to the equipment? • Was video recorded/used? • Was an embedded actor used in the session and, if so, how?* • Is the session intended for formative vs summative purposes?* • Faculty and personnel resources required during the session	• Impression of educator knowledge base* • Impression of clarity of the educator's communication* • Impression of educator knowledge base* • Impression of the educator's facilitation of the introduction of the session* • Impression of the educator's facilitation of the simulation itself* • Impression of the educator's facilitation of the debriefing* • Impression of the educator's attitude toward the learners*	• Faculty assessment of learner's performance (including attitudes, skills, and knowledge)* • Learner/Learner group assessment of their own performance* • Time to initiation of specific lifesaving measures • Did the simulation result in an adverse outcome?* • Qualitative evaluation by participants as to the learning points of each session • Qualitative evaluation by participants as to how the session might affect their behavior	• Impression of the session organization* • Impression of the cognitive content of session* • Impression of the simulation device or actor* • Impression of environmental fidelity* • Impression of the session's length* • Impression of the effectiveness of the introduction* • Impression of the effectiveness of debriefing* • Impression of the effectiveness of video usage*

This table lists possible data points to be collected from individual sessions. Those data points where qualitative measurements are of particular value are marked with an *. Assessments of performance should be performed with a psychometrically validated tool tailored to the specific environment and theme whenever possible. Participant perceptions of session quality will find their primary use in ongoing curriculum development, but may also possess a supplemental role in the performance of retrospective research.

Table 2: Potential Data to Collect on a Recurrent or Annual Basis

Personal Demographics of Surveyed Learners: What are the characteristics of the participant?	**Program/subprogram specific year-end quality assessment:** How do participants perceive the program as a whole?	**Effectiveness Survey:** How do participants perceive the effect of the program on their own clinical performance over the year?	**Effect on Global Institutional Events:** This data is more difficult to obtain and consists of quantitative trends in institutional performance that can potentially be tied to simulation
• Participant identification (protected) • Clinical discipline of participant • Experience level of participant (PGY year, etc) • Amount of prior simulation training experienced by participant • Types of simulation programs engaged in by learners*	• Impression of session organization* • Impression of the cognitive content of session* • Impression of mannequin/standardized patient fidelity* • Impression of environmental fidelity* • Impression of the session's length* • Impression of the effectiveness of the introduction* • Impression of the effectiveness of debriefing* • Impression of the effectiveness of video usage*	• Participant sense of current proficiency at areas covered by aspects of the simulation program* • Participant sense of personal improvement over the course of the year in specific areas covered by the simulation program* • Narratives as to actual patient care events affected by each aspect of the simulation program*	• Effect of simulation on time to initiation of life-sustaining measures during actual crises • Effect of simulation on code reviews * • Effect of simulation on patient satisfaction scores • Effect of simulation on referral patterns (if simulation is outreach oriented) • Effect of simulation on malpractice premiums* • Effect of simulation on patient satisfaction scores • Effect of simulation on referral patterns (if simulation is outreach oriented) • Effect of simulation on malpractice premiums

This table lists possible data points that can be gathered on a recurring or annual basis. Many data points are amenable to both quantitative measurement and qualitative measurement. Those data points where qualitative measurements are of particular value are marked with an *. Narratives of personal performance affected by the program may be particularly useful to document medical culture change surrounding events that occur too infrequently for quantitative assessment. While difficult to collect, patient outcome data potentially attributable to simulation has the most potential value.

INSPIRE was formed in 2011 from the merger of two large-scale existing pediatric simulation research networks (POISE[20,21,65-67] and EXPRESS[68-71]). This merger successfully brought together many of the individuals working in pediatric simulation-based research allowing larger scale questions to be answered and assisting in the development of materials that can provide needed guidance[72,73]. Of particular note, INSPIRE has created a process and organizational structure for assuring effective oversight and mentorship of new project and investigators. This process begins with brief "ALERT" presentations developed and presented by individual investigators who are then paired with experienced mentors that orient them to ongoing research in that area to promote collaboration across projects. Throughout the subsequent research process, the INSPIRE team guides and facilitates the completion of the project, providing the needed IRB templates, data use agreements, grant support, collaborative oversight, and specialty consultation. When the team has completed their work the manuscript oversight committee provides a pre-review of the work product and guidance on submission/publication. This has enabled INSPIRE to achieve an impressive academic productivity, with a current total of 40 grants, 38 peer-reviewed publications, and 130 research presentations.[74]

Essential Elements for Successful Multi-site Simulation Research Initiatives: Adapting the INSPIRE Experience

Certain generalizable principles can be derived from the above examples. The selection of a lead researcher responsible for implementation of the protocol at all research sites, with well-defined and ubiquitous communications among all research participants during the entire life of the project, is of particular importance[75]. This role has been identified as one of the key elements to the success of multi-site research teams that are widely spread geographically, and is exemplified above by the ALERT process used by the INSPIRE group [75,76]. Additionally, adequate representation and dissemination ownership for each of the participating research institutions must be assured. Finally, the identification of mentors for new investigators within the research collaborative is vital for studies originating from novice researchers or simulation centers. Ongoing mentoring has been shown to be a significant predictor of success[77,78]. Although the research navigation and data archival processes discussed above can enable such centers to begin their work, only the creation of multisite networks accessible to novice researchers can truly address the issues raised by the Delphi process.

At the present time, however, such networks do not exist outside of limited domains. To address this need, we offer a **Multisite Research Development Checklist** as an appendix to this document. This process, drawn from the approach used by the INSPIRE group is valuable not only for individual studies, but also as a rubric that could be used by nascent multisite interprofessional groups to develop their oversight process.

Conclusion and Recommendations:

Simulation research is a fast growing area with great potential for advancement. Nevertheless, it can be difficult for those inexperienced in research to "break in." By developing an array of cognitive aids designed to enhance the abilities of novice healthcare researchers to ascertain the current state of simulation research, navigate the initiation of a research protocol, and gather robust data, we can begin to address knowledge and experiential barriers towards research engagement. By encouraging the creation of multisite collaborative interprofessional healthcare organizations dedicated to simulation research that are also easily accessible to newcomers, additional experiential and relational issues can also be addressed. Existing models of such collaboration should be examined by those simulation-based healthcare researchers across the allied health spectrums who wish to explore larger scale multicenter research further, as these represent the greatest and most all-encompassing solutions to the identified issues.

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Categorization of Simulation Research Checklist

Use of Simulation		**Example**
	1. □ Simulation as Training mechanism	A prospective study of the effect of a novel simulation-based medical education intervention on resident performance in medical crises
	2. □ Simulation as Investigative Methodology or Environment of Research	A study of communication pattern differences between surgeons and nursing staff of differing seniority using a simulated environment to recreate relevant clinical situations.
Goal of Research		
	1. □ Assessment	A study assessing healthcare provider competence in sedation with the use of simulation-based methodologies.
	2. □ Learning Outcomes	A study examining the knowledge and skills acquired by learners during a simulation of pediatric resuscitation
	3. □ Translational Outcomes	A study examining the effect of a simulation-based intervention designed to address rapid dysrhythmia recognition on dysrhythmia-based cardiac arrest survival.
	4. □ Instructional Design	A study examining whether a difference in learning occurs depending on whether a simulation session uses traditional post-case debriefing or a “stop and go” debriefing (debriefing conducted at regular intervals throughout the case) format.
	5. □ Systems probing	A study of hospital code team preparedness using in-situ unannounced code simulations as a testing environment.
	6. □ Technology Testing	As study evaluating the use of a novel chest-tube placement trainer and its effect on provider technical skills

This checklist lists the major categories of simulation research and provides clarifying examples. Novice researchers are encouraged to use this as a checklist when considering the overall category of simulation research into which their specific interests fall.

Research Question Refinement Checklist

Initial Research Idea:	
Should the Question be Answered (FINER Framework)	**Refining the Research Question (PICOT Framework)**
1. Is the question *feasible* to study given your resources? Y □ N □	**1.** □ Who are the specific *participants/subjects* in this study?
2. Are you, as a researcher, personally *interested* in this question enough to devote the needed resources? Y □ N □	**2.** □ What is the *intervention* that is being studied?
3. Is this question sufficiently *novel* with regard to the established literature to be worth investigating? Y □ N □	**3.** □ To whom or what are we *comparing* the participant group in order to draw conclusions?
4. Is it *ethical* to address this issue in the proposed manner? Y □ N □	**4.** □ What *outcome* will be assessed to draw our conclusions?
5. If this study is completed, are the results *relevant* to current or future practice? Y □ N □	5. □ What is the appropriate follow-up *time* to assess outcome?
Refined Research Question:	

The FINER and PICOT Frameworks can serve as useful adjunctive tools toward determining and shaping a well-considered research question and have been outlined in the table above in a way that could be used as a checklist by a new researcher. The process of formulating a robust research question should include a literature review and consideration of the conceptual or theoretical framework that guides the hypothesis. A number of readily available resources exist that can assist in this process.

Resources:

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Basic Qualitative and Quantitative Study Design Checklist

<table>
<tr><th colspan="2">Quantitative Study Design</th><th>Open Coding Qualitative Study Design</th></tr>
<tr><td>Steps for prospective study structure</td><td>Steps for retrospective study structure</td><td rowspan="2">1. □ Determine qualitative methodology to be used
2. □ Develop survey or focus group questions
3. □ Select participants
4. □ Determine additional investigators for data triangulation
5. □ Conduct and audiorecord focus group conversations
6. □ Transcribe data
7. □ Independent analysis of transcribed data for themes by investigators
8. □ Meet to triangulate data and determine consensus theme list
9. □ Develop framework from results</td></tr>
<tr><td>1. □ Select participants
2. □ Measure baseline variables
3. □ Randomize (if indicated)
4. □ Blind the intervention (if indicated)
5. □ Collect data
6. □ Measure outcome
7. □ Analyze data</td><td>1. □ Determine study population
2. □ Locate dataset to be analyzed
3. □ Abstract necessary data
4. □ Analyze data</td></tr>
<tr><td colspan="3">Formalize a written protocol that includes the following</td></tr>
<tr><td colspan="2">□ Research question with study hypothesis
□ Definitions of the independent and dependent variables
□ Potential confounding variables
□ Sampling techniques and plan
□ Randomization technique if applicable
□ Sample size calculations if applicable (Includes decisions as to the appropriate alpha (usually .05), beta (usually .10-.20), expected outcome event rate, and amount of difference to be detected.)
□ Inclusion and exclusion criteria (appropriate inclusion criteria are crucial to selecting the appropriate sample. Exclusion criteria can then be used to eliminate confounding variables, and prevent foreseeable issues)
□ Study measurements (measurement types, instruments, timing, validity, and reliability)
□ Plan for data management (where will data be stored? How will it be protected?)
□ Consent documents as required by the study design</td><td>□ Overall research question
□ Proposed questions for focus groups
□ Inclusion and exclusion criteria (appropriate inclusion criteria are crucial to selecting the appropriate participants in the focus groups. Exclusion criteria can then be used to tighten the study population)
□ Plan for data analysis (include transcription, triangulation, and consensus theme generation)
□ Plan for data management (where will audio and written data be stored? How will it be protected?)
□ Consent documents as required by the study design</td></tr>
<tr><td colspan="3">Mitigate Threats to Study Validity</td></tr>
<tr><td colspan="2">□ Minimize additional outside educational exposures that participants may experience
□ Maximize Kirkpatrick Level of collected outcomes data (avoid Level 1 evidence)
□ Consider avoiding repetition of identical test items between assessments (get at the same material in a different way)
□ Consider participant inclusion/exclusion criteria carefully to avoid selection bias
□ Use an appropriately matched control group.
□ Minimize loss of participants</td><td>□ Triangulate research methods
□ Triangulate data sources
□ Triangulate data analysts
□ Triangulate by interpretative theory and/or cognitive framework</td></tr>
</table>

Research Program Development Checklist

Initial Overall Field of Research:	
Initial Specific Research Question:	
Complete Initial Study As Designed Above Before Answering The Questions Below	
Summarize the Results of Your Study:	
Developing New Research	**Developing the Overall Program**
1. □ Were these results *expected or unexpected*? **2.** □ How do these results impact the *overall field of research* identified above? **3.** □ What *new questions within that field* arise naturally from these results? **4.** □ Do these results point toward a *different field of interest?* **5.** □ What question should be investigated in the *next study*?	**1.** □ What *financial resources* will I need to continue to investigate this area? **2.** □ What *mentoring* will I need to continue to investigate this area? **3.** □ What opportunities for *research dissemination* exist in this area? **4.** □ How can this area of research *contribute to advancement* in my career?
Next Research Question to be Studied?:	
Changes to Overall Course of Research?:	

As new researchers complete their initial study, it is vital for them to consider the next phases of their work. Key to this process is the conceptualization of research as an iterative cycle beginning with a question, proceeding through the development and implementation of a specific study to the analysis of the results of that study, and ending with the formulation of a new research question. By engaging in this cycle within a particular field of study, an ongoing program of research can be developed. Flexibility is crucial, as many times unexpected experimental results can lead to unanticipated questions and potentially alterations to the overall direction of inquiry. A series of questions have been outlined above in checklist format to assist in the development of such a program.

Multisite Research Development Checklist

Leadership:

- ☐ **Principal Investigator/Project Director** identified– role to oversee roles/responsibilities of collaborative team partners. Consider also that these roles might be best performed by separate individuals
- ☐ **Determine Study Research Team: Operational Design and Oversight Processes** (scope of work, delineation of deliverables, timelines)
- ☐ **Determine Needed Mentoring Relationships:** role to provide mentoring in protocol design, data gathering, and analysis for principal investigators with less experience.

Initial Multi-site Research Study Organizational Considerations:

- ☐ **Approve a clear conceptualization of the research project**: articulate this *verbally* and in *writing* to ensure consensus and commitment
- ☐ **Establish all team partners roles and responsibilities** for efficiency
- ☐ **Determine policy of transparency and open discourse** for collaborative team partners to address anticipated occurrences (prevent any 'surprises')
- ☐ **Determine source of process/manuscript oversight:** consider the value of a separate committee charged with the objective oversight of the process and resolution of conflict among investigators
- ☐ **Determine contact frequency** [conference calls or face-to-face (F2F)]; Include explicit geographic time zones with consideration to all sites
- ☐ **Address, proactively, any potential political dimensions**
- ☐ **Develop procedures and tracking systems to ensure *standardization of process* and *regulatory (IRB*), governmental compliance*** as well as funding agency requirements are addressed at each site
- ☐ **Determine Fiscal Management: budgeting, tracking and reconciling processes**
- ☐ **Develop processes for data and safety monitoring plan as required**
- ☐ Determine source and availability of **data management/research administrative supports**, clarifying the role, location, and required funding for all necessary support structures or personnel
- ☐ **Determine timeline for project,** setting clear, attainable deadlines for each phase and delineating the expectations for each participant.
- ☐ **Determine process for resolving process-related conflicts** in case deadlines cannot be met
- ☐ **Develop mutually agreed upon guidelines for writing and dissemination process** to proactively address disputes of authorship, including considerations of:
    a) Authorship
    b) Conflict-of-Interest
    c) Publication/Dissemination
    d) Data Sharing/Ownership
    e) Copyrights, Patents, Technology Transfers as required

Ongoing Multi-site Study Considerations:

Operationalizing Multi-site Agreements at Inception of Study:

- ☐ **Re-address any potential conflicts of interest** and logistical issues arising from individual sites on an ongoing basis
- ☐ **Re-visit research methodology** on an ongoing basis: are we maintaining standardization?
- ☐ Continually search for and **systematically eliminate site-to-site variance in implementation strategy** and data collection
- ☐ Engage in **frequent, ongoing communication with co-investigators and oversight committee** to ensure appropriate progress and address nascent conflicts

*IRB – Institutional Review Board