

Improvement Science Research Network Web Event

Transcript of Breaking New Ground: Forming Research Collaboratives to Conduct Improvement Studies Conducted October 26, 2010

I. Presenters

Darpan Patel
Kathleen Stevens
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II. Presentation

Operator

Greetings and welcome to this ISRN event, "Breaking New Ground: Forming Research Collaboratives to Conduct Improvement Studies." As a reminder, this conference is being recorded. It is now my pleasure to introduce Dr. Darpan Patel.

Darpan Patel

On behalf of the Improvement Science Research Network, I would like to welcome everyone to today's Web event entitled, "Breaking New Ground: Forming Research Collaboratives to Conduct Improvement Studies." Again, my name is Darpan Patel and I am the project manager for the Improvement Science Research Network, also known as the ISRN. We are excited about unveiling two of the ISRN Network Studies, and I am glad to see that you share our enthusiasm by your attendance today. In fact, we will poll the audience in a few minutes to get a better sense of who has joined us today. We also welcome your thoughts on other topics we could address that are of interest to you. At the end of today's session, you will be asked to complete a brief evaluation form. Please be sure to give us your feedback since your comments will help us to plan for future events. While we don't anticipate any technical problems, I'd like to give you a few tips in case you experience any difficulties. Next slide please.

For help please notify the Vcall attendant through the questions window. If you have trouble with the slides or have problems with your connection to the Web event, I encourage you to press F5 to refresh your screen. Also, this Web event is being recorded. A download of this recording with slides and a transcript will be archived on the ISRN Web site. If you would like to download the slides today, you can find the PDF file at the bottom of the presentation window. Next slide please.

Note that you can submit questions at any time through the questions window at the bottom of the presentation screen, as pictured in this screen shot. We will be able to answer some of your questions following our speakers' presentations. Before I turn the program over to them, I would like to get a sense of who has joined us today in the audience. Please answer the polling question you

see on your screen describing your role among the categories listed: frontline clinician, nurse management, educator-clinical, faculty/academic, researcher/scientist, or other health care professional.

The information presented in this Web event will be useful to a broad array of participants but it's helpful to know who has joined us today. From the results our top three specific categories are researchers/scientists, faculty-academic, and other health care professional. We welcome you all. The purpose of today's Web event is to provide information about the ISRN Network studies for participants who share our enthusiasm for conducting break through improvement research. Today's presentations will focus on the Frontline Engagement in Quality Improvement and Medication Error Prevention studies. We plan to hold a future Web event on the Team Performance for Patient Safety in the near future. We encourage you to consider joining one, two, or all of these study collaboratives. Directions on how to become involved are included at the end of this Web event. These landmark studies fill an urgent national need for rigorous improvement research. They will generate ground breaking evidence and definitive answers to priority questions in health care delivery. As you listen to the presentation, think about how these studies could fill a gap in or augment current research projects at your current organization. Think about your organization's stakeholders or leaders who you could approach to suggest improvements or involvements in a network study. If you are one of these leaders, consider the numerous benefits of engaging in a research collaborative which include access to ISRN resources, experienced researchers, and well-known thought leaders; the opportunity to network with like-minded colleagues and learn from other organizations; capacity building assistance; and the ability to increase the professional skills and knowledge of healthcare workers at your organizations.

Now, I am delighted to introduce our two speakers for today's session: Dr. Kathleen Stevens and Dr. Lily Thomas. Dr. Kathleen Stevens is a Professor of Nursing at the University of Texas Health Science Center in San Antonio. She is the founding director of the Academic Center for Evidence-based Practice and is a fellow of the American Academy of Nursing and the Academy of Nurse Educators. Kathleen is the principal investigator for both the Improvement Science Research Network and the Frontline Engagement in Quality Improvement Network Studies. Our second speaker, Dr. Lily Thomas is the Vice President of System Nursing Research at the North Shore-Long Island Jewish Health System. In her current role, she is responsible for developing and implementing strategies to promote nursing research and evidence-based practice across the health system. Dr. Thomas will serve as the principal investigator for the Preventing Medication Errors Network Study which she will describe during her presentation. But first, Kathleen, I'd like to turn the session over to you.

Dr. Kathleen Stevens

Thank you, Dr. Patel, for explaining how the Improvement Research Network has launched three Network Studies. The studies are indeed at various stages of development. It is actually possible that listeners and members might engage their agency or site in all three studies as we unfold them. But first for today, we will talk about two of the first three ISRN supported Network Studies. The particular study I will focus on engaging frontline clinicians in improving the quality of patient care. Let me outline the idea for you.

Nurses are indeed the largest sector of the health care work force making up most of what human factor experts call "the sharp end" of the health care system; the segment in direct contact with patients. This is especially true in hospitals, the sharpest, most hazardous site of patient care where 62% of nurses (1.62 million individuals) were employed in 2008. Nurses are thus well positioned to

be leaders on interprofessional teams in the ongoing transformation of American health care, triggered by the release of the 1999 report from the Institute of Medicine (IOM) that we have all heard, To Err is Human. To engage frontline nursing staff in transforming health care, we have proposed the following study: "Small Troubles, Adaptive Responses: Fostering a Quality Culture in Nursing." We also refer to it as STAR-2. The study goal is to leverage nurses' intimate knowledge of their local patient care system and its weakness into nurse-led organizational learning that will indeed provide improved quality and efficiency. In most hospitals, this opportunity for frontline nurses to serve as loci for organizational learning goes wasted.

In the next slide we present a larger context, looking at the potential contribution to safety and quality and how it is embedded in a very difficult context where you have endemic shortages of nursing staff and difficult working conditions. These raise substantial barriers on the path to quality improvement. Nurses face increasing workloads, distractions from bedside care, lack of autonomy and sometimes indifferent administration- significant barriers all to the delivery of effective and safe care. These structural features of nursing work are our targets for improvement. To add to this context, small troubles during the work shift are plentiful. For example, no linens on the unit at 9 p.m. when skin care is scheduled. Frontline nurses respond with work arounds to get through the day. This is not ideal. A better response is a system fix because it has the potential to correct the problem and avoid later recurrence, thus increasing patient safety.

In the next slide, two major features of the background are identified. Most adverse events in health care originate from small process failures. These are common enough to be taken for granted and even reinforced as we teach our incoming new nurses to work around. Although these process failures include both errors and problems, the problems identified, such as task interruptions due to glitches involving people or equipment, are far more common but draw less attention; we study in great depth the errors but not the problems. In fact problems occur about once per hour, per nurse on hospital units and 95% of these problems are managed through work arounds rather than system fixes. How problems are managed therefore is an important determinant of a hospital's organizational culture for quality of care. The implication for practice is that addressing small problems will drive transformation, creating an organizational learning environment that is sensitive and responsive to latent barriers, and removing the small hassles that zap the morale and efficiency of an already over-extended nursing workforce.

In the next slide, you will see an example of a work around. I'll quote it for you. "We never told the pharmacy when we got a dose of medicine that was more than we requested. We just squirted out the extra because we figured they were busy, they had not intended to make the mistake, and they wouldn't do anything about it anyway." This is an actual quote from a study that Anita Tucker conducted in 2008. In the next slide you will see that the rest of the story and part of the awareness come through. "It was sad really because we weren't letting them have the information so they could fix their own problems." This exemplifies a treasure in every error, meaning an opportunity to learn from every failure. While work arounds are common, even encouraged in our current care culture, this approach does not lead to system solutions. Rather, work arounds support the continuation of small failures. The broken system continues to operate at the expense of patient safety and efficiency. So a question I have for you in the next poll, asks you about your experience with first-order operational failures, in whatever your role: a teacher working with students, a direct care provider, or a manager. Which of these categories represent problem areas for your unit or work environment?

Well now that you've answered this, we'll post the responses and have a look at what work arounds you, our audience, experiences. It looks like we have many, many work arounds or many challenges with information and communication, followed by staffing, and equipment and supplies. This is no small surprise given the context. These are validating results that not only Anita Tucker's work and Amy Edmondson's work exemplified that also, next slide please, were found in a study that has already been conducted.

The Improvement Science Research Network Study that we are discussing at this point builds on a project that was made possible through funding from the Robert Wood Johnson Foundation, Interdisciplinary Nursing Quality Research Initiative or INQRI. Dr. Bob Ferrer and I were co-principal investigators on this project from 2008 through this past month. We call today's project STAR-2 because of the need to extend our STAR-1 work into a broader-based study, as proposed through the Improvement Science Research Network. In our Robert Wood Johnson study, we engaged in detecting and intervening with small troubles. In contrast, this Network Study proposes to detect operational failures and engage frontline nursing staff at a later point in generating solutions. Appropriately, solving operational failures with system solutions will shift the organizational culture from one where it is normative to solve only the immediate problem to one where it is normative to solve the problem with a system fix, or second-order solution. The implication for practice then is that addressing small problems will drive this transformation.

Next slide. So as a bit of background, I'll provide more on the Robert Wood Johnson Study or the STAR-1 study. We looked at the goal of increasing first-order operational failure problem solving to determine if a program of addressing small problems in nursing care can lead to improvements in quality and safety and to determine if addressing small problems will reduce distractions from bedside care, leading to greater nurse efficiency and improved satisfaction.

In the next slide, you will see our conceptual model that we used in STAR-1 and are extending to the STAR-2 Network Study. Nursing units are complex adaptive systems as described in the IOM Quality Chasm report. There is a growing recognition that health care teams behave as a complex adaptive system, which is a collection of interacting agents - in this case, nurses, physicians, unit clerks, physical therapists, pharmacists and everyone that shows up on a unit - who are interdependent so that one person's actions modify the conditions for the other people in the microsystem. So a fundamental principle of complex adaptive systems is that they are best managed by understanding patterns of interaction rather than the characteristics of the individuals within them. In clinical settings, this focuses attention on communication patterns because communication is the pathway to organizational learning, adaptation and innovation.

In the next slide you will see a piece of the STAR 1 project, the detection portion that we call the pocket card study. This was, as you might imagine, a pocket card that nurses carried in their pocket to use as a data collection point for small troubles. On the next slide, we will see an example of three units where we did the pocket card study for self-detection. You will see that high among all three units were small troubles categorized as equipment. Then you see a variation across units, and perhaps the green bars reflect your polling in terms of information. So equipment and information in fact were highly self-detected, and then you will see in the orange bar that the staff or the staffing was often identified in one manner or another, as problematic and something that had to be worked around.

In the next slide, you will see our emphasis for the Improvement Science Research Network Study or what we're calling STAR-2. During phase 1 we will really focus on the detections, and we invite you to

join the ISRN Research Collaborative to conduct the STAR-2 study in this initial phase. As an ISRN Network Study, STAR-2 will look at the detection and following this, we intend to conduct an interventional study replicating STAR 1 practice facilitation in phase 2.

In the next slide, you will see our anchoring point. The Improvement Science Research Network, comprised of a group of luminary Steering Council members and also surveying the nation's stakeholders in improvement science research, identified these four categories as main research priorities to be conducted to address the most critical questions. As one of the first three network studies, STAR-2, was selected because, in part, it directly addresses one of these four research priorities established by the ISRN. In this case, you will see we think it most overlaps with item B, "High Performing Clinical Systems and Microsystems Approaches to Improvement." I know that the group is heavily populated in today's discussion with academicians and scientists, and I want to highlight that we have heavy overlap and these are not mutually exclusive topical areas.

Moving on with the STAR-2 Network Study, in the next slide, the questions in the pocket card study will focus on awareness of the frequency and type of problems, compare self-detection with observational detection, and examine factors related to self-detection. The initial assessment entails a month long card study of the frequency and type of small problems encountered in daily practice on a nursing unit. Nurses will record encountered problems on small pocket cards that the study team will review and summarize for presentation to the unit staff and leadership. Of particular interest is comparing self-detected operational failures with those like Dr. Tucker did in her observational study. This method will be compared with the historical results that are published by Tucker. In addition to the pocket card data, multiple sources of data will be collected for correlation with self-detection, including data on the unit's patient volume, personnel list and duty schedule, organizational charts, annual surveys of the nursing work environment that assess the unit's safety culture, and relevant demographic and nurse characteristics. This phase of the Network Study sets the stage for the interventional phase.

In the next slide, we see how the intervention will unfold. As you try this on in terms of thinking if this is a study that you can partner with an academic setting or partner with a clinical setting, you'll know that we're looking at medical surgical hospital units. We will match these on several key variables that will be informed by the Robert Wood Johnson grant that we did, and in the second phase, the dream and the hope is to randomly allocate these units to either facilitated or non-facilitated clinical units, with facilitation being a standardized intervention to facilitate the engagement of frontline nursing staff in creating system fixes that is.

The timeline in the next slide identifies that we have still developmental stages to go through. We know for a fact that we launched this project in July of 2010 at the Improvement Science Research Network's first Improvement Science Summit and you'll see the investigative team there. The Network Study protocol will be reviewed by the ISRN Scientific Review Committee. IRB approval will be a major accomplishment for both the network and the study site and activating the network collaborative to identify site investigators and train study sites, giving you full support with training modules and everything from crossing the T to dotting the I on how to implement and conduct this study and of course gaining IRB approval at the local site. So if we don't set a goal, we end up sort of not having these blanks filled in. We are looking at launching phase 1 pocket card study this March and invite you to think about becoming part of this activated research collaborative and anticipate that once we get the detection portion done, we can launch an intervention study in January of 2012.

If this fits some of the concerns that you might have about the practice settings that you're in either as an academician or a clinician, then do plan to engage with us as we fill in these blanks and continue to evolve this Network Study through this important national initiative. It is now my pleasure to invite Dr. Lily Thomas, who is joined by Patricia Donohue-Porter as network principal investigators to present the second Network Study that you might be interested in. First of all, I have to compliment Lily and Patricia in that they exemplify the academic-practice partnership that the Improvement Science Research Network really hopes to achieve. Their study now on Preventing Medication Administration Errors. Lily?

Dr. Lily Thomas

Thank you, Dr. Stevens. Hello, and welcome everyone. I am Lily Thomas from North Shore-LIJ Health System. I am also a member of the ISRN Steering Council and will serve as PI of this study as Dr. Stevens said. I also want to acknowledge Dr. Porter. She is an associate professor and program director for the doctorate program at Adelphi University School of Nursing. She is in the room with me and will also be available to answer any questions that come up at the end of the presentation.

My purpose today is to provide a high level overview of the proposed landmark study on Preventing Medication Administration Errors. Along with a literature review, we have had several discussions with colleagues across the country and know that efforts to design solutions are underway. We hope that many of you will hear the call today and join hands with us to find solutions, number 1, by sharing your findings and number 2, by participating in the study. Certainly, the synergy will make it richer, and I hope we can hand over one less problem to our next generation of nurses. I'm sure you'll agree with me.

Next slide please. To go over the background, all of you know that medical errors continue to occur, and medication errors are the most frequent type of errors in hospitals. I know the audience here is familiar with the first IOM Quality Chasm report which identified med errors as a significant cause of morbidity and mortality. The conclusion was that a typical patient would be subjected to one error per day and not all errors are detected or reported. But the most important point I want you to focus on is that 96% of these errors are preventable. Next slide please.

We know nursing work is complex, and there are several time-motion studies that were done which found that nurses spent anywhere from 17% to 27% of their work time preparing and administering medications. Think of that, almost a quarter of their time is spent on meds. In several studies, nurses identified that medication administration is their most interrupted activity and held it accountable for errors. So we are talking of a high volume and high risk activity when we talk about medication errors.

Several studies validate this nursing perception regarding interruption. One example is a recent study done in Australia that associated interruptions with increased medication administration errors. It demonstrated a significant association between the occurrence and frequency of interruptions and the incidence of procedure failures and clinical errors. As we can see, each interruption was associated with a 12.1% increase in procedure failures and a 12.7% increase in clinical errors.

Several studies mimic these findings. Another study published in the Journal of Nursing Administration by McGillis and Group, introduced another facet, that only about 11% of their interruptions could improve patient care and were actually relevant. Other studies have focused on interruptions in identifying the type of interruptions, the source of interruptions, as well as the frequency of interruptions.

When you continue to look at interruptions, next slide, and Dr. Stevens had already mentioned Dr. Tucker's work on interruptions and procedures failures, we found that nurses experience an average of 8.4 work system failures, and most of these work environment issues interrupted patient care and increased the risk for errors. You can see also in the evidence review that the majority of the studies have concluded that interruptions have a negative impact on performance as well as emotional responses, including annoyance at being interrupted, and having anxiety and stress related to the interruption. But there are a few which found no significant relationship and also some positive aspect of interruptions. So all in all, we can say that many of the differences can be attributed to definitions, context, and method.

Next, we have a question for you regarding interruptions. Are interruptions an issue in your work place? So you have a chance to answer that question among this audience. Yes. The answer is 75% of you have answered yes, and others have said no as well as not sure. Well we hope to delve in deeper. Next slide please.

What is the significance of this proposed study? Analyses of med errors have revealed that about one-third of these errors occur during the administration phase. Nurses do safeguard up to 86% of all the errors made by others in providing medication, yet, when it comes to medication administration, it has few safeguards because it is the last step in the process. Also, many studies have identified a second phenomenon, telling us that the impact of errors is not limited to patients and families but also to nurses themselves. Several studies say that this is attributable to the embedded principle of accurate med administration. We have learned so many things about medication administration- the five rights, and now the seven rights. It's so deeply embedded in nursing that when our errors happen, it threatens the professional herself, jeopardizing identity and livelihood which give rise to this phenomenon. And we know, as we are standing right now and anticipating nursing shortages, that we cannot let that happen, and we should really focus on preventing such impact on nurses. Next slide please.

So in summary, while health care literature indicates interruptions contribute to medication errors, we found that the definitions of the terms have not been standardized. Many studies have used the terms interruptions and distractions interchangeably, and you will also notice other additional terms such as intrusions. We need to be cognizant also of the impact of culture. Several international studies have been done, and culture can introduce additional variables that increase or mitigate the risk for medication errors. There are also methodological issues such as sample size as well as the type of observation that was done. Therefore, we hope to do this landmark study which will address many of these issues and build further on the studies that have been done. Next slide please.

Interruptions certainly are interesting, so let's review the process of interruptions. What happens while we get interrupted? The same sensory process or pathway is used for both the interruption as well as the primary task, which requires the individual to address two inputs requiring the same physiological mechanism. So what happens in essence then? Of course the original task, or the primary task, has to be stopped. It is then put back in memory to allow you to start dealing with the task with which you were interrupted. The current task is placed in prospective memory and the ongoing task becomes placed in the ongoing memory. As you can see in the next slide, it is found that when you place something as intention to act or in prospective memory, it becomes vulnerable. Meaning when you go back to the original task, there may be a delay or you may require some cues in the environment or within yourself to go back to that task. Many times, as you may have seen in

many errors that have happened, there is not the same level of engagement when you go back to the original task, therefore increasing the chance for errors. Next slide please.

So in the next slide, we see a picture. It is said that a picture is worth a thousand words but yet, I do not know if we have truly captured what goes on. What happens when there is cognitive overload? What is too much? We know that nursing work is complex, nurses multitask, and the health care environment is very intrusive. At any given time, a nurse is responsible for multiple patients. At any given time, she is interrupted perhaps by her peers or perhaps by herself because of something she has forgotten. She may have left a patient on the toilet and has to go back to that, or she is awaiting a phone call from a physician. All at the same time. There are distractions in the environment - loud noises, another patient may be calling out in pain, or she may be fatigued because it may be the third 12-hour shift that she is working. And also, we have introduced beepers and phones to improve access, but we also know what happens with these phones and beepers, is that it increases the likelihood of being interrupted. So you know often solutions to some will have impact on other things.

Next slide please. You have already seen the next slide. Dr. Stevens has explained to you what we found in terms of the research priorities based on the stakeholder survey. The proposed landmark study is in alignment with the priorities of the ISRN and you know, here we have an opportunity to use the infrastructure to do a landmark study, address all the issues that we have seen in other studies, and come up with meaningful findings. Next slide please.

That brings us to the research question – What is the impact of interruptions on medication administration errors? Our specific aims are to find what organizational factors contribute to interruptions, and what inter- and intra-personal factors contribute to interruptions. I know there are multiple definitions, but we hope to standardize them and look at it so that we have a shared mental model on that. Next slide please.

Some of the other aims include also looking at what are the competing quality, safety, and patient care issues that interfere with medication administration and how a nurse prepares a cognitive state that will assist in diminishing the ability to be interrupted. We know that there are several solutions at hand, say for example barcoding, but there are also work arounds.

Therefore, our research plan is going to include a two-phase study. The first phase will be a descriptive correlational study which will really look at interruptions from all the factors that we listed. Also we are aware that there are multiple solutions and that these solutions may not be equal in all the environments that we are dealing with. Different people have different levels of automation so we need to look at the practitioner. Of course it will depend on what we find in phase 1, but we hope to focus on the practitioner to prevent these medication errors.

Next slide please. So the next slide you have also seen, which is the time line. As Dr. Stevens explained, we also have an investigative team that is formulated. I have Dr. Porter with me on this team, and we will go through the same time line template. That means, once a protocol is designed, it will go through the approval of the ISRN Scientific Review Committee. Then we have to apply to IRB for approval and after that is done, there will be information provided for everyone describing the responsibilities and what needs to be done. We hope to launch it in the first quarter of next year. In conclusion, I want to say thank you for participating. I hope many of you will join us in the cause of Preventing Medication Administration Errors, and I want to turn it back to Dr. Patel.

Dr. Darpan Patel

Thank you very much, Lily, for a great presentation. The launch of the Network Studies provides several benefits, one of which includes addressing priority issues in health care focused on improving quality and patient safety. Next slide please.

The goal of this portion of the Web event is to introduce the process for becoming a study site for the Improvement Science Research Network Studies. For all individuals and institutions that are interested in becoming involved, I'll outline the steps that are needed prior to study start up. I will conclude my portion of the presentation today by going over the support services the ISRN Coordinating Center has in place to assist site Principal Investigators and the site coordinators in preparation for the Network Studies. Next slide please.

In order for a site to be selected as a Network Study site, the site principal investigator and the study coordinator must be a member of the ISRN. Many of you that are in attendance today may be aware that the window to become a charter member for the ISRN has closed, but it is never too late to become a member. If you log on to our Web site at www.isrn.net and click on the "join now" button on the top right corner of the screen, you will be directed to our registration Web site. For a breakdown of the fee structure, simply click on the Member Center located on the left hand navigation tool bar or below the "join now" button for more information. While institutional membership is not required to become an active study site, it is encouraged to allow all your associates on your unit to gain all that the ISRN membership has to offer. Next slide please.

In addition to the membership requirements, we ask that all individuals or institutions that are interested in becoming a study site complete a study site application to indicate your interest. This application, which is currently in development, will be downloadable from the ISRN Web site and will be available in the early part of next year which coincides with the time lines presented today. The application will ask for simple contact information for the principal investigator and the site coordinator and simple site facility descriptives such as facility size and the number of beds. Additionally, we will also ask for information with regards to the number of individuals you anticipate being on your study staff and the contact information for your local IRB. If your site is not affiliated with an IRB, the Coordinating Center at the ISRN will work with you to identify a central IRB to which you can submit your project. The application will also include a check list which will assist you in gathering all the necessary documents and letters that are needed for this application, as well as the direction on how to submit the study site application to the ISRN. Included in this packet are going to be for example, the application itself, a protocol signature page acknowledging that the site principal investigator has read the protocol, a readiness assessment questionnaire, and the bio sketch for all research personnel involved, just to name a few. There may be something that we may add or something that we may take away that will be specific to each and every study, but this check list will assist you in gathering all the necessary documents that you would need to complete your application. Next slide please.

The Coordinating Center has also put in place some support services to better assist the site in preparation to conduct research. Prior to the start of this study, a protocol of training sessions, also sometimes identified as a site initiation meeting, will be scheduled to ensure that the site understands the requirements of the study and intricacies of the protocol. Each site principal investigator and study coordinator will be required to attend and it is assumed that the site PI and the study coordinator would disseminate the information to their study staff. The protocol training session will include a number of things. Specifically it will go over an in-depth review of the protocol such as inclusion and exclusion criteria, the data collection methods, and the data collection tools that will be

utilized for the study. It will also review the processes to enter data online into our ISRN database as well as how to send the data to the Coordinating Center. The sessions will be either scheduled as a Web event or teleconference and will also include the Network Study principal investigator and the Coordinating Center. Next slide please.

As a means to assist the site in the implementation of the protocol, study specific tool kits will also be developed for each protocol. These tool kits may include implementation guides on how to accurately and effectively implement these protocols at your site, and check lists to ensure documents that are needed are gathered. It will also include data collection materials in the form of surveys and forms that may be needed for data collection, as well as data entry guidelines on how to accurately enter the data into our online database. Next slide please.

As with any study, IRB approval will be required prior to implementation at the site level. As I indicated a few slides ago, the ISRN Coordinating Center will assist the site in getting IRB approval for this study. When the protocol becomes finalized, our network principal investigators for example, Dr. Stevens and Dr. Lily Thomas will submit their protocols to their local IRB, for example at the University of Texas Health Science Center in San Antonio or Dr. Lily Thomas's facility in New York. Once the network principal investigator gets approval from his or her IRB, the protocol will be uploaded onto our ISRN Web site for site principal investigators to access. When the protocol becomes finalized and becomes accessible, the site principal investigator can do one of two things. The site investigator can submit to his or her institutional or local IRB for review, or the second option is that the site principal investigator signs an IRB authorization agreement through his or her local IRB. An authorization agreement is between two institutions or specifically two IRBs where one institution specifically, the site principal investigator's institution or IRB, relies on the network principal investigator's IRB for the review and continuing oversight of the study. This agreement covers all human research conducted by the institution and all human research conducted under institutional federal-wide assurance. As I indicated before, the Coordinating Center is available to assist the site investigator in the preparation of IRB applications as needed and will assist the site investigator in locating a central IRB if needed. Next slide please.

The ISRN is very excited about the launch of the Network Studies. As a collective, we will uncover solutions to quandaries about quality improvements and how academic-practice partnerships can be formed. We hope this presentation was informative. If you have any questions or you would like to express your interest in becoming a Network Study site, please contact the ISRN at improvementsciencceresearch@ISRN.net and please include in the subject line, "Network Study." Or you can call the toll free number 1-888-271-8938. Again, we hope this presentation was informative, and we would like to thank both Kathleen Stevens and Lily Thomas for introducing their landmark ISRN Network Studies. We also appreciate the many questions that we have received from our audience thus far. I would like to get to a few of those if we can right now. The first question I would actually like to address towards Dr. Kathleen Stevens. Dr. Stevens, the question asked is what educational experience does a local study site principal investigator need to have?

Dr. Kathleen Stevens

Thank you, Darpan, for that and thank you audience for submitting that question. It is what happens at the local scene that really is important. Just to connect it to the national scene. This is an NIH-funded project to create an infrastructure for interprofessional teams led by nurses to improve care for patients, and it is connected to the CTSA programs for those of you familiar with the clinical translational science award programs out of NIH. With that said, it's crucial that the local site team has the skills and experience in the fundamentals of research. These are also reflected through a

degree. Perhaps an indicator of those skills is that you hold a master's degree, but we also believe very heavily in the academic-practice partnership. The academic practice partnership is seen as a huge solution to moving science into direct care, and we see that this is a fundamental principle of the Improvement Science Research Network. So you can construct your investigative team to where perhaps the local collaborators have at least one person with a master's degree or with experience in conducting research and an academic partner, or the academic partner has a practice partner so that he or she has access to the clinical setting. The Coordinating Center here at the University of Texas Health Science Center is here to fill in the rest of the blanks. We have a statistician on staff, and we have access to expert librarian resources, and so the Coordinating Center is seen as a place to even gain greater capacity. Locally, we want to you to own the study and be excited about the study as a study team.

Dr. Darpan Patel

Thank you very much, Dr. Stevens. The second question I think is appropriate for Dr. Lily Thomas to answer. Dr. Thomas, the question asks will participation in a Network Study count towards Magnet recognition requirements?

Dr. Lily Thomas

Thank you, Dr. Patel. Absolutely. In terms of Magnet criteria there has to be an infrastructure in place for clinical research, so even though the study is designed by the network, we are requiring an onsite PI and all the other activities have to take place in the organization, therefore it meets the criteria. Thank you.

Dr. Darpan Patel

Thank you very much. And I think we have time for one last question. Dr. Stevens, I'll direct this question back to you. The question asks what will the tasks, roles, and responsibilities of a local study site be in conducting the research?

Dr. Kathleen Stevens

Well, I would like to begin with reflecting on an experience that I had and the idea really flows out of a number of things that informed the creation and the proposal of the Improvement Science Research Network. Those of you who have been connected with acute care and intensive care units recognize the Thunder project as a way to construct an infrastructure that could move what we know about improvement strategies and whether or not they work. There was a question that needed to be answered with a very large population, with a very large sample size and so the acute care nursing organization sponsored this and rolled out what they called the Thunder project. So, drilling down with that, we would like to see the local task really being a very close partner in implementing, with full fidelity, the research protocol, conducting the study within the regulations offered by IRB, and collecting and uploading data. We envision having the landmark study question answered with the collective data, perhaps from 15 sites per Network Study, and offering for generalization what is known, or what was gained across all the sites and then offering the individual sites the information about their particular data. So, it would be very much along the way of creating a local research team and the secondary benefit would be that this research team can go on and contribute for the agency in additional research projects. Thank you.

Dr. Darpan Patel

Thank you very much, Dr. Stevens. We've had a lot of great questions submitted through this Web event. However, I'm afraid that we are out of time now, and I would like to bring this Web event to a close. I would like to thank both our presenters and our audience for participating in today's Web event. Again, we value feedback and hope you can spend a few minutes completing the evaluation

form that is about to appear on your screen. As you heard today, these landmark studies fill an urgent national need for rigorous improvement research. I hope you all were able to see how these studies could fill a gap or augment current research projects at your organization. Please visit the ISRN Web site at www.isrn.net to learn about how you can become involved in these Network Studies and on upcoming events and other networking opportunities. Thank you and have a good day.