Supplemental material

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TOPIC GUIDE

Evaluation of Safer Clinical Systems – Testing phase

Interviews with site teams about how the Safer Clinical Systems approach is expected to improve patient safety

What is your present job title?

What is your role on the Safer Clinical Systems Phase 2 project within your organisation?

What motivated your organisation to get involved in this project?

What motivated you to join the Safer Clinical Systems team in your organisation?

What did you find appealing about the Safer Clinical Systems approach when you first heard about it? Was there anything off-putting?

Which elements of the Safer Clinical Systems approach did you find the most useful during Step 1 (*Pathway and Context*)? Which were the least useful?

Which elements of the Safer Clinical Systems approach did you find the most useful during Step 2 (*System Diagnosis*)? Which were the least useful?

What elements or tools have most helped your work on the project to date?

What have been the main challenges so far?

How will you know if Safer Clinical Systems has been successful in improving your selected pathway?

Do you think the Safer Clinical Systems approach will work in practice? Can you describe what you think are the mechanisms through which taking part in Safer Clinical Systems will deliver improvements in patient safety in your organisation?

What are the risks associated with this approach?

Are there any other aspects of Safer Clinical Systems and your experiences to date that you would like to discuss?

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TOPIC GUIDE

Evaluation of Safer Clinical Systems – Extension phase

Interviews with site teams about how the Safer Clinical Systems approach is expected to improve patient safety

Tell me about your current project. What motivated your organisation to do this one? What are you trying to achieve with it?

Can you tell me how your team is set up. Who is in the team and why those people? What skills and what roles did you feel were essential?

Why was it felt that the Safer Clinical Systems approach was a good way of achieving those aims?

Which are the really essential parts of the Safer Clinical Systems approach from your point of view?

Which elements of the Safer Clinical Systems approach are you planning to use/have used so far on the project? If you have decided to drop some bits of the approach, why is that?

Can you tell us about the sequence in which you have use or will be using the tools and techniques from Safer Clinical Systems?

If you are planning to use any of the diagnostic tools, can you tell me a bit more about that. Why is it important to use the ones you have chosen and what do you expect the benefits will be?

Tell me more about how you are planning to address any hazards you identify in your clinical systems. What kind of interventions or risk controls are you planning to introduce? How have you (or will you) gone about choosing these? How are you expecting that these interventions or risk controls will address the problems you have found? How much time have you been able to spend looking at the published evidence on these kinds of interventions? What challenges do you expect in implementing the interventions?

Can you tell me about the improvement methods you will be using. Are you planning to use PDSA cycles? If so, why is that the best way of tackling the problems you have identified? What other improvement methods did you consider? If you can't get the change you need using your existing methods, what would you do?

Can you tell me about the measurement in this extension project. Are you still using the Safety Set idea? What data are you collecting? Is it all on reliability or are you measuring other things as well? How have you gone about aligning the measurement to the hazards and the risk controls or interventions. What is your experience of setting up the data collection systems and doing the analysis?

I think you will be preparing at least one Safety Case as part of your project. What is the purpose of the Safety Case? What are your views on Safety Cases, including their strengths and weaknesses, based on your previous experience? Where will it be read and by whom? Do you think Safety Cases are a good way of communicating with the senior people in the organisation – such as those at board and executive level? What kinds of problems do these people have in understanding the Safety Case idea? Do you think they feel that the Safety Case makes clear to them what they need to do to make care safer and do they understand what their responsibilities might be in supporting that change?

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SCS Evaluation Topic Guide

Site Level

What do you think the Safer Clinical Systems approach will do well? Where do you think it is likely not to work so well?

What difference has it made doing the project on your own this time, without the Support Team's involvement?

What support and resources have been provided by your organisation?

Who needs to be engaged in this project for it to work? How easy has it been to engage people in the project?

How will you know if this project has been a success?

TOPIC GUIDE

Evaluation of Safer Clinical Systems – Extension phase

Interviews with senior leaders about how the Safety Case approach

Can you tell me your job title and give a little background to your role in the organisation?

Can you tell me about any involvement you may have with the Safer Clinical Systems project at your hospital?

Can you tell me a little about the quality and safety data that would normally come to you? How useful do you find it? Do you receive it in a timely way? Is it easy to interpret? How easy do you find it to make that information actionable?

How would you know if there was a hazard in a clinical system? Would you normally expect the evidence about hazards to arise retrospectively – in other words after an incident has happened? What would happen once an incident has occurred to fix the problem?

Can you tell me about any ways you could figure out in advance of an incident happening whether there are hazards in your clinical systems?

How valuable would you find it to have a document that reported an assessment of hazards in a system, quantified the risks, and explained the risk controls in place and whether further action was needed? Would it be a useful addition to what you already receive or should it replace any data you get already?

That kind of a document is called a Safety Case in other industries. If they are going to be used in healthcare, it would be very useful to identify the priorities of senior leaders for format and presentation and that's where the rest of my questions will be focused.

First I am going to take you through a possible structure for a safety case. To help keep our discussion focused, we will use the example of maternity care, but we are interested in general reflections.

Safety Cases should explain what clinical pathway they cover and describe the facility or physical structures where care is located. Any comments on what might be helpful in terms of the format or presentation of this kind of information?

Safety Cases should then define what must be right and why for this particular pathway and facility. What would you expect to see here?

Safety Cases then document all the things that might go wrong. Usually this will be the outcome of a structured process for identifying the hazards in the system – for example, not having an intensive care unit co-located with a maternity unit might be identified as a hazard. It also quantifies the risks associated with this hazard – for example a 0.5% risk that a patient might experience a catastrophic outcome associated with not having an ICU nearby. How useful would you find this kind of documentation?

Next a Safety Case will identify the risk controls in place, by describing what is being done to mitigate against things going wrong. For example, it might explain the special training staff that have in preventing post-partum haemorrhage so that the risks of a patient requiring ICU care are reduced. The Safety Case should also explain what will happen if it still goes wrong – what risks and consequences would follow, and what the emergency arrangements would be. Again, how useful would you find this?

SCS Evaluation Topic Guide
Site Level

The Safety Case will explain whether the risks are as low as reasonably practical, and indicate what needs to be done to make the system safer and what the limitations and uncertainties might be. For example, it might recommend that an additional specially trained obstetric anaesthetist is always available. Again, what are your feelings about having this kind of assessment and recommendation? Would it be any more useful than a standard business case? What kind of evidence would you expect to support the claims made in the Safety Case? Do you think you would find it more or less easy to take action in response to a Safety Case compared with the other data you get coming in at the moment?

How would you feel about having a Safety Case from your organisation made publicly available?

In other industries Safety Cases have legal status and are used as the basis of regulating a particular facility. This means that if a particular risk control is identified in the Safety Case as essential to safe operation of the facility, it operates as a legal requirement. How would you feel about this applying in healthcare?

Finally, in terms of presentation: Would you favour having an executive summary at the beginning and a longer technical document that presents the main Safety Case? What's the maximum length of such a document if it's going to be useful for you?