Final Report to Clinical Science Research and Development

Assessing VHA Patient and Provider Perceptions of Point of Care Research (POCR)

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Executive Summary

Randomized clinical trials (RCT) in healthcare are expensive, complex, highly specialized and often fail to recruit their targeted patient numbers. The VA is promoting an innovative research program, called Point-of-Care Research (POCR) intended to mitigate some of these problems by embedding research at the point of care. The purpose of this funded study is to conduct an early evaluation of this program, focusing on the perceptions and beliefs of patients and providers. This summary reports on Phase 1 of the evaluation project.

Methods

Overview and Design. The study uses a 2-phase approach with the first phase consisting of focus groups and qualitative analyses and the second phase consisting of survey development and implementation. Both phases have a patient and provider component. The survey components are not reported here as they are not completed.

Participants and Sites. Overall, patient and provider focus groups were conducted at seven VA sites with 48 patients and 51 provider participants.

Procedures. Focus groups were recorded, transcribed, de-identified and subjected to intensive qualitative review with a group of 4 researchers using the ATLAS@ti software. The results are a set of themes extrapolated from the analysis for each subject group.

Results

Patients. Seven themes were identified from the qualitative analysis of the patient transcripts: consent, autonomy, doctor-patient relationship, adequate understanding, trust, personal effort, and improved care. Overall, patients were quite enthusiastic, although it was apparent that they had little understanding of the research process as it took at least 30 minutes to explain the program. This lack of understanding is best illustrated by their significant concerns over the extra risks associated with being in a research study.

Providers. Six themes were identified from the qualitative analysis of the provider transcripts: uncertainty, autonomy versus compliance, time and burden, scientific validity, patient-provider relationship, and research value. As in the patient groups, providers were generally very positive, but responses varied more by location and personal research experience than in the patient groups. The central concern was the time and burden involved. Fully understanding POCR also took substantial time due to confusion regarding equipoise and mechanics of the program.

Conclusions

This report summarizes interim results of a study assessing the perceptions and beliefs of patients and providers for the POCR program. The report is organized in 5 sections. The first section summarizes the literature for both providers and patients on POCR methods and ethics. The second section summarizes the methods used in the study. The third and fourth sections present the findings for the providers' and patients' focus groups respectively. The fifth and final section provides suggestions and conclusions.

Introduction

Randomized clinical trials (RCT) are the medical standard for evidence-based practice. However, the expense of conducting large clinical trials, difficulties recruiting providers and patients, and concerns about applicability for general practice are increasingly of concern[1, 2] RCTs can differ in the degree to which they require provider expertise, strict eligibility criteria, intense follow-up and monitoring as well as complicated measurement strategies. They also differ in terms of the degree of equipoise between the intervention arms. The more pragmatic trials are embedded in clinical care processes and compare options perceived as having similar risk and outcome profiles. Pragmatic trials are more likely to be able to recruit patients and providers and the results are thought to be more generalizable to practice. To increase the usefulness of RCTs, the VA is developing a new research program, called Point of Care Research (POCR) that extends the idea of a pragmatic trial even more fully into the clinical arena. In a POCR study, the regular healthcare provider or members of their team would do recruitment and randomization of subjects. After randomization, care would continue as usual and follow-up would simply reflect current clinical practice. Measured end-points and compliance with protocols would be extracted through medical record review only. POCR is a significant change in the way that research is normally conducted and is, in many ways, a new paradigm. [3, 4]

The POCR program provides a potential mechanism for improving the breadth and significance of clinical research programs in VA. To maximize the utility of POCR and to facilitate effective implementation throughout VA, it is important to understand what concerns patients and providers have about POCR, how POCR will impact clinical care workflow within VA hospital settings, and how to best support informed decision making within the POCR execution.

This report summarizes interim results of a qualitative study conducted within the VA assessing the perceptions and beliefs of patients and providers to the POCR program. The report is organized in 6 sections. The first section summarizes the literature for both providers and patients on POCR methods and ethics. The second section summarizes the methods used in the study. The third and fourth sections present the findings for the providers' and patients' focus groups respectively. The fifth and final section provides suggestions and conclusions.

Literature Review

Patients

Engagement of patients in clinical studies is challenged by the need to balance patient participation with the ethical standards of informed consent. Integrating informed consent at the point of care under clinical states of equipoise becomes even more challenging. Lessons can be learned from the research literature in shared clinical decision-making, patient preferences, and the engagement literature of patients in their own healthcare, quality improvement and patient safety. Clinical decision making is perceived by patients as "shared" in which they are able to demonstrate expertise in gaining clarification on their condition, participate in the process of care and negotiate with their provider on specific aspects of their care.[5]

Identifying and integrating patient preferences for involvement in research is key to recruitment and to ethical informed consent. However, prior studies have identified significant limitations in patient's decision-making understanding of the research process. Patients often do not understand the purpose of the consent process itself.[6] Specifically, several studies and a review have noted patient's limited understanding of the purpose of randomization.[7, 8] Most patients appear to have a good technical understanding of randomization, however, they might

not think random choice is necessarily compatable with a choice that is in their best interest. They might even view it as unethical for a physician to suggest randomization.[9]

Secondly, patients had a difficult time accepting equipoise. One study found that more than half of the patients could not believe that a provider would really be unsure of which treatment to suggest.[8] Another study found that most patients did understood equipoise, but if they found randomization unacceptable, they were much less likely to enroll.[7]

Variables predictive of patient enrollment include education, prior experience and cognitive capacity. Vulnerability, either due to physical or psychosocial conditions, may be a particularly important consideration for enrollment. This finding has implications for the impact of POCR on the patient-provider relationship and the time needed to adequately address patient concerns. Negotiating the consent process is similar to other areas where patient preferences have to be incorporated into care decisions. Patients exhibit a range of responses from passivity to autonomy in their willingness to participate.[1] Determining the particular state of willingness to participate by the patient also impacts the amount and type of information the patient may seek about his/her condition.

And finally, several studies have been published examining ethical issues relating to consent, enrollment and the definition of equipoise. Bromage et al[10] described the growing need for autonomy dominating biomedical ethics and that this principal must be assessed in the clinical context of other principles. The contextual factors that they assert must be considered include "the invasiveness of the procedure, equipoise and the importance of the patients' values." Rodrigues et al[11] argue that the differences between clinical care and research must be thoroughly explained in order to protect the rights of patients and that there has to be clear-cut equipoise in outcomes across the physician, patient AND investigator.

Providers

The available literature on providers' perceptions and attitudes toward pragmatic trials and point of care research is limited. Clinician's attitudes toward clinical research center around several key issues of expertise, time and credit. Time and workload constraints appear to be the most common complaint and worry regarding clinical research in general.[12] Using the EMR to collect data has also been expressed, including worries about data validity and accuracy.[12] Other issues relate to fears about their own expertise and how conducting research might impact the relationship with their patients. One survey found that not being included in the overall research process and not receiving recognition were significant fears.[12] Overall, there appears to be a significant concern about the usefulness and value of pragmatic trials in general, sometimes even associated with a deep distrust of researchers motives.

AIMS

Aim 1. Identify the barriers and facilitators to adoption of a POCR research innovation program. Assess the perceptions and attitudes of patients, providers, staff and administrators regarding POCR program.

Aim 2. Produce guidelines for VHA regarding implementation of POCR.

Aim 3: Develop and implement a survey to quantitatively assess providers' and patients' beliefs and perceptions about a perspective POCR program.

Methods

Settings and Participants. Overall, patient and provider focus groups were conducted at seven VA sites: Boston, Columbia, Indianapolis, Palo Alto, Salt Lake City, San Diego, and West Haven, . In all, there were 48 patient and 51 provider participants (12 patients and 10 providers in Columbia, 6 patients and 9 providers in Indianapolis, 7 patients and 9 providers in Palo Alto, 8 providers and 10 patients in Salt Lake City, 4 patients and 6 providers in San Diego, and 9 patients and 9 providers in West Haven) and 11 administrators in Boston.

Recruitment: *Focus Groups*: Providers and patients were recruited, enrolled and consented by the local study teams at each site. Providers were recruited by asking the Chief of Staff to send a message to the Service Chiefs and recommend names to the site liaison. Patients were recruited by going to the waiting areas and showing them the flyers for the focus group and asking if they would like to participate, if allowed and approved by the local IRB and R&D. Those that agreed to participate were called or emailed 48-72 hours before the focus group to confirm their attendance. Every participant (patient and provider) was given time during the consenting process to read through the consent and ask questions, and to decide if they then would like to participate or not. Two out of three Salt Lake City team members traveled to each site to conduct the focus groups. The Salt Lake team members also conducted the two administrator interviews while in Boston conducting the administrator focus group.

Phone Interviews: All phone interviews were patients or providers in Boston who were enrolled in POCR. The Boston study team nurse, who actually enrolled and consented the POCR participants in Boston, would ask the participants at the same time if they would participate in a short phone interview. If they accepted, their names and numbers were securely emailed to a member of the Salt Lake City study team who would conduct the interview. The nurse would also setup a time for the phone interview.

Procedures. The same script was used for each focus group session (a separate one for the patients and providers) and consisted of an introduction, description of POCR and how POCR might be used in the VA plus semi-structured questions about how it might impact clinical care, how to inform Veterans, ethical issues, workflow questions and general queries about attitudes. Appendix 1 and 2 contain the scripts. The focus groups were led by two of the research staff and lasted about an hour. Each was recorded. The recordings were transcribed and the transcripts were then loaded into ATLAS@ti, a software used for qualitative analysis.

Phone interviews were also conducted with four providers and one patient who were actual enrollees in the POCR study in Boston. These interviews consisted of the same topics as the focus groups. The interviews lasted approximately 15 minutes each.

Results

Patients

Overall, the patients were very positive about POCR. Seven themes were identified after qualitative analyses. Table 1 lists the themes and the content is presented in text. The full list of quotations is listed in Appendix 3 (separate file).

Table 1. Identified Patient Themes

Consent	Desire to always be part of the process. They want to be consented (even for access to medical records) in order to remain fully informed and in control over some parts of their care.
Autonomy	The choice is essentially their own. They have a need for autonomy and beliefs that the choice is really their own and that it should be honored.

	They do not like feeling like a guinea pig.
Doctor-Patient Relationship	Concern about losing connection with their doctor. Patients have a lot of trust in their doctor and feel that their primary care doctor has their best interest in mind.
Adequate Understanding	Concern that they won't be able to fully understand the research process. Patients worry that they won't have enough information to make a good decision and would have to make decisions beyond their ability.
Trust	Expectation that they will be cared for, respected, protected, tracked, monitored, and not lost in system.
Personal Effort	Participating in research takes time and effort. Patients have concern the personal cost and risk of participating in the study should come with appropriate incentives, no loss of benefits, and minimal personal effort.
Improve Care	Supportive of research if the intent is to improve care and help Veterans.

THEME 1 (CONSENT): DESIRE TO ALWAYS BE PART OF THE PROCESS

Patients generally want to be able to give consent and to be a participant in the decision-making process. Patients universally expressed the sentiment that they wanted to "give consent" even for very low risk studies. The sentiments seemed to center around the three issues of: 1) control; 2) knowing what is happening and 3) being included. As one patient noted in regards to the consent question "*I want to have some control*." Another patient just repeated the theme of wanting to know, " *. . .when you think it's time, at that moment let me know and then we can go from there*." Giving consent is also seen as providing them knowledge as to who has access to their chart. " *I'd want to know what they're looking for, what information they need." " But I'd like to know who's doing the looking."* The patient's view of the consent process is obviously complicated and may involve more than what researchers expect.

THEME 2 (AUTONOMY): THE CHOICE TO PARTICIPATE IS PERCEIVED AS ESSENTIALLY THEIR OWN. THEY DO NOT WANT TO FEEL LIKE A "GUINEA PIG."

The issue of autonomy is complicated for patients. On the one hand, they express the sentiment that it is "their choice" and that they can leave the study at any time. On the other hand, they truly feel like they may not have all of the information to make a reasoned choice and that at some time they will have to let the doctor decide. In many ways, the "choice" as perceived by the patient is the choice of the patient and the provider together. For example, one patient noted: "*And then this new drug, it's not working, but the doctor says, you now, J., let's keep you on it for another couple of months because it takes awhile for your system to build up a level in your blood. I can still say no*." Or, more simply put "*No, don't experiment on me*." The idea of autonomy is tightly linked to being respected as an individual with rights.

"*And a lot of things using us . . .. use us as a guinea pig*." Or:

" *. . .but when it comes to a medication or health remedies or something like that, it does, it makes you feel like, okay, the doctor does care about me. The medical system does care about me because now I'm getting the choice. Do I want to be dry mouth or do I want to go to the bathroom every ten minutes?"*

THEME 3 (DOCTOR-PATIENT RELATIONSHIP): CONCERN ABOUT LOSING CONNECTION WITH THEIR DOCTOR.

Patients have substantial trust in their doctor and feel that their primary care doctor has their best interest in mind. The patients are worried that in a POCR study, the doctor may lose control over their care, or the doctor may be too removed from decision-making – a scenario that made a lot of patients very uncomfortable. Patients appear to want to be able to communicate with

their provider about the study, to have the provider help evaluate the possible risks and even have the provider make the final decision.

" . . you know, I got a wonderful doctor and a wonderful nurse and they, you know, the personal relationship that I have with her...with them, you know, they go above and beyond sometime and they do for me...they take care of me, they really do."

" . . you want to be able to go to your provider and ask questions about what are these risks, if I go A or if I go B, what are the risks, what are my...how am I going to get in trouble?"

"And then, I'm going to go with the physician's recommendation. Says those are both totally fine and I, you know, I'll just follow his lead because he is the expert."

THEME 4 (ADEQUATE UNDERSTANDING): CONCERN THAT THEY WON'T BE ABLE TO FULLY UNDERSTAND THE RESEARCH PROCESS.

Patients worry that they won't have enough information to make a good decision and would have to make decisions beyond their ability. Getting access to all of the relevant information is difficult and one has to depend on the providers and the system. Sometimes the system is corrupt, e.g. doing research to make money or putting out products that don't work.

"More information because you know the medicine they may be giving you, they may give you placebo one even though you're supposed to be on one, your blood pressure might rise up because you're taking, are you taking the medicine, it might do the adverse reaction and make your blood pressure real low without you knowing . . "

"if I stop using this today and start using this, won't that do something? You know, give me the information. Let me know."

" . . how would we as patients know whether A or B worked for us and if we went in for a colonoscopy for medical problems and looking for something and if A didn't work or didn't show what needed to be shown then, what happens?"

THEME 5 (TRUST): EXPECTATION THAT THEY WILL BE CARED FOR, RESPECTED, PROTECTED, TRACKED, MONITORED, AND NOT LOST IN SYSTEM.

The most prevalent theme was the expressed worry that they would get lost in the system if their care were no longer based on their own individual needs, but rather determined by the "computer." Research, in patient's mind seemed to represent substantial higher risks, even when it was explained that the two options in the study would have nearly identical risks. They simply did not accept that two options would be the same FOR THEM***. "I want to be known how I'm going to be cared for if an adverse event occurs."***

These worries extend to being able to contact their doctors in an emergency that might be due to being in the research study (they are expecting that there would be more emergencies). Or, that they would have to not move out of town so that they wouldn't have to worry that another hospital would not understand the research protocol that they are on. They expect that they would need to be monitored more closely and if they were not, they would be "lost" in the system*.* ***"If something that I'm taking is not working, then how will I know it's not working in order for me to get what I need?***" Nobody else would know or care that they were in a research study and that might have dire consequences, such as loss of insurance or benefits. ***"Well, who is doing the oversight?".***

"Here's what's going to happen. Government pulls this letter out of the mailbox and says there's a study going on, I'm 100% disabled, they might take my benefits away. That's the first thing that goes through their head. This is a way for them to get my benefits. I don't want anything to do with it."

"the VA is famous especially regional office for denials"

This full breadth of patient's thoughts about being "lost in the system" is hard to convey with representative quotes as the patients would tell long personal stories exemplifying the problem, ranging from having to put up with interns who know nothing about them, to having to deal with different processes when they change VAs, to having to worry all of the time about losing benefits, or someone losing their records. They want a promise that if something happens as a result of being in the research study, that they will be taken care of well. ***"If you come with a problem and some medication you give me, I want you to be able to...without a whole lot of me going to 50 lawyers and everything else, I want you to take care of it."*** They also want to feel like the provider is still caring for them as much as before and not putting their efforts toward the research project instead of them. And, overall, they express a lot of problems trusting the "computer" to do the right and human thing.

Finally, patients expressed concern that their individuality would not be taken into account, that their unique history would not be captured by the computer, or that they might be picked on because they are drug addicts or of a different ethnic origin.

THEME 6 (PERSONAL EFFORT): PARTICIPATING IN RESEARCH TAKES TIME AND EFFORT.

Very few patients expressed an expectation that they would receive extra incentives for participating, but were especially concerned that they would have to come in more often, spend more money, or take more time. They were especially interested in compensation for travel and for support in case of any adverse events.

"Well let's make sure that they cover any damage that might occur to you because of this research. I mean, make sure that that is covered at least. So it doesn't come out of your pocket."

THEME 7 (IMPROVE CARE): SUPPORTIVE OF RESEARCH IF THE INTENT IS TO IMPROVE CARE AND HELP VETERANS.

Overall, patients were supportive of the idea of POCR. They appeared to like the idea that the VA was innovative and a leader in the field of research methods and they enjoyed being a part of something bigger. They often noted that they were proud to do something that would help other veterans. They felt like part of a "team."

"the research is fine as long as it's giving us...it's helping other veterans have quality healthcare, I'm all for the research, but make sure it's for the veterans, it's not for something that's going to be just for the private sector because let me tell you, 25 veterans right now are homeless, these are veterans."

Providers

The results from the providers' qualitative analysis were more complex than the patients and differences in sites were more apparent. Some of these differences were due to varying levels of experience with research (bedside clinicians versus those used to conducting research). Other differences were due to specialty (mental health versus primary care) or role (MD versus NP versus administrator). Table 2 lists six main themes followed by a discussion of each. The full list of quotations is listed Appendix 3 (separate file).

Table 2. Identified Provider Themes.

Uncertainty	Providers have a pervasive sense of uncertainty regarding POCR goals, boundaries, operational structure, and applicability. Issues of implementation were often confusing. Equipoise was especially confusing
Autonomy versus	POCR creates tension between professional autonomy and responsibility

Compliance	and compliance with protocols and policies. Complying with research protocols may interfere with their independent decision-making about their patient's care.
Time and Burden	POCR implementation is complex and likely to have significant impact on clinical workflow. Research protocols may interfere with communication amongst providers and with the usual flow of patient care. The burden may be extensive.
Scientific Validity	The quality and validity of the research enterprise may be comprised in POCR studies. Data collection may be unsystematic and protocols may not be consistent across settings. The question is if the results or findings can be trusted.
Patient-Provider Relationship	Providers feel a deep sense of responsibility for their patients and want to preserve the trust and respect embodied in the clinical patient-provider relationship.
Valuable Program	POCR is a valuable and innovative program. Belief that the program will be useful to science in general and is within the VA mission.

THEME 1 (UNCERTAINTY). PROVIDERS HAVE A PERVASIVE SENSE OF UNCERTAINTY REGARDING POCR GOALS, BOUNDARIES, OPERATIONAL STRUCTURE, AND APPLICABILITY.

POCR was a new concept to most of the participants. Ensuring that they had a clear understanding was one of the first goals of each focus group and took substantial time and explanation. Presenting a variety of use cases was key to improving understanding as was allowing for questions. Once they achieved understanding, though, there remained some confusion. The full implications of the program usually continued to emerge through discussion. Difficulties with conceiving how the program would actually work in a real setting were very common. Comparing POCR with Quality Improvement was a common comparison. Providers sometimes had difficulty discriminating between a QI study (a local attempt at improving care) with a POCR study that uses randomization (also a possible local attempt to improve care). The issue becomes one of consent, e.g. when and where to acquire consent and who has the liability.

"I'm a little confused. I think the word research here is. . .a point of confusion . . it's interesting that the clinical arm of the VA is actually even engaging in using the word research…."

"Often . . your department has decided that this is how we're going to do this. And the only difference is . ..we're going to try out in a random fashion first, ….As long as they're clear on who the liability lies with."

Confusion about the meaning of equipoise were surprising prevalent as it became clear that two interventions may vary in terms of not only outcomes, but also provider knowledge and values. It became clear that the equipoise was a matter of matching the interaction between the intervention, the provider and the patient's unique clinical condition.

"I think . . .even though equipoise is at the level of the knowledge of the scientific community, that there's still going to be people that are on the fence."

Providers recognize that they would not be equally comfortable with all options, either because they do not have equal experience with all options, or because they are simply not completely aware of the science. They want assurances that the evidence exists to support equipoise.

"I think there should be at least a thoroughly conducted meta-analysis."

"So you've got to be really comfortable with both..."

Theme 2 (Autonomy versus Compliance). POCR creates tension between professional autonomy and responsibility and compliance with protocols and policies.

Providers feel like they hold the main responsibility for their patient's care, that the decisions they make are independent and expressions of their professional practice. Research that takes place as part of regular care appears to conflict with that value.

*"I would **not like to be restricted further** in what types of treatments I can provide based on a study that I haven't participated in or even designed."*

Participating in the study, then, is a matter of choice. Factors associated with that choice would be the relationship with the patient (would the study threaten that relationship?), the condition of the patient, the provider's actual knowledge of the interventions and the degree to which the intervention is judged to be appropriate for the patient's condition.

" . . maybe you already told the patient you want to give him that drug. Puts you kind of in an awkward position"

*"thinking there **would be certain things that I'd have more comfort with** letting go of the control and other things where I think I might want to retain a little bit more control**"***

Theme 3 (Time and Burden): (POCR implementation is complex and likely to have significant impact on clinical workflow.

Providers are very skeptical about the notion that POCR would be a research fully project embedded into clinical care and creating minimal disruption. Every focus group mentioned the perceived extra time that the study would take and the disruptions to workflow. Extra time would be required for several reasons. Often the provider has to take time to learn about the two options and sometimes the learning curve is not trivial. The providers fully expected that even if they did NOT do the consenting, the patients would look to them to do most of the explanations – and that would take time. Communication channels would be disrupted and repaired as different staff caring for the patient need to be informed.

"It's always extra effort, it's always ***extra thinking***."

"…*they would* take that into ***account in their workload***, in their panel size, right?.

" . if it's going to be that I've got to walk the guy over to another building to get his consent form and I'm getting 20 alerts for every one . . ***I'm going to feel differently***..."

Workflow issues are often subtle. For example, providers were very clear that they needed to know that their patients qualify for a POCR study ahead of the time that they were to be seen in order to properly prepare. Sometimes physicians are teaching and they need to be prepared to present the patient to students. They are also worried that if they find out the patient qualifies right at the time of ordering, then they have already explained options to the patient and would have to start over again.

Theme 4 (Scientific Validity): The quality and validity of the research enterprise may be comprised in POCR studies.

Data collection in POCR studies largely relies on chart extraction. Providers often expressed concern that data entry into the chart is known to be somewhat inaccurate and unreliable. They also worry about how protocols may vary across settings. The overall question is the generalizability of the findings from a POCR study.

*" . . . it's very hard to say that I should **trust the data that emanates from a Point of Care study** with the same reliability as I would something that comes out of an RCT."*

However, providers clearly understood the scientific advantages of a POCR program. They appreciated the fact that enrollment would be easier and that the findings should be more generalizable to real clinical practice.

*"My view of Point of Care Research . . . is that the difference centers more on **how subjects are acquired**…, but that the process is still research and that once they're entered within the cohort, their data is going to be investigated in a systematic way."*

THEME 5 (PATIENT-PROVIDER RELATIONSHIP): PROVIDERS FEEL A DEEP SENSE OF RESPONSIBILITY FOR THEIR PATIENTS AND WANT TO PRESERVE THE TRUST AND RESPECT EMBODIED IN THE CLINICAL PATIENT-PROVIDER RELATIONSHIP.

It is difficult to fully capture this pervasive theme as it appeared in so many contexts. Providers overall feel a great deal of responsibility for their patients. They do not want to put them at risk and they do not want to endanger the relationship that they have built. They are worried that patients will suspect their motives if they are the one doing the consenting and feel like they will experience too much pressure. They want to make sure that their patients are informed and are concerned that they do not have the skills.

"So I would like to know right away . . and I'm going to advocate for that patient. . . I want to tell him right now (the risks) when I'm sitting here not a few days later or something like that."

Providers are concerned that a POCR study puts them at increased responsibility to monitor and track the patient and to make sure that the options are both equal for the patient. "Is somebody actually overseeing the adverse events?"

THEME 6 (VALUABLE PROGRAM): POCR IS A VALUABLE AND INNOVATIVE PROGRAM AND WILL ENHANCE THE SCIENCE AND CONGRUENT WITH THE VA RESEARCH MISSION.

Despite their reservations, providers were highly supportive of the POCR program. They believed that it provided an opportunity to answer many questions in their personal practice that would not likely be funded. ***"It's a good idea because a lot of studies will never be funded by anyone . .."*** In other words, they appreciated having the evidence. In addition, the possibility that the kind of patients enrolled would be more diverse and more like their patients was exciting. And, despite the possible increase in workload, having an opportunity to actually engage in research was seen as an opportunity.

*"Well I consider myself, a scientist is a strong word, **but I believe in science**. And I hope that I would be able to be convinced by evidence . .."*

Clinician Suggestions

Clinicians provided many suggestions for implementing POCR. The topics are listed in Table 3, and range from organizational issues to recommendations for patient enrollment.

Table 3. Provider's Recommendations for POCR Implementation.

Governance	Need systematic oversight of POCR operations at the local site.
Enrolling Providers	Practices associated with enhancing provider buy-in
CPRS suggestions	Changes in CPRS that would enhance workflow
Patient Enrollment	Practices associated with enhancing patient buy-in

Governance. Providers often mentioned the need for effective governance of POCR programs, ranging from informing the local IRB, to setting up local oversight committees. Local IRBs need to be educated as to the nature of POCR programs because they would be responsible for ensuring that the rules regarding equipoise are met and that patients would be under little or no differential risk when comparing the two options. They would also have to be sure that the consenting process by physicians would not be coercive and that patient privacy could be maintained. One clinician suggested appointing an advisory board or steering committee to screen what questions would be appropriate for POCR studies. Others suggested incorporating existing governing bodies within the hospital to decide when POCR is appropriate and to oversee the complicated protocols.

" . . . probably (the) Chief of Staff Executive Council (would) meet with the service chiefs and we would talk about it. We might send e-mails out to staff who would be appropriate. We have to tread a very fine line here because we have hundreds of clinical studies ongoing and we don't want to appear to favor one over another so we don't necessarily want to single it out, but here I don't think we're singling out a study so much as an approach and one that is not entirely, but part homegrown."

Enlisting Providers. Many providers expressed the opinion that that they too, needed to be consented. Currently that would be a matter of local policy, but could aid in enrollment. Providers were particularly adamant about being informed ahead of time when they might be asked to participate and also need to be educated about the options. Some providers even had suggestions for marketing and/or rollout (such as posting on VAMC websites). Other clinicians discussed using the clinical practice committee to disseminate and educate managers who would then provide feedback. Starting the program with a sub-specialty unit was suggested as a rollout strategy for the program as a whole.

"maybe it would be better for subspecialty clinics to start as a rollout because subspecialty clinics are usually much more comfortable with their limited repertoire . . "

CPRS Suggestions. The provider groups were appreciative of the work required for CPRS screens. However, they really did not want to be notified of patient eligibility right at the time of ordering. Rather, they wanted the computer to alert them early, either the day before an appointment or upon admission. In addition, they requested that CPRS provide educational materials and links to informative websites so that they can easily educate themselves about the alternatives. They also suggested that it was important to understand if their patients had been enrolled previously, "*There's no trace in the electronic health record of the decision before, right?"* and that CPRS could be used to record information about refusals, "*Might be reasonable for research purposes to have a second button as to why you opted out. Disagree with randomization. And then that's not hard. Disagree with randomization, no time. Patient refused."*

Patient Enrollment. Providers had suggestions about making it more likely that patients might enroll, including further education and pre-screening. *"..you could send all patients (a) letter saying we would like to introduce research and improve research at the VA*. "*Please fill this form out if you are willing to …be informed of all of the research studies that are available at your primary care. We'd like you to know about research here so please sign this if you're willing for us to do that*…" Using existing tools (e.g. MyHealtheVet) or combining with other large-scale programs such as the Million Veteran Program was also proposed. Clinicians suggested using systematic approaches for talking with individual patients such as saying, " *you know, I like to do this, because much of medicine is an art, it's not a science because we don't have evidence about 80% of the decisions we make. So would you be interested in this in the future*?" which might encourage the patients to agree to participate in POCR studies.

Many clinicians gave suggestions for research questions that could be studied using POCR. Most of these suggestions came from their own practice and included:

- randomizing patients with low back pain to interlaminar epidurals versus a non-interventional arm,
- randomizing patients to Coumadin referral compared to Coumadin clinic (because some people monitor just telecom monitor).
- randomizing people to a nurse call –back system to improve compliance (or not)
- comparing duration of antibiotics for bronchitis, "is it five, seven or ten or 14?

Overall, clinicians were very positive about the program. Their unsolicited suggestions reflect this enthusiasm.

Construction of Surveys

Item construction for both the patient and provider surveys will use the Theory of Planned Behavior as the foundational organization. The Theory of Planned Behavior has 6 general categories of constructs: 1) Intention to participate; 2) Overall attitudes (good/bad); 3) Expected outcomes; 4) Value of those outcomes; 5) Control (self-efficacy and ability to make things happen); and 6) Normative expectation (what others expect us to do) and the degree of importance we place on those norms. The provider survey was developed to represent these comprehensively. The patient survey focused on expected outcomes, importance of outcomes and overall attitudes as well as intentions to participate. In both cases, expected outcomes and beliefs were based on the content from the focus groups.

For both questionnaires, items were constructed, piloted multiple times using cognitive interviews. In addition, all questions were assessed for floor and ceiling effects as well as normative distribution. Factor analyses (provider survey only) was conducted on an initial provider analysis.

Summary and Conclusions

The results of these qualitative analyses indicate that both providers and patients would have a positive view of POCR programs if fully implemented in the VA. The overarching issue in both groups was the difficulty in understanding the nature of POCR and how it differed from other kinds of research (such as Quality Improvement and randomized trials). This difficulty was directly experienced by the research team because of the extensive time it took during the focus groups to assure a complete understanding. Once understood, the main concerns in both groups were issues of operations and implementation. Time and burden were the main issues for the providers and getting lost in the system and not being adequately informed seemed to be the significant concerns in the patient groups.

These findings have important implications for implementing a POCR program in the VA. Issues of education, marketing and workflow analysis will all need attention as the VA adapts to this research model. Although POCR is a totally new way of doing research, it also brings with it the ethical and recruitment issues of all research programs.

In addition, these results reflect the ongoing tension between research and clinical care, which POCR studies are bound to exacerbate. Many providers were amazed that the VA was willing to mix clinical care and research so tightly and others wondered if POCR studies would be abusive of practicing clinicians.

In summary, POCR program implementation will likely be well received if it is properly executed and carefully monitored. Both providers and patients expressed pride in the fact that the VA could be a leader in developing this innovation.

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APPENDIX 1

Patient focus group script

I. WELCOME AND INTRODUCTIONS

Welcome and thank you all for coming this <<morning/afternoon>>. My name is _____ and I will be leading the discussion group today. (Introduce co-facilitators and helpers). My role as the moderator is to direct the content and flow of the discussion and to make sure that we cover the main topics. I am also joined by Charlene Weir, the Principal Investigator for this study. Also present is _____ who is coordinating the study at the _____ VA. She will be taking notes and making sure our equipment is working properly.

Has anyone ever participated in a focus group before?

Well, a focus group is an informal group discussion, and hopefully an enjoyable process. Basically, it is a way to gather information about a specific topic. We are interested in your thoughts and opinions.

This study involves conducting focus groups for either providers or patients from 12 different VA facilities across the country. The study is supported by a grant from the Veterans Health Administration.

Objectives and Agenda

First let me explain the overall purpose of this focus group. Our purpose today is to talk about implementation of a new way to do research in the VA called Point of Care research (POCR). Our discussion today will be about (put on board):

1) How POCR might be used in the VA.
2) How POCR might impact clinical care.
3) Ideas for how to inform veterans about POCR in the VA.

Our conversation will include discussions about patient and provider issues, ethics of POCR and other related topics.

Procedures

Let us talk about how this group discussion works.

If you don't understand something we are talking about, please let us know.

What will happen

We will ask you a few initial questions and then we will ask for you to share a few personal experiences. Then we will ask you to read and respond to a couple of vignettes. The case examples are about a typical POCR study and two variations. Please feel free to ask questions and I encourage you to jot down any comments or reactions you may have as we go along. This information will be really helpful in developing different types of POCR studies and also for developing educational materials about the POCR program, so we will collect them at the end of the session.

< hand out paper to jot down notes or you can write comments on the vignette as well>

Throughout the session, I will be asking specific questions to focus the discussion.

Ground Rules

We'll have a few ground rules for today's discussion:

Our discussion will last for approximately **1 hour**. I have a lot of questions that I would like to ask. Therefore, I would like to quickly go over some guidelines for our discussion.

- **First, there are no right or wrong answers.** This is VERY important. All of your thoughts and ideas are important to us. You are the experts and that is why we have invited you here. We ask that you feel free to speak your mind and remember that everyone will respect your opinions.

- **Please speak up so everyone can hear and so that the tape recorder picks up your comments.**

- **All of the information collected today will be completely confidential.** Our discussion will be tape recorded. You are free to leave at any time, without any penalty. All information from the taped discussion will be transcribed and all references to names eliminated. We can turn the tape recorder off at any time. We will prepare a report using the tapes. Our report will not make reference to any one of you by name. By assuring your anonymity, I hope that you will speak openly and candidly about today's topic.

- **All of your comments will be very helpful.** Keep in mind that we are just as interested in negative comments as we are in positive comments.

- **Please do not engage in arguments with other group members.**

- **Before we begin, I want to remind you that we will be tape recording the discussion** so we don't miss any of your valuable comments. I am going to turn on the tape now. I'd also like to remind you that once the tapes are transcribed and we have incorporated all your comments, all tapes will be destroyed. **(Turn on tape recorder)**

We appreciate the time you are generously giving to this important topic this morning/afternoon/evening.

Are there any questions before we begin? Okay, let's get started!

Icebreaker: In order to get acquainted, let's go around the room, please tell us your first name, how long you have been a patient at this VA, in what branch of the military you served, and something you are passionate about.

Present vignettes: Describe critical elements of POCR listing them on board and/or in handout. The case examples describe two different options which are currently used but which we don't have enough information if one is better than the other such as 1) two different drugs which are similar; two different types of diagnostic tests (e.g., virtual colonoscopy vs. conventional colonoscopy); two different treatments (2 different skin topical ointments for a skin condition), two different surgical procedures (total hip replacement v. partial hip replacement) for hip fracture.

<POSSIBLE SAMPLE QUESTIONS>

1. VA is committed to improving quality of medical care. If your physician or healthcare provider wanted to try something new in clinical care because they thought it might improve the overall quality of care in VA or reduce the cost of care how would you feel about that?
2. Have any of you participated in a research study before? How do you feel about participating in research studies?
3. If you were presented with the option to enroll in a POCR study during outpatient care or inpatient care what would your response likely be?
4. Do you have any concerns about issues of getting the right treatment, being denied a treatment or not being told what is going on during your care with a study like this? These are ethical issues; do you have any concerns? << provide examples, if needed>>

   - How would you feel if your healthcare provider told you that there were two different ways to care for you and that he/she did not know which care/ treatment was best for you? <<Relate question to different treatment categories (e.g. which medication was better, which diagnostic test, etc (see above under vignette examples) Patients may respond differently depending on the focus of the research How would this impact your relationship? >>
   - What factors would make you NOT want to participate?
   - Do you see POCR as valuable for improving quality of care?
   - How important are other patients' opinions in your willingness to participate?
   - What kind of incentives would be adequate for you to participate?
   - Do you think patients should be consented for all research studies? In the example above (repeat different scenarios) do you think your healthcare provider should get your consent? <<<Give them more background information about the current consent process and the program's plan to either omit or use an alternate method (general consent, verbal consent)>>> Currently patients who participate in VA research are asked to sign a consent form which describes…. and the form is usually about 5-6 pages. We also ask you to sign a form to collect information from your medical record.
   - Would you be willing to sign a general consent at the time of your care inviting you to participate in any VA POCR (i.e., there were 2 different ways to provide care/ treat you and there was not enough information to know which was best for you so the decision would be based on the computer's selection) your provider offered?
   - If you were willing to sign a general consent form are there any limitations/statements that you want to have on the form?
   - Would you be willing to give verbal consent to your provider?
   - Would you also be willing to let researchers at the VA access your medical record?

V. Wrap Up:

Those are all the questions we have today. Is there anything else you would like to tell us? I'd like to collect all your notes.

Thank you for all your great input today/tonight. This will be very helpful.

APPENDIX 2

Provider focus group script

WELCOME AND INTRODUCTIONS

Welcome and thank you all for coming this <<morning/afternoon>>. My name is _____ and I will be leading the discussion group today. (Introduce co-facilitators and helpers). My role as the moderator is to direct the content and flow of the discussion and to make sure that we cover the main topics. I am also joined by Charlene Weir, the Principal Investigator for this study. Also present is _____ who is coordinating the study at the _____ VA. She will be taking notes and making sure our equipment is working properly.

Has anyone ever participated in a focus group before?

Well, a focus group is an informal group discussion, and hopefully an enjoyable process. Basically, it is a way to gather information about a specific topic. We are interested in your thoughts and opinions.

This study involves conducting focus groups for either providers or patients from 12 different VA facilities across the country. The study is supported by a grant from the Veterans Health Administration.

Objectives and Agenda

First let me explain the overall purpose of this focus group. Our purpose today is to talk about implementation of a new way to do research in the VA called Point of Care research (POCR). Our discussion today will be about (put on board):

1) How POCR might be used in the VA.
2) How POCR might impact clinical care.
3) Ideas for how to inform veterans about POCR in the VA.

Our conversation will include discussions about patient and provider issues, ethics of POCR and other related topics.

Procedures

Let us talk about how this group discussion works.
If you don't understand something we are talking about, please let us know.

What will happen

We will ask you a few initial questions and then we will ask for you to share a few personal experiences. Then we will ask you to read and respond to a couple of vignettes. The case examples are about a typical POCR study and two variations. Please feel free to ask questions and I encourage you to jot down any comments or reactions you may have as we go along. This information will be really helpful in developing different types of POCR studies and also for developing educational materials about the POCR program, so we will collect them at the end of the session.

< hand out paper to jot down notes or you can write comments on the vignette as well>

Throughout the session, I will be asking specific questions to focus the discussion.

Ground Rules

We'll have a few ground rules for today's discussion:

Our discussion will last for approximately **1 hour**. I have a lot of questions that I would like to ask. Therefore, I would like to quickly go over some guidelines for our discussion.

- **First, there are no right or wrong answers.** This is VERY important. All of your thoughts and ideas are important to us. You are the experts and that is why we have invited you here. We ask that you feel free to speak your mind and respect other opinions.

- **Please speak up so everyone can hear and so that the tape recorder picks up your comments.**

- **All of the information collected today will be completely confidential.** Our discussion will be tape recorded. You are free to leave at any time, without any penalty. All information from the taped discussion will be transcribed and all references to names eliminated. We can turn the tape recorder off at any time. We will prepare a report using the tapes. Our report will not make reference to any one of you by name. By assuring your anonymity, I hope that you will speak openly and candidly about today's topic.

- **All of your comments will be very helpful.** Keep in mind that we are just as interested in negative comments as we are in positive comments.

- **Please do not engage in arguments with other group members.**

- **Before we begin, I want to remind you that we will be tape recording the discussion** so we don't miss any of your valuable comments. I am going to turn on the tape now. I'd also like to remind you that once the tapes are transcribed and we have incorporated all your comments, all tapes will be destroyed. **(Turn on tape recorder)**

We appreciate the time you are generously giving to this important topic this morning/afternoon/evening.

Are there any questions before we begin? Okay, let's get started!

Icebreaker: In order to get acquainted, let's go around the room, please tell us your first name, how long you have worked here at this VA, and something you are passionate about.

Present vignettes: Describe critical elements of POCR listing them on board and/or handout. Describe two different options which are currently used but which we don't have enough information if one is better than the other such as 1) two different drugs which are similar; two different types of diagnostic tests (e.g., virtual colonoscopy vs. conventional colonoscopy); two different treatments (2 different skin topical ointments for a skin condition), two different surgical procedures (total hip replacement v. partial hip replacement) for hip fracture.

<POSSIBLE SAMPLE QUESTIONS>

5. What is your prior experience with POCR?
6. What is your understanding of POCR? (Present brief explanation)
7. How might enrolling patients in a POCR study impact your clinical workflow?

8. Would administrators/healthcare providers have concerns about ethics of participation? If so, what are the concerns?
    - How do providers know that the options are equal? What if they disagree?
    - What barriers do you expect in your clinic to adoption of POCR?
    - What would the impact likely be on the patient-provider relationship?
    - Does the POCR program seem complex?
    - Do you see POCR as valuable for quality of care?
    - How important are other providers' opinions in your willingness to adopt?
    - What kind of incentives would be adequate to participate?
    - Do you think patients should be consented under all conditions? Under what conditions might the consent process be loosened?

Wrap Up :

Those are all the questions we have today. Is there anything else you would like to tell us? I'd like to collect all your notes.

Thank you for all your great input today/tonight. This will be very helpful.