



## **‘They need to tell you and not just do it’: Veteran and Physician Perspectives on Point-Of-Care Research in Veterans Affairs**

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### **Abstract**

Point-of-care research (POCr) is part of a larger effort to advance the Veterans Health Administration (VHA) as a learning health system. It has the potential to improve health care outcomes and drive down costs of research by evaluating “in-use” medications and therapies. However, patients and physicians must be inclined to participate in this type of research. There is a need to assess patient and physician willingness, decision making, and methods of informed consent with respect to patient and physician participation in POCr. An exploratory study was conducted involving three focus groups, two with VA patients (n=8) and one with physicians (n=6) affiliated with a Midwestern VA Health Care System, to explore attitudes and preferences towards issues in POCr. Emerging themes were captured through qualitative content analysis. Four primary themes emerged from the focus group data: (1) a qualified willingness to participate in POCr; (2) the doctor-patient relationship as a context for POCr; (3) transparency and choice in POCr participation; and (4) protecting patient confidentiality and privacy. Our exploratory study among VA physicians and patients suggests that POCr may be perceived as intervening or undermining the physician-patient relationship in cases where randomization supplants doctor-patient decision making, or where a waiver of informed consent may diminish the need for physician-patient interaction. Informed consent is important in POCr because it offers a way for patients and physicians to establish rapport and trust, particularly in cases where randomization removes the need for clinical decision making.

*Keywords:* Veterans, Point-Of-Care (POCr), Clinical Decision Support Systems, Doctor-Patient Relationship, Informed Consent

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### **Introduction**

Significant challenges remain in researching and implementing new clinical interventions to improve patient care. Randomized controlled trials (RCTs) have been around since the mid-1940s, but it was not until almost 40 years later that RCTs became the “gold standard” in clinical research (Bothwell et al., 2016). However, RCTs can be costly, time intensive, lack external validity, and delay approval of the drug being studied (Bothwell et al., 2016; D’Avolio et al., 2012). To counter these challenges, new and innovative research designs are coming to the fore (Bothwell et al., 2016). Point-of-care research (POCr) is one of these new and innovative research designs. The POCr research design arose out of a desire to maintain the strength of randomization—eliminating biases—while attempting also to eliminate the disadvantages of RCTs (D’Avolio et al., 2012). POCr seamlessly embeds research into routine clinical care (at the bedside or in the doctor’s office) at the point where clinical decision making occurs in order to compare clinical practices in equipoise (Weir et al., 2014). This is accomplished using a randomized observational research design (D’Avolio et al., 2012).

The Veterans Health Administration (VHA) is an exceptionally conducive setting in which to develop and test these new and innovative research designs because of its nationally integrated system and electronic medical record. VHA has a growing interest in conducting POCr as part of a

larger effort to advance itself as a learning health care system. A “learning health care system” integrates generalizable knowledge into the clinical delivery process in order to advance patient care (Olsen, Aisner, McGinnis, 2007, p.6). One of the first POCr trials conducted in a VA setting compared the effectiveness of two differing standards of diabetes management care (D’Avolio et al., 2012). Diabetic inpatients were randomized to receive either a sliding scale or weight-based insulin regimen at the point when a clinical decision needed to be made regarding how insulin was going to be administered (D’Avolio et al., 2012). The authors reported an enrollment rate of 28% for physicians who were asked to facilitate patient recruitment and 61% for patients (D’Avolio et al., 2012).

Benefits of POCr include more rapidly improving health care outcomes and bringing down costs of research by comparing medications and therapies as they are routinely used in clinical settings (D’Avolio et al., 2012). Efficiency is a driving factor behind POCr; yet, greater research efficiency through clinical integration presents a range of challenges. One issue is whether patients and physicians are willing to participate in research that is highly integrated into clinical care. As noted in D’Avolio and colleagues’ (2012) POCr study, over half of the patients were willing to participate and approved of randomization. However, D’Avolio et al. (2012) suggest that physician reluctance to randomly assign, rather than purposefully select patients’ therapies, appears to be an impediment to POCr (D’Avolio et al., 2012). In another study, Weir and colleagues (2014) conducted focus groups and telephone interviews with VA physicians about POCr. They found that physicians were concerned about POCr because of its unfamiliarity, the validity and reliability of this type of research, added workload, and the effects of POCr on their relationships with patients (Weir et al., 2014).

Another issue is whether or not POCr should be conducted with or without informed consent. Informed consent is an established ethical and legal protection against involuntary research participation (45 C.F.R. §46.116) and the practical application for the ethical principle of respect for persons (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research [National Commission], 1979). Nevertheless, consent processes can be time- and cost-intensive, as well as difficult to implement, in order for patients to adequately understand their options (U.S. Department of Health & Human Services and The Food and Drug Administration, 2015). Proponents of learning health care systems have suggested that informed consent is burdensome and unnecessary in the case of minimal-risk research, including POCr, and thus should not be required in certain instances (Faden, Beauchamp, & Kass, 2014). However, institutional review boards (IRBs) have tended to be conservative in their assessment of the need for traditional informed consent in POCr given requirements of the Common Rule, 45 CFR 46.116 (McKinney et al., 2015). Members of the public also appear to prefer informed consent. In fact, Weinfurt and colleagues (2016) conducted six focus groups with English-speaking adults living in five U.S. cities to assess their views regarding POCr. They found that individuals generally wanted to be told that they were participating in research and that there was support for some sort of informed consent process.

Recently, efforts to revise the Common Rule proposed an exempt category for “research involving benign intervention” (U.S. Department of Health and Human Services [US DHHS], 2017, p. 7185), which would encompass most POCr. However, the final version of the revised Common Rule limits this exemption to “research involving benign behavioral interventions” (US DHHS, 2017, p. 7190). Thus, nonbehavioral, more-than-minimal risk POCr in the future will likely need to be accompanied by informed consent. This means that informed consent remains a critical consideration in the ethics and implementation of much POCr.

Empirical data on VHA stakeholders’ attitudes toward informed consent, random assignment, and decision making in the clinical setting are needed, since there is very little literature on POCr in

the VHA environment. Therefore, the aim of this exploratory study was to identify VHA patient and physician attitudes and preferences with respect to these issues in POCr.

### Methods

The research design for this study is a qualitative case study. The limited availability of empirical data on POCr and its ethics necessitated such a design. Within this framework, we opted for focus group research given its suitability to exploratory work of this nature. Three focus groups were conducted at a Midwestern VA Health Care System (VAHCS), two with VA patients, and one with VA physicians. The researchers operated within the theoretical paradigm of ethical constructivism, “which holds that there are moral facts and truths, but insists that these facts and truths are in some way constituted by or dependent on our moral beliefs, reactions, or attitudes” (The Cambridge Dictionary of Philosophy, 1999, p. 283). In ethical constructivism, the investigator and the variable being studied—in this case attitudes and preferences toward POCr—are interconnected (Guba & Lincoln, 1994, p. 111). This means that the results of the study are generated as the investigator interacts with the participants (Guba & Lincoln, 1994, p. 111). The main goal of ethical constructivism is to extract a consensus of thoughts on a particular topic that is more advanced and enlightened than what was previously known (Guba & Lincoln, 1994, p. 111–112). The theoretical paradigm of ethical constructivism supports the use of focus groups since this methodology is well-suited to the elicitation of peoples’ various perspectives on given issues (Krueger & Casey, 2000).

#### *Recruitment*

Criterion sampling was used to select 90 patients from a Midwestern VAHCS who met the following pre-determined criteria: veteran status and scheduled for primary or specialty care clinic visits (with the exclusion of mental health) at the selected VAHCS on the day of the focus groups. These 90 patients were sent a letter inviting them to participate in a focus group. The invitation letter stated that focus group participants needed to have the capacity to consent and be English-speaking. About a week after the invitation letter was mailed, the research coordinator (Shinkunas) followed up with a phone call. In total, the research coordinator spoke to 43 individuals (48%), which resulted in recruiting 16 veterans. The research coordinator re-contacted these 16 individuals a few days before the focus groups. Out of the 16 originally interested in participating, eight were able to participate, four individuals in each group. Reasons for not being able to participate on the day of the focus group included changes to the patient’s appointment day or time and lack of transportation to the VA.

Two different recruitment strategies were used for physicians: (1) criterion sampling and (2) convenience sampling. In the first recruitment strategy, two rounds of a mass email were sent to all physicians employed at the selected VAHCS. Interested individuals were asked to click on a link within the mass email and complete a brief screening and scheduling survey. Due to a suboptimal response using this recruitment approach, we added a targeted email that involved directly recruiting for a specific focus group date from a pool of available individuals until at least six VA physicians had agreed to participate. All six physicians participated on the day of the focus group. Pre-determined criteria included: resident, fellow, or faculty appointment at the selected VAHCS and primary clinic duties at the VA.

#### *Data Collection*

Focus groups were structured around several scenarios with respect to the integration of research into VA clinical care. To focus discussion on a concrete example, each scenario addressed chronic hip pain (see Box 1 and Box 2). Musculoskeletal infirmities are among the three most common health problems for veterans (Epidemiology Program et al., 2017); the research team concluded that both

patients and physicians from various backgrounds could likely relate to a scenario involving chronic hip pain. The focus groups were moderated by the two principal investigators experienced at focus group research (Reisinger and Simon). Moderator involvement included presentation of the scenarios and posing questions in a conversational style in order to promote discussion.

In the patient focus group, the first scenario had four discussion questions and the second scenario had seven. In the physician focus group, the first scenario had two discussion questions, the second and third scenarios had four. The discussion questions were focused on the perceived advantages and disadvantages of scenario attributes including clinical decision making, randomization, and methods of informed consent as related to POCr. For instance, after reading scenario two, the moderators asked patients the following question pertaining to the attribute of informed consent: “Do you think it is necessary for the researcher or the doctor to ask patients if they want to be in the research study, or would it be okay to just include them?” Similarly, after reading scenario two in the physician focus group, the moderators asked the following question pertaining to the attribute of informed consent: “How important, if at all, would it be for patients to be given a choice about participating in a clinical trial like this?” All discussion questions were open-ended and were arranged under each scenario from general to more specific. The questions were asked in as neutral a way as possible, so that the moderators would not bias the discussion.

The first author (Shinkunas) was present at the two patient focus groups to observe and take notes. No research assistants were present at the physician focus group. The focus groups were audiotaped and the audio files were transcribed by a research assistant working for one of the principal investigators (Reisinger) and verified by the first author (Shinkunas).

#### *Data Analysis*

We conducted a qualitative content analysis of the three focus groups. Qualitative content analysis is “a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns” (Hsieh & Shannon, 2005, p. 1278). There are both deductive and inductive forms of qualitative content analysis (Elo & Kyngas, 2007). We used an inductive qualitative content analysis approach, which means that the thematic categories stem directly from the focus group transcripts and not previous work on the topic of attitudes and preferences toward POCr (Elo & Kyngas, 2007).

Two coders (Shinkunas and Craig) independently reviewed and coded the three focus group transcripts. This approach began with the coders independently reading each transcript from start to finish; a total of 61 typed pages were processed. Then, the coders met to identify themes they felt emerged from discussion of each scenario and developed a first round of coding. These emerging themes may or may not have emerged as a result of the questions that were asked; hence, the themes are not considered *a priori*.

In order to enhance coding credibility, the coders used persistent observation and triangulation (Korstjens & Moser, 2018). Using persistent observation to pinpoint attributes related to attitudes and preferences toward POCr, the coders adapted an iterative process whereby they read and re-read the transcripts and revised the themes until consensus was reached. Investigator triangulation was used given that two coders independently coded the transcripts and were involved in thematic coding and analysis. With the intention of enhancing dependability and confirmability, the coders met with one of the principal investigators (Simon) to discuss the emerging themes and resolve any discrepancies. Data was managed using nVivo, qualitative data management and analysis software (QSR International Pty Ltd, Version 8, 2008).

### **Box 1. Patient Focus Groups.**

**Scenario 1:** Let's say there are two different medications to manage chronic hip pain. Doctors commonly prescribe both of these medications to patients with chronic hip pain. Sometimes they prescribe one medication; sometimes they prescribe the other one. There is no scientific proof that one medication is better or worse than the other. Both medications are covered by medical insurance and both are officially approved for managing chronic hip pain.

**Scenario 2:** Now let's imagine researchers want to learn more about these two medications for chronic hip pain. They want to find out which medication is better at managing chronic hip pain, and which one has fewer side effects. They will ask doctors who treat chronic hip pain to put their patients into the research study.

### **Box 2. Physician Focus Groups.**

**Scenario 1:** Let's say there is a doctor at the VA who has a patient with chronic hip pain. Both the doctor and the patient agree that long-term pain management is needed. The doctor is considering one of two medications. Both medications are commonly prescribed for chronic hip pain. Both are covered by insurance and both are approved by the FDA for this use. The doctor keeps up with the latest scientific information on treating chronic hip pain. However, he is not aware of any research showing conclusively that either medication is more effective than the other, or that one is any safer (i.e., has fewer or less serious side effects) than the other.

**Scenario 2:** Now let's imagine researchers want to compare these two medications for chronic hip pain in a clinical trial. They plan to randomize patients with chronic hip pain to receive one or the other medication for several months. They will use only patients who have not yet taken either one of these medications. They will periodically evaluate the patients for indicators of medication efficacy and side effects.

**Scenario 3:** The researchers are interested in streamlining patient recruitment for their study on chronic hip pain. They want to piggy back on the electronic system that clinicians use to order medications for their patients. In this approach, clinicians would get an electronic message that says, "Chronic hip pain trial. Randomize patient to medication A or B. Choose this option if there is no preference for medication." Alternatively, the clinician can opt to proceed with usual care and keep the patient out of the clinical trial.

## **Results**

### *Participants*

Four veterans participated in each focus group for a total of eight. The first focus group was 53 minutes long, and the second focus group was 55 minutes long. All participants were white, non-Hispanic males. The median age was 67 (range 49–88). Education level varied with one participant attending some high school, one high school graduate, four attending some college, and two with a college degree.

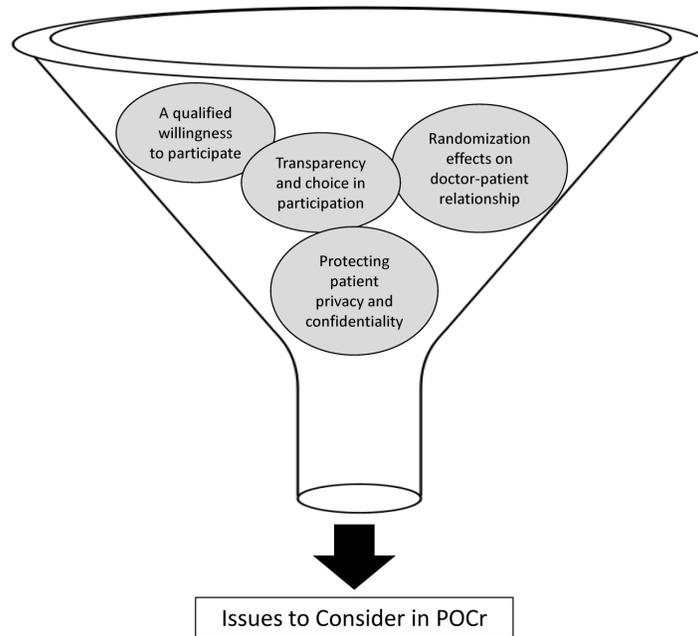
Six physicians took part in one focus group lasting 52 minutes. Four participants were female and two were male. One physician was a resident; the other five were faculty members. One physician

was from cardiovascular medicine, three were from general internal medicine, one from general surgery, and one from pulmonary, critical care, and occupational medicine.

*Focus Group Themes*

Four primary themes were evident in the focus group data: (1) a qualified willingness to participate in POCr; (2) the doctor-patient relationship as a context for POCr; (3) transparency and choice in POCr participation; and (4) protecting patient confidentiality and privacy (see Figure 1). Each of these four themes is described below with illustrative quotations from the data.

**Figure 1. Primary focus group themes: Issues to consider in POCr**



**Focus Group Theme 1: A qualified willingness to participate in POCr.** Both patients and physicians were by-and-large receptive to POCr and expressed a hypothetical willingness to participate. Among patients, this willingness was at least in part attributed to their backgrounds as veterans. As one veteran explained:

*Most people are all about themselves, and, as fellow military people, we signed the dotted line. We already signed our life away, you know, so we just, you know, we, we don't mind helping other people, or none of us would be sitting here.*

For some patients, the question of whether or not they would actually participate in POCr was dependent on a number of issues, including:

- a) Impact of the research study on current medications: *I would participate, but I think I would need maybe a week or two to do some research on my own about the products that I'm going to take and whether there would be side effects. If there are no problems and I foresee no problems, I would have no problem participating in the study.*
- b) Honesty: *If they were honest with me up front what they were doing, I'd probably participate.*

- c) Allaying fear: *I think others, uh, basically what keeps 'em away from research is fear. You know? It, it's, when you're researching, that one word that comes underlying is, uh, unknown, so they don't know what all of the side effects or risks may be.... I think the biggest thing that keeps people out is fear.*
- d) Type of medical condition: *Yes and no—depends on what it's for and with me, if it's, um, if I had cancer, I'd have no problem being a guinea pig, but....*

Physicians in turn, were largely supportive of POCr in view of the comparative effectiveness data they felt would flow from POCr and help reduce uncertainty or ambivalence about specific medications. One physician stated:

*But still, in clinical practice, I never feel like our evidence is a hundred percent...so, if I look at it from that way, then this doesn't seem problematic, even though I can see the other sides. Cause I think it recognizes and clearly articulates, 'We don't know if this is going to help you. We have enough uncertainty; we think either option is safe. Are you willing to be part of this and help us all figure out if, for a patient like you, one of these is better than the other?' That's what we're doing.*

However, physicians did have concerns with respect to the design of POCr studies, including questions of external validity, bias, and generalization in POCr. Randomization in POCr also troubled physicians, with one putting it this way: *Flipping the coin...bothers me a little. I can't really put my finger on it.... We don't have their [patients'] opinion and we're just flipping a coin. But then I understand that by [getting the patient's opinion], you may be introducing a lot of bias.*

Thus, both patients and physicians in this study were in general supportive of and hypothetically willing to participate in POCr, but not without considering factors ranging from health impact to patient opinion and the science of POCr.

**Focus Group Theme 2: The doctor-patient relationship as a context for POCr.** The doctor-patient relationship and particularly the physician's knowledge of the patient emerged as an important context for both patient and physician reflections on the topic of POCr.

Patients stressed that it was vital for their physicians to “know them” and the various medications they might be taking, for example: *In my opinion, the best way to [prescribe medications] is to know the patient; know the other medications that they're taking, if there is any interactions....So they have to take all of that into consideration before they prescribe.*

Another patient said: *...my primary knows my history. He knows that a lot of stuff upsets my system. He'll go with the medication that is less likely to, um, mess up my system.*

Patient trust in their physicians was seen as a key dimension of the doctor-patient relationship in situations where medication changes were being considered. One patient alluded to such trust as follows: *I take so many [medications], I want to be sure that I'm not doing something that's gonna harm me. I think the doctor knows best once he's consulted your record, consulted your allergies, and what have you.*

For physicians in the focus group, the doctor-patient relationship was viewed as an important basis for shared decision making, respecting patient preferences, and treatment adherence. Physicians admitted having personal preferences with respect to certain medications that may or may

not be supported by evidence, for example: *...in all honesty, sometimes we have personal preferences....we have more experience with one medication versus the other.*

Whether or not physicians prescribed a medication based on personal preference, however, depended on their view on many factors including patient condition, medication cost, medication side effects, and patient preference. Physicians in our focus group agreed that doctor-patient communication was a vital element of their prescriptive practices. One physician said, *The patient usually will guide you toward one or the other [medication]. I don't think I've ever been in a situation where they haven't had an opinion.*

When two medications were equally good candidates for a patient based on cost, side effects, and anticipated outcomes, physicians agreed that patient preference should be an important deciding factor. One physician said, *Frankly, I tend to present...both medicines to the patient and ask [for their] preferences....I think that's a reasonable approach.*

Our focus groups highlighted, therefore, that physician-patient relations, communication, and mutual trust are important elements of the context in which VAHC point-of-care research may occur.

**Focus Group Theme 3: Transparency and choice in POCr.** When presented with Scenario 2 (see Box 1 and Box 2) and asked for their initial thoughts about a study like this, patients said that it was important to be informed about the research and to be provided with a choice as to whether or not to participate. One patient said, *I'm thinking they need to tell you before they start and not just do it.*

Another patient indicated, *As long as it's volunteered.*

Transparency was considered important for letting patients assess the side effects of different medications. One patient said: *So, I think they have to be...a little bit more specific about the side effects, about whether it is a major side effect or one that just happened to one person in the study group. 'Cause I know if it happens to one person in the research group, it has to be put down as a side effect, possible side effect. And ...that confuses ya.*

When asked specifically if patients needed to be asked to be in a research study, or simply to be included without being informed, patients felt that there was an unconditional need to be informed and asked before being enrolled in a research study. One patient said: *As an American citizen, I have the right to decide what I'm going to do and that is: you ask me. I answer. You know? I'm sorry. I fought for that right.*

Another patient asserted, *I don't want to be a guinea pig unless I say 'Okay.'*

Informed consent was considered important particularly in the case of research that might involve a change in medications for patients. One patient characterized this importance as follows:

*And then there's a bunch of people out here that are like me. I've got several different things wrong and you try this [new] medication—how bad is it gonna screw up the rest of your medicine? So that's why I said volunteer.*

However, while patients agreed that it was important to be informed about any research involving them, not all patients foresaw a need to be consented. One patient, for example, took the position that, *...as long as I was advised that that was the way it was going to be, I don't know that I would necessarily have a problem with it, but I would like to know.*

Physicians in the study agreed that informed consent was important in the case of most research, including POCr. They talked about the low-risk nature of POCr and the need for streamlined implementation of POCr, but also that informed consent was a means of respecting patient participation in research, regardless of the nature and needs of the research. One physician summed up this theme when he said, *I still think a patient should have the choice to be involved in a study or not, regardless.*

Physicians pointed out that informed consent was not only an established mechanism for facilitating voluntary participation in research, but a context for eliciting patient preferences about treatment. For example: *It [informed consent] allows for my understanding of the patient's preferences...for a discussion to come into play about medications.*

Physicians appreciated the challenges of obtaining informed consent, however, and suggested that perhaps a type of “blanket consent” needed to be considered in order to streamline low-risk, comparative effectiveness POCr. Responding to this suggestion by a colleague, one physician said:

*I think it's a great idea. If they have signed a general consent and then go from visiting with the physician to the pharmacy that is their time to make up their mind, even if it's 24 hours. They can opt out the whole time. [M]aybe that would be a way of streamlining this type of research.*

To summarize, patients and physicians in our study viewed the opportunity to opt for participation in POCr as important and necessary for purposes of respecting patients' right to choose participation in research. Physicians suggested this was the case even in low-risk, comparative effectiveness research, but that prior blanket consent might streamline the decision-making process.

**Focus Group Theme 4: Protecting patient confidentiality and privacy.** Discussion in the patient focus groups turned to issues of confidentiality and privacy when participants were asked for their reactions to the possibility of researchers accessing their personal health records for use in research.

On the one hand, there were patients who felt such access should occur only with a patient's consent, for example:

*I don't think anybody ought to get my personal information without me being aware of it. I don't care who wants it or why. Uh, without my permission, you don't need it and if I don't want you to have it, you shouldn't have it.*

On the other, there were patients who perceived no need to be consulted as long as the researcher in question had the appropriate credentials to access their information, for example:

*...the person has to be qualified to do this research before they come in. In that case I would have no problem with them looking at my records and, to help them determine what they're gonna do. I think it's important that they do.*

Another patient said:

*So, I don't have any issue with that 'cause you need to do it—but what I don't want you to do is run down here to the local tavern and have a conversation, 'Hey, guess what we did today? Well, I went through this guy's record and he's got this problem, this problem.' You know? And, and that's not something I want.*

Physicians were not asked explicitly about privacy and confidentiality, nor did their discussions turn to these issues emergently during the focus group discussion.

### Discussion

We conducted an exploratory study using focus groups to identify VA patient and physician attitudes and preferences to various issues raised in POCr, such as clinical decision making, randomization, and informed consent. The study also compared VA patients' perspectives to VA physicians responsible for treating these patients clinically. Overall, patients' and physicians' perspectives aligned. Both groups expressed a qualified willingness to participate in POCr. Both discussed the patient-provider relationship, transparency, and choice as key factors that need to be considered. Only the patient group discussed patient confidentiality and privacy as a key factor; however, it is important to note that physicians were not explicitly asked about these issues. The physician-patient relationship and its complex dynamics are at the center of POCr, where research and clinical care meet. As Sacristan and Dilla (2015) have commented, the primary goal of clinical care—the well-being of the patient—and that of research—generalizable knowledge—have the potential to conflict. Thus, the integration of research into routine clinical practice requires consideration of the physician-patient relationship as well as various regulatory and ethical factors.

Evidence suggests that the physician-patient relationship, and particularly communication between doctors and patients, has a significant effect on health care outcomes (Kelley, Kraft-Todd, Schapira, Kossowsky, & Riess, 2014) and quality of care (Roter & Hall, 2013). Our small exploratory study sampling physicians and patients suggests that the doctor-patient relationship and its complex dynamics of communication and mutual trust are important elements within the context of POCr, particularly where randomization supplants clinical decision making.

As emphasized in the introduction, another issue in POCr is informed consent. Recent calls for waivers of consent or simplified consent processes on the basis of minimal-risk assessments of POCr (e.g., McKinney et al., 2015) have generally overlooked the impact that POCr can have on the physician-patient relationship. In particular, if random assignment is a component of POCr, there is no longer a need for shared decision-making with respect to a patient's treatment options. Patients and physicians may still wish to meet, as feedback in our study suggests, in order to discuss the option of participating in a POCr study—as required in a face-to-face informed consent process. It is possible that the support expressed in our study by physicians and patients for informed consent is a response to the diminished need for shared clinical decision making in the case of randomized POCr.

Our study identified two themes that are at the center of informed consent: (1) transparency (i.e., creating awareness of the research by informing the patient about it [Dickert, Llanos, & Samady, 2012]), and (2) choice (i.e., supporting an autonomous decision about study participation). The desire for transparency and choice may be particularly strong in a veteran patient population due to the history of research conducted among military personnel (Brown, 2009).

Another important consideration with respect to research participation is privacy, which entitles a person to regulate how one's personal information is used (McGraw et al., 2015). When a physician is transparent with his or her patients, provides them with a choice, and appreciates their privacy, he or she is acting in accordance with the ethical principle of respect for persons, which underlies the informed consent process (National Commission, 1979). Importantly, respect for persons "...give[s] weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions" (National Commission, 1979, p. 4). In other words, respect for persons recognizes the value that needs to be placed on patient preferences as well as the importance of communication and trust in the physician-patient relationship. Obtaining informed consent and protecting patient health information are two ways that exemplify respect for persons (Faden, Kass, Whicher, Stewart, &

Tunis, 2013). Thus, informed consent may provide an important opportunity for patients and physicians to establish rapport and trust through transparency, particularly in cases where random assignment removes the need for shared clinical decision making. This may explain why no patients or physicians in our study associated a low potential for harm in POCr as sufficient reason to waive an informed consent process. Both patients and physicians talked about the need to respect patients' rights to know about participating in research, regardless of research risk.

In addition to respect for persons within the patient-physician relationship, the veterans who participated in the focus groups had nuanced perspectives of how this translated as privacy when accessing patient records for research. Most of the veterans stated they had few concerns with researchers accessing their records as long as they held the appropriate credentialing and did not share personal health information outside the research consent. However, one participant did not want anyone accessing his records without his knowledge.

This study demonstrates the challenges of collecting individuals' perspectives, particularly when not all perspectives can be integrated into cohesive interpretations or recommendations. In this case, numerous research studies exist and are approved by human subject regulatory bodies, which allow researchers to access administrative datasets comprised of patients' health records. Research based on administrative datasets makes important contributions to our health outcomes research. However, without randomization, these studies are hampered by unknown biases, pointing to the importance continuing to work toward balancing research needs and patient and physician perspectives.

The findings from this exploratory study are constrained by the following factors: (1) the study was conducted at only one VAHCS; (2) the sample size was small; (3) focus group participants were fairly homogeneous; (4) focus group volunteers may be more likely inclined to endorse POCr research than those who refused to participate; and (5) the scenario of two treatments equal in perceived effectiveness, cost, side effects, and physician preference may be uncommon and still relatively hypothetical. Future research with larger, more diverse groups of VA patients that use different strategies to elicit views on POCr will be important to corroborate and expand on the findings of this study.

### Conclusion

POCr has the potential to accelerate improvements in healthcare effectiveness through the integration of research with routine clinical practice. This exploratory study among a sample of VA physicians and patients is a first step in providing empirically grounded recommendations for achieving ethical, respectful, and transparent POCr. Our study suggests that POCr may be perceived as intervening or undermining the doctor-patient relationship in cases where randomization supersedes clinical decision making, or where a waiver of informed consent may lessen the need for physician-patient interaction. Our study shows that informed consent is seen as meaningful in POCr because it offers a way for patients and physicians to establish rapport and trust, particularly in cases where randomization removes the need for clinical decision making. An important next step would be to assess VA patient and physician perspectives on POCr more broadly.

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