

Title:

**Primary care physicians' views about gate-keeping in clinical research
recruitment: a qualitative study**

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Abstract

Clinical research is increasingly being undertaken in primary care. This development offers both benefits and challenges. The ethical challenges of occupying the roles of both clinician *and* researcher may be accentuated in primary care, where relationships are longer-lasting and medical conditions are less acute. This paper examines primary care physicians' experiences of undertaking research, particularly their decision-making about recruiting patients in the context of their own dual roles.

Methods

This project comprised in-depth interviews with eight Australian primary care physicians working in general or specialist practices that were involved in clinical research. Data were analyzed using inductive thematic analysis.

Results

Physicians involved in recruiting their patients into clinical trials acted as gate-keepers; they were selective about which patients to recruit and did not necessarily approach all patients who met the research eligibility criteria.

Physicians' accounts suggested they prioritized their clinician role over their researcher role. In addition to the rigor and merit of the research, physicians considered the possible benefit of trial participation for individual patients.

Physicians described making recruitment decisions based on their perceived knowledge of patients' personal, behavioural, and attitudinal characteristics – often derived from their long-standing relationships with their patients.

Conclusion

Our data shows evidence of gate-keeping by primary care physicians when deciding to participate in, and recruit their patients to, clinical studies. We argue that such gate-keeping is a way of addressing the dual and sometimes conflicting roles of clinician and researcher. It need not be ethically problematic, but primary care physicians should be reflexive about their recruitment practices and biases. In addition, this form of gate-keeping should be explicitly recognized in protocol design and the analysis of trial findings.

Keywords

Research in primary care; physician researchers; recruitment practices; ethics; dual roles.

Introduction

General practice remains the most frequent point of initial contact with the healthcare system in many countries. For example, in Australia, 81% of the population accesses primary care annually.¹ Primary care is increasingly seen as an important research environment and a source of research participants.² The types of research conducted within primary care are broad ranging and include, for example: attitudinal studies; research on patient experiences of treatments and interventions,³ and large scale clinical trials (for example ASPREE⁴). The increasing amount of clinical research being conducted in primary care is an international phenomenon, with over 70% of trials in the US in 2012 citing primary care or community physicians as investigators.⁵

Clinical research sponsors have turned to primary care for a variety of reasons, including: the ability to provide multiple sites enabling access to large numbers of participants;² primary care patients may have fewer health challenges compared to non-primary care patients; and research into pharmaceutical and treatment interventions for use in primary care is more robust if undertaken within the target population.⁶ This move towards research in primary care is coupled with increasing emphasis on the need for evidence-based practice in primary care settings.^{7, 8}

For physicians, primary care research offers possible monetary benefits and professional development opportunities, as well as wider benefits to their patients and communities.⁹ Cook and Hoas report that physicians believe that primary care research is good for patients, science and clinical practice.⁵ In addition, patients who participate in research may benefit from early access to new treatments¹⁰⁻¹² and increased monitoring associated with many clinical trials.^{5, 13}

However, there are also recognized challenges and complications of undertaking research in primary care. The dual roles inherent in clinical research – clinician/researcher and patient/research participant – have been recognized as an ethical issue since the 1950s.¹⁴ Dual roles are problematic because the clinician-researcher has to work within two traditionally distinct ethical paradigms: medical (clinical) ethics, where priority is given to individual patient care and wellbeing, and research ethics, where a commitment to the methodological integrity of a clinical trial is maintained for the production of new knowledge for a future benefit.^{5, 14, 15}

Two broad categories of ethical issues associated with dual roles have been discussed in the literature. First, role conflict has the potential to lead to clinician-researchers failing to fulfil their basic obligation as clinicians to act in the patient's best interests, particularly to avoid exposing the patient to unnecessary or avoidable risk of harm.¹⁶ Second, a lack of clarity may result in patients being confused about the roles of researcher and clinician, and this may lead them to fail to distinguish between research and treatment.⁵ Van der Graff et al note the tension between researcher and physician roles arising from the fact that intervention risks which are deemed acceptable to research participants would not be acceptable for patients.¹⁷ Some studies show that physicians involved in clinical research do not always recognize that they have dual, and potentially conflicting, roles.^{13, 18}

In this paper, we explore why primary care physician-researchers participate in clinical research, and how they decide which of their patients to approach about research participation. We argue that the primary care physicians we interviewed engage in gate-keeping as a key strategy for dealing with dual roles. As we go on to demonstrate, this gate-keeping occurred at both the clinic level and the individual patient level. We use the term 'gate-keeping' here to mean the process by which physicians choose not to participate in a clinical

study, or to recruit individual patients who would otherwise be eligible to participate in clinical research studies. We suggest that this practice of gate-keeping is not necessarily ethically problematic, but needs to be reflexive and transparent.

Methods

The findings reported in this paper are from a larger qualitative study that examined physicians' and patients' views on their participation in clinical research in a primary care setting. The total sample comprised 18 participants: eight primary care physicians (hereafter physicians) (seven men and one woman), nine patients who had participated in research, and one clinic research co-ordinator. Participants were from four primary care clinics in a major Australian state capital city. The primary role of all participants was direct patient care, with research occupying a secondary role. All were involved in recruitment to clinical studies, but none were involved in study design or initiating the research. This paper reports on the findings from the physicians only, with the findings from the patient interviews reported elsewhere.¹⁹

The primary care clinics were selected using purposive sampling, to capture general and specialist (for example, women's health) primary care practices

who were involved in clinical research. Contact with the clinics was established through primary care research networks and public listings. If a clinic demonstrated interest in participating, a member of the project team met with the Director of the clinic to inform them about the project. Once the clinic Director agreed to be involved, physicians (and patients) were approached by the clinic's research co-ordinator, on behalf of the research team. A member of the research team then contacted those who agreed to participate to arrange a time for an interview.

Interviewees were given the choice of face-to-face or telephone interviews. All but one chose face-to-face interviews. All interviewees gave written consent prior to participation in the project. The physician interviews were conducted by two members of the research team (RM and MG), both of whom are experienced qualitative researchers. The interviews with physicians were 25-60 mins duration, audio-recorded with participants' permission. Interviews included questions about their experiences, specifically the types of research to which they had recruited their patients; their role in the research (including the process of patient consent to participate); how they decided which patients to invite to participate; what they told patients about the trial; their own and patients' considerations for participating in research; and, the impact research

participation may have on the physician-patient relationship; (see Appendix for a list of key interview questions). Prompts enabled interviewers to follow up responses to questions and elicit detailed accounts. In addition to the interviews with physicians, members of the project team returned to the clinic following analysis of the data, to present the findings and to seek feedback. This enabled physicians to further contribute and engage in discussion with the research team about the project's findings.

The data collected from interviews were analyzed using thematic analysis. This method of analysis results in the generation of common themes and provisional hypotheses from the data.²⁰ Each interview transcript was independently coded by at least two members of the research team who have expertise in thematic analysis. The codes from each transcript were then organized into a system of patterns, from which more generalised themes were elicited. The themes generated were systematically checked across each of the transcripts by different members of the research team to ensure veracity. All members of the research team took part in the generation of themes in the analysis. Approval for the research was given by the institution's Human Research Ethics Committee (HREC number 1238873).

Results

All physicians in our study had been involved in recruiting patients into a clinical study that they had not initiated. That is, the studies were externally designed, and the Principal Investigators had approached the primary care clinic to seek their involvement in recruiting their patients. It should be noted that in the clinics involved in our research, individual physicians could opt out of recruiting to a particular study, even if other doctors in the clinic had decided to take part.

In this section we focus on a number of key findings. When discussing their experiences and involvement with research, the physicians described themselves as adopting a gate-keeping role with regard to research. This was a key way in which they approached the ethical challenge of dual roles. Their accounts suggest that two types of gate-keeping occurred. First, at the level of the study, there were gate-keeping decisions about the studies in which the clinic, or the individual doctor, agreed to be involved. Second, gate-keeping occurred at the level of the particular patient; physicians made case-by-case decisions about whether to offer recruitment information to a specific patient who was eligible for study participation.

Gate-keeping at clinic level

There were two key issues of importance to physicians regarding whether their clinic as a whole, or their particular patients, should be involved in a clinical study; firstly, whether there would be clinical benefits for their patients, and secondly, whether they regarded the study as worthwhile in research terms.

Physician #2 summed this up:

You basically look at what the trial offers the patients, whether we're likely to have patients who could benefit or whether it's addressing an interesting or important clinical question. (#2)

Concern about the scope for patient benefit, and perhaps more importantly, avoiding exposing patients to harm was described more fully by Physician #5.

I wouldn't participate in a trial that is very early stage in development, so Phase 2 or something like that, where you know serious problems cannot be excluded. So I'd really want to be sure that I don't do harm to my patients. And also I don't like trials where you know it's not really anything beneficial for the patient because we get all the drugs already that do the same job. (#5)

Physician #2 described how they had decided to become involved with clinical trials in the past in order to provide therapies that were life saving for patients, and where patients would otherwise not have access to them.

Like ten or fifteen years ago, we desperately needed the next new drug to save lives literally, because people were dying and, and often used up all their options and the currently available [therapies] were not holding them and their health was declining. There have been quite a few trials over the years where it's the patients' lives quite literally, it sounds dramatic, but their lives have been saved by getting them onto a trial of a brand new drug. (#2)

In addition to clinical benefit to patients, the physicians interviewed said that when recruiting patients they also considered factors related to the rationale and quality of the proposed research. Physicians also reported considering whether sufficient information was provided about the research to allow them to make an informed assessment of the study and whether they believed they would be able to recruit sufficient patients from their clinic population. Physician #1 succinctly set out all of these considerations:

We assess the proposals as they come in and think whether one, [it] is feasible and secondly, whether their rationale makes sense and there's enough information....In reality there's some trials that if you think are really hard to recruit, nothing wrong with the design, but if I think at the

most we recruit one person, it's not really worth all the effort for all that – and others have got unfortunately flawed rationales or flawed design which even looking at them now you sort of think you're not going to answer the question by this design so it's pointless going through all the effort. (#1)

The benefits of the knowledge produced by a scientifically worthwhile study were also noted.

There's a new drug coming out and it's going to be another option as a single tablet regimen and it's looking really favourable in its phase two stuff so I like to participate in those sorts of trials because they're answering really important questions. (#4)

I'm particularly interested in the newer drugs that are coming out, obviously if things can improve patient compliance or control X condition better I think it's worth investing in those sort of trials. (#3)

Some drug trials appeared to physicians to be financially motivated, and they decided against involvement in them because of the lack of research merit, and (by implication), lack of benefit to patients.

Some of them, we opt not to go on; there have been a few trials in recent times that really almost look like marketing exercises of trying to get people onto a new drug that doesn't necessarily really offer a great breakthrough ... I'm not so comfortable with those sort of exercises because the sponsoring companies, it's in their interest to get a whole bunch of people onto their drug. (#2)

Financial incentives did not appear to influence study involvement. Some physicians emphasized that they were not motivated by financial incentives in relation to research participation; they stressed that the most important factor in their decision making was whether, in their opinion, it was an ethical trial.

For me there's no financial incentive to recruit someone to the trial. I just don't even know if it's paying much at all of anything. And I think that needs to be an important aspect for primary care doctors in terms of recruitment and we've been aware of trials that pay a lot of money but we haven't agreed with the ethics of it and we've actually refused to do it seeing's it's not actually an ethical trial. (#1)

These findings demonstrate that gate-keeping practices were undertaken by physicians at the level of the clinic in relation to the clinical studies in which they

were willing to be involved. The following section focuses on the second type of gate-keeping, with regard to recruitment of individual patients.

Gate-keeping at the level of the individual patient

Research protocols stipulate inclusion and exclusion criteria for the recruitment of research participants. In our study, an additional layer of decision-making and selection was reported. Potential participants were first identified on the basis of the stipulated criteria in the study protocol; this was often done by the research clinic co-ordinator, who identified a potential pool or group of patients meeting eligibility criteria. However, the physicians reported that it was they who decided which of these potential patients they would inform about the research. If patients showed an interest, they were then referred to the research clinic co-ordinator who provided the details of the research and initiated the process of informed consent as part of recruiting them into the trial. Potential participants were given the opportunity to consider the information provided in their own time, and to ask further questions of the research clinic co-ordinator before deciding whether or not to participate.

One key consideration for physicians in recruiting potential participants was protecting patients from harm. The following physician framed this as a

paternalistic element in choosing not to give information about the research to some eligible patients.

It can be difficult but I guess part of the fact of being a doctor, there is that paternalistic element as well and therefore that's why some doctors choose not to give patients the option of even entering some studies because they're trying to think that, this is my patient, I want to protect a patient. (#3)

A number of physicians discussed the need to establish whether or not a patient was likely to be harmed based on their individual circumstances, even if the patient met the inclusion criteria. This was particularly evident in relation to drug trials.

Was there anything from their history that would make me feel uncomfortable for them either not to be on, or to be on [Drug X]. So there were people in that study who you know when they came, they passed all the inclusion/exclusion criteria by the nurses, the researchers; they had to actually come to the doctor and the doctor then would decide whether they'd be a suitable candidate looking at their risks. So some of the people you know, I said, well look, I'm not really happy for you to go

off [Drug Y] because of your family history and your long standing condition. (#6)

Some physicians considered whether particular patients would be good candidates for clinical trials in terms of their behavior and perceived compliance.

People who miss their appointment frequently, people who aren't very good at taking their medications, people with drug and alcohol issues, people with mental health issues, people who struggle to get here basically would not be good candidates for a clinical trial. (#4)

These clinicians focussed on particular character traits, such as patients being reliable, suggesting their recruitment decisions were motivated by archetypes of the 'good' trial candidate.

If they're very chaotic and unreliable and they're not keeping their appointments, they're coming for the blood tests irregularly, they're already not taking their pills properly, you know they will not be suitable for something that's even more demanding. So definitely it's more the chaotic patient [who would not be offered the opportunity to participate]. (#5)

Another physician discussed patients' availability to take part in the research as an important factor for consideration:

We just in our mind screen: is this person suitable; is this person going to be around; if people travel a lot for work, aren't going to come in every few weeks for a trial visit; people work very fixed hours and have difficulty coming in for their normal consult ... (#1)

An interesting counter-point here is one physician who discussed the opportunity to enroll "chaotic" patients into trials to create a therapeutic structure to their health care:

... I can think of a number of young guys who have pretty chaotic lives: maybe using drugs and a bit erratic and all over the place. Sometimes putting them on a trial, getting them onto a trial, is the best thing that can happen to them, they start to feel some structure in their medical care.
(#2)

These considerations are all based on the physician's sense of an individual patient's interests and attitudes, derived from their often long and close clinical

relationship. This was noted by physicians from both general and specialist primary care clinics.

You know most of the people that I see I've known for many years so I know them very well and they know me very well, so I think it's just another phase in the relationship that we have. (#6: General primary care)

But I guess our patients are different because ...we're very connected so we have a very close relationship and, and then often it's built up over many, many years and so we have a lot of good will of patients but we also have a special relationship with a patient. You might be feeling a lot closer then maybe it's just a person who comes for coughs and cold. (#5 : Specialist primary care)

One physician explicitly discussed the challenges of their dual roles as researcher and clinician, particularly when recruiting patients.

I'm fairly conscious of the double hat I'm wearing and especially in trying to recruit patients. So often I would deliberately frame the language that 'you don't have to be involved, there's no change in your management if

you're involved in the study or not'...I don't want to be seen as forcing my patients to get involved. (#3)

This physician went on to give this concern as the reason for the clinic's practice of having someone else, usually the research nurse, undertake the informed consent process.

It's because of that dual sort of role for us, is that we don't want to be the one that's imposing the study and say 'sign on the line to consent', that's why we've deliberately separated that process. (#3)

As we go on to discuss, awareness of their dual roles may be an important consideration when interpreting physicians' gate-keeping practices.

In summary, while research protocols may be clear about inclusion and exclusion criteria for selecting participants, our findings show additional gate-keeping practices by physicians at the level of both the study and individual patients.

Discussion

In this paper, we have examined primary care physicians' accounts of why they become involved in certain research projects and how they decide which of their patients to approach for research participation. While research protocols may be clear about the use of inclusion and exclusion criteria for recruiting study participants, our findings show that gate-keeping practices were employed by physicians. Other scholars have discussed the practice of gate-keeping by physicians.²¹⁻²³ Although definitions of gate-keeping may differ depending on the context, they commonly refer to eligible participants not being invited to take part in research. Here, we define gate-keeping as physicians selectively choosing, in an ad hoc or a systematic way, not to recruit patients who would otherwise meet eligibility criteria for clinical studies.²³

The physicians in our study were clearly gate-keeping at the level of individual patients, as well as selectively choosing which studies the clinic would agree to be involved in. At the level of the clinic, physicians considered whether there would be clinical benefits for their patients, and additionally, whether the study was rigorous, worthwhile and ethical. At the individual patient level, physicians considered a range of different factors including the patient's clinical situation, time commitments required, and perceived personal characteristics such as a patient's reliability.

We suggest that the gate-keeping behaviors reported by these physicians may be a response to the ethical ambiguities generated by their dual roles as care provider and researcher. Our results suggest that the physicians in our study all had some degree of awareness of these two different roles they were playing when recruiting patients for clinical studies. One physician articulated this very clearly as “wearing two hats”. This awareness is important in itself, as it cannot be taken for granted that physicians recognise it. In an interview study of 82 participants (physician-investigators, nurse-study coordinators and patient-subjects) Easter et al found that clinicians regard their role as researcher to be part of their care role.¹³ Fisher undertook participant observation and interviews with private-sector physicians at 20 sites who were undertaking pharmaceutical studies.¹⁸ Fisher reported that some primary care physicians define ‘clinical care’ and ‘research’ so as to avoid conflicting roles or, alternatively, “assert that there is no difference between practicing medicine and conducting research”.¹⁸ Later analysis of this data illustrated that physicians did not apprehend the potential for ethical conflict arising from their dual roles of clinician and researcher.⁹

A crucial ethical issue is what physicians ought to do about this potential ethical conflict, once it has been recognised. The options are to step out of one role, or to retain both and find an ethically justifiable way to prioritise or negotiate the potentially conflicting ethical commitments. The physicians in our study recognised two roles. As care providers, their focus was on whether research would offer benefits to the patients they cared for, while as researchers, they wanted to contribute to clinical knowledge, and considered the quality of research design, the importance of its goals and its feasibility in their particular context. Where there were possible tensions between the values and obligations embedded in these roles, our interpretation is that the physicians prioritized the clinician role over the research role. This can be seen in the accounts they gave of gate-keeping, especially at the individual patient level. Potential benefits and risk of harm to their patients were key drivers of their decisions about which patients to approach for research, rather than the pursuit of knowledge or promoting the scientific success of studies by adhering strictly to the study protocol's inclusion and exclusion criteria.

Gate-keeping at the individual level has been observed by others and critiqued as problematic.²³ Seeking to protect patients from harm is a potential motivator for clinicians acting as gate-keepers in clinical research. If this is done to protect

patients from perceived risk of harm, it could be argued that is in accordance with the obligation of non-maleficence in *clinical ethics*. On the other hand, Sharkey et al argue that gate-keeping is unethical because it breaches accepted principles of *research ethics*.²³ More specifically, they claim that it violates the principles of autonomy, beneficence and justice in relation to patients who are potential research participants, but are denied access.²³

However, we suggest that the type of gatekeeping described in this study can be seen as an ethically appropriate response to the role conflict experienced by physicians. For this group of physicians, they would not introduce research into the physician-patient relationship unless they believed it to be clinically appropriate in terms of the needs of the particular patient. Rather than trying to fulfil equally the ethical commitments of both role, they made decisions about individual recruitment from a clinician role. This could mean either deciding not to approach patients whom they believed could not cope with the demands of the clinical trial, or would not benefit from it; or alternatively specifically approaching a patient because that patient would benefit from the routine required for the trial.

We suggest that this is an ethically appropriate prioritising of roles. When recruitment occurs in the primary care setting, the agents very clearly enter the clinical encounter as 'clinician' and 'patient'. There is often a long-standing relationship between physician and patient, one which primary care physicians encourage and value as part of these relationships contribute to the holistic, patient-centred care which these physicians provide. We suggest that it is not only futile to ask clinical researchers not to practice gate-keeping when recruiting patients, but also ethically inappropriate. Gate-keeping is a way for physicians to maintain their professional integrity by prioritizing the values and obligations of their clinician role over those of their researcher role. Rather than denounce this practice, we suggest clinical trial sponsors and investigators should accept it, and explicitly build it into study protocols; for example, by asking clinicians to document which patients they decided not to approach and why, as well as the patients' social and medical situation. This will enable study investigators to accurately describe the sample that was recruited and judge its representativeness. Otherwise, these practices remain invisible to study investigators.

Conclusion

Our findings point to the extent of gate-keeping undertaken by the physicians whom we interviewed, and identify some specific factors that were considered relevant by these physicians. The physicians interviewed routinely practised gatekeeping by prioritizing clinical care and therapeutic relationships over inclusion criteria and research protocols. The results highlight the different kinds of gate-keeping practices at the level of the clinic and the individual patient.

The limitations of this study were its small sample and the limited number of primary care clinics represented. Only eight physicians were interviewed due to time and funding limitations. Due to the small sample size, it is unclear if thematic saturation was achieved. However, we identified common themes across the transcripts. The methodology used gave rise to rich data that has led to important analytic insights. We acknowledge that physicians' accounts may be influenced by their desire to present in a good light; in this sense they may have produced an account of their recruitment practice that is driven partly by their understanding of what is ethical best practice in relation to research in the primary care clinic, as much as by what they actually do. However, their beliefs are informative, even if they do not fully reflect their practice. Their perceptions of what they take to be ethically appropriate recruitment practices is the starting point for our argument that gate-keeping in patient recruitment can be an ethical

response to the problem of dual roles in primary care research. To test our interpretation of the ethical role that gate-keeping is playing in primary care research, and to better understand the phenomenon, we advocate further research employing larger sample sizes, and extending to primary care settings involved in different kinds of clinical studies, across different speciality areas of primary practice.

The literature raises two key issues about dual roles: firstly the possibility of conflicts between the researcher and physician roles, and secondly the potential lack of clarity in distinguishing research from treatment from the patient's perspective. Our findings are significant for two reasons. Firstly, they provide additional insight in relation to one of the ethically concerning aspects of clinical research, that of managing the potentially conflicting dual roles in a justifiable way. Secondly, our focus on the primary care setting is important because of the increasing amount of clinical research being carried out in this setting. In addition, the primary care setting is characterised by long-term clinical relationships that exist between physicians and patients, which may make this setting different from the acute, tertiary hospital research setting. Primary care physicians may have a deeper familiarity with patient characteristics and lifestyle factors that could influence their gate-keeping decisions at the

individual patient level. For physicians, our results highlight the importance of being reflexive about their recruitment practices. Physicians need to be reflexively aware of biases and gate-keeping practices which could lead to some patients being inappropriately excluded from research from which they could benefit, or in which they may wish to participate. Training for clinician researchers needs to directly engage with the ethical reasons for gate-keeping during recruitment and selection of patients, and the potential ethical pitfalls.

As clinical research becomes more prevalent in the primary care setting, we recommend that both clinical trial designers and researchers reflect on these findings to better understand both the methodological and ethical challenges that primary care research presents, and to tailor the design of primary care research to address these. Researchers seeking to undertake studies in this context should be aware of these possibilities in order to factor them into the design of study protocols.

References

1. Brodaty H, Gibson LHR, Waine ML, Shell AM, Lilian R and Dimity C. Research in general practice: a survey of incentives and disincentives for research participation. *Mental Health in Family Medicine*. 2013; 10: 163-73.
2. Bodenheimer T. Uneasy alliance - Clinical investigators and the pharmaceutical industry. *The New England Journal of Medicine*. 2000; 342: 1539-44.
3. Peek CJ, Cohen DJ and deGruy III FV. Research and evaluation in the transformation of primary care. *The American Psychologist*. 2014: 430.
4. Lowthian JA, Britt CJ, Rance G, et al. Slowing the progression of age-related hearing loss: Rationale and study design of the ASPIRIN in HEARING, retinal vessels imaging and neurocognition in older generations (ASPREE-HEARING) trial. *Contemporary Clinical Trials*. 2016; 46: 60-6.
5. Cook AF and Hoas H. Clinicians or Researchers, Patients or Participants: Exploring Human Subject Protection When Clinical Research Is Conducted in Non-academic Settings. *AJOB Primary Research*. 2014; 5: 3-11.
6. Brænd AM, Jensen KB, Klovning A and Straand J. Clinical drug trials in general practice: a 10-year overview of protocols. *Trials*. 2013; 14: 1-10.
7. Collier R. Growing interest in primary care research. *CMAJ: Canadian Medical Association Journal = Journal De L'association Medicale Canadienne*. 2015; 187: E5-E.

8. Askew D, et al. General practice research: attitudes and involvement of Queensland general practitioners *Medical Journal of Australia*. 2002; 177.
9. Fisher JA and Kalbaugh CA. United States Private-Sector Physicians and Pharmaceutical Contract Research: A Qualitative Study. *PLoS Medicine*. 2012; 9: 1-8.
10. Brody H and Miller FG. The clinician-investigator: Unavoidable but manageable tension. *Kennedy Institute of Ethics*. 2003; 13: 329-46.
11. Joffe S and Miller FG. Bench to bedside: mapping the moral terrain of clinical research. *The Hastings Center report*. 2008; 38: 30-42.
12. Timmermans S and McKay T. Clinical trials as treatment option: Bioethics and health care disparities in substance dependency. *Social Science & Medicine*. 2009; 69: 1784-90.
13. Easter MM, Henderson GE, Davis AM, Churchill LR and King NMP. The many meanings of care in clinical research. *Sociology of Health & Illness*. 2006; 28: 695-712.
14. Shepherd L and Riley MF. In Plain Sight: A Solution to a Fundamental Challenge in Human Research. *Journal of Law, Medicine & Ethics*. 2012; 40: 970-89.
15. Yap TY, Kassimatis KA and Kodish ED. Both Sides of the Coin: Randomization from the Perspectives of Physician-Investigators and Patient-Subjects. *Ethics & Behavior*. 2010; 20: 380-6.
16. Glass KC and Waring D. The physician/investigator's obligation to patients participating in research: the case of placebo controlled trials. *The Journal Of Law, Medicine & Ethics: A Journal Of The American Society Of Law, Medicine & Ethics*. 2005; 33: 575-85.

17. van der Graaf R and van Delden JJM. Conflating scientific with clinical considerations. *The American Journal Of Bioethics: AJOB*. 2009; 9: 58-9.
18. Fisher JA. Practicing Research Ethics: Private-Sector Physicians & Pharmaceutical Clinical Trials. *Conference Papers -- American Sociological Association*. 2007: 1.
19. McDougall R, Martin, D., Brookes, A., Gillam, L., Hallowell, N., Guillemin, M. . Therapeutic appropriation: a new concept in the ethics of clinical research. *Journal of Medical Ethics*. 2016; (in press).
20. Charmaz K. *Constructing Grounded Theory*. Sage, 2014.
21. Tromp K and Van de Vathorst S. Gatekeeping by Professionals in Recruitment of Pediatric Research Participants: Indeed an Undesirable Practice. *American Journal of Bioethics*. 2015; 15: 30-2.
22. Hudson P, Aranda S, Kristjanson L and Quinn K. Minimising gate-keeping in palliative care research. *European Journal of Palliative Care*. 2005; 12: 165-9.
23. Sharkey K, Savulescu J, Aranda S and Schofield P. Clinician gate-keeping in clinical research is not ethically defensible: an analysis. *J Med Ethics*. 2010; 36: 363-6.

Appendix: Physician-Researcher key interview questions

- Please describe your involvement in clinical trials; with prompts about the type, number, role and level of involvement.

Based on a recent trial that you were involved with:

- What was the motivation for you to participate in this trial?
- Did you decide which of your patients were invited to participate in the trial?
- [If so] how did you decide which patients to invite to participate in the clinical trial?
- How did you decide what to tell your patients about the trial?
- Were you responsible for getting your patients' consent to participate in the trial?
- Did your patients have other sources of information about the trial?
- Did your patients ask for further information about the trial during the research?
- Do you think being asked to participate in the trial influenced the way your patients viewed their health care appointments?
- Do you think participating in the trial influenced the way your patients thought about you as their doctor?

- What do you think motivates some patients to participate or not in clinical trials?
- What do you think motivates other doctors to participate or not in clinical trials?
- Have you had to take a patients' participation in a trial into account when making decisions about their care?
- How do patients respond when you talk to them about participating in clinical trials?
- Overall, how would you describe your experiences of being involved in clinical trials?
- Do you have any comments about your dual roles as a doctor and as a researcher in clinical trials?