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RESEARCH ARTICLE

Paediatric Physician–Researchers: Coping With Tensions in Dual Accountability

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Abstract. Potential conflicts between the roles of physicians and researchers have been described at the theoretical level in the bioethics literature (Czoli, et al., 2011). Physicians and researchers are generally in mutually distinct roles, responsible for patients and participants respectively. With increasing emphasis on integration of research into clinical settings, however, the role divide is sometimes unclear. Consequently, physician–researchers must consider and negotiate salient ethical differences between clinical– and research–based obligations (Miller et al, 1998). This paper explores the subjective experiences and perspectives of 30 physician–researchers working in three Canadian paediatric settings. Drawing on qualitative interviews, it identifies ethical challenges and strategies used by physician–researchers in managing dual roles. It considers whether competing obligations could have both positive and adverse consequences for both physician–researchers and patients. Finally, we discuss how empirical work, which explores the perspectives of those engaged in research and clinical practice, can lead the way to understanding and promoting best practice.

Key Words. Dual Accountability, Paediatric, Pediatric, Physician–researcher, Qualitative, Role Tension

Background

Potential conflicts between the roles of physicians and researchers have been described at the theoretical level in the bioethics literature (Czoli, et al., 2011). In most cases, physicians and researchers are in mutually distinct roles and are responsible for patients and participants respectively. With increasing emphasis on the integration of research into the clinical setting, however, the role divide is not always clear. In such situations, physician–researchers must consider and negotiate the salient ethical differences between clinical–based and research–based obligations (Miller et al, 1998). The physician's fiduciary duty is to act in accordance with the patient's wishes and best interest, whereas the researcher's obligation is to produce generalizable knowledge for society's benefit. Guidance documents from the fields of ethics, law and policy argue that in the face of conflicting duties, a researcher's primary concern should be the health

and well–being of the patient who is also a research participant. These include ethics, law and policy commentaries arguing that in the face of conflicting duties, a researcher's primary concern should be the health and well–being of their patient who is also a research participant (Royal College, 2003; Freedman, Weijer & Glass, 1996). *The Declaration of Helsinki* states that considerations related to "the well–being of the individual research subject must take precedence over all other interests" (World Medical Association, 2008). Physician codes of ethics require consideration of the patient's well–being first (Canadian Medical Association, 2004). Notwithstanding the utility of the above guiding documents, a guideline specific to the situation involving a patient who is also a research participant would be helpful, and currently does not seem to exist beyond a small reference in the Canadian Tri–Council Policy Statement 2 ("TCPS 2") research guidelines. While these documents and related guidelines may help support good practice and research, little is known about how physician–researchers understand their dual roles, negotiate areas of potential conflict and what they consider to be best practice strategies for addressing these challenges. This lack of evidence raises questions as to whether the dual role of physician–researchers might, in practice, cause uncertainty, confusion or harm.

This paper explores the subjective experiences and perspectives of 30 physician–researchers working in three Canadian paediatric settings. Drawing on qualitative interviews, it seeks to identify the ethical challenges and strategies used by physician–researchers in managing their dual roles. It considers whether competing obligations could have both positive and adverse consequences for both physician–researchers and patients. Finally, we discuss how empirical work, which explores the perspectives of those engaged in research and clinical practice, can lead the way to understanding and promoting best practice. The study focuses on tertiary paediatric settings because research and clinical care co–exist for many paediatric conditions due to the absence of standardized, evidence–based therapies; thus, paediatric clinicians are frequently engaged in these dual roles.

Methods

The work reported here was part of a larger mixed methods study, which included a law component, a theoretical component (Czoli, et al., 2011), and a qualitative component—the subject of this paper. This qualitative component of the study was directed by interpretive interactionism (Denzin, 1989) and qualitative inquiry (Devers, 1999). Interpretive interactionism involves a commitment to trying to understand the meanings people make of their experiences in everyday life. Epistemologically, it is based on the position that as people interact, they create their social realities and derive meanings about events in their lives (Denzin, 1989). It assumes that knowledge is socially constructed and that the concept of truth depends on the perspective one takes in interpretation (Greene, 1990; Lincoln, 1990). Consistent with this approach, this study started from the perspective of paediatric specialists who also conduct research. It was designed to yield insight into the subjective experiences of physician–researchers and how they interpret and/or make sense of their dual roles.

Research Process

A national, multidisciplinary advisory committee of relevant stakeholders provided guidance for the project in different areas, including qualitative methodology, research ethics, and education. A medical journal editor, a guardian of a patient–research participant, and physician–researchers currently in practice were also members. Members worked with the research team to ensure that the interview guide was tailored to engage physician–researchers.

Research Sites and Recruitment

Physician–researchers at three paediatric hospitals across Canada were recruited to participate in this study. Maximum variation sampling was used, wherein the sample was selected in ways to ensure a broad range of information (Lincoln & Guba, 1985). Ten physician–researchers from the pool of eligible

candidates at each of the three study sites were selected to include different genders, specialties, lengths of practice, and geography. No exclusion criteria were applied.

Data Collection

Semi–structured Interviews and Field Notes

Amongst the 30 participants, nine subspecialties were represented. Data collection involved face–to–face (except one phone interview) semi–structured interviews on the nature of physician–researchers' clinical and research duties as well as accountability requirements. Interviews averaged 30 minutes in length, and were audiotaped, transcribed verbatim (with identifiers eliminated) and analyzed in keeping with the interpretive interactionist framework. Field notes taken by the research coordinator during and immediately after each interview included information such as non–verbal aspects of the interview, the physical setting, and personal interaction (Hammersley & Atkinson, 1995; Kvale, 1996). Field notes were used in conjunction with the transcripts from individual interviews to assist in the interpretation of data and to provide further in–depth descriptive and reflexive information. Research Ethics Boards (REB) approval was attained prior to study commencement at each of the three research sites.

Data Analysis

Analysis involved an interpretive process and was guided by constant comparative techniques (Denzin 1989; Lincoln & Guba, 1985). Initially, interview segments were grouped into preliminary categories based on our interview guide (e.g. role description–accountability, role separation–strategy, role conflicts, best practices). As more data were collected and coded with descriptive phrases or words, these categories were revised. Comparison of differences and similarities within and between categories and subcategories enabled further refinement, clarification of meanings, and the development of conceptual themes. The data were managed using the NVivo qualitative software program.

In qualitative research, issues of trustworthiness (interpretation and representation of the data) are important to address. Credibility was achieved via the team approach used throughout the entire research process. Confirmability involved an audit trail, which included description of data analysis and processes of reduction, reconstruction, synthesis, and structuring of themes. Themes supported and substantiated with clear descriptions and quotes from several participants ensured dependability of results (Morse & Field, 1994).

Results

Thematic analysis revealed four main strategies used by participants for managing the tensions and conflicts of obligations related to their competing roles: i) reliance on research ethics review; ii) distancing; iii) resisting; and iv) engaging in reflexivity. While separated for analytic purposes, it is important to point out that these strategies were not mutually exclusive. Physician–researchers often drew upon more than one strategy depending on the specific research study situation.

Reliance on Research Ethics Review

Most participants thought current research ethics review processes (ethics policies, guidelines and practices) were working effectively. One strategy that helped to minimize conflict was reliance on the guidelines, professional and ethical codes of conduct and broader research policies that govern the ethical conduct of clinical and community–based research. Implementation of the guidelines directed the behaviour of physician–researchers in their dual roles. Physician–researchers expressed the belief that so long as the protocols and guidelines were followed, potential issues of conflict would be addressed and minimized. The following quotations illustrate the trust participants placed in established research ethics protocols as well as on the safety monitoring board to oversee key safety aspects of the research:

> At the first chance of any harm or you know, lack of benefit, the patient can drop out of the study or they can cross over to whatever might be indicated. So, every clinical study should have that built into it. Plus, you usually have a data safety monitoring board to kind of detect things that you can't see on an individual level.

> The world has evolved to a point that now in 2000's, these things are very strictly and well defined and I think it's very easy to not be in a position of conflict of interest and still do both things very well.

> I think they [policies and procedures] lend tremendous clarity to how we approach patients for studies and you know, how we have to keep the patients' best interests in mind in any of the research that we do. And you know, to that length, I mean, the world has changed so much.

Participants described research protocols that were thoroughly reviewed and approved by local research ethics boards. Others pointed out that screening criteria (also approved by the REB) served as another strategy for minimizing tensions between research and clinical practice. In the following cases, sign off and screening procedures served to minimize tension:

> We always make sure we get that notification and sign off [from the REB] before we even start approaching anybody.

> We screen all our patients first and so wouldn't put anybody in a study whereby they would receive harm from one of the interventions or where they would clearly benefit from something in such a way that an alternative therapy would be denying them that benefit.

Distancing: Taking an 'Arms–length' Position

Some physician–researchers viewed their current practice of 'arms length' distancing as appropriate and, given the pragmatic challenges of available time, resources, procedures and policy, preferred to manage tension in this way. This strategy also adheres to established research ethics guidelines. For example, the Canadian TCPS 2 states that researchers should pay particular attention to elements of trust and dependency in relationships (e.g. between a physician and a patient) as this could create undue influence on patients to participate in research. Participants perceived having a research coordinator provide information and obtain consent to be an effective means of 'distancing' themselves from the research and minimizing the potential for coercion or undue influence:

> Our research co–ordinator will go in. She'll talk to them more about the study. She has the consent forms . . . there is no sense of coercion.

> I rely on the research co–ordinators because they get full experience and I think you know, like it or not, sometimes patients have difficulties dealing with physicians.

> It gets easier as you get more experience . . . you distance yourself from everything.

Strategies of Resistance

While some participants attempted to reconcile competing obligations, others engaged in strategies of resistance. Resistance, as a means of opposing or confronting conflict between duties, was described in a variety of ways. Strategies included: resisting the clinical protocol itself where it is thought not to be in the patient's best interests; resisting pressure from peers, colleagues or the organization to participate in a study; and resisting direct influence by putting the onus on the patient/family to read and understand the protocol themselves; and resisting by not promoting the research study.

Several physician–researchers refused to be involved in research studies (despite the fact that the studies were already approved both scientifically and ethically) because they believed the studies were not in the best interests of the patient under their care. These physician–researchers went beyond reliance on the extant guidance documents, standards and ethical policies and took a more personal approach to deciding whether research participation should be offered to their patients:

> It was an unpleasant situation when I had to take a stand and say this is not in the patient's interests and I was thinking, must not do this. It stopped. I haven't been popular with this person

> since but it doesn't really matter to me. It was the wrong thing to do for him and I think it was the right thing to do for me.

> There are times when we said or I certainly said, no. I will not participate because I don't feel that this . . . that there is a question that merits randomizing people or applying different techniques or something to them.

> I wouldn't participate. I wouldn't have my patients participate in the study where I don't like the protocol and where I'm not very comfortable with the protocol irrespective of what the ethics say you know.

One respondent refused to accept the system pressure to recruit, thus relieving the tension associated with the dual role. Others discussed their resistance to the systemic pressure to engage in more research than they felt they were reasonably able to do in an effective manner:

> I think that I manage reasonably well. You know, like I said, I am involved in some multi–institutional work and therefore the governing agency sometimes puts a lots of pressure on me to beef up the recruitment but that doesn't translate down into anything that happens, you know.

> So, everything comes down eventually to sort of, this publishing and proof that you've done it. And yes, there's the pressure. In the heavy–duty researchers, you've got to just give yourself to it. But then a lot of the rest of us are doing it sort of part time you know. And then that's so much activity profile as we call it . . . our job. That's what it is you know. I put myself down as 20 to 30% research and it's really completely up to me how I count it you know. But then they shouldn't expect me to be a regular producer. They should expect me to squeeze out the odd paper. You always feel like you should be being like them [producers] unless you get old and grey enough to say no. I don't want to be like it. That isn't what I am. But you get swept up on it. You know, the research thing, I get swept along. I have to pull myself back and say, that's not who I am.

Others demonstrate their resistance by failing to promote the research study:

> I thought it was inappropriate that a person be told, before you go into have your test that your doctor wants, you have to sign a consent form [for research]. So I didn't do that even though I was supposed to and I was going to take the heat for it but the risk was small.

Engaging in Reflexivity

Respondents also spoke to the importance of reflexivity in managing their dual roles. Reflexivity refers to the critical self–reflection and self–inspection of one's biases, including theoretical and methodological preferences (Denzin, 1989). Reflexivity not only involved critical thinking on the part of the physician–researcher, but also included being reflexive with others in the social network, particularly with the research team, colleague physician–researchers, ethicists, and other professionals. Physician–researchers described the ways in which thinking critically and constantly questioning their dual roles and each unique situation that presented itself helped them to cope with uncertainty:

> I think the most important thing for me is to . . . to maintain the critical thinking you know . . . not being completely, let's say, just devoted just to research or not being completely devoted to anything else but just always to critically analyze every single situation in which you are. That's the most important thing because that will prevent you from, you know, doing research that maybe finally turns out not to be ethical.

> My concern is that people don't think about it enough and don't really challenge themselves to think about it.

Physician–researchers also engaged in reflexivity by engaging with others who had knowledge and expertise regarding the specific issue at hand. The importance of drawing upon the expertise of others, for example, the hospital ethicist, was emphasized as key to resolving role tension:

> There's the mandatory ethics testing that everyone has to do. I think more importantly, there's the opportunity to involve ethicists at any level, from a patient care perspective and . . . if you need help you call them and involve them.

Others further identify the importance of discussing issues with colleagues and creating a positive team environment, which they believe moves them beyond simply relying on standard

protocols of ethics review, monitoring boards and safety committees:

> Each project is so different that I try to get a dialogue going and it is usually within my lab meeting so there's a discussion around the scenario and it's usually at the time that they're actually writing the protocol, writing the consents and that's the time that I work at that side of things rather than saying well, just fill out the form and you know, read it all . . . I challenge them to think about those issues . . . Sometimes they get pissed off with me because it takes too long.

> In the research group, we discuss new studies because there's then a certain burden to being approached and the consent process and the time all of this takes and so even new studies that the national group is approached with are triaged based on what we think our patient population can handle. If we're trying to do something nationally, we'll agree or disagree as a group whether we can take it so we're not overburdening . . .

> Consulting with others, talking with others, usually my research colleagues. Having a discussion. Often I have trainees and I try to involve them in that process because I think it's really important for them and I discuss it with my research coordinators . . . So, you know, at the end of the day, you come out with what you consider to be a rational conclusion. I have some really wonderful nurse coordinators that work with me who very much advocate for research subjects and I listen to them a lot because they have a lot of insight into this.

> I have my colleagues to help me with that struggle. If I have any insecurity I consult them . . . so that makes me feel better.

Discussion

This study explored subjective experiences of 30 physician–researchers working in a paediatric setting. Drawing on qualitative interviews, it identified four different kinds of strategies used by physician–researchers to manage the tensions created by their dual role. Taken as a whole, our data suggest that physician–researchers seem to have a common goal: to provide the best care possible for their patients, for the research participant and for the patient at large—whether that care or treatment is proven or experimental.

Strategies used by physician–researchers ranged from reliance on REB approved protocols and distancing themselves from subjects to active resistance of research and reflexivity. However, it is important to point out that these strategies used were not mutually exclusive. While some respondents spoke to a single strategy, others often employed a combination of strategies depending on the complexity of the situation. This finding is similar to existing literature on patients/subjects' motivations for enrolling in research—their decisions are typically driven by more than one consideration (Applebaum, Lidz & Klitzman, 2009).

Notably, in this study there was no evidence of physician–researchers experiencing conflict with their clinical practice *per se*. If they stated a conflict, it was with their research role interfering with their clinical practice and finding ways to fit the research into their own expectations or those of others. These data are reassuring with respect to the priority respondents gave to their fiduciary obligations regarding care of patients.

Respondents thought research ethics review was effective for the most part in protecting research subjects. However, REB processes did not completely address the challenges created by overlapping roles and additional strategies were developed. Two are especially worthy of comment. First, some respondents demonstrated resistance as a means of opposing or confronting the conflict created by their dual roles. This included refusal to be involved in or promote particular REB–approved studies and resisting pressure to do more research.

According to Miller et al. (1998), physician–researchers have a responsibility to the individual patient as well as society to promote good science. They state that physician–researchers are not appropriately balancing these competing duties if research is subverted for the individual patient. A significant question for paediatric physician–researchers then is the extent to which their clinical obligations would support them not presenting a REB approved study to a patient if the latter met eligibility criteria. An argument could be made that

a physician's fiduciary responsibility to his or her individual patients would support withholding information about a study, which the physician does not consider to be in the patient's best interests. Research studies are not standard of care and notwithstanding clinical equipoise; individual physicians may not consider all studies for which their patients satisfy REB approved inclusion criteria to be in each specific patient's best interests. Concerns with this argument are (1) that the physician would be limiting the access of patients to studies that have been approved by an REB and as a result, potentially biasing the study sample and (2) the physician would be denying the potential study participant the opportunity to decide for him or herself whether to participate. Recognizing the inherent tensions in the physician–scientist role, Miller et al. argue for a conception of the moral identity of the physician–researcher as one that "integrates the roles of the clinician and the scientist without giving predominance to the one or the other" (1998, p. 1452)

How might this be done? Miller et al (1998) emphasize a focus on ongoing education, namely the ethics of clinical research, in promoting professional integrity and the knowledge to balance these dual roles. Participants in this study also identified another strategy: Reflexivity was seen as key to managing conflicting obligations that were not easily solved by REB rules and guidelines. Respondents spoke to a need to engage in reflexivity in both practice and research, individually and in groups (see, for example, Colbourne & Sque, 2004; Finlay, 2002). According to Arber (2006), reflexivity is the capacity to reflect upon one's actions and values during the research, when producing data and writing accounts, and to view the beliefs we hold in the same way that we view the beliefs of others. Finlay (2002, p. 532) defines reflexivity as follows: " . . . thoughtful, conscious self–awareness. Reflexive analysis in research encompasses continual evaluation of subjective responses, intersubjective dynamics, and the research process itself." In our study, respondents emphasized the importance of critical thinking in assessing the challenges created by merging research with clinical care. Consultation with colleagues and other specialists was seen as particularly valuable to identifying patients' points of view, emergent problems and contributing to the reflective process. The data underscore the need to endorse this strategy, with one participant expressing concern that not enough physician–researchers devote time to do reflexive work.

This study faced several limitations. Data did not allow for comparisons of clinical specialty or area of research[1]. Our sample size was too small to allow for subgroup analysis based on demographic data, which may have revealed partitioning of coping strategies amongst various groups or medical specialties. Likewise, we did not collect data on the type of research done by the participants. It is conceivable that the magnitude of duality conflict might relate to the intensity of the disease or degree of invasiveness of the research. When reflecting on conflicts encountered in their dual role, physician–researchers often stated 'it depends'. Patient factors such as personality, vulnerability, and active involvement may also have an influence on the potential dual accountability conflict for the physician–researcher.

There is a need for future research that examines and compares the different perspectives of novice and more seasoned physician–researchers. For example, seniority may aid the decision to decline research opportunities where an ethical conflict is perceived or identified, because of stronger feelings of job security. Alternatively, new trainees may have received more ethics training than older practitioners and have greater awareness of the ethical complexities of their dual roles.

Lastly, there is a need for research to focus on the experiences and perspectives of patients and their families who are also research participants

1. While the original intent was to include with the interview guide a cover sheet to collect basic descriptive demographic data for the participant group and range of years working as a physician-researcher, it was decided, given the relatively small sample size at each site, not to collect this data so as to better safeguard the identities of participants.

in light of issues related to dual accountability. For example, do patients/participants appreciate the potentially conflicting accountabilities that physician–researchers may experience? McDonald and Cox (2009) begin to address these issues with their study on human subjects. They note that although there is worldwide recognition that the protection of research participants is ethically required for all research involving humans, much of the discourse has centered on norms (rules, regulations, and governance arrangements) instead of on the actual effectiveness of these norms in achieving their goal of protecting participants from undue risk, ensuring respectful treatment, and advancing useful knowledge. There has been an increasing advocacy for research grounded in careful systematic exploration of the effects of research on human participants. McDonald and Cox (2009) offer an analysis of evidence–based protection, drawing on Canadian examples of research in this area.

This study contributes to a growing body of empirical research that aims to better understand the ethical challenges reviewers and researchers face when conducting research (Cox et al, 2009; Beagan & McDonald, 2005). It examined the experiences of a particular group of practitioners: paediatricians who are both physicians and researchers working in a tertiary care environment. It confirmed that conflicts can arise as a result of differing accountabilities or "the clash in agendas" (Yanos & Ziedonis 2006, p. 249) between the researcher and clinician role. Inherent to this situation is a conflict between the clinical duty to act in the patient's best interest and the scientific mandate to pursue new knowledge. However, such conflict is not necessarily a pitfall. Awareness of competing obligations is a critical first step toward developing strategies and promoting ethical judgment for managing these dual roles. At the same time, findings presented here give some cause for concern if the blurring of clinical–research roles affects recruitment and in turn the quality of research activities. Extant ethical guidelines and protocols serve a useful and critical role, but are insufficient by themselves.

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