Ethical and Methodological Considerations for The Clinician-Scientist: a Call for Reflexivity

Allison Shearer, Christine Guptill, Ashley McKillop and Douglas P. Gross

Abstract
Clinician-scientists play a valuable role in bridging the gap between patient care and clinical research. However, there are no clear guidelines that describe how to handle the day-to-day ethical and methodological questions that arise when navigating the competing responsibilities of practitioner and researcher—a situation that can easily leave the clinician-scientist confused and frustrated. This article outlines common ethical and methodological concerns for the clinician-scientist when developing, implementing, and analyzing research in practice, and offers practical suggestions to address these issues. This paper will outline the role that reflexivity can play throughout the research process to assist the clinician-scientist in maintaining ethical and methodological rigor, as well as upholding the moral obligations of both practitioner and researcher.

As the face of medicine and healthcare is changing, there has been a recent push to more fully integrate clinician-scientists into healthcare systems globally. The broad term of “clinician-scientist” refers to a clinician who spends a significant amount of time dedicated specifically to research activities. For the purposes of this paper, clinician-scientist refers to clinicians of all types: medical doctors, nurses, occupational, physical, and speech therapists, and other allied health professionals. Clinician-scientists are healthcare practitioners who blend research endeavors with direct patient care, though these roles are not necessarily concurrent.

Clinician-scientists are uniquely poised to serve as a link between science and the practice of medicine: working at the intersection of clinical practice and research, clinician-scientists function as brokers to reconcile epistemological and culturally divergent contexts of scientific study and patient care. Their role is invaluable: as Larkins (2000) notes, “it is essential that there are individuals who can bridge the chasm between the advances in understanding of the sciences underlying our knowledge of disease and their treatment and the clinical care and public health policies that determine the health of our society.” When clinicians are engaged in the development and conduct of research, the research is often more relevant and representative of the real-world clinical setting, allowing for an acceleration of the translation of research into everyday clinical practice. Furthermore, the synergistic effect of practitioner and researcher viewpoints makes the clinician-scientist well-equipped to be members of task force teams designed to tackle large-scale healthcare problems faced today.

With the responsibility of bridging the gap between research and clinical practice, however, comes a distinct set of challenges posed by the dual role of “practitioner” and “researcher.” Clinician-scientists must uphold the ethical and professional responsibilities of both vocations, and yet must also vary the lens with which they ask clinical questions and approach clinical situations depending on whether they are functioning as practitioner or researcher at any specific point in time. Maintaining adherence to research protocol, ethics, and methodology, may at times be in opposition to one’s clinical opinion about optimal care for a particular patient. At its core, research— with its goal of yielding generalized knowledge beneficial to the population—may be in tension with the focus on individualized patient care in clinical practice.

Furthermore, ethical questions of autonomy, beneficence, and justice take on new meaning when applied to an existing patient-clinician relationship due to the socio-cultural forces at play, and precautionary measures must be taken to avoid...
bias in self-directed research. Grappling with the tension of competing outcomes and moral obligations can easily leave the clinician-scientist frustrated and confused, without sufficient practice guidelines to assist them in navigating this role. The purpose of this paper is to explore ethical and methodological concerns that require consideration for the clinician-scientist at each stage of research implementation—study design, study implementation, and data analysis—and argue for the use of reflexivity throughout the research process. Reflexivity, or systematic reflection on one’s nature, presumptions, decisions, and actions as they relate to the research process, serves as a means to maintain methodological rigor and ethical responsibility, thereby easing the natural tensions that exist between the dual roles of researcher and clinical practitioner.

Guillemin (2008) defines ethical mindfulness as a multi-pronged approach which involves (1) being able to identify ethical questions and concerns (2) being “alert to potential ethically important moments in research” (3) “being prepared to give credence to not feeling quite right about a given research situation, and acknowledging these feelings as potential sources of importance” and (4) having courage to be serious about everyday ethics. In practice, Ellis (2007) suggests using “mild discomfort as a cue to explore further.” Although thoughtful reflection on these uncomfortable moments in research may not yield anything of ethical significance, it is a way to promote ethical rigor and ensure that the clinician-scientist does not overlook anything ethically significant throughout the research process.

Selection

A primary concern with study design is to structure and execute participant recruitment and data collection in such a manner as to avoid selection bias, as this can potentially yield a group of research participants that is systematically different than the population of interest and lead to confounding. As a clinician-scientist, it may be tempting to use one’s clinical “eyes” and expertise to make decisions about research participation for a patient. For example, slightly altering the inclusion criteria, exclusion criteria, or research protocol to accommodate a patient whom a clinician-scientist believes may benefit from the intervention being examined in a particular research study but who doesn’t quite “fit” the a priori criteria is an obvious violation of research ethics. Alternatively—and more subtly—the clinician-scientist may intentionally avoid giving another eligible patient information about the research study, because clinically they are not confident that it would be in the patient’s best interest’ These are both examples of therapeutic misdirection, or the conscious deliverance of individualized patient care within a research study. Therapeutic misdirection typically involves noncompliance with the research protocol in an attempt to balance the responsibilities of clinical practice with that of clinical research, and poses a threat to both methodological and ethical rigor. Although driven by therapeutic intent, making exceptions in this manner has the potential of not only harming the patient since the clinician is making decisions for rather than with them, but also threatening the internal validity of a study, as the study population would no longer be representative of the target population of interest.

In a similar vein, the clinician-scientist is likely to have a pre-existing clinical relationship with potential study participants. They may know which patients are likely to be compliant—and those who are likely to be noncompliant—with study demands. Again, the clinician-scientist must avoid the temptation to “over-recruit” those patients who they think would be stellar participants. One cannot pick and choose who to recruit for research participation based on these personality characteristics, as again this would yield a study population that is dissimilar to the general population of interest, resulting in a serious methodological compromise.

The clinician-scientist must also take care to avoid coercion in study recruitment, a chief ethical concern. Recruitment strategies such as allowing patients to bypass waiting lists for medical intervention if they participate in the study can pressure the patient into participation by making them feel that they will get care faster—and therefore, possibly better—if they agree to participate. Similarly, financial incentives such as routinely waiving patient fees (e.g. insurance co-pays) may cause patients to feel forced into study participation to lessen the financial burden of seeking out care, in addition to having potential legal and ethical concerns for the clinician.

Coercion can also take the form of societal pressures from the clinician-scientist, as there is often an imbalance of power in the relationship between clinician and patient. Particularly if there is an existing clinician-patient relationship, verbal and nonverbal encouragement from the researcher to participate in a study can be interpreted by the patient as a clinical recommendation, or perhaps even a requirement, to receive care. Clinician-scientists should take measures to present study information to all potential participants in a neutral manner. Using written handouts or a practiced verbal script, devoid of leading language, may help to reduce unintended pressure on the patient to participate. Depending on the nature of the clinician-patient relationship, it is often beneficial, and typically an ethical requirement, to have a colleague with whom the patient is less familiar assist in the recruitment process. In all cases, the clinician-scientist is ethically obligated to provide quality, timely, and equitable care to patients regardless of their decision to participate in a research study or not. Patients who are potential study participants should be made aware of all of their treatment options and never be made to feel that there is no alternative treatment other
than that offered by participation in the study. Election to participate in any study must be an at-will decision for all patient-participants, without biased influence or pressure from clinician-scientists. Clinician-scientists must practice reflexivity throughout the research process from recruitment to conclusion, continually analyzing their words, actions, and clinical relationships to avoid potential coercion.

Finally, many patients may approach clinician-scientists with a degree of inherent trust. It is easy for a patient to confuse the role of researcher with that of practitioner, to see research participation as a form of healthcare, and to assume that the researcher is looking out for the best interest of their individual care. It is the duty of the clinician-scientist to explain that the goal of research is to produce medical knowledge to help future patients, and to educate patient-participants in the risks of research participation to their personal wellbeing. Not doing so exploits the power dynamic of the clinician-patient relationship, is contrary to the ethical principles of autonomy, justice, and beneficence, and as such is an ethical violation.

**Measurement**

The principal concerns with study implementation as a clinician-scientist are maintaining methodological rigor by minimizing information bias during data collection—namely observer bias and reporting bias—and maintaining ethical rigor by continuing to avoid coercion.

*Observer bias* is a type of detection bias; it refers to the discrepancy between the true value and recorded observed value of a particular variable being measured. Clinician-scientists are particularly at risk for observer expectation bias, in which the researcher has a preconceived idea of how a patient-participant should perform on a certain measure or task due to their knowledge of the patient’s disease status or treatment group assignment, and adjusts their measurement recording to match this presumption. For example, when manually measuring blood pressure, some clinicians round their measurements up or down to the nearest 0 or 5, or to an even number. When studying an intervention expected to impact blood pressure, the clinician-scientist may gesture or point towards the patient-participant to rate their pain using a visual analog scale, the clinician-scientist may gesture or point towards the right side of the scale. This physical gesture may influence the patient-participant’s response and encourage them to rate their pain as more intense than they otherwise would.

Blinding is the best method to reduce the risk of observer and apprehension bias, but is not always feasible or practical in a clinical setting. Furthermore, a priori protocols should be established for measurement taking; following these guidelines will reduce the likelihood of observer expectation bias if the clinician-scientist is recording outcomes. At a minimum, clinician-scientists should be aware of the potential for observer expectation and apprehension bias and approach each patient-participant in a fresh and impartial manner, remaining neutral with interaction—this can be especially challenging in the context of a pre-existing clinician-patient relationship.

At the same time, clinician-scientists must refrain from over-identification with their clinical self during study implementation. Especially when the clinician has an established relationship with patient-participants, it can be difficult to remain bound by research protocol if a patient is progressing quickly, becomes frustrated with, or is responding poorly to treatment. The clinician is primed to immediately respond to changes in patient status and modulate treatment accordingly by varying treatment approach and even therapeutic use of self (the intentional use of one’s personality, experiences, opinions, and insights to enhance the therapeutic process). The scientist, however, is required to maintain adherence to a research protocol. The clinician-scientist must take care to not let their clinical “hat” overshadow that of science, as this can limit the trustworthiness of study findings.

*Response bias*, in contrast to observer bias, is not the result of the examiner’s actions but rather is due to the actions of the patient-participant. Patients may underreport behaviors which they think are socially unacceptable or mal-aligned with the expectation of the researcher, especially if the researcher is a practitioner with whom the patient has a pre-existing socio-clinical relationship, or if the patient anticipates the clinical relationship with the researcher will extend beyond the bounds of current research participation. For example, the patient-participant may report that they smoke less frequently than they actually do, or avoid reporting inconsistent compliance with treatment procedures if they are concerned that disclosing these behaviors may cause the clinician-scientist to view them in a less positive manner—as this could potentially compromise their future clinical relationship. Similarly, patient-participants may perform or provide
answers in such a manner that they believe is in alignment with the researcher’s expectations or area of interest, so as to “please” or not “disappoint” the researcher. This, too, can be a particular challenge for research within pre-existing clinical relationships, as patient-participants may be more inclined to alter their responses to be in-line with what they believe the clinician-scientist “wants” to see. For instance, if the patient-participant believes that the clinician-scientist is testing a new treatment technique designed to relieve pain, they may exaggerate the degree of pain reduction they experience. Clearly, changing responses in such a way—whether intentional or not—compromises research integrity and the validity of results. As with observer bias, response bias can be reduced with blinding—in this case, masking of the patient-participant to research hypotheses.19

Coercion is a concern during study implementation, just as it is in participant recruitment. When engaging in clinical research, patient-participants should never be overtly or subtly pressured by the clinician-scientist to continue study participation if it is against their will. As with any type of clinical research, consent must be informed and ongoing throughout the study. In the event that a patient-participant elects to discontinue study involvement, the clinician-scientist must display flexibility, readily shedding the lens of researcher and donning that solely of practitioner, moving forward by providing high-quality, timely, and appropriate clinical care to the patient.

Confounding

Financial conflicts of interest are typically easy to identify, but even with rigorous approaches to methodology, the funding effect remains prevalent and poses a methodological concern across all types of research. The correlation of positive study outcomes with funding sources is attributed to research bias in various forms, including unconscious internalization of the funding source’s financial interests by the investigator.21 Having a financial interest in the intervention under study is an enormous confounding factor, as clinician-scientists may (un)knowingly misinterpret results, generate conclusions, and make clinical recommendations in favor of the intervention.

Beyond the funding effect, there can be a less obvious but just as inherent source of bias associated with advancing scientific and professional concerns. Particularly when trial- ing new therapeutic techniques, clinician-scientists stand to gain—or lose—a great deal in terms of their professional and social status in the workplace and in the greater field of healthcare. Quite simply, researchers want their interventions to be successful, and journals like to publish research that demonstrates statistically significant results.22 Any constraint of data analysis as a result of conflicts of interest is problematic, as it allows bias to alter and misshape the literature base. To combat this bias, the clinician-scientist must remain committed to ethical neutrality when reporting and disseminating study results, regardless of research outcome.

Discussion and reflexivity in practice

Clinician-scientists are tethered to the professional and ethical obligations of dual professions: that of practitioner/caregiver, and that of researcher. Challenges arise when the responsibilities and inclinations of the clinician conflict with that of the scientist—but in research, clinician-scientists remain with one hand in each allegorical pot, never fully assuming one role or the other. The metaphor of wearing different “hats” or “glasses” is often used to describe the alternating roles of the clinician-scientist. It is not so easy, however, to switch roles in practice—one cannot fully remove the role of clinician or the role of scientist in practice as one can easily remove a hat or pair of glasses. Rather, one remains bound by the responsibilities of both. As such, the metaphor of “clinical eyes” or a “clinical skin” may be more appropriate, as this implies that a practitioner’s clinical identity is engrained within them, and cannot be discarded in a research setting. Hay-Smith (2016) proposes a middle-ground approach which highlights commonalities rather than differences between the roles: “the dual role might best be understood as a coherent moral identity that recognizes both sets of obligations, rather than oscillating between the two roles.”

Reflexivity a solution for mitigating the ethical issues posed by these competing obligations of the clinician-scientist: one must allow for regular, deep self-reflection on the research methods employed and be able to ask “uncomfortable questions” regarding the integrity, quality, and ethicality of the research being performed,23 and must be unafraid and willing to make changes when appropriate. The onus is on the clinician-scientist to ensure both ethical and methodological rigor of the studies they choose to undertake, though the clinician-scientist ought not act in isolation. Just as the clinician-scientist is obligated to obtain approval from an ethics review board prior to engaging in human research, the clinician-scientist should seek out input from other trusted professionals for regular review during the research process. This offers opportunities for guidance in procedural ethics and can function as a type of supervision for novice researchers. Moreover, it can help even the seasoned clinician-scientist to consider other perspectives and reveal previously unrecognized patterns, connections, and even perhaps flaws in one’s research and analysis, as well as navigate the day-to-day real-world ethical dilemmas that arise. The benefits of practicing reflexivity in cooperation with other researchers and knowledgeable professionals simply cannot be overstated. After introspective reflection on one’s own biases, power dynamics, decisions and actions taken throughout the research process, sharing these reflections with colleagues can be
of great assistance. Meaningful discussion is a crucial and rewarding step in practicing reflexivity: it can assist the clinician-scientist in gaining much-needed perspective, and can help highlight, address, and resolve challenging or otherwise problematic issues that can arise. In this way, practicing reflexivity can strengthen and improve the research process.

Microethics, or “ethics in practice”, refers to these real-world ethical questions and dilemmas that arise as part of everyday clinical practice and are heightened when working in the dual role of clinician-scientist. In order to successfully navigate the field of quantitative and qualitative research, clinician-scientists cannot rely solely on procedural ethics boards for decision-making, and would benefit from reflexivity to assist in making decisions about unexpected ethical situations which require immediate attention as they arise in day-to-day practice. Jootun (2009) defines reflexivity as an “ongoing analysis of personal involvement” involving consistent, thoughtful, and systematic self-reflection. The concept of reflexivity is commonplace in qualitative research, but is not often considered by quantitative researchers; however, clinician-scientists would benefit greatly from applying this practice in their qualitative medical research, as well.

In practice, reflexivity requires the researcher to practice ethical mindfulness and consistently critically evaluate their words and actions—as well as their consequences and possible interpretations—throughout the research process, particularly with regard to the context of the relationship between the researcher and participant. Exercising reflexivity requires practice, but with time can help the clinician-scientist to more fully understand their role as a researcher and enhance their research: reflexivity offers the clinician-scientist a way to check his or her biases throughout the research process, thereby minimizing the potential negative effect their actions and presumptions may have on study recruitment, data collection, and analysis.

Simple yet effective strategies to practice reflexivity include maintaining a written or audio research journal, or reflective mapping of the research process. In each of these exercises, the researcher should implement critical reflection on their thoughts, decisions, and actions, asking questions such as: “Why does this matter?”, “How do I know this?”, “Why do I think that, and what led me to that belief?”, “What steps led me to make that decision?”, and “Why did I make that conclusion?”. One method of practicing reflexivity is not superior to another, and each individual should consider trying each one to determine which is the most effective for them. Regardless of the method employed, the researcher should not discard their thoughts. Rather, maintaining and reviewing previous entries provides the researcher with an opportunity to study their self and their research. Analyzing how one’s perspective changes over time can ultimately yield more thoughtful research and analysis.

The idea of courage in ethics is not a new one, but it warrants particular attention in the dual role of clinician and scientist, as a representative both professions. As a clinician-scientist, having courage means that one may at times have to challenge established norms and use a critical eye to examine practices within one’s own clinical profession. At other times, having courage may mean critically examining the ways in which one conducts research, relates to and interacts with participants. Still yet in other cases, the clinician-scientist must acknowledge the impact that their research has on study participants; for example, they may find that a patient-participant experiences an adverse reaction to a treatment of interest, resulting in a notable degradation in health status. In these cases, the author of this paper suggests that the reflexive clinician-scientist must find courage to put the needs of the patient ahead of their own research endeavors and advise the patient to discontinue study participation. To do so is to be in accordance with basic ethics principles that guide and regulate all research with human participants—most notably, the values of beneficence and non-maleficence. In such cases, the adverse reaction should be documented, but the patient need not continue on a path of harm. Though in some ways this affects study outcomes and the dropout must be adequately and appropriately addressed with data analysis and discussion, the researcher has justifiably used their clinician “skin” to show compassion and humanity towards a patient in need.

Conclusion

The clinician-scientist walks a fine line, straddling the boundary between research and clinical practice and upholding the ethical and moral obligations of both researcher and practitioner. Though they can never fully shed their clinical or scientific “skin”, the clinician-scientist must work to fluidly undulate between the role and lens of researcher and practitioner, without letting one role overshadow the other unjustly. The clinician-scientist benefits tremendously from the practice of reflexivity: taking stock of their actions and influence in the research process and remaining vigilant aware of their implications throughout the phases of research design, implementation, and analysis. Subtle cues of unease should be explored during everyday research in the clinic; the process of regular reflection and critical examination of one’s professional, clinical, and research practices cannot be understated. It is in this manner that the clinician-scientist can retain ethical and methodological integrity in their research endeavors, and uphold the moral obligations of both practitioner and researcher.

Author’s Note

Allison Shearer, Division of Occupational Therapy, Shenandoah University, Winchester, VA, USA. Christine Guptill, School of
Rehabilitation Sciences, University of Ottawa, Ottawa, ON, Canada.

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**ORCID iD**

Allison Shearer [10] https://orcid.org/0000-0002-2965-0352

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