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'Poking the skunk': Ethical and medico-legal concerns in research about patients' experiences of medical injury

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Abstract

Improving how health care providers respond to medical injury requires an understanding of patients' experiences. Although many injured patients strongly desire to be heard, research rarely involves them. Institutional review boards worry about harming participants by asking them to revisit traumatic events, and hospital staff worry about provoking lawsuits. Institutions' reluctance to approve this type of research has slowed progress toward responses to injuries that are better able to meet patients' needs. In 2015–2016, we were able to surmount these challenges and interview 92 injured patients and families in the USA and New Zealand. This article explores whether the ethical and medico-legal concerns are, in fact, well-founded. Consistent with research about trauma-research-related distress, our participants' accounts indicate that the pervasive fears about retraumatization are unfounded. Our experience also suggests that because being heard is an important (but often unmet) need for injured patients, talking provides psychological benefits and may decrease rather than increase the impetus to sue. Our article makes recommendations to institutional review boards and researchers. The benefits to responsibly conducted research with injured patients outweigh the risks to participants and institutions.

KEYWORDS
ethics, injury, medical error, patient research trauma

1 | INTRODUCTION

Vanessa's baby acquired an infection at a hospital in the United States. In explaining why she wanted to participate in research about her experiences with that adverse event, she said, 'I was glad to hear from you because there are a lot of things that have been on my mind for all these years. I kind of wished somebody from the hospital would want to hear too. They never reached out to me and said, 'Hey, what are your feelings on these things?' and I wished that they had. It's good to get a chance to talk about it. There are a lot of feelings about that period of time and, yeah, you don't really ever get a chance to share them with somebody.' (Research interview, 2016)

Benjamin, a 47-year-old New Zealander, explained why he wanted to participate in research about injured patients' experiences of institutional responses to patient safety incidents: 'I am extremely keen to participate in this research because I have a need to have my situation documented. I suffer from chronic pain for which there is no surgical solution available to me.... I earnestly ask that I have this opportunity to be heard.' (Research interview, 2015)

Understanding the perspectives of patients and families affected by medical injuries is crucial to improving the way the health system responds to their needs. Benjamin's and Vanessa's accounts above suggest that patients and family members may provide important insights.[1] Yet injured patients are rarely consulted in research studies about hospitals' responses to patient safety incidents. Although those who suffer medical injuries report a strong desire to be heard, they often do not receive that opportunity in their interactions with health care providers[2] – or in research.

Although the existing research about injured patients' needs establishes some fundamentals,[3] little is known about the range of their needs and about how well health care organizations meet those needs.[4] Some researchers have described patients' experiences of medical injuries, underscoring the fact that health care providers' responses to injury often fail to meet patients' needs.[5] Research results suggest that the following patients' needs are often unmet: being heard, proactive and early offers of compensation, non-adversarial discussion about compensation, and hearing that efforts will be made to prevent recurrences of the event.[6] Researchers recently observed that these findings are challenging to apply to health care providers' responses to medical injuries because they 'lack the granularity necessary to identify specific improvements' to serve patients' needs.[7] Since there are no publications about the medico-legal and ethical concerns involving research with injured patients and family members, this article draws from research about the ethical and psychological concerns involving participants who have experienced trauma.

The paucity of research about patients' and families' experiences of medical injury is attributable to the difficulty researchers have in gaining access to potential participants. One challenge is that institutional review boards (IRBs) and health care providers often worry about potential harms to participants from research that asks them to revisit traumatic events. For example, Australian researchers reported that the 'low number' of hospitals willing to participate in such research (21 of 40 approached) was partly due to non-approval by research ethics committees.[8] Expectations of IRB resistance have also chilled hospitals' participation in our own research into injured patients' experiences, even at institutions with a strong commitment to transparency around patient safety incidents.

A second challenge is fear of malpractice liability. Hospital administrators—particularly risk managers and legal counsels—often express worries that research interviews or surveys asking about patient safety incidents may provoke patients and families into taking legal action. An often-heard response to research proposals refers to the dangers of 'poking the skunk'; that is, the fear that inquiring into their experiences could disturb an otherwise placid state of affairs, with serious consequences, by causing patients and family members to reflect on just how poorly they were treated. Such concerns reportedly have stalled research into patients' experiences in some communication-and-resolution programmes in the USA.[9]

Overall, projects in this field are described as high-risk. The perceived risks are that most patients and families will not wish to participate in research and, if they do, they may be traumatized by the research process and/or provoked to file medical malpractice claims. These perceived risks, and institutions' reluctance to provide researchers with access to injured patients and family members, are among the reasons so little is known about the needs of those who experience medical injuries. This article explores whether the ethical and medico-legal concerns are, in fact, well founded.

We argue that health care institutions make both an ethical and an empirical misstep when they turn away this type of research. First, as health care providers they have an ethical obligation to engage in quality-improvement activities, particularly those that may help them avoid harming patients or mitigate the harm they do cause. This obligation trumps any concerns about research adversely affecting the institution's economic interest (e.g., by increasing medico–legal costs). Second, concerns that research with injured patients will harm them or the institution are not substantiated by the existing evidence.

In advancing that empirical claim, we draw on existing work in the field of trauma research as well as our own research experiences. In 2015 and 2016, two US academic medical centres and a number of institutions in New Zealand allowed us to undertake research with injured patients and family members. We conducted in-depth (30–180 min.), semistructured interviews with 30 patients and family members in the USA and 62 in New Zealand, culminating in two reports on their emotional and practical needs following patient safety incidents.[10] Information about the type and severity of the medical injuries experienced by our research participants is outlined elsewhere.[11] Our sample included patients

[1] In discussing medical injuries, we use the World Health Organization's preferred phrase, 'patient safety incident'. See Wu, A. W., McCay, L., Levinson, W., Iedema, R., Wallace, G., Boyle, D. J., … Gallagher, T. H. (2017). Disclosing adverse events to patients: International norms and trends. *Journal of Patient Safety*, *13*(1): 43–49.

[2] Moore, J., & Mello, M. (2017). Improving reconciliation following medical injury: A qualitative study of responses to patient safety incidents in New Zealand. *BMJ Quality and Safety*, *26*(10), 788–798; McVeety, J. Keeping-Burke, L., Harrison, M., Godfrey, C., & Ross-White A. M. (2014). Patient and family member perspectives of encountering adverse events in health care: A systematic review. *JBI Database System Reviews Implement Reports*, *12*(7), 315–373.

[3] McVeety et al., op. cit. note 2; Mazor, K. M., Goff, S. L., Dodd, K. S., Velten, S. J., & Walsh, K. E. (2010). Parents' perceptions of medical errors. *Journal of Patient Safety*, *6*(2), 102–107.

[4] Moore, J., Bismark, M., & Mello, M. (2017). Patients' experiences with communication-and-resolution programs after medical injury. *JAMA Internal Medicine*, *177*(1), 1595–1603.

[5] Southwick, F. S. Cranley N. M., & Hallisy, J. A. (2015). A patient-initiated voluntary online survey of adverse medical events: The perspective of 696 injured patients and families. *BMJ Quality and Safety*, *24*(10), 620–629.

[6] Moore et al., op. cit. note 4; Moore & Mello, op. cit. note 2.

[7] Moore & Mello, op. cit. note 2.

[8] Iedema, R., Mallock, N. A., Sorensen, R. J., Manias, E., Tuckett, A. G., Williams, A. F., … Jorm, C. M. (2008). The national open disclosure pilot: evaluation of a policy implementation initiative. *Medical Journal of Australia*, *188*(7), 397–400.

[9] Van Niel, M. B., DeVoe, T., Shah, R., & Sands, K. E. F. (2016). Patient representation in communication and resolution programs: What is the best model? *Healthcare Professional Liability Review*, *1*(1), 1–10.

[10] Moore & Mello, op. cit. note 2; Moore et al., op. cit. note 4.

[11] Ibid.

who fell into all injury severity classifications, ranging from the so-called 'minor injuries' to the 'sentinel injuries' (death or permanent injury). Our experience provides no corroboration for anxieties about undertaking research with injured patients. On the contrary, we conclude that when researchers engage responsibly with injured patients and families, the benefits for both individual participants and hospitals are likely to outweigh the risks.

In this article, we use the term 'trauma research participants',[12] rather than 'vulnerable' research subjects or 'victims', to describe these research participants, for several reasons. First, the experience of medical injury is often traumatic. Second, commentators have critiqued the use of 'vulnerable' and 'victim' because these terms may be pejorative and stigmatizing and may preclude recognition of participants' agency.[13] Third, although the research ethics literature stresses that 'vulnerability' is a 'contentious and fluid' term,[14] the typical categories of vulnerable research participants (such as children, prisoners, and persons with cognitive impairments) do not capture the category of participants in our studies—injured patients and their family members.[15]

We begin with a discussion of the ethical case for hospitals to conduct patient safety–related research, and then turn to concerns about retraumatization and medico-legal risk.

2 | ETHICAL OBLIGATIONS TO CONDUCT PATIENT SAFETY RESEARCH

Ethicists have long characterized quality improvement—of which patient safety improvement is a key pillar[16] —as an ethical imperative in health care.[17] Health care providers have an obligation to deliver the best care to patients that they practicably can, 'to learn from instances when care falls short of the ideal, and to seek opportunities to improve care'.[18]

Although ethicists often source this obligation in professional codes for physicians,[19] they have extended the obligation to hospitals.[20] One basis for this extension is that health care organizations exist to enable health care practitioners to carry out their professional roles.[21] In concluding that quality improvement is 'a fundamental responsibility' of health care organizations, for example, John Agich stresses the unique role of the organization in ensuring that practitioners perform well as a team, providing and coordinating 'the capital, fiscal, human, and information resources essential for this style of health care'. A second rationale is that health care organizations are themselves moral agents[22] with obligations to enhance the quality of care they provide.[23] Blending these two arguments, Sharpe argues that because of the complexity of health care delivery today, a strong ethical case can be made for extending responsibility for patient safety 'to those who have indirect but significant control over decisionmaking that affects patient welfare', including hospital administrators.[24]

Although much of the focus of patient safety improvement is on preventing injuries, the quality of care provided after an adverse event occurs is also important—not least because this period offers opportunities for learning. Consequently, hospitals' obligations extend to the realm of quality improvement in injury response. Indeed, as medical injuries constitute a violation of the bedrock ethical principle of nonmaleficence, preventing them and minimizing the harm associated with them is critical.[25]

Medical injury response also implicates the professional ethical obligation to disclose adverse events to patients,[26] and it is well-recognized that institutional support is essential to physicians' ability to discharge that obligation effectively.[27] Finally, because 'the normative commitment at the heart of contemporary health care' is both to improve patient well-being and to increase scientific knowledge, it is not

[12] Legerski, J., & Bunnell, S. L. (2010). The risks, benefits, and ethics of trauma-focused research participation. *Ethics and Behavior*, *20*(6), 429–442; Jaffe, A. E., DiLillo, D., Hoffman, L., Haikalis, M., & Dykstra, R. E. (2015). Does it hurt to ask? A meta-analysis of participant reactions to trauma research. *Clinical Psychology Review*, *40*(22), 40–56.

[13] Fleischman, A. R., & Wood, E. B. (2002). Ethical issues in research involving victims of terror. *Journal of Urban Health*, *79*(3), 315–321; Atwood, M. (1972). *Survival*. Toronto: House of Anansi Press.

[14] Smith, M., Bernard, C., Rossiter, K., Sahni, S., & Silva D. (2010). Vulnerability: A contentious and fluid term. *Hastings Center Report*, *40*(1), 5–6.

[15] Smith, L. J. (2008). How ethical is ethical research? Recruiting marginalized, vulnerable groups into health services research. *Journal of Advanced Nursing*, *62*(2), 248–257.

[16] Institute of Medicine. (2001). *Crossing the quality chasm: a new health system for the 21st century*. Washington, DC: National Academies Press.

[17] Jennings, B. (2007). Introduction. In B. Jennings, M. Bottrell, M. A. Baily, & J. Lynn (Eds.), *Health care quality improvement: Ethical and regulatory issues* (pp. 1–6). Garrison, NY: Hastings Center; Agich, J. G. (2007). Health care organization responsibility for quality improvement. In B. Jennings, M. Bottrell, M. A. Baily, & J. Lynn (Eds.), *Health quality improvement: Ethical and regulatory issues* (pp. 55–68). Garrison, NY: Hastings Center.

[18] Wynia, M. K., & Kurlander, J. E. (2007). Physician ethics and participation in quality improvements: Renewing a professional obligation. In B. Jennings, M. Bottrell, M. A. Baily, & J. Lynn (Eds.), *Health care quality improvement: Ethical and regulatory issues* (pp. 7–28). Garrison, NY: Hastings Center.

[19] Becher, E. C., & Chassin, M. R. (2002). Taking health care back: The physician's role in quality improvement. *Academic Medicine*, *77*(10), 953–962; Brennan, T. A. (2002). Physicians' professional responsibility to improve the quality of care. *Academic Medicine*, *77*(10), 973–980; American Board of Internal Medicine, American College of Physicians–American Society of Internal Medicine, & European Federation of Internal Medicine. (2002). Medical professionalism in the new millennium: A physician charter. *Annals of Internal Medicine*, *136*(3), 243–246.

[20] Wynia & Kurlander, op. cit. note 18; Agich, op. cit. note 17. Lynn, J., Baily, M. A., Bottrell, M., Jennings, B., Levine, R. J., Davidoff. F., … James, B. (2007). The ethics of using quality improvement methods in health care. *Annals of Internal Medicine*, *146*(9), 666–673; Faden, R. R., Kass, N. E., Goodman, S. N., Pronovost, P., Tunis, S., & Beauchamp, T. L. (2013). An ethics framework for a learning health care system: A departure from traditional research ethics and clinical ethics. *Hastings Center Report*, *43*(1), S16–S27; Sharpe, V. A. (2003). Promoting patient safety: An ethical basis for policy deliberation. *Hastings Center Report*, *33*(5), S1–S20.

[21] Dubler, N., Blustein, J., Bhalla, R., & Bernard, D. (2007). Informed participation: An alternative ethical process for including patients in quality-improvement projects. In B. Jennings, M. Bottrell, M. A. Baily, & J. Lynn (Eds.), *Health quality improvement: Ethical and regulatory issues* (pp. 7–28). Garrison, NY: Hastings Center; Agich, op. cit. note 17.

[22] French, P. A. (1979). The corporation as a moral person. *American Philosophical Quarterly*, *16*(3), 207–215.

[23] Dubler et al., op. cit. note 21; Faden et al., op. cit. note 20.

[24] Sharpe, op. cit. note 20.

[25] Ibid.

[26] Institute of Medicine, op. cit. note 16,

[27] Wu, A. W., Boyle, D. J., Wallace, G., & Mazor, K. M. (2013). Disclosure of adverse events in the United States and Canada: An update, and a proposed framework for improvement. *Journal of Public Health Research*, *2*(3), e32.

confined to operating quality-improvement programmes but also extends to learning activity, including research.[28] To the extent that hospitals allow medico-legal anxieties to drive their decisions about research the needs of injured patients, they abrogate their ethical obligations.

IRBs have different obligations, centred on the mission of protecting and promoting the interests of research participants. Under widely accepted principles of research ethics, their willingness to approve research should turn on balancing the risks of the research to participants with the benefits to participants, patients as a group, and society.[29]

Excessive risk aversion or unfounded judgements that research involves substantial risks can lead to distortions in this weighing. Particularly in young fields of inquiry, such as research on injured patients, IRBs should deliberate from a place of curiosity and fact seeking, rather than a prejudgement about how the proposed research will affect patients. Where research involves clear potential benefits and concerns about risks are no more than speculative, IRBs honour their obligations best by ensuring that the project is conducted in a manner that minimizes risks and maximizes respect for participants' rights and interests.

In summary, before foreclosing a line of research that could have substantial benefits for patients, IRBs should be able to defend the conclusion that it involves unjustifiable risk of harm. As we argue below, the existing evidence does not support such a conclusion for research about the needs of injured patients.

3 | RETRAUMATIZATION CONCERNS

Researchers who wish to undertake projects with people who have experienced traumatic events often experience difficulty in gaining approval from IRBs[30] – and the patient safety realm is no exception.[31] In one study of US IRBs' decision-making processes, researchers' applications were more likely to be rejected if they proposed to investigate 'sensitive topics' compared with nonsensitive topics, even when there were no ethical problems.[32] According to the literature, sensitive topic research typically refers to research topics that may be 'laden with emotion'.[33] Examples of such sensitive topics are 'trauma and sex',[34] 'areas of social life surrounded by taboo',[35] 'birth, death, injuries, cancer, grief, sexual abuse, violence, drug use or homelessness',[36] and, more broadly, 'studies in which there are potentially consequences or implications, either directly for the participants in the research or for the class of individuals represented by the research'.[37]

Recently, researchers calculated that 61.4% of trauma researchers had a US IRB 'raise concerns about asking participants questions about their prior trauma experiences' and 13.3% of researchers stated that an IRB had 'refused to approve a protocol due to concerns about the effects of asking participants about prior trauma experiences'.[38]

What lies behind IRBs' concern about trauma research and sensitive topic research? Researchers working with survivors of trauma may ask participants to recount their experiences in detail using methods such as in-depth interviews. IRBs are concerned that probing participants in this way might induce psychological and emotional distress. Specifically, the fear is that 'recounting of a traumatic event will be in and of itself traumatizing, in essence "retraumatizing" participants'.[39] Researchers report that occasionally IRBs have expressed concern that trauma research may cause 'a crisis situation'[40] and/or necessitate 'long term therapy or even cause participants to become suicidal'.[41]

This fear, however, is inconsistent with a growing body of evidence that 'trauma-related research can continue without harming participants'.[42] Scholars have been writing about how to conduct ethically sound, methodologically rigorous research on sensitive topics since the 1990s.[43] In the early 2000s, researchers turned their attention to the methodological, ethical, and practical issues regarding research with 'vulnerable' and marginalized participants.[44] Since the early 2000s, there has been a 'dramatic increase'[45] in studies about the impact of exposure to trauma on well-being, and about participants' reactions to trauma research.[46]

[28] Faden et al., op. cit. note 20; Agich, op. cit. note 17.

[29] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.

[30] Yeater, E. A., & Miller, G. F. (2014). Sensitive-topics research: Is it really harmful to participants? *APS Observer*, *27*(5). Retrieved from https://www.psychologicalscience.org/observer/sensitive-topics-research-is-it-really-harmful-to-participants; Legerski & Bunnell, op. cit. note 12, p. 430.

[31] Iedema et al., op. cit. note 8; Iedema, R., Allen, S., Britton, K., Piper, D., Baker, A., Sydney West Area Health Service, … Gallagher, T. H. (2011). Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: The '100 patient stories' qualitative study. *BMJ*, *343*(2011): d4423.

[32] Ceci, S. J., Peters, D., & Plotkin, J. (1985). Human subjects review, personal values, and the regulation of social science research. *American Psychologist*, *40*(9), 994–1002.

[33] Lee, R. M. (1993). *Doing research on sensitive topics*. Newbury Park, CA: Sage.

[34] Yeater & Miller, op. cit. note 30.

[35] Farberow, N. L. (1963). *Taboo topics*. New York, NY: Atherton Press.

[36] Liamputtong, P. (2007). *Researching the vulnerable: A guide to sensitive research methods*. London: Sage; Dickson-Swift, V. H., James, E. L., Kippen, S., & Liamputtong, P. (2007). Doing sensitive research: What challenges do qualitative researchers face? *Qualitative Research*, *7*(3), 327–353.

[37] Sieber, J., & Stanley, B. (1988). Ethical and professional dimensions of socially sensitive research. *American Psychologist*, *43*(1), 49–55; p. 49.

[38] Jaffe et al., op. cit. note 12, p. 41.

[39] Legerski & Bunnell, op. cit. note 12, p. 430.

[40] Omerov, P., Steineck, G., Dyregrov, K., Runeson, B., & Nyberg, U. (2014). The ethics of doing nothing: Suicide-bereavement and research: Ethical and methodological considerations. *Psychological Medicine*, *44*(16), 3409–3420.

[41] Jaffe et al., op. cit. note 12, p. 41.

[42] Ibid.

[43] For example, see Lee, op. cit. note 33.

[44] Liamputtong, op. cit. note 36.

[45] Legerski & Bunnell, op. cit. note 12, p. 429.

[46] Jaffe et al., op. cit. note 12; Guerra, C., & Pereda, N. (2015). Research with adolescent victims of child sexual abuse: Evaluation of emotional impact on participants. *Journal of Child Sexual Abuse*, *24*(8), 943–958; Morris, A., Hegarty, K., & Humphreys, C. (2012). Ethical and safe: Research with children about domestic violence. *Research Ethics*, *8*(2), 125–139; Bedard, M., Greif, J. L., & Buckley, T. C. (2004). International publication trends in the traumatic stress literature. *Journal of Traumatic Stress*, *17*(2), 97–101; Hlavka, H. R., Kruttschnitt, C., & Carbone-López, K. C. (2007). Revictimizing the victims? Interviewing women about interpersonal violence. *Journal of Interpersonal Violence*, *22*(7), 894–920; Griffin, M. G., Resick, P, A., Waldrop, A. E., & Mechanic, M. (2003). Participation in trauma research: Is there evidence of harm? *Journal of Traumatic Stress*, *16*(3), 221–227; Carlson, E. B., Newman, E., Walker Daniels, J., Armstrong, J., Roth, D., & Loewenstein, R. (2003). Distress in response to and perceived usefulness of trauma research interviews. *Journal of Trauma and Dissociation*, *4*(2), 131–142; Brabin, P., & Berah, E. (1995). Dredging up past traumas: Harmful or helpful? *Psychiatry, Psychology and Law*, *2*(2), 165–171.

We are not aware of any studies about reactions to trauma research among patients who experienced medical injuries. However, the literature about the psychological impact that participation in trauma research has on trauma-exposed populations such as survivors of child sexual abuse, terrorist attacks, crime, natural disasters, motor vehicle accidents, and intimate partner violence is relevant.[47]

A number of researchers have investigated whether trauma research retraumatizes participants and have concluded that participation, in and of itself, is not retraumatizing.[48] In the absence of a standardized approach for measuring distress related to research participation, distress has been measured in different ways, including whether participants reported distress or feelings of anxiety and whether they felt more upset during and after the research process than before.[49] Although a small minority of participants reported that the research process was mildly emotionally distressing, the impact was short-lived and the majority of participants found participation beneficial.[50] Most participants did not regret their participation and many acknowledged the value of the research. Even the participants who reported distress concluded that the process was nevertheless beneficial.[51] Furthermore, participants have reported that disclosure of trauma can feel 'therapeutic'[52] and 'healing'.[53]

A recent meta-analysis of 73,959 participants across 70 samples echoed these conclusions, concluding that individuals generally find research participation to be a positive experience and do not regret participating.[54] There is also some evidence suggesting that certain research procedures are less likely to induce stress than others. For example, interviews may be less likely to cause distress than other data-collection techniques.[55] This strengthens researchers' arguments that qualitative data-gathering techniques provide opportunities to collect survivors' stories in ways that quantitative research may be unable to match.[56] The main limitations of studies about distress relating to participation in trauma research are variable and subjective metrics, a lack of clarity about what evaluation criteria participants use when they rate their levels of distress, and self-selecting bias in the individuals who choose to participate.

The empirical evidence has led scholars to call for researchers who submit trauma research proposals to IRBs to include a brief review of the literature about the risks and benefits of this type of research with their proposal.[57] The aim is to inform IRBs about the evidence.

Consistent with the existing literature on trauma research, the 92 New Zealand and US patients who participated in our studies did not report that they experienced research-related re-traumatization or distress. At the end of interviews, our participants were asked, 'Do you have any other thoughts, concerns or issues that you would like to raise?' In response to this question, most participants offered reflections on the interview and the broader research project. The most frequent comments were that participants appreciated the opportunity to 'give feedback to the hospital' and to tell their 'story'. Even the small number (5/92) who initially expressed concern about being interviewed noted that they felt relieved and pleased afterwards. As one patient explained: 'I was a bit worried I'd be too emotional to do this interview, but it has been great. You have made my day'.

Many of our participants (82/92) commented that it was difficult and emotionally draining to recount their experiences of patient safety incidents. However, they, too, felt relieved and pleased afterwards. One of our 92 participants felt upset enough to ask to take a break in recounting her experiences of trauma that she asked to take a break from audio recording. The interviewer inquired about her well-being after the interview and the participant reported that

> [t]he interview was really difficult because it brought up emotions, but it was good for me to do it. I am so interested in the work that you do not just because you helped us work through things, but also because the work is so desperately needed and you have found such unique ways to get at the problems. Thank you!

We are still in contact with this participant and she voluntarily expressed interest in participating in our next study about this topic.

These findings suggest that emotional distress should be mentioned in the informed consent form as a potential burden of participating in this type of research but does not rise to the level of harm to participants that should undercut the prospects for the research to go forward. In some cases, it may prove to be a benefit, providing an outlet for unexpressed emotion. Consistent with prior trauma research, many participants expressed the view that the interview was a 'healing' or 'cathartic' experience.

[47] Jaffe et al., op. cit. note 12; Guerra & Pereda, op. cit. note 46; Morris et al., op. cit. note 47; Hlavka et al., op. cit. note 46.

[48] Legerski & Bunnell, op. cit. note 12 at 440.

[49] Carter-Visscher, R. M., Naugle, A. E., Bell, K. M., & Suvak, M. K. (2007). Ethics of asking trauma-related questions and exposing participants to arousal-inducing stimuli. *Journal of Trauma and Dissociation*, *8*(3), 27–55; Cromer, L. D., Freyd, J. J., Binder, A. K., DePrince, D. A. P., & Becker-Blease, K. (2006). What's the risk in asking? Participant reaction to trauma history questions compared with reaction to other personal questions. *Ethics & Behavior*, *16*(4), 347–362.

[50] Jaffe et al., op. cit. note 12.

[51] Boothroyd, R. A., & Best, K. A. (2003). Emotional reactions to research participation and the relationship to understanding of informed consent disclosure. *Social Work Research*, *27*(4), 242–251; Legerski & Bunnell, op. cit. note 12.

[52] Stein, D. J., Herman, A., Kaminer, D., Rataemane, S., Seedat, S., Kessler, R. C., ... Williams, D. (2000). Ethical aspects of research on psychological trauma. *Dialogues in Clinical Neuroscience*, *2*(1), 31–36; Pennebaker, J. W., & Susman, J. R. (1998). Disclosure of traumas and psychosomatic processes. *Social Science & Medicine*, *26*(3), 327–332; Pennebaker, J. W., Barger, S. D., & Tiebout, J. (1989). Disclosure of traumas and health among Holocaust survivors. *Psychosomatic Medicine*, *51*(5), 577–589.

[53] Stein et al., op. cit. note 52; Balarajan, R., Stein, D., Swartz, J. L., & Walaza, N. (2000). Mental health beyond the Truth and Reconciliation Commission. *Ethnicity & Health*, *5*(3–4), 189–190. https://www.tandfonline.com/doi/abs/10.1080/713667461

[54] Jaffe et al., op. cit. note 12.

[55] Legerski & Bunnell, op. cit. note 12, p. 437.

[56] Lee, op. cit. note 33; Liamputtong, op. cit. note 36.

[57] Legerski & Bunnell, op. cit. note 12, p. 440.

Study participation also appeared to confer other psychological benefits. For many patients and families, the interview was the first opportunity to share their experiences of patient safety incidents with an empathetic listener. We learned that being heard was a key unmet need,[58] and the interviews served this need. The following observation from one of our participants captures other patients' feelings: 'Thank you so much for doing this study and letting me share our story. I hope it will help other families in the future!' Many expressed gratitude to the interviewer for the experience, after the interview and/or during meetings subsequent to the end of the project.

Consistent with existing evidence highlighting the benefits of participation in trauma research, many of our participants commented that a factor in their decision to participate was the perception of the potential benefit of the research. According to one patient, for example, the research was 'really important' because 'it could make a difference to how hospitals talk to patients'. Participants in the US study were given the option of sharing their interview transcript, or a summary, with the institution. They particularly appreciated the opportunity to provide feedback to an independent person and have it relayed to institutions in a manner and form that they controlled.

4 | IMPLICATIONS FOR RESEARCH PRACTICE

Our studies suggest a number of recommendations for institutions' processes and research practice. For IRBs, we recommend consideration of the growing empirical evidence that the fear about the retraumatization of participants in trauma research may be overestimated. Additionally, as long as study recruitment procedures avoid potentially coercive approaches, IRBs should feel confident that those who do not wish to talk about their experiences will simply decline to participate. In our US study, 30 of the 50 patients and family members who were invited to participate agreed to be interviewed; in New Zealand, 62 of 103 participated. These response rates suggest that individuals felt free to decline, whether out of concern about anticipated distress or for other reasons.

For researchers, our research leads to six recommendations for undertaking ethically sound trauma research. First, use a skilled, experienced, and empathetic interviewer. As trauma researchers have observed, the 'rapport established with the interviewer, and the extent to which the subject feels adequately heard and appreciated' impact on participants' evaluations of the research experience.[59] Trauma researchers should be skilled at 'ethics in practice'—that is, able to anticipate and address 'everyday ethical issues' that arise in the course of research.[60] The nature of the topic, and the types of participants, mean that the research process is not easy for the participants or researchers. Many trauma researchers have made observations such as this:[61]

> I now know why there is little research being done in the area of neighbourhood trauma. It is hard, grinding work—emotionally, spiritually, and psychologically. However … this work can be done.

The research process, particularly data collection, often moves close to the borderline of therapy. According to a trauma social scientist:[62]

> [W]e are seeing efforts to map an intermediate space we can't quite define yet, a borderland between passion and intellect, analysis and subjectivity, ethnography and autobiography, art and life … Call it sentimental, call it Victorian and 19th century, but I say that anthropology that doesn't break your heart just isn't worth doing anymore.

For researchers working with trauma survivors, their roles should be located within an interpretivist, rather than a positivist, paradigm. This is important because trauma researchers need the ability occasionally to remove the cloak of researcher objectivity and decrease the emotional distance between researcher and participant. This reciprocity is recognized as an important aspect of trauma research.[63] It refers to the 'give and take typical of social interactions among people'.[64]

Reciprocity is common in qualitative research about trauma, particularly among feminist social scientists.[65] Two experiences of our interviewer in negotiating reciprocity may help illuminate how it can come into play. The first arose in a project undertaken in Israel in 2002 shortly after the terrorist attack on campus at Hebrew University. The interviewer was on campus at the time of the attack and had to decide whether to share her experiences with research participants. The second arose in our US study about medical injury. The interviewer lost a close family member due to a probable medical error shortly before the study began. For both projects, she decided to share her experiences briefly with participants, but only with those who inquired about her personal connection to the study's topic and only at the conclusion of the interview. The participants with whom the interviewer shared this information expressed great appreciation, which suggests that reciprocity is suitable practice for this topic.

[58] Moore & Mello, op. cit. note 2; Moore et al., op. cit. note 4.

[59] Stein et al., op. cit. note 52, p. 33.

[60] Guillemin, M., & Gillam, L. (2004). Ethics, reflexivity and 'ethically important moments' in research. *Qualitative Inquiry, 10*(2), 261–280, at pp. 263 and 269.

[61] Connolly, K., & Reilly, R. C. (2007). Emergent issues when researching trauma: A confessional tale. *Qualitative Inquiry, 13*(4), 522–540.

[62] Behar, R. (2006). *The vulnerable self: Anthropology that breaks your heart*. Boston, MA: Beacon.

[63] Schwandt, T. (2001). *Dictionary of qualitative inquiry*. Thousand Oaks, CA: Sage.

[64] Connolly & Reilly, op. cit. note 61, p. 534.

[65] For example, see Charmaz, K. (2000). Grounded theory: Objectivist and constructivist methods. In N. Denzin & Y. Lincoln (Eds.), *The Sage handbook of qualitative research* (pp. 509–531). London, UK, and Thousand Oaks, CA: Sage.

A second recommendation is to time the interview appropriately. Hospital personnel who have worked with the family in the aftermath of the patient safety incident can help to establish a feasible time frame for approaching patients for research participation. This may vary from person to person, depending on the degree of disruption caused by the incident. Patients who have had several weeks or months to process the event may be better able to reflect on their experience than those still in the initial coping stage. Although researchers may worry about recall bias, we found that patients and family members had vivid memories of the experience even years afterward because of the profound nature of what they had been through. However, a vivid memory of an event does not necessarily mean that the participants are not subject to recall bias.

It is also important to allow ample time to conduct the interview without time pressure. Although we asked participants for a 60-min. interview, we indicated that they could speak for longer if they desired. All the patient and family member participants spoke for more than an hour. Because being heard has such psychic importance for this group, it is critical to avoid rushing participants and to allow their priorities to lead the discussion. Adopting unstructured or loosely semistructured interview styles helps to ensure that participants' concerns are addressed during the interview.

Third, the research protocols should require a representative of the hospital or its liability insurer to make the initial approach to patients and families about study participation. The protocol should underscore that the researchers are independent. This approach signals the hospital's commitment to learning how to serve patients better, secures patients' permission for release of their personal information to researchers, and maximizes the participants' candour during interviews. Many of our participants made statements such as 'I told you things that I did not tell [the hospital]' and 'It's more comfortable talking to someone outside the hospital, like you, because you're from a university. But I wanted to explain my story and I'm glad you'll be giving the information to the hospital'.

Fourth, researchers should exercise special care when interviewing parents of severely injured or deceased children but should not exclude them. Although concerns about retraumatization may be especially acute for this group, research participation is no less valuable to them than to others. Recent Scandinavian research, for example, found that among 666 suicide-bereaved and 377 nonbereaved parents who participated in a population-based survey, 'positive experiences were widely expressed and 94% of the parents thought that the study was valuable'.[66] In other research about bereaved parents' experience of research participation, parents also reported that their traumatic experiences were difficult to discuss but that the process was worthwhile.[67] The parent participants in our studies made similar comments. For example, a mother who lost her child due to a medical error explained that the 'interview brought up emotions, but it was helpful to talk and this research is greatly needed. I feel like it gives meaning to my child's life'.

Fifth, researchers should ensure that patients have an opportunity to control how their comments are relayed to hospitals. Many participants in our US study wanted the hospitals to receive their individual feedback, but only some were comfortable with providing full interview transcripts. A few desired the hospital to reach out to them to address issues they felt were unresolved. For example, adolescents who had been excluded from conversations about a patient safety incident because they were too young wanted a chance to speak their mind to hospital representatives. The hospitals in our study did reach out to individuals who requested it and appreciated being notified.

Finally, it is important to recognize that receiving research findings and having follow-up contact with the research team may be important to some participants. Patients who opt to participate in this type of research may be motivated by a desire to improve health care and thus may wish to be informed of the research results and their impact. Interview or survey questions thus should elicit participants' preferences on the feedback of findings. In our experience, many participants will be eager to contribute to ongoing research and quality-improvement efforts. Additionally, because of the sensitive subject matter, researchers in interview studies should check in with the participants a few days after the interview to inquire about how they were feeling, and be ready with suggestions for support groups and other resources to address ongoing emotional needs.

5 | CONCERNS ABOUT PROVOKING LAWSUITS

There is widespread unease among health care institutions and their lawyers that research with patients injured during their care will provoke lawsuits.[68] Such concerns present challenges to this type of research because in the USA the statute of limitations (or the time in which patients are allowed to file medical malpractice claims after they are injured) is typically 3 years. Consequently, most patients would be eligible to file a claim at the time a researcher would want to talk to them. In our own work, this concern has shut down several attempts to launch studies of injured patients. Even institutions that ultimately allowed our study decided to limit who we were permitted to speak to. Specifically, hospital risk managers and/or insurance company representatives asked that we limit our study to (a) patients who had already accepted a settlement and signed a release of claims and (b) patients for whom the statute of limitations had already elapsed.

Hospitals' medico-legal risk aversion presents an ethical problem when it interferes with hospitals discharging their obligation to engage in quality-improvement work, including research on injured

[66] Omerov et al., op. cit. note 40, p. 3416.

[67] Dyregrov, K. (2004). Bereaved parents' experience of research participation. *Social Science & Medicine, 58*(2), 391–400.

[68] Van Niel et al., op. cit. note 9.

patients. Hospitals should not permit a self-interested economic concern to undercut their commitment to providing the best possible care.

Prior literature is of limited usefulness in understanding the actual extent of the risk about which hospitals are concerned. There is evidence that in the US delays in filing claims are common. A large study of closed malpractice claims found that the median time from injury date to filing date was 1 year and the average was 2 years.[69] Thus, many potential research participants are indeed potential plaintiffs.

The more trenchant question, however, is how likely it is that being asked about their experiences will prompt patients and family members to file a claim. To the extent that being heard is a key aspect of meeting patients' needs following medical injury,[70] talking may decrease the impetus to sue, rather than increase it. The notion underlying medico-legal anxiety—that patients have not thought about how the hospital treated them in the aftermath of the event and will only be prompted to do so when a researcher interviews them—strains credulity. Our interviews revealed that patient safety incidents are often major events in patients' lives.[71] Their recall is very detailed, and they had given much thought to how they felt about their providers' responses.[72]

We did not specifically inquire, when interviewing patients and family members, whether the experience of being interviewed inspired them to consider litigation. However, in more than 90 interviews, we heard and saw nothing to suggest that the conversation increased patients' feelings of anger or provoked them to feel that they wished they had filed a civil claim. Our sample was biased because 26 of our participants had already received settlements. Those who had not received settlements did not express regret about not suing. Even though some who had received settlements felt the amount was too low, again, there was no indication that the interviews caused respondents to feel resentful or more dissatisfied than they had previously been. Of the 27 US participants who reported that they had received compensation, 16 felt satisfied with it.[73]

There is a substantial body of scholarship in the sociology of law that emphasizes a propensity to claim.[74] It is possible that the concerns about provoking lawsuits are partly informed by this culture, which, in the literature, is referred to as 'naming, blaming and claiming'.[75] However, patient safety researchers have found that few injured patients claim. For example, New Zealand research found that one in 200 injured patients complained to the health and disability commissioner.[76] New Zealanders are statute-barred from bringing personal injury civil claims and instead complain to the commissioner. The researchers also found that the 'under-complaining phenomenon' was not spread uniformly across the patient population: elderly and socioeconomically disadvantaged patients were less likely to complain.[77] These findings suggest that the fear of provoking lawsuits may be overestimated for the injured patient population.

In summary, although there is a theoretical risk that research participation could prompt malpractice claims, empirical evidence for the proposition is lacking.[78] Our study cannot definitively establish the extent of the risk but provides some evidence that it is likely overestimated by hospitals. This is consistent with prior research that found that compensation may be less important than other forms of accountability to people who have suffered bereavement.[79] Notably, no study suggests that talking with injured patients does prompt lawsuits. Because the risk is unsubstantiated, the research holds promise for benefiting patients, and bending to fear of litigation is in conflict with the ethical duty to engage in learning activity to improve quality. Refusing researchers access to injured patients is not justifiable.

6 | RECOMMENDATIONS FOR INSTITUTIONS AND RESEARCHERS

Our studies lead to a number of recommendations for health care institutions and researchers. First, hospitals should recognize that talking about an incident will not dredge up feelings of dissatisfaction if patients feel they were treated well in the first place. Therefore, they should ensure that their responses to patient safety incidents incorporate what has already been learned about patients' needs following injury. Our research, and that of others,[80] suggests that satisfaction with institutions' responses is only partly to do with financial compensation for injuries. Also important are (a) the extent to which patients and family members felt they were truly listened to and given an authentic apology, and (b) whether they were told how the providers would ensure that a similar harm did not happen to another family.[81] In particular, it is important to ensure that patient safety efforts are communicated.

[69] Studdert, D., Mello, M. M., Atul, A., Gawande, T. K., Gandhi, A. K, Yoon, C., ... Brennan, T. A. (2006). Claims, errors, and compensation payments in medical malpractice litigation. *New England Journal of Medicine*, *354*, 2024–2033.

[70] Moore & Mello, op. cit. note 2.

[71] Moore et al, op. cit. note 4; Moore & Mello, op. cit. note 2.

[72] Ibid.

[73] Moore et al., op. cit. note 4.

[74] Galanter, M. (2010). The dialectic of injury and remedy. *Loyola of Los Angeles Law Review*, *44*(1), 9–22; Felstiner, W., Abel, R. L., & Sarat, A. (1981). The emergence and transformation of disputes: Naming, blaming, claiming. *Law and Society Review* 15(3–4), 631–654.

[75] Felstiner et al., op. cit. note 74.

[76] Bismark, M., Brennan, T. A., Paterson, R. J., Davis, P. B., & Studdert, D. M. (2006). Relationship between complaints and quality of care in New Zealand: A descriptive analysis of complainants and non-complaints following adverse events. *Quality and Safety in Health Care*, *15*(1), 17–22.

[77] Ibid.

[78] Vincent, C., Young, M., & Phillips, A. (1994). Why do people sue doctors? A study of patients and relatives taking legal action. *Lancet*, *343*(8913), 1609–1613; Van Niel et al., op. cit. note 9.

[79] Bismark, M., Dauer, E., Paterson, R., & Studdert, D. (2006). Accountability sought by patients following adverse events from medical care: The New Zealand experience. *CMAJ*, *175*(8), 889–894.

[80] Bismark, M. (2009). The power of apology. *New Zealand Medical Journal*, *122*(1304), 96–106.

[81] Moore & Mello, op. cit. note 2; Moore et al, op. cit. note 4.

If learning takes place over a long time frame, hospitals should reach out to patients to share new steps taken.

Our experience was that hospitals expressed unease about that suggestion because by the time they had finalized the lessons about patient safety they wanted to implement, patients were no longer on site and risk managers feared that reaching out to them would dredge up unwelcome memories, resulting in distress and/or lawsuits. However, our data suggest the opposite. Patients and families reported feeling aggrieved and feeling that the incident was not 'resolved' if they did not hear from the institution about its patient safety efforts. In the US sample, 24 of the 30 participants reported receiving no information about safety improvement efforts.[82] For example, the following comments from a family member in our study capture the sentiments of other participants:

> Could you please find out what, if anything, has happened? One of the reasons I participated in this study was to find out if anything happened. I cannot move on until you find out what happened. I should not have to keep putting my hand up to get this information. There's no closure for me until I hear from them.

This quotation suggests that research can help fulfil patients' need to learn about safety improvement efforts—but also that hospitals can set the stage for research to find high levels of patient satisfaction by ensuring that need is met at the outset.

A second recommendation is that interview questions and tone should not plant the seed that the patient should have filed a claim or was treated badly. Interviewers should be empathetic without endorsing a view that the providers should be held to account. Study recruitment and informed consent materials should emphasize that the study is about patient safety and meeting families' needs, not about malpractice.

Third, researchers should convey the notion that the institution has partnered in the research because it wants to serve patients better. This message is important because our studies,[83] like prior research,[84] found that injured patients and families have a strong desire to improve health care for the benefit of other patients. Almost all patients and families (90/92) in our samples expressed hope that the research would improve the health care system. With patients' and family members' permission, the patient safety efforts could be publicized to the general population.

Finally, researchers should make a plan with institutions in advance about how to respond to patients who become angry during the interview, express the view that they have been treated unfairly, or express interest in pursuing a malpractice claim. Asking whether the participants would like the researchers to relay their concerns to the institution is usually an appropriate response to expressions of anger or unfair treatment. If talk turns to legal action, a more pointed question about whether it would be acceptable for a risk manager to contact them about their complaint may be warranted. Such a referral can open lines of communication, defusing the ill feelings that have provoked thoughts of suing or, in some cases, bringing to light a situation that warrants proactive compensation or other remedial gestures.

7 | LIMITATIONS

In this article, we have drawn on existing work in the field of trauma research as well as our own research experiences. Specifically, we drew from research that we undertook in New Zealand and the USA in 2015 and 2016.[85] The main limitation of those studies is generalizability. In the New Zealand study 'the recruitment methods may not have produced a nationally representative sample of all patients with treatment injuries'.[86] In the US study, 'our sample is not representative of all CRP events'.[87]

8 | CONCLUSION

Undertaking research with injured patients and family members requires fortitude on the part of institutions and care on the part of researchers. The caution that IRBs, hospital lawyers, and risk managers typically exercise when asked to permit this type of research is understandable, given that their primary mission is risk management. However, their anxiety lacks an empirical basis and contributes to a distorted weighing of the risks and benefits of research with injured patients. Further, it conflicts with their ethical obligation to facilitate research that holds promise for improving patient safety and health care quality.

There is every reason to believe that the potential benefits of research on injured patients needs to outweigh the benefits. Our studies reinforce findings from the growing body of empirical research showing that participating in research about traumatic events is unlikely to result in retraumatization. Like other victims of trauma, the participants we interviewed reported that the benefits of study participation outweighed any mild emotional distress they experienced, and that they felt the research was valuable. Reviewing our experience and prior work also provides reassurance that patients who talk about their experiences with skilled interviewers are not provoked into legal action. Rather than poking the skunk, the process of eliciting and listening to patients' feedback about their experiences, if done well, can help preserve calm and foster feelings of reconciliation.

These findings add weight to the calls for IRBs to be less hesitant about approving proposals to undertake sensitive research

[82] Moore et al., op. cit. note 4.

[83] Moore & Mello, op. cit. note 2; Moore et al., op. cit. note 4.

[84] McVeety et al., op. cit. note 2.

[85] Moore et al., op. cit. note 4; Moore & Mello, op. cit. note 2.

[86] Moore & Mello, op. cit. note 2.

[87] Moore et al., op. cit. note 4.

about trauma. They also suggest that health care providers consider developing their own debriefing processes with patients and family members to collect feedback on the hospital's response to medical injury. For example, the Stanford University Medical Center's insurer recently introduced a process through which a senior administrator asks patients and families for feedback after their case is evaluated for compensation. This type of communication, whether outside the research context or within it, emphasizes patients' voice and can help hospitals improve the quality of care.

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