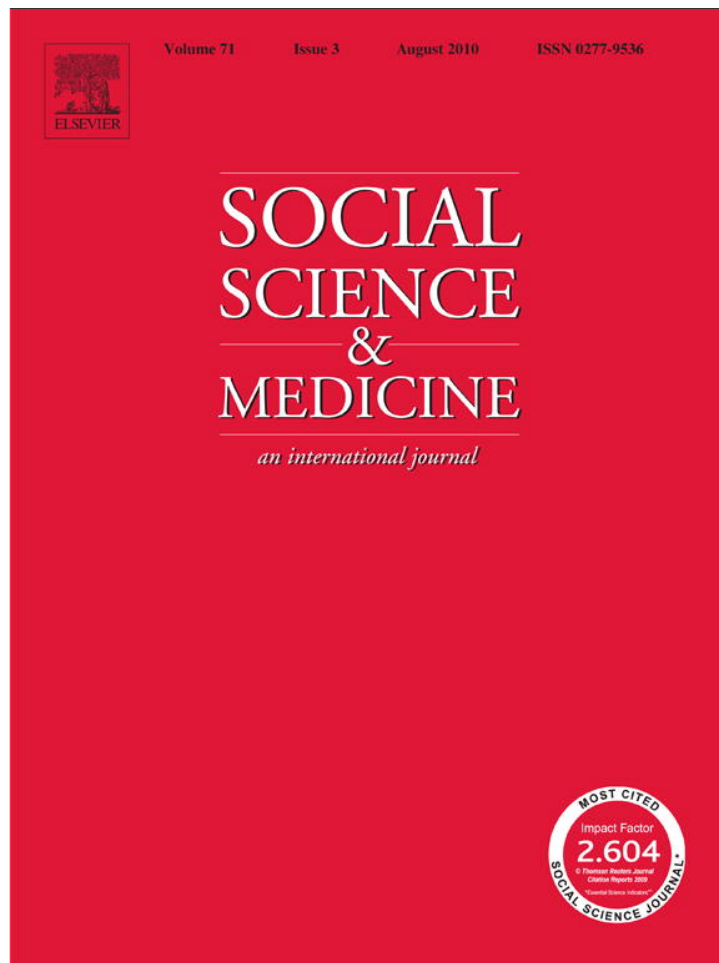


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Harmed patients gaining voice: Challenging dominant perspectives in the construction of medical harm and patient safety reforms

Josephine Enyonam Ocloo*

King's College London, NIHR King's Patient Safety and Service Quality Research Centre, -2 Basement, Strand Bridge House, 138-142 Strand, London WC2R 1HH, United Kingdom

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ABSTRACT

Patient safety is a central issue in healthcare. In the United Kingdom, where there is more accurate information on National Health Service (NHS) hospitals than on primary care or the private sector, the evidence on adverse incidents shows that avoidable medical harm is a major concern. This paper looks at the occurrence of medical harm and argues that in the construction of patient safety reforms, it is important to be aware of alternative narratives about issues of power and accountability from harmed patients and self-help groups, that challenge dominant perspectives on the issues. The paper draws upon evidence from two sources. First, the paper draws on experiences of self-help groups set up as a result of medical harm and part of a campaigning network, where evidence was gathered from 14 groups over more than 2 years. In addition, data were obtained from 21 individuals affected by harm that attended a residential workshop called the Break Through Programme; 18 questionnaires were completed from participants and a written narrative account of their experiences and observational data were gathered from a range of workshop sessions. Looking at the issues from harmed patients' perspectives, the research illustrates that a model of medical harm focussing predominantly upon the clinical markers and individual agency associated with a medical model operates to obscure a range of social processes. These social processes, connected to the power and dominance of the medical profession and the activities of a wider state, are seen to be a major part of the construction of harm that impacts upon patients, which is further compounded by its concealment. Understanding the experiences of harmed patients is therefore seen as an important way of generating knowledge about the medical and social processes involved in harm, that can lead to a broader framework for addressing patient safety.

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Introduction

Widespread agreement now exists on the need to address patient safety in modern healthcare systems (Kohn, Corrigan, & Donaldson, 1999; Wilson et al., 1995; WHO, 2008–2009) and for many countries this has now become 'the key issue in terms of healthcare quality and risk management' (National Audit Office (NAO), 2005:1). Global efforts have further strengthened the call to tackle adverse healthcare events, through the establishment of the WHO World Alliance for Patient Safety, who note that whilst progress has been made in a number of areas, there is 'a vast unfinished agenda that still remains' (WHO, 2008–2009:2). In the UK, whilst the debate about tackling patient safety is relatively well developed, with some progress made in creating a patient safety culture, significant concerns remain (House of Commons, 2009).

Regarding patient safety data, there are few comprehensive studies of the numbers of patient safety incidents (PSIs) in healthcare and these mainly cover hospital settings. Reliable information that does exist suggests that medical harm is widespread in health and a recurring phenomenon in caring for patients (Kohn et al., 1999; NAO, 2005). It is generally agreed that about 10% of hospital admissions result in a PSI. A broader international review of nine retrospective studies of patient records on PSIs found that these made up on average 8.9% of hospital admissions within a range of estimates from 3.8 to 16.6% (NAO, 2005). Most studies suggest that deaths from PSIs are significantly under-reported. In the UK these have been estimated to fall somewhere within a range from 840 to 34,000 deaths a year (NAO, 2005). In the US estimates have ranged from 44,000 to 98,000 deaths each year in hospitals as a result of preventable medical errors (Kohn et al., 1999:22). PSIs have also been found to have considerable economic implications; these have been estimated to cost the NHS £2 billion a year in extra bed days, with hospital acquired infections adding a further billion to these costs (NAO, 2005). In the US, the costs of PSIs have been estimated

* Tel.: +44 0 20 7848 1801.

E-mail address: josephine.ocloo@kcl.ac.uk

(including total national costs for lost income, lost household production, disability healthcare costs) at between \$37.6 billion and \$50 billion (Thomas et al., 1999 cited in Kohn et al., 1999: 22).

To date a key difficulty in addressing medical harm has been how to define and measure the problem (Brennan, 2000; Kohn et al., 1999). Broadly speaking, patient safety refers to the 'prevention of iatrogenic injury—that is, injuries caused by medical management as opposed to the patient's underlying disease process' (Mello, Kelly, & Brennan, 2005:377). The debate about classifying and addressing the issues associated with medical harm has primarily been conducted at a professional and academic level and frequently excluded patients and the public (Coulter & Ellins, 2006; NAO, 2003, 2007). This situation is now being increasingly challenged by patients who have sought to open up a wider debate about addressing patient safety concerns and how they can be part of developing solutions to the issues, both in the UK (Ocloo, 2008) and internationally (Newell, Jones, & Hatlie, 2010; WHO, 2007).

Broadening the discourse on patient safety

This paper looks at research in the UK based upon the experiences of harmed patients and considers what significance these have in the context of a considerable patient safety movement to emerge over the last ten years. This movement has been driven by a number of high profile inquiries into clinical and service failings in healthcare that have frequently been fought for by harmed patients. Examples include the *Bristol Inquiry (2001)* (into children's heart surgery), the *Shipman Inquiry (2001–2005)* (into the murders of large numbers of patients by the GP Harold Shipman) and the *Maidstone & Tunbridge Wells Inquiry, 2008* (which investigated the deaths of several patients caused by outbreaks of *clostridium difficile*). These inquiries have highlighted the importance of developing safety cultures that deal with the prevention of harm to patients and reinforced demands from the public for greater accountability from health services and regulatory bodies (Davies & Shields, 1999; Irvine, 2004).

A considerable discourse has emerged in patient safety calling for the implementation of a systems approach and blame free culture when harm occurs. What is suggested is that harmed patients perspectives provide a unique alternative standpoint to the dominant viewpoint of the medical profession, in highlighting the broader social processes that construct harm that go well beyond the original PSI. This debate is important in a context where evidence-based medicine and the randomized clinical trial are viewed as 'the new gold standards in the healthcare field' (Timmermans & Berg, 2003:27). In patient safety however, Leape et al. have highlighted the need to identify wider forms of knowledge and practice to address issues of patient safety than those produced through traditional biomedical research (Leape, Berwick, & Bates, 2002: 507). From a broader social science perspective, others note, 'What constitutes a "risk", how should accidents be interpreted and how can safety be achieved? These questions are highly contested issues' (Summerton & Berner, 2003:3). When writing about medicalisation in the American context, Conrad (2005) has called for sociologists to adopt a much wider political and economic perspective when looking at processes that are seen to cause considerable harm to patients. Whilst Sharpe and Faden (2001) have argued that the process of defining medical harm is not value free, but tends 'to reflect a narrowly clinical interpretation of harm that excludes non-clinical or non-disease-specific outcomes that the patient may consider harmful' (2001:116). Therefore there is a need for a broader knowledge framework for the evaluation of medical harm and the imposition of risk that is based upon a more patient centred ethos (Sharpe & Faden, 2001: 115).

In developing a patient safety culture Reason (1997) and Perrow (1984) have highlighted the importance of the role of systems and their design in causing error, rather than error occurring in organisations through the unsafe and individual acts of employees. Central to this thinking has been the notion of creating a non-punitive reporting environment that is just and fair to health professionals and which allows them to feel safe enough to report PSIs free from the threat of punishment and litigation (Bristol Report, 2001; Reason, 1997). However, whilst these ideas have assumed a dominant position in the approach to patient safety internationally (Kohn et al., 1999; WHO, 2005), it is argued that the thinking needed to develop a 'just' organisational culture, inextricably tied to issues of accountability, has been far less developed. This is despite the recognition more generally in health that governance and accountability are central to the performance of health systems (WHO, 2008: 2).

In defining a just culture, Marx (2001) has distinguished between four categories of human action: human error, negligence, recklessness, and intentional rule violation. The actor's intention in the process is seen as central to how these categories are applied, with the idea of sanctions reserved mainly for *recklessness* (conscious disregard of substantial and unjustifiable risk) and *intentional rule violation* (Marx, 2001 cited in Rivard, 2003: 16). Rivard argues that the just model provides one antidote to a culture of blame approach that also provides a model for how accountability for adverse events can be 'assigned and categorized' (2003: 4).

This paper suggests however that other questions need to be considered when thinking about how a just model might operate from harmed patients' perspectives. These relate to how systems operate which can independently determine the facts when harm occurs, determine what constitutes individual and organisational culpability and deliver appropriate levels of redress. These questions are important in the light of compelling evidence illustrating that fair and just procedures for dealing with grievances are an important factor in reducing the level of conflict associated with disputes and in enhancing acceptance of decisions, thus healing the social wounds produced by conflict (Tyler (2000)). These issues are therefore explored in the paper by looking at the operation of complaint procedures, professional regulation and litigation. How these systems operate are considered to be an essential part of building a just and accountable safety culture that is fair to both staff and patients and which allow lessons to be learned in the aftermath of harm by health professionals in partnership with patients.

Given this context, this paper will argue that broadening the knowledge base on patient safety has important implications for those affected by medical harm and in developing a patient safety culture that is open and transparent, whilst allowing learning from mistakes. It raises questions about how a systems approach can address the need for the development of a non-punitive culture, but one that also delivers appropriate systems of justice and accountability, that are fair to patients. Understanding these processes through the triangulation of data, that includes involving harmed patients in the process, is gradually being recognised as vital in developing a partnership approach to learning from PSIs (Colin-Thome, 2009).

Methodology

The research in this paper was conducted as part of a wider set of activities connected to working with 'victims' of medical harm and developing patient safety reforms. This meant working with the national charity Action against Medical Accidents (AvMA) in the UK. In addition, work was carried out as a patient's representative sitting on a range of patient safety committees at a large London

hospital and by working with the Patients for Patient Safety Project (P4PS) between April 2006–March 2008. This project was funded by the National Patient Safety Agency (NPSA) (a national NHS body responsible for monitoring and learning from PSIs) and run by AvMA to try and get more patient and public involvement in patient safety in NHS trusts (Ocloo, 2008). The project compliments work being done at an international level, as part of the WHO World Alliance for Patient Safety, to encourage those harmed by PSIs to work in partnership with health professionals in promoting patient safety.

The research data is based specifically upon empirical evidence from two sources. The first is the experiences primarily of self-help groups set up as a result of medical harm and part of a campaigning network called the Medical Harm Self-Help Network (MHSHN). The second source of data was supplied by participants (all of whom had been directly affected by medical harm) who attended a 2-day residential programme called the Break Through Programme. Ethics approval was granted for both parts of the study by the University of Surrey. The research was carried out using participatory action research (PAR) to get at the subjective experiences of participants affected by harm, whilst allowing them to take action to change things from their own perspectives. Gaventa and Cornwall have argued that 'dominant knowledge obscures or underprivileges other forms of knowing and the voices of other knowers' (Gaventa & Cornwall, 2008:178). The narratives from harmed patients were about generating 'other forms of knowing' (Gaventa & Cornwall, 2008: 178) and new forms of understanding from those generated through the dominant positivist research tradition. Less emphasis was given to the "official" medical perspective.

The research with the MHSHN involved working with a range of groups over a period of two and half years from December 2003. Seven formal meetings were held within this period. In total 9 groups attended 2 or more network meetings and 5 groups attended one meeting. As an action researcher my role involved acting as a participant observer, helping to create the network and moderate its activities. This meant organising, chairing, taking minutes and participating in discussions, as well as helping to organise a major conference on medical harm. At other times observation techniques were deployed simply to observe at meetings and listen to speakers and to document proceedings. Data analysis was conducted on the websites of network members and on legal documents and reports of wider inquiries some groups had participated in. Ten interviews were also carried out with individual group members to discuss their personal campaigns and group objectives. In the early stages of building the network all of the groups could be described as self-help organisations, made up of individuals affected by medical harm. These groups formed the majority (11 out of 14 groups) attending meetings throughout the period the research was conducted. However as the network developed, other groups with a more formal structure and wider remit as health consumer groups, but with an interest in medical harm, were also invited to attend meetings.

With the Break Through Programme, which took place in October 2005, the aim was to enable individuals to develop ways of managing the negative psychological effects of medical harm. The research emphasis was on the inter-subjective elements of the personal stories of participants, and the group sessions aimed at enabling them to find strategies for self-empowerment. This focus was very different to the emphasis on political action in the MHSHN. Data were gathered by writing to participants prior to their arrival and asking them to participate in the research, but they were under no obligation to provide information and could still attend the programme if they chose not to participate. After the programme participants completed an evaluation form. Twenty

one individuals attended the workshop (including two couples who completed one questionnaire each). In total 18 questionnaires were received and a written narrative account. In total, programme participants were asked to answer 11 questions as part of the questionnaire. The questions were designed to elicit in-depth, semi-structured data on the personal stories of the participants attending the programme. Participants were asked whether they thought they had experienced medical harm and, if so, to provide details, including the effects on their psychological state, family life, employment and financial situation. They were also asked about whether they had taken any action as a result of the harm (such as a complaint, legal action etc) and to provide details of any support received.

Data from the questionnaires were then collated and analysed, alongside information emerging from group processes on the programme. The accounts were accepted at face value, as valid from the point of view of the social actor, but understood in more detail by listening to the experiences of participants over several days in the small group sessions on the Programme. With these processes my role was to act as presenter and facilitator, as well as to listen, observe and document individual responses. Three presenters recorded data as it was agreed that it would be intrusive to tape sessions. The data were then triangulated, bringing together the different views of the programme participants, combined with observations made by facilitators over the course of the event, and the dynamics of the interaction between the event leaders and the participants.

In terms of analysis, the different approaches and emphasis within the Break Through Programme and MHSHN were seen as an important way of broadening the evidence base and triangulating the data (Mason, 2002), to see how well they corroborated each other or exposed gaps in the data. A range of research methods was utilised, as experimenting with 'novel data collection techniques' has been seen as important in producing data that challenges dominant epistemological positions (Reid & Frisby, 2008).

Thematic content analysis was applied to all of the data. This entailed careful comparison of a range of evidence, noting initially emergent patterns, trends and contradictory evidence, before the data was organised into wider overarching themes (Miles & Huberman, 1994). As part of this process it is important to point out some factors that may have had a particular bearing on the research. Because most of the participants came through AvMA, or from campaigning groups, these experiences were inevitably skewed towards harmed patients who had grievances about their treatment. The issues may therefore have been different with harmed patients who did not have a grievance or complaint. My identity in the research was also important as someone who had been directly affected by medical harm. This background enabled me to build trust and to gain access to harmed patients. However, keeping a reflective journal was crucial in enabling me to be constantly aware of my own involvement in the research process and to enable me to develop a position of 'critical subjectivity' (Reason & Bradbury, 2008).

Findings

The medical harm self-help network (MHSHN)

The groups in the MHSHN from the outset expressed strong views on dealing with issues of medical harm and how health services could be made safer and yet felt they were not being involved in patient safety reforms. The network agreed their focus should be on political action and the need 'to concentrate on lobbying for change' (MHSHN meeting 12th February 2004). The MHSHN could be described as a health social movement (HSM)

providing 'collective challenges to medical policy and politics, belief systems, research and practice that include an array of formal and informal organisations, supporters, networks of co-operation, and media'. (Brown & Zavestoki, 2004: 52). In particular, the activities of the network fitted the notion of an embodied health movement (EHM). These have been described 'as organised efforts to challenge knowledge and practice concerning the aetiology, treatment and prevention of disease' (Brown & Zavestoki, 2004:54). Key to the nature of this movement is the way in which the biological body leads to a particular disease identity emerging and where activists frame 'their organising efforts and critique of the system through a personal awareness and understanding of their experience' (Brown & Zavestoki, 2004: 53).

This emphasis on the 'embodied' personal experiences of medical harm was very much a feature of the MHSN and a key focus of network meetings. Network members had diverse experiences of harm, such as catching a hospital acquired infection such as MRSA, being damaged through a vaccine injection such as MMR, experiencing a birth trauma such as Erb's Palsy, not being diagnosed or misdiagnosed with epilepsy or injured by surgical or other treatments. However, a common denominator for many of the groups was their experiences once harm had occurred in trying to get answers and explanations and in tackling a perceived culture of denial on the part of healthcare organisations. These experiences were reflected in a number of the accounts shared within network meetings.

Action for the Proper Regulation of Private Hospitals (APROP) talked about the failings in the way that complaints were managed in private hospitals. These were viewed as: 'invariably answered by the hospital manager in an evasive, obfuscatory and cavalier manner, rarely admitting to or apologising for error, even in cases of severe injury or death' (APROP Case Summary June 2005). APROP believed that an important opportunity to address their concerns was lost with the passing of the *Care Standards Act (2000)*, which they felt was probably influenced by private healthcare industry lobbying. The Leicester Epilepsy Concern Parents and Carers Group spoke about the way their members had faced enormous barriers in trying to find out what had happened to their children, harmed through the misdiagnosis of their epilepsy. The chair of the group spoke about 'feeling the medical fraternity had closed ranks', when parents tried to raise their concerns. He said that: 'parents in the group had started off not wanting to litigate, but because they couldn't get answers, felt forced to take legal action'. There were now some 700 litigation cases ongoing' (MHSN meeting 13-5-05). Other barriers to getting justice and accountability were seen as the workings of professional regulatory bodies. The chair of the Richard Neale Action and Support Group spoke about the harm caused to hundreds of women in her group by the gynaecologist Richard Neale and highlighted her strong feelings about the failings of the regulatory body for doctors, the General Medical Council (GMC). She thought this body had, 'helped to contribute to a very great extent to the national loss of confidence in the medical profession in general and the NHS in particular. And none of it need have happened' (Witness statement from chair of the Richard Neale Action and Support Group, 26th September 2001).

The groups in the MHSN ultimately wanted to develop a campaigning agenda that challenged dominant medical perspectives that they viewed as working to their detriment. This standpoint about the power of the medical profession and a focus on accountability concurs with other research about the experiences of those affected by PSIs (Fallowfield, 2010). Allsop, Jones, and Baggott (2004) found that what they called 'protest groups' were more likely than other health consumer groups to 'view medical practices as paternalistic and oppressive and to see health professionals as people who withheld information and close ranks against

patients when questioned' (Allsop et al., 2004: 751). What can also be seen as particularly significant when analysing the activities of the MHSN is that their experiences can be connected to a much wider movement of users to emerge in health since the 1970s. These groups have been important in opening up a discourse that has challenged the dominance of a medical model and highlighted the importance of recognising lay perspectives in defining health and illness (Freidson, 1970; Oakley, 1976; Rogers & Pilgrim, 1991; Shakespeare, 1993).

The break through programme

The use of storytelling as a hermeneutic method of inquiry has been seen as important in empowering traumatised groups (Klein & Janoff-Bulman, 1996) as well as enabling a better understanding to be gained of the subjective meaning of events (Berger, 2004). Many of the stories to emerge from the Break Through Programme illustrated a deep-seated anger about the way that healthcare professionals and organisations had routinely covered up harm to patients and then treated the harmed patient as the problem. This situation was seen as compounded by the failings of a range of external organisations to provide an independent investigation into the issues.

Mrs J, for example, believed that she had been wrongly prescribed HRT with Thyroxin for many years, which caused her terrible adverse problems. She had warned doctors repeatedly of adverse effects, but felt no action was taken. It was only once she produced evidence from a private consultation that she was informed that she had grounds for complaint. But despite taking action through the complaints and legal system, GMC and the Ombudsman's office, Mrs J reported that she had been unable to get any redress and had been constantly treated as if she was the problem. In reflecting upon the injustice of her situation she said: 'Too many NHS patients trust the medical profession (and lawyers) until something goes wrong and they are harmed'. Then she said, 'the damaged patient will find a closed shop and a 'gagging order' and no support – only untruths' (Break Through Programme questionnaire).

Mrs G also described her anguish at being harmed both by the medical profession and the systems responsible for regulating the profession and protecting patients. She explained that she had initially consulted her GP about a facial rash and other symptoms that were subsequently misdiagnosed and misrepresented in her medical records. Mrs G thought that she might have a mercury allergy after linking the onset of the rash to an amalgam filling, as well as a malabsorption problem, but this was discounted by her GP. Her observations were later proved correct by private tests carried out at the London Homeopathic Hospital. The difficulties in trying to pursue her complaint led Mrs G to write: 'The strain of pursuing the truth, of injustice, of character assassination without a right of reply, of callousness in the face of the trauma caused, has damaged our lives and it hurts and is impossible to forget' (Narrative account, Break Through Programme).

Despite participants being able to share their personal stories on the programme, a number of participants also wanted to see more of a focus on political or practical strategies for change. This appeared to reflect the fact that all of the participants had attempted to take some sort of legal action after they had been harmed, with only 6 succeeding in their attempts. This situation saw all of the participants on the Programme expressing, in different ways, the feeling that the system had placed extremely heavy barriers in the way of their getting justice and accountability. This was the case even if individuals had been successful in the action they had taken. To accommodate these feelings, key themes emerging from the Programme and some personal stories that

participants wanted to share were written up in a Break Through Programme newsletter. This newsletter was presented to an AvMA conference in May 2006 entitled 'The Patient's Agenda for Safety and Justice'. The conference was held in partnership with the MHSHN and attended by more than 100 people with those affected by harm forming the majority of speakers and conference participants.

The most talked about theme at the conference concerned the way that individuals were treated and faced a number of barriers after medical harm had occurred. These related to issues such as trying to get an open explanation, independent investigation, apology, redress or reassurance that action would be taken to prevent a repetition of the harm in the future. The perception of a lack of access to justice and redress for harmed patients was seen to be caused by a range of failing institutions. The legal system was viewed as containing many barriers to bringing a case for clinical negligence because of the difficulties in getting legal aid, independent medical experts and overcoming the difficult legal threshold, the 'Bolam Test', for proving negligence. Other bodies seen as equally culpable were the NHS complaint procedures and professional regulatory bodies for doctors and nurses such as the GMC and Nursing and Midwifery Council (NMC). In the post conference newsletter these concerns were captured by the phrase: '*The NHS acts as Judge over itself*' (AvMA Newsletter, 2006:2).

What these accounts show is that for the harmed patients in the research, medical harm was a complex process. It was not only about the original PSI, but also about the aftermath of harm and the way that individuals felt that doctors, healthcare organisations and those responsible for regulating health professionals had negatively treated them. In this context, broader issues of justice and accountability when harm occurred were seen as extremely important, raising questions about the power and control of the medical profession and broader organisational systems and which challenged a dominant discourse in patient safety, focussing on developing a 'no-blame culture'. These issues are considered in more detail below by looking at what broader evidence exists to validate these concerns.

Discussion

Accountability systems: litigation and complaints

With regards to the legal system, the issue of proper access to justice for those affected by medical harm in the UK has been highlighted by various reviews (Department of Health, 2003; House of Commons, 2009; NAO, 2001). Whilst no actual data exists on the numbers of negligent PSIs occurring in the UK, only a small proportion of those affected bring a legal claim each year. In 2008/09 the total figure for negligence claims was 6080 and claims have stayed within a range of 5–6000 for the preceding four years (NHSLA, 2010). In contrast, other countries such as the United States have gained a reputation as one of the world's most litigious societies, having seen a persistent growth in medical malpractice litigation since the 1840s (Mohr, 2000). At the same time the US has also established itself as one of the world's most patient friendly systems in this area. Whilst the numbers of claims brought to court have not recently risen dramatically, with only about 3% of 'true' injuries resulting in a claim (Friedenberg, 2004:4). The level of damages has risen considerably, with compensation to victims of medical harm awarded at far higher levels than compensation paid out to equivalent 'victims' of harm in other parts of Europe (HSCNews International, 2006: 28). Friedenberg has argued that 80% of these claims result in no evidence of negligence (2004:4).

The area of medical litigation has become a high-profile issue in the US, which has led doctors to blame the ever-increasing size of

their medical insurance premiums on the growth of a compensation culture fuelled by victims of medical harm. A growing coalition of medical groups (hospital associations, pharmaceutical industry bodies, physician groups), have proved 'remarkably effective' in limiting malpractice awards through lobbying at state and federal level for tort reform (HSCNews International, 2006:28). This focus has been criticised by some commentators for doing little to address wider issues of the prevention of harm and the promotion of patient safety. Consumers Advancing Patient Safety (CAPS) have pointed to the importance of looking at ways to avoid litigation in the first place and highlighted the implementation of a mandatory disclosure law in Pennsylvania, requiring healthcare providers to disclose unexpected outcomes to patients. They note this appears to be having some effect in prompting hospitals to evaluate sooner whether they want to settle or offer to mediate a claim (HSCNews International, 2006: 33).

The importance of open disclosure after a PSI is now becoming increasingly recognised, as a tool in patient safety. Dekker has pointed out that if there is no other route to disclosure, people turn to the legal system as their final platform for forcing out accountability, which can in the long-term lead to less safe systems. This is because a cycle of professional secrecy, evasion and self-protection can occur, which will ultimately prevent learning (Dekker, 2007: 102). This situation has now led to open disclosure policies forming part of health policy reform across the USA, Canada, Australia, New Zealand and the U.K. This approach is considered not only to have financial benefits in terms of its potential to reduce complaints and litigation, but to have ethical and moral consequences as well in affecting the partnership relationship between patients and healthcare professionals (Ledema, Sorensen, & Piper, 2008: 5–6). In several countries such as New Zealand, Sweden, Denmark and Norway, no-fault compensation schemes have been adopted as one way of dealing with competing factors related to issues of blame, cost and justice concerns in managing medical malpractice claims (Tan, 2009).

In the UK however, evidence suggests that a culture of denial in dealing with PSIs continue to raise serious concerns. This led the Health Select Committee into patient safety to strongly criticise the failure of the government to implement the NHS Redress Scheme (as an alternative to litigation in the courts in dealing with negligence claims up to £15,000), three years after Parliament passed the necessary legislation. This situation was viewed as hindering the development of a safety culture, which could not be developed in the context of powerful competing interests between openness and medico-legal concerns (House of Commons, 2009:26). Problems with a lack of openness and transparency when things go wrong have also been reflected in serious criticisms of NHS complaints procedures that have resulted in widespread dissatisfaction from families in getting their concerns addressed (Department of Health, 2003a; NAO, 2008). This has led to the introduction of a reformed complaints system across health and social care from April 2009, with the aim of achieving more comprehensive complaints handling at a local level (following guidance outlined in Department of Health, 2007).

What this evidence raises is a number of questions about the failings of systems to provide harmed patients and their families with answers when things go wrong and about why the harm occurred. In providing some explanation for the failings of these systems, Mulcahy (2000) has argued that clinical negligence claims can represent a strong symbolic threat to the medical profession, because doctors often see claims as the way that patients come to terms with bad news, which is projected onto the doctor. Such accounts she argues, 'have a tendency to deflect blame away from the medical profession' (2000: 97). Annandale (1989) has also identified the strong negative stereotyping of 'suit-prone' patients

in the medical malpractice literature which she argues has been aimed at helping doctors to avoid being sued. Contrary to these negative connotations about 'suit-prone' or litigious patients, various studies have shown that taking legal action for financial compensation is not the primary motive of individuals when something goes wrong with their health care. A key factor shown to cause disputes to escalate has been the inability of families to get adequate explanations to their concerns (NPSA, 2005). Vincent also highlights the further trauma caused to patients when health professionals fail to take complaints seriously and label individuals negatively after an adverse incident (Vincent, 2006: 124).

When looking at written complaints, Allsop and Mulcahy (1998) found that doctors treated them as largely unjustified. They viewed this as an attempt to 'turn responsibility and culpability away from the doctor for the untoward events described in the complaint, and to neutralise the criticisms' (Allsop & Mulcahy, 1998: 811). Criticism has also long been directed at the failings of professional regulatory bodies to protect patients and highlighted the power of the medical profession to act in their own interests (Freidson, 1970; Nettleton & Harding, 1994; Stacey, 1993). More recently Waring (2007) has shown that doctors have continued to resist changes to their professional autonomy in the field of patient safety, both 'seeking to subvert and 'capture' components of reform' (Waring, 2007: 163). Given this situation, Ehrich (2006) suggests a much deeper understanding is required of the organisational and professional cultures that promote a 'closing of ranks' when PSIs occur, by medical practitioners. This analysis is seen as important given that wider evidence in the US suggests that medicine has actually experienced a considerable reduction in its control over its work and institutions (Freidson, 2001). Conrad argues that whilst doctors are still the gatekeepers in terms of access to many drugs, it is the pharmaceutical companies that have become the major drivers in medicalisation processes, causing considerable harm to patients (Conrad, 2005).

As a result of serious criticisms about the failings of regulatory bodies to protect patients rather than doctors (Shipman Inquiry, 2001–2005), a major programme of reform has been taking place in the UK's system for health professional regulation. This saw the establishment of the National Clinical Assessment Service (NCAS) in 2001 (part of the NPSA), which helps to resolve concerns about doctors and dentists' performance. NCAS was established following concerns that tackling problems with medical performance needed specialist skills, not always available in individual NHS trusts, which meant that concerns could be referred to regulatory bodies even when not serious enough to justify regulatory action (Department of Health, 1999; Department of Health, 2001). Further reforms (Department of Health, 2006) have led to the White Paper, *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* (Secretary of State for Health, 2007). This paper sets out the most extensive changes to professional regulation since the Merrison Commission (1975) endorsed a more '19th century light touch regulation' (Davies, 2002: 4), now clearly seen as inappropriate in the 21st Century. The reforms, recognising the importance of a non-punitive approach in addressing patient safety concerns, also incorporate a comprehensive strategy for prevention, treatment and rehabilitation for health professionals.

Conclusion: developing a broader framework for tackling patient safety

Looking at medical harm and patient safety from the standpoint of harmed patients this paper argues that these experiences have acted as an important catalyst for the emergence of a patient safety movement in healthcare over the last ten years. Yet evidence suggests these experiences have been largely excluded in the

construction of patient safety reforms. Addressing this situation is seen as long overdue and requires a major shift in tackling the imbalance of power that currently exists between patients and healthcare providers. Harmed patients gaining voice and contributing their experiences to the development of patient safety reforms is seen as vital in generating new forms of expertise and models of good practice that can help prevent a reoccurrence of harm to others in the future.

The research in this paper, drawing upon the experiences of harmed patients in the MHSN and Break Through Programme and reinforced by wider evidence, suggests that the dominance of a medical model is still a powerful determinant in constructing the context of medical harm and patient safety reforms. This raises important questions about the power, dominance and control of the medical profession, as well as broader organisational systems that support these processes. The links between medicine and the way it is mediated by social forces of power and control, that in turn shape medical knowledge and practice, have been well established (Bury, 1986; Illich, 1974; Taussig, 1980; Wright & Treacher, 1982). Research suggests this thinking has not permeated the area of patient safety (Antonsen, 2009; Currie, Waring, & Finn, 2008:364), which to date has relied mainly upon a 'harmony model of organisational life' (Antonsen (2009:1). Silbey argues that future research on safety should explore 'those features of complex systems that are elided in the talk of safety culture: normative heterogeneity and cultural conflict, competing sets of interests within organisations, and inequalities in power and authority (Silbey, 2009: 343).

The experiences of harmed patients are considered to provide an important source of data in looking at how issues of power and conflict impact upon safety in organisational contexts. These experiences suggest that a more holistic approach is needed in developing new patient safety reforms. This approach needs to go well beyond the clinical markers and individual agency associated with a narrow medical model and to deal with both the prevention of harm and issues of accountability. Adopting this wider approach is seen as vital in identifying the range of social processes associated with medical harm that are also to do with medical dominance and wider issues of power and control. It is argued that these issues have been largely ignored or downplayed in the wholesale adoption of a 'no-blame culture' in patient safety.

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