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**BALANCING INNOVATION AND PATIENT SAFETY
WITHIN THE HIDDEN RESEARCH SYSTEM**

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Introduction

The advancement of medical care is, in large part, driven by clinicians and patients who, respectively, develop and consent to novel healthcare technologies. However, as such technologies develop and are translated into mainstream clinical care, their short and long-term safety can be hard to gauge. History has taught us of the risks associated with experimental/innovative treatments which are not rigorously tested prior to their diffusion into standard practice (Evans et al., 2006:1439). Nevertheless, while the development of pharmaceutical drugs is now tightly regulated, “craft-based” developments, such as innovative surgical and clinical procedures, have largely remained under-regulated. This paper aims to investigate the development, assessment, regulation, diffusion and impact of craft-based innovations to explore ways of supporting such innovation whilst also protecting patient safety and promoting quality of care.

Given the many and varying ways in which it is used, “innovation” is a difficult term to define. Nevertheless, for the sake of clarity we employ the following working definitions of “innovation”: the action or process of introducing something new and significantly different, or a new method, idea or product. In order to better understand the processes that lead to the under-regulation of craft-based innovative procedures, we shall utilise Hopkins’ (2006) distinction between artefact-centred and technique-centred innovations. Using this approach, the mode of innovation involved in developing new pharmaceutical drugs and medical devices, termed artefacts, is differentiated from the more “craft-based”, “technique-centred” modes of innovation discussed above. This distinction is a useful one as the methods used to develop, govern and regulate these two categories of innovation are very different. An example of such difference is the divergent processes of assessment utilised within each mode of innovation.

Technique-centred innovation = Innovative surgical and clinical procedures
Artefact-centred innovation = Innovative drugs and medical devices

The National Institute of Clinical Excellence (NICE) in the U.K., like the Food and Drug Administration (FDA) in the U.S., uses early and late phase clinical trials, and health economic modelling of Quality-Adjusted Life Years (QALYs) to assess artefact-centred innovations prior to their clinical use. However, for technique-centred innovations, which are developed in clinical practice, this method of assessment is often neither possible nor appropriate. Likewise, the degree of industry involvement in these two modes of innovation also differs. Artefact-centred innovation often involves external pharmaceutical or biotechnology industry players, while technique-centred innovations are more often internal developments occurring within the realm of the “hidden research system” (Hopkins 2006:271). The “hidden research system” is the term Hopkins gives to the hospital-centred network of individuals, from clinicians to funding bodies, which is responsible for much of the technological change within hospitals and yet is often hidden from regulatory view. Hopkins consequently suggests that their differing levels of external industry involvement impact on the level of regulation to which artefact-centred, and technique-centred, innovations are subjected. He writes that while “artefact-centred careers are influenced by industrial actors, with more tangible products and obvious appraisal prior to their widespread adoption...it seems the technique-centred mode can occur in a less visible manner within the hidden research system – perhaps further away from the scrutiny of impartial groups – until the technology’s impact, be it economic, social or legal, attracts greater attention” (Hopkins 2006:271).

	Technique-centred Innovation	Artefact-centred Innovation
Industry Involvement	Limited or no industry involvement	Pharmaceutical or biotechnology industry involvement common
Development Process	Often developed internally through clinical practice	Often developed externally prior to use in clinical practice
Assessment Process	Assessment often	Assessment often

	occurs subsequent to diffusion into clinical practice	occurs prior to diffusion into clinical practice
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While it is important that technique-centred innovation is supported and nurtured, it is also prudent that the innovations themselves are monitored and their outcomes assessed; for due to their experimental/novel nature, they carry risks for patients, practitioners and organisations. Addressing this concern, the Safety and Efficacy Register of New Interventional Procedures (SERNIP) was set up in 1996 as a voluntary system for identifying and registering procedures whose safety and efficacy had not yet been established. In implementing this initiative, the UK became the first country in the world to develop a system for monitoring the introduction of new procedures into its national health service (1996:131). In 2003 the responsibility for monitoring the safety and efficacy of new procedures shifted to NICE and its Interventional Procedures Advisory Committee (IPAC). IPAC incorporated the register created by the now defunct SERNIP but made the reporting of new procedures mandatory (Kmietowicz, 2003, Campbell and Barnett, 2004).

Nevertheless, despite this mandatory reporting, the success of IPAC is arguably reliant on a clinical culture that values external assessment and governance. Thus given the reluctance of some clinicians to submit their work for assessment (Reitsma and Moreno, 2002, Montori and Onorato, 2008), and the difficulties that others have in determining when oversight is required (McKneally and Daar, 2003), many new technique-centred innovations have been diffused into clinical practice without adequate clinical and social evaluation (Evans et al., 2006). Consequently, the impacts of these innovations on patients, on the health system, and on society, are often poorly understood. The aim of this paper is, therefore, to explore the issues of development, assessment, governance and diffusion as they relate to the “careers” of technique-centred innovations, and the impact they can have on patient safety and experience. Like “innovation”, the term “governance” has a

myriad of definitions. Here we use it, as Lynn et al. do, to denote the “regimes, laws, rules, judicial decisions, and administrative practices that constrain, prescribe, and enable the provision of publicly supported goals and services” (2001:7). Thus, it refers here to the processes and practices used to oversee and regulate the “careers” of technique-centred innovations.

Like Hopkins (2006), Danjoux et al. (2007) contend that surgical innovations (a prominent category of technique-centred innovation) face different challenges than do artefact-centred innovations. A difference, they propose to be a result of the lesser degree of governance faced by surgical innovations. This raises the questions, how are technique-centred innovations monitored, and what are the impacts of existing processes on clinicians and patients? In order to address these questions we first turn our attention to understanding how and why technique-centred innovations are developed.

Developing technique-centred innovations

Danjoux et al. (2007) contend that surgical innovations are driven by both surgeons’ desire to innovate and their desire to improve healthcare. They propose that, as such innovation is frequently undertaken “in an attempt to improve an existing technique, implement a new technology or enhance institutional productivity, surgical innovations are often introduced by individual surgeons under independent circumstances” (Danjoux et al., 2007:183). However as Troidl notes, an innovative idea “stands a chance only if it appears at the right time and at the right place” (1999:755). The embedded and autonomous nature of such innovation is important, as it permits clinicians to change their practice without involving any external industry or governing body. Thus it is this factor that can lead to technique-centred innovations being introduced following minimal scrutiny. Such changes in practice often stem from the needs of, and challenges posed by, individual patients or groups of patients and can lead to the development of extremely beneficial innovations, for example open-heart surgery, organ transplants and appendectomy (McKneally and Daar, 2003), all of which were initially developed in practice rather than through formal clinical trials.

Nelis (1999) indeed maintains that most, if not all, technique-centred innovations in healthcare can be seen as improvements on previous procedures. Thus innovators use their experience and knowledge, rather than formal research tools, to inform the choices they make. She contends that “every new innovation, in other words, is only partly innovative, since it is at the same time the product of existing heuristics, common methods and theories and former successes. The rules of the regime and the patterns embedded within them structure the choices that are made today” (Nelis, 1999:127). However the incremental and individualistic nature of such innovations can make it difficult for clinicians to determine the degree of oversight necessary. As McKneally and Daar note, in contrast to the “black and white rules and regulations” applied to formal clinical trials is “that large gray zone where surgeons often find themselves – the zone of innovation – where it is unclear whether what they are doing is an evolutionary variation on a standard procedure, a unique departure from accepted standards, or the first stage of what should become recognized as a formal surgical research project” (2003:930).

Challenges for governance

The aim of NICE’s IPAC, as mentioned above, is to protect patient safety while supporting healthcare workers to be innovative. Often NICE is notified of technique-centred innovations by clinicians who are developing them, or wanting to use them in their practice. However anyone, including the public, can nominate a procedure for assessment (NICE, 2008). While this is a rigorous and thorough process of governance, its success is reliant on innovative procedures being referred to NICE in the first place. This prerequisite is itself reliant on the existence of a broader clinical culture of valuing external assessment and governance, which arguably does not universally exist. As both Casper (1998) and Reitsma & Moreno (2002) address, healthcare workers have not always been happy to have their procedures assessed by outsiders. This reluctance may be, as Reitsma and Moreno propose, because they believe “their good intentions toward their patients were being questioned” (2002:796). It could also be, as Casper suggests, that submitting their clinical procedures for assessment, “means

sacrificing some degree of professional autonomy and submitting to routine evaluations by an IRB [Institutional Review Board, the U.S. equivalent of an ethics committee]" (Casper 1998:147).

Another deterrent to clinician's submitting their innovations for external regulation is, as Benditt et al. (1994) suggest, the amount of time external assessment can take. These authors write of their frustrations with the "fact that the rapidity of evolution of the science has outstripped the capabilities of regulatory agencies to assess technological advances and document device safety and effectiveness in a timely manner" (Benditt et al., 1994:371). Their argument not only questions the value of external governance but also the value of researching procedures thoroughly before diffusion. It is a sentiment which, according to Reitsma and Moreno, is relatively common. They contend that "the worry that additional review or regulations would stifle progress is a frequently uttered concern" (Reitsma and Moreno, 2002:796). This concern is not, however, restricted to the realm of technological innovation. Rather, resistance to regulation is common throughout many fields of healthcare related research (Dingwall, 2006) and is fuelled by the belief that the current research governance structures can, at times, be heavy handed (Jones and Bamford, 2004, Shaw and Barrett, 2006, Warlow, 2005, Dixon-Woods and Ashcroft, 2008).

Casler, for example, agrees that "cumbersome regulation and unreasonable limitations stifle creativity and retard the advance of surgical science", and contends that "bureaucratic roadblocks could harm patients" (2003:676). However he also maintains that "while disagreements will likely continue regarding the exact definition of innovative surgery...physicians must constantly be aware that there will always be a difference between what can be done and what should be done" (Casler, 2003:676). Nevertheless, given the differences between how healthcare workers and ethics committees view what is ethical and acceptable in practice (Casper 1998), there exists a distinct possibility that clinicians will not agree with the rulings of ethics and governance committees on what should be done (Shaw and Barrett, 2006). In terms of NICE, the problem is that interventional procedures that should be

submitted for assessment may not be being brought to their attention, despite this being a mandatory requirement. The impact of such omissions would arguably be similar to that seen in the U.S. where, “thanks to a patchwork regulatory system, perhaps a quarter of all clinical research ... gets no federal oversight whatsoever” (Lemonick and Goldstein, 2002:49). Similarly Sade writes of the U.S. that “unlike research, our current process of innovation operates almost entirely under the radar screen” (Morreim et al., 2006:1964). Thus given the hidden nature of innovation, he contends that only success stories are ever heard about, a situation which makes it impossible to conclude whether or not the current governance system is working. While Sade's observations relate to the U.S., his analogy of innovation occurring “under the radar” bears striking resemblance to Hopkins' previously discussed observations of the “hidden research system” in the U.K. (Hopkins, 2005).

It must, however, be noted that very few innovators who forgo external oversight for their innovations do so as an act of conscious avoidance. Rather, for some clinicians the barrier to pursuing external governance is the difficulty they encounter in defining what is innovative and when assessment is appropriate (Strasberg and Ludbrook, 2003). Reitsma and Moreno (2002) contend that this is particularly problematic with technique-centred innovations, as many such innovations occur in the often urgent day-to-day context of attempting to heal sick or dying patients. They assert that, in this context, it is particularly challenging to distinguish “between gradual implementation of minor surgical modifications and more permanent or extensive alterations of a technique” (2002:796). Thus, there exists a grey area wherein innovations may be regarded by clinicians as modifications in technique rather than novel procedures requiring governance (Reitsma and Moreno, 2002). We will return to a discussion of this grey area later in the paper.

The diffusion of innovative procedures into practice

The ambivalence of some healthcare workers about submitting technique-centred innovations for assessment, and the confusion around when external oversight is required, impact on the diffusion of these innovations into clinical

practice, but do not prevent it. For, as Banta contends, there appears to be an implicit assumption amongst the healthcare community “that adoption of an innovation is desirable” (1983:1365). Therefore many innovations, both artefact-centred (e.g. electronic foetal monitoring for low risk women (Banta and Thacker, 2001) and hormone replacement therapy (Wright, 2005)) and technique-centred (e.g. revascularisation of the brains of patients with transient cerebral ischaemia or fixed ischaemic neurological deficits (Wilson, 2006) and laparoscopic cholecystectomy (Strasberg and Ludbrook, 2003)) have been introduced into mainstream practice without sufficient evidence of their safety and efficacy, and have subsequently been found to be ineffectual or potentially detrimental. This is not however, to suggest that all technique-centred innovations should be, or indeed could be, rigorously assessed for their efficacy before clinicians have been able to develop and test them in practice. The point, rather, is that the timing of assessment is crucial. As Banta and Sanes maintain, “each assessment should be conducted after the technology has been sufficiently developed to permit intelligent estimates of its nature and potential uses but before patterns of behavior or utilization have been established” (1978:251). However, as Hopkins’ points out, in some cases “the development phase blends rather indistinctly into the adoption phase” (2006:259). Thus, as demonstrated by McKinlay (1981) and Ferlie et al. (2005), such patterns of behaviour and utilisation are often well developed before rigorous assessment is undertaken.

McKinlay’s (1981) seminal paper tracks what he terms the seven stages of a medical innovation’s “career”; from the issuing of a promising report espousing its utility, to its acceptance as an established procedure, and its eventual erosion and discreditation. McKinlay is quick to point out that not all innovations pass through all seven stages, or at least not in the order he presents them, however he does claim that his “career” model is “the pattern that is followed more often than not” (1981:375). According to this model, most innovations are not thoroughly or formally assessed before stage five of their career, a point that falls after, rather than before, their acceptance as standard practice. This “premature” acceptance is put down to a combination of societal, professional and institutional factors, and suggests once more,

that research evidence is not the only factor in the diffusion process, an argument that is supported by Denis et al. (2002).

Nevertheless, others such as Ferlie et al. (2005) and Van de Ven et al. (1999), disagree with McKinlay's notion of a relatively uniform innovation career. Ferlie et al., for example, contend that the journey of an innovation is "not sequential or orderly, but nonlinear and disorderly" (2005:118). Yet despite their differing opinions, these authors agree with McKinlay that contextual factors can take precedence over research evidence in diffusion decisions. Meyer and Goes make a similar argument contending that the assimilation of an innovation into standard practice is a dynamic, multi-level choice process ultimately determined by the "attributes of innovations, attributes of organizational contexts, and attributes arising from the interaction of innovations and contexts" (1988:901). The prominent role played by contextual factors may, therefore, provide one answer to the conundrum of why, despite the absence of sufficient evidence of their safety and efficacy, some innovations rapidly diffuse into standard practice whilst others do not. As Fitzgerald et al. note "health professionals do not simply apply abstract, disembodied scientific research rigidly to the situations around them, but they collaborate in discussion and engage in work practices, which actively interpret and (re-)construct its local utility. The scientific data are weighed against a range of other factors in the decision-making process" (2002b:1439).

Another potential factor influencing the diffusion of innovations is that "some specialties are uncritically committed to particular interventions, and that they vigorously resist attempts to displace and sometimes even to evaluate them" (McKinlay 1981:383). This was arguably the case with electronic foetal monitoring (EFM), a technology which was introduced into routine maternity care based on the assumption that if it was useful in high risk women, then the same would apply to low risk women. However there was insufficient evidence for its efficacy and safety and evidence has since shown that for low risk women the risks of EFM outweigh the benefits (Banta and Thacker, 2002). Yet despite this lack of evidence, the technology did have, and still

has, substantial support from prominent practitioners. These practitioners may support EFM due to the belief that an imperfect technology is better than none, however they have nevertheless opposed attempts to rigorously assess and question its efficacy (Banta and Thacker, 2001).

This lack of objectivity or, as Banta and Thacker put it, “‘evangelism’ for certain technologies without consideration of evidence” (2001:717) has been attributed to a range of factors. In the case of breast cancer surgery, one factor influencing the uptake of increasingly disfiguring surgical techniques, was the belief that the more radical the treatment, the higher the likelihood of success and cure. This belief persisted among some groups of clinicians despite a lack of evidence that such techniques had any impact on breast cancer survival rates (Evans et al., 2006).

Other factors potentially contributing to a lack of objectivity, and the premature diffusion of innovations, are the influence of industry, the profits and prestige that accompany the use of innovative therapies, the culture of an institution, and the willingness of clinicians to take risks (Banta and Thacker, 2001). As Banta (1983) notes, these factors not only influence healthcare workers to use a technology, but they can also influence the formation of new professional specialities which rise up around an innovation. The clinicians who are encompassed within these new specialities arguably run a higher risk of being uncritical; as not only their work, but their professional identity, is at stake (see for example Casper 1998). The combination of these influencing factors led McKinlay to write, “it is reasonable then to argue that the success of an innovation has little to do with its intrinsic worth (whether it is measurably effective, as determined by controlled experimentation) but is dependent upon the power of the interests that sponsor and maintain it, despite the absence or inadequacy of empirical support” (1981:398).

Thus clinical “evangelism” poses a risk to the safe diffusion of technique-centred innovations. However, a potentially more common cause of early/premature diffusion is the fact that “clear evidence about the appropriateness and conditions for good practice rarely emerges until the

innovation has been experimented with for some time precisely because learning is required to optimize it” (Denis et al., 2002:72). Thus it is here, where innovations are being developed and assessed in practice, that the boundary between treatment and experimentation is particularly blurred.

When is treatment research and when is research treatment?

In the U.K., the NHS Research Governance Framework (RGF) defines research as “the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods” (DH 2005:3). This framework provides, what Dixon-Woods and Ashcroft (2008) refer to as, “a dense regulatory environment” which implements “external oversight and control of the work of researchers in health-related fields” (Dixon-Woods and Ashcroft, 2008). However this definition, and as such this regulatory framework, does not easily fit with technique-centred innovations, which are seldom thought of as research. As McKneally and Daar (2003) contend, such procedures are not systematic but rather are designed to benefit individual patients. Equally, there is seldom a primary, or even a secondary, intention to publish the results of the procedures and thus generate generalisable new knowledge (Morreim et al., 2006). Thus clinicians, who develop technique-centred innovations in practice, are unlikely to see this framework as relevant to them and their work.

This difficulty in defining and determining when clinical care is also research forms the foundation of the blurred boundary between treatment and research where many of the problems with governing technique-centred innovations are located (Margo, 2001, Fox and Swazey, 2002). Fox and Swazey address the difficulty that many physicians have in verbalising what is experimental and what is therapeutic (2002), while Margo (2001) addresses the pressing question of whether altering surgical practice constitutes research. Noting that while “many view the process as within the scope of clinical practice at an academic medical centre and not as research at all. Others consider it human experimentation and are bothered by the lack of disclosure and the absence of informed consent” (2001:40). Margo, however, goes on to write that “the fact that a procedure is experimental, new or untested does not necessarily

mean its use is research” (2001:41). Lotjonen (2002) concurs in her discussion of how novel procedures, which are utilised in the sole interests of a particular patient rather than for research purposes, are classified as “innovative therapy”. This is not to say that such procedures should be exempt from governance, but rather that, as they are not viewed by the clinicians as research, they are unlikely to be submitted to a research ethics committee for assessment. Nevertheless the results of classifying innovative procedures as either “innovative therapies” (Lotjonen, 2002) or as “standard practice” (Casper 1998) rather than as “research”, can be detrimental to the very patients the clinicians are trying to treat. For, as Strasberg and Ludbrook maintain, “unlike a subject of research, an individual who undergoes an innovative procedure has no assurance of the protections provided by government regulations and IRBs” (Strasberg and Ludbrook, 2003:942).

This returns us to the grey area discussed earlier in the paper, where clinicians find it difficult to differentiate between modifications in technique and novel procedures requiring external governance. As Reitsma and Moreno (2002) concluded, many of the surgeons they studied were largely unaware of the regulatory definitions of “research with human subjects”, thus they tended to classify their work as “treatment”. This “(mis)classification” may have stemmed from the surgeons’ difficulties in determining when their work constituted research and when ethical review was appropriate; as well as from the challenges they faced in recognising when their work was truly innovative and not just incremental change (Reitsma and Moreno, 2002).

Do technique-centred innovations need governance?

If innovative procedures are not seen, or classified, as research by healthcare workers, there runs the risk that proper informed consent and governance processes will not be implemented. Consequently, although the boundaries between research and treatment are “not always easy to draw” (Nelis, 1999:138) and the relationship between them is often ambiguous (Fox, 1980), the results of this ambiguity can be unethical and even disastrous (Evans et al., 2006). Consequently, the governance of innovations is vital. Clinicians can have the best of intentions and a wealth of experience however, as Evans et

al. highlight, “medical authority is not infrequently wrong” (2006:3), and “good intentions do not guarantee that more good than harm will be done” (2006:91). Thus, without governance and assessment, “an unproved innovation may become an enduring but possibly harmful standard of care” (Landefeld et al., 2008:1277).

Nevertheless, the use of “unproven” treatments is sanctioned by the World Medical Association (WMA) under certain circumstances (WMA, 2008). They write, in article 35 of the Declaration of Helsinki, that “in the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician’s judgement it offers hope of saving life, re-establishing health or alleviating suffering” (2008:5). The key points are that the use of such treatment not only relies on a physician’s judgment but also takes place following expert guidance and with the patient’s informed consent. What counts as “expert advice” is not clear. However this pre-requisite does suggest the need for some form of expert governance, a subject we will return to after first exploring the issue of informed consent.

Casler addresses the potential impact on patients of undergoing unproven innovative procedures writing that, “unless patients are clearly informed of the innovative nature of the procedure, and proper informed consent procedures are followed, they may become unwitting research subjects and their rights may therefore be violated” (Casler 2003:675). As such, the clinical use of some new healthcare technologies raises, “serious questions about human experimentation and medical ethics” (Banta & Sanes 1978:247) highlighting the conflict of interest for clinicians between their role as healers and their role as “researchers”. This conflict can have detrimental impacts on their patients who, Banta and Sanes claim “are quite often given such treatment without a full explanation as to their prognoses and the effects the treatment can be expected to have on their lives” (1978:248). Thus given this blurred boundary between research and treatment, Oakley contends that it is “hard to know how often health professionals and others experiment in the name of testing

cherished hypotheses, and to what extent the experimented-on have, or have not, known about their status as research participants” (Oakley 2000:267). This, therefore, brings us to a discussion of the role of patients in technique-centred innovation and the impact such procedures have on them.

The role of patients in technique-centred innovation

There is a strong argument that without ‘courageous’ clinicians there would be no progress in healthcare. For, as Margo (2001) and Fox and Swazey (2001) assert, technique-centred innovations, developed in practice, are an important way of improving surgical care and therefore should be encouraged. However, like Reitsma and Moreno (2002), we recognise that technique-centred innovations are also dependent on ‘courageous’ patients who are willing to undergo innovative and at times, experimental, procedures, with no guarantee that they will benefit. Thus, as Margo (2001) maintains, such technique-centred innovation should only take place following patient consent and ethical approval.

The problem of consent

Informed consent is, however, a contentious concept. Some, as Corrigan (2003) outlines, treat it as an “ethical panacea” able to overcome the dangers of paternalistic medical practices, while others see it as a difficult, and at times inappropriate requirement that can unfairly burden patients (Tobias, 1998). Like many social scientists before her (Fox and Swazey, 1984, Lupton, 1997), Corrigan problematises the notion of informed consent writing that “such an ‘empty ethics’ model presupposes that autonomous individuals when presented with adequate information and given time to assess it will subsequently make a conscious decision whether or not to participate” (2003:770). Like Corrigan, our contention with this model centres on its reductionistic tendency to ignore the social and cultural context within which people make decisions. Thus, while informed consent is still an important ethical tool, we agree with Corrigan that “there is a need for more socially nuanced concepts of freedom, autonomy and consent” (2003:771).

Part of the difficulty of obtaining true “informed consent” is the unequal power balance in patient-practitioner relationships (as discussed by Canter (2001)), and the desire to be seen as a “good patient”. Dixon-Woods et al. established, in their study of women undergoing surgery, that “where patients disagreed with the treatment proposed by the doctor, they found it difficult to decline surgery because it risked losing their status as a ‘good patient’” (2006:155). These authors also maintain that the women’s individual agency evaporated as they took on their designated role within the hospital “community”, with its “tacit, socially-imposed rules of conduct” (2006:155). Thus when they were faced with consent forms, “women rarely did anything other than obey professionals’ requests for a signature” (2006:155).

Another potential explanation for this obedience may be the trust patients put in the medical profession. Corrigan (2003), for example, reported that many of the participants in her study put a large amount of trust in this “system of expertise”, believing that their clinicians would never suggest treatments that were not both safe and effective. Yet, as Agrawal et al. (2006) highlight, some patient are still willing to undergo innovative procedures that they have been informed are not completely safe, as long as they believe them to be potentially efficacious. Thus Agrawal et al. (2006) argue that undergoing such experimental treatments performs an important function in allowing patients to “maintain hope”. Similarly Glannon contends that, “there is more to rationality and decision making about whether to take part in medical research than the presentation of information about the research” (2006:253). Such a decision, Glannon contends, is also based on a person’s cognitive and emotional response to the research, which can be increasingly influential if they have exhausted all other treatment options (2006).

The cultivation of hope

Discussing the situation for people with Parkinson’s disease (PWP), Cohen et al write, “is it any wonder why PWP with advancing disease feel a sense of urgency to get improved therapies on the market and into the clinic...Medical professionals may often mistake this urgency for desperation, but patients view themselves as informed and realistic” (Cohen et al., 2007:539). Thus

while Brown (2003) implies that people with currently incurable diseases are persuaded, to their detriment, to share in the biotechnology industry's false hope, like Agrawal et al. (2006), Cohen, Herman et al. counter that "hope and positive expectations are key elements of healing that should be encouraged" (2007:540). Furthermore, partaking in clinical research is not always to patients' detriment, and even when a treatment is not itself effective for the individual patient, they may still benefit from their altruistic gesture (Titmuss, 1971).

Nevertheless the question remains, is it primarily hope that undergoing an innovative procedure or treatment will benefit themselves or others that ultimately motivates people to subjugate the potential safety concerns in favour of potential gain? Ultimately, there is the chance that if their health carers have not properly explained the experimental nature of their treatment, people may be unaware of such concerns. However given the persistence of hope in the face of all the information (Glannon, 2006, Agrawal et al., 2006) are people relying on it as a way of managing uncertainty?

Fox and Swazey (2002) discuss the notion of the "ideal patient" from the physician's perspective as being someone who can cope without knowing what lies ahead. Thus, perhaps healthcare workers can craft such ideal patients by promoting notions of hope and, at times heroism, in their patients. Casper observed such behaviour in her study of foetal surgery, wherein surgeons frequently framed women's decisions to undergo surgery on behalf of their foetuses as acts of heroism. She noted that "somewhere between death and safety is an ambiguous gray zone, in which medical workers define risk through their innovative practices of operating on pregnant women and fetuses, and where some pregnant women 'heroically' accept risk as part of their commitments to saving their babies" (1998:182). These women were seen to eschew other more standard, and potentially safer, options in order to undergo high-tech interventions that they hoped would save their foetuses. Even though, as Casper (1998) noted, very few foetuses were actually "rescued". This is similar to Fox's observations of patients/subjects under the care of the metabolic research group she studied. For, while the patients who

took part in the research were not framed as heroes, they were cast as minor celebrities amongst their fellow patients receiving special treatment, and special mention in academic papers. This, Fox asserted, “did seem to enhance their desire and ability to be ‘good research patients’” (1959:104).

A potential tool for promoting patient/subject hope is the telling of success stories. At one point, Casper describes the central reception area of the foetal surgery clinic as being “dominated by a large desk and a bulletin board covered with photographs of fetal surgery’s success stories – an appealing display of a dozen or more babies with rosy cheeks” (Casper 1998:108). Such a display of success stories may have served simultaneously as a reassurance for the surgeons that their work was worthwhile, and as a tool for promoting or maintaining hope in the desperate women who came to see them. The use of success stories has also been discussed by de Graves and Aranda (2005) in their study of childhood cancer. However such a focus on success stories, and therefore on the skill of physicians and healthcare teams, can equally lead to patients/subjects having their expectations raised and then, ultimately dashed. As Fox discussed within the context of the metabolic research groups’ patients, “if you have excellent medical care administered by physicians as highly qualified as those here, patients reasoned, and if you do everything you can to cooperate with them, then you can expect to ‘get better’” (1959:131), and yet when patients began to realise that they would not make much progress, they felt “frustrated...disappointed...discouraged” (1959:131).

McKneally and Daar pick up similar themes through their work on surgical innovation. They too highlight how patients who undergo experimental surgeries form the “heroic vanguard in the ranks of patients” (2003:931). However where Fox (1959) discusses the risks of raised expectations, they warn of an excessive enthusiasm, writing that patients who undergo experimental therapies should “be protected from an excess of zeal – their own and that of their innovative caregivers” (McKneally and Daar, 2003:931-932).

Is governance and transparency the answer?

This then leads us back to the issue of governing technique-centred innovations to ensure their efficacy and safety. It also raises the questions, is regulation and transparency the answer, and if so, what kind of regulation, and what sort of expert advice would fulfil the WMA's requirements (2008)? In order to explore this we need to extend our scope to the role regulation has played in the wider field of health-related research. Dixon-Woods and Ashcroft (2008) discuss the way in which the governance of health-related research came to the fore in the UK following two well-publicised scandals (child organ retention at Alder Hey and the clinical trial of continuous negative extrathoracic pressure in premature babies). Having previously been maintained by public faith in its "utility and good conduct", the resulting public outrage at health-related research focused on "the absence of clear systems of governance and accountability" (Dixon-Woods and Ashcroft, 2008).

In response to this concern and the perceived loss of public trust, the UK government introduced the previously discussed Research Governance Framework "to increase the accountability of both individual practitioners and institutions" (Checkland et al., 2004:131). The resultant removal of self-regulation from practitioners, Dixon-Woods and Ashcroft maintain, "can be read as a deserved punishment, and the assertion of more formal control over activities can be read as a display of responsible practice" (2008). However, as Checkland notes, such changes "represent a shift away from accountability based on the idea of professionalism and 'reflexive practice' towards accountability based on surveillance and rules" (Checkland et al., 2004:131). Dixon-Woods and Ashcroft (2008) likewise raise this concern, stating that while it is normal for regulation to be resented by a community who are used to relative autonomy, the frustration and dismay expressed by the health research community has deeper roots.

The unintended consequences of restrictive governance

According to Dixon-Woods and Ashcroft (2008) the main issues researchers raise regarding such regulation are as follows: ethical judgements are contestable and at times ambiguous, the risks that regulation seeks to control

are difficult to measure, research governance requirements can introduce an excessive bureaucratic burden, governance processes are often rigid and limited, and governance procedures impose an artificial assumption of sameness thus treating all research projects as if they were clinical drug trials (Dixon-Woods and Ashcroft 2008). Nettleton et al. (2008) and Checkland et al. (2004) would add to this list that strict external governance of clinicians leads to the demise of trust and tacit knowledge. As Checkland writes, “neglect of trust at the micro level by policy makers in favour of ever more complex measures to improve confidence runs the risk of damaging the internal (‘moral’) motivation of practitioners, with consequences that cannot be fully foreseen” (Checkland et al., 2004:134).

As previously discussed, many clinicians have also rallied against restrictive governance. One such clinician is Warlow (2005) who fears that regulation will impede the progress of clinical research. He writes that “there is now so much regulation that clinical research is being delayed, slowed and even stopped altogether. As a result, public health is compromised” (Warlow, 2005:33). Goodwin likewise maintains that regulation stifles innovation as “it is precisely pushing the boundaries of one’s practice that is vital to the development of expertise and a core aspect of safe medical practice” (Goodwin, 2007:274). In contrast, Wilson contends that the wealth of a clinician’s skills and knowledge cannot make up for good clinical governance. He writes, “a surgeon’s skill and ability to perform a procedure well is unimportant, in fact irrelevant, if the procedure should not be done in the first place” (Wilson, 2006:114). Furthermore, despite acknowledging the researchers’ frustrations with regulation, Dixon-Woods and Ashcroft (2008) ultimately argue that regulation confers benefits to researchers as it secures for them the necessary social licence to undertake their research.

Governing technique-centred innovations

Given then, the problems with governing, assessing, and implementing innovations, Strasberg and Ludbrook propose that, “a sure way to avoid risk to subjects of innovations is to stop innovation” but, they contend, “the cure would be worse than the disease” (2003:943). Therefore, if the development

and diffusion of technique-centred innovations is to continue, how best can their safety and efficacy be assessed? The “gold standard” of assessment, according to the Cochrane Collaborative, is usually the RCT. However, it is difficult to perform RCTs for technique-centred innovation (Morreim et al., 2006). As Sade writes “surgical studies are qualitatively different from medical investigations, for example, drug trials, in a number of ways” (Morreim et al., 2006:1957). The differences he outlines are the small size of many target populations, the often impossibility of double blinding a study, the iterative nature of surgery, and the learning curve and skill of individual surgeons which makes it difficult to standardise a procedure. Furthermore, surgery has a powerful placebo effect which may exist independently of the general efficacy of an operation. It is therefore difficult, as it is with drug trials (which also have a powerful placebo effect), to accurately measure the outcomes of surgical RCTs without using a placebo. However it is considerably more difficult to ethically and clinically justify the use of placebos such as sham surgeries in surgical RCTs than it is to justify the use of placebo pills in drug trials (Morreim et al., 2006). Solomon and McLeod (1995) have also addressed the difficulty and appropriateness of assessing surgery using RCTs, concluding that even within an ideal clinical research setting, only 40% of surgical questions can be answered using RCTs.

Despite these concerns and difficulties with assessing technique-centred innovations using RCTs, there is often a reluctance to accept other types of evidence as having the same level of validity as RCTs (see for example McKinlay 1981). This position is not without merit for, as Banta and Thacker (2001) and Wright (2005) have shown, relying on observational studies to assess the efficacy and safety of an innovation can lead to biased results. Nevertheless, RCTs can likewise produce biased results if their sample size is not large enough to detect an increased occurrence of infrequent events. A situation which, Strasberg and Ludbrook argue, occurred with the early RCTs of laparoscopic cholecystectomy which did not pick up the increase in biliary injuries in the treatment arms (2003). As such, it has been suggested that formal prospective registers may be a better way of discovering hidden risks,

or uncertainties in procedures, as they are potentially better able, than small RCTs, to pick up infrequent incidents (Strasberg and Ludbrook, 2003).

A further limitation of using RCTs, and for that matter registers, to assess innovations is that they often do not collect data on longer-term outcomes. Lantos (1997) illustrates this limitation using the example of diethylstilboestrol. An RCT successfully determined that diethylstilboestrol was ineffective for its clinical purpose of preventing premature labour; however it wasn't until a retrospective case-control study was undertaken that the relationship between this medication and vaginal adenocarcinoma was identified. The need for long-term outcome studies has been identified by both social scientists (Casper, 1998) and clinicians (Casler, 2003, Warner et al., 2007) due to the inability of many registers and RCTs to determine the long-term safety and efficacy of innovations. Therefore, if the testing and diffusion of technique-centred innovations is to continue, how can their safety and efficacy be assessed? Perhaps the answer is to steer a middle road between restrictive external governance and HTA assessment by RCT, and an absence of governance or formal assessment.

McKneally (1999), McKneally and Daar (2003), Jones et al. (2004), Morreim (2006) and Spigelman (2006) suggest new models of reviewing governing and assessing technique-centred innovations which they propose would provide the necessary oversight in a positive, constructive and collegial manner. Morreim's "Innovation Review Committee" (IRC) would consist of a group of clinical experts from within an institution whose membership would change to provide the best expertise to advise on each individual innovation under consideration. McKneally and Daar's "Innovative Task Force" would consist of stakeholders from the institution, while McKneally's review boards would include practitioners, potential patients, payers, and institutional representatives. Morreim sees the role of such IRCs as being "to improve good ideas and weed out those that fellow surgeons consider too risky or still too unrefined to try on patients" (2006:1959). This, she contends, would address the need for collective wisdom to "be sought before a surgeon exposes a patient to the risks that inevitably accompany the potential benefits

of a new procedure or a new use of an existing device” (2006:1961). It would also, potentially, fulfil the WMA’s requirement for clinicians to seek expert advice before using unproven treatments on their patients (2008).

Such review boards, McKneally proposes, should assess planned innovations, evaluate ongoing activities, and consider their endpoints and outcomes. Morreim concurs but explores the role and tasks of such a committee in more depth. She suggests that IRCs address the following issues in regards to each innovation they review: whether the current clinical management of the condition is truly inadequate or problematic; the theoretical merit of the proposed innovation; the adequacy of the preparatory work; potential refinements of the idea; the selection of patients and surgeons; the need for training before the procedure is undertaken; the adequacy of resources; the patient information and consent process; and the requirement that clinicians provide the IRC with follow-up information on patient outcome (Morreim et al., 2006). This last element is seen by Morreim as of particular importance as she believes that “the review process should not just be prospective. It should be retrospective” (2006:1960). Therefore Morreim contends that the same group of experts meet after an approved innovative procedure has taken place in order to discuss the following: whether the procedure went as planned, whether there were any unanticipated problems, whether it warrants repetition, and if so what sort of patients would be suitable for the procedure, and how best to address any problems that arose in terms of the procedure and subsequent care. The reporting back of outcome data would also fulfil the WMA’s requirement that clinicians who use unproven treatments, record any new information gained from their use, and make it publically available where appropriate (2008). Like McKneally and Daar (2003), Morreim maintains that such internal, flexible review is preferable to mandatory external review, where “form could dominate substance” (Morreim et al., 2006:1960).

There is, however, some scepticism and opposition to such a model of governance. Contrary to Morreim’s endorsement of IRCs, Mack (Morreim et al., 2006) maintains that it is both wrong to suppose that healthcare

organisations will have appropriate personnel to form such committees and to assume the any such review would be collegial and altruistic. He writes, “the assumption that there would be unbiased, beneficent peers willing to ‘curbside consult’ in the current practice environment is not realistic” (Morreim et al., 2006). Furthermore, Mack argues that the expansion of oversight procedures into the arena of technique-centred innovation would impede rather than promote innovation. Yet, despite encountering such reservations, Spigelman concludes that the model of local governance of technique-centred innovation he examined had “facilitated and not inhibited innovation” (Spigelman, 2006). What is more, the promotion of local, in-house assessment and governance procedures to supplement external, national procedures has not been restricted to technique-centred innovation, but rather has also been proposed in regards to HTA (McGregor and Brophy, 2005). Nevertheless, the feasibility of forming appropriate, collegial, and altruistic review committees requires further investigation.

Conclusion

It would appear that restrictive, external governance may not be the best way to provide oversight for technique-centred innovations. Stringent monitoring and regulation may have the unintended consequence of undermining innovators’ ability and opportunity to innovate, and clinicians may not recognise when external governance is required. Furthermore, it seems that RCTs may not always be the best way of assessing the efficacy and safety of these innovations. However, given that technique-centred innovations can raise serious issues in terms of patient safety and quality of care, it would seem that some form of evaluation and governance is necessary, governance that may also provide clinicians with the all important social licence to perform their innovations and research (Dixon-Woods and Ashcroft, 2008). A model of internal oversight, drawing on the ideas put forward by Morreim (2006), McKneally (1999) McKneally and Daar (2003) and Spigelman (2006) may, therefore, provide a useful first line of governance for technique-centred innovations which complies with the WMA’s requirements. Especially if the resultant IRCs were accompanied by the implementation of registers for

recording information on the approved innovations and for monitoring patients' short and long term outcomes.

Yet, before we can begin to design and assess such procedures to improve safety and quality, we must first unpick the complicated network of decisions that currently surround the development, assessment, governance, diffusion and patient-uptake of technique-centred innovations. For as the literature on the diffusion of innovations (Meyer and Goes, 1988, Fitzgerald et al., 2002a) and on patient experience (Brown, 2003, Agrawal et al., 2006, McKneally and Daar, 2003) shows, it is not yet clear how “decisions” – informal, formal, collective and individual – about technique-centred innovation actually get made. Thus before exploring the feasibility, impact and effectiveness of internal assessment and oversight procedures for technique-centred innovations, we must first explore the complexity of meaning surrounding the term “innovation”. Likewise we must explore the significance that “innovation” holds for patients, practitioners, governing bodies and organisations, and the differing methods employed by these groups and individuals to manage the accompanying risks and uncertainties.

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