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What is This?



A Novel Framework for Reflecting on the Functioning of Research Ethics Review Panels

Colin Macduff, Andrew McKie, Sheelagh Martindale, Anne Marie Rennie, Bernice West and Sylvia Wilcock

Key words: ethical review panels/committees; framework for reflection; malt whisky

In the past decade structures and processes for the ethical review of UK health care research have undergone rapid change. Although this has focused users' attention on the functioning of review committees, it remains rare to read a substantive view from the inside. This article presents details of processes and findings resulting from a novel structured reflective exercise undertaken by a newly formed research ethics review panel in a university school of nursing and midwifery. By adopting and adapting some of the knowledge to be found in the art and science of malt whisky tasting, a framework for critical reflection is presented and applied. This enables analysis of the main contemporary issues for a review panel that is primarily concerned with research into nursing education and practice. In addition to structuring the panel's own literary narrative, the framework also generates useful visual representation for further reflection. Both the analysis of issues and the framework itself are presented as of potential value to all nurses, health care professionals and educationalists with an interest in ethical review.

Introduction

Procedures for the ethical review of health care research vary considerably across, and sometimes within, different countries. As Uys¹ notes, compulsory prior review is increasingly the norm in North America, while many developing countries have yet to establish adequate capacity and capability in this regard. Within Europe, the UK has one of the most complicated and arduous processes,² despite being structured around one national health service (NHS). For nurses in the UK, particularly those engaging in research for higher degrees, there may also often be a requirement to consult a university-based research ethics committee. The latter bodies can be

Address for correspondence: Colin Macduff, School of Nursing and Midwifery, Robert Gordon University, Garthdee Road, Aberdeen AB10 7QG, Scotland, UK. Tel: +44 (0)1224 262647; E-mail: c.macduff@rgu.ac.uk

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single university committees (central model) or based within specific disciplines (devolved/multiple model).

As relatively little is known about the functioning of discipline-specific committees,³ this article presents reflections from a group of researchers and educators who have recently developed a research ethics review panel within a university school of nursing and midwifery. A novel framework has been developed by the authors to structure such reflection, and the article describes the process of development and application of this framework. Although the resultant analysis of issues is necessarily conducted from a contemporary UK nursing perspective, most of the themes that are seen to emerge have clear relevance across geographical and disciplinary boundaries. The new framework may itself have potential value for any ethics review committee or panel. In the context of this article, the words 'panel' and 'committee' are seen as synonymous.

Background

During the last decade structures and processes for the ethical review of UK health care research have undergone rapid change. Increasing centralization gained momentum in 1997 when the existing system of local research ethics committees (LRECs) was supplemented by the establishment of multicentre research ethics committees for research carried out within five or more LREC regions. In the new millennium the pace of change increased, driven primarily by a series of well-publicized scandals about the conduct of medical research, such as the removal of internal organs from the bodies of dead children without parental consent.⁴ A new UK framework for governance of NHS research was launched in 2001. The resultant increased regulation and standardization of procedures became further centralized in March 2004 when the new Central Office for Research Ethics Committees (COREC) introduced a standard national application form. This in turn enabled the UK to comply with European Union Directive 2001/20/EC on Clinical Trials of Medicinal Products.

Although many health care practitioners and educationalists have recognized the need for better structured systematic scrutiny, widespread concerns have been raised about the means of enactment and resultant functioning. Within nursing these have centred on inconsistent decisions/interpretations between different LRECs,⁵ inappropriate application of new procedures,⁶ greatly increased bureaucracy and paperwork leading to time delays,⁶ and conflict over the goals of postgraduate nurse education.⁷ Medical disquiet has been vociferous and broadly similar in nature,^{8–10} adding distinct (and richly ironic) concerns about research ethics committee (REC) paternalism.¹¹ With pharmaceutical companies also lobbying vigorously for improvements, the UK government set up a review of the operation of NHS RECs. This has made some recommendations,¹² which may not only streamline application processes but which also seem to signal a reverse in the trend for more regulation. For example: 'The remit of NHS RECs should not include surveys or other non-research activity if they present no material ethical issues for human participants.'¹²

Meanwhile, partly in response to these health service developments and related public concerns, most UK universities have been engaged in a process of formalizing research governance and ethics policies and procedures across all disciplines. In a very useful research-based snapshot of the recent state of this art, Tinker and Coomber³

outline a picture of substantial activity. Three-quarters of the surveyed universities had formal policies for scrutiny of research and 80% had at least one REC. Of those with RECs, one-third had one central REC only, while around two-thirds had more than one (eg RECs within faculties or particular schools such as nursing).

In this changing context, the School of Nursing and Midwifery at the Robert Gordon University, Aberdeen, established a new School Ethics Review Panel (SERP) in May 2004. As the panel's main remit has been to scrutinize research into nurse education and practice, it seems both timely to take stock of progress since its inception and potentially useful to share some of the emergent issues with a wider audience who may have similar interests. This would appear to address a knowledge gap because a formative literature review identified only one substantive and recent reflective analysis, ¹³ and this was by members of a LREC charged with an exclusively qualitative remit.

Local context and initial review

The establishment of our SERP followed on closely from publication of the university's new research governance and research ethics policies. The former seeks to define and communicate clear quality standards concerning ethics, scientific quality, the performance of research, and safety and finance. The latter seeks to: provide standards to protect those researched and researching; educate staff, students and other interested parties; and provide a clear understanding of all relevant mechanisms and procedures. Although the university had also established central research governance and ethics subcommittees, the setting up of school-based review panels was seen as important professionally and operationally (ie for relevant disciplinary scrutiny and adequately timed processing). Where school-based review identified issues that required wider consideration or further guidance, referral to the central university ethics subcommittee could be made.

The six-member panel was formed through the initial purposive selection of a core of school staff with very extensive experience of health service and educational research. This was augmented by the inclusion of staff with less research experience. Care was taken to include a range of cognate expertise (eg midwifery, mental health) and a range of methodological expertise (eg qualitative and quantitative approaches).

After approximately 18 months of operation, the SERP identified the need to take stock of progress through initial internal review. The first part of this process involved content review of the formal minutes from the six meetings that had taken place. This produced an overview of the main topics/issues with which the panel had been concerned (Table 1).

A further useful overview was obtained by collating details of the main types of formal applications that the SERP had scrutinized. These are detailed in Table 2.

It is difficult to gauge how typical the number and type of applications described in Table 2 are for a nursing school review panel. However a more general comparison is afforded by Tinker and Coomber,³ who found that half of the central university RECs who responded to their survey processed less than 50 applications each year. This would suggest that our panel may process a relatively high volume of applications. The research methods outlined in these applications vary, but it is striking that many mix qualitative and quantitative approaches, and the use of questionnaires is typical.

Table 1 Overview of main topics addressed by SERP meetings in the first 18 months

Months	Topic
1–6: initial establishment	 Purpose and membership of committee (driven by: new university structures and policies; changes in NHS ethics procedures; concerns about student projects; and increasing interest from external researchers) Relationship to other university committees Understanding and explaining/disseminating new university procedures Understanding and explaining/disseminating new NHS procedures Recording existing and new school research and audit activities Developing a process for reviewing whereby two panel members scrutinize and decide on each application, but seek advice and/or full SERP review if problematic issues arise
7–12: consolidation and development	 Addressing issues around NHS procedures and their relationship to the university (eg sponsorship and liability) University support structures for the SERP Issues around new university forms developed for applicants Clarifying processes/procedures re internal school applicants, applicants from other schools and external applicants Intra-school issue about honours students no longer doing empirical research What is research and what is audit? Production of good practice guidance documents for panel and for all staff Explanation/dissemination events for above new documents Awareness of wider local and national developments/policy reviews etc
13–18: further development towards initial review	 Committee constitution: student representatives and external membership? Overviewing applications received and highlighting arising issues for discussion Concern at e-mail appeals for research volunteers, leading to setting a school minimum standard, then submitting this to the university Review of quality issues by focusing on standard of questionnaire surveys, leading to more formal acknowledgement of the role the panel has in informing/developing research standards Discussion on prevention of coercion of students and how to deal with monitoring of research practices Discussion on issues raised by more involved external applications such as large national studies Relationships with other school panels Issue of what educational evaluation is, and when it is research; identification of need for culture change

In addition to the activities detailed in Tables 1 and 2, the SERP members have dealt with numerous internal enquiries about research ethics, methods and related processes. They have also considered a number of approaches from external bodies to carry out research that never progressed into satisfactory applications. These aspects

Table 2 Types of formal applications scrutinized by SERP in 18 months

Type of research (in terms of parties involved)	No.	Nature of research		
parties involved)		Undergraduate	Postgraduate	Other (eg external contract)
School staff researching our school staff	2		1	1
School staff researching our school students	7		4	3
School staff researching our students and NHS staff/ patients ^a	1		1	
School staff researching NHS ^a or external organizations	13	1	6	6
Our school students researching our staff	1	1		
Other RGU staff researching our school's students	1		1	
External organizations researching our staff only	2		1	1
External organizations researching our students only	3		1	2
External organizations researching our staff and students	2		1	1
Total	32	2	16	14

RGU, Robert Gordon University.

have required particularly significant time input by the Convenor. In this regard Table 1 alludes to a key mechanism developed by the SERP to focus expertise and resource efficiently so that applications can normally be processed within 15 working days. Reviewing in pairs has become standard practice for non-complex applications, and there is always the option to seek advice and/or full SERP review if problematic issues arise. Pairing usually seeks to match very experienced and less experienced reviewers, and this mechanism has enabled individual professional development. It has also enabled full SERP meetings to focus on complex applications, emergent internal issues and emergent external issues.

The development and application of a new framework for structured reflection

Although the review of activity described above has proved a very useful starting point, the SERP has been keen to reflect more fundamentally on its purposes, values and related functioning. Formative review of the relevant literature on nursing ethics proved useful in a general way, highlighting the move away from principle-based prescriptive codes to virtue ethics and the importance of individual and contextual narrative. ¹⁴ Nevertheless, it proved difficult to find a suitable 'off-the-peg' framework

^aThese applicants also had to submit their proposals to the relevant NHS REC(s) for scrutiny.

that might help us to move meaningfully and easily between the realm of principles and that of panel performance. However, breakthrough was forthcoming late one evening when the SERP Convenor poured a large glass of malt whisky, accessed a very useful web site on whisky tasting, ¹⁵ and sought further immersion in a dictionary. The outcome of this singular, and inherently volatile, conjunction is now presented.

One of the starting points in the art and science of malt whisky tasting is recognition of the four primary tastes: sweet, bitter, sour and salty. By analogy, we can posit four primary modes of functioning for a research ethics review panel: prevention, proscription, palliation and promotion. Whisky lore draws attention to the fact that there are 32 primary smells. With a more conservative transposition, we can propose that 12 characteristics may, to a greater or lesser extent, be descriptive of the approach that a panel takes to its work. Table 3 lists these 12 characteristics along with the four primary modes of panel functioning and initial operational definitions.

Having identified these key items as potentially apposite and having operationally defined them, there was now basis for structuring both individual and group reflection. The first aspect was taken forward by developing a common rating scale

Table 3 Proposed primary modes of functioning and characteristics of an ethics review panel

Modes/characteristics	Initial operating definition	
Primary modes of functioning	ng	
Prevention	Anticipating events and acting to try to keep them from happening	
Proscription	Prohibiting something by decree; forbidding	
Palliation	Lessening the severity of; relieving without curing; improving/making the best of what is there	
Promotion	Moving something forward by highlighting qualities	
Characteristics		
Prescriptive	Giving directions beforehand; making recommendations, normative rules	
Protective	Shielding to prevent threat of harm	
Paternalistic	Acting in the manner of a father making decisions on behalf of	
	one who is presumed to have less capacity	
Policing orientated	Tendency towards enforcing conditions under which the research must take place	
Perfunctory	Doing something superficially or as a matter of routine	
Practice monitoring	Tendency towards monitoring how research is actually practiced	
Practice supporting	Tendency towards giving active support to approved research as/when it is actually practiced	
Pliant	Supple, flexible, perhaps easily influenced?	
Permissive	Inclined towards allowing and/or tolerating, rather than prohibiting or enforcing	
Politically aware	Actively fostering awareness of, and managing the influence of, relevant trends in social relations and power	
Policy perplexed	Experiencing puzzlement or confusion in relation to relevant individual policies affecting ethics (or the interaction of several such policies)	
Policy engaged	Actively engaging in the creation, translation and application of relevant policies affecting ethics	

for the items and formulating this into a questionnaire, which was offered to panel members. Although the panel had previously committed itself collectively to this type of reflective exercise, it was also agreed that individual members could choose whether they wished to participate or not. In this way panel members were asked first to rate the extent to which the panel's work had been concerned with each of the four primary modes of functioning. The response choices offered were: 'not at all', 'a little', 'substantially' and 'very substantially'.

A mid-point rating was deliberately omitted. A generous space for explanatory written comments was presented under each item in the questionnaire. Panel members were then invited to undertake the same process with the 12 characteristics (ie 'to what extent has the panel's approach been: prescriptive; protective' etc).

The next stage in this structured reflective process involved a specially convened meeting of the SERP at which members were invited to share their individual ratings and comments. The aim of this discussion was twofold. First there was the desire to see if consensus could be achieved on a single panel rating for each item. Second, and more importantly, there was the hope that the process would facilitate deeper analysis of the work in which we had been engaged. In particular we hoped that it might be a useful catalyst for exploration of principles and values and the extent to which these were reflected in examples of panel actions.

Findings

This section of the article now presents the main findings of the exercise by discussing each item, the panel's rating, and relevant issues that arose in discussion. Where appropriate there is extended consideration of some examples and these are informed by relevant literature. Owing to other commitments, one of the six panel members had been unable to attend the meetings relating to the reflective exercise. Accordingly the findings are based on the discussions of the remaining five.

Primary modes of functioning

Prevention

There was clear agreement that this had been a 'substantial' concern driving the panel's work. Much of the first 18 months' work had involved trying to move from an essentially reactive, formative position to one where we could anticipate events and act to try to prevent some from happening. Within this latter category we had been particularly concerned to prevent confusion for applicants in terms of application processes and procedures. This was a constant struggle because panel members themselves had to interpret and clarify rapidly evolving documentation from within the university and the NHS.

Proscription

There was ready agreement that the panel had been concerned with proscription only 'a little'. Although it had not been thought necessary or useful to issue explicit written edicts forbidding ways of conducting research or ways of formulating applications, there was recognition in the discussions that proscription could often be implicit within the university and NHS policy documents that we were interpreting. The

Convenor described becoming more explicit in articulating the 'don'ts' when prospective applicants asked what sort of issues the panel were concerned with.

In this regard the panel had become particularly concerned with the manner in which many applicants were proposing to involve students in their research. Clark and McCann¹⁶ usefully highlight the need to pay particular attention to four issues when involving students as research participants: unequal power relationship and coercion; obtaining a valid informed consent; anonymity and confidentiality of data; and fair treatment. However, internal and external applicants often omitted to acknowledge some of these issues and/or design specific research procedures to address them. Accordingly, this was highlighted in feedback on applications, but increasingly the Convenor had been explicitly emphasizing this up front when consulted preapplication (eg 'don't put students in a position where they have only minutes to decide on their participation and they have to do this publicly'). In effect this exemplifies proscription as a means of prevention.

Palliation

The mutual benefits accruing from consultations prior to submission of applications were emphasized again during discussion of the panel's palliative function. All members agreed that palliation had at least been a substantial part of the panel's work. Further consideration resulted in a 'very substantial' rating, reflecting a shared feeling that we had very often been concerned with improving what had been presented in applications. This is alluded to in Table 1, whereby one panel meeting had explicitly focused on the standard of survey questionnaires as a way of enabling broader consideration of the panel's role in scientific quality issues.

The latter subject is topical; the recent review of NHS ethics committees¹² is very clear that adequate scientific review should take place before a separate process of ethical review. However, our panel has clearly been engaged in simultaneous evaluation of these two aspects in the belief that they are explicitly related within the principle of beneficence. If any proposed study is going to have potential to do good, it must be well designed and use methods that are likely to be valid and reliable. It is interesting to note that many of our concerns with scientific quality related to the postgraduate research dissertation studies that have made up just over half of our applications (Table 2). The UK research governance framework¹⁷ states that 'for many student research projects the university supervisor may provide an adequate level of review', but our experiences of internal and external applications so far tend to call into question the level and/or effectiveness of such input prior to application.

Interestingly, another recent UK review has relevance here. The Working Group on Ethical Review of Student Research in the NHS, ¹⁸ which was set up under the auspices of COREC, has recommended the creation of student project ethics committees. Aligned to LRECs, and drawing membership from health service and university staff, these new committees would 'evaluate the risk–benefit ratio of projects, as demanded by the Declaration of Helsinki, but would do so in relation to their educational rather than scientific value'. ¹⁸

Thus, a third dimension, educational value, enters the picture and poses particular challenges when the proposed student research is to involve health service patients or staff. From Table 2 it can be seen that around a quarter of our applications fell into this category in that our school staff have often been researching in the NHS for postgraduate degree purposes. In effect, our panel is already providing scientific

and ethical peer review for these applications before they go through the present NHS ethical review procedures. Table 2 also shows that our school staff's postgraduate research may focus solely on students and immediate colleagues. Again, clear separation of educational, scientific and ethical value judgements can be difficult in this context.

These discussions show how a university ethics review panel based in a health care discipline necessarily has to address questions of educational and scientific value in most deliberations. As Ellis and Peckover⁷ point out, there are usually significant tensions between these values. The review of applications typically involves consideration of a mix of matters of principle and matters of practical enactment, and these may be evoked as much by what is not said as by what is stated explicitly.

By far the most common outcome of formal review has been 'approved subject to amendments', and herein lies the source of the panel's perception of very substantial palliation activity. The panel has endeavoured to make related feedback constructive, both in terms of content and manner of delivery. This seems an important consideration as nursing is trying to build research capacity¹⁹ and inexperienced researchers are likely to find current ethical review processes at least daunting and, at worst, damaging. The panel has therefore tried to incorporate significant educational and supportive elements into the interpersonal feedback process. In the case of postgraduate students, however, care has been taken to limit this so that the supervisor's role is not supplanted.⁷

In discussing palliation, the panel acknowledged that the parts of the initial operational definition relating to 'lessening the severity' and 'relieving without curing' involved a more negative way of viewing matters that might nonetheless be applicable in some cases. Indeed, this sparked deeper discussion of the extent to which we were involved in preventing bad research (non-maleficence) or promoting good research (beneficence).

Promotion

Accordingly, discussion of the last main panel function centred on whether our approval of an application became a public endorsement that amounted to promotion. On reflection, the consensus view was that the act of approval equated more with the meeting of a minimum standard rather than the active highlighting of qualities. However, it was noted that the panel had more actively promoted the new procedures related to the application process and some of the panel's other activities. This resulted in an overall rating of 'a little' and recognition that we should strive to be more proactive in promoting: approved research, policies and procedures, and the profile of the panel itself.

Characteristics

Prescriptive

When considering the first of 12 possible panel characteristics, individual ratings were initially spread over three of the response choices. However, through further discussion it was agreed to focus on the extent to which we had been prescriptive of local procedures, as the university itself prescribed the 'should do's' of overall ethics policy. With this understanding there was consensus that we were 'substantially' prescriptive, because we had produced and promoted good practice

guidance documents for submission of applications and for the panel's own reviewing procedures.

Protective

Having established in earlier discussions that prescription for preventive purposes was substantial, and that some proscription also took place, there was ready agreement that our panel was 'substantially' protective in its approach.

Paternalistic

Again, for this item, individual ratings were initially spread over three of the response choices. Those panel members who had been most involved in dialogue with enquirers and applicants tended to see the panel as more paternalistic in approach than did those with less user contact. This cast paternalism as a negative attribute, but some members raised the possibility that a degree of paternalism was welcomed by users. In turn, this provoked discussion of a possible user survey in order to gain better insights into how panel function and attributes are seen. In the interim it was decided that a 'substantial' rating might be most appropriate.

Policing orientated

There was ready agreement that the panel's approach was only 'a little' orientated towards the proactive enforcement of conditions for conduct of the research. The feeling was that our own panel's scrutiny tended to be 'front-loaded' and focused on the proposal on paper. Researchers and supervisors were then honour bound to respect relevant requirements in research practice. In this regard, all research, audit and consultancy is subject to audit through the university's central committees. Tschudin²⁰ provides summation when stating: 'There is a balance to be struck for ethics committees between being overprotective and watching the researcher's every step on the one hand, and being too unconcerned and detached on the other.'

Perfunctory

The panel's approach was seen as 'not at all' perfunctory. Review was seen as engaging and scrutiny was substantial, rather than superficial or routine. After consideration of the main ethical principles, review also took into account details of applicants' own contexts/narratives as presented in their application. Accordingly, the process went beyond passing judgement and also typically included the palliation approach to feedback outlined previously. Nevertheless, there was some recognition that the 'approved subject to amendments' category could become a perfunctory default outcome if used indiscriminately.

Practice monitoring

This was seen as closely related to practice policing, but as having a wider remit in the sense of pertaining beyond approved research projects. For example, in response to enquiries, we have been concerned to clarify when activity should be seen as routine educational evaluation and when it is research. As with the difference between research and audit, we have found that this question is usually resolved by examining the reason for the activity and its proposed nature and scope. Nevertheless, we have identified a need to increase local awareness of this issue, to question established

practices and to monitor activities more closely. As such, the panel rated itself as doing 'a little' practice monitoring to date. Tschudin's review²⁰ suggests that this may not be unusual for many ethics committees. In effect, monitoring often relies on researchers building quality assurance mechanisms into their projects, in the knowledge that they may also be subject to audit from internal and external bodies.

Practice supporting

The panel saw its approach as being 'a little' concerned with supporting ethical aspects of research as they were actually enacted in practice. This was for the simple reason that panel members were usually not present, especially for research taking place in the NHS. There was recognition that staff and students frequently approached panel members for advice about ongoing research that they were conducting in the school, but this usually focused on methods more generally and on specific analysis techniques rather than ethical issues.

Pliant

This item produced a wide spread of ratings and panel members sought to clarify what the term meant in relation to its approach. Perhaps not surprisingly the notion of being easily influenced was rejected and the connotation of flexibility was seen as the applicable part of the operational definition. In particular, our responsiveness to evolving ethical policies and procedures was cited, along with responsiveness to the school's own evolving narrative regarding building research capacity. Finally, examples of responsiveness to the needs of individual applicants were discussed. This resulted in a 'substantially' pliant rating.

Permissive

Initial opinions varied for this characteristic, but consensus emerged that we tended to be 'substantially' permissive. This was predicated on the basis that very few applications had resulted in complete rejection. There was acknowledgement, however, that this interpretation focused on eventual outcome and that permissiveness was not characteristic of our approach to processes of application and scrutiny.

Politically aware

Discussion of this item tended to centre on the panel's interface with other schools and committees in the university and relationships with external organizations. Consideration of the former had become a regular opening agenda item for panel meetings. Input to, and update from, the respective research governance and ethics subcommittees was thereby regularly reviewed and related to other external developments such as national higher education research/policy documents. Implications for local action were usually appraised and, in this sense, it was felt that the panel had been 'substantially' politically aware.

Policy perplexed

Initial ratings varied for this characteristic. This stimulated debate about whether we were typically perplexed by policy, by related emergent procedures, or by both. As indicated above, in the section on palliation, the interpretation of changing NHS policies and their interface with university policies required a high level of ongoing engagement and necessarily involved periods of collective perplexity. The

recommendations of the most recent review of NHS ethics committees¹² suggest further changes that will necessitate our own review of aspects such as survey research. Although transient puzzlement has been more characteristic than lasting dysfunctional confusion, we eventually decided a 'substantial' rating best reflected our experiences.

Policy engaged

Finally, as suggested above, we readily agreed that it had been necessary to stay 'substantially' engaged with policy. This was particularly true for translation and application of new policies, and a regular agenda item was allocated for this topic at panel meetings. We also cited evidence of local policy creation in terms of setting a minimum standard for e-mail appeals for research volunteers.

Visual overview

As the previous section demonstrates, ethical matters tend to be characterized by discourse involving the spoken and written word. Although this may be unavoidable, some leavening through the use of other media can be useful. Recourse to malt whisky again offers interesting possibilities in this regard. Figure 1 presents a tasting star, which gives a visual overview of the characteristic profile of one particular malt whisky. As can be seen, a visual analogue scale has been used to gauge each of 10 individual characteristics. In the case of malt whisky, each of these 10 individual characteristics refer to distinctive conjunctions of several of the following properties: appearance, aroma, flavour and texture (known rather splendidly as 'mouthfeel'). Taking into account the sound of pouring and its associated emotional arousal, it is evident that the evaluation of whisky will usually involve all of the senses.

Although rather more prosaic, evaluative reflection on the functioning and characteristics of ethics review panels may also benefit from the type of visual overview afforded by the tasting star. Figure 2 presents our resultant 'SERP star'.

Discussion

The 'SERP star' illustrated in Figure 2 provides a useful summary by mapping where our panel has been in the past 18 months. The primary modes of functioning form the main axes within the diagram. Our ratings pattern depicts conservatism to proscription and promotion, with much more active emphasis on prevention and palliation. In effect, so far, we have tended to say 'should' then 'could' before 'can't' or 'can'. Four main fields of activity are also clearly evident. The upper left hand quadrant shows substantial activities that can be summarized as essentially protective in nature and intent. Similarly, sustained activity is evident in the lower left hand quadrant, and this has focused on ethics policy. The link between these two quadrants (running back and forth along the line of the web) has usually been preoccupation with processes and procedures. This has been a major dynamic in the work of the panel so far. Most of the activities on the left hand half of Figure 2 have been concerned with anticipating and preventing problems, both at the level of generic issues and for individual research applications.

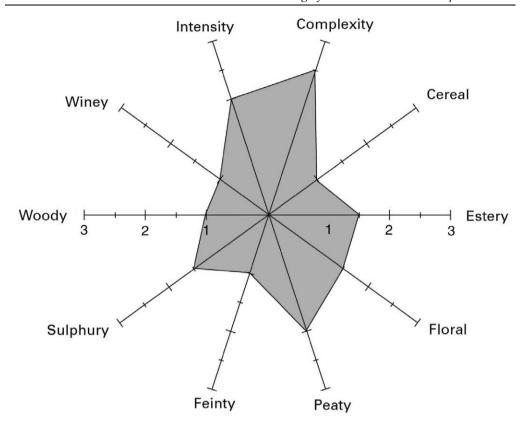


Figure 1 A malt whisky tasting star (© Copyright 1997 Distillers.com Ltd. Permission granted for use in this context.)

The lower right hand quadrant of Figure 2 shows a picture of mixed functioning in relation to researcher-enablement activities. The panel's perception that it gives high levels of support around the whole process of considering applications seems to be offset by less engagement once research has actually been approved. This is corroborated in the upper right hand quadrant, which is mostly, but not exclusively, concerned with awareness of research as it is actually practiced.

Thus the star diagram provides a profile that also highlights possibilities for future panel developments. In doing so, it begs the question of what an optimal ethics review panel star should look like. For example, should our ethics panel be much more actively concerned with monitoring? It is worth citing Parker's clear view that:

the responsibility of an ethics committee does not cease with the approval or non-approval of a project, and RECs should monitor the progress of the projects that they have approved in an attempt to ensure that their conduct remains ethical, particularly in the light of any proposed significant deviations from the original protocol or of any unusual or unexpected results that may raise concerns about the continued safety of the research (p. 81).²¹

However, Tschudin²⁰ casts some doubt on the extent to which such vigilance actually happens. Indeed it is difficult to make normative comparisons with other

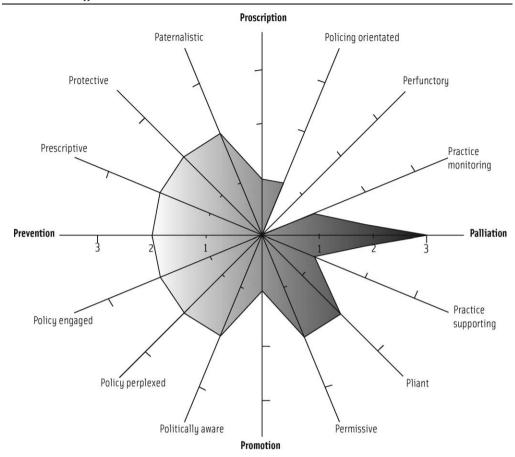


Figure 2 SERP star: profile of a school ethics review panel

university schools of nursing because it has proved hard to find either a reflective inside view or a systematic collation of users' views. It would seem likely that monitoring activities are one of the later aspects to develop after a panel becomes established. In our own local case, the relevant central university committees already have a monitoring function and carry out random audits of individual research projects.

Accordingly, we have decided that increased future efforts in this area will be part of a broader promotional approach for raising awareness of the panel, its activities and the importance of ethical research practice. This strategy includes the recruitment of a student representative. The need for promotional activities emerged clearly in other parts of the reflective exercise and, by accentuating the positive, the 'research police' label may be avoided.

Undoubtedly, one of the issues raised when considering future activities is capacity in terms of time and personnel. In our experience of ethics matters in the current regulatory climate, addressing one issue in depth usually reveals a need to address several others. The underlying aspirational logic is that the present increase in time investment may prevent significant longer term problems of the sort that arose in

medical research. As practising researchers, all panel members have noted the professional value of being involved in a body that necessarily has to keep abreast of developments. The amount of learning has been substantial, even for the more experienced panel members.

The above considerations lead to the related point that different profiles may be optimal at different stages in a panel's development. Indeed it seems unlikely that a fully-rounded profile would be desirable if the 12 posited characteristics are used. As has been seen, a few of these characteristics seem unambiguously positive and desirable, such as being policy-engaged. Yet even these require discussion to clarify application before a meaningful shared rating judgement can be made (eg is it engagement with policy creation, translation or application via procedures?). Other possible characteristics, such as being perfunctory or policy perplexed, have an inherently negative connotation. Perhaps the modes of functioning and characteristics that have emerged as most interesting are those that can be interpreted both negatively and positively. Items such as palliation, paternalistic, and pliant provoked very useful discussion that led to deeper reflection on our purposes and principles. This was the main aim of the exercise: to facilitate a reflective process.

The postulated functional modes and characteristics have been a means to this end and represent a tentative initial formulation. At worst, a few of these items seemed contrived or led more to semantic than substantive discussion. Overall, however, the points of reference for this 'first tasting' proved both meaningful and useful. One of the key points about item selection and placement on the tasting star structure is that true opposites (if such things can be said to exist) are avoided. Rather, this method works by presenting areas of more subtle contrast. This seems particularly well suited to mature ethical reflection. Despite the need for anchoring principles and codes, this article has highlighted how absolutism is seldom the cardinal feature of practical review. On the contrary, there are usually some ongoing trade-offs, for example, between notions of scientific and educational value.

Ethics review panels, like malt whiskies, should mature and generally improve over time. Like malt whiskies, they may also each have a distinctive recognizable profile influenced by local conditions. Experienced health service researchers can often cite the distinguishing features of their local committee and in such knowledge can lie strength. However, local distinctiveness is also probably at the root of the inconsistencies that arise when the same proposal is reviewed by different regional committees.⁵ This serves to emphasize that, as with malt whisky, the perception of the consumer/user is very important. It is interesting to note that studies of users of LRECs²² may show predominantly positive perceptions, although negative experiences have prevailed in recent health care publications. Concerns within nursing have focused on LRECs rather than university research ethics review committees, but it remains rare to find a systematic study of nurses' experiences of either. As such, we must acknowledge that one of the main limitations in our reflective process has been the absence of formal feedback from users. Undoubtedly, a survey of applicants' experiences would be informative and salutary.

In concluding this discussion section, we attempt to compensate readers and committee users for this omission. Some knowledge of whisky lore provides useful context and analogy. As malt whisky matures over the years in wooden casks, a percentage of the spirit evaporates. This is known as 'the angels' share'. In conducting our reflective exercise we have described an early sampling from a maturing cask. In

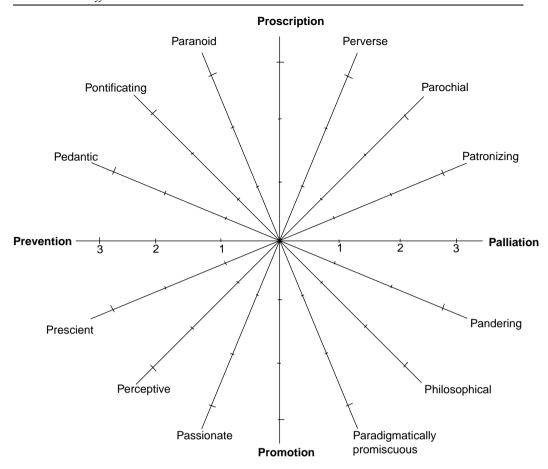


Figure 3 An alternative 'SERP' star for user evaluation

the course of this exercise we may also have managed to capture a little of the angels' share. In this spirit we present a final, alternative star formulated for users to evaluate the functioning and characteristics of their local panel/committee (Figure 3).

Figure 3 may be seen as a tentative initial formulation that will require refinement as the art and science of ethical review panel appreciation evolves.

Conclusion

In the context of reviewing European experiences of ethics committees, Tschudin²⁰ concludes: 'Only by being challenged by others and being willing to challenge oneself can any committees, and all health care professionals, maintain their ethical integrity.' We hope that this article exemplifies one valuable approach to doing this. We contend that the methods used can yield productive analysis and visualization, while incorporating a light-hearted perspective. The reflective analysis in this article shows how a committee based within a specific health care discipline is subject to many wider organizational and multidisciplinary influences, and how its ethical

considerations necessarily address generic issues such as scientific and educational value. These influences and issues have to be anticipated and/or responded to. Thus, although our experiences have particular relevance for UK nurses and midwives involved in the ethical review of research (both as reviewers and applicants), we believe that many of the issues analysed will have relevance in other countries and in other disciplines. We also believe that the methods used to structure reflection could be adopted and adapted by other ethical review panels in different disciplines and in different countries.

It would be presumptuous and premature to suggest that whisky holds a monopoly on relevant transferable wisdom. Other ethanological approaches involving other dictionaries may have much to offer. In particular, the art and science of viniculture may have a distinctive contribution to make. Alternatively, further illumination may be gained by focusing on beverages that are more traditionally associated with the work of ethics review, namely: tea, coffee and water. We look forward to further contributions to this emerging discourse.

Colin Macduff, Andrew McKie, Sheelagh Martindale, Anne Marie Rennie, Bernice West and Sylvia Wilcock, Robert Gordon University, Aberdeen, Scotland, UK.

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