

Audit of the GMC Confidentiality Guidance Consultation, 2008-9

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Introduction

This Report has been prepared in response to a request from the GMC to provide an independent assessment of the process undertaken to collate, analyse and present information gathered as part of the formal consultation process undertaken to assist with the revision of the Council's confidentiality guidance previously issued in 2004. Attention was required, in particular, to the process for seeking responses, the preparation of data for analysis, the procedures used in the conduct of the analysis and the interpretation of results. It was agreed that other elements may be included where they related to the overall purpose of the consultation. The audit would not, however, be concerned with the overall approach of the GMC to engagement with its stakeholders, something already subject to other plans for evaluation.

The work has been conducted to a tight timetable. A brief literature search was carried out to locate relevant developments since the preparation of an earlier audit assessment for the Council (Harrison 2006). Several site visits were made to the GMC to clarify procedures undertaken, to source key documents, and to sample raw data. The report is thus based largely on a documentary audit trail, supplemented by interviews with staff. Given the required emphasis on methodologies, no attempt has been made to ascertain the views of members of the Working Group who steered the consultation process and took decisions on the basis of its findings. Nor have any of the respondents to the consultation been approached for their assessments of the conduct and value of the exercise. I am particularly grateful to Farkhanda Maqbool, Policy Officer of the Standards and Ethics Team for patiently answering many questions and in particular for a detailed compilation of a timeline and associated documents for this review.

The Report begins with some background to public consultation, making clear that this remains more of an art than a science. It then introduces a ten question framework to guide the evaluation and summarises the various stages of the consultation process as undertaken by the GMC for this topic. A brief final overview is followed by a number of recommendations.

My overall assessment, to anticipate, is that there is a great deal to be commended in the process that was set in train for this consultation. My main concern is with the balance of activities in the design as a whole and how far it was able to gather fact and opinion from different groups, particularly from patients and the public.

Background – the state of the art on public consultation

Public consultation has seen a remarkable growth in the UK in recent years, across central and local government and amongst statutory bodies. It has spread across sectors, from early practice in the field of planning, to education and health and to diverse controversial topics including for example, nuclear waste management, genetically modified foods and the direction of science policy. Democratic renewal through active citizenship and greater public participation is a vision of all major political parties and this is unlikely to change. Advocates claim a range of benefits including better decisions, consensus-building, and enhanced trust and legitimacy. Detractors doubt the value of gathering views from a less than well-informed public, point to the potential for manipulation by the hosts of a consultation and to final

decisions that can take little or no account of a consultation exercise. There is no doubt that consultations can create a backlash (Davies et al 2006: ch 1). The author of one academic study of public participation on the future of science is quoted going so far as to describe consultation as 'riddled with ambivalence' (Kerr 2004). Others, however, while specifying shortcomings, pinpoint areas for development (Ahteensuu and Siipi 2009; Abelson et al 2008).

On the question of different types of consultation and how to carry them out, the range of possibilities is now large and overlapping. There are guides to techniques in the health field (Sykes et al 1992). Energetic advocates of particular methods (citizens' juries, planning cells, deliberative polling etc) have emerged. The Consultation Institute, formed in recognition of the need for support for organisations seeking to consult, identified 30 techniques (Jones and Gammell 2004), and a later academic assessment listed many more (Rowe and Frewer 2005). There is a transition in approaches from sole reliance on 'passive' methodologies (the public opinion survey, the white paper style consultation document) to more interactive and dialogic events. Typologies of consultation mechanisms have been suggested (Rowe and Frewer 2005) but the differences between (broad-based) public consultations, (more specific) stakeholder consultations and those - as with the consultation which is the subject of this audit - that include both, are not well discussed. Researchers and practitioners, however, are increasingly emphasising the need for multiple techniques to deal with heterogeneous publics, who may have differential access to relevant knowledge and experience, and varying motivations for participation. A robust public consultation will now use more than one technique.

What kinds of evidence are available to assess the appropriate contexts for and value of different methods? Descriptive accounts by practitioner advocates reflecting on a single example, or a small set of examples, dominate the field. They can be very helpful in offering practical tips and insights (see e.g. Summers and McKeown 1995), although, of course, their status as objective evidence can be questioned. Independent evaluations, using direct observation and other techniques, supply more robust data which often bears out some of the same lessons, but again are often case study based (Barnes et al 2007; Davies et al 2006). Stakeholder satisfaction studies commissioned following a consultation can add useful information about how to work best for example with a service user group (Whatling 2003). None of this, however, amounts to a strong and generalisable evidence base. In an agenda-setting review, Rowe and Frewer (2004:551) acknowledge that there is no established and tested theory of 'what works best, when' and that development is hampered by poorly defined concepts, few adequate measuring instruments, many potentially confounding variables and little possibility of introducing experimental controls. Four years on, a Canadian study was still observing that decision makers struggle with questions about when and how to involve the public (Abelson et al 2008). This study was unusual in interviewing consulters (health authorities) across two settings and a variety of consultations. The researchers found that respondents did not always agree amongst themselves on the purposes of a consultation exercise and tended to highlight risks as well as advantages.

An Audit Assessment Framework

What can be gleaned from the research literature to help devise a framework for an audit? Available material refers in broad terms to the importance of both transparency and fairness. Brief and overlapping evaluation criteria have also been advanced by a number of academic authors. Rowe and Frewer (2005:262), for example, propose that effectiveness of a consultation should be seen in terms of two elements. The *fairness* of the exercise encompasses matters such as equity transparency and influence, whereas its *competency/efficiency* refers to the extent of achievement of the intended purpose. Ahteensu and Siipi (2009:n27) suggest that there is general agreement on the importance of four questions - whether a consultation is sufficiently 'upstream' (i.e. timed early enough for influence), whether it is sufficiently open-ended, whether it includes a deliberative element and whether there is an opportunity to influence decisions. Lists such as this are suggestive, but they are rarely developed in such a way as to make them usable in a sustained way for audit purposes. An alternative route is to consider well established bodies of knowledge that surround research methods in the natural but particularly the social sciences. A good understanding of concepts of validity and reliability, of principles of questionnaire design, opportunities for triangulation and so on, are certainly relevant and will be drawn upon in what follows. Further reliance on the standard research methodology tests, however, would entail an exercise in disentangling them from underpinning assumptions concerning matters such as probability sampling, formal hypothesis testing, scaling and measurement, and is well beyond the brief of this exercise. Finally, there is a certain amount of good practice guidance. The audit for the GMC of 'Good Medical Practice' (Harrison 2006) made reference to the then Cabinet Office Code of Practice, utilised by many government agencies and others. That work is currently in a third edition, published in July 2008. Its list of seven consultation criteria is reproduced in Annex 1.

Given that there is no widely accepted methodology, auditors will draw from their own background and expertise. I have been influenced by a professional research career including specialisation in patient and public engagement and in academic literature in the field of public consultation to devise a ten question framework for process evaluation. This framework enables comment to be made on the major stages of the consultation on confidentiality as carried out by the GMC team. For convenience, the ten questions are set out below. It should be noted that questions were deliberately devised prior to consideration both of the Government's current consultation criteria and of the procedures used in the 'Good Medical Practice' audit. In practice, there are considerable overlaps. The approach contrasts with that for 'Good Medical Practice' in one key respect, however, in that no attempt has been made on this occasion to re-work any of the analyses carried out by the Standards and Ethics Team.

The questions addressed in this report are:

1. Is there a clear statement of the purpose of the consultation, properly integrated into the core business of the GMC?
2. Have the procedures succeeded in informing relevant stakeholders and giving them all a reasonable opportunity to respond?

3. Are the forms of data capture such that different kinds of stakeholder have an equal opportunity to contribute?
4. Does the design of data collection instruments follow accepted practice in the field?
5. Can we be confident that the processes of data capture have generated a sufficiently comprehensive list of issues on which there is at present a felt need for guidance?
6. Are the mechanisms that have been used for data organisation (e.g. data cleaning, data reduction) and data analysis appropriate and defensible?
7. Is the interpretation of the issues raised a fair and balanced reflection of the complexities of the data gathered?
8. Are the stages leading to decisions on a final draft guidance document transparent and defensible?
9. Is there provision to put an account, both of the process and its outcomes, into the public domain?
10. Is there provision for further learning about improvement to the process?

This ten question framework has the advantage of enabling comment to be made on each of the various stages of consultation and the way in which it has been conducted. The framework also allows for a strong focus, as requested, on the procedures for analysis of the materials. Noting the controversy and scepticism that often surrounds consultation, it allows for the identification of a number of points of potential vulnerability to criticism. Areas of possible policy development are then identified. Discussion of each of the ten questions now follows. For reference, an outline of the stages of the GMC's consultation on confidentiality guidance is set out on the accompanying page.

The GMC's consultation procedure for revising the confidentiality guidance

The GMC last issued guidance to doctors on confidentiality in 2004. Its Standards and Ethics Committee returned to the subject early in 2007. After commissioning a literature review on the topic of confidentiality, it formally agreed (Feb 2007) that the current guidance on this topic should be reviewed making use of relevant external consultation. The planned date for the launch of the revised guidance is September 2009. Work associated with the consultation for this review will thus have extended over a period in total of around 30 months.

The key stages of the work programme were:

- an initial *scoping exercise*, including a review of in-house information and meetings with key organisations
- the establishment of a *working group* to steer the project through all its stages and receive and approve material
- the decision by this group, following the scoping exercise, to carry out an *initial consultation* to help shape a revised draft of the confidentiality guidance
- preparation of *revised draft guidance* on which to consult
- preparation of a *formal consultation questionnaire* in both long and short form
- the setting up of a *consultation website* enabling participants to complete questionnaires online, together with the provision for an alternative hard copy submission
- the conduct of *consultation meetings* during the period of the formal consultation with a range of organisations and in four UK sites
- the creation and use of procedures for *data checking and analysis of results*
- the presentation of results for *working group comment* and integration of consequential changes to the draft guidance
- further discussion at the Standards and Ethics Reference Group (a newly constituted body replacing the Standards and Ethics Committee)
- *presentation to Council* of the draft guidance and subsequent integration of results from the meeting and from further correspondence with members
- *legal opinion* on the near final draft
- *plain English accreditation*
- *A launch plan* for the final document and a date at which the guidance would become operational

Ten Questions Reviewed

Question One: Statement of Purpose

The fundamental purpose of the GMC in issuing both general guidance to doctors on good medical practice and in providing further advice on confidentiality and other matters, is clear. It is to set out the standards expected by patients, carers, the public and the profession. It is recognised that new issues will emerge and that changes in technology and in health care practice as well as shifts in public opinion will influence thinking about appropriate standards of conduct. The guidance is therefore reviewed ‘to ensure that it is up to date and fit for purpose’.

An explicit rationale for employing a public consultation with stakeholders as the major means for achieving the aim of up to date and fit for purpose guidance and for allocating resources to such a consultation as the mechanism for achieving this appears most obviously in two places. On the consultation website there is a statement which reads

Formal consultation is a key part of the guidance development process as it allows us to find out what our key interest groups, including individual doctors, patients and members of the public think of the revised guidance.

The Communications Plan (Aug 2008) states:

The GMC seeks to provide all those affected by the issues raised by the guidance with sufficient and appropriate ways to participate in the consultation process. A written consultation is therefore supported by other opportunities to respond, such as meetings and a short, more accessible series of questions.

These two statements offer the possibility of devising criteria against which both internal and external evaluations of performance can be made. They are consistent with the 10 question framework which may be regarded as unpacking them further. Early production of a statement of purpose or rationale and explicit consideration of its elements helps to focus and refine a data collection strategy. It can then guide those responsible for carrying out the consultation, indicating areas that perhaps might need more detailed attention and steering them towards priorities when time and other resources are limited. I would have expected such a statement to have had some prominence in the discussions of the Working Group and in the documentation on results of the consultation. It does not appear to have done so. The clearest and fullest statement appears not as a consideration of the purpose rationale and thus design of the whole of the consultation process but as noted above, part of a Communication Plan, under the heading of ‘positioning and key messages’.¹

A stakeholder mapping also appears in the Communications Plan. It indicates how the notions of ‘key interest groups’ and ‘all those affected’ were operationalised for this

¹ It should be clear that none of this is to criticise the Communications Plan as such. Viewed as a statement of the design for the consultation, however, it will, not surprisingly, fall short. It frames key objectives in terms of risks and vulnerabilities for the organisation, rehearses responses and sets out ‘the line to take’. I would argue that it can very usefully be set against the consultation design, and can help test that design, but is not a substitute for it.

consultation, and as such adds focus to the overall purpose of the consultation. Seven main stakeholders are listed: the profession, the public/patients, special interest groups, UK parliamentarians and elected representatives, employers, representatives of other healthcare professions, and government and relevant public bodies. For some, but not all of these seven, there are sub-categories, giving 13 groups in all. A categorisation such as this, of course, is a significant building block in a stakeholder consultation exercise. It can be used to shape who will be approached for meetings at the various stages and how many different data capture mechanisms will be employed. By influencing coding categories for respondents in the questionnaire, it can also determine what analysis and evaluation of response success will be possible. There was little early stage debate about these categories at the meetings of the Working Group – whether, for example, the headings and sub-headings were sufficiently comprehensive and usable for this particular consultation, whether some groups should be subdivided further, whether there was a rationale for treating some groups (the key knowledge expert informants perhaps at one extreme and patients who are potential users yet have no current experience at the other) differently from others, and so on. The Standards and Ethics team had done some thinking about this, building on earlier consultations without necessarily making this fully explicit at meetings and in the documentation. A briefing paper prepared for the Communications team, for example, makes clear that although the written consultation was to be the primary consultation method there was also a wish to reach audiences who might not respond, including patients who could have particular concerns about access to their personal information. Those with cancer, HIV and mental illness and those in some minority ethnic communities were mentioned. It was noted at this point too that that different formats might be needed, for example, focus groups rather than a public meeting. Documentation designing these aspects of the formal consultation however, is not as clear as with the written consultation.

In the main, as will be seen, the conduct of the consultation holds up well in relation the ten question framework employed here. But the lack of explicit attention to reasons why a consultation with stakeholders is the technique of choice and to a mapping covering the different characteristics of the GMC's stakeholders and hence how they could be classified and approached, gives rise to several of the potential areas of challenge highlighted in this report.

Question 2: Informing relevant stakeholders

The Standards and Ethics Team took a number of steps to ensure that as many as possible of those who might have relevant experience and opinions on the matter of confidentiality were given opportunities to respond. Preliminary scoping work analysed statistics of relevant Fitness to Practise cases and enquiries that had been received that related to issues of confidentiality. This served to alert the team and the Working Group to a range of likely issues and stakeholder interests arising from historical data. Eleven organised groups received invitations to preliminary meetings. The list included a range of medical bodies, government organisations and one broad-based and one specialist patient organisation. The rationale for selecting and thus alerting these groups in particular was not very clear.² The subsequent introduction of

² In pure research design terms, such a rationale might involve selecting particularly diverse respondents or perhaps hard to reach groups for a preliminary stage in order to generate have some initial understanding of the range of views, or selecting organisations found to hold contrasting

an initial consultation, however, will have given larger numbers of bodies and individuals advance warning of the GMC's wish in due course for responses, even if they were not able to respond to what at that point was a tight timetable. Once there was a date for the formal, written consultation, the national press, the professional press and potential routes to particular groups (vulnerable patients, older people, black and ethnic minority groups, patients with long-term conditions, ex-offenders, people who had experienced domestic violence) were identified. Individual requests to respond were also sent out at this point to a total of 1339 individuals and groups. The stakeholder contact lists for Wales, Scotland and Northern Ireland were reviewed and updated for this purpose by the respective devolved office teams. The list for England is the responsibility of the Standards and Ethics team and is regularly updated. While it clearly covers stakeholders under all the main groups on the stakeholder list, its alphabetical presentation did not allow any consideration of match against the 13 group stakeholder classification.

In all, a great deal was done to inform relevant parties; those receiving letters and making use of the website had ample warning of the formal, written consultation – enabling them if they so wished to convene groups of members for further discussion in the period of three months from the availability of the long and short questionnaires to the final submission date. What was less clear for groups and individuals at this point was who was being invited to the meetings that were also part of the consultation process - both those at the initial engagement stage and those that were part of the formal consultation. What were the inclusion and exclusion criteria, and would they be likely to be acceptable to included and excluded alike?

Question 3: Equal opportunity to contribute

As well as informing stakeholders of an opportunity to contribute there must be arrangements that will enable them to contribute. The GMC team was clearly alert to the need to ensure that different kinds of participants had a chance to contribute in ways that made sense them, fitting with their daily lives, motivations and access to resources. As far as the written element of the formal consultation was concerned, respondents could submit their returns electronically or by hard copy. It is beyond the brief of this exercise to comment in any detail on the consultation website and its accessibility (both at the time of the consultation and later to check results). However, it is clear that the website conformed to web accessibility guidelines, included opportunities to resize the text and to have the site read. (For a recent evaluation of a number of e-consultations, see Fagan et al 2006).

Importantly, there were both long and short versions of the questionnaire, this explicitly predicated on an appreciation that not all would be in a position to or wish to consult detailed documentation. That so many did respond to the long questionnaire is no reason not to use such a strategy in future. Timing can often be a barrier to

positions for later stage dialogues to test the nature of the arguments in more depth and address potential reconcilability. In practice, both here and later during the formal consultation, multiple considerations shaped the list. These included: the need to be seen to be addressing issues of known controversy; the need to gather up to date knowledge and understanding of legal issues and government guidance from expert informants; and the need to ensure meetings took place in Scotland, Wales and Northern Ireland.

responding to a consultation. A 12 week consultation period, as here, however accords with current good practice.³ All these were excellent moves displaying a sound understanding both of pitfalls that have been encountered in practice and of ways of addressing them.

Opportunities for a face to face contribution at the initial stages, as already noted, were more selective. The initial consultation which followed this necessarily worked to a rapid timetable which could well have excluded some. The Working Group saw it as an opportunity to raise awareness of the review as well as demonstrating a proactive response from the GMC at a time when privacy issues were in the media. The disadvantage of two stages is that some interested parties may feel they have had a say and thus fail to submit to the main consultation. It has not proved possible to establish whether or not this kind of consultation fatigue occurred in this case, but it is something that has been recorded for service user stakeholders (Whatling 2003).

Outcomes from the written consultation can be used as some measure of success both in informing different stakeholders and in giving them opportunities to contribute. At the initial consultation stage there were 180 registrations of intent to respond, just under half of which (86) converted into responses to the questionnaire. The split between individual and organisational responses was fairly even. The formal consultation, taking both the long and short consultations together, produced a total of 244 replies, again with a fairly even individual/organisational split. It is satisfying to see that organisational responses did not dominate overall – a danger in a field where there are multiple member and professional organisations representing the profession. Interestingly too, there was no clear difference between the number of organisations and the number of individuals choosing to fill out long or short versions of the main formal consultation questionnaire. Individual doctors (including doctors in education) were the largest single group of respondents overall, accounting for just over one third. Doctors' organisations dominated the organisational replies although the number of individual NHS organisations employing doctors almost equalled these numbers. Notably small numbers of responses, however, came from patients and patient organisations. Taken together they accounted for only 9 per cent of the total. Similarly and slightly smaller numbers of responses were submitted by other health care staffs.

Four points can be made about opportunities to contribute to the formal written consultation (noting that the pattern of responses was very similar both at the initial and full consultation stages). *First*, comments from less than 100 doctors on a register of around 260,000, on the face of it look disappointing. Any thought of calculation of a classic survey 'response rate', however, is probably unhelpful in this context. Submissions from as many as 19 medical organisations should be set alongside the figures since replies here may be seen as able to reflect concerns that have been reported to them by members of the profession. What is of more concern is that it is not possible, given the nature of the data set, to check whether there is a good spread of individual responses from different fields of practice where confidentiality issues potentially produce different challenges. With a coding category 'doctor' distinguished only from 'medical educator, it is not clear, for example, whether both

³ The current Government good practice criteria (see Annex 1) include advice on the length of time a consultation should stay open and its accessibility for those it is intended to reach. Criterion 5 also refers to 'keeping the burden of consultation to a minimum if buy-in to the process is to be obtained'.

hospital doctors and GPs are well represented; whether locum doctors have responded; whether there are responses from those working in research, or those in clinical management positions – all of whom might perhaps be expected to have particular issues.⁴ Organisational responses may compensate to some extent for this, but neither here nor among coding for individuals can one try to distinguish NHS versus independent sector. Tolerance of background questions by respondents and the placing of these questions (at the beginning or at the end) can be tested through piloting.

Secondly, the number of written responses from patients and members of the public is very disappointing. A sense of issues where the patient viewpoint may depart significantly from that of the doctor and where feelings are likely to run high does emerge at a number of points in the analysis but it comes largely indirectly. Information may, of course, be expected to come more from the face to face elements of the design. The team had consulted two patient organisations as part of an initial set of face to face meetings and there are further comments below on the face to face meetings that were part of the formal consultation.

Thirdly, while there were written responses from as many as 18 employing organisations, very few responses were received from other health professionals either as individuals or from organisations. This is unfortunate both because directly relevant questions concerning confidentiality and the wider health care team are part of the subject matter of the consultation and because co-ordinating, simplifying and ensuring consistency of guidance *across* the statutory regulatory bodies for the professions is a wider policy goal currently and is in the interests both of health professionals and of those who use their services.

Fourthly, although there is provision in the questionnaires, analyses by age, sex, ethnicity and disability and country of residence/of organisational base do not seem to have been reviewed. These can provide an important alert in terms both of whether relevant groups were informed as well as enabled to contribute.

Further opportunities to contribute were afforded by the various meetings that were also part of the formal consultation. There is an early stage reference in internal papers to several possible ways forward on this. An idea for research with doctors working in different settings was rejected as not cost effective. The possibility of exploring scenarios with members of the profession either by telephone or by using a reference group was noted. There is also mention of the ‘11th hour’ decision to convene a parents group in the previous consultation on children. In practice, 16 events took place during the formal consultation period across all countries of the UK. Ten of these took a formally introduced meeting format – seven were specific issue based⁵ and three were broader, roundtable type discussions. There were five one to

⁴ It is worth discussing not only expansions to the background variables to cover more potential stakeholder groups but also in doing so giving attention to ambiguous or overlapping categories where self-report of those who work in different capacities and across sectors may result in error. I note also that the organisational coding, relying on self-report, has resulted in missing data and ‘other’ as rather large proportions of the total. Investigator coding is of course time-consuming but there are instances where it is necessary.

⁵ The specifically topic focus discussions were on secondary uses of data (2), serious communicable diseases (3), vulnerable adults(2) and gender based violence, although, of course these, and other themes would have emerged in roundtable and one to one meetings also.

one meetings with organisations. There was also one focus group, held with the help of the Minority Ethnic Women's Network Wales. Although in the main, the meetings mixed stakeholders, separate meetings were held with professional representatives and with patient representatives in Scotland.

Did these meetings provide opportunities to contribute for those unlikely to have given a written contribution? The answer to some extent is yes. The black and ethnic minority focus group is certainly an example. There were also opportunities also for a number of organised patient groups to give their views, particularly in Scotland where these stakeholders came together as a single stakeholder group and not as one among many at a meeting. But the events were more issue-focussed than stakeholder focussed. The purpose was more to generate depth information on issues from various points of view rather than to give an issue-generating voice as such at this point to specific stakeholders who may not have participated in the written consultation. It is certainly worth discussing, however, whether an otherwise strong consultation process made sufficient place for imaginative, early stage, opinion-forming and issue-generating events for individuals and groups who needed 'something extra' to bring them into the debate.

In all, and taking both aspects of the formal consultation together, many organised stakeholder groups were given opportunities to contribute. The meetings stage undoubtedly produced useful information that clarified areas of disagreement and aided with refining drafting of the guidance. But the strategy at this point was not designed in a direct way to compensate for weaknesses in the reach of the written consultation. Indeed, it could be argued, that many of those who attended the meetings also had an opportunity to contribute to the written consultation.

Question 4: Design of Data Capture Instruments

Taking the formal written consultation first, this relied on a semi-structured questionnaire as its main means of data capture. Following demographic and monitoring information, an introduction covered the background and aims of the consultation. The exclusion of issues related to children and young people and the reason for it was made very clear, notwithstanding the few who failed to heed it.

Questions were preceded by explanatory comment and variously concerned the direction of the advice, the level of detail, balance, usefulness, and clarity. It is not perhaps entirely clear whether it was intended that the questionnaire was to be completed without having a considerable amount of original and revised documentation to hand. Practice is likely to have varied. Some will certainly have answered without reference to any further documentation and the format of most of the questions made this is possible. On matters of substance, respondents were largely offered yes/no/not sure responses followed by space for open-ended comment. There were 57 questions in all in the main section of the document. The short version of 17 questions made clear that it was not necessary in this case to have further documents to hand for reference. Both questionnaires followed good practice in providing adequate covering information and thanks.

I find the questionnaires to be well produced; they certainly approach the standards one would expect from a professional survey agency. The layout was clear, with a

minimal amount of typographical error. There were no glaring question design faults. I note however, that there was no piloting with end users, a step which is accepted good practice and would have given more confidence that the design was fit for purpose. Also, a final question which in principle could capture some user views of fitness for purpose of the main questionnaire was itself ambiguously phrased, asking for comments ‘on the consultation documents and/or process’.

The two versions decision requires comment. While in principle versioning is a good idea and helps maximise contributions from diverse stakeholders, it will inevitably pose dilemmas of how to handle two data sets. Results should only be aggregated where there is a clear intention that the responses should be equivalent. Even where this is done, checks should be made to demonstrate the robustness or otherwise of the results by disaggregating and checking. More could be done in future on clarifying the basis on which questions are to be reduced and hence the exact relation between the versions. An advance decision on what analyses are intended helps give a steer to questionnaire design.

Multi-method approaches to data capture were demonstrated in the use of consultation meetings alongside the written consultation. This is something increasingly advocated by consultation experts. Methodological guidance for combining quantitative and qualitative research designs offers a number of relevant points on the overall logic of the process. One choice is a sequential exploratory design, where qualitative work precedes the design of quantitative. A second is the reverse of this, where qualitative work is used to gain a depth understanding of the quantitative data. A third is a concurrent triangulatory design where different techniques are used to address the same question and provide some cross-validation.⁶ In a real-world consultation, practicalities and politics are likely to play some part. The danger in such circumstances is that the design can take on an *ad hoc* character leading both to problems at the data analysis and integration stage and to less defensibility in face of potentially hostile critics. As has already been noted, the documentation is less clear in pinpointing both the underlying reasons for the design of the more qualitative work and the forms of data capture that flow from this.

There is no one best way either for the design itself or for the methods of qualitative data collection, particularly qualitative data. Designs will always need to vary depending on the nature of the question and the nature of the groups with an interest or potential interest in it (see e.g. Summers and McKeown 1996). A second stage qualitative exploration, for example, may make use of ‘questerviews’ (in-depth interviews to follow up questionnaire responses); it may entail focus group exploration for a single type of stakeholder, or employ facilitated dialogue between stakeholders. An early stage qualitative design may collect personal narratives, or provide vignettes or scenarios for later stage discussion (see Donovan and Sanders 2005). Each of these has advantages and disadvantages and choices need to be deliberate and to fit context in terms of who is being asked, what they are being asked and why. It is widely accepted, for example, that being the single representative of a minority viewpoint will inhibit contributions and that like groups are preferable to

⁶ This interpretation of triangulation is challenged by those who argue, perhaps more usefully in the present context, that different data techniques produce *complementary* information and thus add to a complex picture of different perspectives on the world. For discussion of this point and of the issues in this paragraph see e.g. Cresswell (2003) and Adamson (2005).

mixed groups in enabling positions to be articulated. Like groups and also more concrete examples and scenarios are to be preferred when group members have not previously considered an issue and where an opportunity to reflect together and form and change opinions might be needed. It did not prove easy to piece together how much of this thinking informed the data capture strategies of the 16 events held in the consultation period.

Notwithstanding these remarks, the overall results still seem in most key respects fairly robust. The initial state of knowledge of the team was considerable and supplemented by analysis of in-house data. The extent and range of consultation was such, as the discussion of the next question demonstrates, that a good range of issues was captured, that technical knowledge issues and expertise were identified, that prominent players were brought into the discussion and the points of view of a number of special interest groups on particular topics were included. The danger remains, however, that the perspectives of the less organised and less articulate may be missed.

Question 5: a comprehensive list of issues on which to consult

To gather a fully comprehensive list of issues and to identify all eventualities that might arise in relation to them is impossible. The work of the team however, was particularly impressive in the efforts made to ensure coverage. Multiple actions were taken to identify key issues, including commissioning a literature review, reviewing queries received and fitness to practice cases, engaging with agencies that had raised matters, and making space on the initial and main questionnaires to invite further issue identification. It did not prove possible within the constraints of this exercise to identify in any exact way the extent to which new topics emerged from each source, though this might be a useful in-house exercise in gleaning information for the future on which techniques might prove most valuable.

Points that would bear further attention in future consultations concern issues that have *not* reached prominence and positioning by organised groups and media and, from among the more high profile issues, the mechanisms for selection of those that will be treated in more depth. Much attention in this case was focussed on secondary uses of data, on communicable diseases and on certain kinds of vulnerable patients. What was the process which generated these and rejected other issues? How confident can the team be that other issues did not justify similar depth of treatment? This links once again with the point about perspectives that may not have been heard and the need to build in more explicit strategies for addressing this.

Question 6: Data organisation and analysis.

The Standards and Ethics team has clearly been able to draw on knowledge of research methodology in these areas as well as in the area of questionnaire design. Basic principles have been well understood and drawn upon appropriately. The team was able, for example to explain procedures for data cleaning, details of which would meet a reliability test in an empirical research setting. The questionnaire produced substantial amounts of open-ended qualitative commentary. The coding of qualitative data is an area where the dangers of subjective judgement and hence incommensurability of coding decisions between team members are rife. Again there

was a good appreciation of this; coding rules were put in place and checks were made by core team members on the work of others who were brought in to help with data analysis.

Simple descriptive statistics were produced for the initial consultation using an in-house statistical package. The broad-brush quantitative picture produced by these statistics was used appropriately to give an overall picture of where there was consensus and where controversies might reside. It also enabled the team to drill down and explore a number of patterns by type of stakeholder in the material. Greater use of simple cross-tabulations and refinement of coding to enable these to occur would make for more robust analyses of patterns by main stakeholder groups and subcategories of stakeholder in future. It is understood that there are aspects of the operation of the statistical package that will need to be resolved for this purpose. While more might be done here, it is wise not to go a great deal further or to attempt more ambitious statistical analysis given that the exercise is not one that utilises random sampling.

The team created and shared guidelines both about producing and presenting results for each of the main questions. The result was a substantial size of document with a fairly uniform structure underlining the statistics and adding illustrative quotations and identifying areas of disagreement both when the overall consensus was strong and when it was not. The nature of the material meant that there were decisions to make about potentially aggregating information from different data sets. There was also the issue of just what weighting could reasonably be given to opinions and arguments coming from different stakeholders but also coming from single individuals and from organisations that may in some cases represent many thousands of such individuals. Some aggregation was performed bringing together information from the long and short consultations and the topic of aggregation was touched on earlier. Aggregation should only be used where questions are identical and after checks are performed to explore whether the two data sources, when analysed separately give similar results. Weighting, strictly speaking, has no place in a consultation such as this.⁷ The relative priority to give to different views is always a matter of judgement and a greater legitimacy is lent to a consultation where the problem is openly acknowledged, where different sources are explicitly cited and where the basis for decisions is made plain (cf Harrison 2006:9-10).

Meeting notes were mapped onto a specific issues grid that was emerging from the written consultation. This enabled the team to illustrate, supplement and sometimes challenge the data from the questionnaires. While questions have been raised earlier about what is lost from an issue focus rather than a stakeholder focus in the meetings, undoubtedly it made for both a systematic and more straightforward handling of the data at this point.

Overall, and with caveats as noted above, I found the data organisation and analysis to have been carried out fairly. Considerable care was exercised to ensure that members of the team worked consistently.

⁷ Weighting is a device employed when a sample does not match the known characteristics of the total population from which it is drawn. Responses from subgroups are given differential weights to reflect the proportion in the population and findings are recalculated on this basis.

Question 7: A fair and balanced interpretation

Those who act in a research capacity in service of an organisational goal must be prepared to offer a commentary and an interpretation of the data produced, reminding decision-makers of weaknesses and cautioning about the drawing of particular inferences. They also need to point to what appear to be the policy implications of the results and to be prepared to participate fully in discussions. There is always a fine line for an organisation's officers to tread in relation to its members.

It is already evident that the team provided a meticulous and detailed report of findings for consideration by the Working Group. The standard format was designed to enable readers to grasp the overall results and to have a flavour of the kinds of comments and strength of feeling on some issues. Furthermore, asking Working Group members to introduce particular sections of an inevitably long document at the meeting is likely to have worked well, both in ensuring fuller assimilation of the material and in checking that the team's presentation of it did not produce misinterpretations and misunderstandings. While there was a somewhat mechanistic system of presenting results, it had the advantage of keeping a working team working consistently. More depth attention to selected areas might, however, have been merited in order to make more clear the depth of feeling or the degree of disagreement. The lack of an altogether successful use of cross-tabulation of statistics as noted earlier, may also have made identification of different stakeholder views more difficult.

These points are considerations for the future, however. They do not detract from a process that in general has been robust and defensible in terms producing a fair and balanced interpretation for discussion by decision-makers.

Question 8: Decision stages

An audit of a consultation process cannot confine itself solely to the creation and analysis of data but should set this in the context of the overall process. This includes examining how the findings are received and interpreted within an organisation and how decisions are made. It can thus include focussing in particular on areas where the balance of data is such that it is not straightforward to see implications and on areas which are already known to be, or have emerged as, particularly controversial. In principle, it is possible, given sufficiently detailed minutes of meetings and records of issues settled through post meeting exchanges, to track decision points and evaluate the basis for each decision taken. This was a route travelled in the Good Medical Practice audit (Harrison 2003) under the heading of 'responsiveness'. In practice, no effort was made to match it in context of this audit.

The result of a consultation, however, is necessarily shaped by the structure of and exigencies in the organisation as well as by the analysis of the data itself and it is worth identifying the multiple points where interpretations will be made and substantive decisions will be confirmed or changed. The *Standards and Ethics Team* had an initial role. Use of systematic rules for presenting the data cannot ever altogether obviate the need for judgment in reducing and selecting information and in drawing initial inferences about the implications of the data for the development. The *Working Group* was then influential in making an assessment of the material they

received and in taking a number of decisions, confirming, disconfirming and supplementing the suggestions made by the team. The *Standards and Ethics Reference Group* had an opportunity subsequently to add comments. GMC Council also made decisions about what should and should not appear in the final draft. Finally, a *legal opinion* stage may give rise further modifications. The source and basis of final decisions will be a focus of attention from critics, who are likely to raise questions about the composition of the Working Group and of Council and to draw conclusions about the weight which might be likely to be given in cases of controversy to different stakeholder views. The inclusion of patient/public members, and the decision to appoint an external Chair for the Working Group were important acknowledgements of this.⁸ From a patient and public engagement point of view, however, critical comment about influence at the various stages might still be anticipated.

Question 9: Results in the public domain

The legitimacy of a public consultation process will be judged by many in terms of how far the organisation initiating the consultation is prepared to place details of its process and outcomes in the public domain. Contributors to the consultation and other interested parties, including the media, will wish to know how many people of what kinds contributed to the consultation, what responses there were on the various issues, what controversies there were, and how the organisation ultimately responded. Sceptics will want to be assured that there is sufficient material in the public domain to enable them to make their own assessment of the adequacy and fairness of the process and the robustness of the decisions arising from it. They may or may not wish to drill down to include some of the process detail covered in this report.

There is a great deal to be commended on this score. A statement of intent at the outset, together with updates on progress and a final, accessible public account are key elements of good practice. There was careful attention to this. The background sections of the website provide detail on the process and signposting to particular documents. The commissioned literature review can be accessed, as can a summary of the initial consultation. A paper was placed in the public domain in April 2009, providing an outline of the formal consultation process, including responses to it, how they were handled and the outcomes. A final document describing all stages of the process was in draft at the time of writing. It is not clear how far it will respond to issues identified in this audit or engage with its recommendations concerning future consultation activities. The intention, however, is that the audit report, once accepted, can also be accessed through the GMC's website.

Question 10: Further learning

It is good practice to glean whatever further learning is possible from a consultation exercise and to arrange to ensure that that learning is integrated into any future

⁸ The records show that appointing an external chair was a deliberate move to create more robustly defensible procedure and to avoid criticisms that the GMC in any way sought to 'stack the odds'. There is, however, a difference between an external chair and an independent chair and an objection could be raised that although the Chair was indeed external to the organisation, she was a member of the medical profession and thus associated with arguably, the dominant stakeholder groups. Three working group members, however, were from outside the medical profession.

consultation work. The Standards and Ethics Team already plans to provide feedback for participants to the consultation as discussed above. The provision of a final feedback report for interested parties, as noted above, is an exercise which itself is likely to provoke an assessment of the process and to suggest improvements for the future. Commissioning an independent audit such as this provides another opportunity to review practice and initiate developments.

Ongoing learning about the value of the revised guidance itself can be had arising from queries received by the Standards and Ethics Team and through continuing to monitor fitness to practice cases that might involve issues of confidentiality and provide some test of the value of aspects of the new guidance. It was not clear whether this would be carried out prior to any further revision of guidance or whether it would form part of a routine annual or biennial review thus prompting consideration of the need for a revision. There is an intention to explore the possibility of preparing case studies to supplement guidance – something that seems indicated by the wish on the part of some respondents for more detail than a guidance document can supply. In all, therefore, it seems that this criterion has been anticipated and is likely to be met.

Finally under this heading, is the question of keeping up with developments in the field of good practice in consultation and taking steps to ensure that staff are afforded opportunities to attend discussions, undertake relevant training and identify relevant experts. It has not proved possible to review this in any depth although it is clear that there are links already, for example, with The Consultation Institute and that it has been possible in some degree for members of the team to attend seminars and training events. The design and conduct of public consultations is a substantial undertaking, however, and consideration should perhaps now be given to the need for staff to specialise or to have access to expertise on a consultancy basis.

Overview and Recommendations

Public and stakeholder consultation has been a rapidly growing activity in government and across the public sector. It is now occurring increasingly frequently as a mechanism for improving policy and guidance across the Directorates of the GMC. The Standards and Ethics Team are clearly no strangers to how to approach public stakeholder consultation. This Report shows that they have built up considerable in-house expertise that draws on current thinking and good practice. Their design and implementation of a questionnaire-based consultation is impressive. Subsequent data-handling has been carried out with care and attention to appropriate techniques of analysis and presentation. Resources have been set aside to ensure that respondents are able to receive feedback both on the process and outcomes – an important step in a field where legitimacy and credibility can easily be lost. There have been positive points to report under each one of the ten audit questions and I find no major faults with the conduct of this consultation exercise.

There are two main areas, however, where there is particular room for attention and further discussion. The first relates to stakeholder mapping - the explicit identification and further differentiation of stakeholder groups. I have stressed the importance of strengthening this aspect via early consolidation of thinking around this in a stakeholder consultation exercise - integrating it with a statement of purpose and

demonstrating clear follow-through into the analysis and feedback. The second area for further development relates to the design and conduct of the very necessary qualitative elements of a consultation. The logic and rationale for qualitative work using up to date techniques for engaging with citizens on unfamiliar issues and for tapping in to less organised and hard to reach groups was not well documented. It was less easy to follow the paper trail for this aspect compared with the written consultation. On the face of it, there was less clarity of thinking about rationales for choosing different mechanisms and handling data recording and analysis. However, earlier consultation work by the team on the guidance for doctors on dealing with 0-18 years belies this conclusion. The issue thus seems to be less a matter of developing new competencies than of consolidating learning and, in particular, making choices more explicit.

In the light of this assessment, I make the following recommendations

1. Always prepare a statement of the reasons for undertaking a public consultation with stakeholders, integrating this as a strategy with the current mission of the GMC.

Fully discussed at the outset, such a statement will link the consultation firmly with the core business of the organisation, and provide a baseline against which its overall design and its ongoing progress can be assessed. It will also facilitate both internal and external audit and evaluation.

2. Name groups/ subgroups of stakeholders who are considered relevant to a particular consultation; test this stakeholder mapping widely, and identify the most appropriate ways to collect information from the different groups – particularly in cases where the survey is not ideal.

This will go some way towards countering any argument that consultations prioritise the views of doctors over those of patients and the public and thus fail to achieve the balance between supporting doctors and protecting patients which is fundamental to the underlying purpose of the GMC. It will also help to counter criticisms from registrants who might feel that not all interest groups are being heard by the GMC.

3. Focus particular attention on state of the art thinking for identifying and engaging patients, patient groups, carers and the wider public in consultation processes, and draw from the full range of methodologies available.

The array of qualitative consultation techniques beyond the formal survey is now very substantial. Consideration will need to be given to raising awareness and to the alternatives of building greater in-house competence, using external experts and outsourcing, for example, imaginative issue-generating events, deliberative forms of public engagement and facilitated dialogue.

4. Timetable a mid-point review.

This can alert a team not only to headline findings and controversial issues but also to emerging patterns of absent and under-represented stakeholder voices, giving an opportunity to collect supplementary data to ensure a more comprehensive balance of views.

5. Include a critical assessment of how successful the process has been when feeding back to stakeholders on the decisions and outcomes of a consultation. This

will enable statements about the degree of support for an action to be qualified and put in context of variable success in reaching groups. Stakeholders will appreciate honest assessments of what has worked well and less well and a mention of any lessons that have been learned.

6. Ensure that a project timeline and associated document log is regularly updated while a consultation is in progress. *This will facilitate internal review, external audit, and the preparation of feedback to stakeholders.*

7. Consider commissioning research on stakeholder satisfaction.

Jones and Gammell (2004) identify decision audit, process review and stakeholder satisfaction as three of the main ways of evaluating consultations. The first was used for the 'Good Medical Practice' audit and the second here. Neither covers stakeholder satisfaction. Carried out at the close of a consultation, an independent stakeholder satisfaction exercise would have time to feed in to the final result as well as influencing future consultations.

Finally, it is clear that stakeholder consultation raises issues that go beyond the remit of a single Directorate of the GMC, and indeed, beyond the GMC to the conduct of the statutory bodies as a whole. Regulatory business is conducted much more in the spotlight than it used to be. Public involvement in governance has risen markedly, and, in response, a 'consultation culture' has now been developing for some years. Public expectations will continue to rise, however, and the risks of both public and professional criticism of decisions will remain. Consultation is thus core business and the GMC is already assessing its patient and public engagement strategies. This may be the moment to embed stakeholder consultation more firmly as part of this core business, and to review the costs and benefits of drawing in expertise in the shape of a dedicated support team for consultations. A wider consideration of this sort has the potential to enhance still further the considerable achievements on the part of the Standards and Ethics team which have been demonstrated in this Report.

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Annex 1: Seven Consultation Criteria

Criterion 1 When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 Capacity to consult

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

These criteria should be reproduced in consultation documents.

Source:

H M Government (2008) Code of Practice on Consultation. See www.berr.gov.uk