

Consultation response: review of the General Medical Council consent guidance

Submitted to
General Medical Council

Submitted by
Alison Hall
alison.hall@phgfoundation.org

January 2019

The General Medical Council (GMC) has been consulting on their revised Consent guidance which outlines what doctors should consider when discussing treatment and care with patients. The following is our response, submitted in January 2019.

About the guidance, scope and application

Comments on scope and application

The idea of a legal annex that summarises and simplifies the complexity of the ethical and legal framework is a good one. However we found it difficult to comment on this in more detail without seeing the draft annex and it seems that this will be drafted only once the consultation has closed.

It would be particularly important to clarify the similarities between different terms across devolved nations. In determining its usefulness, it would be important to understand how often the legal annex will be updated to take account of new case law (for example the Montgomery, and ABC cases) or revised guidance (such as the NHS Code of Practice on Confidentiality).

It will also be important to understand to what extent the legal annex will cover 'consent' which applies to slightly different contexts (e.g. the legal basis of consent which is used to underpin certain types of data processing under the GDPR). Discussions about the impact of the GDPR on clinical practice have sometimes confused the legal basis of consent that might be used in medical research, with consent as intended in this guidance.



In the context of genomics, paragraph 8 is important in relation to genomic sequencing tests being rolled out to mainstream clinicians.

Main principles of the guidance

Is the summary helpful?

Yes. We suggest that there should be more emphasis placed on the possibility of consent being an ongoing dialogue with patients than a one-off process, which legitimises an intervention or treatment. This is particularly the case in diagnosis of rare inherited diseases, where testing and feedback of results might be a lengthy process, involving a number of appointments with patients. In clinical genetics, the process of diagnosis may be iterative, so that genetic tests then guide further clinical examination, which eventually culminates in a diagnosis.

How decisions are made (paragraphs 1-8)

Is it helpful to include these frameworks?

Yes. Distinguishing between these frameworks is helpful. In terms of formatting - more could be done to highlight the text in the first sentences of options 2(a), (b) and (c) (i.e. the short descriptions that are elaborated on in each sub-paragraph). It would also be helpful to clarify that for any decision, only one of these frameworks will be relevant at any one time, but that patients might fluctuate between frameworks depending on the complexity and significance of the decision being made.

Is the guidance on delegation helpful?

Yes. The considerations in sections 4-8 seem sensible. For some interventions, there may be uncertain benefits and risks as well as outcome. We would like to suggest that 5(b) includes that the person delegated to has sufficient knowledge of uncertainties associated with other aspects of treatment (and not just outcome in 6(b)). In the context of genomics, paragraph 8 is important in relation to genomic sequencing tests being rolled out to mainstream clinicians.

As part of the genomic medicine service, it is intended that additional findings will be offered to be looked for, when testing for a known clinical problem. The extent of knowledge required by doctors who take consent for a clinically appropriate test, and also have to take consent for these additional findings is an ongoing source of debate and concern.

The top-line point is that an increasing number of tests (e.g. genomic sequencing and imaging) have the potential to reveal clinically relevant findings outside the expertise of the person taking consent. More discussion and work is needed to clarify what competences are needed by the health care professional taking consent in this type of situation.

Some hospital trusts ... prefer to mandate where possible, the use of a single patient information sheet/ consent - on the grounds of reducing potential liability should a dispute subsequently occur as to the legitimacy of the intervention.

Supporting patient decision making (paragraphs 9-38)

Is the guidance on sharing information helpful?

Yes. This seems to be the approach post-Montgomery. However some of the literature on the effects of Montgomery distinguishes between the choice of a particular intervention (which is largely based on clinical judgement) and the risks of that intervention (which is based on patient values, preferences etc).

This parsing of different types of information into intervention based and risk based, is not an approach which the GMC has adopted. It seems that in this guidance that the GMC has taken the view that all information must be tailored to the patient's values and preferences. Is this the case?

Do you agree with this approach?

Yes. In the past, a more paternalistic approach which invoked the therapeutic exception was invoked much more frequently. It is now entirely appropriate for this text to be relegated to a footnote. Stress and anxiety might also negatively impact on a patient's ability to take in and evaluate information. These psychological factors could be added to the list of physical things that potentially affect capacity (such as pain or medication).

Is the guidance at paragraphs 20-24 helpful?

Yes. It's very important that this principle is emphasised - if only to point to the fact that consent should be a partnership or collaboration between doctor and patient.

Is the guidance on benefits and harms helpful?

Yes. Although we support this approach since risks are probabilistic, it could sometimes be rather simplistic and misleading. Benefits could also be probabilistic but are less likely to be, depending on the intervention offered. 'Removal of cancer' and 'orthopaedic surgery to alleviate pain' are examples where benefits are hoped for but not inevitable.

The discussion in paragraphs 26-27 points to the need for doctors to have adequate training in communication - and for sufficient resources to be available to fund the development of infographics or other materials. Some hospital trusts are not supportive of these materials being developed, and prefer to mandate where possible, the use of a single patient information sheet/consent - on the grounds of reducing potential liability should a dispute subsequently occur as to the legitimacy of the intervention.

The term 'overall benefit' might mask a distinction between benefiting the patient and benefiting their family member, which might also impact on a patient.

Are paragraphs 33-35 helpful?

Yes. More clarity about this aspect is very useful.

Making a decision (paragraphs 39-102)

Is the guidance on expressions of consent helpful?

Yes. It would be helpful if paragraph 44 gave an example of being pressurised by a family member for example - the words undue influence or external pressure are not very accessible to a lay audience.

Paragraph 48 is very important - namely the proportionate nature of consent. I'd like this highlighted in the summary section on page 5, otherwise it could seem as if the requirements for a valid consent might be very onerous and are difficult to meet.

Is the guidance on planning future care helpful?

Yes. This could be framed more positively in terms of putting the patient at the centre of the decision making process, even when they are not so able to contribute to the decision making process in the future. In short, it's about respecting their autonomy.

Is the guidance at paragraphs 61-65 helpful?

Yes. This section is good in that it highlights the potential for a range of factors to limit patient behaviour ranging from pressure from an individual to a large scale system. It's useful to be reminded of this here.

Is the guidance on assessing capacity helpful?

Yes. It might be helpful to remind the reader early in this section that the extent of capacity required to make a particular decision is proportionate to the seriousness, and significance of the decision. Thus the level of capacity varies with the complexity and significance of the decision to be made (para 74, 81, and 85(d)). Arguably this might be more helpful earlier in this section.

Should use the term 'overall benefit'?

Not sure. The term 'overall benefit' might mask a distinction between benefiting the patient and benefiting their family member, which might also impact on a patient. Such a distinction was relevant in the bone marrow donation cases which came before the courts in the 1990's. In general though, it seems sensible to have one term that can be applied across the devolved nations without confusion.

Emergency treatment should not be seen as a means of attempting to gain a valid consent. This approach is an improvement on the existing guidance.

Is the guidance on emergencies clear?

Yes. Emergency treatment should not be seen as a means of attempting to gain a valid consent. This approach is an improvement on the existing guidance.

Are paragraphs 92-95 helpful?

Yes. This provides welcome clarity.

Overall comments

These seem sensible changes and in general, the wording seems clear and accurate. Much, however, will depend on the law annex and it's unfortunate that this wasn't available at the time of this consultation. The PHG Foundation would be interested in seeing and commenting on this legal annex, and would be happy to do so during the drafting process if this would be helpful.

In the clinical genetics field (the area of our expertise) there are some pending cases which may have a significant influence (e.g. ABC v St Georges Healthcare NHS Trust).

Other areas that might warrant some consideration include:

- Seeking consent for tests that might generate actionable medical findings that are outside the clinical expertise
- The use of artificial intelligence to support decision making (e.g. in decision support or to guide
- Imaging or pathology, or public health stratification)
- More routine use of remote consultations or telemedicine

These examples are likely to become more routine over the next few years.

The PHG Foundation is currently undertaking research in these areas, and are exploring the impact of these new technologies on the consent process.

Putting the principles into practice

As previously mentioned, we are working on aspects of this from a policy perspective. Organisations like Health Education England are leading the production of materials in clinical genomics.

Some interesting approaches are being explored in some research contexts (e.g. the Cambridge Winton Centre working with clinical geneticists to explore how genetic test results could be reported in a more accessible manner to patients).

In the context of clinical genetics, the British Society for Genetics in Medicine is in the process of updating its guidance on consent and confidentiality. This process is being led by Professor Anneke Lucassen (Chair of the BSGM; University of Southampton) and Alison Hall (Chair of the Ethics and Policy Committee BSGM; PHG Foundation). This guidance includes a suggested record of discussion form which tries to address some of the very specific issues that might arise in the context of clinical genetics (such as that test results may have implications for family members; that actionable incidental findings might be generated outside a particular clinical area, and that findings might be generated that have uncertain implications).

We would be happy to explore ways in which the BSGM could work with the GMC in highlighting the new consent guidance to its members.

Equality and diversity

No adverse comments.

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