BSGM
The British Society for Genetic Medicine

Consent and confidentiality in genomic medicine

Genethics meeting, Wellcome Trust, 3.7.19

Anneke Lucassen and Alison Hall

Background

Report of the Joint Committee on Genomics in Medicine

Comprises:

- Royal College of Physicians
- The Royal College of Pathologists
- The British Society for Genetic Medicine

Background to the Guidance

- 1st Edition (2006)

Builds on the responses from members (2003)

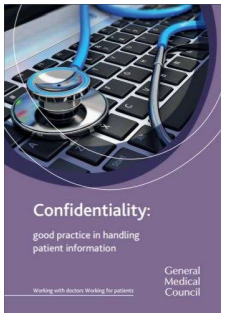
- 2nd Edition (2011)
- Rationale for revision:
  - Changing face of genetic testing
  - Legislation in force e.g. Human Tissue Act 2004
  - Supervisory authorities operational

Why is revision of the guidance needed?

- New technologies
- Mainstreaming of genetic/genomic tests beyond clinical genetics services
- Large scale genomics projects emerging
  - Deciphering Developmental Delay
  - 100,000 Genomes Project
  - UK Biobank

Changing legal context

- General Data Protection Regulation 2018 (and UK Data Protection Act 2018)
- Legal cases
  - *Montgomery v Lanarkshire Health Board (2015) UKSC 11 1 AC 1430*
  - *ABC v St George's Healthcare NHS Trust and others (2017) EWCA Civ 336*
- Revised GMC confidentiality guidance



Features of this version

- Complete revision
- Emphasises the importance of familial information to support clinical services
- Broader range of case studies
- Template documents including a record of discussions form
- Data protection summary

How was this guidance was developed

- Sandi Dheensa – background paper
- Multidisciplinary workshop – July 2017
- Contributors early drafts: Lettie Rawlins, Irene Estaban, Arijit Mukhopadhyay, Corrina Powell, Lowri Hughes and Alice Garrett. Later draft: Rachel Horton
- Composite case histories from eg Genethics meetings
- Peer review: Many! Especially: Members of the BSGM Council and JCGM; Michael Parker; Sarah Wynn; Caroline Wright; Angus Clarke

How is the guidance laid out?

- Introduction
- Confidentiality
- Consent
- Templates
- Legal annexes
- Cases interspersed throughout

Confidentiality

Foreword: "The assumption that confidentiality towards individuals is always paramount is as inappropriate as the assumption that disclosure is always permissible, and any decision will need to be tailored to the individual circumstances of the case."

"Respect for individual privacy need not, and should not, prevent health professionals advising patients on genomic risks that have come to clinical attention through the results of another person."

Harms of not respecting confidence

Harms of not disclosing potentially relevant information

LA11

The ABC case

ABC v St George's Healthcare NHS Trust and others (2017) EWCA Civ 336

- Daughter claims she should have been told about her risk of HD because it is significant for her own health and reproductive choices.
- She sues for non-disclosure. The courts initially rule against her, but at appeal, rule that it is arguable that clinicians in the NHS could owe her a direct duty of care. The case iwill be heard in the High Court later this year.
- Health professionals ***could*** have used existing GMC guidance to tell the daughter
- The law accepts that HCPs are ***allowed*** to use information where they judge this balance to be in favour of so-doing – even where the father's consent is not given. But is there a legal recompense if this does not happen?

Slide 10

LA11 We could replace this slide with case 15. we have talked about ABC so much in genethics!
Lucassen A.M., 04/07/2019

Case 15

Henry has recently received a diagnosis of Huntington's disease. This serious hereditary condition has no cure and early death (aged 40–60) is likely. Henry's daughter, Jane, knows that her father is ill, but not that his condition is heritable. She is pregnant and mentions this to Henry's clinicians. They wonder whether Jane has a right to know that she has a 1 in 2 or 50:50 chance of developing HD (which may have significant implications for her own health and reproductive choices). Henry refuses consent for Jane to be told his diagnosis, as he is worried that she might terminate her pregnancy.

Key points Case 15

- Need to balance the harms of potentially disclosing Henry's diagnosis against his wishes, with the benefits to Jane of having access to information about her risk of HD
- The balancing act involved in reaching a decision should be clearly documented in the medical notes.
- The genetic risk of Huntington's disease could be considered as familial information rather than information that is confidential to Henry.
- If disclose to Jane, this should be done in a way that protects Henry's confidentiality as far as possible. Eg making Jane aware that she may be at risk of developing HD without disclosing information such as the details of Henry's clinical history.
- The fact that Jane may correctly deduce these more personal details about Henry should not necessarily prevent disclosure of the genetic information.

What this means in practice

Health professionals worry about the law and sometimes misinterpret it: "X is the right thing to do, but the law prevents" "ABC means can't disclose unless your patient"

Particularly so for familial aspects of genomics, e.g.:

- Alerting relatives about their risks
- Use of a relative's sample as positive control
- Access to records/ tissue blocks of deceased relatives to guide management in proband
- Confirming family histories/ results to other centres

Consent
A Summary

- Ensures understanding of the nature and purpose of a procedure or intervention
- Primarily through discussion. A signature is helpful but not sufficient
- 'Fully informed, specific' consent is difficult to achieve especially where information is complex or where a test might yield new information in unpredictable ways

Elements for discussion

- Diagnose current problems + predict future health
- Relevance to other family members
- Likely timescale
- Scope and limits of testing
- Possibility of additional, incidental, unexpected findings
- Outcomes may be uncertain/unclear
- Interpretation of genomic results may change over time
- Samples may be stored routinely
- Comparison with genomic data from other NHS patients

Record of discussion rather than consent form

- Complicated disclaimers on consent forms
- Many different versions, some amended by governance departments as if they were REC approved forms
- Over reliance on a signature on a form rather than real consent
- A standard set of issues for a genomic consultation in a form as summary for patient

Case 14

Caroline is seen in the genetics clinic when she is 10 weeks pregnant. Multiple boys in her family have died young due to an X-linked condition.

Caroline does not know which of her relatives have had genetic testing. Caroline currently does not want anyone in her family to know about her pregnancy, as if she knew that she was pregnant with a boy with the X-linked condition she would plan to have a TOP, and she thinks that her family would not support this.

However, in order to provide an accurate carrier test and potentially a prenatal test to Caroline, the genetics service would need to access the exact details of the disease-causing X-linked variant in an affected relative of Caroline.

Case 14
Key points

- The public interest in keeping Caroline's pregnancy confidential (and in maintaining trust between patient and physician) may be more important than the requirement for consent to the disclosure of a test result from a family member. However, there is also a clear public interest in maintaining a confidential health service in which people are not deterred from having genetic testing by concerns that their confidential information might be disclosed.
- Consent conversations for genetic testing should ideally encompass the issue that results may be used to inform the care of other family members, and this discussion should be documented at the time of testing.
- It may be appropriate to view the details of the X-linked variant as being confidential on a familial level, such that this information could be used to allow Caroline's carrier testing. The personal details of the relative(s) in whom the X-linked variant has been identified should not be disclosed to Caroline.

Case 17

George is seen in the genetics clinic concerned about his risk of cancer. Several of his relatives have died of cancer at a young age.

His half-brother and cousin both died in their thirties and George remembers being told that they both had bowel polyps. The genetics department seeing George requests histology information from these two relatives. The histology department are not willing to provide the histology information from the relatives as they are concerned that this would be in contravention of GDPR. They ask for written consent from the next-of-kin of each deceased relative before they can search for or access the histology reports.

Case 17
Key points

Written consent from the next-of-kin of a deceased person is not required to authorise the disclosure of confidential information such as histology reports. Disclosure canbe justified in the interests of living relatives who may provide verbal consent.

Seeking consent from the next-of-kin of George's relatives could compromise George's confidentiality, and would create an additional administrative burden while having limited usefulness (as signatures of the next-of-kin are unlikely to be verifiable by the pathology department in any case).

Some cancer registries refuse to release information that would previously have been happy to disclose, on the mistaken belief that the *legitimate basis for data processing is consent*; it is not in this situation.

Mainstreaming Points for practitioners

- Genomic information is often complex
- Genetic tests may be predictive or diagnostic
- Context is very important
- Information from one person may inform the treatment of others
- Testing may yield unexpected information
- International data comparison may be necessary to guide interpretation

Discussion points

- **variants of uncertain/unknown significance** and the need for recontact in the future
- **Periconception** testing and testing of **children**
- **Hybrid uses** as the boundary between clinical and research uses become increasingly blurred
- **Commercial uses** of genetic/genomic data
- **GMS and mainstreaming**

Guidelines