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Using and disclosing confidential patient information and the English common law: what are the information requirements of a valid consent?

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General Data Protection Regulation

- Article 9 Processing of **special categories** of personal data
- explicit consent
- carrying out the obligations of data controller
- protecting the vital interests of the data subject

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GDPR – Article 9 continued

- legitimate activities of a charity or not-for-profit body with respect to its members
- Reasons of substantial public interest
- Public health
- Historical, statistical or scientific purposes
- **Member States may maintain or introduce further conditions, including limitations with regard to genetic data, biometric data or health data**

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GMC - Confidentiality good practice in handling patient information (2017)

- The patient explicitly consents
- The disclosure is approved by law or under a statutory process that sets aside the common law duty of confidentiality
- The disclosure can be justified in the public interest

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Consent as the preferable legal basis?

- Protect consent as a legal basis for use or disclosure of identifiable patient data in the context of alternatives

- Promotes patient autonomy

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Question

What information needs to be provided to an individual for them to be able to consent to the disclosure or use of confidential patient data so that the disclosure or use does not amount to a breach of confidence?

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Challenging preconceptions of consent

- What do we mean by informed consent?
- Developed in the context of medical **treatment**
  - Consent to the physical intervention
  - Consent to running the physical risks associated with that intervention

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Consent in the context of medical treatment

- Consent to the physical intervention
  - Informed in broad terms of the nature of the procedure
- Consent to run risk associated with medical intervention
  - Informed about the risks and alternatives and implications of non-action

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Application to the confidentiality context

- Which of these informational foci is more relevant for in consent preventing breach of confidence?
- Consent about the nature of the uses
- Not a consent to the risks which usually arise from negligence, wrongdoing, unlawful activity

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Consent in the context of medical treatment

- 'informed' consent in negligence:

  'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk'

Montgomery v Lanarkshire Health Board [2015] UKSC 11, Lord Kerr and Lord Reed 87

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Achievable informational levels

- Difficulty in achieving standard referenced to reasonable person may force reliance on alternatives to consent
- Consent based on broad awareness rather than informedness may make consent more achievable

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What information would need to be disclosed?

- Significant evidence about what the public do and do not find acceptable with regard to uses of their health data
- Does acceptability mean people want and expect it to happen?
- Acceptability generating reasonable expectations which affect level of information required

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Generating reasonable expectations

- Specific information disclosure in the consent process can then focus on uses which people find unacceptable and the concept of reasonable expectations is not therefore helpful in generating broad awareness

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What information needs to be disclosed?

- Acceptable use by acceptable organisation
- Acceptable use by not-so-acceptable organisation
- Not-so-acceptable use by acceptable organisation
- Not-so-acceptable use by not-so-acceptable organisation
- Perhaps consider whether this last use should occur at all

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Conclusion

- Allows consent to be the basis of disclosure
- No need to assess materiality in every case
- Specific information threshold low in most cases because of acceptability
- More efficient, safe and effective healthcare

