Patient Participation in Research in Primary Care

There is a strong public interest in ethically approved health and social care research carried out in primary care. Identifying suitable patients and seeking their consent to participate is normally part of the process.

To facilitate such work, Privacy Advisory Committee (PAC) has considered whether there may be a lawful basis for research staff, such as research nurses, employed by the HSC Trusts accessing the general practitioner records of patients, where they do not have any direct care relationship with the patients in question and in the absence of patient consent.

While similar arrangements exist in England, important for our consideration is that Section 251 approval will have been sought to permit research applicants access to patient identifiable information, in the absence of patient consent. Section 251 of the Health and Social Care Act 2006 provides a statutory gateway for setting aside the common-law duty of confidentiality. However, these regulations apply only in England and Wales.

In April 2016, equivalent provisions, the Health and Social Care (Control of Data Processing) Act Northern Ireland, received Royal Assent. That said, before this law can become operational, detailed regulations will have to be prepared, consulted upon and approved by the Assembly. This is some way off. There is therefore at present in Northern Ireland no equivalent of Section 251 to set aside the common-law duty of confidentiality.

The DHSSPS Code of Practice on Protecting the Confidentiality of Service User Information significantly informs PAC considerations. Respect for patient confidentiality requires patient consent to access or disclose their personal identifiable information. In the context of direct care, implied consent is considered acceptable. However, for all secondary uses that person's express consent is normally required[1]. In the case of deceased individuals, while a strong public interest in confidentiality remains, a balancing may be required with competing public interests in disclosure for specific uses.

PAC has also noted the revised GMC guidance on confidentiality (2017) which, like the Code of Practice, provides an overview of the legal and ethical basis for disclosing or accessing confidential patient information. The public interest justification is carefully explained including the exceptional nature of any such disclosure, the requirement of an overriding public interest and the uncertainties surrounding any proposed disclosure[2].

Consideration also needs to be given to public attitudes to such proposed disclosures. In the recent Life and Times Survey on attitudes of the public in Northern Ireland to uses of patient data for research, there is strong public endorsement for the right to privacy being respected over everything else[3].

The findings are in keeping with other recent studies of public opinion on the uses of personal health and social care information for other than the provision of direct care.

Given the strong public interest in ethically approved health and social care research carried out in primary care, PAC is available to advise on ways which may enable such work to proceed, compatible with the common-law duty of confidentiality.

Privacy Advisory Committee Northern Ireland
March 2017

1. **Code of Practice on Protecting the Confidentiality of Service User Information DHSSPS 2012** Para 3.16 *"When the proposed use or disclosure relates to health and social care, but is not directly for the care of that service user, the express consent of that service user is usually required, unless the information is in an unidentifiable form. The possible exceptions to this requirement for consent are where a statute, court or tribunal imposes a requirement to disclose or there is an overriding public interest in the use or disclosure."*

2. **Confidentiality: good practice in handling patient information GMC 2017**
106 In exceptional circumstances, there may be an overriding public interest in disclosing personal information without consent for important health and social care purposes if there is no reasonably practicable alternative to using personal information and it is not practicable to seek consent. The benefits to society arising from the disclosure must outweigh the patient's and public interest in keeping the information confidential.
107 You should not disclose personal information without consent in the public interest if the disclosure falls within the scope of any of the regulations described in paragraphs 103–105, and the disclosure is not permitted, or has not been approved, under those regulations.
108 If the regulation described in paragraphs 103–105 do not apply, you may need to make your own decision about whether disclosure of personal information without consent is justified. The circumstances in which the public interest would justify such disclosures are uncertain, however, so you should seek the advice of a Caldicott or data guardian or a legal adviser who is not directly connected with the use for which the disclosure is being considered before making the disclosure.

3. **Public Attitudes to Data Sharing in Northern Ireland, Robinson G, Dolk H**
ARK Research Update Number 108, August 2016
"The overwhelming majority of respondents (83%) agree that the right to privacy has to be respected over everything else. An equally impressive 85% maintain that if personal data can be made anonymous and a person's right to privacy maintained, then the data should be used where there is a benefit to society."