Principles of Advice: Exploring the concepts of ‘Public Interest’ and ‘Reasonably Practicable’

Context

The Health Service (Control of Patient Information) Regulations 2002 (‘the regulations’) establish circumstances for the lawful processing of confidential patient information, despite any obligation of confidence that may be owed: they establish circumstances for the common law duty of confidence to be set aside for particular medical purposes.

The regulations establish two circumstances (which have come to be known as instances of ‘specific support’) related to information concerning (1) diagnosis of and treatment for cancer, and (2) communicable disease and other risks to public health. These two types of processing, and the considerations relevant specifically to the requirements of specific support, are not the focus of this paper.

Beyond ‘specific support’, the regulations also allow for confidential patient information to be processed for medical purposes in a number of situations of more general application. Known as instances of ‘class support’, these are applicable to any processing of confidential patient information for medical purposes where the intention is one or more of the following:

1. To de-identify the patient.
2. To use information about geographical locations of patients for medical research
3. To enable identification and contact patients for the purposes of obtaining their informed consent to participate in, or allow the use of information for, medical research or to allow the use of tissue or samples for medical purposes
4. To link, validate and complete information from different sources
5. To audit, monitor or analyse patient care and treatment

From 01 April 2013, in the case of medical research the Health Research Authority will approve the purposes, along with a favourable opinion from a research ethics committee. The Secretary of State for Health must approve processing for any relevant non-research activity purpose.

The Health Research Authority and the Secretary of State for Health’s decisions on approval are currently informed by advice from the Confidentiality Advisory Group (CAG). When

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1. This document was originally authored under the remit of the Ethics and Confidentiality Committee and will be updated to take into account any changes relating to the remit of the Confidentiality Advisory Group and subsequent advice provided by CAG. It is provided here as a useful reference point for applicants.
2. S.251 (12) NHS Act 2006: In this section “medical purposes” means the purposes of any of—(a) preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health and social care services, and (b) informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care and treatment.
offering advice, the CAG must take into account the restrictions and exclusions that are contained within the regulations. In particular, where an individual is processing confidential patient information under the regulations he or she must not process that information any more than is necessary to achieve the permitted purposes and also they shall not process confidential patient information unless they owe a duty of confidentiality which is equivalent to that which would arise if they were a health professional. In addition, they must

- a. so far as is practical, given the purposes of the processing, reduce the identifiability of the information
- b. restrict access to those who need to access it for the purposes of processing and know the purposes of processing
- c. adopt appropriate technical and organizational measures to prevent unauthorized access
- d. review at least every 12 months the continued necessity for the processing, and extent of the processing, of the confidential patient information
- e. make available on request by any person or body information about the steps taken to comply with the Regulations.

The CAG will be concerned to ensure that it does not advise the Health Research Authority or Secretary of State to support any application inconsistent with these restrictions and exclusions. In addition, the Group must advise the Secretary of State on an interpretation and application of the regulations that is consistent with s.251 NHS Act 2006.

The NHS Act 2006 is the Parent (or Enabling) Act for the regulations. S.251 NHS Act 2006 enabled the Secretary of State to make the regulations and it also set limits on the possible content of any regulations made under it. For this reason, the regulations have to be understood and interpreted in the light of the Parent Act. For example, regulations made under S.251 NHS Act 2006 “may not make provision for the processing of confidential patient information solely or principally for the purposes of determining the care and treatment to be given to particular individuals.” Furthermore, regulations made under s.251 may not make provision for processing “in a manner inconsistent with any provision made by or under the Data Protection Act 1998.”

Two of the most significant safeguards, limiting the scope of any permissible interpretation and application of the regulations, concern the issues of ‘public interest’ and ‘practicable alternative’. Regulations can only be made under s.251 where considered by the Secretary of State to be either necessary or expedient (a) in the interests of improving patient care, or (b) in the public interest. Also, regulations made under s.251 may not make provision for the processing of confidential patient information “for any purpose if it would be reasonably practicable to achieve that purpose otherwise than pursuant to such regulations, having regard to the cost of and the technology available for achieving that purpose.”

As well as being important to an interpretation of the regulations consistent with s.251 NHS Act 2006, the Group is required to take into account the ‘public interest’ in any intrusion into privacy, as well as any ‘reasonably practicable alternatives’ to such intrusion, due to the requirements of the Human Rights Act 1998. This was first made clear during the

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4 S.251 National Health Service Act 2006 superseded S.60 Health and Social Care Act 2001 under which the 2002 regulations were made.
5 S.251(6) NHS Act 2006
6 S.251(7) NHS Act 2006
7 S.251(1) NHS Act 2006
8 S.251(4) NHS Act 2006
parliamentary debates establishing the authority to make regulations that could set aside the common law duty of confidence:

“...”

For each of these reasons, and due to the fact that the meaning of either term is always to be straightforwardly understood, there is a particular interest in further exploring and explaining the CAG understanding of the terms ‘public interest’ and 'reasonably practicable alternative’. This document seeks to clarify the position of the CAG when considering the issues of ‘public interest’ and ‘practicability’. It is hoped that it might improve the transparency of the advice process as well as acting as a guide for future applicants.

Public Interest and Reasonably Practicable Alternative

1. Public Interest

Regulations made by the Secretary of State for Health under s.251 NHS Act 2006 may only be made as considered necessary or expedient (a) in the interests of improving patient care, or (b) in the public interest. It follows that any advice given, in relation to the regulations, must be consistent with one or both of these purposes.

When considering whether processing is ‘in the interests of improving patient care’ the CAG considers not only the intended consequences of the processing but also the potential damage to patient care that might follow a loss of trust in the confidentiality of the information held by providers of healthcare services. In this respect, the CAG is always mindful of two public goods: the public good in a health care service which holds and processes patient information confidentially and the public good in improving that health care service through the use of confidential patient information for medical purposes without patient consent.

Having considered the potential impact of any particular proposal on each of these public goods, the Group will only advise the Health Research Authority / Secretary of State for Health to support processing under the regulations if it considers that processing to be ‘in the public interest.’ The CAG understanding of ‘public interest’ is, therefore, of special significance to its decision-making.

1.1. Basic Principle

The ‘public interest’ is not a concept usually unpacked in the abstract. Rather it is an idea given substance by the specifics of a particular case. For this reason, it is most important to describe those things relevant to determining the public interest in the context of CAG decisions and these things are set out below. However, as a basic principle, the more readily that one can anticipate acceptance for a proposal across a broad range of ‘user groups’ – e.g. if one can anticipate acceptance not only from those that might benefit from the processing but also those whose data is to be processed without consent – then the clearer the indication, that the processing is, at least prima facie, in the public interest. The CAG is thus seeking to anticipate the ‘reasonable acceptability’ of a proposal by patients and public.

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a Lord Lester of Herne Hill, Hansard, 3 May 2001, 6pm.
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If one can demonstrate that there is common value to a particular reconciliation of (at times competing) interests, then this helps to demonstrate public interest. For this reason, there are a number of things that are taken into consideration by the CAG when assessing ‘public interest’ and, accordingly, a number of things that an applicant can do to help inform the advice provided by CAG.

1.2 Clarifying Benefit
   1.2.1 Example Outcomes
   1.2.2 Improved Understanding as an Outcome
   1.2.3 User Involvement
1.3 Avoiding Harm
1.4 Relative Risks
   1.4.1 Overriding Dissent
   1.4.2 Disclosure to be permitted not mandated
   1.4.3 Minimising Risks
   1.4.3.1 Involving Recognised Health Care Professional Contacts

1.2. Clarifying Benefit

Applicants should be clear within an application of the (intended) benefits of the proposed processing. For example, how is it anticipated that particular objectives of the processing will benefit patient care or achieve some other tangible benefit that might be reasonably described as a public good? Sometimes applications explain what it is hoped to learn, for example from a research proposal or a national audit, without making clear how that knowledge will be usefully applied in the future. It is not necessary to indicate precisely who will benefit, how much, for how long, but any indication of benefit might usefully reference such considerations. In every case, when assessing the public interest, the CAG must consider not only the potential positive (future) impacts of a proposed disclosure, but also the relative risks of any negative (future) impacts that might follow the non-consented disclosure of confidential patient information.

1.2.1. Example Outcomes

If a proposal relates to an activity that is on-going, or has been carried out in similar form before, then specific examples of the benefits that have flowed from the processing can effectively support any claim to expect similar benefits from the proposed processing. Likewise, if an applicant returns to the CAG to seek continued support for a particular activity, e.g. at the time of (annual) review, then a failure to demonstrate any tangible benefit following previous support can raise questions about the public interest in continuing to breach patient confidentiality.

1.2.2. Improved Understanding as an Outcome

It is appreciated that, sometimes, one cannot reasonably expect processing for medical purposes to yield immediate and tangible benefits. An example here might be medical research that is intended to improve a basic understanding of disease or disorder with no immediate expectation that this will improve treatment outcomes in either the short- or medium-term.

The CAG supports fundamentally the principle that research, and generally progressing human understanding, is in the public interest. Not least of all because most medical research is intended to contribute toward future improvements in patient care. However, it does not follow from this that every research study, or activity to support research or further particular understanding, is sufficiently in the public interest or is necessary or expedient in
the interests of improving patient care in order to justify processing confidential patient information without consent.

1.2.3. User Involvement

Claims about the importance of processing confidential patient information without consent can often be supported through involvement with (and testimony from) those who stand to benefit from the processing and/or whose confidential information is to be disclosed.

The Ethics and Confidentiality Committee (ECC) had consistently encouraged applicants to positively involve appropriate user groups (including, of course, patients), and this is expected to be continued under the CAG. Previous experience from the ECC has shown that this can improve applications in a number of ways, both enhancing the benefits and supporting any claim that those benefits are sufficient to justify relative risks. Effective involvement must, however, typically be planned at an early stage, prior to funding applications being submitted, and considered an integral part of the research.\(^\text{10}\)

It is the case that applications have previously found support from the ECC, including where initially unsupported, due to the evidence provided from positive involvement with user groups. One example here is a study that looked at cerebral palsy following assisted reproductive technology.\(^\text{11}\) The initial application did not involve any user involvement and, particularly because one of the express aims was to provide public and professional education, this initially frustrated effective demonstration of the potential value of the work.

1.3. Avoiding Harm

A particular kind of benefit is implied when an applicant seeks to rely upon the regulations to avoid causing harm. For example, where applicants are concerned with the impact that seeking consent might have upon an individual.\(^\text{12}\) In such cases it should be made very clear why it is in the patient's best interests not to be involved in a decision about what happens to information about them. CAG is fully supportive of the principle 'no decision about me, without me' and any such claim will be subject to very close scrutiny.

The potential for distress is not, in itself, a sufficient reason to avoid seeking consent. The extent, level and nature of any potential harm must be properly considered and will not always justify reliance upon the regulations. For example, the Ethics and Confidentiality Committee had not been persuaded by a previous application that alleged sending a letter to patients, in order to obtain consent to the use of their confidential information, would constitute an infringement of their privacy sufficient to justify not seeking consent.

On the other hand, the ECC had been persuaded that the extent, level and nature of the distress that would be caused by the only available means of advertising a confidential inquiry into the relationship between schizophrenia and homicide was sufficient to justify the claim that notification in the circumstances was not practicable. In that case, experienced clinicians were able to point to prior experience of significant distress being caused to patients through similar notification of studies. They successfully demonstrated that there was no practicable method of notification that would not violate professional and ethical responsibilities to their patients.

\(^\text{10}\) See also Tarpey M., (2011) Public involvement in research applications to the National Research Ethics Service, INVOLVE, Eastleigh.

\(^\text{11}\) PIAG 1-05(b)/2007

\(^\text{12}\) This is related to the claim that it is not practicable to seek consent for reasons of ethic, law, or professional principle discussed below.
One of the reasons that CAG closely considers any claim that seeking consent will cause harm to an individual is that it can appear, at times, as though applicants sometimes seek to avoid consenting individuals – particularly to studies investigating associations that might be considered unwelcome – because of a concern that, if individuals were to be asked, they might say ‘no’.

### 1.4. Relative Risks

Establishing the public interest in proposed processing requires consideration of more than the potential benefits. As well as considering the benefits (including harms avoided), the relative risks must also be taken into consideration. These include the possibilities of overriding dissent or requiring disclosure in circumstances that would be considered objectionable by the health care professionals to whom the confidential information was originally confided.

The relative risks are determined by considering, inter alia, the risks posed to individual privacy and public trust in the confidentiality of the health care service relative to the benefits of the proposed processing. There may be occasions when the CAG will recognise there to be good reason for the proposed processing - it is well motivated by pursuit of public good - but it will not be persuaded that the benefit pursued has justified the relative risks (and so the particular reconciliation of interests could not be described as in the ‘public interest’).

#### 1.4.1. Overriding Dissent

PIAG and the ECC had taken a very clear position on the fact that it will not advise the Secretary of State for Health that the public interest lies in overriding a recorded dissent. There might be occasions when, through the use of the regulations, individuals’ information is used in circumstances where, if they had been asked, they would have preferred it not be used. This is an unavoidable and necessary consequence of the use of the regulations. Hence the need for risk assessment as described in 1.4. The CAG will not advise the Secretary of State for Health that it is in the public interest to override a known dissent in anything other than the most exceptional circumstances, e.g. serious public safety concerns.

In practice, the opportunity for an individual’s data to be used in the face of an active objection will be minimised anyway by the requirements of fair processing notification and the right of data subjects to object to processing that are contained within the Data Protection Act 1998. As noted above, the regulations do not affect the principles of good data processing established by the 1998 Act and data subjects are entitled to object to the processing of their data if it would cause unwarranted substantial damage or distress.\(^\text{13}\)

#### 1.4.2. Disclosure should be permitted and not mandated

Although the regulations make provision for the mandating of the disclosure of confidential patient information, early in its life the Patient Information Advisory Group, which was a forerunner of the CAG, adopted the view that the regulations should be applied permissively, rather than in mandating disclosure.\(^\text{14}\) This was a view continued by the Ethics and Confidentiality Committee and now the Confidentiality Advisory Group. Even if the Secretary

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\(^{13}\) s.10 Data Protection Act 1998

\(^{14}\)PIAG, *Minutes of Meeting held on 12 September 2007*, Agenda Item 3.6. ‘Using Section 60 to require Processing’.
of State for Health approves an application, and the common law duty of confidence is effectively set aside for the purposes of particular processing, it still remains open to those holding confidential patient information to decide that the risks to their relationship of trust with patients are too great to justify the disclosure. In such circumstances, the CAG does not consider the public interest to lie in mandating disclosure.

1.4.3. Minimising Risks

The justification of risk is informed by steps taken to clarify benefit (See above, e.g. example outcomes, user involvement etc.) and is independent of the minimisation of risk. Even if particular risks are justifiable, then the public interest lies in the minimisation of risk of harm wherever practicable.

1.4.3.1. Involving Recognised Health Care Professional Contacts

Confidential patient information is disclosed to an appropriate health care professional during a confidential healthcare interaction. However, applicants are often not seeking disclosure from the individual to whom the information was originally disclosed. It is the original contact who is at most obvious risk of losing patient confidence if patients consider their confidential information to have been processed inappropriately. These individuals are often well placed to assess the relative risks for individuals known personally to them and to assist in exploring how such risks can be minimised. For example, there are occasions when GPs checking lists of patients prior to non-consented disclosure can protect those patients most vulnerable to particular risks.

1.4.3.2. Covering Letter from Recognised Contact

If there is an intention to contact patients directly, then it is also usual for this contact to be made with the collaboration of a recognised contact. If it is possible for initial contact (with the patient) to be made via a recognised health care professional, then support under the regulations is not needed (and could not be advised due to the existence of a practicable alternative). There are occasions, however, when although the initial contact cannot be reasonably made, in practice, by a health care professional, it is nevertheless practicable for contact to be made with a covering letter from a recognised contact, e.g. a letter from a GP or a treating clinicians could accompany any correspondence with patients explaining, among other things, the reasons for the non-consented disclosure.

For example, if support under the regulations has been sought to enable an approach to patients for the purposes of seeking consent to research participation, then that approach for consent should typically be made with a covering letter from the health care professional contact that the patient would recognise to hold their confidential patient information.

1.4.3.3. Reducing levels of disclosure

Using recognised contacts is just one way to minimise and justify the relative risks associated with intended non-consented processing. Minimising risks also involves considering and planning for the possibilities of unintended further processing as a result of, for example, accidental loss or theft of data. For a number of very good reasons (including lawful requirement under the principles of data protection) applicants should be seeking to minimise the flows of confidential patient information, and the risks associated with unintended disclosure, wherever practicable.
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Careful consideration should be given by an applicant to the sensitivity, range and number of data items to be disclosed, the number and position of individuals that will have access to them, and the length of time for which they will have access. It is also a requirement of both the regulations and also the Data Protection Act 1998 that identifiers are reduced to the minimum necessary for the purposes of processing, e.g. year (and month) of birth, rather than date of birth, partial postcode rather than full postcode (and in postcode is to be converted into deprivation index, then conversion performed at earliest point practicable and postcode not retained).

Even where it is necessary to use and retain particular data, there are often things that can be done organisationally to reduce risks. For example, it is good practice, to keep clinical and demographic data items apart where practicable. A number of very good applications have planned to build in role based access controls to reduce the risks of inadvertent and unnecessary disclosure of clinical and/or sensitive data items.

2. Reasonably Practicable Alternative

2.1. Relationship between Practicability and Public interest

There is an overlap between a consideration of the public interest in the disclosure of confidential patient information and the assessment of any reasonable practicable alternative. An example of this was provided when a pilot study for a survey demonstrated that it was possible for the survey to be administered without recourse to the regulations but with the limitation that reminders could not be sent\(^{15}\). This limitation was the basis of a request for support from the ECC at that time. On that occasion, the ECC had felt that the public interest in maintaining public trust in the confidentiality of patient information overrode the marginal gains that could be gained through the use of the reminder.

While the CAG is not responsible for evaluating the science of a proposal – or judging the scientific merit of a particular method or methodology – it is required to consider the viability of any reasonably practicable alternative method of achieving an applicant’s aims. The CAG will, therefore, need to be assured that any relevant alternative has been properly considered. In the case referred to above, the ECC had advised the Secretary of State for Health that, as a majority of the survey aims could be achieved without non-consented use of confidential patient information, there was a reasonable alternative in practice that undermined any claim that the public interest was in disclosure. In short then, whether there is a public interest in disclosure will be informed by whether there is a reasonably practicable alternative.

2.2. Basic Principle

The regulations cannot be used to set-aside the common law duty of confidence if it would be ‘reasonably practicable’ to achieve the purposes of the processing ‘otherwise than pursuant to the regulations’. When assessing the reasonable practicability of alternatives, regard must be had to the cost of, and the technology available for, those alternatives. Typically, when considering its advice on the issue of reasonable practicability the question that the CAG has to consider is:

\textbf{Is it reasonable to expect the applicant, in practice, to either seek consent for the proposed use of confidential patient information or to achieve their purposes using data in a de-identified form?}\n
\(^{15}\) PIAG 3-05(b)2007
When considering whether there is a ‘reasonably practicable alternative’ the Committee typically will consider a number of things:

2.3 Available Evidence
   2.3.1 Previous experience and Third Party (incl. Service User) Testimony
2.4 Reasonable impracticability of Consent
   2.4.1 Demonstrating impracticability
      2.4.1.1 Impossibility
      2.4.1.2 Emergency Care
      2.4.1.3 Large Size of Sample
      2.4.1.4 Costs and Failures to Plan for Consent
      2.4.1.5 Consent via Lawful Holders of Data
      2.4.1.6 Complete Ascertainment and Bias
   2.4.2 Demonstrating that it is not reasonable, in practice, to seek consent
   2.4.3 Greater Disclosure
   2.4.4 Anticipating Dissent
2.5 Exit Strategy

2.3. Available Evidence

There have been occasions when applicants have claimed impracticability without apparently having even considered, much less tested, the alternatives. Unless the impossibility is obvious from the circumstances (see below), any claim of impracticability is most persuasive when it is evidenced.

There should be no assumption that, for example because data was originally collected for clinical purposes, there is now no opportunity to seek consent for an existing collection for research purposes. Even if consent is ultimately determined to be impossible, or that it would involve the taking of either disproportionate or inappropriate steps, the positive consideration of the opportunities will help to evidence any claim of impracticability.\(^{16}\)

Similarly, one should not conclude from the fact that data is currently held in identifiable form that a researcher must access it in that form. There are sometimes alternatives where linkage, extraction, redaction, pseudonymisation etc. can be performed by third parties (who already have lawful access to the data in identifiable form) so that a researcher may process data only in a form that is, to them, effectively de-identified.

The CAG recognises that it is not always reasonable to expect a researcher to pursue such alternatives in practice. This can, however, usually only be effectively demonstrated if the alternatives have been seriously considered and, sometimes, impracticability is only properly evidenced through testing. It will, sometimes, therefore, be appropriate to pilot alternatives where it is not possible to demonstrate either previous experience or alternative evidence, such as third party testimony.

2.3.1. Previous experience and Third Party (incl. Service User) Testimony

\(^{16}\) It should be noted in this context that not only does s.33 of the Data Protection Act 1998 (‘the research exemption’) have no application to the common law duty of confidence but it also does not exempt researchers from the data protection requirement that data be processed ‘fairly and lawfully’. ‘Fair and lawful’ processing requires satisfaction of not only the provision of a ‘privacy notice’ where practicable but also satisfaction of one of the conditions set out in Schedule 2 of the Data Protection Act 1998 and in the case of sensitive personal data also one of the conditions set out in Schedule 3. The fact that data have originally been gathered for one purpose does not excuse a data controller from any responsibility to notify a data subject, where practicable, of an intention to process personal data for a further research purpose.
Applicants should consider the role that previous experience, including that of third parties, might play in supporting any claim of impracticability.

Support for claims that there is a lack of reasonably practicable alternatives can be offered, for example from people that have attempted particular approaches before (with published or unpublished success or failure), funding bodies, the individuals or organisations that would need to be involved in any attempt to gain consent or de-identify data, and the individuals (or representatives) who would have their confidential patient information accessed without consent.

A claim that the difficulties associated with alternatives (e.g. either de-identifying data or gaining consent) would meet ‘substantial difficulty’ or suffer ‘disproportionate costs’ is more persuasive if supported by those that would actually meet the difficulties, bear the costs, or suffer the breach of confidence and not simply asserted by an applicant.

Pilot projects, gathering evidence and testimony regarding the impracticability of particular methods of gaining consent and use of de-identified data, can be extremely persuasive and should be considered for suitability.

2.4. Reasonable impracticability of Consent

As with other considerations, there is a series of relatively straightforward indicators of (im)practicability and, then in their absence, a more nuanced range of factors that would tend toward indicating that it would be unreasonable to pursue particular alternatives in practice.

2.4.1. Demonstrating Impracticability

The first and most straightforward indication of impracticability is impossibility. If it would not be possible for a researcher to gain consent, then they are not able to do so in practice.

2.4.1.1. Impossibility

A clear example of impossibility would be processing that involved a retrospective study of the records of the deceased. While consent could technically be sought from a legal representative, details identifying that representative are not typically contained within the databases accessed for medical purposes and it will not often be reasonable, in practice, for consent to be sought.

2.4.1.2. Emergency Care

There will be occasions when a patient’s consent cannot be sought due to incapacity: they are unconscious, in debilitating pain or they are occupied by the immediate needs of emergency care. Examples of such research projects have, unsurprisingly, often been associated with care and treatment within Accident and Emergency Departments and Critical Care Departments.

The Committee has been sympathetic to such applications in the past but has also required that consent for continued inclusion is sought as soon as practicable.

2.4.1.3. Large Size of Sample

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17 Even where it is possible for access to the records of the deceased to be consented (e.g. during life) this may not constitute a reasonably practicable alternative in the circumstances (see 2.4.2)
The fact that a study involves very large numbers, or is even national in scope, is not automatically a reason for assuming that consent is impracticable. It is the practicability of contacting the cohort, within the relevant time-period, that is key and that is not determined simply by the issue of numbers. If the cohort is one that is in regular and on-going contact with a health professional, and the intention is to gather data prospectively over a time-period likely to include at least one such contact, then the impracticability of gaining consent needs to rest on more than simply the size of the cohort. Such arguments were rejected by the Ethics and Confidentiality Committee, for example, when presented within an application to establish a prospective national register on a non-consented basis even though large numbers were involved because the condition in question required regular and frequent contact with a health professional.

2.4.1.4. Costs and Failures to Plan for Consent

While disproportionate costs or burdens, such as might be associated with extremely large numbers, might mean that it is reasonable to rely upon the regulations, a disproportionate cost is the kind of cost or burden that would not be reasonably provided, e.g. to a researcher by a funding body, given the nature and extent of disclosure of confidential patient information proposed.

The Ethics and Confidentiality Committee has previously not been sympathetic toward claims of impossibility where the impossibility appears entirely to be a result of financial barriers that should have been anticipated and avoided at an early stage of the planning process. For example, a failure to take account of the costs of a consented approach at the stage of a research proposal is not a good reason for a subsequent attempt to rely upon the regulations to avoid the need for consent.

2.4.1.5. Consent via Lawful Holders of Data

The ECC had declined to support applications in the past where, with reasonable financial or administrative assistance (e.g. provision of pre-stuffed envelopes requiring only address labels), those currently holding confidential patient information lawfully could seek consent on behalf of applicants.

With moves to establish research as a core part of NHS business, the competencies and capacities required to facilitate collaboration between those currently holding confidential patient data and those seeking to process data for ‘medical purposes’ should continue to improve. There have been a number of examples of effective collaboration in the past, e.g. between GPs and Cancer Registries where cancer registries initially identified the cohort and then contacted GPs on behalf of researchers.

2.4.1.6. Complete Ascertainment and Bias

The CAG will receive requests for support that claim the need for 100% ascertainment. These requests are not always convincing. While it is appreciated that 100% ascertainment may be ideal, the reality is that it is rarely actually achieved in practice and researchers have developed many ways to accommodate a less than perfect sample within their analyses. The CAG will want to see evidence that the applicant has considered, for example, why it would not be possible to weight for bias within a sample. It is, however, accepted that the argument of intolerable bias is typically more easily made where there are very small numbers involved, for example, in the study of a rare condition. Examples can be found in a number of prevalence studies of extremely rare conditions coordinated by the British

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18 See n.2
19 PIAG 3-05 (h)/2007
Paediatric Surveillance Unit (BPSU) and CAG noted the good practice demonstrated by the BPSU methodology.

2.4.2. Demonstrating that it is not reasonable, in practice, to seek consent

There are, albeit rare, occasions when it is not reasonable to seek consent even though it might be quite possible in practice. The CAG recognises that legal and ethical concerns and standards can demonstrate that it is not reasonably practicable to seek consent in particular circumstances.

Examples here would include studies that have sought to investigate the records of the deceased and have had the opportunity to consent the subjects of those records while still living if such opportunity could only have been realised by consenting a much larger cohort including those that had no reason to suspect that the treatment episode in question would result in their death. To consent these individuals to the use of their records in the event of their death would have caused unnecessary, understandable and inappropriate distress. This should not be considered an excuse for paternalism where genuine opportunities exist to involve patients, or their parents or carers, in discussion about their involvement in research. If, for example, children are being cared for at the end of life within a hospice environment, then there should be opportunity to, ethically and appropriately, raise with a family the possibilities of using information about their care for medical purposes in the public interest or specifically to improve the care and treatment of others.

2.4.3. Greater Disclosure

Sometimes seeking consent would necessitate an applicant having access to more information than they need to achieve their proposed purposes. In this case, advising access to more confidential patient information than is currently held in order to enable them to seek consent may pose greater relative risks than would otherwise be the case. This is, however, a judgement that must be made on a case-by-case basis depending upon the level of disclosure that is proposed and the availability of the additional information that would be required to seek consent in practice.

2.4.4. Anticipating Dissent

As stated above, the CAGs starting position is that it will not advise that it is in the public interest to override a recorded dissent. Similarly, it will not generally accept as a valid argument that it would not be practicable to carry out the processing on a consented basis because people have been asked and they do not want their data to be used in this way: they would say no if we asked them.

However, in certain specific and exceptional cases, advice has been provided that supports applications where there have been good reasons to expect that individuals would object if they were to be asked. A fine distinction has been drawn between advising that a recorded dissent be overridden (which has not been advised to date) and advising that the regulations be used in cases where one can anticipate dissent (which has been advised very rarely). The subtlety of the distinction is not lost on the CAG and it will only countenance advising the Secretary of State for Health or Health Research Authority that the anticipation of dissent warrants reliance upon the regulations in those cases where the public interest is exceptionally high and there really is no other way in which the purposes could be achieved, e.g. important research in the public interest could be conducted, other than with the Secretary of State for Health or Health Research Authority’s support. (See 1.4.1)

2.5. Exit Strategy - Shifting what is practicable
There are occasions when it is recognised that those lawfully holding data may not currently be in a position to support the proposed processing but that it is reasonable to expect moves to be made to ensure that they are able to do so in the future. In such cases, it has been made a condition of approval that the applicant work with those lawfully holding data to ensure future applications of the regulations are not necessary. For example, an application to link national cancer registry data with national HES data was approved but the applicant was encouraged to work with the cancer registries and the Health & Social Care Information Centre to ensure that disclosure beyond the life of the first iteration of the project was not necessary. As a means of encouraging continual movement towards the alternatives of either consent or de-identification, the need for an exit strategy is explicit.

MJT
Vice Chair, NIGB ECC
19th April 2012

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