Use of Clinical Recordings in non-Clinical (eg Educational) settings: Next steps (November 2009)

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Background

Clinical pictures, videos and other recordings are vital to good teaching and learning within the health-care professions. Increasingly these are originated outside the institution that wishes to use them. This raises a number of legal, ethical and other issues relating to their re-use.

Nationally the JISC is investigating sharing of resources through its Open Educational Resources (OER) and repository programmes, and JISC Collections developing banks of re-usable images and video. Within the clinical field there are special circumstances involving confidentiality and privacy which are in addition to the necessity to negotiate copyright and other issues relating to re-use.

The JISC commissioned a study, Common Healthcare Educational Recordings Reusability Infrastructure (CHERRI: http://www.cherri.mvm.ed.ac.uk/) to investigate good practice and define a framework and model for clearing of media to enable sharing across the health-care professions. Undertaken by Edinburgh University, CHERRI made a number of recommendations of which the main one was to develop a UK-wide common consent and license model (C+LM) for the use and sharing of clinical recordings. The report also identified a lack of common processes and standards at local level and further recommended that all users of clinical recordings for academic non-clinical settings (CRANCS) be better educated and supported in the use of such recordings.

CHERRI 2, being carried out by Bristol University and due to report shortly, has been tasked with exploring how the CHERRI model and recommendations could be implemented in practice and what needs to take place within the Further and Higher Education and NHS communities for this to be realised.

Through the JISC's OER Programme, the Higher Education Academy subject centre for Medicine, Dentistry and Veterinary Medicine is leading a consortium to investigate sharing of educational materials with the aim of identifying barriers to their re-use. The project is developing a number of toolkits including ones for intellectual property rights, patient consent, institutional policies, quality assurance, and describing, locating and accessing resources.

In additional, the General Medical Council is currently revising its guidelines for the recording of medical image, video and other recordings.

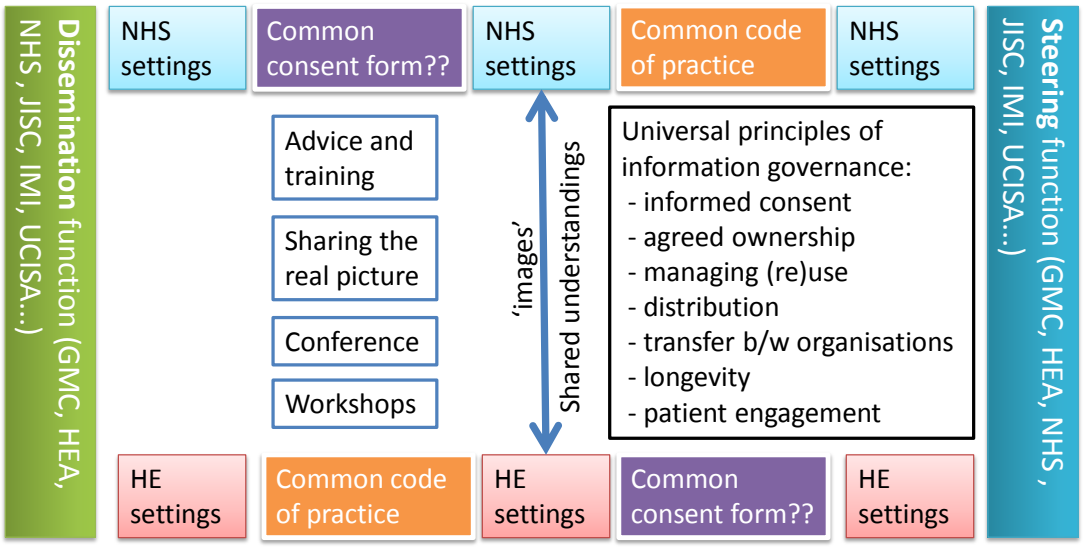
In this context, CHERRI2, JISC Digital Media and JISC co-sponsored a workshop to bring together both national and local initiatives and to work to foster greater communication and identify steps towards ensuring re-use of health-care recordings to support training and educational of all health-care professions within health-care and educational settings.

Workshop outcomes and proposal for the next steps

Detailed notes from the workshop are included as an annex to this paper. In broad outline, the recommendation from the workshop was to pursue a range of activities that are represented in

Figure 1. This outline was presented to the NHS-HE Forum on 19th November 2009, and gained unanimous support, with a recommendation that steps be taken to realise it as a matter of urgency.

Figure 1: Proposed next steps to enable more effective and trusted use of clinical recordings for educational purposes



The use case being supported is the use of clinical recordings ('images') that are created in NHS settings, for educational purposes in a range of HE settings. At present the advice and guidance available to those engaged in this work is extensive, but complex and rather overwhelming. In addition, some NHS and many HE settings lack the infrastructure properly to manage such material. It is likely that images are being used without sufficient reference to the consent granted at the time the image was created. There are risks both that:

1. Images without adequate consent are inappropriately distributed, leading to a breakdown of trust between patients and clinical staff, and between NHS and HE settings;
2. As a result of a perceived risk, NHS and HE managers 'lock down' their systems, preventing clinical recordings from leaving the NHS setting, which would significantly damage medical education

To address these risks, the workshop participants recommended that a project be funded whose aim is to increase the confidence with which clinical recordings are used for educational purposes, by addressing organisational, cultural and technical factors. The project objectives are to:

1. Encourage shared understandings between managers and practitioners across both NHS and HE settings on the rationale and good practice for the creation and use of medical images for educational purposes. This would be achieved by working together on a simple set of principles for information management in this area, covering such issues as informed consent, ownership, transfer between organisations and wider distribution.
2. Create advice and guidance that is targeted at, and appropriate for, busy practitioners who need to have specific information to enable them to create, manage or use images.
3. Provide a safe way for practitioners and managers to share 'horror stories' wherein guidelines have not been followed, with risky or damaging consequences. These will help make the case that this area of work is important and needs to be resourced, both nationally and within each HE and NHS organisation.
4. Provide opportunities for those engaged in work in this area to exchange experiences and build a community via workshops, conferences and so on.
5. Give the initiative a practical sense of direction: two targets were identified; a common code of practice between NHS and HE settings; and a common consent process and form. Neither of these may, in fact, be feasible. However, efforts to achieve them will ensure progress is made in the right direction.
6. Disseminate progress to a wide range of staff and students, via top-down, bottom-up and 'middle-out' methods.
7. Gain endorsement of the above activities by the key national bodies such as GMC, HEA, IMI, Department of Health, UCISA and Connecting for Health. This endorsement would be shown, for example, by:
    - an agreement by these bodies to engage fully with the project and, where possible, to adopt and endorse any relevant outcomes as common ways to implement high-level guidance on these issues;
    - commitment to take a steering role in the project;
    - contributions to the project, including financial or 'in-kind' contributions.

Annex: Detailed notes from the 'Medical Images' Workshop held at Grays Inn, London. 18 November 2009

Neil Jacobs

Present:

Adrian Longstaffe - Interactive Consultancies
Andrew Farrell - Division of Clinical Neurosciences, University of Edinburgh
Angela Miller - University of London
Catherine Draycott - Head, Wellcome Images
Christopher Trace - eMedia Unit, the Royal Veterinary College
David Kernohan - Programme Manager - eLearning Team - JISC
David Rodriguez-Gonzalez - SINAPSE Collaboration, National e-Science Centre
Emma Beer - JISC
Geoff Glover - Faculty of Education, Health and Science, The University of Derby
Helen McEvoy - Faculty Team Manager (Medical, Human and Life Sciences), University of Manchester
Ian Berle – Institute of Medical Illustrators
Jane Williams – Faculty of Medicine and Dentistry, University of Bristol
Jane O'Brien – Head of GMC Standards
John Bradfield – Interactive Consultancies
Julia Goodwin - Information Officer, Open University
Karla Youngs – JISC Digital Media
Kate Lomax - eLearning Repository
Maeve Rea - Queens University Belfast and clinical academic
Malcolm Teague - NHS-HE Co-ordinator
Maria Toro-Troconis - Faculty of Medicine, Imperial College London
Mark Packer - University of Brighton
Michael Barrett - Faculty of Medicine, Imperial College London
Michael Begg - eLearning Manager
Natalie Lafferty - Lecturer (E-learning)
Neil Jacobs – JISC
Olivia Stapleton - GMC
Sally Holden - eLearning Support Manager
Steven Wood - Dept Medical Physics, Royal Hallamshire Hospital
Sue Turner - Information Governance Manager and Caldicott Lead, National
Centre for Young People with Epilepsy.
Suzanne Hardy - Newcastle University
Trevor Bryant - Senior Lecturer in Biocomputation

Malcolm Teague's introductory comments:

- Value of existing GMC guidelines, key role for GMC in the future
- How things have changed with the web, and the implications for archive material

GMC presentation

- Statutory role for GMC giving advice to doctors on good practice, used in undergraduate education, NHS appraisal, re-certification, etc. This is high-level guidance.
- From 1994. GMC has been giving advice on making and using audio and video recordings. Advice updated in 2002, and now reviewing it again, eg in the light of revised advice on consent and confidentiality, and new legislation.
- 85 responses to recent GMC consultation, positive overall, but with detailed comments. This going to a committee this afternoon, leading to recommendations and redrafting until February. In the meantime there is still an opportunity for dialogue with GMC.
- Principles of guidance are respect for privacy and dignity, and for patient autonomy. These need to be balanced against rights and public interest in use of images, for example in education.
- Key issues include definitions of anonymisation, ensuring meaningful general consent, and using images of patients with long-term incapacity.
- Doctors can only act in patients' interest (or 'benefit' in Scotland), so how can reuse of images meet this requirement?

Questions to GMC

Many NHS Trusts have good advice and consent forms. The GMC makes no comment about this, despite it being the everyday context of doctors.

GMC: For the sake of simplicity the GMC guidance does not reference local documents that comply with it. If it would be helpful for the GMC documents to reference the existence of local policies then that can be done.

Senior doctors can argue that local policies can be over-ruled by their interpretation of GMC guidelines, which leads to conflict. Junior doctors will learn from their seniors. GMC needs to alert doctors that they need to work within the policies of their local NHS Trust.

GMC: Yes practice is governed by a range of policies, from GMC, common law, local Trust guidance, legislation. These things need to dovetail so that practitioners do not get conflicting or confusing guidance.

The GMC guidance assumes that images stay within NHS. But a lot of them have to move across into the HE domain, and therefore they become the responsibility of HE. The transfer from NHS to HE needs to be addressed in the GMC guidelines.

Would you say that those making recordings are aware of professional guidelines?

GMC: It is not possible to generalise. GMC would welcome input on any references to additional reading or guidance from professional associations that should be referenced by the GMC guidelines.

Image mobility: clinicians may record images, then move between Trusts, can consent migrate with the images? It would be helpful to have some minimum top-level policy into with Trusts etc can plug their local policies; a layered approach.

Also, many clinicians and patients are not always fully aware of the implications of consent.

GMC: Yes it is a very complex area. One area we don't understand enough about is ownership of images, and clinicians' and lecturers' views and traditions on this.

Yes, it is the traditional and practice for lecturers and clinicians to take 'their' images with them.

A further use case is the sharing of images as a part of international clinical trials, and local Trust rules are a real barrier.

Does the Creative Commons concept have a contribution to make, eg release for non-profit use. One problem is with legacy material.

GMC: Guidance is to get consent for legacy material, but is that realistic?

Ownership and provenance of images becomes blurred as the chain extends from NHS to HE settings, eg the link to the patient's medical record is rightly broken.

Consent form is in the form of a contract between patient and Trust's representative. GMC needs to make it clear who is the representative and what liabilities flow from that.

GMC: Our advice is to doctors. Perhaps the guidelines need to be clearer about the boundaries of reasonableness (what counts as acting in good faith?) and limits of their responsibility in ensuring that images are properly used later by third parties.

Another issue is the textbooks in the libraries (and other paper records) that include legacy material that may not have proper consent. By focusing as we are, are we being overly concerned about a limited range of images?

GMC: Yes, this is a fine balance to strike.

Malcolm Teague: the sense of the meeting is that there is an ongoing need for dialogue with the GMC on this issue.

GMC: issues around generalised consent and anonymisation are key for the GMC, and they would welcome feedback on these.

Organising Open Educational Resources presentation

'Medical images' – a better, more inclusive phrase would be 'clinical recordings'

OER programme from JISC and Higher Education Academy, about making existing educational resources freely available and widely used.

Rapid development of technology means we need continually to review IPR and consent issues and the ways in which they are managed, practice, guidance, etc.

OOER project developing toolkits for programmes delivered by non-HEI employed staff and support staff within HE, who are often working at some steps removed from the site at which the recording was made and consent obtained.

Project is mapping potentially open resources and assessing the feasibility ('readiness') of moving them to 'open'. Project is developing workflows to move resources to 'open'.

IPR and consent issues include:

- Who owns the recordings? Is this clear to those who need to know? How does this fit with traditions and practice?
- Ubiquity of digital technologies means processes and guidelines can sometimes be bypassed
- How can the consent status be checked, interpreted and, where needed, changed?

It is now time to engage all stakeholders to get sound, clear, UK-wide guidance (from GMC, HEA, JISC, etc) that is patient centred, future-proofed, encouraging trust between NHS and HE, with proper consent management, and is explicit about its relation with legislation, and dovetailed with guidance for other practitioners.

The position at Bristol

Bristol's clinical students are on NHS site, so there is an increasing transfer of clinical recordings between NHS and HE settings.

- The available guidance is overwhelming for ordinary teachers
- There is a variety of guidance and advice across Trusts, not all of which is helpful in moving recordings from NHS to HE
- Incomplete understanding of consent issues within HE

Bristol is now completing an online resource for teachers and clinicians, bringing together advice and guidance from disparate sources.

In responding to CHERRI report, Bristol found a lot of bottom-up good practice. Top-down (GMC, IMI, etc) role is in agreeing principles to which local advice and practice can refer.

A scenario:

- Someone setting up a course using medical images has to find information from a wide range of information sources; overwhelming. CHERRI suggested a top-down approach to harmonisation. Or the information is synthesised, either at local or national level. Or examples of local good practice are disseminated widely.
- Within the hospital in which the pictures are to be taken, there is good advice and guidance, but this is not joined up with GMC and HE advice and guidance necessarily.
- Tutor is now at a new HEI, and has copied resources there. Who is responsible for managing the long term storage and use of images?

Sinapse project

There is also a domain of research, and reuse of images therein is important and needs to be reflected in guidance and advice.

Six Scottish universities and a range of NHS Trusts, which have very different infrastructure, practices and guidance. For example, Lothian NHS Trust and the University of Edinburgh have, after some years, put an MoU in place covering data sharing across the NHS and HE. Perhaps this could be replicated nationally? Sinapse is exploring other ways in which NHS and HE institutions can cooperate.

Open Educational Resources rationale

There are a range of benefits in making educational resources openly available on the web.

Queens University Belfast

As part of a European project on aging, I am producing images of older people (research subjects), who have given their images and recordings, and consent to use these to produce a book, website, etc. These resources are very powerful. But how do existing guidelines affect what I am able to do with these recordings? I am hesitant about putting them on the web, despite having consent, as I am worried about appearing to exploit people.

Due diligence is the answer, and having gone through the ethics committee (etc), then you have demonstrated due diligence. Informed consent has been freely given. This is very similar to sociological and 'living history' projects that have undertaken similar work.

Institute for Medical Illustration

Issues are privacy and consent, and privacy and confidentiality. These are different; privacy is about unauthorised disclosure of information. Disclosure of information by a doctor (eg sharing a picture) falls under this. But does a doctor have a right under the Human Rights Act of freedom of expression to teach using medical illustrations? The balance has moved away from this. Patients could exercise their rights to withhold consent and impede medical education.

Use of digital technologies is allowing abuse (eg use of camera phones by junior doctors to create a 'visual notebook'). There is an assumption that this is part of the learning process, but this should be a patient rights issue. We need to be diligent at explaining consent (and any time limits for withdrawing consent? NB- It is not possible to retract consent once an image is on the web), or we risk a major court case.

Remaining issues

Trusts are not the only actors. GP partners are also relevant, and each practice will not develop and use its own guidance, so a national approach is essential, to which people can sign up.

NHS Business partners are interested in standards for sharing resources with NHS.

Resources from VLEs are often composites of many images, etc, then re-purposed again to create (eg) virtual patients. How / whether to track consent through these pathways?

There is also the issue of non-clinical consent (eg patient relatives, NHS staff, etc).

Clear principles lead to complex, intelligent behaviour. Model release forms might be an approach.

Medical and public health education will continue to be important, so we should keep the communication open with patients, etc. Many will support the aims of sharing medical images.

European guidelines on drug trials have shut down possibilities for sharing information, which has had negative implications. We need to ensure that doesn't happen in this area. The public need can outweigh patient rights.

'Project' ideas

Attendees were asked to work in groups to describe the priorities for next steps in the form of notional 'projects:

1. Common code of practice

Common code of practice that all using images can agree on. A starting point for common standards in using images. This group has the potential to be a good starting point to start this agreement, though it would need to be expanded.

Dissemination:

Top-down – national bodies can disseminate this

Bottom-up – medical students and trainees, their training programmes and professional bodies need to be engaged

Middle – Many people are in between, eg in NHS. These are often the information gatekeepers.

Outcome: to have connected thinking, so everyone is aware of different policies and practices.

2. Common consent form

Every institute that puts material into the repository uses this consent form. A blanket policy that:

- Covers all future uses of the material
- Understood and accepted by patients and their representatives
- Satisfies regulatory bodies
- Satisfies users that they have confidence to use the material
- Department of Health and other

The policy makes it clear that there are a common set of uses to which these materials could be used. It might cut down the amount of material made available, but it would be worth it.

3. TRIP ("the real picture")

Documenting at local practice

Confession box / amnesty for "scare studies" of bad practice, to galvanise people to action

TRIP website to advise people on the next steps, referencing the GMC and other information

Training module units on information governance, linked to NHS staff record

4. Top down and bottom-up approach – a dynamic equilibrium

We need six clear universal principles for good information governance:

- Informed consent – what constitutes informed consent? Role of various copies (see below). Consent needs to reference all the other principles below. Consent could then be yes / no.
- Ownership – who owns the asset? Need to establish this as part of the process.
- Use and reuse – relation to ownership; licensing model? Reuse might be limited in various ways, which need to be transparent to the patient
- Distribution and dissemination – use on the web?
- Transfer of ownership – does the patient authorise transfer to the doctor's professional colleagues. Transfer of material outside NHS to (eg) HE
- Longevity – for how long is consent granted?

There should be a patient copy, and Trust copy, and education copy and a clinician's copy.

These principles should be developed into workpackages – how to operationalise the principles.

(An example; the UN Declaration on the Rights of the Child – these are widely applied, not reinvented)

It needs to be widely applied and embedded within institutional policies and practices

How to get local adoption?

Digital fingerprinting, the need to tie the material and the consent, and keep them together.

5. Model pathway

Need a system for join-up thinking and common purpose. Need to get stakeholders together.

Convergence in a big summit conference with good speakers representing GMC, HEIs, DoH, etc. This would cover staff development, training, policies and practice, etc.

Discussion

Does this above describe a single project, each of these form a workpackage thereof?

Does this begin to cover other aspects of HEI activity, not just medical issues? Need to define the scope of this activity. Eg, common themes include rewards and incentives, and the use of vocabulary such as 'publishing' rather than 'OER'.

The project needs to embedded in HEI and NHS practice.

There are detailed issues, eg when a parent gives consent on behalf of the child. Due diligence would imply considering how these issues (the principles noted above) apply in the particular case.

Proposal for a further principle – simplicity / clarity. Consent forms generally have too much information. This cannot be overstated: the old post-mortem consent form was very simple but not understood by those giving consent.

There is a risk of not getting any material at all if we ask for too wide consent.

Proposal for a further principle, that of discussion. Consent is a process, eg consent to take a picture, then discussion and separate consent to use the picture. The image (if it were as simple as an image) could then be attached to the patients' copy of the consent form. There is practice already along these lines in NHS.

Who are the stakeholders for this programme of work? GMC, IMI, RCN, RCVS, allied health professionals, academics, ethics people, and law, social science and humanities academics (this could be of wider use that simply medical). Note, the Strategic Content Alliance has done a lot of work about permissions, IPR, etc, which is available in the form of toolkits, etc.

Does a patient own their medical record? Conventionally the NHS claims ownership of recordings taken on their premises. Patients of course would have a right of access. And would these images be a part of the medical record, or separate but related to it in some way?

What would your one message be to NHS-HE Forum or elsewhere?

- Should this group continue to frame and develop the above?
- If hospital systems are very locked down, then this has implications for the sharing of clinical recordings for educational purposes. Hospitals need to be aware of these implications and of their responsibilities with respect to medical education. Many of the policies have been developed bottom-up by technical people who did not want to own the risks, and so locked down the systems excessively. Arguably, though, some higher level managers are taking on the risk and developing and directing policies to enable sharing. Or, are the high profile data loss headlines leading Trusts to become even more risk-averse?
- The IT department is often the biggest obstacle to sharing.
- Learning agreements have been made through Strategic Health Authorities, which have helped learning professionals engage with IT departments.
- Education is about undergraduates, postgraduates, doctors, patients, etc. These arguments need to be made.

The outcomes from this meeting will be presented to the NHS-HE Forum tomorrow. The Forum is not an executive body and relies on voluntary action or projects funded elsewhere to take forward work that is identified as important. The lack of such an executive body limits coordinated action. However, backing by the NHS-HE Forum has led to some very good joint work and tangible outputs.