6. Electronic documents (E-documents)

This chapter considers the issues around document storage and disposal in relation to electronic patient records.

6.1 Retention periods, audit trails and persistence

The Principles of the Data Protection Act 1998 makes it a requirement that data should not be held inappropriately, or for longer than is necessary. In the context of an electronic patient record for a GP this would reasonably be interpreted as meaning that when the patient moves away and/or registers with a new GP the electronic records held by the former GP should be deleted.

Unlike their paper record however, a patient's EPR cannot at present be transferred from one practice to another. Although work on the electronic transfer of electronic records is going on (see chapter 5) implementation is not expected to be widespread before the end of 2007. Another aspect for consideration is the dynamic nature of EPRs. They change over time and there are justifiable reasons why entries in the record may need to be changed, amended or in some cases removed from the viewable record (commonly described as deletion although what in fact happens is that the unwanted record is merely flagged so as to not be displayed, it is not actually deleted from the system). The tracking of these changes is captured in what is known as the "audit trail". This is a separate chronological record held alongside the current patient EPR. It acts as a log of all additions, changes or "deletions" to the patient's record. It is the audit trail that enables a record to be taken back to any date and viewed as it was on that date. Audit trails are of great medico-legal importance in determining the true state of entries in the EPR at any time in the past. Without its associated audit trail, there is no reliable way of confirming that an entry is a true contemporaneous record for that patient. Patients and GPs therefore have an interest in ensuring that EPRs and their associated audit rails continue to be maintained.

Projects to allow exchange of records between systems such as GP2GP and GPEX aim to ensure that EPRs can be sent from one practice to another (see chapter 5 and appendix 2 of these guidelines). However, because of differences in design between different systems, the receiving system may not be able to retain the structure and inter-relationships of the data elements of the transferred record.

Neither will it be possible to transfer the EPR audit trails between systems in the foreseeable future.

With this in mind the GPC has reached an interim agreement with the Information Commissioner that aims to preserve patient EPRs with their associated audit trails. Until such time as electronic transfer of GP EPRs is able to include the associated audit trails, GPs are exempted from complying with the Fifth Principle of the Data Protection Act 1998 and are not expected (or advised) to delete the records of ex-patients. Ideally the EPR should be 'deactivated' on the system so that it is not readily accessible to GP practice staff. It should be possible to 'reactivate' the EPR, but only in limited circumstances (e.g. in order to defend a legal claim etc). Where a record is reactivated, a robust audit trail should show the following;

who reactivated the record;

when the record was reactivated;

why the record was reactivated.

Practices and PCOs should carefully consider the issues around preservation of EPR audit trails before planning changes to GP clinical systems or suppliers (see previous chapter of these guidelines).
The current recommendations from the NHS in Scotland are contained within NHS MEL(1993)152 (http://www.show.scot.nhs.uk/sehd/mels/1993_152.htm) advise that medical records should be retained for the following periods;

Obstetric records – 25 years after ther birth of the child

Records relating to children and young people (including paediatric, vaccination and community child health records) – retained until the individual reaches the age of 25 years or 3 years after death if this is earlier.

Mental Health information recorded before 31st December 1960 is to be kept indefinitely, and that from 1st January 1961 is to be kept for the lifetime of the patient and then for a period of 3 years after death.

GP records must be retained for the lifetime of the patient and for three years after death. Where a patient cannot be traced the records are normally held for 6 years by practitioner services.

Understandably, confusion can arise because of the conflicting demands of the Data Protection Act, medico-legal requirements and SEHD recommendations. In view of this, the agreement between the profession and the Information Commissioner is paramount and GPs must not destroy or delete their electronic patient records for the foreseeable future. (Unless and until such time as these records are transferable in their entirety (including the audit trail) between clinical systems).
The rules regarding retention of medical records in Scotland are currently under review and a consultation paper is available from September 2005.

6.2 Summarising and shredding

With the move to EPRs attention needs to be given to the 50 years of paper records currently held by GPs, PCTs and Practitioner Services Division (PSD).
Practices that wish to be paperless need to develop and implement a process by which records can be moved from paper to electronic format (see chapter 4 of these guidelines). For the purposes of legal admissibility, GPs should obtain and keep written evidence (which may be incorporated into the EPR) of the destruction of the original document. This means;

Identifying each file or document to be destroyed

Recording that the complete file or document has been stored electronically

Ensuring that the electronic version is a true and accurate copy of the original or stating how it is different

It is potentially dangerous for both paper and electronic records to co-exist and this raises issues about keeping both sets of records up to date. It is preferable to have a patient's record as either paper based or electronic. However the reality is that parallel records will remain for some time until practices can summarise their records onto their computer systems. This is a complex and sizeable task. Until a patient's records are summarised then it may be acceptable for elements of the records to be either paper or electronic; such as prescribing records, immunisation, cytology and biometric records. The guidelines below for scanned documents also hold true for summaries of other records or documents in terms of coding and attribution.

The Medical & Dental Defence Union of Scotland (MDDUS) reminds its members that medical records play a major role in medico-legal defence. They advise members to ensure they have taken steps to manage the risks before shredding any scanned information.
The steps should include:

a) A robust backup procedure which includes tape verification

b) A check is made to ensure that there is actually data on the tape

c) A check is made to ensure that scanned documents/data can be reproduced and are legible

The important point is that practices have taken steps to ensure they have a robust system of backing up, verifying and restoring information before shredding the original documents.

6.3 Attachments to the EPR

Clinical systems are becoming more and more sophisticated allowing both export and import of records as well as the incorporation of increasing amounts of external material. Examples include;

Clinical photography

Scanned Images from paper

emails

Images from diagnostic equipment

6 ECG, Ultrasound scanners

Clinical communications (e.g. referral letters)

7 Word-processed Documents, Email

External Hyperlinks

Numeric Data

An ‘attachment’ should always be linked to an appropriately coded entry indicating content. Examples include (table 6.3.1)

6.3.1 Table

Version 2 Clinical Code	Rubric	Note
9N36.	Letter from Specialist	Document in appropriate format
3215.	ECG normal	May be a scanned image of the printed ECG or an electronic version in a variety of formats as below
3395.	Peak Flow Rate	Attached numeric information with appropriate units recorded as well

6.3.2 Legal status

Any attachment to an electronic clinical record should be regarded as having equal medico-legal weight as a notes made within the system and should be accorded the same stringencies around audit trail and backup (see previous chapter of these guidelines). It should also be possible to extract these attachments and send them to the requesting practice either electronically using GP2GP transfer or as a printout or secure file archive. (see chapter 5 and appendix 2).
Before starting to use such facilities a practice should satisfy itself that the system does meet these requirements. Wherever possible all attached data should be stored on the clinical server and not on a separate server. If a separate server is used to store attached data the practice must ensure adequate and appropriate backup provision to ensure seamless continuity should failure occur on either clinical or attachment serving system. Normally practices should expect a system supplier working in conjunction with a PCO to install, configure and test any scanning system.

6.3.3 Attribution

As with any clinical record it is vital that the attribution of the attachment is captured so that date, time and where appropriate clinician or operator are available as well as the date and time and operator making the attachment.

6.4 Format of attachments

Modern operating systems allow the attachment of almost any file and its viewing providing the viewing software is installed on the client machine. Normally these functions are provided by the use of approved software such as Docman, as supplied nationally for all new paperlight practices in Scotland. This provides a standard Index for the filing of the attached records that is transferable with the main clinical record. If use of this is not possible then, wherever possible, the following rules should be followed for the storage of clinical attachments (table 6.4.1).
Practices should take care to make and save a close facsimile of the original document, retaining colour information where it is important to do so (e.g. highlighted information in a letter). File formats and viewing applications should be industry standard rather than proprietary.
A major distinguishing feature between TIFF and JPEG formats is that TIFF can store a number of images in a single file whereas JPEG, in its standard form, can only store a single image per file. This means that a multi-page document stored in JPEG format, consists of a number of files. Medico-legally it may be important to be able to identify these as a single entity.

7.4.1 Table

Word-processed documents	Microsoft Word 97 and above.	Any changes after attachment must be represented in the clinical system's audit trail.
	Adobe Acrobat 4 (or higher)	Use of the ability to lock the document, control comments and printing should be

		considered. Audit trail comments as above
	Rich Text Format Version 1.5 and above	Audit trail comments as above. For compatibility with non-Microsoft viewers images and graphics should not be embedded. Complex layout may also not be retained
Clinical Photography	Tag Image File Format (TIFF) v6 http://partners.adobe.com/public/developer/tiff/index.html	This is an old but well tested and legally admissible file format that will handle colour and black and white images. It is difficult to edit but still must be covered by the audit trail of the clinical system. Care should be taken if the TIFF file is compressed as not all viewers will handle compression. Audit trail comments as above
	JPEG (Joint Photographic Experts Group)	A popular standard supported by the web. The format specifies a compression and hence loss of original data. It works well with natural pictures and less well with line drawings Audit trail comments as above
Scanned Images	Tag Image File Format (TIFF) v6 or JPEG Resolution of 150x150dpi is suitable for document archiving but not for diagnostic images.	For documents for which monochrome representation is sufficient, use TIFF with compression scheme 4 (COMPRESSION_CCITTFAX4) at a minimum resolution of 150x150dpi. For documents that need to

		be rendered with the original colour information, JPEG is recommended with a minimum resolution of 150x150dpi and a compression quality >=50%. Audit trail comments as above Data loss comments as above
Images from diagnostic equipment	Proprietary	Wherever possible this should be avoided for reasons of future legibility. Where this is not possible clear reasons for recording in this way should be retained along with a CD containing the viewing software
	JPEG	Still image – As above for clinical photography
	TIFF	As above for clinical photography
	High Quality Diagnostic moving images	Most modern X-ray and Ultrasound devices will produce high *diagnostic quality* images. They are generally out of the scope of this document but potential users in General Practice should satisfy themselves that the system's storage conforms to the clinical system's audit trail requirements as well as published standards such as DICOMM (http://medical.nema.org)

	AVI, QuickTime and MPEG2	Moving image These are all popular methods of delivering moving information. Both may involve significant compression and data loss and should be used for thumbnail and aide-memoire purposes. They should not be generally used for diagnostic purposes.
Email	Plain text	Preferred
	HTML	Should not include external references, hyperlinks, backgrounds or fonts which may not be available on other systems
External hyperlinks	http://<resource URL> ftp://<resource URL>	The resource should be available to all potential users of the clinical record and should not link to resources only available at the practice. Commitment to the continued maintenance and backup of these resources must be assured.

6.5 Scanning content

When a practice makes the decision to scan incoming patient specific data, several aspects of the process as well as the physical act of scanning should be formalised and controlled. Scanning is an area where many potential gains can be made within a practice. It is also an area where most diversity has occurred. This diversity unfortunately has led to both loss of transferability as well as loss of clinical data; although both of these will be improved with uptake of the new National Index for filing, there is already a substantial number of records to which this has not been applied. . The following guidance should reduce these risks

6.5.1 Workflow

The movement of paper around a practice is complex and specific to each organisation. The move to scanning should ensure that the following issues are covered;

All appropriate people see and comment upon the document

Actions are achieved

8 Patient follow-up / Appointments made

9 Prescriptions issued / medication altered

10 Letters written

Exceptions are covered

11 Holiday absence – who actions documents and how is this logged?

12 Holiday absence – how is catch-up achieved?

Comments and content are added to the clinical record as coded data to ensure clinical system functionality

6.5.2 Specific details surrounding the scanning of a document

When a document is scanned there are two possible outputs;

1. An image of the document – quite simply this is an electronic photograph. Many formats are possible. From the point of view of the Electronic record only the formats detailed above in table 6.4.1 will normally be acceptable.
2. An image is created as above. The computer then attempts to 'read' the document as best it can and turns the image into a word-processed document. This process is known as Optical Character Recognition (OCR). The original image may or may not be kept in this process.

The following table (6.5.3) clarifies which processes are acceptable. It should be noted that a document should also be attached to an appropriate clinical note within the electronic patient record and stored under the same circumstances as any other attachment. The identity of the original author of any document (attribution) must be preserved in the scanned document.
Once a document has been scanned and stored in an appropriate format, and subject to the appropriate system safeguards detailed in these guidelines, then the paper original can be shredded.

6.5.3 Table

Method	Acceptable?	Notes	Dispose of paper?
Storage of image file	Yes	Image be in accepted format Practice must code enclosed data and assure proper attribution for scanned document	Yes

OCR with no storage of original image	No	OCR is never 100% accurate. For medico-legal reasons where the transposition of a single character or number can result in catastrophic errors this mechanism is not acceptable. Clinical decisions should not be made on the basis of OCR'd documents. Previously when disk space was at a premium some practices used this method to capture text from the document for the electronic record while retaining the original paper. This method is no longer acceptable.	No
OCR with storage of original image file	Yes	Image must be in accepted format Practice must ensure that data extracted from the record by OCR matches the original text. Practice must code enclosed data and assure proper attribution for scanned document.	Yes

6.6 Other documents

Practices maintain many different forms and documents about patients that are essential to their day to day operations. Some of these do not form part of the patients' records but carry information about patients, carers and others. Below, we give some examples of these documents and advice about their retention and disposal.

Notification of infectious disease – no need to retain counterfoil providing there is an appropriate entry in the relevant EPR

Message books/logs – ensure any action taken (e.g. phone call/consultation/visit) is recorded in the EPR. No need to retain these books/logs

Ambulance request logs – ensure any action taken is recorded (as above)

X-ray films. These should be retained in line with the DoH guidance above (see section 6.1)

Most of these are "process" forms but may be important medico-legally. If practices are in any doubt about retaining a document we recommend that they scan and store an image of the document in an appropriate format (see table 6.4.1) and then shred the original document. However, where any records relate to patients where there are known medico-legal issues (complaints, civil or criminal law) then practices should keep all relevant records pending further advice from their medical defence organisation, NHS Board or LMC.

6.7 Record completeness on patient transfer

The GMS Contract terms require general practices in Scotland to send "the complete records relating to a patient to the Health Board" upon the patients death or transfer to another practice.
The regulations state that where such records are computerised a copy of records can be returned either on paper or in any other format agreed with the Health Board. Written consent is required from the HB to return records in any format other than "written". Practices with records incorporating attachments must be able to gather these together into one place – either paper or electronic formats – for transmission to

the next practice. Where the receiving practice requests paper formats the sending practice is obliged to provide records as a printout.
The use of compact discs (CDs) to exchange attachments or other electronic records is not currently formally supported by the NHS in Scotland. Any such arrangement should be agreed on a per-case basis between sending and receiving practices