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Recommendations for the retention of Pharmacy records

Although guidance for the retention of medical records has been introduced in the past few years, that for pharmacy records is not as clear cut. This article discusses the background that led to a group of pharmacy managers drawing up a set of recommendations for the retention of pharmacy records

When the Health Service Circular HSC 1999/053¹ providing guidance on managing records in NHS trusts and health authorities was published, it was apparent that pharmacy records had been largely excluded. Statutory guidance exists for those elements of practice covered by the pharmaceutical manufacturing “Orange guide”², and UK Medicines Information have produced policies for retention of their records, but there is a considerable range of pharmacy records that are not covered currently by any legislative or consensus guidance.

It was against this background that pharmacy managers of the then Eastern region agreed to attempt to produce a consensus document on pharmacy records retention that could be used within the region. In the event, it has proved to be a long and complicated project to produce a document that has broad consensus. In the process of pulling the recommendations together, other people became aware of this project and were keen to be kept informed and to see draft versions. It was decided, therefore, that there was a need for the document to be disseminated on a national basis once it was completed. Once the senior pharmacy managers had produced a draft that they were happy with, it was shown to the Royal Pharmaceutical Society via its Hospital Pharmacist Group, and the Pharmacy and Prescribing Branch at the Department of Health. Both made comments that have been incorporated. This is the version that is now being published.

THE RECOMMENDATIONS

These recommendations are intended as guidance only. They have been assembled from consensus views and interpretation of such legislation as has

These recommendations have been prepared by the Eastern Pharmacy Network senior pharmacy managers

impact, however peripherally, on the need for retaining pharmacy records. Before adopting them for local use, it is essential that a risk assessment be undertaken, including, if appropriate, input from the trust’s legal advisers. A key element of any local risk equation must take into account that the storage of the large volumes of paper records that pharmacy departments produce is a difficult, costly and space-consuming process. Retrieval of specific records can also prove problematic unless much time and effort has been invested in efficient archiving systems. It is to be hoped that these recommendations enable secondary care trusts to rationalise the records that they retain and thereby minimise the costs and efforts required for record storage in the future.

The recommendations need to be a dynamic document, so that it can be amended as experience is gained in its use, and as guidance and legislation changes. Any feedback from users will be welcome in order that periodic refinements can be made. Comments should be made via the Hospital Pharmacist Group secretariat, telephone 020 7572 2409, or e-mail lfearon@rpsgb.org.uk.

GUIDE TO TABLE 1

The notes to be found in Table 1 can be explained as follows:

Note 1 GMP stands for good manufacturing practice.

Note 2 Note 1 is a reference to the Consumer Protection Act 1987, which allows patients to make a legal claim up to 10 years after a medicine has been administered. (in paediatric patients this is extended up to 28 years — maturity plus 10 years). If adequate records are available in the patient’s notes, the records should only need to be kept for the period stated under the recommendation.

Note 3 GCP stands for good clinical trial practice.

Note 4 Either delivery notes or invoices should be kept for 11 years as product liability records.

Note 5 The sponsor of the trial is responsible under current legislation for keeping trial records. In-house trials records should be kept for 15 years.

Note 6 All enquiries received by the medicines information service and answers or advice given should be documented using an appropriate form, and kept for a minimum of 10 years. Enquiries relating to children, fertility, gynaecology and obstetrics should be kept for up to 25 years or agreement obtained in writing from the employing authority that the risk of possible litigation after 10 years does not warrant the cost of storage (UKMI Code of Practice, amended 1999).

This document is intended as a guide to pharmacy trust managers based on the best available evidence at the time of publication. Trust pharmacy managers must discuss these recommendations with their clinical governance managers and the trust solicitors before putting them into practice. This is particularly important where current practice varies from that recommended in this document. The Eastern Pharmacy Network senior pharmacy managers accept no liability for the recommendations made, and accept that this is the best available advice at present.

REFERENCES

1. HSC 1999/053 For the record. Managing records in NHS trusts and health authorities. London: Department of Health; 1999.
2. Rules and guidance for pharmaceutical manufacturers and distributors 2002. London: The Stationery Office; 2002.
3. Duthie R.B. DoH guidelines for the safe and secure handling of medicines. London: Department of Health; 1988.

Table 1: Recommendations for the retention of pharmacy records

	Record	Unique record	Reasons for keeping	Recommended minimum period	Comments	
Type of prescription	FP10 (to take out)	No	Audit	2 years	Electronic patient record (EPR) in place would eventually negate this completely — duplication of record held in notes	
	Outpatient	No	Audit	2 years	EPR will eventually hold all details — duplication of record held in notes	
	Private	Yes	Audit	2 years	According to Royal Pharmaceutical Society ethics guides, this is the minimum requirement	
	Unlicensed medicines dispensing record	Yes	Legal	5 years	Requirement of Guidance Note 14. Permanent record of batch details kept in patient notes	
	Parenteral nutrition	No	Audit	2 years	Original valid prescription should be kept in patient's notes	
	Chemotherapy	No	Reference	2 years after last treatment	EPR will eventually hold all details — duplication of record held in notes	
	Clinical drugs trials (non-sponsored)	Yes	Against future claims	2 years after completion of trial		
	Worksheets	Paediatric	Yes	GMP (Note 1)	At least 5 years	Product liability extends to up to 28 years (Note 2)
		Chemotherapy/aseptics worksheets	Yes	GMP	5 years	Product liability extends this to 11 years after expiry
		Parenteral nutrition	No	GMP	5 years	Product liability extends this to 11 years after expiry
Resuscitation box		Yes	GMP	1 year after expiry of longest dated item	Applies only to repackaged items (eg, ampoules separated from outer packaging)	
Production batch records		Yes	GMP	5 years	Product liability extends this to 11 years after expiry	
Extemporaneous dispensing records		Yes	Product liability	5 years	Product liability extends this to 11 years after expiry	
Raw material request and control forms		Yes	GMP	At least 5 years	Part of batch record so product liability issues apply	
Quality assurance		Any QC documentation	Yes	GMP	5 years or 1 year after expiry date of batch	Whichever is the longer. Article 51(3) of Directive 2001/83
		Certificates of analysis	Yes	GMP	5 years or 1 year after expiry date of batch	Whichever is the longer. Article 51(3) of Directive 2001/83
		Standard operating procedures	Yes	Health and safety	15 years after superseded by revised version	As electronic record in perpetuity
	Environmental monitoring results	Yes	GMP	1 year after expiry dates of products	As electronic record in perpetuity	
	Validation of operators	Yes	GMP	For duration of employment	In personal portfolios	
	Validation of equipment	Yes	GMP	For life of equipment		
	Refrigerator temperature	Yes	GMP	1 year	Refrigerator records to be kept for the life of any product stored therein — particularly vaccines	
	Recalls	Recall documentation	Yes	Audit	5 years	Recommendations from the 'Good distribution guide' — especially for those with wholesale dealers licence
	Orders	Order and delivery notes	No	Audit	2 years	Current financial year plus one (Note 3)
		Requisition sheets	Yes	Audit	2 years	Current financial year plus one
Controlled Drug registers (pharmacy based)		Yes	Legal	2 years	Misuse of Drugs Act 1971, and Misuse of Drugs Regulations 2001	
Controlled Drug registers (ward based)		Yes	Audit	2 years	Duthie guidelines ³ recommend that person in charge of ward should keep register	

Table 1: Recommendations for the retention of pharmacy records (continued)

Record	Unique record	Reasons for keeping	Recommended minimum period	Comments
Controlled Drugs prescriptions (TTOs/OP)	No	Legal	2 years	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 years
Controlled Drug order books	No	Legal	2 years	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 years
CD ward orders or requisitions	No	Legal	2 years	Misuse of Drugs Regulations 2001 states that all CD prescriptions should be kept for 2 years
Ward pharmacy requests	No	Uncertain	1 year	Record of what was originally requested by ward pharmacist — unlikely benefit after 12 months
Picking tickets/delivery notes	Yes	Uncertain	3 months	A “reasonable” period — for verification of order only
Old order books	No	Audit	2 years	As for requisition sheets
Ad hoc forms (eg, dispensary requisition forms to stores)	No	Uncertain	3 months	Reasonable period and current practice
Invoices	Yes	Legal requirement	6 years	Limitation Act 1980 (Note 3)
Clinical trial Production batch records	Yes	GMP/GCP (Note 4)	5 years after completion of trial	Article 13 of Directive 2001/20/EC
Protocols	Yes	Reference	2 years (Note 5)	
Dispensing records	Yes	Reference	2 years	
Destruction records	Yes	GMP	2 years after completion of trial	
Errors				
Dispensing error records (internal)	Yes	Audit	1 year plus current	Database should be kept permanently
Dispensing error records (external)	Yes	Audit	1 year plus current	Database should be kept permanently
Stock control				
Medicines				
Stock check lists	Yes	Audit	1 year plus current	As in HSC 1999/053
Enquiries	Yes	Reference and audit	10 years (25 years for those relating to children, fertility, gynaecology and obstetrics)	(Note 6)
Miscellaneous				
CD destruction record (pharmacy based)	Yes	Legal requirement	2 years	Misuse of Drugs Regulations 2001 — CD destruction records should be made in the CD register
CD destruction record (ward based)	Yes	Audit	2 years	Duthie guidelines recommend that destruction of CDs should be witnessed and a record made in CD register
Doctors’/nurses’ signatures	Yes	Reference	Duration of contract plus 1 year	1 year after termination of employment (not referenced)
Self administration records	No	Reference	Not required	Will be kept in nursing notes/main medical record
Clinical interventions	Yes	Audit	2 years	Two-part form recommended, original to be added to patient record, duplicate kept for 2 years (not referenced)
Destruction of patients’ own drugs (includes CDs)	Yes	Audit	6 months	Duthie guidelines ³ state that patient’s own drugs are property of patient and should only be destroyed with patient’s permission

NB: Notes 1, 2, 3, 4, 5 and 6 can be found on p222