

Recording of drug allergies: are we doing enough?

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Abstract

Objective To assess the implementation of local and national guidelines concerning documentation of drug/clinical hypersensitivities.

Design Audit with retrospective and prospective components used to assess the process of drug hypersensitivity documentation.

Patients Fifty surgical inpatients' notes were retrospectively analysed followed by 63 patients prospectively.

Setting West London teaching hospital.

Main outcome measures Drug hypersensitivity status correctly indicated on clinical notes, drug 'Kardex' charts, and anaesthetic records; these three documents were to concur. Hypersensitivities qualified according to symptoms experienced.

Recommendations Standardization of preoperative clinical notes and multidisciplinary responsibility for records between doctor, nurse and pharmacist.

Results Hypersensitivity documentation in clinical notes improved by 7% after the introduction of a formalized history sheet for preoperative clinics. These were based upon the anaesthetic charts, which had demonstrated 100% documentation previously. Considerable improvements (70.8%) in the clarification of adverse reaction symptoms post recommendation were shown; this was also attributed to the new history sheet. Concurrence improved by 2%.

Conclusions The original study revealed areas for improvement and provided part of the solution – a more standardized preoperative assessment tool. Multidisciplinary cooperation in addition to formalizing the assessment process has led to a more efficient and safer service for patient and medicolegally for health care professionals.

Key messages (1) Standardized forms, for the recording of clinical information preoperatively, ensure relevant guidelines are implemented in practice. (2) Multidisciplinary teams provide a vital safety net for their patients and colleagues.

Introduction

An adverse drug reaction (ADR) defined by the World Health Organization (WHO) as 'a response to a drug that is noxious and unintended which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the restoration, correction or modification of physiological function' [1]. Some drug reactions occur in anyone, known as augmented reactions or type A and include side effects and drug interaction. Others occur in susceptible patients, known as bizarre reactions or type B and include intolerance, allergies or pseudo allergic reaction.

Adverse drug reactions contribute significantly to patient morbidity and mortality [2]. Hospitalized patients are at an extremely high risk of ADRs due to the number of diagnostic and therapeutic

procedures that they undergo on a daily basis [3] which was emphasized further by the National Audit Commission's 'Spoonful of Sugar' report [4], which reported 1100 deaths directly linked to drug errors at an overall cost to the National Health Service (NHS) of £500 million per year in addition to similar reports from the US [5–9] and Australia [10]. The NHS has begun to place greater emphasis on patient safety and published two further reports [11,12]; both pressing for improvements and the National Patient Safety Agency was launched in April 2001.

It has been suggested that 7% of inpatients are affected by an ADR [13], a potential 7% [9] of these are due to medical error and of these 12.1% are directly due to poor appreciation of drug allergies [14]. Adverse reactions have been attributed to many different mechanisms, many not fully understood, which may

explain the inconsistencies in differentiating between drug allergy and other drug reactions. Fatal allergic reactions, that is, anaphylactic shock occur in 0.01% of surgical patients and 0.017% of patients undergoing general anaesthesia [15] but drug hypersensitivities are still underestimated by the health care profession.

To establish whether true allergy is the trigger for an adverse reactions the following need to be considered; nature of reaction, timing, dose relationship and other possible causative factors; all of which can be obtained during a precise and detailed patient history. Doctors, nurses, pharmacists and medical students are aware of the importance of establishing whether a drug allergy is present or not, but this is not routinely recorded or even asked.

Medication errors are multifactorial and multidisciplinary. Errors can occur at any point during the process of prescribing, dispensing, administration or communication. Contributory factors include; illegible handwriting, inaccurate or incomplete drug history/allergy taking, drug name confusion, lack of pharmaceutical knowledge and a non-questioning work culture.

Critically a national reduction of drug errors by 10% in the NHS in 2001 could have potentially saved 110 lives and £50 million. Only through audit and implementation of new interventions can these figures improve resulting in enhanced patient safety.

The study presented here analyses the implementation of national and local Trust guidelines [5,11,12,16–18] within the Academic Surgical Unit, St Mary's Hospital, Paddington.

The overall intention of the study was to assess the recording and quality of recording of known drug/clinical material hypersensitivities within patients' clinical notes, drug charts and anaesthetic records and determined the degree of concurrence between the three documents. Further if the results did not meet the set criteria recommendations for improvement were made and a further prospective study was carried out to assess their impact.

Method

We retrospectively reviewed the notes of 50 surgical patients over a 7-month period from August 2003 to March 2004. Operation types included both acute, for example appendicectomy, and elective, for example planned laparoscopic cholecystectomy.

Clinical notes, drug charts, anaesthetic charts for the admission in question, that is, from preoperative 'booking clinic' till discharge were scrutinized for the set criteria (Table 1). Of the 50 patients most sets of notes were found in medical records or around different departments within the hospital; however, four sets of notes remained untraceable, leaving an audit population of 46.

Evaluation included the confirmation of the following:

- to ascertain whether the patient had a known, documented drug/clinical material hypersensitivity by performing a search of all clinical notes within the medical record system;
- to determine whether the above information was documented within the patient admission notes;
- to assess whether the severity/nature of the hypersensitivity had been considered; and
- to ensure correct transfer of information from clinical notes to all drug charts and anaesthetic records for that admission.

Target criteria and standards were set up to meet these aims as part of the audit cycle, as shown below (Table 1).

Table 1 Audit criteria and standards

Target criteria	Target standards
The presence or absence of known drug/clinical hypersensitivities should be clearly indicated in the preoperative clinical notes for the current admission.	100% of preoperative clinical notes clearly identify whether a drug/clinical hypersensitivity is present or not.
Drug charts should correctly indicate in the designated box the presence or absence of known drug/clinical hypersensitivities.	100% of drug charts indicate correctly the presence or absence of known drug/clinical hypersensitivities in a formalized manner
Anaesthetic records should indicate correctly the presence or absence of known drug/clinical hypersensitivities in a formalized manner.	100% of anaesthetic records indicate correctly the presence or absence of any known drug/clinical hypersensitivities in a formalized manner
The nature of the hypersensitivity reaction should be documented in the preoperative clinical notes for the current admission.	100% of preoperative clinical notes identify a past hypersensitivity reaction with symptoms denoted.
Clinical notes, drug charts and anaesthetic records should be in agreement.	100% of patient information in accordance.

Areas that were lacking in the initial study were addressed and through multidisciplinary involvement recommendations were implemented. The aim was to prevent further omissions within medical notes and therefore to reduce the possibility of potential adverse drug reactions.

Interventions and recommendations

1 Introduce a formal document for preoperative booking clinic (Appendix 1). This form was designed to address all the information required, such as history, examination and plan not just to improve drug allergy status documentation. The case notes were analysed, by an independent assessor, after each clinic for the documentation of drug allergy status and relevant reaction details – according to the criteria.

2 All members of the team to look for drug allergy documentation. Individual key members of the medical, nursing and pharmacy teams were approached and a discussion pertaining to the initial results and recommendations occurred. All personnel were keen to check documentation when appropriate (see below)

3 Nursing staff to confirm that allergy status is documented. This was agreed to be carried out during drug rounds as part of the '5Rs'; right patient, right drug, right dose, right time and via the right route indoctrinated into nursing practice.

4 Pharmacists to detect if the drug allergy status is unrecorded or drug brand name used. To achieve this the ward assigned pharmacist screened all charts and corrected/highlighted relevant cases on the drug charts and communicated this to either nursing or medical staff. The pick-up rate and therefore success of this recommendation was not formally assessed only via the overall improvement seen.

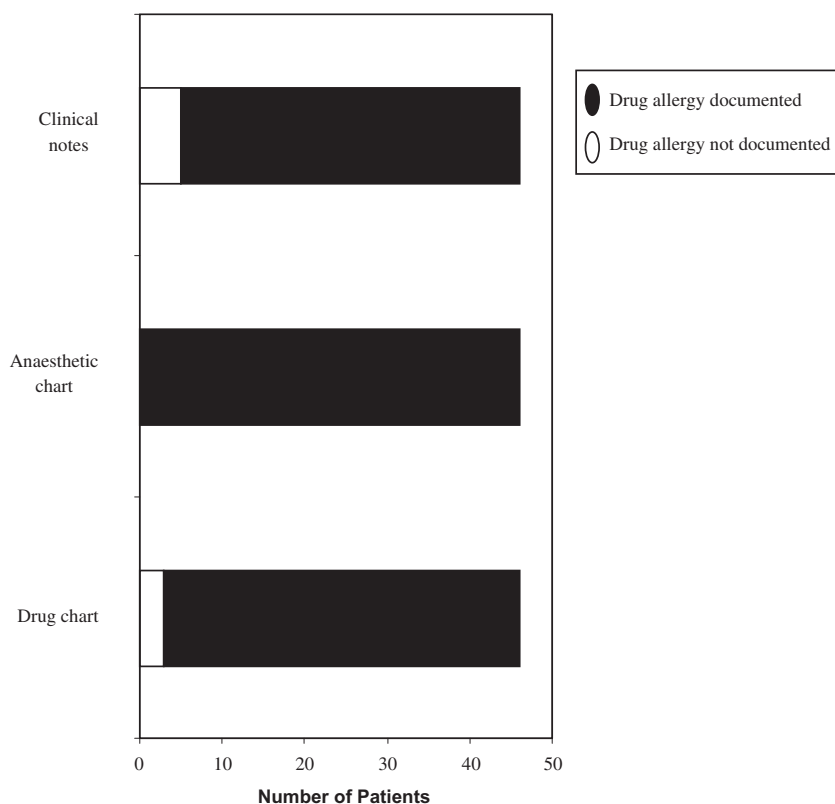


Figure 1 Judiciousness of drug allergy documentation in the first audit.

5 Medical staff to refrain from rewriting drug charts when distracted and to make surreptitious checks.

Following the recommendations the process was repeated to evaluate the implementation of the recommendations and if the target criteria had been met as per previous study.

In the second study 65 sets of notes were studied; 41 were inpatient notes from the surgical department, which included drug charts and 24 preoperative booking clinic notes over a 6-week period from 6 October 2004 to 19 November 2004. Operation types included both emergency and elective.

Two inpatients had also been seen in the preoperative booking clinic and assessed using the new forms and were therefore analysed only once when calculating an overall figure for drug allergy documentation in the clinical notes.

Clinical notes for the admission in question, that is, from preoperative 'booking clinic' till discharge, including all drug charts, were scrutinized for audit criteria.

Results

- Clinically relevant hypersensitivities should have either their presence or absence clearly indicated in current clinical admission notes.

Forty-one of 46 (89.13%) of all clinical notes pertaining to the current operation had the allergy status documented (Fig. 1), which does not meet the criteria standards (100%) set by this audit. One out of the five omissions had a drug hypersensitivity to amphotericin (Fig. 2); this was, however, indicated on all drug charts and anaesthetic records.

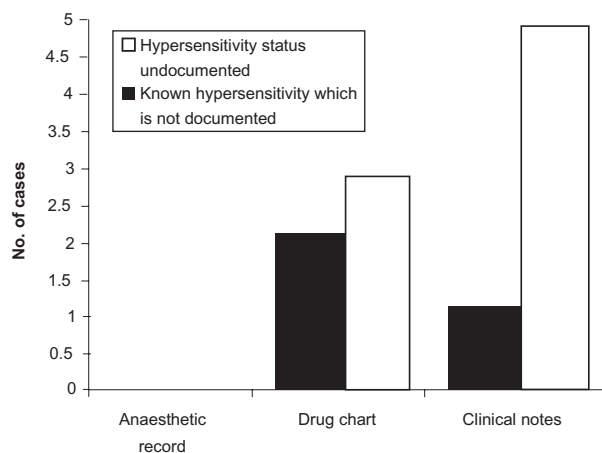


Figure 2 Failure to document hypersensitivity status and known allergies in first audit.

Post-recommendation inpatient preoperative notes had the patient's drug hypersensitivity status documented in 95.1% of cases, preoperative booking clinic identified drug allergies in 100% of the 24 cases and both these figures when considered jointly provided an overall rate of 96.8% (Fig. 3). Although this still falls below the audit standards set in this study there was an improvement of approximately 7% when comparing with the previous study.

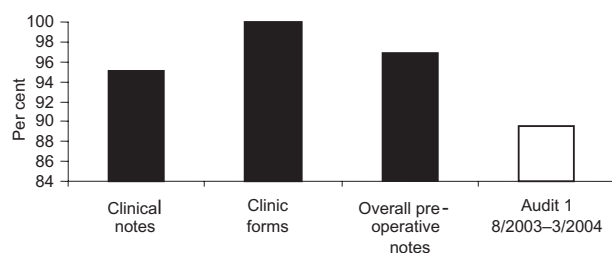


Figure 3 Second audit – improvements in drug hypersensitivity documentation in clinical notes: 10/2004–11/2004.

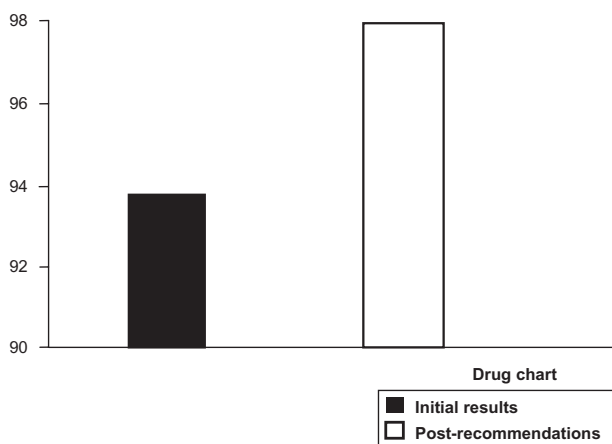


Figure 4 Comparison of drug hypersensitivity documentation on inpatient drug charts in both audit cycles.

- All drug charts should correctly indicate in the designated box the presence or absence of known drug/clinical hypersensitivities for the current admission.

Forty-three out of the 46 patients (93.5%) had their drug hypersensitivity status documented on their entire drug charts, again this failed to meet the 100% target set in this audit. Of the three cases unrecorded two had reported hypersensitivities (Fig. 2) to penicillin and plaster tape respectively.

Drug charts had drug hypersensitivities recorded in 98% of the patients studied after recommendations were made. In the case of the one patient in whom the drug chart had not been completed, the pharmacist had highlighted the omission. As shown in Fig. 4 compared to the results from audit 1 there was an approximate improvement of 3%; however, audit standards were not fulfilled.

- Anaesthetic records should indicate correctly the presence or absence of known drug/clinical hypersensitivities for the current admission in a formalized manner.

Correct anaesthetic recording of known drug hypersensitivities or otherwise was 100%, which meets the standards set by this audit (Fig. 1).

- The nature of the hypersensitivity reaction should be documented in the preoperative clinical notes for the current admission.

One of the seven patients (14.3%) with documented hypersensitivities had the symptoms of the reaction clarified and documented within their clinical notes (Fig. 5). When corrected for the patient whose hypersensitivity was undocumented, the figure becomes

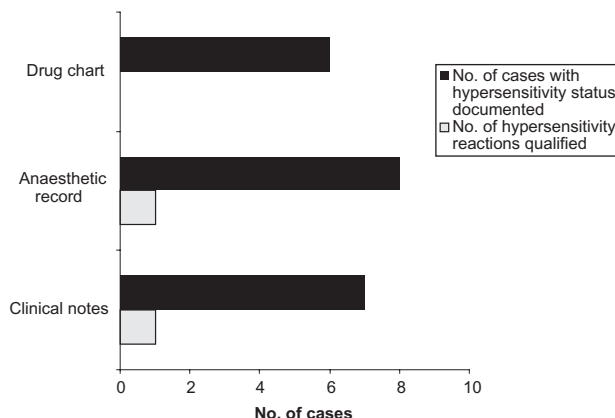


Figure 5 Assessment of symptoms caused by hypersensitivity in first audit.

Table 2 Failure in documents to agree in one patient

	Allergen recorded
Clinical notes	Elastoplast, Chlorhexidine & Iodine
Anaesthetic record	Elastoplast & Iodine
Drug chart	Elastoplast & Iodine

one in eight patients or 12.5%, well below the 100% criteria standard set by this audit.

Documentation for the same one patient was noted in the anaesthetic records and therefore this also had a 12.5% rate for qualification of symptoms. The patient had suffered anaphylactic shock on treatment with penicillin – this reaction, however, was not noted on the relevant drug charts. Drug charts failed to document any symptoms in the eight cases of hypersensitivity identified, that is, 0%.

Six patients from the 63 patients in total (post-recommendations) reported having drug hypersensitivity, out of these 5 patients had the type/symptoms experienced documented (83.3%). Three of these were from the preoperative booking clinic. Compared to the results from the prior audit, which yielded a result of 12.5%, this is an improvement (+70.8%) even though the 100% set as a standard was not reached.

- All three areas of documentation: clinical notes, drug charts and anaesthetic records should be in agreement.

Concurrence standards set by this audit required 100% of reviewed data to be the same in all documentation. Documentation of whether a drug allergy was present or not (Fig. 1) did not provide data that could conflict as no record was made and therefore is omitted here. In terms of actual recorded details and information 98% (Fig. 6) concurrence was met. A patient with known hypersensitivities had the nature of the allergen differing in the three documents analysed (Table 2) and audit standards were not met because of this one inconsistency.

Post recommendation there was a concurrence of 100%.

Discussion

Documentation of drug allergy status in clinical notes and drug charts, in the first study, fell short of standards, unlike the 100%

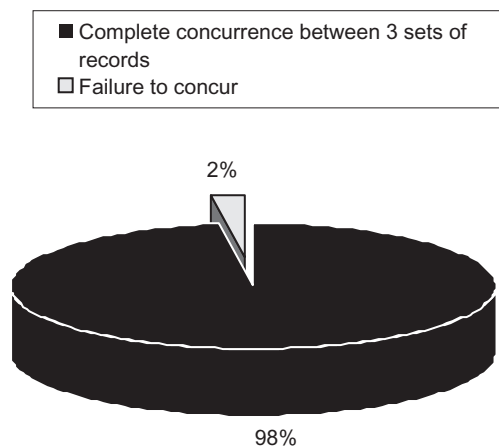


Figure 6 Concurrence between clinical notes, anaesthetic records and drug charts in first audit.

achieved by the anaesthetic records for the same patients. Reasons for the high standard displayed by the anaesthetic team were sought. Drug hypersensitivities to anaesthetic agents are severe and common they are therefore actively sought by anaesthetists and it was felt that the 'tick box' style of the blue anaesthetic record form encouraged consistent documentation, unlike the standard continuation sheets commonly used by PRHO's in the preoperative booking clinic and on the wards.

Recommendation 1

- Introduce a formalized document for preoperative booking clinic, which will be easily identifiable within the notes, that is, coloured and include a box for drug allergies and type of reaction experienced.
- Members of the team should actively seek drug allergy documentation within the notes in an emergency admission or to ask those patients not seen in a preoperative booking clinic as part of routine admission procedure.

Drug charts are a standardized format with a specified box for drug allergy documentation, but these were not always completed. Predominant factors are, as highlighted by junior doctors, time pressure and late night/overnight requests for prescribing requiring charts to be rewritten. Both of these concern the transfer of information between charts. Dispensing drugs is one of the high-risk areas in nursing practice leading to the development of the 'five rights' – right dose, right medication, right patient, right time and the right route. Pharmacists also ensure that these principles are adhered to and that the appropriate treatment regime is given. Several members of the multidisciplinary handle drug charts, therefore a multidisciplinary solution may be required.

Recommendation 2

- Nursing staff to confirm allergy status is documented on every drug chart of every patient during medication rounds, that is, 'right documentation'. If an omission is noted this should be brought to the attention of a member of the relevant team, this will safeguard the patient, nursing and medical staff.

- Pharmacists to highlight if the drug allergy status is unrecorded, or if a brand name is used instead of a generic name, which may lead to confusion.
- Medical staff to refrain from rewriting drug charts when distracted, for example, during ward rounds and to make surreptitious checks that the drug allergy status is present while prescribing a drug.

Consideration was given to secondary methods of identifying patients with hypersensitivities, for example, red 'allergy' wristbands and/or bedside signposting; however, inconsistent use of these measures may lead to an increase in risk.

General practitioner (GP) practices are using computerized systems as a virtually standard resource in identifying patients with drug hypersensitivities as well as checking for interactions, a system which is continued at the pharmacist during prescription dispensing. Nonetheless, the number of tertiary centres employing such measures is low and it has been estimated that by the end of 2005 less than 10% of hospitals will have an electronic prescribing system. However, it must be considered that doctors, on call and at night, will not necessarily have access to such a system and the continued manual recording of information is more reliable as all members of the team responsible for patient care can have quick, open access to such details. Transfer of information is also essential, for example, through the GP's referral letter, discharge summary, etc. for any system whether computerized or written to function effectively.

Conclusion

The problems and sources of all medical errors can be summarized as (1) illegible handwriting, (2) inaccurate/incomplete history taking, (3) drug name confusion (use of brand name), and (4) use of abbreviations and verbal reporting, all of which are factors pertaining to the individual. Institutional factors such as poor procedures, inadequate checking, unreasonable workloads, poor housekeeping standards and a reluctance to highlight another's mistake or omission only increase the risk to the patients.

It is hoped that this audit has underlined the past failings to adequately record and appreciate the role of drug hypersensitivity within the department. Although, thankfully, none of the patients experienced an adverse drug reaction due to medical error during this audit, a case was reported in another department whereby a patient was given morphine during a night shift – no record of their past anaphylaxis was noted and they experienced another, severe reaction.

Since the initial results, the recommendations made in response to these appear to have had a positive effect. An effort was made to consider the importance of the multidisciplinary team in the maintenance of accurate record keeping. All staff, regardless of their job title or whether they are experienced or inexperienced can be responsible for mistakes and therefore all of us need to be aware of the possible consequences of a failure to meticulously record information in patients notes, in terms of patient care and medico-legally.

Overall improvements were seen in both documentation of drug allergies in preoperative clinical notes and the bedside drug charts. Multidisciplinary cooperation is essential and with the advancement and continuation of the measures introduced within the remit of this audit standards should be maintained and improved. A

much larger study is required to confirm the benefits of such an intervention.

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Appendix

Pre-operative booking clinic form

ASU BOOKING CLINIC DATE:

NAME:

D.o.B:

HOSP. NO.:

TCI	OPERATIVE DATE:	
PC:	SEEN BY IN O/P:	
HPC:		

PMH:

T B HT RF Epi Asth DM CVA MI Jau Chol GA reactions

SYSTEMIC REVIEW:

CVS: CP Palp. SOB, Orth. PND IC O

Resp: Cough, Sputum, Blood

GI: WL, Change, Blood, Mucus, Reflux

GU: Dysu Freq, Blood, Prost

Neuro: LOC, Fits, Visual

RELEVANT FHx:

DH:

ALLERGIES:

TYPE OF REACTION:

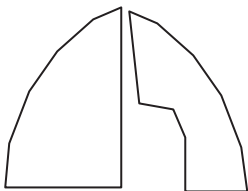
DRUGS STOPPED PREOPERATIVELY:

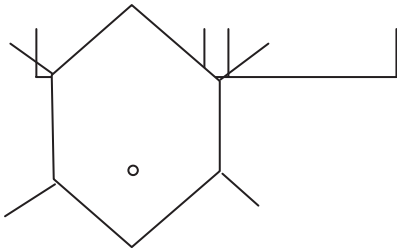
SH:

SMOKING:

ETOH:

ON EXAMINATION:



GENERAL: Obs: BP HR RR Sats % BM J A C I C y O L 	RESPIRATORY: Expansion: R L PN: Wheeze: Crackles:
CVS: HS: I II I JVP: Apex: Pulse: NEURO: Grossly intact: Y/N	GI: Abdo: soft tender distended Masses Organomegaly AAA BS Herniae:
<u>PLAN:</u> BLOODS: ECG: CXR: ECHOCARDIOGRAPHY: OTHER IMAGING: LUNG FUNCTION TESTS: OTHER TEAM TO REVIEW: ADMISSION REQUIREMENTS, e.g. ITU bed: SIGNED:	