Quality of electronic records documenting adverse drug reactions within a hospital setting: identification of discrepancies and information completeness

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ABSTRACT

AIM: Incomplete and incorrect documentation of adverse drug reactions (ADRs) can restrict prescribing choices resulting in suboptimal pharmaceutical care. This study aimed to examine the quality of information held within electronic systems in a hospital setting, to determine the preciseness of ADR documentation, and identify discrepancies where multiple electronic systems are utilised.

METHOD: Over a four-week period, consecutive patients admitted to the general medical ward at the study hospital had their electronic profiles reviewed. Patient demographic information (de-identified), ADR history and discrepancies between information sources (as recorded in all electronic systems utilised at initial prescribing) were recorded and analysed.

RESULTS: Over the four-week period, 332 patient profiles were reviewed, and over 1,200 alerts were identified and analysed (including duplicates of ADR reactions). Of these patients, 151 (45.5%) had at least one documented allergy or intolerance which generated 585 reactions, relating to 526 unique events. A further 151 (45.5%) were classified as having *no known* (drug) allergies or intolerances; however, 20 (15%) of these patients did have at least one allergy documented in at least one other electronic system. The remaining 30 (9%) patients were classified as having an *unknown* allergy status and of those nine had allergies documented in at least one other electronic system. Further, most systems contained information duplication, which had not been addressed during the admission process.

CONCLUSION: ADR information was both imprecise and inaccurate, as multiple discrepancies between ADR information recorded in different electronic patient management systems were found to exist. Information sharing between systems needs to be prioritised in order to allow full, accurate and complete ADR information to be collected, stored and utilised; both to reduce current inadequacies and to allow optimal pharmaceutical care.

Incomplete documentation of known adverse drug reactions (ADRs), which includes both allergies and intolerances to medications, can potentially lead to inappropriate prescribing, compromised patient outcomes and patient harm.[1–3] The World Health Organization (WHO) defines ADRs as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man" and can range from intolerances such as mild gastrointestinal upset, headache, nausea or diarrhoea to medical emergencies involving true hypersensitivity such as anaphylaxis involving rash, angioedema and respiratory distress.[4–5] In general, ADRs are not well understood by patients, which can lead to both over- and under-reporting of reactions. This may lead to misdiagnosis and inaccurate or incomplete classification and documentation by healthcare professionals.

As ADRs related to medicines could be intolerances or allergies, re-exposure becomes problematic. True allergic reactions can be life threatening and therefore re-exposure should be avoided if at all possible, whereas intolerances do not necessarily preclude the use of the suspect medication or medications with possible cross-sensivity.[2]

This means inadequate documentation of ADRs can lead to suboptimal patient care. For example, if allergies are listed as intolerances and prescribers rechallenge with the offending agent, this may lead to severe allergic reactions and a risk of death that could have been avoided with proper documentation.[7] Conversely, intolerances listed as allergies often limit the therapeutic options available to prescribers; prescribers then resort to prescribing second- or third-line medications, which may be less effective or carry higher risk of further adverse reactions.[1]

The increasing use of technology and integration of electronic health records (EHR) allows information to be held "permanently" and to be more easily accessed at the time of therapy initiation, such as on admission to hospital. Within New Zealand, integration of electronic patient management systems and national reporting of ADRs against patient unique National Health Index (NHI) numbers[8] means there is the potential for enhanced sharing of information that is more timely and complete, making prescribers more appropriately informed.

However, these systems are only as accurate as the information that is currently entered (or historically held).[9] Additionally, with the convergence of multiple information systems that may not be fully integrated, this can contribute to data loss or duplication when the systems cannot accurately communicate.[11] This contributes to cluttered patient profiles, which may obscure important information. Further, the electronic inputting of allergy and intolerance information can become complex due to system deficiencies. For instance, some systems are limited in that they cannot record the difference between an allergy or an intolerance, or they can record a class allergy but not a class intolerance, and this results in information being entered in a suboptimal manner with the possible loss of information or in cumbersome entering needing to be duplicated. This leads to further issues when the doctor needs to make a prescribing decision. Ideally, electronic prescribing systems should have the capacity to allow accurate and precise, or correct and complete, data entry of medication allergies and intolerances and should allow conservation of high-quality information.[12] There should also be safeguards against duplication of information, conservation of inferior information and removal of information.

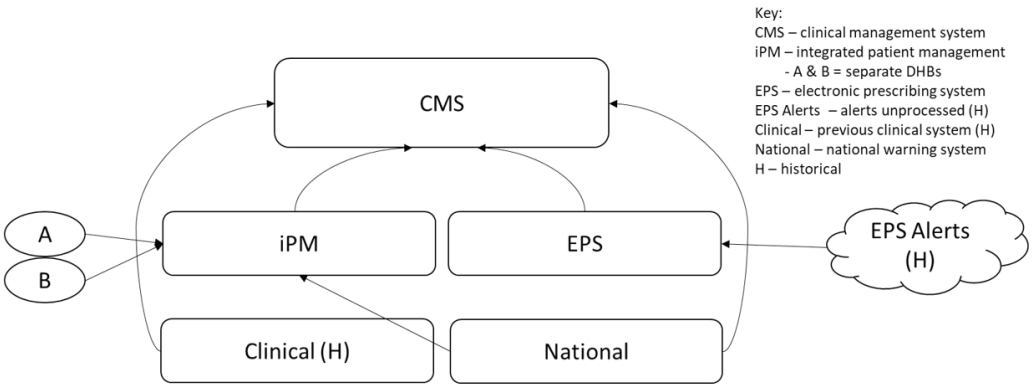
In a previous study comparing paper-based and electronic storage of ADR information, it was found that there can be suboptimal, incomplete and conflicting ADR reporting documented in patient management systems (both paper and electronic) used in this hospital in New Zealand.[13] The aim of this study was to assess the quality of ADR information by identifying the nature of discrepancies, duplications and incomplete information within the current *electronic* prescribing tool. Once the scale and complexity of poor information storage and transfer for ADR records are quantified, it will be possible to determine how this information can be better utilised and to appropriately prioritise information storage for ADR information. This will then allow prescribers to efficiently and confidently access information on ADRs that is both accurate and precise, so as to inform prescribing practice for optimal pharmaceutical selection to allow best possible patient outcomes.

Method

Study context

This study was undertaken at a tertiary hospital in New Zealand with approximately 400 patient beds. Various electronic systems, including an electronic prescribing system (EPS), are utilised within the hospital to manage patient data, including documentation of ADRs. Additionally, an integrated clinical management system (CMS) which merges information from multiple databases to maintain a comprehensive patient summary is used and this overarches the other electronic systems (see Figure 1).

Figure 1:



There are three key databases relevant for holding ADR information that were focused on in this study. Firstly, the integrated patient management system (iPM) which holds information such as a patient's address, contact details and some background clinical information. Secondly, there is the overarching clinical management system (CMS), which holds the clinical information relevant for the current admission, and thirdly, the EPS. However, as the electronic system has changed over time, there are also the previous versions of the patient management systems (iPMA and iPMB) that feed into the CMS. This is also complicated by the fact the current district health board (DHB) is a merger of two previous DHBs, each of which had its own patient management system. All of these historical electronic systems hold ADR information. Finally, in New Zealand external information is pulled into a patient's DHB profile from the National (Medication) Warning System, which 'houses' individual alerts and national warnings linked to an individual via use of the National Health Index (NHI) number. All of this information feeds into both the CMS and the iPM.

When accessing and prescribing in the EPS, the initial task is to review all information that has been imported into the electronic medication chart. This consists of viewing all (previously) processed and unprocessed ADR listings, including historical EPS alerts held and generated from the previous versions and updates of the EPS. This requires a clinician to review the ADR records to allow them to move into the current EPS. In all there are six separate repositories that hold ADR information and can be accessed at admission in the prescribing process. This does not include any community-held ADR information, eg, from the patient's community doctor.

Given these different information sources, not all information is current, validated or appropriately detailed, so ADR information can be incomplete and/or inaccurate. Further, there is significant duplication in reports and variation in quality, that is some only list the agent implicated, while others also give the clinical reaction experienced, but few list the date when the ADR occurred, while it is very rare to find information of re-challenge and/or cross sensitivity. Until very recently, this information was currently only available to prescribers and not associated healthcare team members such as pharmacists and nurses. In summary the data transferred between systems is currently non-synchronous which, in many cases results in an inadequate and incomplete summary of patient-specific ADRs.

Data collection

This study was intended as a quality improvement audit which did not require HDEC ethical approval as all patients were 18 years or over and patient data was de-identified at initiation of the audit. Local approval was completed, as was Māori consultation. All electronically recorded patient-specific ADR information available to prescribers at initiation of prescribing (from all six sources) were accessed over a four-week period between 8 January and 7 February, 2018. Patients admitted to the general medicine service at the study hospital during this time were included in the analysis. Patient demographics including age, gender and number of documented ADRs were collected. Where available, the causative agent, drug or drug class, reaction and classification (ie, allergy or intolerance) were recorded. Patient profiles were viewed in the CMS and the EPS to determine if there were known ADRs, no known ADRs or an unknown allergy status (ie, the allergy status has not been determined), as well as

the status selected by the initial prescribers on the EPS. These are the two systems that prescribers would access when initiating therapy. All six repositories were then accessed to determine if there was other ADR information held. The veracity of the ADR information was not independently investigated and verified with patients during this study.

Data analysis

Data collected was compared between the different electronic patient management systems to determine the content and extent of information held across the systems, to examine the level of detail present and to identify discrepancies and where they occur. Discrepancies were identified when systems contained information that did not match. For example, medication class or reaction manifestation was incomplete or intolerances and allergy appeared to be misclassified. Evaluation of ADR classification, that is allergy versus intolerance with regards to the causative agent and reaction documented, was then conducted where appropriate (reaction types were defined as per Inglis 2017),[6] that is a rash was deemed to be an allergy whereas diarrhoea was deemed to be an intolerance.[5,6] Table 2 outlines the respective reactions and whether they are more likely to be classed as an allergy or intolerance.[6]

All data analysis was completed in Microsoft Excel. The number of medication classes implicated in ADRs from patients in this study was quantified as was the frequency of agents and common reactions implicated in documented ADRs.

The number of entries in each electronic patient management system was also quantified. The amount of non-ADR clinical information that was listed in the databases was also documented. This highlights the problem that non-ADR information is stored as ADR information because there is no other way to flag highly important clinical and non-clinical information. Other discrepancies concerning duplications and duplications where some information was incomplete were also documented.

Results

Over the four-week period, data from 332 patients admitted to general medicine wards were included in our study. Of the 332 patients included, 57% were female (n=190) and 43% male (n=142). The age distribution is shown in Figure 2 and includes all patients and those patients with at least one documented ADR (whether allergy or intolerance), which had been processed in the EPS. A total of 1,260 adverse reaction events were listed (including duplicates) from all of the study databases.

Figure 2: Age distribution of patients from the general medicine wards.

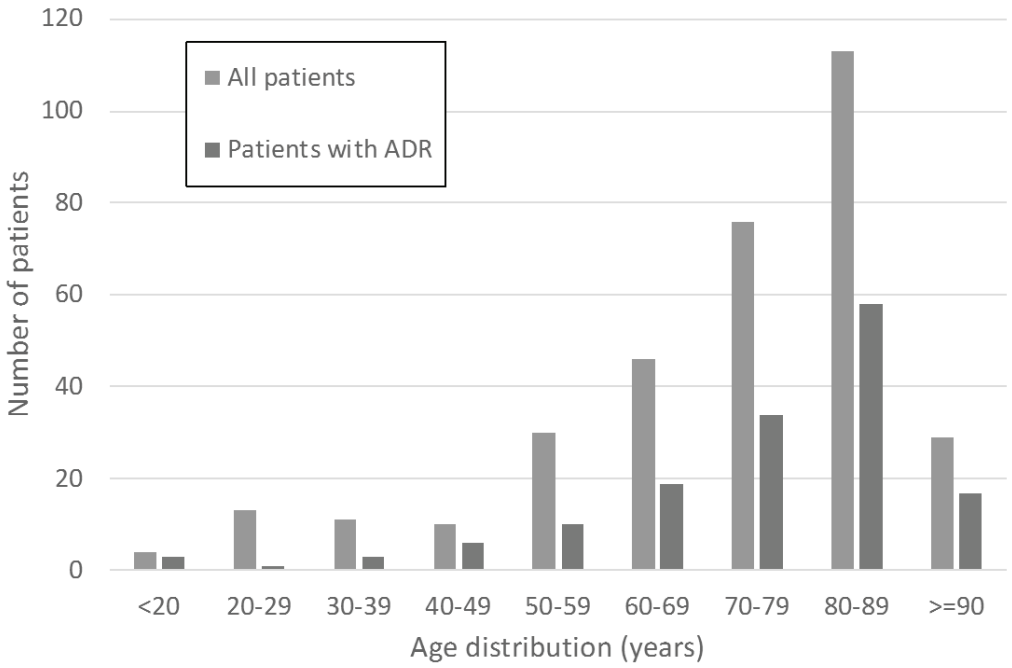


Table 1: Agents implicated in ADRs documented from any electronic patient management system.

Causative agent	Number of patients with ADR	Entries[a] documented as 'allergy'	Entries[a] documented as 'intolerances'	Other entries[b]
Penicillins[c]	65	33	17	24
Cephalosporins[d]	11	7	3	4
Sulfur-containing antibiotics[e]	39	18	8	13
Other antibiotics[f]	29	8	11	10
Opioids	76	25	51	18
NSAIDs*	58	33	20	10
ACE* inhibitors	30	20	11	2
CCBs*	16	8	11	1
Diuretics	12	7	4	1
Statins	10	6	5	1
Sulfur	11	2	1	8
Iodine/contrast media	4	2	1	3
Non-drug[g]	34	16	1	16
Other medicines[h]	132	51	60	34

[a]Note: all entries include duplications.
*NSAIDs—Non-steroidal anti-inflammatory drugs; ACE—Angiotensin converting enzyme; CCB—Calcium channel blockers
[b]Include entries with no recorded reaction (ie, unclassified/unable to classify as either an allergy or intolerance) or entries that were ADRs recorded as non-drug.
[c]Includes; penicillin antibiotics, penicillin, amoxicillin, amoxycillin, Amoxil, Aaugmentin, flucloxacillin.
[d]Includes; cephalosporin, cefaclor, cefuroxime, cefazolin, Ceclor.
[e]Includes; sulfamethoxazole, cotrimoxazole, sulfonamide, sulpha, Bactrim, Triprim.
[f]Includes; erythromycin, ciprofloxacin, nitrofurantoin, norfloxacin, clavulanic acid, roxithromycin, tetracyclines, aminoglycoside antibiotics, Chlorsig, neomycin, griseofulvin, Bactroban, vibromycin, clindamycin, doxycycline, metronidazole, trimethoprim.
[g]Includes; foods, sticking plasters.
[h]Includes all other medications/allergens not listed above.

Within the EPS, 45.5% of patients (n=151) were classified as having at least one allergy or intolerance. Another 45.5% of patients (n=151) were listed as having no known allergies or intolerances, however 20 (15%) of these had information regarding adverse drug events found in other databases. Nine percent of patients (n=30) were classified with an unknown allergy status, a status which indicates that the patients allergy status has not (yet) been assessed by the admitting doctor(s). Of this group, nine patients had documented reactions held in another database. Causative agents implicated in documented ADRs were tabulated to determine the number of patients with each ADR and the frequencies of allergies or intolerances associated with each agent (Table 1).

Clearly shown in Table 1, antibiotics account for the majority of documented ADRs. Combining penicillins, cephalosporins, sulfur-containing antibiotics and other antibiotics, this accounts for 27% of all ADRs (143 of 526). The penicillins accounted for a large portion (12%) of antibiotic-related ADRs (n=65). Opioids 14% (n=76) and NSAIDs 11% (n=58) were agents that also accounted for a large portion of documented ADRs found in this study.

Similarly, the types of common reactions (at least five entries per reaction) implicated in ADRs are shown in Table 2. No reaction information was included in 19% of the documented ADRs.

Table 3 shows classification discrepancies noted for the 585 documented ADRs from any of the six electronic patient management systems accessed in this study.

As mentioned previously, discrepancies were identified when either systems contained information that did not match, or the information listed in any one system was incomplete (eg, lacking reaction information) or contained inaccurate classifications of intolerances/allergies. Although

Table 2: Types of reactions implicated in documented ADRs from any electronic patient management system.

	Total number of entries	Percentage of all reactions
Symptoms reported typical of allergic reactions		
Rash and/or urticaria	83	12%
Swelling or angioedema	31	5%
Respiratory distress[a]	12	2%
Anaphylaxis	11	2%
Symptoms reported typical of intolerances		
Nausea and/or vomiting	81	12%
GI[b] upset	43	6%
Diarrhoe[a]	21	3%
Muscle effects[c]	20	3%
Cough	20	3%
Sedation[d]	13	2%
Hallucinations	11	2%
'Unwell'	11	2%
Confusion	10	2%
Renal dysfunction[e]	9	1%
Hyponatremia	9	1%
GI[b] bleed	9	1%
Abdominal pain	6	1%
Headache	6	1%
Sleep disturbances[f]	5	1%
Other[g]	139	20%
No reaction listed	130	19%
Total	682	101%[h]

[a]Includes; wheeze, tight throat, and dyspnea.
[b]GI = gastrointestinal.
[c]Includes; a rise in CK, myalgia, myositis, muscle weakness/soreness, myositis and muscle cramps.
[d]Includes; drowsiness, grogginess, tired, sleepy and fatigue.
[e]Includes; poor kidney function, urinary retention, decline in renal function.
[f]Includes; nightmares, poor sleep, and bad dreams.
[g]Includes all other symptoms that had less than five entries.
[h]Greater than 100% due to rounding of percentages.

there were 526 unique allergies documented for the population of 332, before removal of the duplicates there were 585 documented reactions. Out of 585 reaction entries, 12 allergy entries (2%) were incorrectly documented as intolerances, 124 intolerance entries (21%) were incorrectly documented as allergies, nine drug allergy/intolerance entries (2%) were classified as non-drug entries and 135 entries (23%) had no reaction listed (and so could not be assessed). Conversely, 112 entries (19%) were correctly classified as allergies, and 192 as intolerances (33%).

Of note, across 47 patients there were 59 non-ADR information notes recorded in the patients ADR information, these ranged from clinical information not related to medicines to who to phone following a procedure.

Table 3: Classification discrepancies for 585 documented ADR entries from any electronic patient management system.

	Accurately documented allergies	Accurately documented intolerances	Allergies documented as intolerances	Intolerances documented as allergies	Allergies/ intolerances classified as non-drug reactions	Unclassified reactions
Total	112	192	12	124	9	136
Penicillins[a]	24	16	1	9	0	24
Cephalosporins[b]	7	2	1	0	0	4
Sulfur-containing antibiotics[c]	14	6	2	4	2	11
Sulfur/sulphur	1	0	1	1	1	7
Other antibiotics[d]	4	10	1	4	0	10
Opioids[e]	3	51	0	22	0	18
NSAIDs[f]	11	18	2	22	0	10
Other[g]	48	89	4	62	6	52

[a]Includes; penicillin antibiotics, penicillin, amoxicillin, amoxycillin, Amoxil, Augmentin, flucloxacillin.
[b]Includes; cephalosporin, cefaclor, cefuroxime, cefazolin, cCclor.
[c]Includes; sulfamethoxazole, cotrimoxazole, sulfonamide, sulpha, Bactrim, Triprim.
[d]Includes; erythromycin, ciprofloxacin, nitrofurantoin, norfloxacin, clavulanic acid, roxithromycin, tetracyclines, aminoglycoside antibiotics, Chlorsig, neomycin, griseofulvin, Bactroban, vibromycin, clindamycin, doxycycline, metronidazole, trimethoprim.
[e]Includes; morphine, codeine/dihydrocodeine, tramadol, oxycodone, methadone, Oxycontin, DHC continus, dextropropoxyphene.
[f]Includes; NSAIDs (non-steroidal anti-inflammatory drugs), diclofenac, aspirin, ibuprofen, naproxen, Voltaren, Celebrex, Naprosyn, tenoxicam, celecoxib.
[g]Includes all other medications/allergens not listed above.

Discussion

Overview

Within this study over 1,200 medication "alerts" were identified for 332 patients. This information related to 585 recorded reactions from 526 unique events, as over 600 were exact duplicates. It was noted that more than half of those individuals in this study had at least one documented ADR.

Rates of patients with at least one "allergy" within inpatient hospital populations have previously been reported as high as 39%,[3] however these are not always true allergies but rather encompassed intolerances as well.[3] This study found that within the sample investigated, 46% of patients had a documented allergy in their profile, however subsequent evaluation of the information found that those with a true hypersensivity ("allergy") was actually only 20%.

Of the individual ADRs, 23% had no information on the type of reaction, ie, there was no clinical description of the adverse reaction experienced by the patient previously and therefore no way to determine the clinical significance of the event, which could guide future prescribing.

Where reaction information was documented, 21% of these were suggestive of an intolerance rather than an allergy as documented. This incorrect documentation is important from a clinical perspective, as an intolerance such as mild gastrointestinal distress does not usually preclude future use, in comparison to a true allergic event such as anaphylaxis.

Differences between allergies and intolerances are important, as the exclusion of potential therapeutic options based on information that is inaccurate can lead to second- and third-line therapeutic choices, which may be less effective, have a larger financial cost, and lack of medication familiarity can increase the risk of medication errors.[1–2] Additionally, with antibiotics, poor treatment choices may also impact on future patterns of resistance.

Interestingly, there were 59 non-ADR, non-clinical events listed in the ADR warning system, highlighting a deficit in current systems, as there is no other warning system distinct from ADRs. Worryingly, this incorrect inputting of information, both clinical and non-clinical, may be potentially problematic in the future. The need for

a non-ADR alert system within the hospital EMR program has been identified. This is so that valuable and important clinical information can still be communicated to all healthcare team members without cluttering the ADR documentation system.

This current study found that 9% of patients were "allergy status unknown". That is, the allergy status of the patient has not (yet) been assessed, and this may be for a variety of reasons ranging from not being able to speak (eg, if unconscious), not being able to comprehend (eg, if dementia is present), to not remembering this information (eg, if the reaction was in childhood). While some patients may not be able to provide any information on admission, it was concerning that within this group there was information for nine of the 30 that they had a documented ADR. This important, as the implementation of electronic medical records has largely been promoted as being more accurate and more complete. The rate of unstated allergy documentation may be high in our study of electronic records due to data overload (eg, duplicates of ADRs) and cluttering (eg, non-clinical information) within the system.

In an attempt to address this, one hospital in the literature required allergy status information to be recorded and signed off before any medication could be prescribed. Even after these requirements, it was found that 2.6% of patients had nothing recorded (signature/date also absent), and an additional 10.3% of the studied patients reported that the ADR information recorded was incorrect.[14] This is similar to the current study hospital in that the EPS requires allergy status to be completed prior to prescribing, however in practice (and in this study) it appears that prompts and warnings are commonly over-written.

Specific ADRs

Antibiotics have frequently been reported as the most common cause of drug allergies.[15] One paper found 33% of recorded allergies were attributable to antibiotics, while NSAIDs represented the next significant group with 13% of allergies.[15] This current study found that of the entries deemed true allergies, 44% (54/124) were attributable to antibiotics and 9% to NSAIDs (11/124).

Historically and in this study, 'sulfur' allergies were reported—where this generally refers to sulphonamide antibiotics, however except for sulfamethoxazole in co-trimoxazole these are little used. Entering them in a modern database is also fraught, as often practitioners look for a 'sulfur' allergy but only find the term 'sulfur' as an extemporaneous compound. If this is then selected the alert will not appear when a sulphonamide agent is prescribing, making this safety function useless. So drug allergies that are incorrectly classified as non-drug allergies can lead to avoidable life-threatening allergic reactions.

Veracity of information

Lyons et al have previously noted a low percentage of agreement between inpatients' electronically documented allergies and their allergies identified via interview, which agrees with our conclusion that inaccuracies in electronic ADR documentation is common in hospitals.[16] This highlights the need for better ADR documentation across hospital electronic medical record systems, and that this does also interface with community electronic records, and the need for improved communication with patients regarding allergy status.

DHBs and the New Zealand Pharmacovigilance Centre (NZPhvC), Centre for Adverse Reaction Monitoring (CARM), can add to the national warning system. Reports entered via CARM have been medical assessed for causality, however those reports entered from DHBs have not. Further, the national system warnings contains "other" information (ie, clinical trial information). Again, the ability for multiple agencies to add to this system without verification or completeness of information can lead to similar concerns regarding accuracy of information.

Limitations

This study was limited in that the accuracy of the information was not confirmed with the patients or healthcare providers themselves. This contributed to our large number of ADRs that we were unable to classify due to the absence of reaction information. This however is similar to the problem faced in 'real life' when prescribing medicines to patients who are unable to provide this information. While doctors or other healthcare practitioners should review the

ADR status of all patients admitted with the patient themselves, often in emergency situations doctors do not have time to confirm accuracy and thus must rely on the accuracy of the electronic medical records program, but also in many other situations, eg, dementia and when reactions occurred in childhood. Therefore, there is a crucial need for complete and accurate documentation of ADRs, including reaction data in order to facilitate optimal healthcare decisions.

Recommendations

Recommendations from this work include firstly, the need for systems to have an 'archive' function for historical or duplicate information so that it is still retrievable, but does not clutter other valuable information. Secondly, the electronic prescribing systems have a field for important non-ADR alerts separate from ADR information, which would allow for easier readability of patient ADRs at initiation of prescribing. Thirdly, improved system functions such as the ability to enter a 'class intolerance' would be ideal, as this would prevent intolerances being entered as allergies, as well as being able to manage colloquial terms such as 'sulfur' allergy. Fourthly, it is recommended that any time an allergy or intolerance is entered it should be required that the user input a reaction, even if the reaction is 'unknown', to ensure that all information documented is as precise and accurate as possible with a high level of relevance and reliability.

Fifthly, it is suggested that there is improved education nationally to healthcare providers about which medication and non-medication (eg, latex) reactions are to be reported. National systems that communicate warnings should ensure that the data integrity is preserved so that it is useful, providing the medication name, the reaction description and the date when this happened. This may require changes in the capacity of data that is allowed to be transmitted between multiple systems. The infrastructure currently in place for national medication warnings has potential to allow important medication allergy information to be communicated nationwide and the suggested improvements can facilitate capitalisation of this potential.

In summary, information transfer between electronic systems needs high-quality data to be entered at the time of a reaction initially being recorded to ensure there is appropriate robustness and maximal clinical utility of information through sharing of the information. Further education of the importance of documenting the causative agent, the type of reaction, date of event, and subsequent rechallenges or cross-reactivity (whether positive or negative) and better understanding of the differences between an allergy and an intolerance will enhance patient care and safety and ensure that each patient receives the most appropriate pharmaceutical therapy.

Competing interests:
Nil.

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