

# DOCUMENT: a system for classifying drug-related problems in community pharmacy

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**Abstract** *Background* Drug-related problems (DRPs) are a major burden on the Australian healthcare system. Community pharmacists are in an ideal position to detect, prevent, and resolve these DRPs. *Objective* To develop and validate an easy-to-use documentation system for pharmacists to classify and record DRPs, and to investigate the nature and frequency of clinical interventions undertaken by Australian community pharmacists to prevent or resolve them. *Setting* Australian community pharmacies. *Method* The DOCUMENT classification system was developed, validated and refined during two pilot studies. The system was then incorporated into software installed in 185 Australian pharmacies to record DRPs and clinical interventions undertaken by pharmacists during a 12-week trial. *Main outcome measure* The number and nature of DRPs detected within Australian community pharmacies. *Results* A total of 5,948 DRPs and clinical interventions were documented from 2,013,923 prescriptions dispensed during the trial (intervention frequency 0.3%). Interventions were commonly related to *Drug selection* problems (30.7%) or *Educational* issues (23.7%). Pharmacists made an average of 1.6 recommendations per intervention, commonly relating to *A change in therapy* (40.1%) and *Provision of information* (34.7%). Almost half of interventions (42.6%) were classified by recording pharmacists as being at a higher level of clinical significance. *Conclusion* The DOCUMENT system provided pharmacists with a useful and easy-to-use tool for recording DRPs and clinical interventions. Results from the trial have provided a better

understanding of the frequency and nature of clinical interventions performed in Australian community pharmacies, and lead to a national implementation of the system.

**Keywords** Documentation system · Australia · Classification system · Drug-related problems · Clinical interventions · Pharmacy interventions

## Impact on practice statements

- Document is a validated classification system to categorise drug-related problems and clinical interventions performed in community pharmacy.
- The DOCUMENT system is regarded as easy to use, and is now being implemented in Australia.
- Use of the system has improved our understanding of the frequency and nature of clinical interventions in community pharmacy in Australia

## Introduction

A drug-related problem (DRP) is commonly defined as “an event or circumstance involving drug treatment that actually or potentially interferes with the patient experiencing an optimum outcome of medical care” and can broadly be related to errors, adverse effects or adherence issues [1–4]. Internationally, DRPs are a frequent cause of morbidity, hospital admission and mortality, with an estimated 5–7% of admissions to medical inpatient services resulting from DRPs [5, 6]. Furthermore, nearly 60% of these admissions are considered preventable [5]. An Australian review of adverse drug events and medication errors determined that

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2–3% of all hospital admissions were medication-related and 75% of these were potentially preventable [4]. A survey of ambulatory care patients showed that approximately 25% had experienced a DRP with approximately 39% thought to be preventable [7, 8].

There has been considerable interest in interventions that may result in early detection and prevention of DRPs, to decrease the associated morbidity and mortality. Community pharmacists are well-placed to detect and either prevent or resolve DRPs during the course of routine dispensing and counselling [9]. For the purposes of this paper, a clinical intervention by a pharmacist is defined as ‘*any professional activity by the pharmacist directed towards improving the quality use of medicines and resulting in a recommendation for a change in the patient’s medication therapy, means of administration or medication-taking behaviour*’. Therefore, the detection of an actual or potential DRP can lead to the pharmacist performing an intervention, which may result in one or more recommendations to solve the DRP.

The classification and documentation of DRPs and clinical interventions by pharmacists is desirable for several reasons. These include optimising inter-practitioner communication for maintenance of patient care, avoidance of litigious situations, and utilisation for research purposes. Previous research has led to the design of several DRP classification systems that allow community pharmacists to consistently record the interventions occurring within their daily practice. These include PI-Doc [10], PCNE Classification for DRPs [11, 12], and systems developed by Westerlund [13] and Hepler and Strand [1]. However, they have deficiencies. For instance, the Hepler and Strand system does not include coding for activities intended to resolve the DRP (the actions taken and recommendations made by the pharmacist). The Westerlund system focuses more on the cause and classification of the DRP, rather than the intervention and its clinical significance. Consequently, records may be incomplete and reliable post hoc interpretation of the situation may not be possible. The PCNE system requires assessment of the cause of a DRP, which is difficult to determine in many community pharmacy situations, and the outcomes recorded in this system do not provide sufficient detail to enable economic analyses. The PI-Doc system is complex and unsuited to use in the community pharmacy environment.

This paper describes the development of a DRP classification system that overcomes these problems. This system, termed DOCUMENT, has been used and refined in three studies spanning 10 years of research into DRP detection and resolution by Australian community pharmacists, termed the Pharmacy Recording of Medication Incidents and Services electronic documentation system trials (PROMISE I, II and III) [14–16].

## Aim of the study

The aim of this study was to develop and validate an easy-to-use documentation system for classifying DRPs, examine its use in practice, and investigate the nature and frequency of DRPs detected and clinical interventions undertaken by Australian community pharmacists.

## Method

### Development of the DOCUMENT system

An open, hierarchal classification system was developed, based on the types of DRPs identified by Hepler and Strand [1] and the PCNE classification system [11]. The system facilitated the classification of five aspects of the DRP and the clinical intervention undertaken to resolve it. These were:

- the type of DRP;
- the actions undertaken to investigate it;
- the recommendations made to resolve it;
- the outcomes of the actions undertaken to resolve the DRP; and
- the perceived clinical significance of the DRP.

### Type of DRP

The system consisted of eight categories (types) of DRP, with each category encompassing between one and five subcategories to further classify the DRP (Table 1). This system was used during the PROMISE I and PROMISE II studies, and was refined for the PROMISE III study. The types of DRP classified in the DOCUMENT system were defined as follows:

- *Drug selection*—DRPs related to the choice of drug prescribed or taken (such as drug duplication, drug interaction, wrong drug and no apparent indication).
- *Over or underdose prescribed*—DRPs related to the prescribed dose or schedule of the drug (such as dose too high, dose too low and incorrect schedule).
- *Compliance*—DRPs related to the patient’s medication-related behaviour (such as taking too little, taking too much, intentional drug misuse and difficulty using a dosage form).
- *Untreated indications*—DRPs related to actual or potential conditions that require management (such as a diagnosed condition not adequately treated or preventative therapy required).
- *Monitoring*—DRPs related to inadequate monitoring of the efficacy or adverse effects of a drug (including laboratory and non-laboratory monitoring).

**Table 1** DRP categories and subcategories described by the DOCUMENT system as used in PROMISE II and PROMISE III

Code	Category	Sub-category	Sub-category description	PROMISE III results		
				Number (%) of category	Number (%) of total	Number (%) of Moderate to high clinical significance
D	<i>Drug selection</i> (Problems relating to the choice of drug prescribed or taken)	D1	Duplication	Inappropriate use of two drugs from the same therapeutic class	232 (12.7%)	982 (38.7%)
		D2	Drug interaction	Likely interaction between two prescribed drugs (no symptoms evident yet)	265 (14.5%)	
		D3	Wrong drug	Incorrect drug supplied, either by an incorrect doctor's prescription or incorrectly dispensed by the pharmacy	223 (12.2%)	
		D4	Incorrect strength*	Incorrect or no details about strength of medication is supplied	347 (19.0%)	
		D5	Inappropriate dosage form	Formulation is inappropriate in terms of the intended use of the product	211 (11.5%)	
		D6	Contraindications apparent*	Patient has a contraindication or precaution to the drug being used due to their medical conditions, or a previous allergy to the drug or drug group	141 (7.7%)	
		D7	No indication apparent*	No clear indication for the use of the drug	42 (2.3%)	
O	<i>Over or underdose</i> (Problems relating to the prescribed dose or schedule of a drug)	D0	Other drug selection problem	Other drug selection issues, such as the patient is taking expired medication or a more effective drug than the one prescribed is available	368 (20.1%)	
		O1	Prescribed dose too high	Total daily dose exceeds guidelines, either due to reference dose ranges or patient parameters (age, renal function etc.)	384 (32.5%)	573 (22.6%)
		O2	Prescribed dose too low	Total daily dose is not adequate for treatment	316 (26.7%)	
		O3	Incorrect/unclear dosing instructions*	Specified dosing frequency/schedule or duration of treatment is unclear or incorrect	392 (33.1%)	
		O0	Other dose problem	Other dose related problem, such as incorrect frequency or schedule	91 (7.7%)	
		C1	Taking too little	Patient using too little of the medication due to forgetfulness or poor understanding of therapy	116 (20.8%)	200 (7.9%)
		C2	Taking too much	Patient using too much of the medication due to forgetfulness or poor understanding of therapy	101 (18.1%)	
C	<i>Compliance</i> (Problems relating to the way the patient takes the medication)	C3	Erratic use of medication*	Patient using medication on an erratic basis	100 (18.0%)	
		C4	Intentional drug misuse (including OTC medications)	Suspected overuse of a drug that is potentially abused	34 (6.1%)	
		C5	Difficulty using dosage form	Patient has a physical problem using the dosage form due to swallowing difficulties, manual dexterity etc.	56 (10.1%)	
		C0	Other compliance problem	Other compliance issues, such as patient choosing not to take the medication due to the product information or a media release etc.	150 (26.9%)	

Table 1 continued

Code	Category	Sub-category	Sub-category description	PROMISE III results		
				Number (%) of category	Number (%) of total	Number (%) of Moderate to high clinical significance
U	<i>Undertreated</i> (Problems relating to actual or potential conditions that require management or prevention)	U1 Condition undertreated†	Patient has a symptom or condition that is not currently being treated adequately	164 (60.3%)	272 (4.6%)	185 (7.3%)
		U2 Condition untreated†	Patient has a symptom or condition that is not being treated	42 (15.4%)		
		U3 Preventative therapy required	Patient requires additional therapy to prevent an adverse event occurring (due to patient's therapy, coexisting diseases or risk factors)	58 (21.3%)		
M	<i>Monitoring</i> (Problems relating to monitoring the efficacy or adverse effects of a drug)	U0 Other undertreated problem	Other untreated indication problem	8 (2.9%)		
		M1 Laboratory monitoring	Patient requires a laboratory test, such as serum electrolyte or drug levels (no symptoms evident yet)	42 (30.0%)	140 (2.4%)	74 (2.9%)
		M2 Non-laboratory monitoring	Patient requires a non-laboratory test, such as BP, BSL or weight check (no symptoms evident yet)	81 (57.9%)		
		M0 Other monitoring problem	Other monitoring problem, such as patient unable to afford monitoring	17 (12.1%)		
E	<i>Education or Information</i> (Where a patient requests further information about a drug or disease state)	E1 Patient requests drug information	Patient requests information about their medication	668 (47.3%)	1,412 (23.7%)	196 (7.7%)
		E2 Patient requests disease management advice	Patient requests information about the management or prevention of a condition	278 (19.7%)		
		E3 Confusion about therapy or condition‡	Patient has a poor understanding of their medical condition, but their medication compliance appears to be adequate according to the dispensing history	N/A		
		E4 Demonstration of device‡	Patient has a technical problem with the administration of a device	N/A		
		E0 Other education or information problem	Other education problem, such as another health professional requests information	466 (33.0%)		
N	<i>Not classifiable</i> (Problems that cannot be classified under another category)	N0 Clinical interventions that cannot be classified under another category§	Clinical interventions that the pharmacist feels does not belong elsewhere (must still be a clinical problem, not administrative)	110 (100.0%)	110 (1.8%)	43 (1.7%)
T	<i>Toxicity or ADR</i> (Problems relating to the presence of signs or symptoms that may be attributed to a drug)	T1 Toxicity caused by dosell	Patient has signs or symptoms of an adverse reaction that is likely to be dose-related	445 (100.0%)	445 (7.5%)	282 (11.1%)
		T2 Toxicity caused by drug interactionll	Patient has signs or symptoms of an adverse reaction that is likely to be related to the presence of an interacting drug			
		T3 Toxicity evidentll	Patient experiencing symptoms of toxicity where there is a suspected medication cause			
		T0 Other toxicity problemll	Other toxicity suspected of being related to a drug			
Total				5,948	5,948 (100%)	2,535 (100%)

\* Sub-category added for PROMISE III

† Sub-categories were combined in PROMISE II, but split into two sub-categories for PROMISE III

‡ Sub-category was removed for PROMISE III

§ Category was called 'Non-clinical' in PROMISE II, but altered to 'Not classifiable' for PROMISE III

ll All four categories combined for PROMISE III with the definition 'Toxicity, allergic reaction or adverse effect present—patient has signs or symptoms that suggest toxicity, an allergic reaction or an adverse effect'

- *Education or information*—DRPs related to knowledge of the disease or its management (such as requests for drug information, confusion about therapy or disease states and demonstration of dose administration devices).
- *Non-clinical*—DRPs related to administrative aspects of the prescription.
- *Toxicity or adverse reaction*—DRPs related to the presence of signs or symptoms which are suspected to be related to an adverse effect of the drug (such as toxicity caused by dose, drug interaction or unknown causes).

#### *Actions to investigate the DRP*

The types of actions undertaken to investigate the DRP (Table 2) were created following examination of a previous study of community pharmacists' interventions [14]. It was believed that these activities would be associated with a substantial component of the time involved in an intervention and therefore may be used as a predictor for length of time taken to complete the intervention, as well as create a more complete record.

#### *Recommendations to resolve the problem*

The codes and categories for recommendations to resolve the DRPs (Table 3) were also determined following evaluation of clinical interventions from a previous study [14]. Since a clinical intervention, by definition in these trials, must involve the pharmacist making a recommendation to the patient or prescriber, it was considered vital that details of the recommendations made were included in the documentation process. The recording of the pharmacist's recommendations also helped other parties to perform better post hoc interpretations of the situation.

**Table 2** Actions described by the DOCUMENT system

Action	Description of action
Investigation: written material	Pharmacist consults a text book or other written reference material
Investigation: software	Pharmacist consults decision support software on the pharmacy computer
Investigation: patient history	Pharmacist consults a formal patient history, such as dispensing history
Investigation: other (specify)	Pharmacist consults another health professional, the internet, the manufacturer, a drug information service etc
Contacted prescriber	Pharmacist contacts the patient's prescriber
Discussion with patient	Pharmacist discusses the issue with the patient to clarify a DRP
Corrected without discussion	Pharmacist corrects the DRP without discussion, such as administrative issues
Other action (specify)	Pharmacist undertakes another action not listed here

#### *Outcome/acceptance of the recommendation*

A simple acceptance code for the recommendation was developed for the system, including a partial acceptance code for when only some of the recommendations made by the pharmacist were accepted.

#### *Clinical significance*

Five levels of clinical significance were defined (Table 4). This measure was included as it was expected to provide an indication of the relative economic value of an intervention.

#### *Validation of the DOCUMENT system*

The DOCUMENT system was validated for reliability and internal consistency. Twenty scenarios were selected from the pilot dataset where each scenario described a DRP situation that occurred in community pharmacy [14], and 92 pharmacists classified the DRP using DOCUMENT. The pharmacists did not receive any initial training on the classification system, but did have access to explanatory notes during the validation process. The system's internal consistency was assessed through a randomly selected sample of 18 pharmacists who completed the original scenarios and repeated the classification approximately one month later.

#### *Modifications to the DOCUMENT classification system*

After validation, the DOCUMENT system was used to classify DRPs during the PROMISE II trial and detailed examination of these interventions was undertaken to refine the classification system for inclusion in the larger PROMISE III trial [15]. The purpose of the revision was to simplify the documentation process, with the differences between the original and final versions being shown in Table 1. The major change was the removal of the Action and Outcomes components. PROMISE II determined that knowing the pharmacist's actions was of no benefit as the actions did not predict the time required for the intervention. The Outcomes were removed because pharmacists were often unable to determine the outcome of the intervention. The 'Nil' clinical significance option (Table 4) was also removed.

A simple decision-tree was also developed to assist pharmacists in identifying the main DRP category (Fig. 1).

#### *PROMISE III trial*

An electronic documentation system incorporating DOCUMENT was integrated into 185 pharmacies throughout

**Table 3** Recommendations described by the DOCUMENT system

Recommendation	Definition of recommendation	Sub-category #	Category #
<i>A change in therapy</i>			
Dose increase	Pharmacist recommends the daily dose of medication is increased	642 (16.7%)	3,833 (40.1%)
Dose decrease	Pharmacist recommends the daily dose of medication is decreased	652 (17.0%)	
Drug change	Pharmacist recommends a change in current medications, such as initiating or ceasing a medication	846 (22.1%)	
Drug formulation change	Pharmacist recommends a change in formulation that does not alter the drug or its total daily dose	383 (10.0%)	
Drug brand change	Pharmacist recommends a change in the brand to improve compliance or due to stock unavailability etc	96 (2.5%)	
Dose frequency/schedule change	Pharmacist suggests a change in the number of times per day or timing of the doses, without changing the total daily dose	527 (13.7%)	
Prescription not dispensed	Pharmacist does not dispense the prescription due to the circumstances, such as when the patient needs to visit the prescriber prior to dispensing	307 (8.0%)	
Other changes to therapy	Pharmacist recommends another change to patient’s current therapy	380 (9.9%)	
<i>A referral required</i>			
Refer to prescriber	Pharmacist refers patient to their prescriber to resolve the DRP	1,786 (91.3%)	1,956 (20.5%)
Refer to hospital	Pharmacist refers patient to the hospital to resolve the DRP	36 (1.8%)	
Refer for medication review	Pharmacist recommends patient have a medication review to resolve the DRP (known as a Home Medications Review or HMR in Australia where a pharmacist visits the patient at home and sends a clinical review letter to their treating physician)	76 (3.9%)	
Other referral required	Pharmacist refers patient to another health professional to resolve the DRP, such as a dentist, podiatrist, diabetes educator etc	58 (3.0%)	
<i>Provision of information</i>			
Education/counselling session	Pharmacist provides a detailed counselling or education session to the patient to resolve the DRP	2,437 (73.6%)	3,312 (34.7%)
Written summary of medications	Pharmacist provides patient with a detailed list of their medications to resolve the DRP	260 (7.9%)	
Commence dose administration aid	Pharmacist suggests that the patient start using a dose administration aid (such as a Webster pack or dosette box)	75 (2.3%)	
Other written information	Pharmacist provides other written information, such as Self Care cards	540 (16.3%)	
<i>Monitoring</i>			
Monitoring: laboratory test	Pharmacist suggests that the prescriber undertake some laboratory monitoring to monitor for DRPs	277 (61.6%)	450 (4.7%)
Monitoring: non-laboratory	Pharmacist suggests that the patient or prescriber undertake some non-laboratory monitoring to monitor for DRPs	173 (38.4%)	
<i>Other</i>			
No recommendation necessary	Pharmacist has investigated the problem and finds that the problem does not need to be addressed with any changes	111*	
Total		9,551 (100.0%)	

\* Not included in the recommendation analysis

three states of Australia, accounting for approximately 4% of all Australian pharmacies. For 12 weeks, 531 participating pharmacists used the system to record any prescription-related DRPs and clinical interventions that occurred. Each pharmacist was encouraged to undertake training in both the electronic software and the

DOCUMENT system, and all pharmacies were provided with a DOCUMENT classification booklet and help files within the software, which included definitions and examples for each of the categories. For analysis of trial data, the pre-determined level of statistical significance was  $P = 0.05$ .

**Table 4** Clinical significance of the intervention as described by the DOCUMENT system

Clinical significance	Brief description
Nil	No consequence to the patient
Low	Consequences to the patient are related to costs or information only
Mild	Consequences to the patient are that they have improved compliance, or improved or prevented a minor symptom. The sign or symptom should not require a doctor's visit to treat
Moderate	When, if the intervention did not occur, it was likely that the patient would have had to visit the doctor because of the consequences. Also covers the situation where the pharmacist needs to refer the patient to the doctor because of the seriousness of the situation
High	When, if the intervention did not occur, it was likely that the patient would have had to go to a hospital because of the consequences. Also covers the situation where the pharmacist needs to refer the patient to a hospital because of the seriousness of the situation When, if the intervention did not occur, it was likely the patient would have required assistance from a regular nurse visit, or would have required placement into residential care

## Results

### Validation of the DOCUMENT system (PROMISe II)

Two hundred and forty-one Australian pharmacists registered to undertake the validation, with 156 assessing at least one scenario and 92 assessing all 20 scenarios. The majority of participants (70.2%) were able to identify the correct category of DRP (as determined by the two research pharmacists who scripted the scenarios) for most of the scenarios. The level of agreement between the pharmacists was assessed using Fleiss' Kappa, resulting in a value of  $\kappa = 0.53$  (indicative of moderate agreement between the raters). There was substantial concordance between the first and second attempts in the selection of categories by 18 pharmacists attempting the re-classification, with an average concordance rate of 69.2% across all DRP types.

### Use of DOCUMENT in the PROMISe III study

During the 12-week trial, participating pharmacists documented their clinical interventions using the PROMISe III software embedded within their dispensing systems. A total of 5,948 clinical interventions were documented from 2,013,923 dispensed prescription items, representing a mean intervention frequency of 0.3% (3 clinical interventions for every 1,000 prescriptions dispensed).

### Types of interventions

The types of interventions documented are shown in Table 1. The two most common types of interventions were related to *Drug selection* problems (1,829; 30.7%) or *Educational* issues prompted by patient requests (1,412; 23.7%).

### Intervention recommendations

Pharmacists recorded 9,551 recommendations over the course of the trial, which equated to a mean of 1.6 recommendations for each clinical intervention. The most commonly selected category related to *A change in therapy*, being selected on 3,833 (40.1%) occasions (Table 3).

The types of recommendations were compared to the initial DRP categories. Interventions where the recommendation was for *A change in therapy* were more likely to be either *Drug selection* or *Over or underdose* problems ( $\chi^2 = 2,165.2$ ,  $df = 7$ ,  $P < 0.001$ ). Clinical interventions where *A referral was required* were more likely to involve a DRP associated with *Toxicity* or an *Undertreated* indication requiring addition of therapy ( $\chi^2 = 659.2$ ,  $df = 7$ ,  $P < 0.001$ ). Recommendations associated with *Provision of information* were more likely to be associated with *Education* or *Compliance* issues ( $\chi^2 = 1,691.3$ ,  $df = 7$ ,  $P < 0.001$ ).

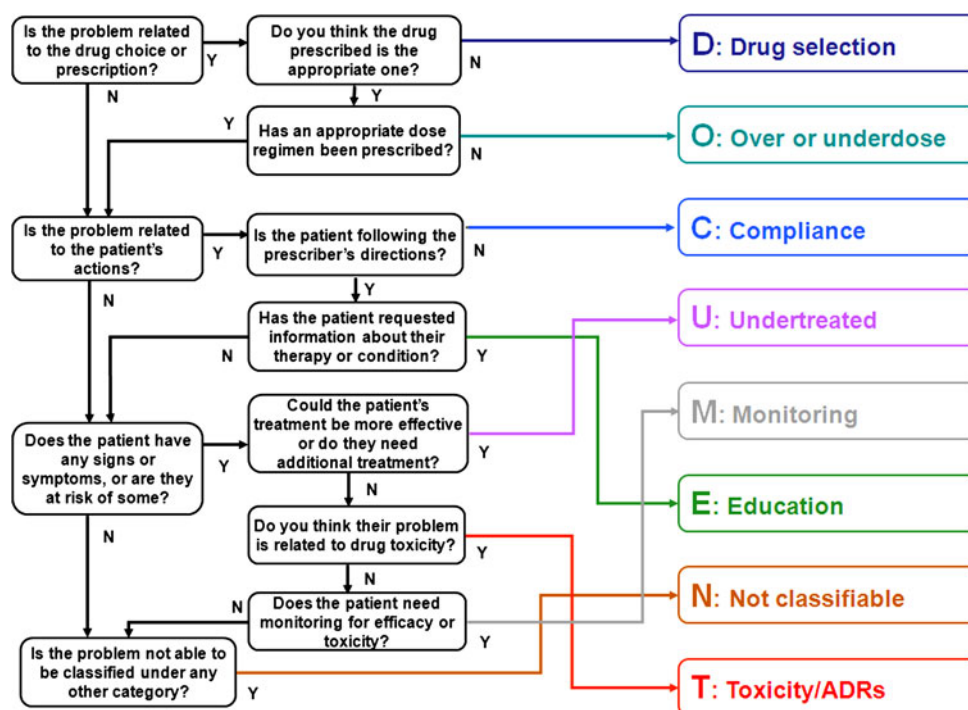
### Clinical significance

Almost half of the clinical interventions (42.6%; 2,535 occasions) were classified as being at a moderate or high level of clinical significance by the recording pharmacist. When the number of interventions in each category was split into two groups of clinical significance (lower and higher), the pharmacists were more likely to rate *Undertreated* and *Toxicity* problems as having higher clinical significance (Table 1;  $\chi^2 = 751.8$ ,  $df = 7$ ,  $P < 0.001$ ). The clinical significance reported by the pharmacists appeared to correlate well with the economic value determined by a commissioned independent expert panel. As the significance code increased, the average cost saving to the Australian healthcare system (as determined by the panel) also increased (*Kruskal–Wallis*  $\chi^2 = 17.9$ ,  $df = 3$ ,  $P < 0.001$ ; *Jonckheere–Terpstra statistic* = 4.2,  $P < 0.001$ ).

### Analysis of clinical interventions within the 'Other' categories

Despite the refinement that the DOCUMENT system underwent before being used in the PROMISe III trial, 1,210 (20.3%) interventions were still recorded under the 'Other' categories. However, only 353 out of 2,535

**Fig. 1** DOCUMENT classification system flowchart



(13.9%) interventions of higher clinical significance were recorded in an 'Other' category, compared to 857 out of 3,413 (25.1%) interventions of lower clinical significance ( $P < 0.01$ ).

#### User opinions

A post-trial survey was answered by 267 pharmacists to determine the ease of use of the software and the DOCUMENT system. The first question asked if 'the number of DOCUMENT intervention classifications should be increased', with 231 (86.5%) 'No' responses and 36 (13.5%) 'Yes' responses. The second question asked if 'the number of DOCUMENT intervention classifications should be decreased', with 225 (84.3%) 'No' responses and 42 (15.7%) 'Yes' responses. Overall, 190 (71.2%) pharmacists thought that the number of classification categories was optimal, responding with 'No' to both questions. The majority of pharmacists (86.2%) also indicated that they felt the overall system was easy to use.

#### Discussion

A moderate level of agreement between the pharmacists was achieved during the validation of the DOCUMENT classification system ( $\kappa = 0.53$ ). Although the level of agreement is not ideal, it is similar to the agreement achieved with a recent study classifying interventions

identified during medication reviews, where a modified Kappa score of between 0.5 and 0.8 was achieved for each question [17]. Given that the pharmacists had no previous experience with the DOCUMENT system and received no training before undertaking the validation process, and the majority of them completed the exercise in a short period of time, this level of agreement was considered acceptable, allowing consistent categorisation for post-trial analysis. In the future, training prior to the use of the DOCUMENT system should further improve the Kappa score. This study also found that the DOCUMENT system was easy to use and the majority of the participating pharmacists felt that the number of classification categories was optimal.

The PROMISE III trial found that the most common clinical interventions were related to *Drug selection* (30.7%), *Education or information* (23.7%) and *Over or underdose* (19.9%). This was consistent with the range of categories and subcategories which were documented throughout the PROMISE II study [15, 18]. The variation between the DRP classification systems in international literature again makes direct comparisons difficult; however, most studies show drug selection, drug–drug interactions (which are classified as a *Drug selection* or *Toxicity* issue in the DOCUMENT system, depending on whether symptoms have occurred) and dosage problems as the most common interventions [12, 19–21]. During the trial, the most common recommendations were a *Counselling or education session* for the patient and *Referral to the prescriber*.



Almost half of the clinical interventions (42.6%) were classified as being at either a moderate or high level of clinical significance by the recording pharmacist. It is a limitation of the study that pharmacists may overstate the clinical significance of an intervention, however the clinical significance did appear to correlate well with the economic value determined by the independent expert panel.

There are several possible explanations for the finding that around 20% of interventions were recorded in the 'Other' categories. In most cases, it appeared that the pharmacist chose the correct DOCUMENT category, but then chose 'Other' as the sub-category, despite the fact a more appropriate sub-category was available. This may have been caused by a lack of time or lack of motivation causing the pharmacists to select 'Other' rather than refer to the help files to classify a difficult case. This is supported by the finding that there were a significantly lower proportion of highly significant interventions recorded within the 'Other' category, possibly indicating that pharmacists spent more time and effort classifying an intervention they felt was highly significant. Within focus groups conducted post-trial, participating pharmacists also admitted to using the 'Other' sub-categories or not recording the intervention at all if they found the intervention hard to classify.

The DOCUMENT classification system has recently gained some international acceptance, with Kwint et al. [22] modifying the original PROMISE II DOCUMENT system (as shown in Table 1) for use in the Netherlands. Interestingly, the authors have made changes to the original DOCUMENT system that are similar to those made for PROMISE III. For example, the authors also added the sub-categories 'Lack of indication', 'Lack of effectiveness' and 'Contraindication' to the *Drug selection* category. Additionally, they expanded the *Toxicity* category to include 'Risk of adverse effects' and 'Possible drug treatment in response to adverse effects', whereas this article shows the *Toxicity* category being condensed. This indicates that DOCUMENT may be easily adapted to accommodate requirements within other countries. Also, the DOCUMENT system has been used in a recent national roll-out of a clinical intervention recording system to pharmacies in Australia, similar to the Swedish system described by Westerlund [23].

## Conclusion

The DOCUMENT classification system was successfully trialled within Australian community pharmacies and provided pharmacists with a useful and easy-to-use tool to record the clinical interventions that they make on a daily basis. This classification system has allowed researchers to gain a substantially better understanding of the frequency

and nature of clinical interventions which are performed by pharmacists. The DOCUMENT system was well received by the users and resulted in nearly 6,000 clinical interventions being recorded from over 2 million prescriptions during a 12-week period. A nationwide implementation of the system in all pharmacies has been recently commissioned by the Australian government.

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