Decisions Surrounding Adverse Drug Reaction Prescribing: Insights from Consumers and Implications for Decision Support

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This paper presents findings from case studies of health consumers who each suspect they may have experienced an adverse drug reaction (ADR). These case studies are part of a larger study involving consumer/doctor decisions surrounding suspected adverse drug reactions and prescribing. Decision support to assist with the diagnosis and management of ADRs has, to date, primarily focused on providing in-time information to prescribers about factors that pertain to the consumer and the medications they are taking. Decision support that includes consumers usually targets treatment decisions. The results of this paper indicate the prescriber is only one decision contributor in a rich tapestry of decision contributors and decision types, and consumer decision types are significantly broader than treatment decisions. The results provide guidance for the development of decision support within this domain.

ACM Classification: J.3 (Life and Medical Sciences), K.4 (Computers and Society)

1. OBJECTIVES

This paper presents preliminary findings from 15 case studies of consumers who each suspect they may have experienced an adverse drug reaction (ADR). These case studies are part of a larger qualitative study involving consumer/doctor decisions surrounding suspected adverse drug reactions and prescribing, which is captured in Figure 1.

The key problem identified from our preliminary background work is that there appear to be gaps in our knowledge about the decision environment surrounding suspected ADRs. The key gaps identified in the preliminary work included the following:

- each of the groups interviewed (for details refer to Section 3.1 of this paper) involved in the detection and management of ADRs had a different focus, indicating that there are multiple groups of people involved, each with different data requirements,

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- the single consumer study indicated that ADR decisions may not purely be medical decisions and others, including the consumer, may be involved in making decisions surrounding ADRs, and finally,
- a longitudinal perspective of an ADR, which includes the consumer view and multiple components of the medical history, may provide information that is not available from any single view.

The aim of this study is to gain further insights into the ADR decision environment to assist in the development of decision support software tailored to this specific domain.

2. BACKGROUND

The Second National Report on Patient Safety: Improving Medication Safety by the Safety and Quality Council of Australia (Roughead and Semple, 2002) describes adverse drug reactions as a particular type of adverse drug event which includes side effects associated with medications.

Roughead and Semple (2002) reported that in Australia, between 1999 and 2000, 2–3% of total Australian hospital admissions may have been associated with medications. This equates to about 140,000 of the total 5.9 million hospital admissions across Australia.

Pirmohamed *et al* (1998) from the University of Liverpool, state that 5% of all hospital admissions are caused by ADRs, and 10–20% of all hospital inpatients experience ADRs. They also state that ADRs are responsible for the death of 0.1% of medical and 0.01% of surgical inpatients.

"To Err is Human. Building a Safer Health System" (Kohn, Corrigan and Donaldson, 1999) provides incidence figures which have been quoted extensively as a rationale for continuing research and development within this field. They state that the number of Americans to die each year from medical error is somewhere between 44000–98000 reflecting 2.9–3.7% of hospitalisations. These figures refer to adverse events, a term which covers any accident that occurs in medicine such as errors in surgical procedures, incorrect medical procedures and equipment failure.

We use the World Health Organisation (WHO) definition of an ADR which is "a response to a drug which is noxious, unintended, and which occurs at doses normally used or tested in man for prophylaxis, diagnosis, or therapy of disease, or for modification of physiological function." (WHO, 1972). We have defined a suspected ADR as a set of symptoms that have been associated with a therapeutic medication by either the consumer or treating clinician, but have not been verified by the Australian Adverse Drug Reaction Advisory Committee (ADRAC).

ADRs are known to occur for a number of reasons. They can be caused by the pharmacological action of the drug, changes in drug properties, such as an error in the manufacturing of a drug, and drug interactions. Reactions can also be caused by the effects they can have on individuals. These individual consumers may have particular hypersensitivities, idiosyncratic absorption or metabolic characteristics, or particular conditions that are contra indicatory to particular drugs. Two of the key reaction types are Type A and Type B reactions. Type A reactions are common, and dose related. They are accounted for by a drug's known pharmacological properties, (Kalachnick, 1999). Type B reactions are uncommon and independent of a drug's known pharmacological properties. They are considered the most serious and are potentially life threatening, (Kalachnick, 1999).

Edwards and Aronson (2000) expand these categories including:

Type C, dose related and time related. Uncommon and related to the cumulative dose,
Type D, delayed. Uncommon, usually dose related and usually becomes apparent some time after the use of the drug,

Type E, withdrawal. Uncommon, occurs soon after the withdrawal of the drug and
Type F, unexpected failure of therapy. Common, dose related and often caused by drug interactions.

Efforts to reduce the incidence of ADRs appear to fall into five major categories:

- voluntary reporting surveillance systems around the world such as the Therapeutics Goods Administration, ADRAC system in Australia (TGA, 2003a; Grant, Coulson and Wood, 2000; Hartmann *et al*, 1999; Kubota, 1999; Orsini and Funk, 1995; Sutcliff, McMorran and Morawiecka, 2000),
- the World Health Organisation (WHO) reporting system which collects data from over 60 countries around the world in an attempt to detect signals that are too weak for any individual country to detect (Lindquist *et al*, 1999),
  The above two systems detect ADRs and then report recently discovered ADRs back to the prescribers to assist with prescribing decisions.
- desktop prescribing systems that have built in alerts (Medtech, 2003; Medical_Director, 2003),
- medical guidelines available on the Internet. (Beliakov and Warren, 2001; Barnett, Famiglietti, Kim, Hoffer and Feldman, 1998; Thomas, Dayton and Peter, 1999) and
- hospital based early detection systems that use data such as lab results, pathology results and medications to alert staff to a possible ADR in its early stages so that it can be detected quickly. These systems have also been used to estimate the number of ADRs occurring in a particular hospital setting. Some examples include Payne *et al* (2000), Raschke *et al* (1998), Caldwell (2000), Bates, (2000).

The results of voluntary reporting, product information and alerts built into desktop prescribing software and medical guidelines, all provide information to the prescriber about the specific drug and the illness or disease. The hospital-based systems provide information about illness and disease, and additional specific information about the consumer such as lab results, pathology results and medications.

There is a significant body of research addressing the role of consumer decision-making within a medical context (Charavell *et al*, 2001; Bankhead, 1999; Scott and Lenert, 2000; Coulter, Entwistle and Gilbert, 1999; Benson and Britten, 2002; FDA, 2003; Bruera *et al*, 2001; Mcvea, Minier and Johnson Palensky, 2001). These papers predominantly address treatment decisions. Our preliminary background studies indicate consumer decisions surrounding ADRs may be broader than decisions concerning treatment options, and that with or without decision support consumers may be making diagnostic decisions. In some countries, consumers report suspected ADRs to health authorities (NAPRA, 2003; TGA, 2003b; Safety And Quality Council, 2003). Each of the other decision support strategies mentioned above do not consider consumer decisions.

There are many additional sources of information that may be used by prescribers and consumers that are not currently included in the systems listed above. We aim, within this study, to learn more about these information sources, understand more about how people currently use the information that is available, the nature of the decisions being made, who makes these decisions, and the additional requirements people have that may be able to assist in the prevention, early detection and management of suspected ADRs.

3. METHODS

Figure 1 shows the groups of data that have been collected within the study described in this paper. The shaded sections indicate the data collection that has been completed. Data were collected using

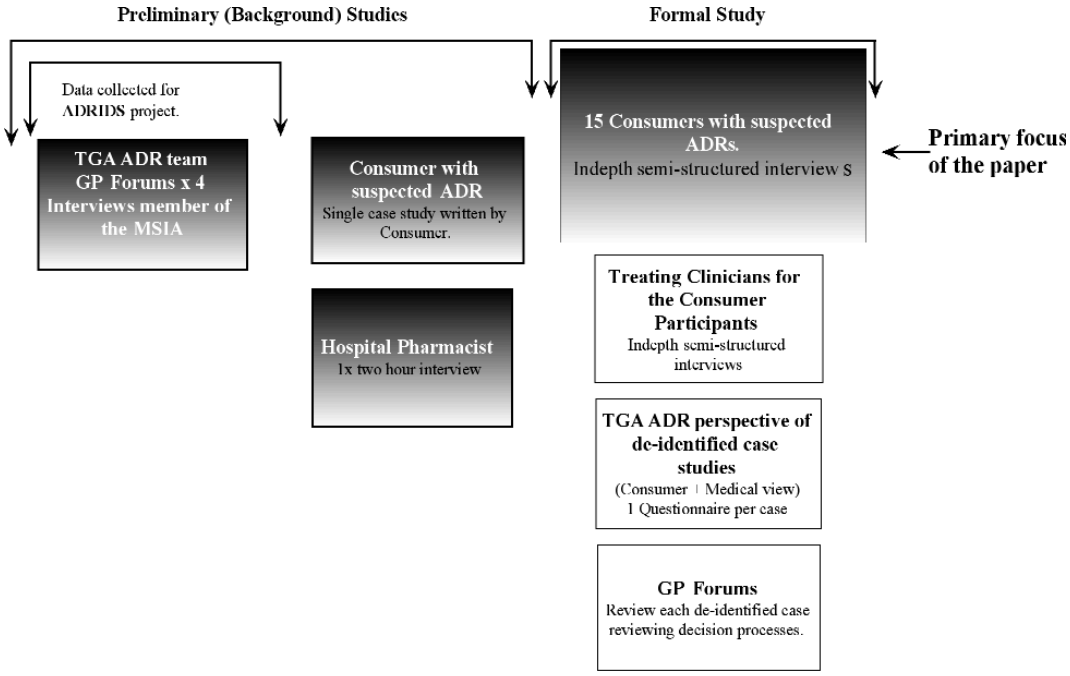

Figure 1: Data collected for the larger study of Consumer/Doctor decision making surrounding adverse drug reactions and prescribing.

informal methods within the preliminary background studies. These data were used as background investigations to the formal study, which used a modified grounded theory approach, described further in this section. The first component of the data was collected as a part of a General Practice Computing Group funded study, Adverse Drug Reactions Improved Decision Support (ADRIDS) (O'Brien, 2001). The first component of the formal study, consumers with suspected ADRs, is the key focus of this paper.

3.1 Preliminary (Background) studies

For each group illustrated in Diagram 1, notes were taken and fed back to each group member for verification, except for the initial consumer case study where the consumer wrote the notes. The analysis of this preliminary data was informal. The data were reviewed and summarised. Key points were highlighted that were then used as a basis for the development of the formal study.

3.2 Consumer study

Subjects

Consumers who believe they may have experienced an ADR within the past 12–18 months answered either an advertisement that was placed in a local newspaper, or one placed to staff and students at the University of Ballarat, via a research newsletter and via e-mail. 20 consumers responded, 15 met the selection criteria and were interested in participating in the study.

The 15 participants have the following characteristics:

- age range of 29 to 76, with the following breakdown.
  - 20% aged 21–40, 60% aged 41–60, 20% aged 61–80

  - 67% female, 33% male,
  - 40% from Ballarat University, 60% from the community,

The suspected ADRs experienced by the participants have the following characteristics:

- **Level of certainty that symptoms were caused by an ADR** – 7% low, 13% medium, 7% moderately high, 73% high
- **Level of severity of the suspected ADR** – 13% minor, 53% moderate, 34% moderately severe
- **Who diagnosed the suspected ADR** – 26% consumer only, 22% collaborative decision between doctor and consumer, 21% collaborative decision between consumer and family, 26% doctor only.
- **Level of consumer concern** – 20% low, 13% medium, 67% high
- **Type of medication** – 100% prescription, 0% non-prescription, 0% complimentary.
- **Number of medications** – 53% single medication, 47% multiple medications

These characteristics have been categorised by the principal researcher based on the descriptions provided by the participants. These levels are from the consumer perspective.

Self selection of consumers

This is an exploratory study, with the aim of performing a detailed, in-depth qualitative analysis of a small number of case studies that include multiple views. The self-selection process may have resulted in a set of consumers with particular characteristics.

The principal researcher noticed that the consumer group appeared to be particularly analytical, as several of the participants maintained detailed diaries over a number of years, and the majority used logical processing to determine the likelihood that the medication taken caused the suspected reaction.

It is also possible that the consumers volunteered for the study because they were particularly concerned, angry or frustrated by their suspected reaction. As described in the previous section, the group did have a significant level of concern, with 67% displaying a high level of concern as observed by the principal researcher. It is not known if this level of concern is due to a bias in the sample, or whether it is representative of consumers who have experienced a suspected reaction to a medication.

Attempting to minimize the effects of self-selection is difficult for the following reasons:

- It is not practical to observe consumers in a medical practice and collect cases of ADRs, as the incidence is sparse compared with the number of cases seen within a practice,
- In order to collect the data, consumer consent is required. Beginning with a self-selection process ensures consumer consent is obtained, and privacy is maintained,
- Medical staff could be approached to put forward cases of consumers who may have experienced ADRs. Issues raised by medical staff to this proposal included the following:
  - Some consumers may not be aware they have experienced an ADR,
  - The medical staff and/or hospital would need to contact each of these people to see if they are prepared to participate in the study maintaining strict confidentiality, until such time as the consumer signs a consent form to release their details to the research team, which is time consuming for medical staff who are already extremely busy,
  - Medical litigation may result from drawing attention to suspected ADRs, especially in light of the fact that in the majority of cases it is not 100% certain the medication caused the reaction.

As a result of the complexities above, the research team decided to begin with consumers who were self selected, even though the self-selection may result in bias, rather than choose not to study

this domain. As stated previously, this study is exploratory in nature and qualitative. We have the aim of locating themes and emerging theory, which may be explored for generalisability in a follow-up quantitative study, although the sampling issues will remain.

Method of Data collection

Each consumer participant was asked to do the following: Participate in a single in-depth semi-structured interview with the principal investigator, assist in completing a time line of events surrounding the suspected ADR, and complete a consent form to provide the principal investigator with permission to access medical records, and discuss their case with their treating clinician.

Analysis of the Data

Each interview was transcribed and de-identified. The data were coded using Nvivo 2.0 as an analysis tool and using a modified form of grounded theory described by Miles and Huberman (1994). Grounded theory, described by Strauss and Corbin (1998) is a method of developing theory that has been derived from real world data. A social constructionist epistemology underpins our approach. Miles and Huberman (1994) state that their preferred method of generating codes is to begin with a "start list" of codes which came from prior fieldwork, the conceptual framework, research questions, hypotheses and the literature. Our "start list" came from the preliminary work described in Section 4.1, the literature and the research questions. This list evolved as cases were analysed, allowing the data to expand and develop the code set.

4. RESULTS

4.1 Preliminary background Studies

The preliminary background studies highlighted key points that influenced the direction of the formal study. Details can be found in O'Brien (2001). Below are the key points that were highlighted from each of the initial data gathering phases.

GP Forums

The perception of the group was that:

- ADRs occur infrequently within a community setting,
- the number of medications on the market is increasing. As a result, updating their knowledge about potential ADRs is also increasingly difficult,
- a computer program that sits in the background of their prescribing software would be useful. Because their perception is that ADRs occur infrequently, they believe it is a high priority to prevent them when possible, but a low priority regarding the time spent on ADR prevention compared with the other demands within their workload.

TGA discussions

The members of the TGA ADR team reported that:

- their primary role is to discover previously undocumented ADRs, to document them and alert the public as to their existence,
- background information about how the TGA ADR team operates was recorded. Detailed information about this has been documented in O'Brien (2001),
- a key element in identifying an ADR is to differentially diagnose between an ADR, the presenting disease, or a newly presenting disease. Generally this can be done with only a limited level of certainty, particularly if the ADR is one that has not been previously documented. Often

it is not possible to do this differential diagnosis at the time the ADR occurs, but new ADRs can be discovered if prescribers report suspected ADRs. If there are enough reports from within Australia or around the world to produce a signal, ADRAC can be more certain that there is a relationship between a drug or group of drugs and a symptom or set of symptoms.

Consumer

This single case study highlighted the following:

- Medical data for this consumer was stored in many locations. The consumer was the only person who knew where the complete medical history was located, and she was too ill to alert medical staff. She had experienced similar symptoms 10 years earlier, but had only limited information about that suspected reaction,
- The consumer made decisions that may have impacted on the outcome of the ADR. These decisions included, when to seek medical assistance, who to seek medical assistance from and what information from her past medical history was relevant to relay to the doctor,
- Having experienced a life-threatening ADR, she is highly motivated to prevent future ADRs.

Pharmacist

The pharmacist provided insight into the ADR reporting practices within a single Melbourne hospital.

He also highlighted the following:

- If a person has experienced an ADR, ensuring the person has enough knowledge to prevent a second exposure to that medication was a high priority,
- Accurate diagnosis is essential, although often extremely difficult. He stated that blaming a drug for an ADR means the person does not have access to that form of drug therapy in the future. Not detecting the drug, results in an increased risk of the person being re-exposed to the same drug a second time.

Summary of Preliminary (Background) Study Results

The results of the background study highlighted specific issues to explore in detail in the formal study (below). In particular, the complex nature of ADRs was highlighted. The number of drugs on the market and drug complexity is increasing. ADRs are often not diagnosed definitively, but are suspected to a particular level of certainty. There are many views of an ADR – emphasis on minimizing risk of experiencing an ADR, early detection, prevention of re-exposure to a medication that has previously caused a reaction and the impact of implicating a drug. Another aspect highlighted in the background study is the role of the consumer. This consumer was highly motivated to prevent further ADRs due to the severe nature of the ADR. She made a variety of decisions, not just treatment decisions and she held key information needed for the diagnosis of the ADR. The final and most significant aspect highlighted is that ADRs appear to cross multiple decision makers, information is in multiple locations, and the interrelations between these factors is not clear. The Formal study described below aims to explore these factors in detail. The formal study includes 15 additional consumer case studies, discussed below.

4.2 Consumer study

Following the background studies, the larger study includes 15 consumer interviews, which have generated a large quantity of data, resulting in a large number of factors that may be of significance. The suspected ADRs for the 15 cases have been summarised in Table 1, below. Five key points will

be discussed in this paper: the perception of the severity of suspected ADRs, multiple decision makers, types of decisions made by consumers throughout a suspected ADR, knowledge sources used by consumers, impact of a suspected ADR linked to consumer understanding of the source of the symptoms.

It should be noted that the suspected reactions below are from a consumer perspective only, and have not at this stage of the research process been verified by a Medical Officer.

Perception of the severity of suspected ADRs

Although the suspected reactions of the 15 consumers reported in Table 1 (below), are not life threatening and did not cause death or permanent physical injury, each consumer found the suspected reaction distressing. Column 7 in Table 1 shows the impact of the suspected reaction on each of the consumers, in most cases, using the consumer's own terminology. The impact appeared to fall into three key categories; impact of the suspected reaction, impact that continued after the initial symptoms had subsided, and impact on others as a consequence of the suspected reaction. Below are some examples.

The first two quotes, below, indicate the impact on the consumer whilst experiencing the suspected reaction.

> "I got home but I had to go to work for half an hour so my husband was going to drive me there because I really felt like I couldn't drive, I was feeling really miserable." (C02)

> "I said (to GP) I'm miserable, I said my legs, I said I've got pain, I've got this restless legs, I've got this thigh pain around here and stuff like that and I said I'm miserable you know I really am. Is this the way life's supposed to be" (C17)

C02 had 8 weeks of illness. C17 indicated that the symptoms had persisted for three years progressively getting worse.

Consumer Code	Symptoms	Drug	Level of Certainty	Source of knowledge used by consumer and doctor as perceived by consumer	Who diagnosed	Impact
C02	Severe flu style illness	Tegretol	High	GP consulted specialist	Doctor	"I really felt like I couldn't drive, I was feeling really miserable." "he said (GP) "you are seriously ill""
C04	Itchy in absence of rash	Tramadol Hydro-chloride	High	Internet, observation and asking the doctor	Doctor	Concerned and confused not knowing the cause
C05	Grand Mal first for 20 years.	Generic brand of sodium valproate	Consumer High, Doctor, Low	Elimination of other possible factors	Consumer and doctor	"The impact for me personally was huge"
C06	Convulsions	Panadeine Forte	Medium	Advice from doctor	Doctor	"I won't take it again, just in case."

C07	Aches in legs, nausea	Tamoxifen	High	Consumer's reflection and specialist's medical knowledge	Consumer suspected medication – Doctor confirmed	"I just felt I was getting weaker and sicker and I was angry by this stage too…. I felt that I was bit fobbed off"
C08	Slow recovery from epidural	Inderal	Medium	Observation and prior knowledge of medication	Consumer and GP suspected	"I don't want to be prescribed drugs again if it's not necessary."
C09	Bells Palsy	Zyban	Mod High	Observation	Consumer	"I was nearly in tears, I didn't know what was wrong"
C10	Vomiting after second dose for 2 weeks	Efexor	High	Symptoms immediately following taking the drug.	Consumer	"Nobody on earth could talk me into trying it again."
C11	Drug induced lupus	Hydral-azine	High	Observation, Internet	Consumer, confirmed by doctor	"I was just in agony"
C12	Felt ill enough to miss work.	Panadeine Forte	High	Observation over several uses over time	Consumer and wife	"It delayed my return to work"
C13	Photo-sensitivity – pustule rash	Celebrex	High	Observation and the Internet	Consumer	"The impact was major. For the period of the reaction I was miserable."
C14	Photo-sensitivity – itchy rash	Vioxx	Low	Observation and information from friends	Consumer, wife and daughter.	Searching for an, explanation for the symptoms for 18 months.
C15	Double vision	Maxolon	High	Doctor referred to ADR reference material.	Doctor	"I'm terrified of having any more surgery absolutely terrified" (after a series of unpredic table reactions to drugs)
C16	Induced severe seizure – similar to psychotic episode	Sabril	High	Timing of medication with suspected reaction.	Consumer and husband	"was terrifying" "It did shatter me psychologically"
C17	Restless legs, unwell, pain in legs	Lipitor	High	Observation by the consumer and his wife, own medical knowledge, Internet.	Consumer	"I'm miserable…. [its] the decrease in the quality of life"

Table 1: Detecting suspected ADRs from a consumer's perspective

The following case indicates how a suspected reaction may have an initial impact, but then has a longer-term impact such as increased sensitivity to the sun, impacting on lifestyle for a number of years.

> "I would say the impact was major. For the period of the reaction I was miserable. I needed to miss work because of it. I felt sick with it as well. So from that point of view that episode was major. It impacted on my holiday. And then I had had subsequent episodes with Ultra violet light exposure, since then. So to me, that's a major impact, because I enjoy the sun, I enjoy being outside, and I enjoy outdoor activities. It means that I have to be extremely careful with exposure to the sun. Wear sunscreen, cover up. That sort of thing." (C13)

A secondary impact for C10 was that he was the primary carer for his wife who had a progressive disease. The impact, included the immediate illness he experienced, but the secondary impact of being unable to care for his wife for this period of time. When asked about this impact, he indicated that they were able to call on the support of family and home carers, however, he said "we battled on I guess, sometimes we didn't get much for tea if anything. Sometimes we did."

Multiple decision-makers

Within these 15 cases, the people involved in decision-making (either making decisions or providing observational input into the decision-making) included, the prescriber who was either the GP or a specialist, the consumer, members of the consumer's family and the consumer's friends. Table 1, column 6 shows that from the consumer's perspective, the consumer involved in suspecting the symptoms to be an ADR in 11 of the 15 cases and in 7 of the 15 cases describe this decision as collaborative. The collaboration is with a family member in four of these cases and with the doctor in three cases.

As can be seen from the data presented in Table 1, in the majority of cases, from the consumer's perspective, they were significantly involved in the diagnostic decision of whether or not to suspect a drug of causing a reaction.

Types of decisions made by consumers throughout a suspected ADR

Table 1 explores the decision type of "suspecting a drug to have caused an adverse drug reaction". Other decisions made by the consumers within these 15 cases are described in Table 2.

As can be seen from Table 1, consumers are involved in a wide range of decisions surrounding suspected ADRs. As indicated in the background section to this paper, the majority of decision support is provided to the prescriber, and the majority of decision support systems that involve consumers are focused on treatment decisions. The results of this study indicate that the decision types made by consumers are significantly broader than the current decision support focus.

Knowledge sources used, and usages of knowledge sources by the consumers

The sources of knowledge/information used by the 15 consumers included:

- the product information sheet (when available),
- observations of own symptoms,
- personal diaries,
- knowledge of when medications were commenced and/or ceased,
- dosage, and awareness time required for medication to reach therapeutic level,
- logical processing of events and symptoms,

Decision Type	Description
Seeking information	Who to seek information from; Doctor, pharmacist, naturopath, friend, family
	When to seek information. Immediately, symptoms severe?
	Where to seek information – internet, person, media, drug information
Diagnostic decisions	Decision to suspect a drug of causing a reaction
	Decision to suspect a class of drugs of causing a reaction
	When given a diagnosis, whether to accept the diagnosis
Treatment decisions	Which medication to take – prescription, non prescription or complimentary
	Decision to request a specific drug from a medical practitioner
	Decision between multiple suitable drugs
	Decision to take medication prescribed for self, for a previous illness
	Whether to take prescribed medication
	When to begin or cease a drug
	Frequency of drug
	Whether to follow recommendations by doctor or product information
	Choosing a medication prescribed for a family member or friend
Information sharing	Whether to report a suspected reaction to a medication practitioner
	Whether to report new symptoms
	Which information to share
	Whether to request specific information about a drug
	Determine the priority for treatment
	Inform medical practitioner of ceasing a medication
	Inform a medical practitioner of non-compliance – eg higher dose than recommended.
Side effects/reactions	Whether to accept a side effect because of the benefits of the medication.
	When to report a suspected reaction to a medical practitioner

Table 2: Decisions made by consumers during a suspected ADR

- consumer drug information sheet from the pharmacist,
- the Internet to search for current drug or class of drugs or an alternative drug,
- information about a specific condition and progression of the condition,
- case studies similar to own,
- advice from doctor,
- advice from a family member,
- own knowledge of medicines from past experience,
- family members' recollection of events and observations of symptoms,
- family friends and
- the pharmacist.

Sources of knowledge used by the doctor as perceived by the consumer included feedback from specialists and accessing reference materials about known ADRs.

As can be seen by the list of information sources, above, the consumer group accessed information from a variety of sources, only one being from a medical practitioner.

More data will be available about information and knowledge used once data has been collected from the remainder of the treating clinicians, the GP group and the TGA ADR team.

Impact linked to expectations

In a few cases the consumers were accepting of uncomfortable symptoms that they expected but were distressed when they did not know the cause of symptoms. One example was the consumer who suspected Zyban of causing Bell's Palsy. The quote below indicates an acceptance of some symptoms that were severe enough to stay home from work.

> "Headaches are one of the side effects of Zyban as is throwing up." "they were enough to prevent me from working, lying in bed in darkness." "The doctor said no, no, no that's alright it's just side effects so I continued." (C09)

The following two quotes indicate the stress associated with not knowing the cause of the symptoms of the suspected ADR.

> "I think that if I'd known that that was possibly a side effect it would have been less traumatic because it was really quite stressful not knowing why." (C04)

> "The double vision was distressing, because I'd never had it before, and didn't know why I had it."(C15)

The consumers were asked if they would do anything differently or would have like the medical staff to do anything differently if they were to face the same circumstances again, using the advantage of hindsight. The majority of the participants indicated they would have liked to have been warned that the medication they were taking may result in a reaction. Some also indicated that some idea of when to seek medical advice would also have been useful.

5. DISCUSSION

The results of this paper suggest that there are multiple decision-makers involved in ADR decisions. If, as indicated here, consumers are making decisions with or without support, it seems reasonable to suggest that decision support be tailored to accommodate different and collaborative perspectives. Also, decision-makers working together more explicitly may assist in the prevention, and in particular the early detection and management of suspected ADRs. To date decision support for ADRs has been directed towards prescribers as described in the background section (Section 2) of this paper.

Benson and Britten's (2002) study on consumer decisions surrounding hypertensives, explore the factors consumers use when weighing up treatment decisions, and found that the reasons are broader than those relating to the pharmacology of the drug, and that pre-conceived ideas about medicines can have an impact on decision making. Benson and Britten (2002) support the notion of shared decision making concluding that "doctors who want their patients to make well informed choices about antihypertensives and to reach concordant decisions about prescribing should explore how individuals strike this balance to personalise discussion of drug use".

The decision types made by consumers were significantly more extensive than treatment decisions. To date decision support for consumers has focused primarily on treatment decisions, with little or no information found by the authors exploring the role of consumers in diagnostic decisions. This study suggests the need to broaden the decision types used in decision support.

ADRs that are not life threatening or causing permanent physical illness were, in this study, significant to the consumer. In the preliminary work, the consumer case study included a consumer who was highly motivated to prevent further ADRs when the ADR was life threatening. The consumers in this study, who suspect they experience ADRs, also had high motivation to prevent further ADRS. This observation provides a rationale for providing resources to aid in the management of this class of ADRs.

Information that relates to ADRs is held in many locations by many decision-makers, and includes pharmacology of drugs and the likely physiological impact of a reaction, but also information held by the consumer such as personal experiences, observations of family and friends and knowledge of their own body. The combining of that partial knowledge may assist with the prevention, early detection and management of ADRs.

Coulter *et al* (1999) state "patients cannot express informed preferences unless they are given sufficient and appropriate information, including detailed explanation about their condition, likely outcomes with and without treatment." This statement is true of medical information, but as expressed by Benson and Britten (2002), consumer decisions involve information that is broader than medical information, implying that providing access to consumers about medical information, although important, is not the entire solution.

Finally, if awareness that a medication may result in an unwanted reaction decreases the severity of the experience of an ADR, as indicated by some of the cases within this study, perhaps increased awareness is important. This issue is complex. It is difficult to predict which person may react to which medication. There is also a risk of information overload, and increased anxiety to consumers if they are informed of a severe, yet unlikely reaction. It is possible for a consumer to experience the nocebo effect, i.e. " a harmless substance that when taken by a patient is associated with harmful effects due to negative expectations or the psychological condition of the patient". The results, however, indicate that there are also some benefits to having prior warning, which may be useful when considering the development of decision support in this field.

6. CONCLUSION

Decision support to assist with ADRs has, to date, primarily focused on providing in time information to prescribers about factors that pertain to the consumer and the medications they are taking to prevent, detect and manage ADRs. Decision support that includes consumers usually targets treatment decisions. As can be seen from this work, multiple decision makers were involved in ADR decisions, and consumer decision types were significantly broader than treatment decisions. The consumers in the study used a variety of sources of information to make their decisions, seeking advice from a medical practitioner being only one information source. This study indicates that decision support aimed only at prescribers, will result in a system that only partially meets the needs of the ADR decision domain, and is likely to be less effective that one that attempts to incorporate the requirements of consumers also, as active decision makers.

Two additional factors were highlighted from this study. Firstly that the less severe ADRs, in medical terms, were significant to the consumers experiencing them, indicating a need to address this subgroup of ADRs, and also, awareness that a medication may cause specific ADRs, although difficult to predict, may assist in the reduction of the experience of an ADR.

It is planned that future research will look at the implications of this research on decision support technology within an ADR decision environment. As this study is exploratory in nature using a qualitative methodology, allowing previously unknown issues to be raised, follow up quantitative studies may be required in order to generalise these results to the general population.

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REFERENCES

BANKHEAD, C. (1999): Educated patients make better stone Tx decisions. *Urology Times*, 27 (11): 30.

BARNETT, G.O., FAMIGLIETTI, K.T., KIM, R.J., HOFFER, E.P. and FELDMAN, M.J. (1998): DXplain on the Internet. Paper presented at the Proceedings of the 1998 AMIA Annual Fall Symposium.

BATES, D. (2000): Using information technology to reduce rates of medication errors in hospitals. *British Medical Journal*, 320 (March): 788–791.

BELIAKOV, G. and WARREN, J. (2001): Fuzzy logic for decision support in chronic care. *Artificial Intelligence in Medicine*, 21: 209–213.

BENSON, J. and BRITTEN, N. (2002): Patients' decisions about whether or not to take antihypertensive drugs: qualitative study. British Medical Journal, 325 (7369).

BRUERA, E., WILLEY, J. S., PALMER, J. L. and ROSALES, M. (2001): Treatment decisions for breast carcinoma. Patient preferences and physician perceptions. American Society of Clinical Oncology 37th Annual Meeting, San Francisco, California

CALDWELL, R. (2000): Alerting staff to medication errors. *Health Management Technology*, 21 (Aug): 52.

CHARAVELL, M., BREMOND, A., MOUMJID-FERDJAOUI, N., MIGNOTTE, H. and ODILE CARRERE, M. (2001): Shared decision-making in question. *Psycho-oncology*, 10: 93–102.

COULTER, A., ENTWISTLE, V. and GILBERT, D. (1999): Sharing decisions with patients: is the information good enough? *British Medical Journal*, 318: 318–322.

EDWARDS, I. R. and ARONSON, J. K. (2000): Adverse drug reactions: definitions, diagnosis, and management. *Lancet*, 356: 1255–59.

FDA (2003): Improving healthcare through better information.U.S. Food and Drug Administration, www.fda.gov/oc/mcclellan/strategic_consumer.html

GRANT, E. M., COULSON, R. A. and WOOD, S. M. (2000): ADROIT and AEGIS: An IT Solution to the Challenge of Drug Safety Monitoring, 28: 551–574.

HARTMANN, K., KOLLER DOSER, A. and KUHN, M. (1999): Postmarketing safety information: How useful are spontaneous reports? *Pharmacoepidemiology and Drug Safety*, 8: s65–s71.

KALACHNICK, J. E. (1999): Measuring side effects of psychopharmacologic medication in individuals with mental retardation and developmental disabilities. *Mental Retardation and Developmental Disabilities Research Reviews*, 5: 348-359.

KOHN, L., CORRIGAN, J. and DONALDSON, M. (1999): To err is human: Building a safer health system, Institute of Medicine National Academy Press. Washington.

KUBOTA, K. (1999): A design for prescription-event monitoring in Japan (J-PEM). *Pharmacoepidemiology and Drug Safety*, 8: 447-456.

LINDQUIST, M., EDWARDS, I. R., BATE, A., FUCIK, H., NUNES, A. M. and STAHL, M. (1999): From association to alert – A revised approach to international signal analysis. *Pharmacoepidemiology and Drug Safety*, 8: s15–s25.

MCVEA, K. L. S. P., MINIER, W. C. and JOHNSON PALENSKY, J. E. (2001): Low-income women with early-stage breast cancer: Physician and patient decision making styles. *Psycho-oncology*, 10: 137–146.

MEDICAL_DIRECTOR (2003): Medical Director. http://www.australiandoctor.com.au/md_details.asp

MEDTECH (2003): Medtech. www.mdtech.com.au

MERRIAM-WEBSTER (2003): Merriam-Webster Medical Dictionary. http://www2.merriam-webseter.com

MILES, M. B. and HUBERMAN, A. M. (1994): Qualitative Data Analysis: An expanded source book, Sage Publications, London.

NAPRA (2003): Canadian adverse event reporting. National Association of Pharmacy Regulatory Authorities, http://www.drugintel.com/public/canadian_adverse_event_reporting.htm

O'BRIEN, M. C. (2001): Final report to department of health and aged care for contract for services GPCG #12. Adverse drug reactions improved decision support (ADRIDS).Collaborative Centre for E-Health, http://www.gpcg.org/publications/docs/projects2001/GPCG_Project12_01.PDF

ORSINI, M. and FUNK, P. A. (1995): An ADR surveillance program: Increasing quality, number of incidence reports. *Formulary*, 30 (8): 454–61.

PAYNE, T. H., SAVARINA, J., MARSHALL, R. and HOEY, C. T. (2000): Use of a clinical event monitor to prevent and detect medication errors. http://www.amia.org/pubs/symposia/D200317.PDF

PIRMOHAMED, M., BRECKENRIDGE, A. M., KITTERINGHAM, N. R. and PARK, B. K. (1998): Fortnightly review: Adverse Drug Reactions. *British Medical Journal*, 316(7140) (April): 1295–1298.

PURCELL, P. (2001): Presentation: Adverse Drug Reactions University of Ballarat

RASCHKE, R. A., GOLLIHARE, B., WUNDERLICH, T. A., GUIDRY, J. R., LEIBOWITZ, A. I., PEIRCE, J. C., LEMELSON, L., HEISLER, M. A. and SUSONG, C. (1998): A computer alert system to prevent injury from adverse drug events – Development and evaluation in a community teaching hospital. *JAMA: Journal of American Medical Association*, 280 (15): 1317–20.

ROUGHEAD, L. and SEMPLE, S. (2002): The second national report on patient safety: Improving medication safety. Safety and Quality Council, http://www.safetyandquality.org/articles/Publications/med_saf_rept.pdf

SAFETY AND QUALITY COUNCIL (2003): Alerts. www.safetyandquality.org/links_alerts.cfm

SCOTT, G. C. and LENERT, L. A. (2000): What is the next step in patient decision support? Proceedings AMIA Symposium, 784-8

STRAUSS, A. and CORBIN, J. (1998): Basics of qualitative research: techniques and procedures for developing grounded theory., Sage, Thousand Oakes, California.

SUTCLIFF, H., MCMORRAN, M. and MORAWIECKA, I. (2000): Canadian Adverse Drug Reaction Newsletter. *CMAJ: Canadian Medical Association Journal*, 162 (7): 1044–47.

TGA (2003a): Adverse Drug Reactions Unit.Therapeutics Goods Administration, http://www.health.gov.au/tga/adr/index.htm

TGA (2003b): Adverse Drug Reactions: Frequently Asked Questions. http://www.health.gov.au/tga/adr/adrfaq.htm#who

THOMAS, K. W., DAYTON, C. S. and PETER, M. W. (1999): Evaluation of internet-based clinical decision support. *Journal of Medical Internet Research*.

WHO (1972): Adverse Drug Reaction Definitions.World Health Organization, http://www.who-umc.org/umc.html

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