Submitted to the Journal of Research and Practice in Information Technology

Insights into consumer/doctor decisions surrounding adverse drug reactions and prescribing.

M. C. O'Brien and J. L. Yearwood
School of Information Technology and Mathematical Sciences,
University of Ballarat,
University Drive, Mt Helen, Vic, 3350.

m.obrien@ballarat.edu.au
Phone: - + 61 3 53279390
Fax: - + 61 3 53279289

j.yearwood@ballarat.edu.au
Phone: - +61 3 53279272
Fax: - + 61 3 53279289

Abstract:

This paper provides insight into the data requirements of unwanted reactions to medications, from the perspectives of General Practitioners (GPs), a Hospital Pharmacist, a Consumer and the Therapeutic Goods Administration (TGA) in Australia. The results are used as a basis for developing an in-depth study of the Consumer/Doctor decision, prescribing environment, to inform the development of adverse drug reaction aware prescribing decision support systems.

The results from these studies indicated differentialed data requirements, and that decisions surrounding ADRs are not just medical decisions. Most importantly, the study suggests the consumer perspective, when combined with clinical and expert perspectives, provided insight not gained by any of the individual views.

Keywords:- decision support, medical information systems, health.

1 Introduction

Adverse drug reactions (ADRs) continue to cause injuries and deaths in Australia and around the world, despite efforts in pre and post marketing surveillance, and the development of decision support alert systems.

The landmark article "To Err is Human. Building a Safer Health System" (Kohn et al., 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.

The Second National Report on Patient Safety: Improving Medication Safety by the Safety and Quality Council of Australia (Roughead and Semple, 2002) describe Adverse Drug Reactions as a particular type of Adverse Drug Events which include side effects associated with medications.

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. (Roughead and Semple, 2002). This report also illustrates the rising incidence of ADRs, which appears to be related to the rise in the number of prescriptions dispensed per year.

(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 inpatints.

For the purposes of this article, we use the World Health Organisation definition of Adverse Drug Reaction.

> "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)

ADRs are known to occur for a number of reasons. They can be caused by drug properties, changes in drug properties under certain conditions 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 contraindicatory to particular drugs. Two of the key reaction types are Type A and Type B reactions. Type A reactions are common and 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).

The above reactions are triggered by the drugs themselves. Another set of reasons contributing to the incidences of ADRs may be related to the decisions made by those

involved in the prevention, detection and management of ADRs in Consumers. These decision-makers include GPs, Consumers, Pharmacists, Medical Specialists and Hospital Health Professionals. The decisions may include individual and collaborative decisions, as indicated in Figure 1.

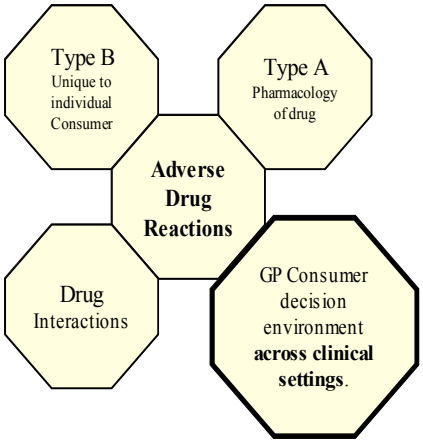

Figure 1. Adverse drug reactions

Understanding why ADRs occur, and exploring methods to increase this understanding are the first step in finding ways to decrease the incidence and severity of injury caused by ADRs. The preliminary investigations discussed in this paper are at the requirements analysis end of the software design process. It is hoped that the results of this and further research into the consumer/doctor decision environment will provide fertile ground for the development of decision support that may assist in the prevention, detection and management of ADRs in Consumers in the future.

Efforts to solve the ADR problem appear to fall into three major categories, drug surveillance, alert systems to prevent ADRs, and early warning systems to flag Consumers who are at high risk of or have begun to experience ADRs.

With the introduction of electronic medical records, opportunities for decision support technology that works with electronic record are increasing. Decision support modules are being developed that can assist Health Professionals access critical information at the time of decision making, in order to prevent, detect and manage ADRs.

It is beyond the scope of this paper to discuss the decision support tools that have been developed thus far. Fields currently being explored include electronic clinical guidelines, (Beliakov and Warren, 2001, Barnett et al., 1998, Thomas et al., 1999), electronic prescribing with decision support modules such as drug interactions databases, and modules that provide alerts about Consumer conditions or allergies, and early warning alert systems that have been primarily implemented in hospital environments. Some examples include (Payne et al., 2000, Raschke et al., 1998, Caldwell, 2000).

The study described in this paper was initiated by a request from the TGA, in Canberra, Australia. The TGA have been collecting information about ADRs in Australia using their drug surveillance program for the past 30 years. The request was to investigate how to disseminate critical results from this information in a timely manner so that prescribers had access to the information that pertains to the Consumer in the clinic at the time of prescribing. Early studies have shown that disseminating the information is about more than simply sending the information to prescribers. It appears to be about understanding the data requirements of each of the parties involved, and the decision environments at the point of utilization. This paper outlines our preliminary investigations.

2 Early Investigations

An early component of our research was carried out as part of a General Practice Computing Group (GPCG) funded projected called ADRIDS – Adverse Drug Reactions Improved Decision Support. The goal of ADRIDS was to determine the most effective way to provide GPs access to the ADR data collected by the TGA. The rationale behind the project was that valuable information about ADRs is collected by the TGA via their spontaneous reporting system (described in Section 3.1), but that the GPs do not have access to that information at the time of prescribing or diagnosing potential ADRs. The aim of ADRIDS was to provide a functional specification to assist developers of clinical software to incorporate up-to-date ADR data in their prescribing software. The project focussed on the raw data in the Adverse Drug Reactions Advisory Committee (ADRAC) database that was use to develop summary information from the analysis of these reports, complied by ADRAC - the ADR bulletins (O'Brien, 2001).

This project involved a consultative process of interviews and discussions with the TGA and a series of forums with a group of GPs. Following this initial study, we have also interviewed a Hospital Pharmacist, and a Consumer who experienced a severe ADR who agreed to be a pilot in our research.

This paper begins with a presentation of what was learned from the investigations with the TGA, GPs, a Hospital Pharmacist, and a Consumer who experienced a severe ADR. Section 4 describes the methods used for collecting the data, and the participants in the studies. In Section 5 we focus on the outcomes of these interviews

and forums, followed by an analysis of these four perspectives in Section 6. Finally, in Section 7 we look at the implications for decision support.

3 Four Perspectives of an ADR; TGA, GPs, Hospital Pharmacist and Consumer

3.1 Background

In Australia, the central body responsible for collecting information about ADRs is the TGA. Prior to release onto the Australian market, drugs are trialled using between 3000 and 10,000 people. Reactions are monitored. As this is a subset of the community, once the drug has been released onto the market, drug safety is monitored using voluntary reporting from prescribers.

The process for voluntary reporting is that if health professionals prescribing drugs suspect a drug reaction that is unexpected or particularly severe, they can report it to the TGA. Drug companies are required by law to report these to the TGA.

The TGA receives approx 11000 reports per year, of which about 8-9000 come in blue cards or similar format.

The data collected by the TGA is then stored in a large database. Currently the database has 30 years of data accumulated. The database can be used to detect new ADR signals. The aim of the TGA ADR data collection is to gather summary information that can be analysed to highlight trends in the data that may indicate a newly evolving ADR. They are primarily interested in collecting new and previously undocumented ADRs or information about ADRs that have only been partially documented. They are particularly interested in new drugs released onto the market,

and sudden changes in drugs that have been used for longer periods of time that may indicate a change in the drug or a change in the type of Consumers using the drug.

Similar systems exist in many countries around the world. Many large hospitals and pharmacy departments have their own drug surveillance systems that then feed into national and international data collection systems. (Hartmann et al., 1999, Kubota, 1999, Sutcliff et al., 2000, Orsini and Funk, 1995). The World Health Organisation (WHO) 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 role of these systems is specific. They are a security measure. Most severe reactions are found prior to release onto the market. Once the drug has been released into a population much wider than the population used for the initial drug trials, these services capture any unforseen severe reactions that may only be obvious in a wider population with a broader spectrum of users. In Australia, this information is then communicated to prescribers via bulletins which are posted out 4 times/year. Extremely serious reactions may result in a drug being withdrawn and the community alerted through the media.

3.2 The role of the preliminary studies.

The role of the initial study (ADRIDS) was to investigate a perceived gap in the process. It appeared that this critical knowledge gathered by the TGA was not reaching the prescribers in a format that was easily useable at the time of prescribing. It was hoped that by developing a database of bulletins and incorporating them into the medical software at the time of prescribing, this critical information may be utilised readily, and that it may also increase the motivation of prescribers to send in

reports to the TGA, by seeing a direct benefit from their reports. Figure 2 outlines the process identified from the initial investigations.

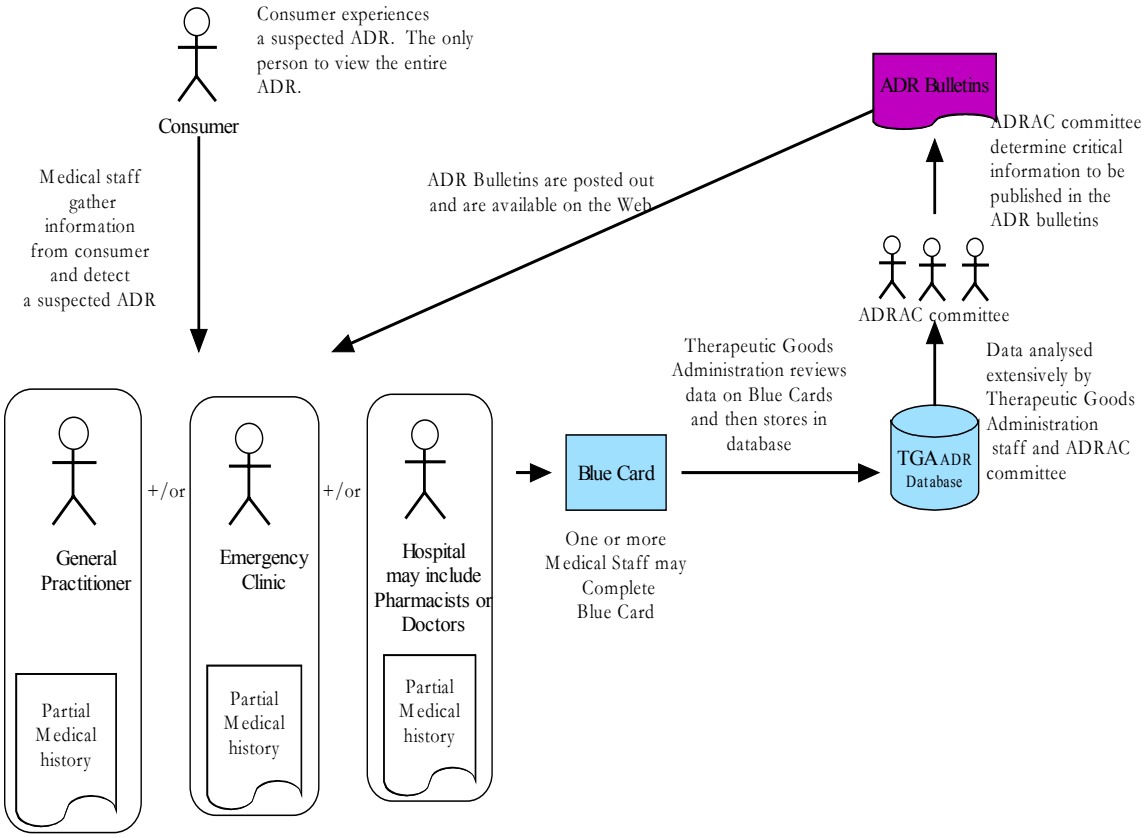

Figure 2. ADR reporting and feedback process

4 Four perspectives of ADRs

4.1 TGA

As discussed in the previous section, staff at the TGA participated in the initial studies through meetings, teleconferencing and e-mails. Their participation was in the form of discussing their current practices and providing insight into the reasons for their

data collection processes, the data they collect, and their view of the effectiveness of their current system.

4.2 GP Forums

Having determined the processes used by the TGA, the next stage was to discuss the needs of GPs. We wanted to find out the types of information needed by GPs, when they were likely to use this information, how they would like to access the information and ideas on what would assist GPs prevent, detect and manage ADRs.

Four forums were conducted with eight GPs from the BDDGP (Ballarat and District Division of General Practitioners) between March and June 2001. The reports from these forums can be found in the Final Report to Department of Health and Aged Care for Contract for Services GPCG #12 Adverse Drug Reactions Improved Decision Support (ADRIDS) (O'Brien, 2001).

4.3 Hospital Pharmacist

A pharmacist at a leading Melbourne hospital was consulted about their internal ADR monitoring program and how their program links into the program run by the TGA. Although the goal of the initial project had the focus on prescribers, it was felt that an understanding of a pharmacist's perspective may add additional insight into the issues surrounding ADRs.

A single pharmacist is unlikely to be representative of the population of hospital pharmacists. The perspective, however added to our growing knowledge of the processes surrounding ADRs.

4.4 A Consumer who experienced a severe ADR

A Consumer who had recently experienced an ADR, who knew we were conducting research in this area, alerted us to her experience and offered to be a pilot in the study. This Consumer wrote a detailed account of her experience, indicating the clinics she attended, and her understanding of the diagnoses, treatments, and treatment outcomes, from her non-medical perspective.

Again, a single participant is unlikely to be representative of the population of Consumers who have experienced moderate to severe ADRs. The insights from this study, however, provided a perspective not seen by any of the other participant groups.

5 Outcomes of the Studies

5.1 TGA

The TGA indicated that their voluntary reporting drug surveillance program has the specific goal of capturing drug/s that may result in moderate to severe ADRs, and taking action to prevent serious reactions. Their actions may include removing a drug from the market, alerting health professionals via bulletins and the media. They also noted that there are many issues that impact its effectiveness. Below are some of the issues they raised:

5.1.1 ADRs ARE COMPLEX

- ADRs are diagnosed with only a degree of certainty.
- It is rare that a drug will definitely cause a reaction.
- Often there is missing information such as gaps in the Consumer history

- The TGA report on individual cases, providing case descriptions, and by stating how many reports they have received

5.1.2 REPORTING IS LOW

If prescribers do not report, the ADR database is less complete, and therefore the trends found have less strength with less data. Some possible reasons for this are thought to be:

- Prescribers may not see the benefits of the reporting.
- Reporting is time consuming.

5.1.3 DELAYS IN COMMUNICATING THE ADR INFORMATION

- ADRAC meets 8 times/year, and bulletins are published 4 times per year. Although the decision to publish bulletins 4 times/year has been a consious decision, there may be a delay in communicating this information to prescribers.
- information does eventually get into prescription information, but may take up to a year.

As can be seen, the TGA data collection process is for a specific purpose, drug surveillance and protection of the community. Difficulties with the system include the complex nature of ADRs, under reporting, and communicating findings in an effective, timely manner to health professionals.

5.2 General Practitioners

Throughout the four forums, the GPs were asked to describe their current practices, issues with those practices, and what data and/or tools may assist them prevent, detect and efficiently manage ADRs

5.2.1 SOURCES OF ADR INFORMATION

GPs reported that information about ADRs is in multiple locations and difficult to access. They reported that there is too much information about drugs, to keep abreast of it all, and that it is difficult to be sure of the reliability of some of the sources. A method commonly used to manage the large quantities of information is to have a list of commonly used drugs, and learn as much as possible about those drugs. Attempting to keep up to date with all drugs on the market, they saw as unrealistic. Sources of information about ADRs include prescribing software, discussions with drug representatives, personal experience, word of mouth, discussions with colleagues, documentation in a Consumer record, journals and medical publications including the TGA ADR bulletins, Continuing Medical Eduction meetings and the Media

5.2.2 ACCESS TO TGA ADR BULLETINS

Not all of the GPs in the forum had seen the ADR TGA bulletins. Although the bulletins are freely available to health professionals through the Australian Prescriber (http://www.australianprescriber.com), or by a request to the TGA to be put on the mailing list, and accessible on the Internet, many of the GPs in the forums were not aware of their availability. They indicated they do not have time within a consultation to look up the Internet. Those who do receive the bulletins said it is time consuming

to find the information they require, as they are in paper format with no overall index. They said it is difficult to determine which components are relevant to the particular Consumer in their rooms at the time.

5.2.3 ADR WORKFLOW

A critical element in developing decision support is understanding the decision environment. What are the decisions made by GPs that use ADR information? When do they need it and in what format? Over the four sessions, the GP group teased out a set of situations or decisions they feel they require in order to access information about ADRs. Each one was then expanded into a scenario. The detailed accounts can be found in the Final Report to Department of Health and Aged Care for Contract for Services GPCG #12 Adverse Drug Reactions Improved Decision Support (ADRIDS).(O'Brien, 2001) Below is a list of situations identified in these forums.

- deciding on a drug to prescribe;
- a Consumer requests information about a specific drug;
- a Consumer requests potential side effects of a drug prescribed for him/herself of a family member;
- a Consumer requests potential side effects about a newly prescribed drug and a drug s/he is currently taking;
- a pharmacist dispenses a drug;
- differentially diagnosing a disease verse a drug reaction;
- a Consumer phones or presents about a possible reaction having commenced drug therapy;
- determining which drug to cease;

- investigating a new drug on the market;
- deciding whether to report an ADR to the TGA.

5.2.4 KEY INFORMATION REQUIRED BY GPS WHEN MAKING ADR DECISIONS

The elements and characteristics of the information they felt was needed included the following:

- the source of the ADR information needed to be identified and known to be from an unbiased source;
- any information needs to be concise and relevant. They do not have time to read screeds of information in order to get to the relevant information. They would like the option of reading in more detail at a later stage if necessary.
- severity of the potential reaction.
- the frequency of the potential reaction. How many reactions have been reported per number of prescriptions dispensed?
- severity of the potential reaction.
- the frequency of the potential reaction. How many reactions have been reported per number of prescriptions dispensed?
- in order to differentially diagnose a disease and a reaction, the GP needs to have considered a reaction to be a possibility. Highlighting this possibility may be a role of the decision support software.
- Information including specific Consumer characteristics is useful, in order to know the potential risks for the specific Consumer in the consultation.

- warning "loudness" needs to be in proportion to the severity. The GPs would like software to stop clinician if the risk is high, verses a warning in the background, if minor reaction is likely or possible.
  (O'Brien, 2001)

5.2.5 GP MOTIVATION TO USE ADR DECISION SUPPORT TOOLS

The GPs in the forum were very interested in participating in the discussions and provided some valuable information. One factor that was highlighted several times, was that they do not see moderate to severe ADRs very often. The GPs reported that they are interested in having a product that sits in the background and provides alerts as required, however their experience thus far of software using alerts, is that the alerts occur too frequently, often highlighting information they are aware of, or that is not relevant to the Consumer in the rooms, and the information highlighted is not critical enough to interrupt. The result they described is one of being de-sensitised and in some cases turning off the alerts.

If, as the GPs report, moderate to severe ADRs are seen infrequently in the GP environment, the authors feel that decision support in this environment may not be a high priority for GPs which may impact on the uptake of any technology developed for this group. This perspective is interesting when compared with seriousness of the issue as discussed in the introduction of this paper, and in light of the number of reports received by the TGA. One possible explanation is that GPs may see the reaction in its early stages as reported in the Consumer pilot study in section 5.4. Once the reaction has reached the moderate to severe level, the Consumer may be

receiving treatment at in a hospital setting. It also raises the question of who has the motivation to develop and utilise decision support technology to assist with ADRs?

5.3 Pharmacists

The Pharmacist's view was that if a Consumer has experienced an ADR, there is a very high chance that the individual, if given the same medication again, would experience a reaction again, and possibly to a more serious degree as the body has set up immune defences against that medication. His focus, therefore is on making very sure that the correct cause of the reaction is identified, and that the individual Consumer never experiences it again. He also emphasised the fact that in cases of misdiagnosis, a Consumer may be excluded from using a drug therapy unnecessarily, limiting their treatment options in the future.

5.3.1 KEY FEATURES OF THE PHARMACIST'S REQUIREMENTS:

- emphasis on the Consumers who have already experienced a moderate to severe ADR;
- the pharmacist is not confined to a 15 minute consultation – there is more time for research;
- the pharmacist is interested in detailed case information – detailed descriptions of similar cases;
- correct diagnosis is viewed as critical – the pharmacist did not want to blame a drug unnecessarily and therefore restrict future options of treatment, but also did not want to allow a Consumer to re-experience a moderate to severe reaction, that may have been able to be prevented.
- emphasis on communicating to the Consumer so s/he understands the reaction and can pass this information on to future prescribers.

- view TGA ADR data as just one source of ADR data, and that there are many other sources that also need to be consulted

5.4 A Consumer who experienced a severe ADR

A 42-year-old woman went to see her General Practitioner (GP) for dental pain. The GP advised her to see a dentist after the infection had subsided. Having checked with this woman as to whether she had ever experienced a reaction to Penicillin, the GP prescribed Penicillin for the infection.

This woman moves house every couple of years. Over the years she has experienced problems with her sinuses, frequent throat infections, sleep apnoea, and high blood pressure. She has been to many GPs, some of whom she found extremely helpful, but some of her experiences were negative and as a result she is reluctant to seek assistance for medical problems.

Eight days after she began taking the Penicillin, the woman felt unwell, nauseated and lethargic. She noticed some small red spots on her arm, the size of a match head. By mid afternoon, she noticed swelling on her right eye and right lip. She made the decision not to seek medical assistance at this stage, hoping the symptoms would subside. By late evening her hands and face had swollen, both eyes were swollen and she had severe joint pain. The spots had grown into "vivid red rashes" on her arms, legs abdomen and neck. Movement was "excruciatingly painful".

Eventually the woman went to an after hours-medical clinic. The GP (a different GP to the one who prescribed the Penicillin) managed to extract some case history

information from the woman, even though she was feeling so unwell. She told him she had experienced swelling like this in 1994, but the medical staff were not able to find a cause. She also told him she had been on blood pressure tablets since 1997. The GP diagnosed the problem as a delayed reaction to a recently completed course of Penicillin, and treated her with Phenergan and Cortisone. The GP advised her to go back to the original GP or to the hospital if the swelling did not subside.

By morning, the swelling had subsided and the pain had eased. That day she took her normal blood pressure medications (Tritace and Felodor). That night, the swelling began again. At 4.00 am in the morning, she found it difficult to sleep as her throat was swelling and breathing was difficult when lying down. She was staying with some friends and did not want to wake them. She waited until 5.30 am before she asked them to take her to the hospital emergency clinic (a third clinic).

The Doctor at the hospital also diagnosed the problem as a delayed reaction to Penicillin and treated it accordingly. Whilst in hospital, she began to feel clammy and nauseated. Her blood pressure dropped suddenly and she had a brief cardiac arrest. The next day, she had stabilised, but the swelling did not go down, so she was kept in hospital for observation. A specialist saw her (a fourth Doctor) who decided the reaction was unlikely to have been Penicillin alone as she had no prior history of having experienced this problem. The Tritace she had been taking for her blood pressure, she had been told was a short-term drug, and she had been on it long term. This may have caused a toxic build up. The Penicillin may have triggered the reaction caused by the Tritace. The Doctor decided to stop the Tritace, and increase the doses of the Felodur, the other blood pressure medication she had been on.

The symptoms gradually subsided.

The Consumer participant has no medical training. The information she provided about her case is her interpretation of the events only. However, this single case has provided some additional insight that is not available when studying ADRs from the perspectives of an individual clinic, a hospital or cumulated data collection.

The Consumer is the only person who was present throughout the entire reaction. The consumer was present at each of the medical clinics. Of the four doctors she saw, each one only had access to any prior medical history in their clinical file or any history the Consumer was able to relay. Due to the severity of her illness, by the time she reached the emergency medical clinic, she was unable to provide any medical history, including the names of the doctors who had treated her previously. Each of the clinics had access only to a small proportion of the data. Their view, therefore is a very different view from the view of the Consumer. The Consumer does not (in the majority of cases) have a medical background in order to make sense from a medical perspective of their case, but they do have data that is not accessible to the medical practitioners who do have the medical training to interpret the incident through a medical lens.

A Consumer, generally, does not record information received during medical consultations. In order to discuss their medical history, therefore, they are reliant on memory. This may be further impeded due to the fact that they will be remembering

their interpretation of what was said to them, and if information was of a medical nature, their understanding of what was said, may not be accurate.

What they do have, however, is motivation and an intensity of experience that is unlikely to have been experienced by the staff working with them. For a mother of 5 children, the youngest 3 years old, the experience of a reaction that resulted in hospitalisation and from her perspective, could have resulted in death, is likely to be one firmly imprinted in her mind. Not only is she likely to remember the details surrounding the incidence, but also she is also likely to be highly motivated to ensure it never happens again. In cases where the Consumer has remembered the details with limited accuracy, they may have remembered the clinics they attended and approximate dates, which provide pointers to the data that was recorded by the medical practitioners who was present during that episode of care.

6 Analysis of the Studies

Below, is a table summarising the key differences in the data requirements between the TGA ADR surveillance program, GPs in community settings, a Hospital Pharmacist and a Consumer

Agency	**Data required**	**Purpose of data**
TGA	Summarised aggregated data with a drug focus.	Detect new, previously undocumented and undetected ADRs to protect the community as a whole.
GP	Concise, specific data	Minimize risks of medication.

	with a Consumer focus. The relative risk between two medications for the same therapeutic purpose.	Diagnose reactions if they occur
Hospital Pharmacist	In-depth case history data with a Consumer focus.	Prevent severe potentially life threatening reactions for Consumers who have previously experienced ADRs.
Consumer	Access to their full medical history. Information about what information is critical to the doctor or pharmacist so it can be conveyed at the time of the consultation.	To decrease the chance of taking a medication that may do them harm. If a reaction has occurred in the past, protect themselves from a repeat experience.

Table 1. Summary of ADR data requirements from three groups.

6.1 Data requirements of each group

It is clear that each of these groups has a specific purpose for ADR data, but that their needs are different.

The TGA can state how many cases have been reported, but are not able to collect incidence information. At this stage it is not possible to collect accurate incidence information. All incidences of a reaction are not reported, and the number of people who used the medication without a reaction is also not available. A figure that can indicate the relative incidence risk between two medications appears to be a key element in GP decision-making.

The GPs in the forums, indicated little interest in the number of cases that have been reported. They are interested in case descriptions similar to a case they are attempting to differentially diagnose. They are interested in the likelihood of a Consumer reacting to a drug. Is it one in 10 or one in 10 million? If there is a high risk, is there a similar drug that has a lower risk, and what is it? Are there specific Consumer risk factors that can be identified?

GPs indicated that as severe reactions are rare, they would like software that can sit in the background as a monitor, but that is not intrusive in everyday practice.

The hospital pharmacist did see moderate to severe reactions in the hospital environment, and is very interested in detailed case analyses. This pharmacist was less interested prevention. His focus was on prevention of a patient experiencing the same reaction a second time.

6.2 Patterns seen from a longitudinal perspective

The Consumer's high level of motivation, combined with access to a longitudinal view of the ADR, when combined with expert ADR knowledge, provided diagnostic information that is critical in the future management of the Consumer.

When this case was presented to an ADR expert, he stated that a characteristic of the drug, Tritace (active ingredient, ramipril), is that a Consumer may be symptom free for many years, whilst taking the ACE inhibitor. The symptoms of a reaction to ACE inhibitors such as ramipril (Tritace), include face oedema and throat swelling. He also stated that the initial symptoms of a rash and joint pain, indicate serum sickness, a delayed hypersinsitivity that may well have been due to the penicillin.

The Consumer may not know which components of their case history are important. A Doctor knows which aspects of a case history are important, but in emergency situations may not have access to this history. An ADR specialist may know the characteristics of a reaction to a drug such as Tritace – information that may not be common knowledge to a GP who rarely sees severe ADRs, however the ADR expert is not the person treating the Consumer.

A pattern existed, that when highlighted by a consumer and then viewed through the eyes of an ADR specialist, resulted in a diagnosis that had not previously been made; information that the Consumer could use to assist in the prevention of such a reaction in the future. One implication of this observation is that the Consumer perspective may be valuable in understanding ADRs.

6.3 GP involvement in moderate to severe ADRs

Of the four doctors who treated the Consumer, the first did not see any reaction. The second doctor only saw a mild to moderate reaction. The next two doctors saw a severe reaction. The GPs who discussed ADRs stated that they rarely see a severe ADR. The pilot study confirms that the GPs did not see the extent of the reaction. They were, however treating a Consumer who had a severe ADR, but they were not aware of it.

This pilot study has provided insight into a GP perspective that was not seen when viewing the issue from the GP perspective, the hospital perspective or from the perspective of the cumulated data collection.

6.4 Decisions surrounding ADRs are not just medical decisions

Consumers make decisions about their treatments, about which doctors to consult, and when to seek advice.

In this case, this Consumer has a life style that requires regular travel. She has visited many GPs throughout her life as she has lived in many locations. This is her choice, or her lifestyle decision. The consequences of this decision is that her medical history is in multiple locations.

The consumer has had some negative experiences with some of the GP services she has accessed. As a result of this experience, she made a decision to only access medical services when she could see no alternative. Her decision to delay visiting a

medical service had the consequence of her accessing an after hours clinic rather than going back to her original GP who had access to her medical history.

The Consumer's decision to disclose a previous reaction that was undiagnoses from many years ago, assisted in the diagnosis of the reaction to Tritace. A key characteristic of this reaction is a history of long periods of no reaction, whilst still taking the medication, as discussed in section 6.2.

7 Implications for Decision Support

7.1 Full consumer history and pattern detection using ADR expert knowledge.

Even when medical records are electronic and a Consumer can store their entire medical history in one repository, accessing patterns such as the one highlighted in the pilot study is unlikely to be an easy task without some assistance. It is possible that such a large document may obscure vision rather than clarify it.

Decision support may be able to assist in locating critical factors within a Consumer electronic medical file that pertain to his/her ADR. By developing a knowledge base, which includes known patterns for rare ADRs, that can support a search through an electronic medical record for critical features, ADRs may be detected earlier, or those patterns may be able to be used to prevent reactions in the future.

This pilot study demonstrated that by studying a single Consumer history from the Consumer perspective, one of these patterns was highlighted. By studying more

Consumers in conjunction with accessing information known about ADRs by ADR experts, these patterns may be able to be developed

7.2 Consumer access to a DSS

The request at the beginning of the study was to provide decision support to GPs so that they can prevent, detect and manage ADRs more effectively. It is the Consumers, however, who have either experienced a reaction in the past, or who are at risk of experiencing a reaction due to a complex history, that appear to have the highest motivation to prevent reactions.

If the reaction is not prevented, it is the Consumer who experiences the consequences. These scenarios suggest the consideration (and possible development) of decision support that is accessible not just to a GP, but to a GP and a Consumer.

Consumer needs highlighted from this pilot study were,

- a need to understand the critical components of the medical history when speaking to a new doctor, to make sure that relevant information is highlighted to assist their communication,
- the ability to store and recall the medical information that was provided to them, so they can pass this information on to other doctors accurately to assist with diagnosis,
- the ability to store all of their medical history from multiple clinics in the one location.

If these facilities were available to a Consumer, s/he may be able to provide a detailed case history to a new GP, access critical factors with accuracy to pass on to a GP,

continue to protect information within their case history s/he does not choose to share with the new medical practitioner.

7.3 GP feedback

If, in each of the cases such as the one presented, there were processes in place to inform GPs of the outcome of cases that escalate, such as the pilot study discussed it would be interesting to see if awareness and motivation increased. The second GP, if aware of the history and if s/he had access to the ADR expert information about the drug Tritace, may have been able to diagnose the reaction at an earlier stage, thus preventing it from developing further. Obviously there are dangers in using hindsight, as blame can be attributed where it is not warranted. The second GP did not have access to the critical pieces of information, and made a diagnosis based on incomplete information - a task doctors are regularly required to do. The point is that providing increased access to critical information, if those critical components can be isolated, may lead to decision making which is more informed, with less uncertainty.

7.4 Decision Environment

As was highlighted in this pilot study, the Consumer did make decisions that had an impact on the outcome of his/her injury and treatment.

It is not clear at this stage whether any of the decisions made by the Consumer had an impact on her illness. Whether treatment could be assisted with decision support is another question. What is clear, however, is that an understanding of the decisions that Consumers make with respect to when they seek medical treatment, who they

seek it from, which information they choose to disclose and why, their compliance with medical recommendations decisions, if understood, may assist in the management of ADRs. Some of these may be by educating Consumers to make decisions that assist their treatment, or assist GPs in understanding what they can do differently to understand the needs and expectations of Consumers, which may result in more effective management of ADRs.

Conclusion

This preliminary work has provided the following insights that will further our study:

- Each of the clinical groups appear to have different data requirements
- The GP's perception that ADRs are infrequent, may be paritally due to their involvement in the early rather than latter stages of an ADR.

Decisions surrounding ADRs are not just medical decisions. The majority of decision support systems for medical purposes are built for the use of medical staff. This study indicates that Consumer decisions may also have an impact on whether an ADR is prevented, or detected quickly.

Studying the role of Consumers in the decision environment surrounding ADRs appears to be an important stage in determining the benefits of Consumer/GP decision support.

The Consumer case study clearly demonstrated some benefits of a longitudinal view of an ADR. When this view was compared with the views of the other clinical groups, it became clear that the combination of each view provided insight not gained by any of the individual views, and that this combined view may provide an important

path for future decision support. Patterns of ADR behaviour not visible from a single clinical perspective were visible from the longitudinal Consumer view. A full consumer history in an electronic medical record in conjunction with an ADR pattern detection module using ADR expert knowledge, may assist in prevention and early detection of ADRs.

Acknowledgements

Industry Partners include the following:

- Dept. Health and Aged Care – Therapeutic Goods Administration (TGA)
- Ballarat and District Division of General Practice
- Medical Software Industry Association
- Therapeutic Guidelines Ltd

also

Collaborative Centre for E-Health.

REFERENCES

BARNETT, FAMIGLIETTI, KIM, HOFFER and FELDMAN (Year) of Conference *DXplain on the Internet,* Proceedings of the 1998 AMIA Annual Fall Symposium, 607-611

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

CALDWELL, R. (2000) Alerting Staff to Medication Errors, *Health Management Technology,* **21,** 52.

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 Medicaiton in Individuals With Mental Retardation and Developmental Disabilities, *Mental Retardation and Developmental Disabilities Reasearch Reviews,* **5,** 348-359.

KOHN, L., CORRIGAN, J. and DONALSON, M. (1999) *To Err is Human: Building a Safer Health system,* Institue of Medicine National Academy Press. Washington.

KUBOTA, K. (1999) A Design for Prescription-Event Monitoring in Japan (J-PEM), *Parmacoepidemiology 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 Aproach to International Signal Analysis, *Parmacoepidemiology and Drug Safety,* **8,** s15-s25.

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 Center 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,** 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),** 1295-1298.

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, *Journal of American Medicine Association,* **280,** 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

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

THOMAS, K. W., DAYTON, C. S. and PETER, M. W. (Year) of Conference *Evaluation of Internet-Based Clinical Decision Support,* Journal of Medical Internet Research,

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