1. Drug use and Quality Use of Medicines

"Medicines are nothing in themselves, but, are the very hands of the gods if employed with reason and prudence"

-Herophilus 300BC

More than two thousand years after Herophilus made this observation, the issues of quality use of medicines continue to be challenging.

Medication use is the most commonly used intervention in health care.(5) Medication use in Australia is extensive. In excess of 12 million Australians (representing 68% of the population) have used at least one medication in the two weeks preceding the 1995 Australian National Health Survey.(6) This is comparable to the data recorded in the National Health Surveys of 1989-1990 (70.4%) and the 1983 National Health Survey (67%).(7)

The use of medications also represents a significant economic investment. According to the latest Australian Institute of Health and Welfare (AIHW) Health Expenditure report, Australia spent AUD$72billion on health services in 2002-2003. Of this, about AUD$10billion was spent on pharmaceuticals. This represented a 10% increase compared to the spending in the previous financial year (2001-2002).(8, 9) The estimated total expenditure on health in Australia in 2001-2002

was AUD$66.5billion (equivalent to 9.3% of the national gross domestic product). Pharmaceuticals represented the third largest health expenditure, totalling AUD$8.9billion (14.4% of all recurrent expenditure).(10)

The increase in medicine use leads to an increase in problems associated with medication use. Drug-related morbidity continues to be a major concern in Australia, with an estimate of 80,000 hospital admissions per annum being associated with medicines use.(11)

There is evidence of inappropriate use of medicines in Australia. In a review of Australian studies published between 1988 and 1996, Roughead et al estimated that drug-related hospital admissions (in public hospitals alone) cost taxpayers about AUD$350 million annually.(12) In the 2002 Australian Council on Safety and Quality in Healthcare's national report, it is estimated that 140,000 hospital admissions, costing AUD$380 million each year, were associated with medication use.(13)

Problems relating to drug use are not isolated to Australia. A review of 3277 coroner's inquests in a district in the United Kingdom between 1986 and 1991 showed that 10 deaths were due to medication prescribing errors and 36 were due to adverse reactions to medications. This relates to 1 in 2000 of all deaths being directly attributable to medication use.(14)

A meta-analysis of 39 prospective studies in the United States showed medication-related events are the fourth leading cause of death. The estimated cost of drug-

related hospital admissions from this study was USD$1.6 billion.(15) The 2nd Harvard Medical Practice Study reviewed more than 30,000 randomly selected hospital records. The results of this study indicated that medication related events were the single largest category of adverse events, accounting for 19% of all events.(16) When used appropriately, medicines are highly beneficial, but inappropriate use causes negative health outcomes, leading to drug-related admissions and a waste of health care resources.(17, 18)

Pharmaceuticals are developed based on a rational scientific model.(19) However, the manner in which they are used may not be in accordance with that model.(20) The World Health Organisation (WHO) claims that the ways in which medicines are used, generally reflect a matrix of societal, economic and health factors.(21)

Inability to afford health care and medicines causes loss of working days and a decline in economic productivity.(22) Accessibility to drugs, in a safe and cost effective manner, could have an impact on the health status of a country.(17) A major step towards addressing the accessibility to drugs at an international level was taken when the World Health Organisation established the Essential Drugs and Medicines Policy. The concept of an essential drugs list is to ensure that the medication needs of the majority of the population are met.(23)

A World Health Organisation conference on rational drug use, in Nairobi, provided the impetus for governments to implement national policies to ensure rational drug use in their countries.(17) Since this worldwide movement towards rational drug use, about 160 countries now have essential drug lists. Over 100 countries around

the world have national drug policies in place or under development.(17) Australia's National Medicines Policy is a drug policy reflective of Australia's commitment to the goal of achieving rational drug use.(24)

1.1 Australia's National Medicines Policy

Australia has been described as one of the leaders in the global rational drug use movement.(25) Some aspects of Australia's vision on rational drug use have been in development since the 1950's.(26) Australia's National Medicines Policy has been in place since the early 1990s, although it was not gazetted until year 2000.(27)

The overall aim of the policy is to "meet medication and related service needs", so that "both optimal outcomes and economic objectives can be achieved for all Australians".(24) The policy highlights the necessity for stakeholder partnerships in order to achieve the objectives of the policy. The National Medicines Policy identifies four key areas relating to medicines and their use.

One area is *access to medicines*. Cost may constitute a substantial barrier to the public's access to the medicines they require.(28, 29) The National Medicines Policy notes that access to medications should be timely and equitable. The Pharmaceutical Benefits Scheme (PBS) facilitates access to selected medicines by subsidising costs of drugs prescribed by doctors in the community setting and private hospitals. The PBS is a Commonwealth-funded initiative and covers about 80% of prescription medicines available through pharmacies in Australia. In 2003, 163 million prescriptions (about 8 prescriptions per person) were obtained through

the PBS.(30) PBS expenditure is uncapped with regard to volume. However, this funding does not extend to the use of medicines within the public hospital setting.

Public hospitals in Australia provide the major proportion of inpatient care. They are funded and managed by the states and territories in Australia.(31) There has been a decrease in recurrent expenditure on hospital-based services as a proportion of all recurrent health services expenditure.(32) This is likely to have resource implications. Use of medicines in public hospitals is funded through this system. Subsidies for medications occur when hospitals supply medications to patients. It is estimated that a total of 13% of all state governments' budgets, was spent on public hospitals in the 1999-2000 financial year. Five percent of the budget allocated to public hospitals was used to subsidise patients' medicines.(33) In most public hospitals, the cost of medications is considered as part of hospital care. However, the PBS system (i.e. Commonwealth funding) is available for outpatient services in public hospitals in some states (e.g. Victoria) and for High Cost Drugs funded under Section 100 of the PBS system in all Australian states and territories.

The National Medicines Policy also addresses the issues of *quality, safety and efficacy of medicines* available in Australia. The Therapeutics Goods Administration (TGA) is responsible for assessing and monitoring therapeutic goods (including medicines – prescription, non-prescription and complementary; medical devices, blood and tissue products) to ensure that those available in Australia are of an acceptable standard.(34) The TGA collaborates with the government and the pharmaceutical industry to ensure medicines are produced according to appropriate practices. They are also involved with pre and post-marketing surveillance.(27)

The continued existence of a *responsible and viable medicines industry* is the third arm of the National Medicines Policy. The policy calls for a coordination of industry and health policies so that the pharmaceutical industry is able to conduct research, manufacture, and supply medicines under a consistent and supportive environment.(34) There is emphasis on the consumer (patient) in that the pharmaceutical industry should, where possible, communicate clearly with consumers through educational materials, consumer medicines information and responsible advertising.(35) In Australia, direct to consumer advertising is proscribed. However, important information about medicines relevant to consumers (eg consumer medicines information, patient counselling materials) may be obtained from pharmaceutical companies. Prescription medicines may only be promoted to health professionals, and these advertisements must comply with the Medicines Australia (self-regulated) code of conduct.(36)

The Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee produced the *Quality Use of Medicines (QUM)* policy which is incorporated as the fourth aspect of the National Medicines Policy.(37) The QUM policy is a significant part of the National Medicines Policy as it articulates the principles that underpin the improvement of the rational use of medicines in Australia.

1.1.1 National policy on Quality Use of Medicines

The goal of Australia's policy on Quality Use of Medicines (QUM) is to improve health outcomes for all Australians by optimising medicinal drug use (prescription, non-prescription and complementary medicines).(37) The QUM policy proposes that medicines should be used *judiciously*, assuring that the best possible

treatments are chosen to treat an illness (this may or may not include the use of medicines); *appropriately*, after establishing that the medicine is needed to treat an illness – medicines should be carefully selected, managed, monitored and reviewed; *safely*, assuring that there is no misuse, overuse or underuse of medicines; and *efficaciously*, ensuring that the medicines used are achieving the goals of therapy by delivering beneficial changes in actual health outcomes.(11, 38, 39)

The principles of Australia's QUM policy are corroborated by the World Health Organisation's definition of quality drug use, "Drugs are often required for prevention, control and treatment of illness. When a drug is required, the rational use of drugs demands that the people can afford it, that it be dispensed correctly, and that it be taken in the right dose at right intervals and for the right length of time. The appropriate drug must be effective, and of acceptable quality and safety."(17)

The National Strategy for Quality Use of Medicines has been described as the required approach for achieving QUM. It is based on the principles of education, behaviour change, community development, health promotion, public health and social advocacy.(38) This national strategy (Figure 1.1) acknowledges that the four central objectives of the National Medicines Policy are interdependent. The QUM policy is at the core of this strategy to ensure that the emphasis is always placed on improving health outcomes.(39)

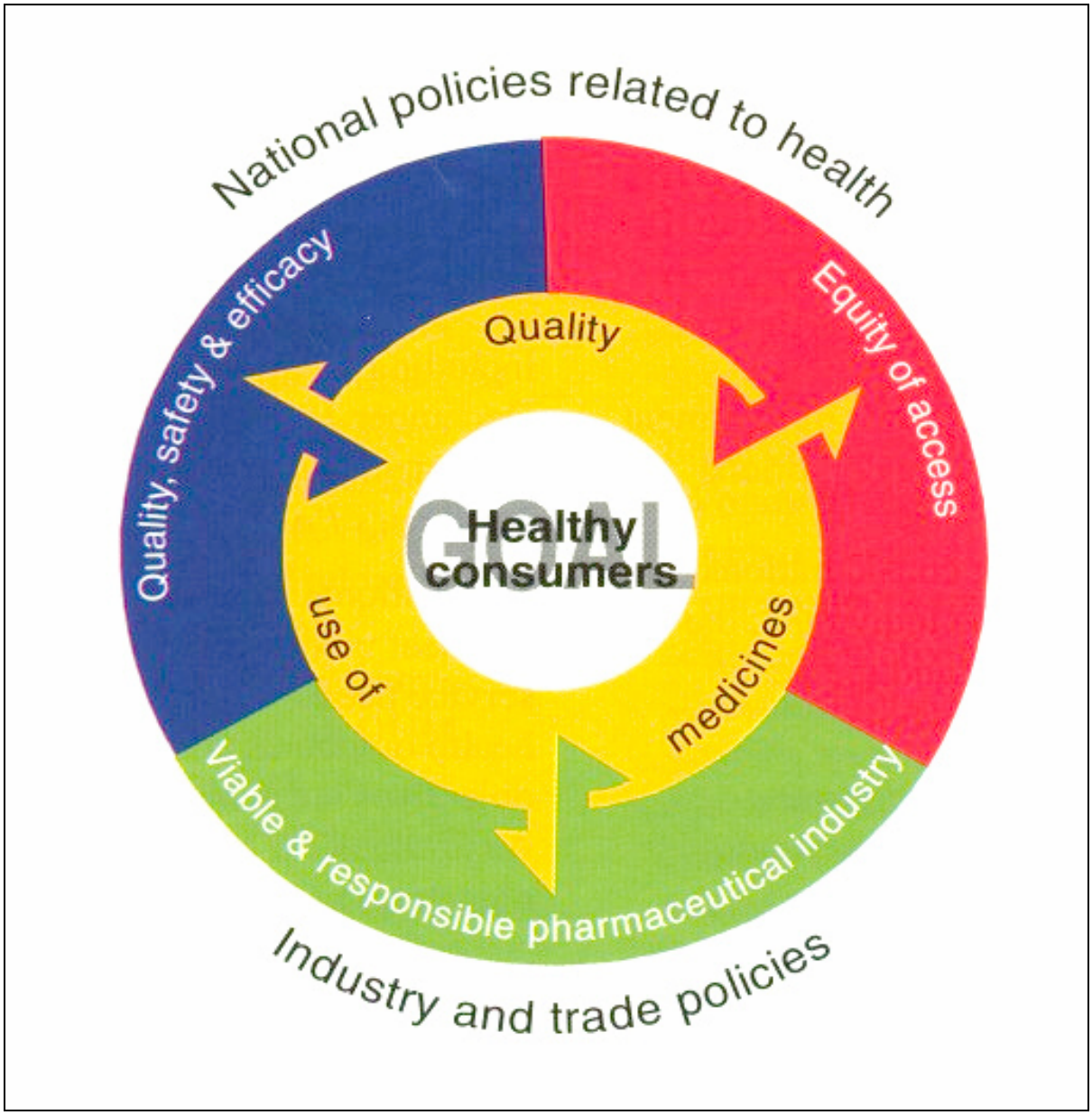

Figure 1.1: Australia's National Medicines Policy(11)

1.2 Quality in health services

Since the dissemination of the QUM policy, the commitment to quality of care in health has been increasing in Australia.(40) There is now a greater recognition that a comprehensive evaluation and improvement of quality in health services is required.(41) Until recently, health performance monitoring has been focused on activity and economic efficiency.(42) Clearly, these continue to be important aspects. However, emphasis on other dimensions of quality of health care is also needed. In keeping with the National Strategy for quality use of medicines, the focus has moved towards the improvement of patient health outcomes.(43) Health Departments have been actively seeking means to meet this challenge.

A Framework for Managing Quality of Health Services is a New South Wales Health Department initiative, and is typical of programmes in other states and the Commonwealth. The framework is a practical approach to monitor and manage the quality of **all** aspects of health care, within which performance in six dimensions of quality and five cross-dimensional issues provide the basis for measurement, reporting and improvement.(44) Synonymous to the QUM policy, the six dimensions of quality stated in the framework include safety, effectiveness, appropriateness, consumer participation, access and efficiency.(44)

This approach represents a major step forward for the improvement of health services, because initiatives, such as this, will firmly place the quality of patient care on the agenda of health policy makers and administrators. It also provides a method for benchmarking activities across health care settings.(45, 46)

1.3 Use of medicines in hospitals

The use of medicines constitutes a large part of patient care. This is especially true in a hospital setting, where the use of drugs is associated with many facets of the delivery of care.(47) For in-hospital medicines use, it is important for hospitals to have a model for maximising the health and economic outcomes achieved via drug use. This is challenging, in part because of the multiplicity of available medications and complexities surrounding their appropriate selection and effective use.(12, 48)

1.3.1 Ensuring rational and evidence-based drug use in hospitals

The World Health Organisation has identified and promoted the Drug and Therapeutics Committees (DTCs) at district and hospital levels, as being one of the pivotal models to promote rational use of medicines.(49) It is suggested that augmenting the performance of DTCs may lead to improvements in the quality of drug use, and ultimately improvements in patient care.(50)

There is evidence that hospital-based drug use may have an impact on drug use in the broader community. A qualitative study examining the influences on prescribing showed that general practitioners (working in the community) are influenced by hospital prescribing.(51) These findings were similar to another study conducted in the Australian setting.(52) Further, an analysis of general practitioners' prescribing data also showed that hospital prescribing was an important influencing factor.(53) The use of new drugs in the primary care setting frequently mirrors the use in hospitals.(54)

Thus, it is accepted that hospital-based practices have the potential to have an influence beyond the hospital setting into community practice.(55) This means that the DTC's influence will frequently extend beyond the boundaries of its local organisation.(56)

2. Drug and Therapeutics Committees

2.1 Introduction

In the previous chapter, it was ascertained that the irrational use of medicines is a major problem in health care. There are lessons to be learnt from experiences in countries where there is lack of control over the use of medicines.(57) The magnitude of irrational use of medicines may have a significant impact on health expenditure. As well as being a waste of available resources, irrational use of medicines affects the safety and quality of patient care.(17) The emphasis on rational drug use in the last 40-50 years has highlighted the need for forums of relevant stakeholders (clinicians, pharmacists, administrators, etc).(4) DTCs provide a multidisciplinary forum for opinion leaders to work jointly towards the goal of rational drug use.

This chapter presents a review of the literature on DTCs. The primary purpose of this review was to gain an understanding of DTCs, in terms of its development, structure, roles and how DTC decisions are implemented. In addition, the literature on quality assessment and improvement efforts relating to DTCs were examined.

The literature search was conducted to locate English-language studies published between 1970 and 2004. Search terms including “Drug and Therapeutics Committees”, “Pharmacy and Therapeutics Committees”, “quality improvement”, “quality assessment”, and “indicators” were used in Medline. The websites of health

departments and the World Health Organisation (WHO) were also searched for publications of interest. In addition, a manual search of the list of references in articles of interest was undertaken. This strategy identified 1682 articles.

The titles and abstracts were reviewed to identify those which were not focused on DTCs and quality improvement in health care (eg studies to improve the quality of diagnostics to detect genetic disorders). These were excluded from the final review. Sixty-five manuscripts, reports and publications were included in this review.

2.2 The development of DTCs

The principles of systematic drug selection in the development of drug lists have been used since the 18th century in the United States.(58) By the 1930s, there was a global movement to establish formal committees to develop medication lists available in hospital pharmacies. These became known as Pharmacy and Therapeutics Committees, or P&TCs.(59) In 1959, the American Hospital Association (together with the American Society of Hospital (now Health-System) Pharmacists) officially described P&TCs as having the role of drug formulary development.(60)

The development of DTCs varies between the European countries. However, the Nordic countries seem to have developed a notably large number of DTCs and support the concept of DTCs. In Denmark, the “Pharmacopoeia of the Poor” was available in 1799. By 1979, about 90% of Danish hospitals were reported to have DTCs.(61) In Sweden, DTCs have been in existence since Karolinska Hospital in Stockholm set up a “committee to select pharmacotherapeutic armamentarium” in

1961.(62) In 1997, through the Swedish Drug Reform Act, each region in Sweden was required to have at least one DTC.(63) In contrast, DTCs are not mandated by German law. However, most DTCs were established in German hospitals between 1970 and 1984.(64)

DTCs were established in English hospitals in the 1940's.(65) By the 1980's a national survey documented the presence of 198 operational DTCs in the United Kingdom.(66) In Ireland, less than half of the respondent hospitals to a survey conducted in 1984 reported the presence of a DTC. In addition about half of these DTCs were formed after 1981.(67) In 1989, an Area Drug and Therapeutics Committee was established in Scotland. This area committee advises the Greater Glasgow Health board on matters relating to rational drug use.(68)

In developing countries, it has been recommended that DTCs be established in all hospitals to serve as an organisational tool to promote rational drug use.(69) In countries, such as those in Africa, the WHO has been working to establish hospital-based DTCs because they are recognised to be an important intervention in the WHO Global Strategy to prevent inappropriate use of medicines.(70, 71) In Thailand, the Ministry of Public Health requires that DTCs be established in all hospitals.(72)

The research detailed in this thesis had been conducted in Australia, where the first hospital-based DTCs were formed in the 1960s.(73) A 1996 survey indicated that 92% of hospitals reported the presence of a DTC.(74)

2.3 Representation and structure

The representation and size of DTCs varies between committees. The WHO recommends that DTCs should be multidisciplinary in order to have technical competence to make wise and transparent decisions.(4) It has been suggested that "key members" of DTCs should include representation from medical, pharmacy, nursing and hospital administration staff.(60)

The Glasgow Area DTC consists of specialist doctors, pharmacists, a general practitioner and medical advisers.(68) Danish DTCs consist mainly of pharmacists, nurses and doctors (including hospital specialists and general practitioners).(61) In Sweden, clinical pharmacologists, pharmacists and district nurses (who have some prescribing rights) are represented.(63)

Fijn et al reported that the number of committee members on Dutch DTCs varied from three to fourteen members (median=8). Pharmacists acted as chairpersons for 37% of committees. Most DTCs (95%) had pharmacists as secretaries.(75)

A survey of DTCs in Germany found that the number of members on their DTCs corresponded to hospital size, with larger hospitals having more DTC members. In almost all DTCs in Germany, all clinical specialties within the institution were represented. The number of members of German DTCs range from five to forty. Pharmacists chaired 53% of German DTCs, with only eight percent of DTCs being chaired by clinical pharmacologists. (64) This was unusual because DTCs are largely chaired by doctors.(4)

The American Society of Health-System Pharmacists' (ASHP) Statement on P&TCs recommends that P&TCs should comprise at least three physicians, a pharmacist and a nurse. In addition, the chairman should be one of the physicians, and pharmacists should be appointed as secretaries.(76) It has been reported that eight to twelve members, including a cross section of physicians, pharmacists and nurses were members of P&TCs in the United States.(58)

In Australia in the 1980's, DTCs were reported to consist of senior medical staff (of various specialties), pharmacists and nurses. In some DTCs, administrative staff acted as *ex officio* members. The size of DTCs in Australia is comparable to those in other countries, with the number of members ranging from two to sixteen people. Again, doctors most commonly held chairmanship of DTCs.(73) The results of another similar survey conducted in the 1990's indicated that membership and structure had not changed significantly over time. Medical, pharmacy and nursing representatives continue to dominate the membership of DTCs in Australia, although consumers, general practitioners and community pharmacists are starting to be included on some DTCs.(74)

DTCs have generally been regarded as a forum of experts and opinion leaders.(77) It has been suggested that the chairmanship of DTCs is important to the success of DTCs. It is desirable to have chairpersons who hold an interest in rational drug use, as well as having political leadership.(77-79) A study in 1983 suggested that DTC chairmanship was critical in ensuring effectiveness as it determined the credibility of the committee itself.(73) Cohen et al states that although strong leadership is essential for DTC success, other factors such as a well prepared agenda, a

multidisciplinary and active membership as well as the committee's ability to educate and influence practice also come into play.(80)

The literature is not clear as to how DTCs fit into the hierarchy of their organisations. DTCs report to area health services, hospital and health departments, various medical boards as well as quality improvement units in the health care system.(73)

Although patients, consumers and lay people have started to be included as members of DTCs in the 1990s, it was unclear how these representatives are being selected. Some authors believe it is important that DTCs include consumers who are active in representing the views of the majority of patients.(81) Whilst consumer representation was meant to "represent the interest of patients", (82) there is no evidence in the published literature with regard to the specifics of what was expected of consumer representatives on DTCs.

It was unclear from the literature as to the optimal frequency of meetings. Having said that, the ASHP recommend DTCs to "meet regularly, at least six times per year and when necessary".(76) Heemink et al reported that most of the P&TCs in the United States meet on a monthly basis for one to one-and-a-half hours.(83) In Australia, the most recent data indicate that Australian DTCs hold an average of six meetings per annum. However, these results indicate that there was a wide variation in the number of meetings held (none to more than twelve per year).(84, 85)

2.4 Roles and function

A report on the P&TC at Brigham and Women's Hospital in Boston, revealed that the mission of the committee is to ensure safe, effective and cost-effective use of medicines.(86) Manenbach suggested that the general vision of DTCs was to maximise access to drugs while minimising cost and adverse outcomes.(87) DTCs may be described as the cornerstone of rational drug use in organisations. The specific roles of DTCs in medical institutions represent a complex status of diverse factors associated with organisational behaviour as well as specific issues associated with the use of drugs.(4, 76, 88, 89) The WHO suggested that the DTC may have many possible functions depending on committee capacities and local demands.(17)

Patients are (and should be) the focus of the activities of DTCs.(76) The DTCs' goals are to determine what medicines will be available and how they should be used so that patients could be provided with optimal and cost effective quality of care. In order to achieve these goals, the WHO recommends that DTCs have the following objectives:(4)

- to develop and implement a formulary system which includes standard treatment protocols
- to ensure only efficacious, safe, cost effective and good quality medicines are used
- to ensure drug safety through monitoring, evaluating and preventing adverse reactions and medication errors
- to develop and implement interventions to improve use of medicines by prescribers, dispensers, administrators and patients

Traditionally, the DTCs' primary responsibility lies in developing, revising and managing a formulary or list of drugs for use in an organisation or health care setting.(58, 90, 91) The evaluation of medicines for inclusion in the drug formulary requires significant expertise. This is because DTCs are required to take a rigorous and transparent approach in the evaluation of scientific, technical and commercial sources(92) of information as the basis for DTC decisions.(4)

Formulary lists are intended as a mechanism for cost-containment.(93) With advancements in health and biotechnology in the 21st century, medicines are also becoming increasingly effective. However, these therapeutic advancements have also led to escalating costs.(94)

Drug budgets are no longer able to accommodate all the "new and savvy" therapies.(95) DTCs, through their role as financial gatekeepers have the mandate to evaluate the cost effectiveness of these new therapies. A New South Wales Therapeutic Assessment (now Advisory) Group (NSW TAG) survey showed that DTCs used pharmacoeconomic information in their decision making 60% of the time.(96) However, Rucker and Visconti argue that DTC members often lack the expertise to interpret pharmacoeconomic data. (97) This was supported by Anell, who reported that whilst DTC members surveyed generally had a interest in pharmacoeconomics, none had the competence to identify and translate results of pertinent pharmacoeconomic studies.(98)

Health practitioners need to grasp the concept that optimal health benefit is not necessarily the result of maximum expenditure.(93) A change of paradigm is required, and formularies do not provide a means to elicit behaviour change.(99) Whilst formularies continue to have a role in quality use of medicines, it should be acknowledged that formularies do not work in isolation, in the health care arena. Drug formularies should be used as a part of a larger coordinated system in order to influence practice and improve patient care.(100)

In order to influence clinical practice, DTCs should also have a role in the education of prescribers, dispensers, administrators and consumers. The ASHP calls for DTCs to "recommend or assist in the formulation of programs designed to meet the needs of professional staff (eg prescribers, dispensers) for complete and current knowledge on matters related to drugs and drug use".(76) Increasingly, DTCs have also been called on to advise on the education of patients and consumers.(101) Rational drug use encompasses appropriate prescribing, dispensing, administration as well as adherence.(17) It must be kept in mind that prescribers may not always be doctors. Similarly, pharmacists may not always be involved in dispensing medications. Nurses, care givers, and often, the patients themselves may be involved in any of these processes. Promotion of rational use of medicines therefore requires that the behaviour of all those involved (from doctors to pharmacists, nurses to carers, as well as patients themselves) be addressed.

DTCs also provide advice to health practitioners within their local institutions on issues concerning the selection, distribution and use of medicines.(88) The DTC recommends the adoption of policies regarding the evaluation, selection and therapeutic use of medicines in hospitals. Where these are not available, DTCs

may choose to develop, or may assist in the development of these policies and guidelines for drug use.(101) Many methods have been used by DTCs in order to fulfil this role. Some DTCs may set up specific subcommittees to address and target specific issues.(102) (80)

Given the potential for medication misadventure (Chapter 1), DTCs also have the responsibility to ensure that patients are being treated as safely as possible. One of the most important functions of DTCs is in monitoring and minimising adverse reactions and medication errors and incidents.(101) Safety data play an important role in DTCs' decisions regarding formulary changes.(103, 104) A survey of Australian DTCs found that 71% of respondents considered adverse effects data when making decisions about the drug formulary.(74)

Weekes and Day reported that there may be major limitations to the safety data provided to DTCs. These include: 1) new drugs with relatively short post-marketing surveillance and little safety data; 2) trial data may not be representative of patient group; and 3) lack of comparative studies evaluating the safety of the drugs.(105) Denig reported that when safety and all other relevant data being equivocal, DTCs usually preferred the drugs which committee members have experience with.(104)

Medication errors occur in all health care settings.(106) There are numerous causes for these, including inexperience, tiredness, attitudes and human error.(107) The active involvement of DTCs in monitoring and addressing medication errors and adverse drug reactions (ADRs) can help ensure the safe use of medicines.(79) The WHO recommends that DTCs should review all medication errors so that

individual incidents could be addressed. System, managerial as well as environmental problems should also be corrected.(4)

DTCs, in carrying out their roles and functions can have an impact on the ways in which medicines are being used. DTCs may use regulatory strategies (eg formularies) to restrict practice, managerial strategies (eg policies and guidelines) to guide practice, and educational strategies to inform practice. Increasingly, DTCs also have a role in risk management and clinical governance issues. The literature suggests that there may have been a shift in roles, from being merely formulary managers to being in a position to have an impact on risk management and clinical governance issues. More importantly, DTC decisions and policies may have an influence on the quality of patient care. It is therefore vital to ensure that DTCs function effectively.

2.5 Quality of DTC performance

It is important to measure the performance of committees that operate in highly complex environments despite the challenges this presents.(83) (87)

Quality activities need to be regarded as “normal business” so that health providers will be conscious of the potential deficits of care provision and be aware of the ways in which quality could be improved.(108) Performance can be considered in terms of processes, impact and outcomes.(109) Performance indicators are available to assist in measuring the quality of DTC performance.

2.5.1 Indicators as a tool for performance evaluation

A clinical indicator is defined as a

"**quantitative** measure of an aspect of patient care that can be used in monitoring, evaluating, and improving the quality and appropriateness of health care delivery".(110)

Whilst this definition is mostly applicable to clinical indicators, it may not be applicable to system or organisational issues. However, this definition does illustrate that indicators are screening mechanisms which are used to detect potential problems in quality.(111) Indicators may also reveal ways in which care can be improved.(112) In order for indicators to be useful, they must be valid, sensitive and specific.(41, 109)

An indicator's validity refers to the degree to which the indicator is able to identify situations for quality improvement. Sensitivity refers to the extent to which the indicator is able to detect cases in which a process or an outcome has occurred. An indicator which is specific, is an indicator which could identify *only* those cases in which the process or the outcome which is being measured has actually occurred.(110)

Any given set of indicators should be designed to measure "across the continuum of care or across defined episodes of care that extend beyond the traditional institutional boundaries".(45, 46) This implies that indicators should be made pertinent and quantifiable so that there can be some sense of comparison; be it

within or between institutions.(113) If this could be achieved, then benchmarking across various health care settings could be made possible.(114)

Even though indicators are highly beneficial, it must be kept in mind that they are only surrogate measures of quality. They merely “screen” and “flag” areas in need of further analysis.(112) Variances in indicator data may not signify problems. Likewise, problems may not always be exposed by variances in indicator rates.(115) The way indicator data is collected could potentially be a major impediment to its reliability.(113) The importance of accurate, reliable and unbiased documentation is essential because the application of the data is highly dependent upon the quality and the consistency of available information.(41) This is especially true if they are to be used for benchmarking purposes.(114)

Field-tested performance indicators for DTCs have been developed.(116) The NSW TAG produced *Indicators for Drug and Therapeutics Committees* and *Indicators for Drug Use in Hospitals.*(117, 118) These include process, impact and outcome indicators which are relevant to DTCs. The Australian Council on Healthcare Standards (ACHS) indicators also include various clinical indicators that are relevant to DTCs.(119)

Although P&TCs are not required in all hospitals in the United States, they serve the purpose of fulfilling standards relating to pharmacy and drug use according to accreditation requirements determined by the Joint Commission of Accreditation of Health Care Organisations (JCAHO). Patient and medication-related indicator data

are required for the accreditation of health institutions in the United States.(www.jcaho.org)

Budgetary constraints, leading to staffing inadequacies, may bring many quality activities to a standstill. However, in a health care arena where there are escalating demands for high standards of clinical practice, quality assessment and improvement is essential in ensuring safe and effective patient care. Enhancing DTC performance should perhaps be considered a priority, given the role DTCs potentially play in safeguarding the interests of stakeholders within the health care system.

2.6 Implementation of DTC decisions

In spite of many years of research to improve the quality of patient care, it seems that many patients continue to suffer the consequences of inappropriate clinical care.(107, 120) DTCs evaluate and select medicines with a view to manage the drug formulary. They also make decisions, and develop and adopt policies that may influence the quality use of medicines.(116) If attention is not paid to the implementation and adoption of these policies, then inappropriate use will continue to undermine any good work which the DTC has achieved using sound decision making.

2.6.1 Strategies used for policy implementation

The literature suggests that there are major challenges in eliciting change in practice behaviour.(121) Behaviour change is a complex process involving internal

factors (eg willingness to change) as well as external factors (eg a conducive environment). This may have led to the gap between available evidence and routine practice in health services.

Behaviour could either be affected directly, or indirectly.(122) The use of formularies, as well as other structural or administrative programs to restrict or influence prescribing are direct strategies. Although direct methods have been shown to be effective in inducing changes in practice, these could be seen as “sticks” to restrict what could, and could not be prescribed. It is not known if these direct methods have an effect on the way practitioners prescribe outside the boundaries of the institution in which these strategies are enforced.(122)

Indirect methods involve the use of strategies aimed at changing thought processes.(123) The use of educational materials, local opinion leaders and academic detailing are examples of commonly used indirect strategies. Published or printed materials,(124) drug usage guidelines, decision support systems,(125) educational programs,(126) and academic detailing(127) have been used to directly influence prescribing within their local institution. There does not seem to be much research with regard to the effectiveness of these within organisations (such as hospitals). Most of the evidence for effectiveness of these strategies was derived from studies conducted in the primary care setting. The strategies used for policy implementation will be described in Chapter 4 of this thesis.

2.7 Conclusions

There is a paucity of literature relating to the quality improvement of DTCs. The literature on drug committees comprises primarily of survey data, editorials and opinions. Although many authors suggest that DTC activities may influence the quality use of medicines,(4, 69, 74, 75, 116) there is no clear evidence in the literature directly linking DTC activities to improved QUM. However, there are some publications, particularly from national and international health organisations (eg WHO) describing DTCs as advocates of rational drug use. Upon examination of the DTCs' roles and function, it could be concluded that DTCs may indeed have an effect on the quality of drug use.

Hospital-based DTCs have long been established in many countries around the world, most notably as managers of the hospital drug formulary. The formulary has been used as a tool to ration drug use. In recent times, DTCs have also been entrusted with risk management and patient safety issues. For the most part, DTCs around the world seem to be similar in terms of structure and function.

In terms of quality improvement of DTCs, there are performance indicators which are relevant to DTCs. Although some institutions are required to submit indicator data for accreditation, it is not evident that any institutions are using these indicator data as a means of self-reflection and subsequently performance improvement.

There is little to no evidence about the best or most effective approaches that DTCs could use to disseminate and implement evidence and clinical guidelines. It is

unclear if the intervention strategies used in primary care could be applied to DTC decisions, or indeed, if these are effective in influencing hospital clinical practice.

The literature also does not provide straightforward answers to the question of what is being done in terms of quality assessment and quality improvement of DTCs. An opportunity for research is clearly identified where little has been done to gain insight into the challenges facing DTCs. Only then can practical approaches to performance augmentation be explored.

3. Evaluating Australian DTCs: A national survey

3.1 Introduction

For many years hospitals have used DTCs, traditionally to oversee hospital formularies. It has also been recognised that DTCs have a unique opportunity to be a major influence on practice because of the educational, advisory and regulatory responsibilities they possess.(56, 58) To date, there have been few studies addressing the quality of DTC performance. This is a lost opportunity, because DTCs clearly can, and should, play a pivotal role in ensuring quality of medicinal use, and yet, their effectiveness is unknown.

Performance indicators are used as an index of activity in the quality approach to care delivery in health systems.(112) The New South Wales Therapeutics Assessment Group (NSW TAG) has produced field-tested process, impact and outcome indicators for assessing the performance of DTCs.(117) Also, the NSW TAG Indicators for Drug Use in Hospitals and the Australian Council on Healthcare Standards (ACHS) Drug Indicators include various indicators relevant to DTC performance.

As an initial step to assist DTCs in improving the quality use of medicines in their institutions, this survey was undertaken to describe Australian DTCs. This was considered an essential first step to testing and ultimately implementing strategies to improve DTC performance and effectiveness.

3.2 Aims

The aims of this survey were to:

a. investigate the DTCs' self-reported functions
b. investigate DTC activities relating to performance evaluation
c. document the level of resources available to DTCs
d. document the perceived influence of DTCs on prescribing
e. document the representation of members on DTCs in Australia

3.3 Methods

A semi-structured questionnaire was developed based on previously validated surveys from the literature,(73-75) incorporating suggestions by NSW TAG and DTC members.

The questionnaire collected data on:

a. Principal functions of DTCs (perceived and ideal principal functions respectively)
b. Level to which the DTCs were achieving their principal function(s)
c. Barriers to fully achieving their principal function(s)
d. Indicator use (what indicator data were collected, and what they were used for)
e. Barriers to indicator data collection
f. Person(s) or department(s) responsible for indicator data collection
g. Resources available to aid DTC operations

h. What was perceived to be the extent of the DTCs' influence on prescribers' practices

i. Current representation on DTCs

The specific details of data collected are summarised in Table 3.1.

Table 3.1: Details of data collected in questionnaire

Issue	Details collected
a. Principal functions of DTCs (perceived and ideal principal functions, respectively)	- options developed based on common DTC functions from the literature (Chapter 2) - respondents were able to choose (tick box) more than one option where applicable - respondents could also include other principal functions in a free text area if the principal function(s) of their DTC was not listed
b. Level to which the DTCs were achieving their principal function(s)	- responses were collated on an 10-point Likert Scale (0=DTC does not achieve any principal functions; 10=DTC fully achieves all principal functions)
c. Barriers to fully achieving their principal function	- tick boxes include options used in other surveys - respondents could also include other barriers in a free text area
d. Indicator use (what indicator data were collected, and what they were used for)	- respondents were asked to indicate which of the indicators listed below were in use: *1. New South Wales Therapeutics Assessment Group (NSW TAG) Indicators for Drug Use in hospitals* *2. New South Wales Therapeutics Assessment Group (NSW TAG) indicators for Drug and Therapeutics Committees (DTCs); and* *3. The Australian Council on Healthcare Standards (ACHS) Drug Indicators* - in addition, respondents were also asked to list any other indicator sets used by DTCs in their hospitals
e. Barriers to indicator data collection	- tick boxes included options used in other surveys - respondents could also include other barriers in a free text area
f. Person(s) or department(s) responsible for indicator data collection	- tick boxes included options used in other surveys - respondents could also include other persons or departments in a free text area
g. Resources available to aid DTC operations	- respondents were asked to indicate the degree of organisational support received by their DTC *(none, very little, quite a bit, a lot)* - if their DTC was receiving any organisational support at all, respondents were asked what level of organisational support (on a 10-point Likert scale; where 0=no support at all; and 10= a high level of support) has been provided in the following areas: *1. financial – budget line (operational budget) to support the DTC's activities)* *2. financial – other (eg funds for research)* *3. allocated staff support (eg secondment to or from the Quality Improvement unit)* *4. Allocated administrative support (eg secretarial help)*
h. DTCs' influence on prescribers' practices	- respondents opinions of the extent of the DTC's influence on prescribers' practices was scored on a 10-point Likert scale (0=no influence at all; 10=DTC influences prescribers' practices highly within the local organisation)
i. Current representation on DTCs	- tick box options were developed based on the literature (Chapter 2) - free text area was provided for respondents to include other representatives not included in available options

3.3.1 Pilot study

A pilot study was conducted including eleven Directors of Pharmacy from eleven different hospitals. The hospitals represented in the pilot study were from five Australian States; including metropolitan and rural hospitals; as well as primary and tertiary referral hospitals.

Respondents were asked for comments as to how the survey instrument could be improved (with regard to structure and content). Upon return of the pilot questionnaires, responses and respondents' comments were reviewed. As a result, some questions were rephrased to improve clarity.

The final study questionnaire is attached as Appendix 3.1.

3.3.2 Data collection

Contact details of Directors of Pharmacy in Australia were obtained from the *Directory of Hospital Pharmacy and Pharmaceutical Organisations*.(128) This Society of Hospital Pharmacists of Australia (SHPA) publication was considered to be a comprehensive and up-to-date listing of contact details of Directors of Pharmacies or Chief Pharmacists, in Australian hospitals.

In September 2001, 300 Directors of Pharmacy or Chief Pharmacists, from public, private, metropolitan and rural hospitals listed in the SHPA's *Directory of Hospital Pharmacy and Pharmaceutical Organisations* were sent the final survey

questionnaire. This respondent group was targeted as it has been established they play a pivotal role in most DTCs.(74) Each survey questionnaire was accompanied by a cover letter explaining the purpose of the study. Confidentiality and data handling issues were also addressed in this letter. (Appendix 3.2)

Questionnaires could be returned using a reply-paid envelope or fax. Questionnaires not received two weeks after mail-out were followed-up by a phone call to ensure that the questionnaire had been received. At this time, respondents could elect to complete the questionnaire over the phone with the researcher (ET). Another copy of the questionnaire was also mailed or faxed to those respondents who elected not to complete the questionnaire over the phone.

3.3.3 Analysis and reporting

Responses were entered into a Microsoft Access 97 (Microsoft Productions Inc. 1992-1996) database. Data were subsequently imported into the Statistical Package for the Social Sciences (SPSS) for Windows Version 10 (SPSS Inc., Chicago, USA) for statistical analyses.

Generally, descriptive statistics were used (frequencies, medians and ranges) to described collected data. As data collected were not normally distributed, chi-square (χ^2) tests for independence or relatedness were used to test relationships between categories of data. A p-value of less than 0.05 was applied to indicate statistical significance.

Collected data were stratified according to hospital categories provided by the Australian Institute of Health and Welfare (AIHW) and state Departments of Health. Responses were compared according to hospital peer group categories.

3.4 Results

The questionnaire was mailed to Directors of Pharmacy (or Chief Pharmacists) of the 300 Australian hospitals as listed in the SHPA's Directory of Hospital Pharmacy and Pharmaceutical Organisations. Two hundred and twenty were returned, including 39 (17.7%), which were completed over the phone, giving a response rate of 73.3%.

Of the 220 Directors of Pharmacy (or Chief Pharmacists) who responded to the survey, 127 (57.7%) reported the presence of an in-house DTC. Of this 127, two questionnaires were excluded from further analysis because these respondents could not complete the questionnaire. These respondents noted that pharmacy was not represented in the DTC at their local organisation. As such, 125 questionnaires comprised the final dataset for subsequent analysis.(Figure 3.1)

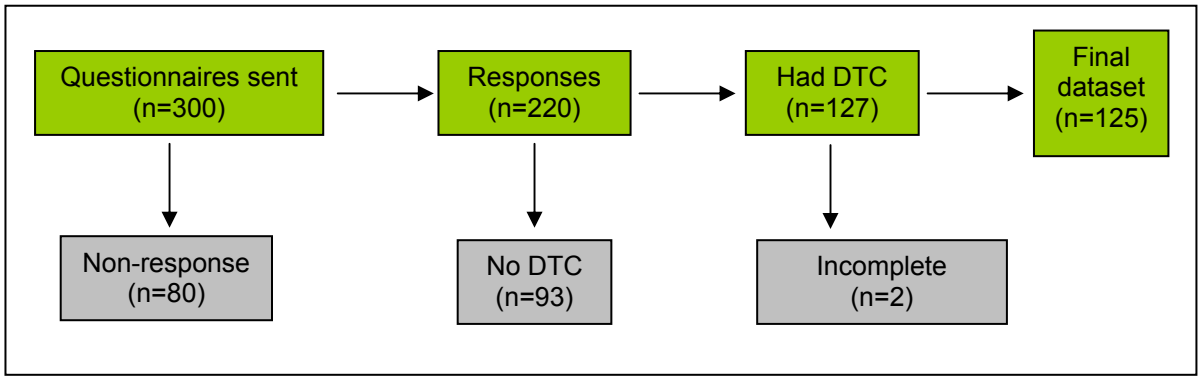

Figure 3.1: Selection of final dataset

Response rates from all states and territories in Australia were between 66% and 80%. There were no significant differences in response rates between the states ($p=0.258$). based on the Australian Institute of Health and Welfare (AIHW) and state Departments of Health information on the “categories” for all hospitals in Australia 18% (n=35) of Directors of Pharmacy surveyed represented “primary referral” hospitals. There were no significant differences in response rates between categories of hospitals sent the questionnaires ($p=0.264$). However, the likelihood of having a DTC related strongly to the category of hospital ($p<0.0001$), with primary referral hospitals most commonly having DTCs (33 of 127 hospitals with DTCs). (Table 3.2)

Table 3.2: Categories of hospitals involved in the survey (as defined by the Australian Institute of Health and Welfare)

Hospital categories	Questionnaires sent	Questionnaires returned	Final dataset (those with DTCs)
Hospice	1	0	0
Large metropolitan (>10,000 separations)	20	10	8
Large rural (>8000 separations) & remote (>5000 separations)	19	15	8
Medium (2000-5000 separations)	42	30	13
Medium (5000-10,000 separations)	28	22	14
Mothercraft	1	1	1
Multi-purpose services	1	0	0
Other non-acute	3	2	1
Primary referral – Metropolitan (>20,000 separations); Rural (>16,000 separations)	54	42	33
Psychiatric	12	8	4
Rehabilitation	3	2	2
Remote acute (<5000 separations)	11	9	0
Small non-acute (<2000 separations)	2	1	0
Small acute (<2000 separations)	3	2	0
Unpeered hospital (<200 separations)	1	1	1
Women's and children's hospital (>10,000 separations)	10	9	7
Private hospital	49	33	24
Defence force hospital	4	4	0
Other/unknown	36	29	11
TOTAL	300	220	127

3.4.1 DTC functions

3.4.1.1 Principal functions of DTCs

The current principal functions of the DTC, identified by respondents included "promoting evidence based medicine" (71.4%); "developing and maintaining formularies" (67.5%); "governing clinical practice" (52.4%); and "acting as financial gatekeepers" (42.1%). Most respondents agreed that DTCs were also involved in "ensuring patient safety" (83.3%).

We compared the responses between private hospitals and primary referral hospitals. Primary referral hospitals were defined by the Australian Institute of Health and Welfare, as Metropolitan (>20,000 separations) or Rural (>16,000 separations) (Table 3.2).

Current principal functions of DTCs in private hospitals and primary referral hospitals did not differ in the following areas:

- "acting as financial gatekeepers" (χ^2=0.457; df=1; p=0.457)
- "governing clinical practice" (χ^2=1.156;df=1;p=0.282)
- "ensuring patient safety" (χ^2=0.030; df=1; p=0.862)

"Developing and maintaining formularies" was one of the current principal functions of 72% of DTCs in primary referral hospitals compared to 26% of private hospital DTCs (χ^2=10.529; df=1, p=0.001). There was also a significant difference between

DTCs in primary referral hospitals and private hospitals in “promoting evidence based medicine” (χ^2=13.125; df=1, p<0.0001). Analyses did not reveal any other differences in principal functions between the other hospital categories.

Respondents were asked to comment on what the DTC’s *ideal* principal functions should be. The most common responses corresponded to the practice of evidence-based medicine (31%), the promotion of patient safety (30%), cost-effective use of medicines (13%), as well as Quality Use of Medicines (12%),

3.4.1.2 Extent to which current functions were achieved

The questionnaire sought opinions from respondents as to the extent to which the DTC was achieving its principal functions, on a scale of 0 to 10, where 0 represented the DTC not achieving its principal functions at all, whilst 10 denoted the DTC was fully achieving its principal functions. Responses ranged from 0 to 10 (Median=5). (Figure 3.2)

Six (4.7%) respondents felt that their DTC was not achieving its principal function to any level (score of 0 out of 10). Three respondents (2.4%) believed that their DTC was fully achieving its principal functions (score of 10 out of 10).

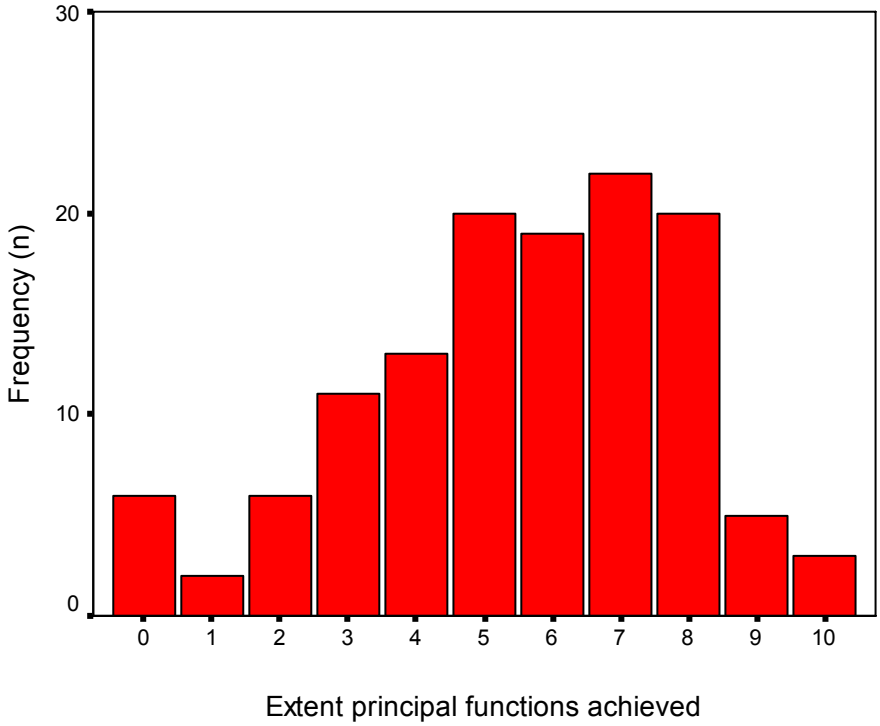

Figure 3.2: Extent to which DTCs were achieving their principal functions.
(0=DTC not achieving principal functions; 10=DTC fully achieving principal functions)

3.4.1.3 Barriers to fully achieving principal functions

The questionnaire also explored respondents' opinions of the reasons why DTCs are not fully achieving their principal function. Respondents identified lack of time (65.6%), lack of staff (65.6%) and lack of administrative support (45.6%) as major impediments to their DTC fully achieving principal functions.

In addition, some respondents added that other barriers include lack of:

- commitment from members of the committee (low and infrequent attendance, not reading agenda/accompanying literature prior to meeting, few opinions and feedback)
- vision and leadership from chairpersons

- regular meetings
- adherence to policies/guidelines set out by the DTC (particularly in private hospitals)
- interest from medical staff

3.4.2 DTC activities relating to performance evaluation

3.4.2.1 Indicator use

The ACHS indicators were the most commonly used (n=78). Although the NSW TAG Indicators for DTCs were developed specifically to evaluate DTC performance, only 16% of the respondents reported the use of this indicator set. Further, the NSW TAG Indicators for Drug Use in Hospitals were only used by a quarter of the respondents (n=32).

Respondents were also asked if other “drug use” or DTC indicators were used in their hospitals. Twenty-five of the 125 respondents (20%) reported use of other “drug use” indicator sets in their hospitals. Most of these indicators were developed in-house according to the needs of the hospital.

The reasons DTC indicator data were collected are shown in Table 3.3. Most of the indicator data collected were for ACHS accreditation purposes. Indicator data were also used for “benchmarking” and, in a small number of instances, to contribute to research projects designed to investigate ways to improve clinical practice.

Table 3.3: Reasons for collecting indicator data (more than one reason may be chosen)

Indicator set and number of respondents using (n)	Feedback to:					TOTAL
	ACHS	DTC‡	Dept Heads	QI Unit§	Hosp/area health¶	
NSWTAG DU Indicators* (n=32)	14	20	3	10	9	56
NSWTAG DTC Indicators† (n=20)	8	15	2	8	4	37
ACHS Drug Indicators (n=78)	66	39	22	42	18	187
TOTAL	88	74	27	60	31	

(*New South Wales Therapeutic Assessment Group Indicators for Drug Use in hospitals; †New South Wales Therapeutic Assessment Group Indicators for Drug and Therapeutics Committee; ‡Drug and Therapeutics Committee; §Quality Improvement Unit; ¶Hospital or Area Health services)

3.4.2.2 Barriers to indicator use

Lack of pharmacy staff was the most common barrier to indicator use, and was reported by half of the respondents. Lack of time (40.8%) and lack of financial resources (25.6%), were the other major barriers to indicator use. About 5% of the respondents stated that the indicators "do not apply". Some respondents also commented (in free text responses) that the available indicators were "too open to interpretation", and this diminished their usefulness and applicability.

3.4.2.3 Collectors of indicator data

Of the respondents (n=125), thirty-six reported that their DTCs did not collect any indicator data (28.6%). Table 3.4 shows the number of persons collecting indicator data at the hospitals that did collect indicator data (n=89). The number of collectors may add up to more than 100% because some hospitals had more than one person collecting indicator data.

The results indicate that in the majority of the hospitals responding to the survey, the Pharmacy Department (either the Director of Pharmacy, a pharmacy graduate/student/trainee or a pharmacist) is responsible for the collection and compilation of indicator data. Respondents also noted that Secretaries of DTCs (usually Directors of Pharmacy) were responsible for collection of indicator data.

Table 3.4: Collectors of indicator data

Collector	Number of hospitals (n=89)	%
DTC Chairperson	5	5.6
DTC Secretary	14	15.7
Other DTC member	9	10.1
Quality Improvement Unit	15	16.9
Director of Pharmacy	50	56.1
Pharmacy graduate/student/trainee	8	9.0
Pharmacist	59	66.3
TOTAL responses	160*	

*The number of collectors may add up to more than 100% of responses because some hospitals had more than one person collecting indicator data.

3.4.3 Resources available to DTCs

Twenty-nine (23.2%) respondents indicated that the DTC did not receive any organisational support. Fifty-four (43.2%) of the respondents were of the opinion that the DTC received very little organisational support. This meant that there was little or no organisational support available to most DTCs in Australia.

Of the 125 respondents, 29 (23.2%) indicated that “quite a bit” of organisational support was given to the DTC. Only 13 (10.4%) DTCs were receiving “a lot” of organisational support, that is, about one-third of respondents indicated that their local organisation provided “quite a bit” or “a lot” of support.

Respondents were asked to indicate the level (if any) of resources (financial – in terms of an operational budget, other financial (eg funds for research), allocated staff support (eg secondment of researchers) and administrative support) that were made available to support the activities of the DTC. The level of available resources was "scored" from 0 to 10; where 0 indicates no resources available at all and 10 indicates a high level of resources available to support the DTC.

Fifty-seven percent of respondents indicated "no (financial resources) support at all" for the DTC. Seventy eight percent of respondents claimed that there were no funds allocated for specific DTC activities (e.g. funds for DUE). Two-thirds indicated no formally allocated support for staffing DTC functions (e.g. secondment from Quality Improvement unit for DTC projects). Sixty percent indicated no administrative resources (e.g. secretarial) were available from their organisation.

Respondents were also asked to describe any other forms of organisational support and the extent to which these were provided. The only other form of organisational support, stated by a few respondents, related to the "moral support" received from their organisation. This usually referred to philosophical support from the organisation, in the form of an endorsement of the DTC decisions.

3.4.4 The extent of the DTCs' influence of prescribers' practices

Respondents were asked to rate the extent of their DTCs' influence on prescribers' practice at their institution on a scale of 0 to 10; where 0 corresponds to the DTC having no influence on prescribers' practices and 10 corresponds to the DTC having a high influence over prescribers' practices.

Scores ranged from 0 to 10 (Median=5, Mode=7).(Figure 3.3) Interestingly, 8% of respondents believe the DTC had no influence on prescribing at their institutions. Only one respondent considered their DTC having high influence on prescribers' practice (score of 10).

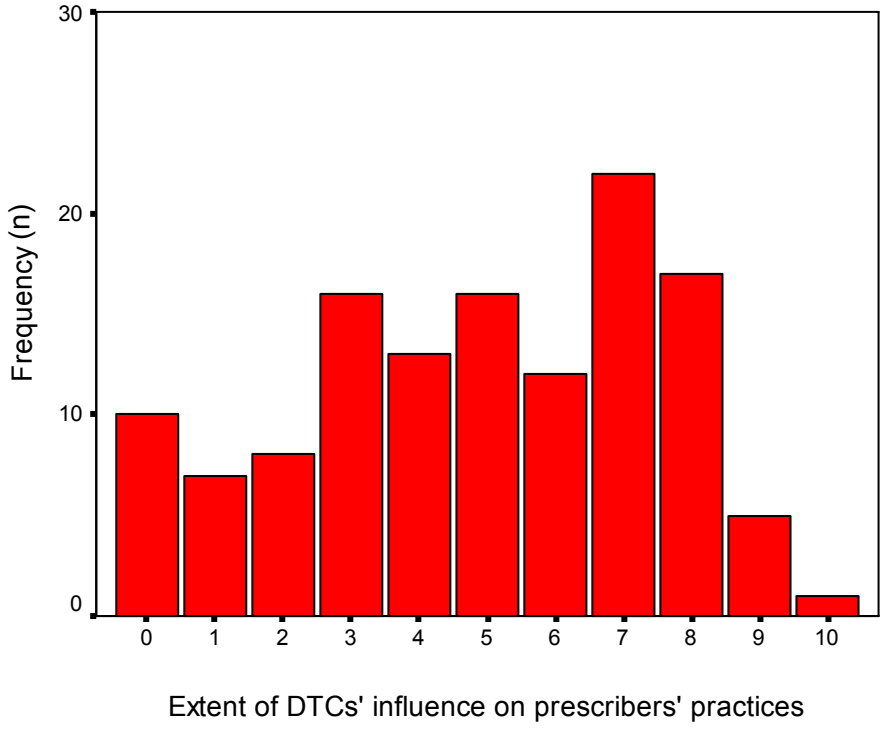

Figure 3.3: Extent of DTCs' influence on prescribers' practices
(0=no influence; 10=high influence)

3.4.5 Representation on DTCs

Of the 127 with a DTC, 3 respondents did not complete this part of the questionnaire. The results of this section are therefore based on 124 responses. (Table 3.5).

Medical officers were commonly represented in DTCs (98%). On average, there were six medical officers represented on DTCs (standard deviation=3.34). Whilst some DTCs did not have any medical officers, there were DTCs with as many as 16 medical officers. Most often, DTCs have either two (n=25; 19.8%) or three (n=24; 19%) medical officers.

Representation for Directors of Pharmacy was 96% and hospital pharmacists 71%. The number of hospital pharmacists represented on DTCs ranged from none to six. Close to 40% (n=50) of DTCs had only one pharmacist represented.

Community representatives, either a general practitioner or a community pharmacist, were present in 28 DTCs. Twenty-six of these DTCs had general practitioners whilst community pharmacists were only represented in six of these DTCs. Consumers were only represented in nine DTCs.

Table 3.5: Representatives on DTCs

Representative	Number (n=124)	%
Director of Pharmacy	119	96.0
Clinical Pharmacologist	25	20.2
Consumer representative	9	7.3
Pharmaceutical Industry representative	2	1.6
Hospital Pharmacist	88	71.0
Community representative – General practitioner	26	21.0
Community representative – Pharmacist	6	4.8
Community representative – Consumer	2	1.6
Medical Officer	122	98.4
Nurse	111	89.5
Medical Administration	63	50.8
Financial Services	18	14.5

The specialist units represented reflect the range of expertise of DTCs.(Table 3.6) Other specialist units reported by respondents (but not commonly represented) include rheumatology, endocrinology, ophthalmology, drug & alcohol, urology, thoracic & respiratory medicine, epidemiology, renal, pathology, orthopaedics and forensic psychiatry.

Table 3.6: Specialist units represented on DTCs

Specialist Unit	Number
Medicine/General Practice	72
Anaesthesia	42
Neurology	38
Microbiology/Infectious Diseases	33
Intensive Care	24
Emergency	22
Palliative Care	22
Medical Oncology	16
Obstetrics & Gynaecology	12
Paediatrics	12
Aged Care/Geriatrics	10
Cardiology	9
Gastroenterology	5
Haematology	5
Psychiatry	3

3.5 Discussion

Our study investigated the functions of DTCs and the perceived level to which DTCs were achieving these functions. We documented the Directors' of Pharmacy perceptions about the current and ideal functions of DTCs and the resources available to support the DTC in its work. We also investigated DTC activities relating to performance evaluation (indicator data collection, the purpose of indicator data and barriers to data collection). This survey received a good response rate and its findings are likely to be representative.(129) The results of our survey provide a comprehensive snapshot of the DTCs in Australia, with respect to DTC activities, DTC representation and challenges facing DTCs in Australia in 2001.

In the interpretation of the results of this study, it is important to be aware of potential limitations. Although the results were deidentified, they were based on respondents' (DTC members) reported perceptions. It is possible that responses may be biased. For example, the DTCs' influence on prescribers' practice may be overestimated. Therefore the results of this study should be generalised with caution. However, the findings of this study are comparable with other surveys found in the literature.(73, 74, 130) Also, in the presentation of the results to other DTC stakeholders, the findings have been found to be an accurate representation of the current situation of DTCs in Australia.

Our 2001 survey of Australian hospitals indicated that 58% had an in-house DTC. In comparison, a 1995 survey indicated that 92% of respondents had a DTC in their

hospital.(74) Weekes et al indicated that their survey was posted to all public & private hospitals in Australia. This differs from our own survey where the addressee was the Chief Pharmacist, care of the hospital. This difference in addressee may be associated with the different response rates. Weekes et al reported a response rate of 52% (n=148) whereas in our study, the response rate was over 70%.

Our dataset includes hospitals listed in the SHPA's *Directory of Hospital Pharmacy and Pharmaceutical Organisations*, including other health facilities, such as defence force hospitals and psychiatric units which may not have in-house DTCs.(Table 3.2) A higher proportion of "other health facility" category institutions in our survey compared to Weekes et al in particular, might be associated with differences in DTCs across surveys.

A 1993 Australian study indicated that formulary management was the most common DTC function.(85) Our study suggests that the perceived roles of DTCs may have expanded since that time. During this time, the principles of rational use of medicines and demands for improved quality and safety had been embraced more widely in Australia and this may have influenced perceptions concerning DTC roles. Promulgating evidence-based practice and patient safety with regard to medicines was perceived to be a principal function of DTCs in our survey.

It is important to note that about eight percent of respondents believed that their DTCs had no influence on prescribing practices. However, the majority of respondents reported their DTC had some influence on prescribing practices.

Only 2.4% of respondents believed that their DTCs were fully achieving their perceived principal functions. In interpreting this finding, it should be acknowledged that this self-assessment of the extent to which each DTC was achieving its perceived principal functions would be influenced by what those functions were. Thus, the lower the expectations of a DTC's function, the easier it would be to fulfil those expectations.

In terms of performance indicators, ACHS Drug Indicators were most commonly employed (used by 62.4% of respondents). This is most likely due to the imperative of hospital accreditation. As such, although this may not be specific to DTC activity, this has been reported by respondents as these are often collected and reported by members of the DTC. The ACHS oversees Australia's national quality assurance activities, which allow for benchmarking across institutions. Many hospitals also have in-house quality improvement activities.

We found that the majority of indicator data were collected for accreditation purposes only (in 70.4% of responses). Some indicator data were fed back to the DTC, prescribers and various parts of the institutional administration suggesting a limited role of drug and DTC indicators for quality improvement cycles. Current DTC performance indicators typically concentrate on "processes" DTCs might undertake. It is unusual that they examine health outcomes or changes in clinical practice that could be influenced by DTC activities. Given the expressed desire of respondents that DTCs improve clinical practice, the use of indicators of "impact" and "health outcomes" pertinent to DTC activities would be beneficial, although more difficult to establish.

Twenty percent of the respondents reported the use of “indicator sets” developed in-house. The rationale for these were “hospital’s needs” and to “answer research questions”. This finding suggests that the available indicators, notably ACHS, and the two NSW TAG sets, are not adequate for a substantial proportion of hospitals. Indeed, DTCs noted that collection of indicators related to medicines use was not useful for quality improvement purposes because of the subjectivity around indicator use.

Nearly ten percent of respondents stated that "indicators don't apply" (to the needs and purposes of data collection). The most common comments concerning the limitations of indicators were that the available indicators were “too open to interpretation”, subsequently diminishing their usefulness and applicability. Whilst the current indicators were designed to be open to interpretation in order that they may be applied to variable environments,(116) respondents in this survey reported that this had, in fact, deterred them from using the indicators.

Despite the criticisms and concerns, there seemed to be a desire to use the available indicators. However, Weekes et al reported that few DTCs had adequate resources to meet the expectations (self and externally) imposed upon them.(74) This was consistent with the findings of this study. Most of the barriers to indicator use identified in this study (lack of staff, time) could be attributed to the lack of resources available to the DTC. At a deeper level, a lack of administrative commitment may be more important.

Demands for judicious, appropriate, safe and efficacious drug use appropriately continue to increase.(44) This has highlighted the resource-poor environment in the health care system and lack of support for many of the DTC's functions. The appropriate but difficult solution may be to allocate available resources to that which are most necessary - perhaps by linking funding to DTC functions and performance. Bochner commented that enhancing performance of DTCs should be considered a high priority,(95) given the significance in costs, outcomes and risks associated with the therapeutic enterprise.

A surprising result was that hospital pharmacists were only represented in 71% of DTCs, compared to 98.5% reported by Weekes.(84) Our finding may not be a true indication of the current situation because Directors of Pharmacy were represented in 96% of DTCs and letters were directly addressed to them in our survey. Pharmacist representation could be a result of respondents reporting that the Director of Pharmacy was a member of the DTC but did not feel the need to report that another pharmacist was also a member of the DTC.

Within the capped budget of the public hospital system, DTCs may need to assess the effectiveness of available services, and make decisions, which result in maximum health benefits.(131) As pharmacists seem to be well-represented on DTCs across the country, this places pharmacists in an important position to be key players in the critical evaluation and performance augmentation of DTCs.

Action could be taken to assist DTCs to perform their function of assuring QUM in health institutions. These data we believe are a useful starting point for designing

strategies to assist DTCs achieve their QUM ambitions. Strong leadership, from hospital and area chief executive officers as well as departments of health, is needed to ensure adequate resourcing for DTCs. DTCs should be encouraged and assisted to undertake quality improvement activities. Assistance to promote the effective use of available indicators and, perhaps, further development of targeted indicators may be considered. Critically, implementation of such a programme must have a QI goal, and a strategy for using collected indicator data to that end.

Finally, in the development of indicators and use of indicator data, we have to be cognisant of the gap between obtaining more and better data and actually achieving beneficial improvements. Collected data offer only a starting position for assessing and improving the quality of performance. Indicators should be used to initiate or measure the impact of change. The interpretation of the data, and the effort invested in acting upon the findings is what results in outcomes improvement.

In conclusion, this survey indicates that DTCs are seen to be in a position to have an influence on QUM. It is important to note that stakeholders have begun to embrace QUM principles as part of their DTCs' principal functions. There is little support available to DTCs in spite of their increasing role in patient safety and clinical governance. There should be increased resources (both in terms of quality and quantity) available to DTCs to achieve QUM. However, one needs to realise that it is unlikely for the problem of inadequate resources to be solved in the immediate future. Practical means to assist DTCs to make the most of available resources should be explored.

4. Implementation of DTC decisions and policies: A local audit

4.1 Introduction

DTCs are considered advocates of rational drug use.(4) This was also described in our review of the literature. (Chapter 2) Our national survey of DTCs (Chapter 3) suggests that the performance of DTCs in Australia may not always be evaluated. The national survey reported in the previous chapter was useful in informing us of the roles and structure of Australian DTCs. In addition, DTC performance evaluation, available data on support available to DTCs as well as the DTCs' perceived influence on prescribing were explored.

Whilst DTCs often make decisions which could affect QUM, how (or if at all) these decisions are disseminated and implemented is most often not evident. The literature suggests that there are intervention strategies which could be used in the implementation of guidelines and policies.

4.1.1 Intervention strategies for policy implementation

Available data indicate that there are many approaches to disseminate and implement evidence and clinical guidelines. These may include intervention strategies such as clinical audit (± feedback to clinicians);(132) educational strategies (such as continuing medical education,(133) academic detailing(134), or

the use of opinion leaders(135) to deliver an educational message); and the use of published or printed materials(136, 137). However, it is unclear how successful these would be in influencing clinical practice in hospitals, following a DTC decision.

In a review of 59 papers that evaluated clinical guidelines, Grimshaw and Russell found that all but four were associated with significant improvements in the process of care following the introduction of the guidelines. However, the size of the improvements seemed to vary significantly depending on how these guidelines were disseminated. There was significant improvement in the quality of care in nine of the 11 studies, which assessed the outcome of care. Studies reporting large improvements in clinical care suggest that the potential effectiveness of the guidelines could be influenced by their development, dissemination and implementation processes and strategies.(138)

The majority of relevant published studies have been conducted and evaluated in the primary care setting. Little has been done to assess the effectiveness of these implementation strategies in organisational settings.(18) Most systematic reviews rarely include studies that were conducted in complex organisational settings (such as hospitals). These reviews included only randomised controlled trials in their evaluations. This may have excluded potentially valuable information from other studies.(139) A report by the WHO Health Evidence Network suggested that when studies are done within organisational settings, the studies are mainly small-scale, not hospital-wide, and poorly designed.(140) It is unknown if this could be a reflection of the complexities inherent within the culture of organisations.

In order to gain an insight into the depth and detail of DTC operations, as well as how these intervention strategies are currently being applied in an organisational setting, a case study approach was undertaken.

4.1.2 Aims and objectives

The aim of this study was to investigate how a DTC in an Australian teaching, tertiary referral hospital implements decisions. The specific objectives were to:

- identify the types of decisions made by the DTC which lead to directives, guidelines or policies that require implementation
- identify intervention strategies planned for implementation of these decisions, and
- identify whether intervention strategies were in fact undertaken to implement DTC decisions

4.1.3 Setting

The DTC at St Vincent's Hospital, Sydney was chosen for this study. St Vincent's Hospital, Sydney was founded in 1857, in Potts Point. From its origins of 22 beds, the hospital relocated to its current premises in Victoria Street, Darlinghurst in 1870. St Vincent's Hospital has since grown into a leading medical, surgical and research facility. Today, St Vincent's is a 326-bed, university affiliated, tertiary care facility with specialist programs including heart/lung transplant, bone marrow transplant and HIV medicine.(141)

The DTC at St Vincent's Hospital comprises 25 members from disciplines including medical administration, senior medical staff of various specialties, nursing, pharmacy, community representatives (including community pharmacy and general practice). A consumer representative is a member of the committee. This DTC reports to the Executive Director of the Hospital as well as the Hospital's Quality Improvement Committee. The St Vincent's Hospital DTC meets monthly.(142) There are no defined resources allocated for the activities of this DTC or to the implementation its decisions.

4.2 Methods

A data collection form was developed. The form was used to record the issues discussed at DTC meetings as well as the decisions made that would be expected to lead to action. Strategies selected by the DTC to implement these decisions were also documented. Classification of these strategies was based on a review of the literature.

4.2.1 Pilot study

A pilot study was conducted. An archive of the DTC's meeting minutes was obtained from the Secretary of the DTC at St Vincent's Hospital. A review of the archived meeting minutes from January 2001 to June 2001 was conducted.

The pilot study identified a number of deficiencies in the data collection instrument. The form did not allow for issues discussed to be organised chronologically, according to the time the issue first emerged at the DTC. The data collection form

also did not allow documentation of follow-up action actually undertaken. It was decided that more information regarding the types of intervention strategies selected by the DTC was required to appreciate these strategies selections better.

Accordingly, the data collection form was amended. Modifications enabled the recording of:

- which kind of continuing education strategies were employed
- what kind of educational materials were used
- to whom were referrals were made
- if the intervention strategies decided upon were actioned
- recording of when decisions were documented in the archived minutes
- recording of when intervention strategies were decided upon
- a separate column was created to record any (ie what type of) follow-up that was undertaken by the DTC on decisions or directives that needed to be actioned

This final data collection form was used in the review of DTC minutes. (Appendix 4.1)

4.2.2 Data collection

The archived DTC meeting minutes from January 2001 to December 2002 were obtained from the Secretary of the St Vincent's Hospital DTC, and included in this study. DTC minutes from January 2001 to June 2001 were reviewed again using the modified data collection form, and included in the final dataset for the study.

This review was conducted in February 2003 to allow time for implementation and follow-up of decisions made in December 2002.

4.2.3 Data analysis and reporting

Data were entered electronically into a table in a Microsoft® Word 1995 (Copyright© Microsoft Corporation) document. Details of the data were then coded into a database in the Statistical Package for the Social Sciences (SPSS) for Windows Version 10 (SPSS Inc., Chicago, USA) for analysis. Descriptive statistics (frequencies and ranges) were used to describe collected data.

4.3 Results

The archived minutes of the DTC at St Vincent's Hospital from January 2001 to December 2002 revealed that a total of 153 issues were discussed. The details of these issues are shown in Appendix 4.2.

The number of planned intervention strategies to implement directives related to these issues ranged from none to six strategies per issue. (Table 4.1) There were no intervention strategies planned around 51 of these issues (35%). On the other hand, six strategies were planned for one issue. This issue related to some reports of medication errors which had arisen because patients were returning from theatres with unlabelled intravenous (IV) infusions. The strategies planned for this issue were: an audit, an (unspecified) educational program, use of the hospital's drug committee bulletin to highlight this problem, as well as referrals to the hospital's Medication Incident Committee, the Patient Safety Committee, as well as theatre staff for expert advice (n=6).

Table 4.1: Number of issues and the number of strategies planned per issue

Number of strategies planned per issue	Number of issues	%
None	53	34.6
1	53	34.6
2	20	13.1
3	15	9.8
4	6	3.9
5	5	3.3
6	1	0.7
TOTAL	153	100

In total, 193 strategies were planned by the DTC at St Vincent's Hospital to implement the decisions emerging from the issues identified by the DTC between January 2001 and December 2002.(Table 4.2)

Table 4.2: Total number of strategies planned by DTC

Number of strategies planned per issue	Number of issues	Total number of strategies
None	53	0
1	53	53
2	20	40
3	15	45
4	6	24
5	5	25
6	1	6
TOTAL	153	193

Of these 193 strategies planned, there was no evidence from the DTC minutes review that 55% (n=107) of these were ever carried out. (Figure 4.1)

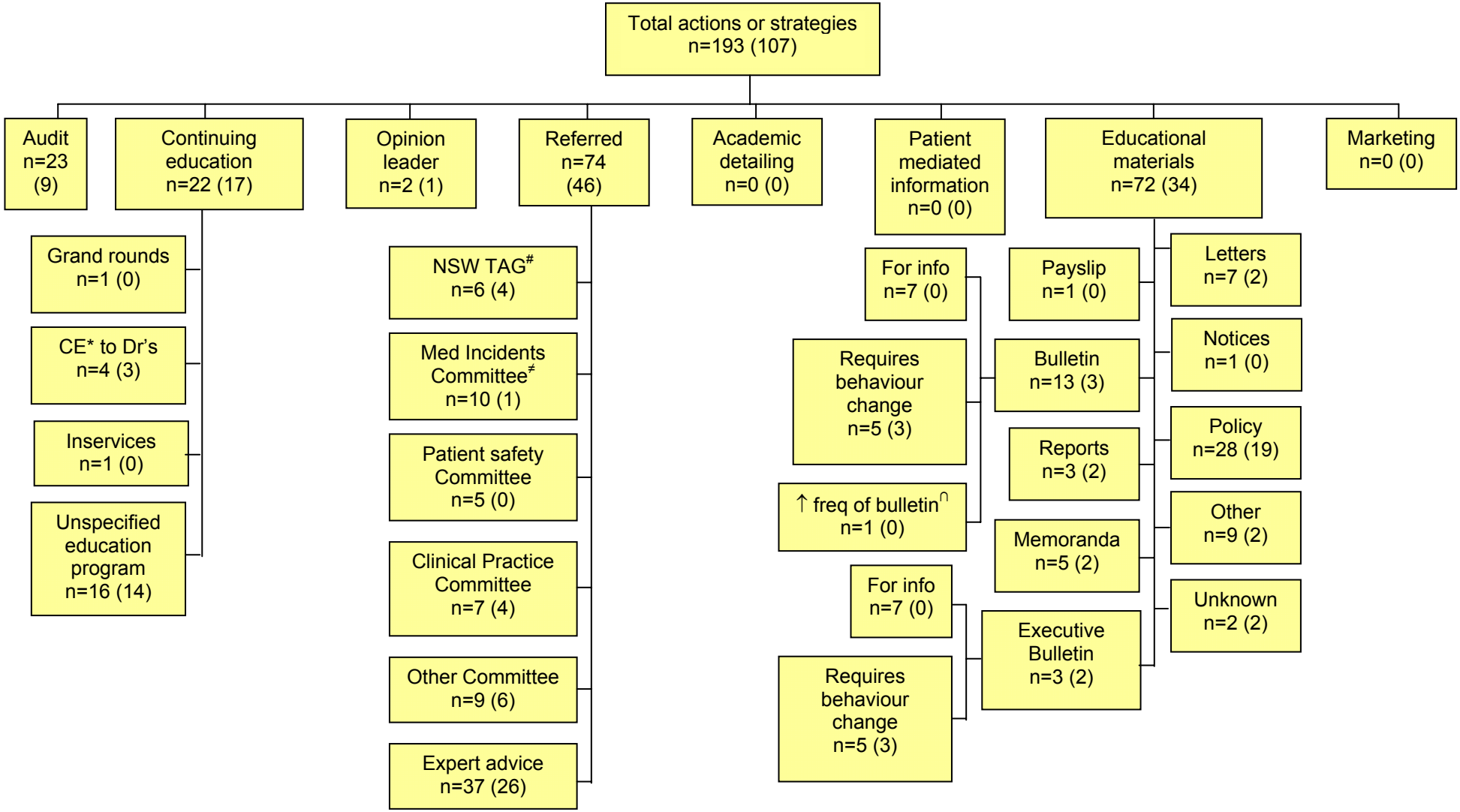

Figure 4.1: Number of intervention strategies planned (Planned strategies for which there was no evidence of action taken to carry out the strategies are shown in brackets)

*Key: *CE=continuing education; #NSW TAG= New South Wales Therapeutic Advisory Group; ≠Med Incidents Committee=Medication Incidents Committee; ∩↑freq of bulletin=Increase the frequency of bulletins*

Of the 193 strategies planned, the distribution of published or printed materials was most commonly employed (37%; n=72). Published and printed strategies included plans to: send out letters (n=7); attach messages to payslips (n=1); put up a notices (n=1); publish information in the drug bulletin (n=13); develop a policy document (n=28); produce a written report (n=3); send out memoranda (n=5) and send out executive bulletins (n=3). There were nine other kinds of printed or published materials (eg publish on hospital intranet site) planned. In two instances, there was mention made in the minutes that pertinent educational materials should be published, however, there was no further information on these matters found.

Twelve percent (n=23) of the 193 strategies involved conducting an audit of medication use. However, of these 23 planned audits, there was no evidence that nine occurred. Continuing education sessions were planned in 22 instances. These include Medical Grand Rounds presentation (n=1), continuing education sessions for doctors (n=4), ward-based in-service presentations (n=1) and other (unspecified) continuing education programs (n=16). There was no documentation in the DTC minutes as to what these 16 continuing education programs entailed or whether they occurred.

Seventy-four issues involved referrals to individuals for expert advice (n=37). Other planned referrals included referrals to NSW TAG (n=6); the hospital's Medication Incidents Committee (n=10); the hospital's Patient Safety Committee (n=5); the hospital's Clinical Practice Committee (n=5) and other committees (n=9).

Interestingly, the DTC did not plan to use any academic detailing to implement any decisions in the two-year period which was audited. The audit results are summarised in Figure 4.1.

4.4 Discussion

This study was an audit of the archived minutes of the DTC at St Vincent's Hospital in Sydney over a two-year period. The issues and decisions of the DTC during this period were identified. The intervention strategies planned to implement these decisions were also identified. This audit also sought to determine if these planned strategies were carried out from the minutes of the DTC.

This audit depended on the accuracy of documentation of the DTC meetings and decisions made in the DTC minutes. This was a limitation because this aspect was not assessed. Reliance upon the DTC membership to warrant the accuracy of the minutes is unlikely to be well placed as the consequences of incomplete or inaccurate minutes might not be considered a critical issue by DTC members.

The results indicate that there were no strategies planned to implement more than half of the DTC decisions. However, as only documented plans could be assessed, this may reflect the record-keeping role of meeting minutes. Additionally, it was not possible to confirm from the DTC minutes that a significant number of planned strategies and actions had been undertaken at all. Whilst this may be an alarming rate of unimplemented decisions, it may be that some undocumented action occurred to implement these decisions. Other sources of information such as minutes of quality improvement, infection control, patient safety and other relevant committees might have revealed implementation activities not recorded in DTC minutes. However, it is reasonable to expect that if a DTC decision requires implementation then the DTC should be assured at some point that effective

implementation has indeed occurred, and the fact should be recorded in DTC minutes.

In considering the question whether DTC meeting minutes are a reliable source of documentation of action planned and undertaken, stakeholders could have been interviewed in order to determine their recollections of strategies used to implement DTC decisions. However, this would also rely on stakeholders' recollection of decisions and policies being implemented, as well as the potential impact of the strategies employed.

In health care, often action is only considered to have occurred if it has been recorded (eg clinical care carried out needed to be recorded in patients' medical record). Arguably, the same standard of documentation should also be applied to the decisions and actions undertaken by the DTC. Therefore, it was decided that only documented evidence from archived DTC minutes was to be included in this audit. Perhaps, one of the issues highlighted by the results of this audit, is that DTCs need to more accurately document their actions, otherwise, the reasonable assumption might be that the action has not occurred.

Academic detailing has been shown to be an effective strategy to influence prescribing behaviour. In a large-scale randomised controlled study conducted in the ambulatory care setting, academic detailing was shown to be highly effective for guideline implementation. In this study, academic detailing was also shown produce significant cost savings.(143) The evidence from academic detailing had primarily been derived from studies conducted in the primary and ambulatory care settings.

However, there had been some work done in hospital settings proving the effectiveness of academic detailing as a strategy for policy implementation.(127, 144)

Given this evidence, it was interesting to note that the DTC audited did not use (or even plan to use) academic detailing as a means to implement their decisions. Lack of use of this modality was not due to a lack of evidence of effectiveness. Rather, it is possible that the limited resources available to the DTC precluded academic detailing as a method of implementation.

Printed materials may be valuable in raising awareness of clinical issues, and therefore increasing practitioners' inclination to change.(136) In this audit of DTC minutes, bulletins & executive bulletins were planned to promulgate "for information" type messages. However, the DTC also decided to use this approach to disseminate policies and decisions which require changes in behaviour.(Figure 4.1) The literature shows that passive dissemination of published materials is ineffective in bringing about behaviour change.(137) DTCs should use printed materials to carefully emphasise important messages so as to reinforce other strategies (such as educational messages delivered by an opinion leader) to influence behaviour.

Thirty-four percent of decisions of the DTC had only one intervention planned (Table 4.1). This is also surprising considering there was good evidence that multifaceted intervention strategies were generally considered to be more effective.(137) Again, this could possibly be a reflection of the lack of resources

(particularly time, manpower, and finances) available to the DTC. Having said that, the impact or effectiveness of single-faceted, or multifaceted intervention strategies was not established in this study. There is also no evidence that multifaceted strategies were significantly more effective for policy implementation in the organisational setting.(145)

Inadequate resources seem to be a significant barrier for many of the DTCs' activities.(74, 87) One solution is to acquire more support, the other is to target available resources to activities considered to be most important.(95) The first has become more and more challenging to justify and achieve.(146, 147) This means that, in reality, DTCs are left with the option of apportioning scarce resources to important issues. It is therefore imperative to understand what stakeholders consider to be important.

Further research to investigate the application of effective, evidence-based approaches to disseminate and implement DTC decisions should to be conducted. In the meantime, a systematic method of resource-allocation needs to be explored. It should be kept in mind that the DTC members' time, effort and expertise invested in decision-making for QUM should not be undermined by ineffective implementation and inadequate resources.

5. Perspectives on DTC policy implementation: A qualitative study

5.1 Introduction

It was noted that DTCs are intimately involved in organisational culture and change. The latter can be encouraged by the involvement and participation of stakeholders. The research undertaken in this chapter aimed to explore, through focus group discussion, stakeholders' expectation and opinions of DTCs, the intervention strategies used and how policy implementation might be improved.

Increasingly, DTCs are expected to make difficult decisions that may have an impact on the clinical and economic outcomes of drug use.(148) In examining DTC decision-making processes, Weekes concluded that DTC decisions are complex, and are influenced by rules, consequences, information use, politics and accountability.(84)

5.1.1 Study reference group

A reference group was formed to guide the development of this study. This reference group consisted of doctors, pharmacists, health administrators (area health and hospital), nurses and academics. Members of this reference group all had an interest in DTCs. Most members of this group were DTC members. Others

had been involved with DTCs in a consultative manner. Members of this reference group were based at various institutions across metropolitan New South Wales.

5.1.2 Organisational culture and change

DTCs could be seen as formal groups operating within the context of the wider organisation (hospitals). Many DTC decisions and policies aim to elicit change. An understanding of the organisational culture provides a context in which change could be managed. Furthermore, the dynamics of social interaction within the context of DTCs as a group may also have interesting consequences on change management.

Roles, norms, conformity and cohesiveness are the four characteristics of a group.(149) Groups consist of individuals playing different roles. Dartnell alluded to this phenomenon within the hospital system, in commenting that there are *"many actors involved in drug use"*, and *"the role and attitudes of each of these actors are polemical and dependent on the discipline, experience and politics of the observer"*.(150)

The concept of organisational culture is based on the proposition that, *"not only do organisations operate within a cultural/social context, they are also, culture-bearing entities"*.(151) There are basic assumptions, values and artefacts which form the basis of organisational behaviour from a cultural perspective. Basic assumptions are those beliefs which are deeply entrenched (usually unconscious) in members of the organisation about how the organisation operates.(89) In other words, basic assumptions could be seen as what Gray and Stark describe as "fundamental rules

of an organisation".(152) Values are expressed beliefs about the nature of such rules.(152) Artefacts are those manifestations by which the members are most likely to be able to see the essence of the organisation. Artefacts may take many forms, including language, rituals, and management practices.(89)

Organisational change is typically in response to changing environmental conditions, that is, as an attempt to ensure that an organisation remains relevant to those conditions.(153, 154) What seems to be undisputed in the literature is that change is often resisted. Among the explanations for this are innate dislike of change, the institutionalisation of practices, threat to personal interests or dislike of uncertainty.(153, 155, 156) According to Rogers, organisational change could be encouraged if the participation and needs of stakeholders are sought.(153)

In the previous chapter, we conducted an audit of a DTC's meeting minutes. The results of this study suggested that there may have been no action taken to implement some DTC decisions.(Chapter 4) Currently there is no research investigating the reasons for this. There are few, if any, studies investigating the barriers and enablers to DTC policy implementation. As a consequence, there are gaps in our understanding of the effectiveness of DTC policy implementation.

5.2 Aims and objectives

The aim of this study was to explore stakeholder expectations and opinions of DTCs and intervention strategies used to implement DTC policies.

The specific objectives of this qualitative study were to explore stakeholder opinions with respect to:

1. how DTC decisions and policies were currently being implemented;
2. how intervention strategies for policy implementation should be applied in an organisational environment (hospitals);
3. the perceptions of barriers to DTC policy implementation; and
4. ways to improve DTC policy implementation

5.3 Methods

Corporate marketing methods have been applied to collect and obtain information on opinions. Market research may be broadly defined as either “basic” or “applied”.(157) Basic research aims to understand and build knowledge about problems that occur, whereas applied research is conducted to solve specific problems currently being experienced. Research design approaches may be either quantitative or qualitative.(158)

5.3.1 Selection of methods

5.3.1.1 Quantitative vs qualitative methods

While qualitative and quantitative methods may be used to answer research questions, the type of data generated are likely to be different.(159)

Quantitative research methods are used to collect structured data or numerical measurements from a large number of respondents based on a prior understanding

of the nature of the issue being investigated. This is a common methodology used in health care research, which allows the researcher to quantify (ie count) and generalise results from the selected sample to a population. The data collected are generally structured and will allow for statistical manipulation, however, it is necessary for the sample size to be adequate so as to be able to be representative of the population of interest. The sampling process is key to the accuracy and applicability of conclusions drawn from the results. This process involves definition of the population, specification of the sampling frame, specification of the sampling unit, specification of the sampling method, determination of a viable sample size and the selection of the sample population.(160)

The first step towards sampling requires a definition of the population of interest. Then, a set of records from which the sampling frame (subjects) could be selected should also be specified. To ensure a representative sample, each and every subject in the defined population should have an equal chance of being selected. If there are exclusions, then results may be biased because the excluded subjects may be different to those included in the study. The sampling unit (subject) should also be specified. Sampling units could be an individual (eg from a list of patients) or a group of which the individual is a part (eg a list of a hospital's departments). If it is the latter, then it is necessary to specify the method by which the individual is chosen from the group.(161) Quantitative methods were used in the nationwide survey of directors of pharmacy undertaken as part of this thesis.

Qualitative research methods, on the other hand, collect non-numerical data from respondents. The quality of the collected data is usually rich in detail, relatively complex but generally unstructured and is especially suited to interpretive methods

of analysis.(162-164) Qualitative research allows the researcher to gain an in-depth understanding of underlying reasons and motivations for a particular behaviour or decision.(165) Qualitative research also allows for exploration of opinions and ideas.(162) The usefulness of qualitative research is not determined by the number of respondents who have a particular opinion, but, by what is being said and how it is being said.(163) In the search for an in-depth insight into the subjects it is not the power of the numbers that is important, but the power of words and images which are reflective of opinions and ideas.(166, 167)

Qualitative research can be characterised by the use of relatively small sample sizes. Representativeness on the basis of a small sample is not possible. But, this is not the aim of qualitative research. In qualitative research, the aim of sample selection is NOT to represent, but to reflect the population of interest.(166) Data collection is considered to be complete when a saturation of themes occurs.(168, 169)

Although qualitative research has been commonly used in market research,(170) it has also been used in behavioural science,(171) as well as in health care.(172, 173)

Qualitative and quantitative research methods are often used in a complementary fashion. The traditional characteristics of qualitative and quantitative research approaches (summarised by Minichiello et al) are presented in Table 5.1.

Table 5.1: Traditional characteristics of qualitative and quantitative research approaches(174)

	Qualitative	Quantitative
Conceptual	♦ Concerned with understanding human behaviour from the "informant" perspective ♦ Assumes dynamic and negotiated reality	♦ Concerned with discovering facts about social phenomena ♦ Assumes a fixed and measurable reality
Methodological	♦ Data collected through participant observation, unstructured interviews ♦ Data are analysed by themes from descriptions by informants ♦ Data are reported in the language of the informant	♦ Data are collected through measuring things ♦ Data are analysed through numerical comparisons and statistical inferences ♦ Data are reported through statistical analyses

5.3.1.2 Focus groups as a tool for qualitative research

Relative to other methods of data collection, focus groups provide an efficient means to collect data from a group of people with similar characteristics in a quick and (relatively) inexpensive manner.(175) Similarly to individual interviews, focus groups allow direct interaction with participants for clarification of responses, and in-depth probing of issues of interest.(176) A significant advantage of focus groups over individual interviews is that it allows participants to react to and build upon responses of other participants. This synergistic effect, unique to the group setting, could potentially uncover many issues and ideas that may not be uncovered in individual interviews.(177) This also contributes to the richness of the qualitative data.

Focus group discussions were conducted to obtain stakeholders' perceptions and opinions of DTCs and intervention strategies used to implement DTC policy, influence prescribing and clinical practice within the hospital setting.

5.3.2 Participation in focus groups

5.3.2.1 Selection of participants

Purposive sampling is used to identify subjects who are likely to be informative about the topic of interest. The logic and power of purposive sampling lie in selecting "information-rich cases" for in-depth study. Information-rich cases are those from which great deal could be learnt about issues of central importance to the purpose of the research.(159)

Purposive sampling was selected for this study because it was pertinent to identify those who could shed light on policy implementation within the context of hospital DTCs. This method of purposive sampling could potentially provide more meaningful data than a random sample of DTC stakeholders with little or no knowledge of DTCs and may not be able to contribute to focus group discussions.

Purposive sampling was used to select stakeholders in NSW who:

- are currently members of DTCs
- do not currently hold membership of DTCs, but have been a DTC member at some point

- have never been DTC members, but have knowledge of, as well as experience with DTCs (eg consultant physicians who have been involved with DTC policy development)

All members of the reference group were invited to participate in focus group discussions. In addition, Nurse Unit Managers of four wards within St Vincent's Hospital who have been involved with DTC activities were also invited.

5.3.2.2 Recruitment of participants

A letter of invitation to participate in focus group discussions about DTCs was mailed to thirty potential participants. (Appendix 5.1) After two weeks, non-responders were followed-up with a phone call.

One week prior to scheduled focus groups, another letter reminding participants to attend their selected focus group discussion was mailed-out. (Appendix 5.2) A reminder email (Appendix 5.3) was also sent to participants on the day prior to scheduled group discussions.

5.3.3 Data collection & instrument development

Focus group discussions, of approximately 90 minutes duration, were conducted at a meeting facility within St Vincent's Hospital, Sydney. One of the researchers (ET) attended a qualitative study methods training course. In this course, the researcher acquired skills required to facilitate focus groups. The trained moderator (ET) facilitated all focus group discussions.

It was anticipated that approximately six focus group discussions would be conducted. However, upon data analysis, if emerging themes appeared to be inconsistent, or if new themes continued to emerge, then subsequent focus groups would be conducted until themes were saturated (ie no more new themes were emerging).(159, 168)

5.3.3.1 Focus group discussions

A schedule was developed to guide the moderation of focus group discussions. However, rather than having a rigid set of questions for discussion, flexibility was allowed during the discussions so as to be able to obtain information which was pertinent to the issues of interest. This schedule was pilot tested on one focus group. As a result of this, the wording of the questions, style of facilitation, and flow of questions were refined. A copy of the focus group schedule used is shown in Appendix 5.4.

Focus group discussions commenced with a brief discussion of participants' understanding of drug committee roles, representation and decision making processes. The majority of discussions focused around intervention strategies used to implement DTC decisions. The moderator allowed for an in-depth discussion of issues amongst participants. Each focus group discussion was digitally audio-taped with the approval of participants.

5.3.3.2 Demographic data

At the end of each of the focus group discussions, participants were also asked to complete a data collection form for demographic details. (Appendix 5.5) Demographic data collected were participants' age group, gender, professional representation and their experience with DTCs. Demographic data sheets were de-identified. Demographic data collected were entered into a SPSS© Version 10.0 (SPSS Inc.) database.

5.3.3.3 Transcription and thematic analysis

Field notes, including key points were noted on paper during the focus group discussions. The moderator also noted physical interactions amongst participants (including laughter, nodding, facial expressions, moments of silence, and thoughtful looks). The moderator (ET) also acted as note taker during four of the six focus group discussions. Another investigator (JB) took field notes at two focus group discussions.

The audio files were transcribed verbatim into Microsoft® Word 97 (Copyright© 1983-1997 Microsoft Corporation). Transcripts were checked for accuracy. Field notes were also inserted into the transcripts. This resulted in the collection of a rich body of data. These documents were then imported into QSR NVivo© Version 2.0 (QSR International, Australia), which was used as a data management tool for content analysis.

5.3.3.4 Reliability and validity

For this study, a number of measures were undertaken to ensure the reliability and validity of the data. The literature on qualitative research defines reliability as "replicability" of the research findings; and validity as "correctness, or precision" of the findings.(178)

"Multiple coding" is a response to the charge of replicability sometimes associated with qualitative data analysis. This process of multiple coding involves cross-checking of coding strategies and interpretation of data.(179, 180) Armstrong noted that even though there may be substantial agreement between multiple coders, there was considerable variation in the ways in which these coders packaged coding frameworks.(181) This is an expected finding given the complexity of qualitative data. The central issue to using multiple coders is to provide opportunities for refinement of the coding frame through exploration of alternative interpretations of the data. For this study, all transcripts were separately coded by two of the investigators (JB & ET) according to emerging themes. The researchers then met to compare, discuss and refine the coding frame.

The process of triangulation addresses the issue of internal validity by comparing the findings of the qualitative study with other methods of data collection.(182) Data relating to DTC roles, structure and DTC policy implementation were triangulated to previous quantitative studies described in Chapter 3 and 4.

The validity of qualitative data could also be ensured through a process of cross-checking research findings with respondents (ie DTC stakeholders). This process is

called respondent validation.(183) It has also been noted that this process of respondent validation is particularly valuable in action research and health services research, as stakeholder input is needed on an ongoing basis in order to facilitate change.(184) The results of this study were presented to participants, as well as other pertinent DTC stakeholders, including clinical pharmacologists, hospital doctors, and hospital pharmacists for respondent validation.

Theories in organisational culture and organisational change management were used to underpin the thematic analysis of this study (ie these theories form the framework in which data was analysed).

5.3.4 Ethical considerations

Participation in the focus group discussions was voluntary. All participants were provided with a Participant Information Sheet, (Appendix 5.6) which gave a thorough explanation of the purposes of the study, as well as information regarding their rights and confidentiality. The focus group moderator elaborated on this at the commencement of each focus group.

Participants then signed a consent form (Appendix 5.7) in the presence of a witness.

This study was approved by the Human Research Ethics Committees of The University of Sydney and St Vincent's Hospital, Sydney.

5.4 Results

In total, thirty stakeholders were invited. Twenty-four agreed to participate in focus group discussions (acceptance rate of 80%). However, three participants were excluded as they were not able to be present at agreed times. In total, twenty-one participants attended focus group discussions. This represented a final response rate of 70%.

5.4.1 Demographics

Six focus group discussions were conducted, each having between three to six participants. The majority of participants (n=8) were in the “46-55 years” age group. Twelve participants were male. Two-thirds were currently members of a DTC. There were also sixteen participants who had prior experience of membership of a DTC. Seven of these participants had academic appointments.(Table 5.2)

Table 5.2: Demographics of focus group participants

	Number of participants
Age group	
≤25 years	0
26-35 years	7
36-45 years	2
46-55 years	8
>55 years	4
Gender	
Male	12 (57.1%)
Primary professional affiliation	
Senior medical staff/Consultant	8
Hospital pharmacist	5
Nurse	2
Clinical trials manager	1
Consumer	1
General practitioner	1
Hospital administrator	1
Area Health administrator	1
Executive officer	1
Has been a DTC member	16 (76.2%)
Current DTC member	14 (66.7%)
Years of DTC membership (for current members)	
<1 year	2
1-2 years	2
2-5 years	3
>5 years	7

5.4.2 Themes

5.4.2.1 Understanding of DTCs

When asked to comment on their understanding of DTCs, participants generally commented on the DTC's roles and representation. There were also comments with regard to the decision-making process on DTCs. A summary of the findings in this section is found in Table 5.3.

Table 5.3: Summary of themes (Understanding of DTCs)

Themes	Keypoints
DTC roles	- DTC's traditional role is in formulary management - DTCs are now involved in all aspects of medication use - DTC roles have expanded to include roles in promoting QUM - DTCs play an important role in controlling cost, particularly in relation to high cost drugs
Representation on DTCs	- multidisciplinary representation is very important - multidisciplinary representation affects the success of DTCs - traditionally doctors, pharmacists, nurses and health administrators are represented - currently, DTCs have wider representation (eg consumers, ethicists, community representations)

5.4.2.1.1 DTC roles

Most participants acknowledged that one of the traditional roles of the DTC is to oversee the hospital drug formulary. There was general recognition across all focus group discussions that the roles and functions of DTCs now have expanded beyond formulary management. One participant, a longstanding member of a DTC, clearly summarised this, saying,

"The Drug and Therapeutics Committee is an important hospital committee….(they are) given the mandate of deciding which medicines are to be used at the hospital, how they should be used, and, how to use them safely….historically, the roles probably would be more to do with what's on the formulary, but in more recent times, the mandate has widened to cover the actual uses and outcomes from therapy, and there's a general move towards what we might call - quality use of medicines responsibility - in the hospital…"

There was agreement that the DTC is seen as having an important role in promoting quality use of medicines. The drug committee was said to have some level of responsibility and accountability in all processes involving medication use, including the practice of evidence-based medicine. In fact, DTC decisions were being viewed as having important legal and ethical consequences. The roles of the DTC in patient safety, drug policies, education and cost-containment were also constantly reiterated in this part of the discussion. In relation to cost containment, the budgetary implications of high cost drugs and recent DTC efforts to address this issue featured strongly in many discussions.

"Mainly we focussed on things like high-cost drugs, which are taking a much larger part of the hospital's budget…."

" ….more recently, and increasingly importantly, the issue of high cost drugs and growing cost of the drugs…(are) starting to consume more and more time of the committee…"

5.4.2.1.2 Representation

The consensus amongst participants was that the representation on DTCs was, and should always be, multidisciplinary. Participants felt that multidisciplinary representation was necessary in order for the DTC to be effective. It was felt that a wide representation would improve a sense of ownership of DTC decisions across the institution in which it operated. Multidisciplinary membership could also potentially contribute to the expertise required for a successful and effective DTC.

"….in order for it to be accepted campus wide and for the hospital to feel it has ownership of the committee…you need to have very broad participation right across…it certainly should be multidisciplinary...from, certainly I believe, medical, pharmacy, nursing, but administrative also….."

DTC representation had commonly included doctors, pharmacists, nurses and administrators. However, some participants also identified consumers, general

practitioners, community representatives, bio-ethicists and research personnel as being members of DTCs.

DTC decision making frequently involves the evaluation of clinical evidence, pharmacoeconomics and safety. As illustrated by one of the participants, DTC processes are complex, and implementation may involve many discrete steps.

"…for a drug to get onto the hospital formulary….a submission needs to be made to the drug committee. There are specific forms …to fill in, they are required to attach a few good reviews…or original clinical trial or scientific study articles…Ideally we would like relative efficacy to other drugs, but very rarely is that data available…we will then look at safety…we will look to see if there is any contraindications, any drug interactions… We decide initially whether we think, what we go through is efficacious, is it safe etc...Having done all that, we look at what it costs. The other thing we do in the process is decide who will be authorised to prescribe it…"

5.4.2.2 Currently used intervention strategies

Some of the implementation strategies currently used by the DTC to implement their decisions, as identified by participants included:

- published on printed materials
    - bulletins
    - letters
    - drug formulary
    - payslip attachments

- educational strategies
    - presentation at the hospitals' Medical Grand Rounds
    - in-services on wards
- development of policies
- referral to other groups
    - other formal committees within the hospitals
    - external organisations (eg New South Wales Therapeutic Advisory Group)
    - formation of a subcommittee of the DTC to implement decisions
- audit and feedback
- drug utilisation evaluations (DUEs)
- local opinion leaders

One of the participants highlighted the importance of having a multidisciplinary DTC in decision implementation:

"People on my committee, I think it's fair in saying that, that pharmacists and doctors are going out and talking and influencing their own areas. So that's why it's important to have this cross-section of people on the committee who are advocates for what we are doing."

5.4.2.3 Application of intervention strategies

Participants acknowledged that some of these strategies were already being employed by the DTC.

"Well, I mean, we've just done all of this in the past, I mean, you mightn't get the complete package, you get bits of it usually."

Six issues regarding the application of intervention strategies in organisational settings emerged from discussions (Table 5.4). These were that intervention strategies chosen should be targeted, timely, and provided at the point of care. Participants felt that printed materials had little impact, they commented that face-to-face strategies were more effective. Participants also suggest that DTCs should implement policies and decisions through existing forums.

Table 5.4: Summary of themes (Application of intervention strategies)

Themes	Keypoints
Targeted strategies	- strategies need to be targeted to the audience *"…based on the type of problem, the people involved, and the local issues…tailor-make using evidence based approaches…"*
Timely implementation	- decisions and policies should be implemented in a timely manner *"It is (effective) if it comes out regularly…it's got to be timely."*
Delivered at the point of care	- strategies should ideally be delivered at the point of care *"…needs to be available at the point of care, not in a policy manual, somewhere else…"*
Printed materials	- printed materials did not seem to have much of an impact on clinical practice *"..it's still up to people to read it…"*
Face-to-face strategies	- face-to-face strategies were considered to be more effective *"Well, you can't beat verbal communication…"*
Use existing forums	- policy implementation should be conducted through existing forums within the organisation *"I don't really know about this, but every department has meetings, that's the other obvious place…"*

5.4.2.3.1 Targeted strategies

Participants were of the opinion that targeted intervention strategies were considered to be effective. Participants felt that strategies should be tailored to the type of decision or policy being implemented.

"If the goal is to have some information available, and that's all you want to do…

then having it on the website's fine…"

Participants also said that intervention strategies should also be tailored so that messages for delivery are applicable to the audience receiving them.

"I'd go very much for...the targeted option (ed: referring to intervention strategies), based on the type of problem, the people involved, and the local issues….. In other words, tailor-make using evidence based approaches…"

5.4.2.3.2 Timely implementation

In addition to having tailored strategies, most participants emphasised the importance of implementation in a timely manner. Irrespective of the type of intervention strategy used – the timeframe in which information is provided was seen to be important.

"It (ed: bulletins) is (effective) if it comes out regularly, and when it only comes out every 6 months or something like that, I don't think it is very effective….it's got to be timely!"

5.4.2.3.3 Delivered at the point-of-care

Participants felt that intervention strategies which were delivered within the context of clinical decision making were most useful. This was because this met the information needs of clinicians. Participants commented that intervention strategies should be delivered at the bedside, or at the point of care.

"I think all that (ed: information and procedures) needs to be available at the point of care, not sort of in a policy manual, somewhere else…"

5.4.2.3.4 Printed materials

Participants were of the opinion that whilst printed materials have their place, especially in information dissemination, their effectiveness was limited.

"You can send bulletins, you can send emails, you can send (via the) intranet and it is amazing what doctors, and I'm not going to speak about the nurses, but doctors will fly past those things and never glance at them…."

The general perception was that intervention strategies involving only the use of printed materials did not seem to have much impact, primarily because they were usually not read. One of the participants (who had never been a DTC member) commented that very few of the stakeholders at the coal-face actually read published materials.

"..It's still up to those people to read it (ed: the bulletin), because I know for my nurses, unless I've got a really motivated, really keen, really interested nurse, then they don't read them, and even if I publicise it at ward meetings, at handover, the majority of my nurses wouldn't actually read the bulletin."

In addition, stakeholders suggested that printed materials were not presented in the clinical context.

"…I think the payslip concept is a bit of a worry I think from the point of view of being essentially administrative. It has a great advantage of reach, because everyone picks up their payslips, but it has some definite disadvantages…..you've got a different headset on…."

5.4.2.3.5 Face-to-face strategies

In general, participants' opinions were that intervention strategies which were delivered face-to-face were more effective. Face-to-face strategies allowed for, what many participants termed "a transaction of information".

*"Well, you can't beat verbal communication, face-to-face between two people for a proper transaction of information...you know if [chair of DTC] calls me up to talk about something, then there's a bit of an interaction...but if it comes as memo or an email ...then I'm much more likely to go "Ah!" **action of throwing paper away** & the email goes to the trash."*

The effectiveness of the range of educational strategies was also widely discussed. Whilst one-on-one education (eg academic detailing) was viewed to be effective, education involving groups of individuals was believed to have less impact on practice. One-on-one education was seen as being a "burden" on resources.

"…academic detailing involves one-on-one teaching. I think that is more likely being effective than a group in service type teaching. The question is the affordability of that sort of thing, presumably that costs a lot more to have one-on-one teaching compared to group type teaching."

Group teaching was seen to be able to reach a greater number of people. As attendance at large educational sessions (such as attendance at medical grand rounds) is often voluntary, many participants felt that in fact, messages conveyed at these forums were, in a sense, "preaching to the converted". A consultant physician at a large teaching hospital illustrated this by saying.

*"We hardly ever get a VMO at grand rounds and unless it's their department or they're presenting….We get a lot of staff specialists. Our **senior staff** never comes. In fact, none of our **senior staff** ever comes, unless it's specifically their area, and maybe that's, well, the culture is wrong….we have lots of students there, which is good, because we should be getting at that generation, but it certainly doesn't have penetration to all the people you want to talk to. Those who are listening to you are probably already on your side..."*

5.4.2.3.6 Using existing forums within the organisation

Whilst grand rounds were generally seen to be an effective means to reach a broad audience, it was felt that DTC messages disseminated at smaller, more targeted forums were more appropriate. A senior medical officer commented that in her experience, only a select group of people would attend the medical grand rounds. She suggested the use of weekly departmental meetings instead. However, she

also cautioned that there should be careful planning involved so that these forums could be effectively used.

"I mean do you also find that, you mentioned grand rounds, I don't really know about this, but obviously every department has it's meetings, that's the other obvious place…there are at least two opportunities a week quite apart from grand rounds…"

A hospital pharmacist also suggested,

"…I mean you should look at existing forums. Do you get a regular spot for example in the nurse's open forum and those sorts of things and say, it needs to be of importance, like "Pethidine is no longer being used in the hospital" or, you know, something like that nature…that's how I envision getting the message out."

5.4.2.4 Barriers to DTC policy implementation

Perceived barriers to DTC policy implementation were the lack of resources, lack of follow-up of DTC decisions, a lack of ownership of DTC policies, low DTC profile within its organisation and the DTC being to reliant on the pharmacy department for policy implementation. The summary of themes relating to barriers to DTC policy implementation can be found in Table 5.5.

Table 5.5: Summary of themes (Barriers to DTC policy implementation)

Themes	Keypoints
Lack of resources	- DTC roles are expanding, however, DTCs are expected to operate with little or no allocated resources *"there are no people, no dollars assigned to drug committees…"*
Lack of follow-up	- there is no systematic follow-up on DTC decisions and policies - there is also no review of implemented decisions - as a result, it is not known if decisions are properly implemented *"We haven't ever really evaluated entirely whether our decisions have been appropriately disseminated, or implemented…"*
Lack of ownership of DTC policies	- lack of ownership of policies from the DTC affect the extent of the uptake of the policy within the organisation - dissemination of information does not guarantee the success of the implementation *"..by and large, they (stakeholders) either don't want to know, or don't feel that they have ownership over them…"*
Low DTC profile within its organisation	- even though DTCs consisted of opinion leaders, DTCs themselves have a low profile within their organisation *"..I didn't realise how big it was, or how many well respected and what a broad-based committee it was….yet it seems to have such a low profile and unable to implement a lot of policies…"*
Reliant on the pharmacy department	- the support of pharmacy was seen as a strength of the DTC, however, DTCs should not rely on the pharmacy departments to implement all their decisions - DTC members, themselves, should be active in policy implementation *"..the power and the muscle of the drug committee…it's more than pharmacy….I'm pretty passionate about not relying on pharmacists in getting that information out…"*

5.4.2.4.1 Lack of resources

The lack of resources within the health care system was clearly identified as the major barrier to the success of decision implementation. Participants inferred that the roles and expectations of the committee cannot be adequately met if resources available to the DTC continue to remain scarce. Currently, the running of the DTC is dependent upon individuals with various other job descriptions. The impact of running the DTC with little or no resources available was becoming increasingly evident given the expanding roles of DTCs.

"There are no people, no dollars assigned to drug committees. Drug committees are being given more and more responsibilities in handling risk, safety, clinical governance issues. The amount of work that is required is much more detailed work. There are many more policies that the drug committee is required to comment on, for example, in response to the paracetamol circular. It was a simple circular…(but) involves about ten or fifteen implementation steps. That's going to take probably forty hours of work to implement. And there are no people, no resources, and no secretary to do that. I think that's one of the greatest barriers."

"At the moment we're not as good as we should be in following that up because we have no person designated to do it and the Chief Pharmacist is already doing three other jobs, so she hasn't got time all the time."

This was of concern not only to health care professionals. A participant (consumer) commented,

*"…I'd be, well, obviously *sighs* I'd be concerned. Is it that…there's too much to cope with in terms of the day-to-day running…maybe a drug committee employee needs to be taken up."*

The lack of resources possibly contributes to the lack of follow-up of decisions being implemented.

5.4.2.4.2 Lack of follow-up

There seemed to be a lack of continuity in documenting, implementing and auditing of DTC decisions.

"I think part of it is just the follow-up system. We just don't have the follow-up system there or the resources with which to follow-up, because really you have to put in a data base and you have to start auditing what decisions, how they're made and how they're implemented and start reviewing the practices."

This was echoed at another group discussion:

"I think policies are out there and no one then actually monitors whether the people are actually following the policy, so somewhere within the communication there needs to be what the follow up mechanism is, who's responsible for auditing the compliance with the policy etc, etc, that goes back to the drug committee."

Discussions elucidated that this inadequacy of a review process may have led to a failure of decisions and policies being effectively and adequately implemented. Without a system of following-up implemented decisions, there would be no way of knowing if the policy has been properly implemented.

"We haven't ever really evaluated entirely whether our decisions have been appropriately disseminated, or implemented, etc. so I guess because things are fragmented or ad-hoc or whatever, we assume sometimes that we have disseminated information appropriately, and then you see adverse outcomes or whatever, and think "Well, maybe we didn't". So personally I don't think there has been an entire evaluation, locally anyway, to ascertain that."

Without a proper follow-up process, participants state that there was a danger that ineffective strategies could be continued to be used.

"We will put posters up until the cows come home. However, how many of those things are actually taken up? We have no idea. We have no idea of finding out."

5.4.2.4.3 Lack of ownership of DTC policies

It seemed that the participants believed that a lack of ownership of DTC policies and decisions may be a barrier to successful implementation. One major problem was that the efforts to change behaviour will be resisted. When the policies and decisions coming from the DTC are not communicated properly, stakeholders generally will have little ownership of the policies. A nurse unit manager, who is not a DTC member commented that:

"…we often have very limited knowledge of where that change has happened and why it has happened, and from one perspective is now when someone says well why do we have to change now? I don't have the information to say well there was an incident or there was an occurrence of something happening, which is why, or what brought about the policy change, and this is the end result."

One participant noted that the difficulty in implementing decisions and policies is in getting people to embrace and own them, not merely in disseminating the information. Participants acknowledged that just because information is being disseminated does not necessarily guarantee the success of policy implementation. One participant said,

"It's easy enough to get the information out there…(the problem) is getting people to (a) read it and (b) take it in! I agree that's a major problem, by and large, they either don't want to know, or don't feel that they have ownership over them…."

Participants were of the opinion that the issue of ownership has an effect on the extent on uptake of DTC policies within their organisation. Therefore, it was important to have stakeholder involvement. Participants state that DTCs should be consultative rather than authoritative.

"Well I just see the barrier is if the key people aren't involved in the decision in the first instance, if you don't at least have some open discussion with the person who has asked for the new drug or with the people with whom you need to change policy and even if they don't agree with it, at least they have had an opportunity to talk to you about it and say, well look we'll put this into place but I don't agree with it, but if you don't do that then the barrier is up before you start, so circulating information subsequent to that is less likely to be of particular use or to change people's opinion or behaviour."

However, participants also noted that engaging people in the decision-making process may not necessarily be a straightforward exercise.

"Another thing I just thought it would be good to add is it's often difficult to engage all the people that you need to engage to really be able to make some of the changes that you need to make. Often, we've got some of the converted who believe in what the drug is going to do, and are very happy to be involved in our processes. But there also a group of people who they think they know better than the drug committee, and that they don't really want to be involved in the drug committee processes. And it's difficult sometimes to engage those people."

This problem could be perpetuated by the high rate of staff turnover. A hospital administrator noted that

"….there are a lot of constraining issues and one of those is staff turnover and medical staff, and particularly surgical registrars, they turn over every six months and there's a certain culture that goes with those registrars that they want to modify the hospitals to their systems rather than they comply with the hospital system, so there's a real issue about how do you get to those people with the myriad of policies and processes that you expect them to comply with."

5.4.2.4.4 Low DTC profile within its organisation

In many group discussions, participants pointed out that the DTC needed to have (and to be given) more prominence in the hierarchy of the organisation. Participants felt that the DTCs generally have a low profile in their local organisation even though the DTC is a consultative group of experts, consisting of members who were highly regarded as experts and opinion leaders in their field.

"I guess anecdotally, when I first went to my first committee meeting, I didn't realise how big it was or how many well respected and what a broad-based committee it was, all the people on it, and yet it seems to have such a low profile and unable to implement a lot of policies"

Given the roles which were expected of the DTC, this has evidently had weakened the ability of the DTC to implement their decisions and policies. One of the partipants noted that

"….the committee actually had a lot of teeth, in terms of implementing, and I think this is one of the real challenges about how a committee such as this with a very broad hospital-wide influence actually can influence the practices"

This has evidently led to some frustration, particularly amongst those who actually sit on the DTC.

"I just can't understand why the drug committee at some stage, (ed: doesn't say) enough is enough, I've had enough. That's it. This drug is blah blah blah (sic). If anyone has a disagreement, we'll meet with [the CEO of the hospital], [head of clinical pharmacology] or [chair of the DTC], and you know that's it, there's no more discussions…."

In some cases, participants also noted that many of the staff who were expected to adopt or adhere to DTC policies may not even know of the existence of the DTC. This lack of authority could lead to a lack of adherence to DTC decisions,

"I guess, just following that my comment is that there are a number of prescribers, I guess when we're talking about formulary, that don't know the drug committee exists.."

An increase in the DTC's profile was strongly supported by participants. This was because it was recognised that the DTC's "stamp of authority" could be closely linked to success in decision implementation and QUM outcomes. Participants were of the opinion that the organisation as a whole need to recognise that, DTCs are not merely financial control measures. Participants said that DTCs need to be seen as being a gathering of local opinion leaders with a keen interest in quality use of medicines.

"I think there has to be a huge attitude change. I suspect if you went and talked to anyone in the hospital, assuming they've heard of the drug committee, and some of them probably haven't, I would think they see it as judge, jury and prosecuting council all rolled into one."

"...somehow there has to be a whole sea change so that everybody in the hospital sees the drug committee not as something legalistic, but as the experts best equipped to make decisions about drugs, who are there to discuss new drugs and changes to old drugs with the prescribing and the dispensing community for the benefit of the patients. We're not perceived like that, although it's how we like to perceive ourselves and until or unless we can achieve that whole shift of perception, I don't think we're going to improve our implementation."

Participants agreed that the DTCs' roles need to be enhanced in order to safeguard the quality and safety of drug use within hospitals. The organisation needs to place the DTC in a more prominent position in the hierarchy.

"The only thing I'd say is that the contribution and the role and importance of (ed: the) drug and therapeutics committee needs to be enhanced, and that's a big and on-continuing role…"

5.4.2.4.5 Relies on pharmacy for implementation

The implementation of many policies and decisions coming from the DTC seemed to have fallen on the shoulders of the pharmacy department. Currently, participants were of the opinion that the pharmacists were the ones who implement and police DTC policies.

"…there's a danger of the focus being that drug committee decisions is actually something that pharmacy police, their decisions come out, and the pharmacy are the ones promoting it…"

In one of the group discussions, a pharmacist commented that it was near impossible to give the under-resourced pharmacy department the responsibility of implementing DTC decisions. When asked how this problem could be overcome, participants' responses were,

-Participant 0007 -

You could arm the pharmacist.

-Facilitator-

Say that again?

-Participant 0007-

You could arm the pharmacists…

-Facilitator-

What do you mean?

-Participant 0008-

Baseball bats!!

-ALL-

laughs

-Participant 0007-

*Say with stun guns. No you can't have Botox!!! *pretending to use stun gun**

Pharmacists, and the pharmacy department in general, have always been regarded as the "eyes and ears" of the drug committee. Participants were careful to emphasise that pharmacy support should be regarded as a strength of the DTC. Participants emphasised that DTCs should be regarded as a multidisciplinary, consultative group of experts. As such, DTC members themselves should have ownership of DTC decisions and policies. The DTCs should also be wise in allowing DTC members themselves, to champion policy change.

"….ideally, the composition of our committee, made up of people who are there to contribute and be a part of the decision-making and implementation process. They weren't just there to attend the meeting. And that they would rather be our peers

and our people who made changes to the people who are going to assist us in this mission of improving patient safety and developing good policy that's going to help us."

"…(have) an active group of people who were the leaders who helped us to implement those policies… it would make the way that the drug committee is perceived quite different rather than people who sit around and discuss, and say you can do this you can't do this. You can have this, you can't have that. It would change the group to an active group who were working towards quality use of medicines, trying to affect practice, improve practice and to come up with some guidelines, rules, decisions, that were very implementable and that did embrace evidence, and best practice."

Participants said that there needs to be a distinction of roles between the DTC and the pharmacy. Whilst the pharmacy was available to support decision implementation, participants agreed that it should be made clear to stakeholders that the decision itself has been made by the DTC, not the pharmacy.

"…the power and the muscle of the drug committee…it's more than pharmacy and I guess that's why I'm pretty passionate about not relying on pharmacists in getting that information out. It actually needs to be a broad range of people responsible for it….drug committee members!!"

"So it does get back to us better explaining the role of the drug committee, and then the role of the pharmacists is understood in that context, as opposed to being the

first barrier to getting what I want, and not getting what's on the script. Or I can't have 'em."

5.4.2.5 Ways to improve DTC policy implementation

Participants were asked for their opinions regarding how DTC policy implementation could be improved. Participants suggested that DTCs prioritise their decisions for implementation, optimise the role of pharmacists, provide "real time" information and to seek greater organisational commitment. A summary of the findings is tabulated in Table 5.6.

Table 5.6: Summary of themes (Ways to improve DTC policy implementation)

Themes	Keypoints
Prioritise decisions	- DTCs function in a resource-poor environment, and decisions need to be prioritised so that decisions which are implemented could be done properly *"…if you're doing so much that you don't actually do anything properly, it's not clear to me that you're actually going to benefit that many patients…."*
Optimise pharmacy roles	- the role of the pharmacy department needs to be redefined and optimised - pharmacists should inform and influence drug use, rather than police the use of drugs *"…pharmacists are conduits of information…it's by a long way the most effective thing…"*
Give "real time" information	- implementation should be conducted in "real time" (ie at the point where clinical decision making occurs)
Seek organisational commitment	- support and commitment of the local organisation was fundamental to the success of an effective DTC *"the hospital itself has got to have ownership…because without that then it's next to impossible to implement..."*

5.4.2.5.1 Prioritise decisions

Participants acknowledged that the DTC functions in a resource-poor environment, and the DTC could not be expected to "do everything".

"…we are in an environment where there isn't enough to do all these things (ed: referring to DTC decisions). So, we have to think laterally and innovatively to deal with key priorities. That's what we have to do…"

The results indicated that participants were mindful of the fact that the DTC needs to be realistic about what it is able to achieve.

"…probably we ought to be very realistic about the priorities. You know, trying to do the important things and not trying to do everything…."

Participants stressed that the DTC needed to prioritise decisions. Participants felt that greater effort at implementation was needed for decisions which were seen to be more important (eg having a greater effect on patient outcomes). The consensus from discussions was that prioritising DTC decisions was important as this would allow the DTC to be clear about the goals to be achieved with each decision. DTC implementation could then be streamlined in order to achieve specified goals.

"*In an ideal world, you know, you might like to have text book quality use of medicines for everything and you might like to dictate how that be done…if you're*

doing so much that you don't actually do anything properly, it's not clear to me that you're actually going to benefit that many patients or the hospital's budget in the long run by doing that."

In this way, participants felt that there would be less of a risk of the DTC "spreading itself too thin" considering the lack of resources. In addition, the effect of high-impact strategies would not be watered-down because of "over-use". Intervention strategies could be tailored to meet the needs of stakeholders among whom the decision or policy was to be implemented.

"…..one of the reasons why it works is that we don't do it (ed: sending out personal letters from the chair of the DTC) too often. We only do it when we think it's really important and people, I hope, respect that and don't think that I'm just being a control freak…"

5.4.2.5.2 Optimise pharmacy roles

Participants felt that the "way forward" was to create a paradigm shift with regard to the roles of the pharmacy department and pharmacists. Currently, pharmacists are being regarded as those who police "drug use". As one participant puts it,

*"…often, the message is of gloom, not much good tidings from our way. I think people think we are the Nazi's. **everyone laughs** We are! We are the bastards!! **everyone laughs** That's all it is. 95% of the time is saying "NO"…."*

Participants suggested that a better focus would be to have pharmacists be "informers, or influencers, of drug use". One participant commented

"…I think Pharmacists are conduits of information….it's not a formalised thing, but in reality, it's by a long way the most effective thing…"

In their clinical role, pharmacists are already in a position to be a positive influence on the use of medicines within their organisation.

"I think ward pharmacists at a local level can often correctly influence drug prescribing, particularly to junior medical staff and I'm sure even to senior medical staff and I don't think you should underestimate that."

Together with DTC members, it was anticipated that pharmacists could be change facilitators within the organisational setting.

5.4.2.5.3 Give "real time" information

Participants often used the term "real time" to describe the type of information they regarded as useful. Participants felt that it was critical for DTC decisions and policies to be implemented so that it was relevant to when stakeholders (particularly prescribers) need it most.

"What I mean is because a real time, you are dealing with real patients. That's what it means when I say real time about clinical decision making. So the critical time for the drug committee decision, is the implementation in real time, and that's why even though it might be better to have a, you know, great looking bulletin on the web site or something, in the end that's not real time that you're talking about, that's some form of reflective time."

The use of support systems, such as electronic prescribing as a means of decision implementation was viewed favourably by many participants. Participants commented that there was a need to build the systems where people could be guided using some sort of a decision support system at the point of care (the bedside), particularly for drugs having complex management pathways.

"I think one thing that would be very beneficial is electronic point of care prescribing and decision support, so that your pneumonia, for example, is diagnosis pneumonia, these are the antibiotics that you can choose from and the whole decision support tree is there and you order it electronically at the point of care."

Payslip attachments were one of the frequently used strategies to disseminate key messages from the DTC. It was interesting that many participants used payslip attachments as an illustration of *not* giving "real time" information. Participants say that the main reason for this was the fact that people are usually not thinking about their clinical work at the same time as when a payslip is being reviewed.

"I think the payslip concept is a bit of a worry, I think, from the point of view of being essentially administrative. It has a great advantage of reach, because everyone picks up their payslips, but it has some definite disadvantages…..you've got a different headset on…."

This was, yet again, clearly emphasised in this segment of interaction among participants at another focus group,

-Participant 0015-

"My past experience is whatever's on the payslip goes in the filing cabinet, you know, the round one on the ground."

-ALL-

laughs

-Moderator-

"So, you reckon people just, usually just rip them off?"

-Participant 0015-

"I think it goes back to the information is needed when you're actually doing whatever the practice is…. in real time."

-Participant 0016-

"When you're looking at a payslip you're not thinking about which antibiotic you're going to prescribe, you're thinking about what jacket you're going to buy or I could do with a holiday."

-Participant 0013-

"The only time, I think, I could ever see that people have effectively done with payslips is the one that says "would you like to make a donation for so and so". The only time you're thinking of money and that's when you can think about giving back money. But, you're right, the relevance is when you open a payslip you're not really….you know…"

5.4.2.5.4 Seek organisational commitment

The various focus groups discussions acknowledged that the support and commitment of the organisation was fundamental to the success of an effective DTC. It was stated DTCs currently receive "philosophical" support from their organisation. Participants stated that it would be ideal that the organisation itself had more ownership of decisions coming from the DTC.

"The hospital itself has got to have ownership of the process by which the drug committee goes through, because without that then it's next to impossible to implement your decisions, so there's kind of got to be an awareness at all strata, you know that's what the hospital needs to do…"

There was much discussion around whether institutions would feel that the role of the DTC was sufficiently important to justify support (in terms of resources).

"I suppose it's whether the institution feels that the activities that relate to drug use and drug expenditure are of sufficient import that ought to be much more substantively supported by the institution."

Many were certain that the DTC will, in the future, be used as a vehicle to drive many patient safety issues. Even so, participants felt that the DTC would not be able to successfully accomplish this with the current level of financial and staff support. One participant remarked,

"I guess you could put the case that is this actually a worthwhile undertaking and the hospital should view that as being a sufficiently high priority that it actually pays for that person to undertake that role, so there is a resourcing level for the drug committee which would assist in that process occurring. And, I suppose it's whether the institution feels that the activities that relate to drug use and drug expenditure are of sufficient import that ought to be much more substantively supported by the institution."

Many felt that a "drug committee employee" as such, should be employed to carry out many of the implementation steps required for its policies and decisions.

"I think if the executives are really serious about that, then you need to resource the committee more than it is at present because at the moment, we have a secretary who actually is already doing several other jobs, and we've got a chair, who also has a significant, you know, full time job as well, so you almost need a dedicated drug committee person."

Individuals at several group discussions stated that they would like to see support, particularly from the higher authorities or the organisation, so that the DTC would be clearly established in the hospital hierarchy.

"…well they (ed: the hospital administration) have to put more resources, staff resources, time, clinician time, into backing up that process in a way…"

5.5 Discussion

This qualitative study reports stakeholder opinions regarding intervention strategies, barriers to DTC policy implementation and methods to increase DTC effectiveness. Although conducted at St Vincent's Hospital in Sydney, there were participants with expertise in DTC operations who were from other hospitals too. The demographics reported in the study concern only the participants' primary profession. Most of the participants in this study held multiple appointments, and therefore had the unique ability to be able to express views from differing paradigms.

Most of the participants (81%) had had recent contact with a DTC. This was expected given the recruitment procedures and subsequent self-selection of those with an interest in DTC activities. The added advantage of this purposive sample was that participants were very well informed of the issues discussed.

One of the limitations of the study was that the moderator (ET) also acted as a note-taker for most of the focus group discussions. This may have led to inadequate attention being paid to the process of note-taking. As a result, many non-verbal cues may have been missed.

The participants of these focus groups are from institutions in Sydney. Although effort has been taken to invite participants from a variety of institutions, it should be acknowledged that the majority of these participants work in large metropolitan hospitals. As a result, the opinions of DTC stakeholders in other parts of Australia – in particular in remote and rural institutions - may not be represented in this piece of

work. However, these results have been presented at national and international conferences attended by health professionals from variable health settings (including remote and rural institutions). Anecdotally, practitioners attending these conferences identified with the findings of this study.

With respect to the methodology chosen, focus group discussions are considered one of the best approaches in exploring opinions.(185) as they provide a forum in which respondents are able to present positive and negative viewpoints, and it also allows respondents to react to and build upon the responses of other members of the group.(175) This synergistic effect results in the production of data or ideas that may not be uncovered in one-to-one interviews.(176, 177) However, this type of interaction also means that the responses of group members may not be independent of one another. Dominant or influential group members may also bias the opinions of others in the group.(177) These limitations need to be kept in mind when interpreting the results of this study.

Stakeholders acknowledged that the environment in which the DTCs function, is complex and recognised that DTCs often have to make important decisions, which could potentially have an impact on risk management and patient outcomes. There are also ethical issues (particularly with regard to equity and access) in this decision-making.

When discussing DTC roles, it was expected that the focus would be on formulary management. Whilst this was still considered a “routine” task of the DTC, participants recognised that DTC decisions are often made in an environment of

scarce resources, and a culture of organisational bureaucracy. This was supported by the complex social scientific framework of drug committees described by Henriksen.(61)

Multidisciplinary representation on DTCs was seen to be a key advantage. It is also acknowledged in the literature that broad stakeholder representation on DTCs is important.(56, 75) The presence of experts from various areas of therapeutics was seen to be a great contributor of knowledge to the DTC in decision-making. However, it was noted that the responsibility of implementing DTC decisions was often vested in the pharmacy department. It was suggested that members of the DTC should be given the opportunity to promulgate DTC decisions and policies, and be champions of policy change in their respective areas of influence. In 1984, a panel of experienced leaders of Pharmacy and Therapeutics Committees (P&TC) participated in a discussion at the 41st Annual Meeting of the American Society of Hospital (now Health-System) Pharmacists. These participants discussed P&TCs as a “Practice Spotlight Topic”. This panel highlighted an active membership (who are involved in decision-making as well as implementation) as one of the keys to a successful committee.(80)

It was commented, at focus group discussions, that DTCs needed to be consultative rather than authoritative with their decisions and policies. In line with the literature on change management,(186) stakeholder involvement in policy implementation is essential.(187) Consultation is necessary, even in the policy development stages.(188) Failing that, it was felt that there will be great resistance to change resulting from a lack of ownership of decisions made.(189) People at the coal-face need to have an understanding of the “whys and hows” of what they have

been told to do. This sense of ownership can only be achieved, “by participation, communication, consultation and service”.(56) Wide involvement of key leaders, particularly DTC members, is required in policy implementation and evaluation. These collaborative and consultative approaches are thought to have an effect on the success of policy implementation.(190)

A broad range of implementation strategies was discussed in focus groups. The education of doctors, nurses and pharmacists through strategies such as drug bulletins and public forums was seen to be valuable. Whilst participants successfully identified the advantages of these strategies, they were quick to point out many shortcomings as well. The perceived effectiveness of the various strategies discussed by participants concurred with evidence in the literature (Chapter 4). However, participants mostly mentioned strategies assuming they are used as single-faceted interventions. Whilst single-faceted interventions may be used, the literature indicates the importance of multifaceted intervention strategies if a change in practice was desired.

What was most clearly articulated in group discussions was that information dissemination needs to be timely. This was felt to be critical no matter what kind of strategy was selected to disseminate those messages. The participants felt that messages conveyed to stakeholders should be up to date and relevant. It was clear that participants felt that messages were most effectively delivered in “real time” – at the bedside when the message is of relevance to the situation.

All groups identified the “resource-poor environment” in which the DTC functions to be a major barrier to decision implementation. This finding was unsurprising as it has been also been reported in previously published studies of Australian DTCs.(74, 191)

Participants indicated that the lack of resources was a major issue because it could have a significant impact, not just on the process of implementation, but also the follow-up of policies and decisions which had been implemented. Many DTC decisions appeared not to have been followed-up in an audit or similar activity. Many participants alleged that this could be linked to the lack of resources available to the DTC. In any case, a lack of follow-up was seen to be detrimental to decision implementation because the success or failure of the implementation process could never be established. Valuable and effective strategies could not be repeated. Similarly, shortcomings could not be reassessed and corrected.

Stakeholders suggested that decisions needed to be prioritised so that decisions and policies which were deemed important could be implemented effectively. However, it was not evident from the results of this study what constitutes an “important decision”. Even if important decisions could be identified, the results from these focus group discussions did not give a clear indication of stakeholders’ opinions regarding *how* these important decisions should be implemented (eg only implement the most important decisions, or use more intervention strategies for the more important decisions?). Given that DTCs function in an environment lacking in resources, the notion of prioritisation of decisions need to be further explored.

In conclusion, these discussions have been valuable in informing us of stakeholders' expectations and opinions of intervention strategies, and how these are being applied, and should be applied within the organisational setting. The participants at these focus group discussions articulated that the impact of the DTC lies beyond that of decision making. It is in the implementation of those decisions and policies into day-to-day practice that will have an impact on patient care.

6. Prioritising DTC decisions based on "importance": A national survey

6.1 Introduction

DTCs function in an advisory manner to promote rational use of medicines within their institutions.(101) Despite the expanding roles of DTCs, they continue to function in a resource-poor environment.(191) In the qualitative study reported in the previous chapter, stakeholders suggested that one way to overcome barriers to decision implementation was to assign priority to DTC decisions. (Chapter 5)

What was not evident from the results of this previous study was *how* DTC decisions should be prioritised. While there was some suggestion that "important" decisions should be assigned a higher priority, it was not clear from our previous work what constituted an "important decision". There is a gap in the literature with regard to the factors contributing to priority assignment for DTC decision implementation.

6.1.1 Aims

The aims of this national survey were to explore stakeholder opinions about:

- the domains, or criteria, used to determine “important” decisions
- the “importance” of DTC decisions as an appropriate approach for prioritising implementation and actions
- how DTC decisions could be prioritised for action

6.2 Methods

6.2.1 Questionnaire development

A semi-structured questionnaire was developed. The details of data collected are presented in Table 6.1. This questionnaire was developed based on the results of the qualitative study, in consultation with members of the reference group formed to guide the development of this study.

Table 6.1: Data collected in questionnaire

Study questions	Data collected
1. What are the domains/criteria of important DTC decisions?	- five tick box options - as there is no guidance regarding what these criteria may be from the literature, options provided incorporated suggestions from reference group members - respondents could also include other domains/criteria in the free-text area
2. Is "importance" of DTC decisions an appropriate approach for prioritising implementation and actions?	- five-point Likert scale (Strongly Agree to Strongly Disagree) was used - respondents were asked to rate their level of agreement to statements (See statements in Appendix 6.1) - respondents were also asked if DTC decisions could be prioritised for implementation (choice of yes, no and maybe)
3. How can DTC decisions be prioritised for implementation?	- in the free-text area, respondents were asked to suggest ways to prioritise DTC decisions for implementation

6.2.1.1 Pilot study

The questionnaire was piloted to assess content validity and test for clarity of questions. The pilot study involved all members of the St Vincent's Hospital DTC and participants of focus group discussions described in the previous chapter. However, reference group members were excluded from this pilot study as they contributed to questionnaire development. The pilot questionnaire was distributed to 32 stakeholders. Respondents were asked to include any comments about the structure and content of the questionnaire.

As a result of the pilot study, two statements were added to the questionnaire (Item K and Item L). These were added to ensure acquiescence using the Likert scales. In other words, the same idea is presented in positive and negative statements. Respondents who agree with the positive statement should disagree with the negative statement. For example, respondents who agree to the statement "Some DTC decisions are more important than others" should disagree with the statement "All DTC decisions are equally important".

The final version of the questionnaire also contained information about participants' membership of DTCs, duration of DTC membership and professional representation. A copy of the final questionnaire used for data collection in the main study is attached in Appendix 6.1.

6.2.2 Data collection and analysis

Responses from all DTCs in Australia were sought. The latest version of the *Directory of Hospital Pharmacy and Pharmaceutical Organisations* (updated 20th May 2004)*(192)* was obtained through the Society of Hospital Pharmacists of Australia (SHPA).

In our 2001 survey (Chapter 3), we contacted potential participants using the 1998 version of this SHPA directory. The results of that survey indicated that there were 127 DTCs in Australia. The contact details of Directors of Pharmacy or Chief Pharmacists of these institutions were identified in the 2004 version of the SHPA directory. There were twenty-five institutions listed in the 2004 version of this

directory, which were not present in the 1998 version of the directory. These hospitals were also included in the mail-out.

In June 2004, 152 Directors of Pharmacies or Chief Pharmacists, in public, private, metropolitan and rural hospitals in Australia, were sent the survey questionnaire via email.(Appendix 6.1) Each survey questionnaire was accompanied by an invitation to participate in the survey explaining the purpose of the study. (Appendix 6.2) Confidentiality and data handling issues were also addressed. In the event that emails were returned, a copy of the questionnaire and the cover letter were sent via fax.

Questionnaires could be returned by email or by fax. If a response was not received by two weeks after mail-out, a reminder email (or fax), together with a follow-up letter (Appendix 6.3) was sent with another copy of the questionnaire.

Responses were collated and data entered into the Statistical Package for the Social Sciences (SPSS) for Windows Version 10 (SPSS Inc., Chicago, USA) database for statistical analyses. Descriptive statistics (eg frequencies, proportions, percentages) were used to summarise collected data.

The free-text responses regarding respondents' opinions of how DTC decisions could be prioritised were collated in a Microsoft Word® 2002 (Copyright Microsoft 1983-2001) document. QSR NVivo© Version 2.0 (QSR International, Australia) was used as a data management tool for content analysis. The major themes are highlighted in the results.

6.3 Results

6.3.1 Response rates

The questionnaire was sent to Directors of Pharmacies (or Chief Pharmacists) of 152 Australian hospitals according to the 2004 SHPA *Directory of Hospital Pharmacy and Pharmaceutical Organisations*. Of these, 15 questionnaires were unable to be delivered (emails and faxes both rejected). As such, the respondent pool was reduced to 137 directors of pharmacy or chief pharmacists (1 invitation per hospital).

Ninety questionnaires were returned at the end of the data collection period (response rate of 66%). Six questionnaires contained missing data and were excluded from data analysis. The response rate for questionnaires used in the analysis was 61%. Analysis was conducted on 84 questionnaires. (Figure 6.1)

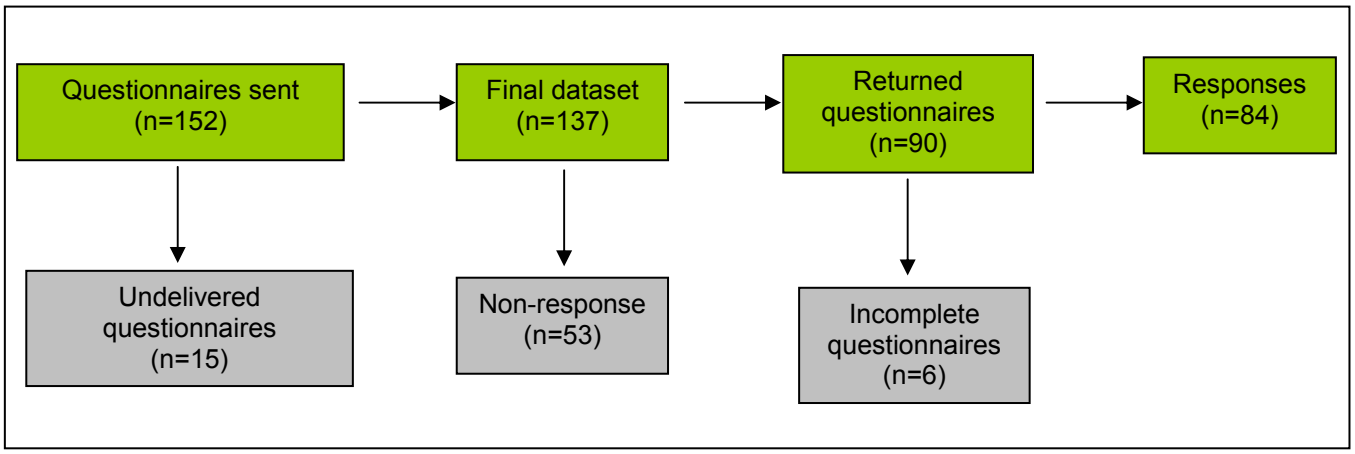

Figure 6.1: Selection of responses for analysis

6.3.2 Demographics of respondents

Seventy-four respondents (88%) were currently DTC members, of which 53 had been members for more than five years. (Table 6.2) Only two respondents had been a DTC member for less than a year.

Table 6.2: Characteristics of respondents

	Number of participants
DTC membership	
Current DTC member	74
Never been a DTC member	5
Used to be a DTC member	5
Years of DTC membership (for current members)	
<1 year	2
1-2 years	7
2-5 years	12
>5 years	53

6.3.3 Perceptions of domains (or criteria) of "important" decisions

All respondents indicated "patient safety" as a domain in the importance of a decision. Seventy-nine respondents (94%) considered DTC decisions involved with "ensuring the practice of evidence based medicine within their institution" as being important decisions. Other domains which conferred importance upon DTC decisions included those dealing with "cost" (93%) and decisions that "ensures practice is according to legislative requirements" (87%). Approximately one third (n=24) of respondents considered "urgency" as a characteristic around a decision that could confer a significant importance rating.

6.3.4 Stakeholder opinions of "importance" and decision prioritisation

Forty-four percent of respondents agreed with the statement "prioritisation of decisions may allow the less important decisions to be not implemented". However, 41% of respondents disagreed with this proposition. The majority of respondents (78%) did not agree that "decisions of low priority should not be implemented". The results indicate that responses had concordance for statements of acquiescence on the five point Likert scale. All responses to the propositions put to respondents as rated on the 5-point Likert scales are tabulated in Table 6.3.

Table 6.3: Respondents' opinions about the prioritisation of DTC decisions

Statement	N (%)				
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Some DTC decisions are more important than others	30 (38.5)	40 (51.3)	4 (5.1)	3 (3.8)	1 (1.3)
There are domains (elements) of a decision that make a decision important	25 (32.1)	50 (64.1)	2 (2.6)	0	1 (1.3)
Important decisions involves at least ONE of the domains listed in item D*	37 (47.4)	36 (46.2)	3 (3.8)	1 (1.3)	1 (1.3)
Given constraints on time and resources, the option of prioritising decisions for implementation should be considered	21(26.9)	46 (59.0)	6 (7.7)	4 (5.1)	1 (1.3)
Prioritisation of decisions enables the important decisions to be implemented effectively	23 (29.5)	36 (46.2)	10 (12.8)	6 (7.7)	3 (3.8)
Prioritisation of decisions may allow the less important decisions to be **NOT** implemented	5 (6.4)	29 (37.2)	12 (15.4)	25 (32.1)	7 (9.0)
All DTC decisions are equally important	2 (2.6)	13 (16.7)	8 (10.3)	45 (57.7)	10 (12.8)
Decisions of low priority should not be implemented	0	0	17 (21.8)	40 (51.3)	21 (26.9)

*domains listed in Item D include patient safety, cost, ensures evidence-based practice within the institution, ensures practice according to legislative requirements and urgency

Most respondents (90%) agreed that some DTC "decisions were more important than others". Only four respondents disagreed with this statement.(Table 6.3) The respondent who strongly disagreed with the statement noted in the free-text section of the questionnaire:

"…the secretary of the DTC does a lot of work in order to bring the decision to the DTC…if the decision is not important it should NOT be tabled at the meeting…ALL decisions are important…"

This same respondent also did not agree that "there are elements of a decision which makes it important". Given constraints on time and resources, 86% of respondents agreed that prioritisation for implementation should be considered.

In response to a direct "Yes/No" question about whether DTC decisions can be prioritised for action, about two-thirds of respondents (n=57, 68%) believed that they could. Three respondents (4%) believed that DTC decisions could not be prioritised for implementation. One of these respondents who disagreed commented,

"Prioritising for implementation defeats the purpose of the DTC. All decisions have to be implemented otherwise abandon the committee."

Twenty-four (31%) of respondents indicated that they were unsure if DTC decisions could be prioritised (selection of "maybe").

6.3.5 Stakeholder opinions about how DTC decisions could be prioritised

There does not seem to be consensus of opinions of how DTC decisions could be prioritised. There were 21 respondents who had no suggestions or opinions with regard to this (with responses such as: “Don’t know”, “Not sure”, “No comment”, or with the free-text area left blank).

When asked how DTC decisions could be prioritised for implementation, there were 15 respondents who were of the opinion that decisions which impacted on patient safety needed to be given higher priority for implementation. Some of the responses included,

“Issues relating to patient safety must receive highest priority…”

“If v (sic) important, and has impact on patient safety - make sure do it NOW!!”

There were also a number of respondents who were of the opinion that those decisions involving *“drugs that have the largest cost”* should be given priority for implementation.

Many respondents also suggested some sort of a scoring system. One of the respondents suggested,

“Given (sic) an importance rating, 1-5. Start with number 1 and when complete move to number 2 etc.”

There were other respondents who likened the scoring system to the Severity Assessment Code (SAC) system for quantifying the actual or potential risks of medication incidents.

"I think something like the "SAC" system prioritising on the basis of consequence with some element of the number of patients affected."

Whilst respondents did not agree that "urgency" was a feature of decision that contributed to its importance rating, many respondents suggested that urgency does have an influence on priority for implementation. One respondent suggested implementation based on an "importance-urgency grid" (Table 6.4).

Table 6.4: Importance-urgency grid (suggested by respondent)

	High importance	Low importance
High urgency	Do NOW!	Do on abandon
Low urgency	Plan and then do later	Set aside

6.4 Discussion

There is no evidence in the public domain regarding the way in which DTC decisions should be prioritised for implementation. From the results reported in Chapter 5, priority assignment was seen as a practical means to improve DTC performance. Stakeholders were of the opinion that important decisions should be given priority. This is a pertinent issue to address, particularly given the resource-poor environment in which DTCs functions.

This survey achieved a response rate of 61%. The sampling procedures meant that only pharmacists were invited to participate in this survey. This respondent group was targeted for two reasons. Firstly, it is well established that pharmacists are widely represented in DTCs in Australia.(74, 130) Our national survey of DTCs presented in Chapter 3 also confirmed this. Second, there was a readily available reliable source of contact details (SHPA's *Directory of Hospital Pharmacy and Pharmaceutical* Organisations) for Directors of Pharmacy and Chief Pharmacists in Australia. Therefore, the results of the survey may not necessarily reflect the opinions of other DTC stakeholders.

The results of our qualitative study (reported in Chapter 5) suggest that DTC decisions and policies are currently implemented by pharmacists. Arguably, pharmacists are the appropriate stakeholders to shed light on the issues at hand. Also, respondents in this survey have extensive experience with the operations of DTCs. This is reflected by the high percentage of respondents who were current

DTC members (88%) and of those, the percentage who had been members for more than five years (72% of current DTC members). (Table 6.2)

This study focussed on the "importance" of DTC decisions and documented what respondents thought were the domains that were associated with perceptions of importance. The three domains rated as of highest importance were "patient safety", "cost", and "evidence-based medicine". It has been reported that the three essential types of information DTCs use to make decisions are evidence of effectiveness, safety and cost.(105) Therefore it was not unexpected that these domains were identified as most important.

Interestingly, stakeholders in a previous study of this thesis also identified these domains as comprising the principal functions of DTCs. (Chapter 3) A key component of "quality" in patient care is effectiveness.(193) The practice of evidence-based medicine aims to promote effectiveness so that patient safety is improved, and health care resources are not wasted.(2) These very principles are also promoted through Australia's National Medicines Policy.(24) A culture of risk management is very much on the health care agenda because it is expected that such a culture will deliver improved patient safety.(13)

Stakeholders' opinions about priority assignment for implementation were also determined. Although there were a few stakeholders who expressed reservation with regards to the notion of prioritising for implementation, most respondents agreed (87%) that assigning priority to decisions for implementation should be considered. Whilst it is appreciated that *all* DTC decisions could potentially have an

impact on QUM, the reality facing DTCs is that there are not enough resources to properly implement all of them.

It seemed that few respondents considered “urgency” around decisions under the purview of the DTC, to automatically confer a level of importance that might guide priority for implementation. Having said that, respondents did seem to take “urgency” into consideration when prioritising for implementation. This suggests that the way the proposition concerning urgency was put to respondents may have affected the responses. A respondent suggested an “importance urgency grid”.(Table 6.4) This insight seems to be appealing and should be given further and wider consideration. This respondent suggested further that those decisions of low urgency and low importance should be “set aside”. It was unclear if this method of assigning priority for implementation was being used by this respondent’s DTC, but either way, this was a very interesting suggestion.

The results of this study suggest that stakeholders recognise that DTC decisions need to be prioritised for implementation because of constraints on time and resources. However, stakeholders were uncomfortable if any DTC decisions, even those of low priority, were not implemented. Ideally all DTC decisions should be implemented. But, in reality, resources will be directed towards the implementation of decisions considered to be of high priority. The suggestion from this work is that rating of DTC decisions according to importance ought to guide priority for implementation. If the direction that this thesis has suggested is taken up, then stakeholders (broader in definition than included in this survey) would need to be mindful that decisions of low importance and thus, lower priority would only be

implemented after those decisions assigned higher priorities. Consequently, decisions of low priority may not get implemented.

In a previous study (Chapter 3), respondents to our national survey were asked to rate the extent to which their DTCs achieved their functions. Only three respondents (2.4%) believed that their DTC was fully achieving its principal functions (score of 10 out of 10). Six (4.7%) respondents felt that their DTC was not achieving its principal function to any level (score of 0 out of 10). One of the barriers to DTCs fully achieving their functions was noted to be a "lack of adherence to policies/guidelines set out by the DTC". The implication seems to be that DTC decisions should be adhered to in order for DTCs to achieve its functions. This may be unrealistic and unachievable. Work will need to be done to implement a "sea-change" in thinking and perceptions about DTCs' functions and effectiveness.

The environment in which DTCs function is complex.(84) Given the expertise around the table, DTCs are likely to be called upon to make even more difficult decisions. The lack of resources in health care is unlikely to be solved in the immediate future. Thus, there is a need to balance the tension and conflict between greater responsibilities and less resources. To deal with this tension, we suggest that the DTC may choose to have a practical means of efficiently achieving these goals. This study suggests a rational approach to achieving better results from DTC deliberations.

7. The effect of level of importance and the primary domains of DTC decisions on priority assignment

7.1 Introduction

The results of the study reported in the previous chapter (Chapter 6) suggested that specific characteristics of DTC decisions influence the perception of importance of that decision. It was also found that current DTC decisions and policies may not be being implemented effectively (Chapter 5 and Chapter 6). Stakeholders suggested that DTC decisions could be prioritised for implementation so that available resources are used to implement effectively the decisions and policies of high priority.

Results of previous studies conducted in this thesis indicate that stakeholders would assign higher priority to DTC decisions if they were considered important. We used five hypothetical case-based scenarios to explore the relationship between the assignment of priority and importance.

7.2 Aims

The aims of this study were to investigate the opinions of DTC stakeholders regarding the:

(1) primary domains stakeholders would assign to five hypothetical DTC decisions;

(2) level of importance stakeholders would assign to these DTC decisions; and

(3) level of priority stakeholders would assign to the implementation of these DTC decisions

Based on these responses, we examined the relationship between assignment of importance and priority in each case scenario; and also according to the primary domain identified across the five scenarios.

7.3 Methods

7.3.1 Instrument development

A survey semi-structured questionnaire was developed. The questionnaire described a hypothetical DTC. (Figure 7.1)

You are the chairperson of the Drug and Therapeutics Committee (DTC) at St Elsewhere hospital. There are no resources assigned to the operations of the DTC you chair. The DTC at St Elsewhere comprises of 2 pharmacists (the director of the pharmacy department who is also secretary to the DTC, and a clinical pharmacist), a nurse, and 4 senior medical officers (from clinical pharmacology, microbiology, cardiology and intensive care respectively).

Figure 7.1: Hypothetical DTC described in questionnaire

Five scenarios were presented in the survey reflecting decisions commonly made by many DTCs. (Figure 7.2) The scenarios were based on examples of DTC decisions reported by New South Wales DTCs through NSW TAG.(194) The scenarios did not identify patients, prescribers, nor the DTCs making those decisions.

The scenarios included decisions about:

- a hospital drug formulary,
- a health department circular,
- review hospital guidelines,
- high cost drugs, and
- medication incidents

Figure 7.2 shows the scenarios used in the survey.

Scenario 1 (relating to drug formulary)
Your DTC received an application for a “me-too” proton pump inhibitor (PPI) to be included on the hospital formulary. Currently another PPI is on the hospital formulary. The new PPI is an isomer of the one currently on formulary. There was no evidence of clinical and/or economic benefit of the new PPI over the PPI currently used in the hospital. After discussions at a DTC meeting, the request for the addition of the “me-too” PPI was denied. Guidelines are needed for patients admitted to the hospital on the new PPI (ie started in community, or at another facility).

Scenario 2 (relating to a health department circular)
The state health department has issued a circular about the prescribing of paracetamol. Your DTC reviewed the circular and agreed that the current practices with regard to paracetamol prescribing within your hospital were not in accordance with the health department recommendations detailed in this circular. At a DTC meeting it was decided that new guidelines for paracetamol prescribing were to be implemented. Implementation may need to include communication to staff (medical, nursing, pharmacy), staff education and possibly audits.

Scenario 3 (relating to review of in-house guidelines)
The Head of the Pain and Palliative Care Department at St Elsewhere Hospital, Dr Pain, wrote a letter to the DTC requesting a review of the hospital’s prescribing guidelines for pethidine. After an extended discussion, the DTC is supportive of Dr Pain’s proposal. The clinical pharmacist was requested to report on the usage patterns of pethidine in the last 6 months at the next DTC meeting. A Pethidine Working Party was formed to review the hospital’s prescribing guidelines. The redrafted guidelines must address occasions when pethidine may be used, as well as issues regarding morphine allergy. Redrafted guidelines must be circulated to clinical staff for feedback. An educational campaign targeting interns, residents, registrars, nurses as well as pharmacists needs to be conducted.

Scenario 4 (relating to high cost drugs)
A medication was supplied for patients free of charge through an expanded access program. A small number of patients from St Elsewhere were supplied with this medication through this program. The DTC and the Ethics Committee at St Elsewhere were unaware of this program. This medication is now marketed and the Drug Company will no longer make this medication available to patients free of charge. The costs for maintaining these patients on this medication is expected to be about $200,000 per annum. The DTC decided that it was not ethical to stop this treatment for these patients. However, the DTC decided that no new patients could be commenced on this medication. Guidelines with regard to the use of this medication need to be developed, with input from the relevant specialist prescribers. A policy regarding the enrolment of patients from St Elsewhere in trials and access programs needs to be developed. A letter needs to be written to the Drug Company to seek support with regard to the supply of this medication for existing patients. The Executive of the hospital needs to be consulted regarding ways to cover the cost of this medication for these patients.

Scenario 5 (relating to medication incidents)
The DTC was reviewing medication incident reports at the meeting. DTC members present were concerned about the number of incidents relating to insulin. One of the senior medical officers present noted that these were not isolated as similar incidents have been reported. The DTC decided that a strategy to prevent the recurrence of insulin-related errors need to be developed. Representatives from the hospital’s Endocrinology Department and Diabetes Clinic were invited to provide recommendations. Prescribers, pharmacists and nurses should be educated with regard to the types of insulin available and how these should be used.

Figure 7.2: Scenarios developed for questionnaire

A pre-determined list of primary domains was developed based on the results of the study reported in Chapter 6. For each scenario, stakeholders were asked to identify, from the pre-determined list, the primary domain (or main issue) of the decisions addressed. The primary domain options provided were:

- “ensures patient safety”,
- “relates to cost”,
- “ensures the practice of evidence-based medicine within the institution”,
- “ensures practice is according to legislative requirements”, and
- “urgency”.

Respondents were able to suggest another primary domain if they felt that the options listed were not appropriate.

Stakeholders were also asked to assign a level of importance and priority to each scenario. The response options for level of importance were on a five-point Likert scale from 1 (very important decision) to 5 (unimportant decision). Response for levels of priority were:

- “High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision”
- “Medium priority: this decision should be implemented with remaining resources (time, manpower, money) after other decisions of high priority are implemented”

- "Low priority: this decision can be implemented only if possible, after implemented decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)"

The questionnaire also collected demographic information about the participants (age, gender, professional representation and membership of DTCs). It was anticipated that respondents would not need more than 10 minutes to complete the questionnaire.

7.3.2 Pilot study

The questionnaire was pilot tested among ten DTC stakeholders, including three hospital pharmacists, two senior medical officers, one community pharmacist, two junior medical officers, a research pharmacist, and a nurse. An electronic copy of the questionnaire was emailed to participants. A hard copy of the questionnaire was also available upon request.

Respondents were asked to note the time taken to complete the questionnaire. Participants in the pilot study indicated that the time taken to complete the questionnaire was between five minutes and fifteen minutes. Most of the participants (n=6) completed the questionnaire within five minutes.

Respondents were asked to include comments about how the questionnaire could be improved (in terms of structure and content). The form used to collect this information is attached in Appendix 7.1.

As a result of this pilot testing, some of the scenarios and instructions were rephrased for clarity. The final questionnaire is attached in Appendix 7.2.

7.3.3 Data collection

7.3.3.1 Selection of participants

All Directors of Pharmacy and Chief Pharmacists listed in the Society of Hospital Pharmacists of Australia (SHPA) *Directory of Pharmacy and Pharmaceutical Organisations* (last updated May 2004) were included in the sampling frame. There are no official lists of hospital-based doctors, nurses or DTC members in Australia. However, six state-based therapeutic advisory groups (or their equivalent) have memberships that include hospital doctors, nurses and DTC members. Letters of invitation to participate in the survey (Appendix 7.3) were distributed to these stakeholders. Due to privacy issues, the names and contact details of stakeholders invited through the state-based therapeutic advisory groups could not be made available to the researchers. However, the therapeutic advisory groups in each state provided the number of invitations disseminated.

The questionnaire was made available online at www.dtcsurvey.com. (Appendix 7.4) Stakeholders were asked to complete the survey online. Alternatively, the questionnaire (available as a "word document" or a "pdf document") could be downloaded from the website. Upon request, a hard copy of the questionnaire was also made available to stakeholders (via fax or post).

It was expected the survey would not be completed more than once by the same individual. However, in order to ensure that participants did not complete the survey multiple times, the following measures were undertaken:

- In the body of the email inviting potential participants to complete the survey, participants were asked to complete the survey **once only**
- If participants completed the questionnaire online, participants' Internet Protocol (IP) addresses were recorded. This was used only to check for duplication of responses. The recorded IP addresses did not identify the exact location of participants, and were not included in any of the data analysis.

A follow-up reminder letter (Appendix 7.5) was sent two weeks after initial dissemination of the questionnaire. This letter was emailed to stakeholders identified through the Society of Hospital Pharmacists of Australia (SHPA) *Directory of Pharmacy and Pharmaceutical Organisations* according to the email contact listed in the directory. State-based therapeutic organisations distributed this follow-up letter to their members on our behalf.

7.3.3.2 Analysis

De-identified data were collated into a Statistical Package for the Social Sciences (SPSS) for Windows Version 10 (SPSS Inc., Chicago, USA) database for statistical analyses.

Descriptive statistics (means, frequencies, percentages) were used to report primary domains identified assignment of importance and priority in each scenario. For each scenario, we used Spearman's rho (*r*) to examine the relationship between the non-parametric ordinal variables (ie "level of importance" and "level of priority"). Further, using data for all scenarios combined, we conducted five separate correlation analyses using Spearman's rho (*r*) to examine the relationship between assignment of importance and priority for each of the primary domains identified (ie separate analyses for "ensures patient safety", "relates to cost", and so on).

Due to the multiple comparisons performed, the level of significance (p value) was adjusted to reduce the risk of Type 1 error using the Bonferroni correction. For comparisons according to scenario and primary domain, results were considered statistically significant when the p value was less than 0.01 (i.e. 0.05 ÷ 5).

7.3.3.3 Ethical considerations

This study was approved by the Human Research and Ethics Committee (HREC) at The University of Sydney. By returning the questionnaire, stakeholders were deemed to have given consent to participate in the study.

Only the researchers involved in this study had access to the original data. All data were de-identified. Participants' identities were not revealed in any presentations/publications arising from the study.

7.4 Results

Two-hundred-and-seventy-six Directors of Pharmacy or Chief Pharmacists and 251 individuals (including doctors, pharmacists, nurses, DTC members) were invited to participate in the survey. Of these, 119 invitations could not be delivered. As such, 408 invitations were delivered.

In total, 104 stakeholders completed the questionnaire, giving a response rate of 25.5%. Of the 104 responses, 83% (n=86) were completed online. Twelve questionnaires were not sufficiently completed and were excluded from analysis. The final dataset for analyses included 92 questionnaires. (Figure 7.3)

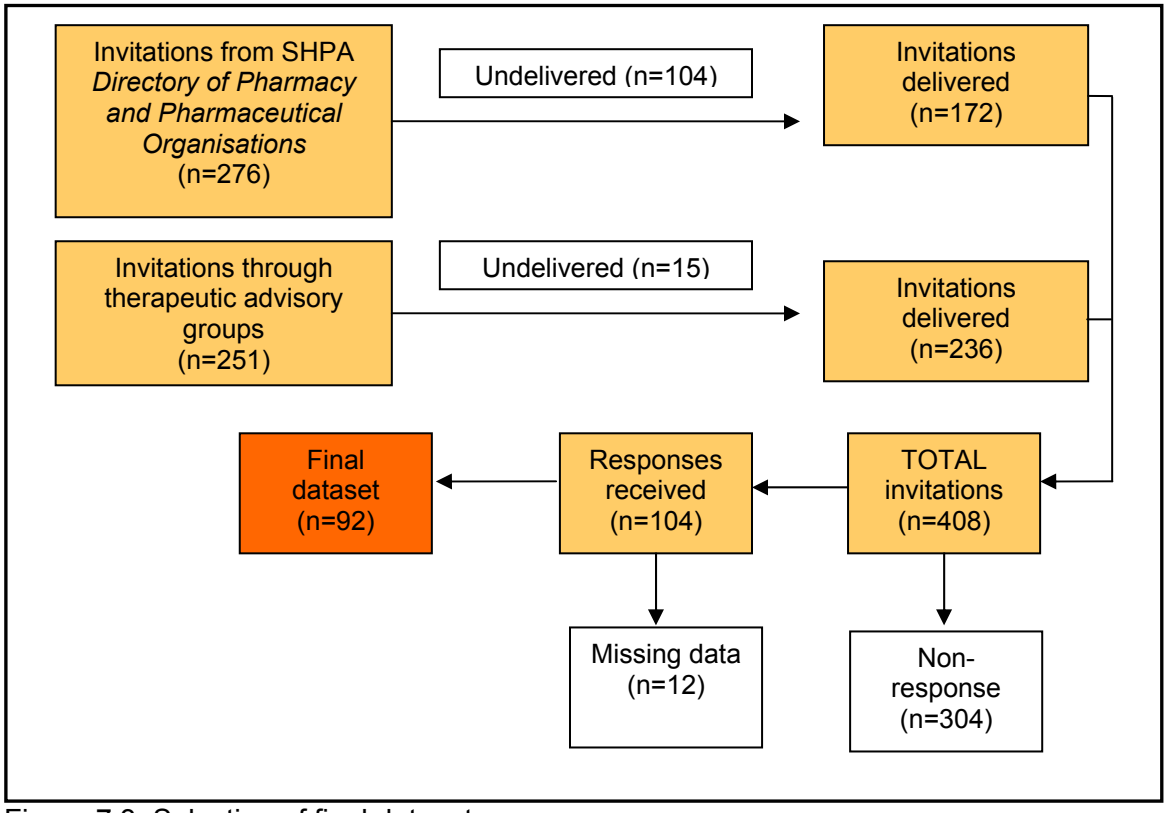

Figure 7.3: Selection of final dataset

7.4.1 Respondent characteristics

Of the 92 respondents, 49 (53%) were female and 28% were within the “36-45 years old” age group. More than half of the respondents were hospital pharmacists (n=47). Eighteen (20%) senior medical staff also responded. Most of the respondents (n=88) had been DTC members between six months to 30 years (mean=7.9 years, SD=7.2 years). Four respondents had never had DTC membership. (Table 7.1)

Table 7.1: Characteristics of respondents

Characteristics	Number of respondents,n (%)*
Age	
< 25 years	2 (2.2%)
26-35 years	16 (17.4%)
36-45 years	26 (28.3%)
46-55 years	24 (26.1%)
> 55 years	24 (26.1%)
Gender (Female)	49 (53.3%)
Professional representation	
Hospital pharmacist	47 (51.1%)
Senior medical staff/Consultant	18 (19.6%)
Nurse	8 (8.7%)
Junior medical staff/Registrar	5 (5.4%)
Hospital administrator	4 (4.3%)
General practitioner	2 (2.2%)
Community pharmacist	2 (2.2%)
Consumer representative	2 (2.2%)
Director of pharmacy services	1 (1.1%)
Hospital projects officer	1 (1.1%)
Quality improvement manager (area health)	1 (1.1%)
Senior pharmacy technician	1 (1.1%)
DTC membership	
Current DTC member	83 (90.2%)
Previous DTC member	5 (5.4%)
Never been DTC member	4 (4.3%)

*Total responses, N=92

Table 7.2 details the distribution of responses for each scenario according to the primary domain identified and the assignment of importance and priority. Correlation coefficients and associated p-values representing the relationship between assignment of importance and priority are also presented.

Table 7.2: Summary of results for DTC decision described in each scenario

	Primary domain identified, n (%)						Level of importance[ψ], n (%)					Level of priority[ξ], n (%)			Correlation[π]		
	Safety*	Cost[#]	EBM[^]	Legislation[+]	Urgency	Other[φ]	1	2	3	4	5	High	Med	Low	*r*	r^2	p
Scenario 1	10 (11)	17 (19)	59 (64)	1 (1)	0	5 (5)	8 (9)	13 (14)	30 (33)	17 (18)	24 (26)	2 (2)	40 (43)	50 (54)	0.710	0.504	<0.0001
Scenario 2	43 (47)	3 (4)	5 (5)	39 (42)	1(1)	1 (1)	39 (42)	43 (47)	6 (7)	4 (4)	0	54 (59)	33 (36)	5 (5)	0.541	0.292	<0.0001
Scenario 3	28 (30)	0	54 (59)	0	4 (4)	6 (7)	29 (32)	41 (45)	17 (18)	3 (3)	2 (2)	28 (30)	60 (65)	4 (4)	0.622	0.387	<0.0001
Scenario 4	3 (4)	81 (88)	2 (2)	2 (2)	0	4 (4)	59 (64)	17 (18)	14 (16)	2 (2)	0	67 (73)	25 (27)	0	0.576	0.332	<0.0001
Scenario 5	91 (99)	0	0	0	1 (1)	0	78 (85)	10 (11)	2 (2)	1 (1)	1 (1)	81 (88)	9 (10)	2 (2)	0.417	0.174	<0.0001

Scenario 1 (Formulary decision), Scenario 2 (Response to health department circular), Scenario 3 (Review of guidelines), Scenario 4 (High cost drugs), Scenario 5 (Medication incident)

*"Ensures patient safety"; [#]"Relates to cost"; [^]"Ensures practice of evidence-based medicine within the institution"; [+]"Ensures practice is according to legislative requirements"; [φ]Other primary domain (suggested by respondents)

[ψ]Level of importance of DTC decision scored on a five-point Likert Scale (where 1=very important decision, and 5=unimportant decision)

[ξ]Level of priority of the DTC decision for implementation. The definitions of the levels of priority include:

- High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
- Medium priority: this decision should be implemented with remaining resources (time, manpower, money) after other decisions of high priority are implemented
- Low priority: this decision can be implemented only if possible, after implemented decisions of high and medium priority (**note that given the lack of resource, the DTC may not get to implement this decision)

[π]Correlation between level of importance and priority assignment (*r*=Spearman's rho for ordinal data; results considered statistically significant if p<0.01)

7.4.2 Identification of primary domain

The results tabulated in the blue section of Table 7.2 related to respondents' identification of the primary domain.

Respondents clearly favoured one primary domain for scenarios 1 (formulary decision), 4 (high cost drugs) and 5 (medication incident). The first scenario relating to a drug formulary decisions was considered an evidence-based medicine issue by 64% of the respondents. Eighty-eight percent of respondents identified cost as a primary domain in Scenario 4. All, but one respondent identified Scenario 5 as a decision relating to patient safety.

In contrast, responses to Scenario 2 about a Health Department circular indicated that this DTC decision was seen as a patient safety (47%) and a legislative (42%) issue. For Scenario 3 (review of guidelines), respondents mainly considered the primary domains to be related to evidence-based medicine (59%) and patient safety (30%).

7.4.3 Stakeholders' perception of importance

The majority of respondents considered four of the five DTC decisions presented as important. The results tabulated in the pink section of Table 7.2 related to stakeholders' perception of the level of importance of DTC decisions described in the scenarios.

Respondents indicated that the decision described in Scenario 1 (formulary decision) was not important. This was reflected by 41 respondents allocating a score of 4 or 5 on the Likert scale (where 5=not important at all). Most respondents (89%) indicated a score of 1 or 2 for the decision about a health department circular (described in Scenario 2). The DTC decision relating to the review of medication guidelines was also seen to be important with 72% indicating a score of 1 or 2 on the Likert scale.

For Scenario 4 (high cost drugs), 64% of respondents allocated a score of 1 on the Likert scale (where 1=very important) and in Scenario 5 (medication incident) 96% of respondents chose a score of 1 or 2.

7.4.4 Priority assignment

The green section of Table 7.2 tabulated results relating to stakeholders' assignment of priority to DTC decisions described.

The level of priority assigned varied by scenario.

High priority for implementation was assigned by the majority of respondents to Scenario 2 (health department circular), Scenario 4 (high cost drugs) and Scenario 5 (medication incident). The majority of respondents assigned the DTC decision described in Scenario 3 (review of medication guidelines) to be of medium priority

for implementation. Scenario 1 (formulary decision) was considered to be of low priority for implementation by the majority (54%) of respondents.

7.4.5 Relationship between level of importance and priority assignment

Correlation coefficients and associated p-values representing the relationship between assignment of importance and priority are also presented in the orange section of Table 7.2.

The correlation analysis by each scenario showed a significant positive relationship between assignment of priority and importance. However, the strength of the relationship varied according to scenario with the percentage of the variance (r^2) explained ranging from 17% to 50%.

7.4.6 Impact of primary domains on perception of importance and priority assignment

Table 7.3 presents that distribution of responses for assignment of importance and priority according to the primary domain identified. Correlation coefficients and associated p-values representing the relationship between assignment of importance and priority are also presented for each primary domain.

Too few respondents chose the “urgency” as the primary domain. These responses were excluded from further analysis.

Table 7.3: Summary of results according to primary domains identified

Primary domains identified (n)	Level of importance[Ψ], n (%)					Level of priority[ξ], n (%)			Correlation[π], n (%)		
	1	2	3	4	5	High	Medium	Low	*r*	r^2	p
Safety (n=175)*	122 (70)	31 (18)	15 (8)	6 (3)	1 (1)	128 (73)	38 (22)	9 (5)	0.620	0.384	<0.0001
Cost (n=101)#	54 (53)	17 (17)	20 (20)	8 (8)	2 (2)	60 (59)	33 (33)	8 (8)	0.799	0.638	<0.0001
EBM (n=120)^	19 (16)	45 (38)	28 (22)	7 (6)	21 (18)	15 (13)	70 (58)	35 (29)	0.800	0.640	<0.0001
Legislation (n=42)+	12 (29)	22 (52)	3 (7)	5 (12)	0	24 (57)	13 (31)	5 (12)	0.301	0.09	0.053
Urgency (n=6)≠	2 (33)	1 (17)	0	0	3 (50)	1 (17)	3 (50)	2 (33)	N/A	N/A	N/A

≠Note: Correlation coefficient and p-value could not be obtained for the primary domain "urgency"

*"Ensures patient safety"; #"Relates to cost"; ^"Ensures practice of evidence-based medicine within the institution"; +"Ensures practice is according to legislative requirements"

ΨLevel of importance of DTC decision scored on a five-point Likert Scale (where 1=very important decision, and 5=unimportant decision)

ξLevel of priority of the DTC decision for implementation. The definitions of the levels of priority include:

- High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
- Medium priority: this decision should be implemented with remaining resources (time, manpower, money) after other decisions of high priority are implemented
- Low priority: this decision can be implemented only if possible, after implemented decisions of high and medium priority (**note that given the lack of resource, the DTC may not get to implement this decision)

πCorrelation between level of importance and priority assignment (*r*=Spearman's rho for ordinal data; results considered statistically significant if p<0.01

Respondents predominantly assigned a high level of importance to decisions in the domains of “ensures patient safety”, “relates to cost” and “ensures practice is according to legislative requirements”. Respondents also assigned decisions in these domains a high level of priority for implementation.

In contrast, the assignment of importance was less clear in the domain of “ensures practice of evidence-based medicine within the institution”. There were 21 instances (18%), when stakeholders selected this as the primary domain but assigned low importance (score of 5 on a 5-point Likert Scale, where 1=very important, and 5=unimportant) to the associated decision.

The correlation analysis by each primary domain showed a significant positive relationship between assignment of priority and importance. However, the strength of the relationship varied according to each domain with the percentage of variance (r^2), ranging from 9% to 64%.

7.5 Discussion

This study reported how DTC stakeholders identify the primary domains of DTC decisions, stakeholders' perception of the importance of different types of DTC decisions as well as how stakeholders assign priority. Given the current environment in which DTCs function, it would seem useful to be able to direct available resources to implement those decisions considered to be of high priority to DTCs.

It was noted that a significant number (104 of 276) invitations disseminated to potential participants identified through the *Directory of Pharmacy and Pharmaceutical Organisations* (May 2004 edition) were returned undelivered. A possible reason for this would be that the contact details in the directory were out of date five months post publication. It was also possible that the publication contained some typographical errors resulting in undeliverable invitations. As a consequence, not all of the Directors of Pharmacy in Australian hospitals were invited to participate in this survey. However, those who received an invitation to participate included Directors of Pharmacy from all states and territories of Australia, representing those practicing in metropolitan, urban, remote and rural locations. Hence, it is unlikely that the undeliverable questionnaires significantly impacted on the sampling frame for this study. This study also included other DTC stakeholders (such as doctors, nurses and consumers) recruited through state-based therapeutic advisory groups (or equivalent). Recruitment of non-pharmacists may broaden the opinions and results in this survey being those of DTC stakeholders, not specifically the opinions of pharmacists only.

It was anticipated that a number of participants received multiple invitations, as pharmacists listed in the SHPA directory (particularly Directors of Pharmacy and Chief Pharmacists) are also likely to be members of the state-based therapeutic organisations. Consequently, the response rate (25.5%) reported in this study was possibly a conservative and perhaps biased, finding.

More than half the respondents in this study were hospital pharmacists. (Table 7.1) This could be the result of the recruitment process. Nevertheless, it should also be noted that pharmacists have been established as playing a pivotal role in DTCs in Australia.(74) In fact, according to the results of our national survey (reported in Chapter 4), pharmacists were highly represented on DTCs in Australia.

Less than five percent of the respondents had never been DTC members. Therefore the results of this study comprise the opinions of stakeholders who have an understanding of the operations of DTCs. Further, stakeholders who participated in this survey have a range of experience being members of DTCs (half a year to 30 years).

One of the traditional and most common roles of a DTC was to make decisions regarding the drug formulary (Chapter 2). This role was described in the DTC decision in Scenario 1. The majority of stakeholders were of the opinion that this decision was one of low priority. In the hypothetical scenario presented, the DTC decision was to *not* add a drug to the formulary. It could be postulated that a higher

level of importance and higher priority would be assigned to such a decision, had it involved a change to the drug formulary.

It was not surprising that most of the respondents perceived decisions involving the implementation of policies from external governing bodies (in the case of Scenario 2 – the state Health Department) to be decisions which were important and generally of high priority. It was possible that hospital protocols needed to quickly and effectively comply with these recommendations as it could possibly be a risk management issue for the institution.

Whilst most respondents perceived the decision described in Scenario 3 (review of in-house guidelines) to be important, many respondents did not assign this decision to be of high priority for implementation. Most respondents perceived this to be a decision relating to “ensuring of evidence-based medicine within the institution”. The review of guidelines could be a resource-intensive process. Often, experts (eg specialist doctors, nurses and pharmacists) needed to be consulted in the development of new guidelines. The implementation of new guidelines may necessitate educational programs in order to result in practice change.(122)

In Scenario 4, a situation related to high cost drugs was presented. The majority of the respondents in this study were of the opinion that this decision “relates to cost”. Interestingly, these respondents also considered this decision to be one of high priority for implementation. Most of the DTCs in Australia function within the capped budget of the public hospital system.(195) Hence, when a situation such as that

described in Scenario 4 arises, it was not surprising that stakeholders perceive this to be an important DTC decision with a high priority for implementation.

In Scenario 5, “ensuring patient safety” was clearly the primary domain selected by almost all of the respondents in this survey. Most respondents also believed that this decision should be assigned a high priority to the implementation of this decision. In our national survey of DTCs in Australia (Chapter 5), stakeholders self-identified their DTCs’ principal functions to be ensuring patient safety (83%), promoting evidence based medicine (74%), formulary management (68%), governing clinical practice (52%) and acting as financial gatekeepers (42%). Stakeholders’ responses to this scenario reinforce the notion that patients should continue to be the focus of DTC activities.(4)

In general, many respondents agreed that the primary domain for each of the decisions detailed in the scenarios in the survey. There were one (sometimes two) predominant primary domain(s) identified. However, there did not seem to be consistent agreement between the assignment of importance or of priority.(Table 7.2)

In considering the ways that stakeholders view the importance and priority of these DTC decisions, it seemed that stakeholders generally regarded decisions posing immediate consequences to patients and costs to be those of higher importance and higher priority. (Tables 7.3) When stakeholders selected the primary domain of “ensures the practice of evidence-based medicine within the institution”, it appeared that most perceive it to be of medium importance and medium priority for

implementation. For these three primary domains of DTC decisions, the results of this study show that level of importance is positively correlated to priority assignment. However, for the domain “ensures practice is according to legislative requirements”, there was no relationship between importance and priority assignment.

It is possible that the experience of individuals based on the DTCs they have been involved with may have influenced their perception of which decisions are more important, and should be assigned higher priority. The literature supports the notion that past experiences may have an influence on one’s perceptions, attitudes, and behaviour.(196, 197) This finding also supports the literature on the decision making.(151)

Decisions made within the DTCs may be complex, because of the influences from organisational and environmental factors.(84) The process of decision making varies from committee to committee as many aspects (including non-biomedical factors) may come into play. It is important to recognize the importance of social factors associated with decision making. Routines and traditions which constitute the “social norm”(80, 89) within specific committees and organisations may also have an influence on stakeholders’ perceptions of importance and priority of a DTC decision.

Given that available resources can only be allocated to the implementation of *some*, but not all, DTC decisions. It would be recommended that individual DTCs should discuss and determine (at meetings) which decisions made were considered

important to their institution, and how available resources could be allocated to those decisions considered highest priority.

Overall, the results of this study did not consistently show strong correlations between the levels of importance of a DTC decision and priority assignment. However, in general, stakeholders seemed to assign a higher priority to those decisions which they consider to be more important. There were a small number of respondents in this survey who assigned almost all the decisions to be of high priority for implementation. Perhaps these respondents took the view of one of the participants of our previous survey (Chapter 6), that all DTC decisions should be given high priority for implementation.

An important finding in this piece of work is that there is a range of views regarding "importance" and prioritisation for implementation. This is a surprising and interesting finding. We have acknowledged the social and environmental factors which may contribute to this. Although prioritising for action and resource allocation has been an approach applied in health care decisions, prioritising for implementation of DTC decisions may not occur if there is no reproducible "method" for assigning priority which would be widely applicable to all DTCs and stakeholders.

Perhaps, future research in this area could involve the use of qualitative (eg focus groups, interviews) and quantitative methodologies (eg factorial vignette surveys(198, 199)) to ascertain the impact of other possible factors (other than

primary domain of decisions) contributing to stakeholders' understanding and perceptions of importance and decision making regarding prioritisation.

8. Summary and future directions

DTCs are considered to be advocates of rational drug use within the hospital setting. (63, 70) The WHO also recommends that DTCs play a significant role in the prevention and management of drug safety problems.(4) The fundamental assumption in the conduct of this research is that DTC functions lead to improved quality use of medicines within hospitals, and better patient outcomes. It might be assumed that augmenting DTC performance may lead to gains in patient outcomes. The work presented in this thesis has explored the under-researched area of drug committee performance.

There are several studies in the literature regarding the monitoring and evaluation of DTC performance.(58, 74, 95) However, there has been insufficient work and emphasis on what could be done to improve DTC performance. The quality and effectiveness of DTCs should be subject to critical evaluation given the significance of their responsibilities.(200)

The research reported in this thesis documents the current challenges facing DTCs, and has investigated ways in which DTC performance might be improved. Principles of quality use of medicines, and the literature on DTCs provided the framework for this research.

Although reviews of Australian DTCs have been conducted previously, these studies focussed on structure, roles and functions.(73, 74, 85) Some of these studies have elucidated some of the problems facing DTCs, but none have researched practical approaches to overcoming those problems. Further, our review of DTC research from other countries also does not provide sufficient answers to the question of how DTC performance could be improved.(58, 60, 64, 65, 67, 75, 83, 88, 101) The national survey reported in Chapter 4 provides an up-to-date snapshot of the structure, roles and functions of DTCs in Australia. This was important baseline information to help us understand Australian DTCs for our subsequent studies. These findings reinforce the evidence in the literature about the structure, roles, functions and importantly, expectations of DTCs. Our research adds perspective to this picture of DTCs in Australia as it also seeks to identify the types of quality improvement initiatives conducted by DTCs, as well as perceived barriers to effectiveness facing DTCs.

This research shows that stakeholders continue to recognise DTCs as drug use experts to promote rational drug use in the public health system. Another important finding was that, DTCs are no longer responsible *only* for managing hospital drug formularies. They are increasingly being called upon to make important decisions relating to cost, safety and risk management. This may have important implications on the structure of DTCs. It is possible that future DTC membership may require the expertise of economists, ethicists and lawyers. Committee structure and expertise influences how decisions are made as well as the authority and credibility of those decisions.(58, 84, 93)

We found that membership of DTCs in Australia has also evolved. Weekes et al found that few DTCs included representatives from the local community (eg general practitioners, community pharmacists and consumer-advocates).(74) We found that 21% of Australian DTCs now included general practitioners as members. However, only five percent included a community pharmacist, and two percent included consumer advocates.

Consistent with international recommendations,(17) “patient representation” should be included in the membership of Australian DTCs. The quest to “find the consumer’s voice” is important as it reflects a key principle of the QUM movement.(173) Consumer involvement in decisions about health care is high on many health policy agendas.(201) However, we found no evidence for strategies to support consumer-patients on DTCs.(81) As a result, their roles have not yet been clearly defined.(202) It is anticipated that a clearer definition of this role and strategies to increase consumer-advocates may add value to the decisions made by DTCs.

Quality improvement in health services is important.(44) Performance indicators for DTCs have been developed.(84, 117) These field-tested indicators stand as an important tool for DTCs to continually strive for improvement. They also provide DTCs with an opportunity for self-reflection as they are useful screening mechanisms which could potentially detect problems in quality. However, our research shows that DTCs do not routinely utilise such a tool.

We sought to identify the challenges faced by DTCs. A consistent finding in this thesis was that a perceived lack of resources posed a significant barrier for DTCs. Lack of resources also seemed to be a barrier for decision and policy implementation. There was little evidence of routine and effective follow-up on the outcomes of DTC decisions. As a result, it was not known if DTC decisions were implemented appropriately, or if at all. The effectiveness of strategies used to implement DTC decisions and policies also could not be ascertained.

This work also explored practical means to improve DTC performance. It was reported that DTC decisions and policies currently are being implemented in an *ad hoc* manner, and, as a result, implementation may be incomplete and ineffective. An implication of this was that important policies and decisions were not being realised in day-to-day practice. In keeping with stakeholder suggestions, our research investigated the notion of prioritising DTC decisions and policies for implementation. This was to explore the option that allocation scarce resources could be directed to decisions and policies considered most important.

In this study the identification of primary domains or criteria of DTC decisions by stakeholders (eg relating to patient safety, relating to cost) were explored. It was found that stakeholders were generally in agreement as to what the primary domains of DTC decisions were. The results presented in Chapter 7 of this thesis showed that there was concordance amongst stakeholders with regard to the primary domains of decisions. However, it was discovered that only those DTC decisions relating to the primary domains of patient safety, cost and evidence-based medicine correlated with the importance rating and priority assignment. Our results did not find the expected strong associations between “importance” and

priority assignment across all primary domains of DTC decisions. More research is required in this area.

It may be that individual experience, local needs or even the area of clinical practice (eg oncology, paediatrics, HIV) to which the decision may relate, may have an influence on which decisions and policies are given priority for implementation. The impact of other potential factors influencing importance and priority assignment was not examined in our studies. There is an opportunity for further research in this area. If the relative impact of different factors relating to the perceived importance of DTC decisions could be mapped, then an algorithm could be developed to help DTCs more objectively assign priority to their decisions.

Currently, Australian DTCs are evolving as there are many changes to the environment and context in which they function. In particular, there is discussion about the role of local/hospital-based DTCs versus Area Health or even, state-wide DTCs. In our opinion, the issues surrounding policy implementation are unlikely to be solved by having state-wide, or even area-based, DTCs. However, as it is expected decision-making at the Area Health or state level will have implications on policy implementation at an institutional level, we feel that the lessons learnt from the work in this thesis could be applied, not only to institutional, but also area or state-based DTCs.

The issues of ownership and social marketing during policy development stages will affect all policy implementation.(203, 204) Stakeholder opinions and consultation from opinion leaders (from relevant departments and hospitals) need be sought if

developed policies are to be successfully adopted. Also, DTCs need to ensure that there is accountability so that there is continuity from policy development through to implementation. It is only then, that policies could be realised in day-to-day practice.

The audit described in Chapter 5 showed that some intervention strategies are currently being used to implement DTC decisions. However, in the review of the literature of effective intervention strategies, there seemed to be more questions than answers about the relative effectiveness of various implementation strategies. An opportunity for more research on this matter is clearly identified within the organisational setting, where relatively little has been done to evaluate the effectiveness of implementation strategies. A model for future work could also include an investigation into appropriate ways in which prioritised decisions could be implemented.

The studies presented in this thesis provide useful insights to performance improvement for DTCs in Australia. Because the challenges facing DTCs in other countries are likely to be similar, these findings could be applied more widely.

Ultimately, the improvement of patient health should be the focus and measurable result of DTC activities. If the investment of time and effort into DTC decisions are not providing appropriate “returns” in health outcomes because of ineffective and inadequate implementation, then a reassessment of organisational priorities is warranted. This inadequacy is not just a matter of resources. It lies in understanding how to implement policy and influence clinical practice. The core issue remains that

health care should aim to reproduce the high standards of safety and cutting-edge practice demonstrated in other high-risk industries.(205)

Research on ways to improve DTC performance is still in its infancy. However, in spite of limited resources, DTCs should not passively accept the *status quo*, as this may have an impact on health outcomes and Quality Use of Medicines. To sit and wait would be “a prescription for inaction and an abdication of responsibility”.(205) The work detailed in this thesis may be a start in bridging the gap between policy and practice.

List of appendices

Appendix 3.1

Questionnaire used in national DTC survey

Survey no:-
Form no:-

Drug and Therapeutics Committee (DTC) questionnaire

1. Does your hospital have a Drug and Therapeutics Committee (DTC)?
   Yes ❑ No ❑
   If no, then please return this questionnaire using the reply-paid envelope. Thank you for your time.

2. Are these indicators being used in your hospital? *(tick where applicable)*

Name/Title of indicator set	In use	Not in use	Don't know if in use
NSWTAG Indicators for Drug Use in hospitals			
NSWTAG Indicators for Drug and Therapeutics Committees (DTCs)			
ACHS Drug Indicators			

a) Are you aware of other drug use/DTC indicators in use in your hospital?
   Yes ❑ No ❑
   Please list these other indicators/sets.
   1. _____
   2. _____
   3. _____

b) If no indicators are used, what are the barriers preventing their use?
   (more than one option can be chosen)
   Lack of pharmacy staff ❑ Lack of time ❑
   Lack of financial resources ❑ Indicators too hard to understand ❑
   Indicators don't apply ❑ Should be collected by Quality Improvement (QI) unit ❑
   Other reasons ❑_____
   _____

3. Who actually collects DTC indicator data? *(more than one option can be chosen)*
   Indicator data not collected ❑ **(go to Question 5)**
   Chairperson of DTC ❑ Secretary of DTC ❑
   Other member of DTC ❑ QI unit ❑
   Director of Pharmacy ❑ Pharmacy student/graduate/trainee ❑
   Pharmacist ❑
   Other: ❑_____
   _____

4. If DTC indicator data is collected, what is it being used for? *(tick where applicable)*

Name/Title of indicator set	For accreditation (ACHS)	Feedback to:				Other reasons for collecting data
		DTC	Heads of Dept	QI Unit	Hosp/area health services	
NSWTAG Indicators for Drug Use in hospitals						
NSWTAG Indicators for Drug and Therapeutics Committees (DTCs)						
ACHS Drug Indicators						

5. Please attach a copy of the DTC's terms of reference.

6. In your opinion, what is the principal function of the DTC in your hospital?
(more than one option can be chosen)

Act as financial gatekeepers ❑ Develop and maintain Drug Formularies ❑
Promote evidence-based medicine ❑ Govern clinical practice ❑
Ensure patient safety ❑
Other: ❑ _____

_____

a) Ideally, what should the principal function be?

_____

_____

_____

7. In your opinion does the DTC in your hospital get organizational support?
None ❑ Very little ❑ Quite a bit ❑ A lot ❑

a) If receiving organizational support, what degree of organizational support has your DTC been getting in the following areas?
(Circle the corresponding number- 0=no support; 10=high level of support))

- Financial - budget line to support DTC's activities
0 1 2 3 4 5 6 7 8 9 10
Comments: _____

_____

- Financial - other (e.g. funds for research)
0 1 2 3 4 5 6 7 8 9 10
Comments: _____

_____

- Allocated staff support (e.g. secondment to or from QI unit)
0 1 2 3 4 5 6 7 8 9 10
Comments: _____

_____

- Allocated administrative support (e.g. secretarial help)
0 1 2 3 4 5 6 7 8 9 10
Comments: _____

_____

- Other *(please state)* : _____
0 1 2 3 4 5 6 7 8 9 10
Comments: _____

_____

8. What is the representation on your hospital's DTC? *(tick all that are applicable)*

Director of Pharmacy ❑ Clinical Pharmacologist ❑
Consumer representative ❑ Pharmaceutical industry representative ❑
Pharmacists ❑ *How many pharmacists?* ____
Community representatives ❑ *Who are they? (e.g. GP, community pharmacist)* _____

_____

Medical officers ❑ *How many medical officers?* _____

*List the specialist units represented?*_____

Other DTC member(s): ❑_____

9. In your opinion, what is the extent of your DTC's influence on prescribers' practices?
(Circle the corresponding number - 0=no influence; 10=high influence)

0 1 2 3 4 5 6 7 8 9 10

10. In your opinion, to what extent does the DTC achieve its principal function?
(Circle the corresponding number - 0=does not achieve at all; 10=acheives all goals)

0 1 2 3 4 5 6 7 8 9 10

a) What reasons may contribute to the DTC not fully achieving it's principal function?
(more than one option can be chosen)

Lack of time ❑ Lack of financial resources ❑
Lack of staff ❑ Lack of data ❑
Lack of administrative support ❑
Other reasons: ❑_____

11. Do you have suggestions to better describe the processes, impacts and outcomes of the DTC in your hospital?

12. How could the current available indicators be modified to make them easier to use?
*(more than one option can be chosen, please comment on options marked with *)*

More allocated staff ❑ Needs another system (e.g. electronic) ❑
Needs to be rephrased ❑ Needs to be made quicker to use ❑
Needs to be easier to understand ❑ Needs to be more relevant* ❑
Doesn't matter, we won't be using them*❑ Other* ❑
*Comments:_____

13. If you would like the results of this survey reported to you, please provide an address/fax no:

Thank you for your time and participation.

Appendix 3.2

Invitation to participate in DTC survey

The University of Sydney

ST VINCENT'S HOSPITAL SYDNEY LIMITED

A.C.N. 054 038 872

UNDER THE CARE OF THE SISTERS OF CHARITY

<Title> <First_name> <Surname>
<Position>
<Institution>
<Address_1>
<Address_2> <State> <Postcode>

24 September 2001

Dear <Title> <Surname>,

We are investigating **the role of hospital Drug and Therapeutics Committees in the provision of quality use of medicines (QUM)**. We would really appreciate it if you could take 5-10 minutes of your time to fill in this questionnaire. Thank you for considering this request.

Drug and Therapeutics Committees optimize use of medicines so that health outcomes will be improved. Given the importance of Drug and Therapeutics Committees, there is an urgent need to optimize performance, especially in the current "resource poor" environment.

Process, impact and outcomes indicators of Drug and Therapeutics Committee performance are available. However, there seem to be barriers in utilising them. We want to help rectify this situation.

Your opinions and views in this survey will help us to:

- Determine which quality improvement and quality assurance indicators are being used
- Understand what the indicator data are being used for
- Document barriers to indicator use
- Investigate the current functions of Drug and Therapeutics Committees
- Record resources available (if any) to aid in the operations of Drug and Therapeutics Committees

This questionnaire will be sent to all types of hospitals across Australia anticipated to have a Drug and Therapeutics Committee. Completed questionnaires can be returned **using the reply-paid envelope enclosed** or by **fax to 02-83822686** before **05/10/2001 (Friday)**. If we do not hear from you, we will contact you by phone to check that you have received the questionnaire. You can also complete the questionnaire over the phone **(02-83822352)** with the researcher if it is convenient for you to do so.

The information provided by you in this survey will be kept confidential. If you would be interested in the results of this survey, please include your fax number or mailing address at the end of the questionnaire. Thank you once again in advance for your invaluable participation. Your opinions and views are highly appreciated.

Yours sincerely,

Ee Lyn TAN BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Member of Drug and Therapeutics Committee, St Vincent's Hospital, Sydney
Any questions or queries regarding this survey can be directed to Prof Jo-anne Brien (☎02-83822605) or Ms Ee Lyn Tan (☎02-83822352).

Appendix 4.1

Data collection form used in review of DTC minutes

Audit of DTC minutes: Interventions

Issue discussed:_____

Interventions decided by DTC:

Strategies	Planned	Done
Audit		
CE		
To doctors		
Medical grand rounds		
Unknown/unspecified		
Published/printed materials		
Letters		
Notices		
Bulletins		
For information		
For behaviour change		
Other:		
Executive bulletins		
For information		
For behaviour change		
Other:		
Reports		
Policies		
Memoranda		
Payslip attachments		
Other/unknown		
Academic detailing		
Opinion leader		
Patient mediated information		
Marketing		
Referred		
NSW TAG		
Medication Incidents Committee		
Patient Safety Committee		
Clinical Practice Committee		
Other individual for expert advice		
Other/not stated		

Appendix 4.2

Details of issues discussed at DTC from January 2001 to December 2002

Key: 1=Medication Incidents; 2=New Drugs; 3=IPUs; 4=Policy

Cat.	Issues	Date documented in minutes	Decision(s)/ Intervention strategy(ies)	Follow-up
4	Need policy for pethidine use	02/01	Form group to draft pethidine guidelines	
		02/01	Plan for guidelines to be drafted and circulated to NSW TAG	
		02/01	Plan for guidelines to be circulated via Executive Bulletin	
		03/01		Working group convened
		04/01 06/01		Guidelines to ED and Anaes for comment
		09/01	Plan for final draft of policy to be written	
		11/01		Policy written and ready for release
		11/01	Educational campaign for new interns, residents and registrars planned for Jan 02	
2	New drugs: Chlorhexidine patch	02/01	Seek consultation from Microbiologists	
		03/01	Campus group rationalising antiseptic formulations to comment	
		04/01		Rationalisation as new agenda item (see below)
	Pharmacy Department needs help handling offers of high cost drugs from drug companies	02/01	Deals tabled for consideration by DTC or a smaller group of DTC members	
		02/01	Risk management issue to be raised with SESAHS Risk Management Director	
	Difficulty obtaining non-PBS drugs for Palliative Care patients	02/01	Matter to be raised with NSWTAG	
3	IPU: Aerolised Cyclosporin A	02/01	More evidence required, formal request needed for Cardiac Transplant pts	
3	IPU: MS Contin for patient	02/01	Approved	
		02/01	Letter to be sent to treating Dr.	
3	IPU: Infliximab for patient with Behcet's Disease	02/01	Approved	
		02/01	Close monitoring required, if no defined effects supply to cease	
4	Cytotoxic Medication Management Policy	03/01	NSWTAG Subcommittee to prepare discussion paper	
		04/01	Draft guidelines to be circulated for comment	
		04/01	Draft guidelines to include harzadous drugs	

		06/01 07/01	Guidelines planned for expert review	
		06/01	Interim guidelines prepared and endorsed by DTC used re: handling of cytotoxics and hazardous substances whilst awaiting NSWTAG paper to be finalised	
		07/01	NSWTAG current opinion document to be forwarded to Clinical Practice Committee (CPC)	
		08/01		Draft guidelines to be circulated to DTC members
	Multicentre DUE of A/B treatment of LRTI in ED	03/01	SVH to participate in DUE	
		07/01		DUE almost completed
		07/01	Data to be submitted to co-ordinators	
	Multicentre PPI DUE	03/01	SVH will participate	
		07/01		DUE completed, report being prepared
		08/01		Report presented at DTC
	Increasing patient demand for complementary medicines. Healthcare practitioners need to know about them	03/01	Therapeutic update sessions to be held	
		03/01	Complementary meds to be topic in DTC bulletin	
		12/02		Complementary meds topic in DTC bulletin
2	Formulation changes: Atrovent Nebules – change in concentration	03/01	Memo noted	
2	Formulation changes: Go Kit Plus to substitute Durolax-X-Pack	03/01	Memo noted	
	There seems to be increase in tobramycin use	03/01	Review of Tobramycin use over last 2 months needed	
1	Medication incidents: Patients returning from theatre with unlabelled IV infusions	03/01		MI Committee to detail these events to DTC
		04/01	Planned meeting with Anaesthetists to develop action plan	
		04/01	Meeting with Anaesthetists to develop action plan	
		06/01		Met with Anaes to develop action plan
		06/01	Anaesthetists and Drs to be "informed" re documentation required: • Double checking (Dr x2 OR Dr+RN) • IV meds to be charted on Anaes charts	
		06/01	Need to monitor process in ITU regularly	

		12/01	Medical Students' project to audit the appropriateness of labelling infusion bags post surgery – none properly labelled	
		12/01	Additive label needs to be improved	
		12/01	Another audit planned when new labels used	
		01/02	Anaesthetists to be informed regarding need for double checking of all infusions	
		01/02		Development of new additive label referred to CPC
		03/02	Recommend educational package re: correct labelling procedures for IV solutions to be prepared and "implemented"	
		03/02	Suggested snapshot audit of labelling practice of IV infusions by Clinical Practice Committee to obtain baseline	
		03/02	Plan audit post educational campaign	
		03/02	Recommend clarification of EN role	
4	Hydromorphone guidelines prepared by SVH	04/01	Reviewed and signed off	
2	New drugs: Diclofenac PR	03/01	Added to formulary	
		03/01	Need to rationalise NSAIDS on formulary	
2	New Drugs: Glimepiride (Amaryl)	03/01	Added to formulary	
	Health Care Complaints Commission Report & TAG recommendations following Canterbury & Dubbo incidents	03/01 06/01	Convene subcommittee to follow-up recommendations for SVH campus	
		06/01		SVH response presented to SESAHS Audit team & SVH CEO – awaiting feedback
	SVH – Australian importer of Thalidomide. ?? Risk management	03/01	Area Health Service advice re: risk management to be sought	
		04/01	SVH insurer needs to be contacted re: coverage	
		06/01		Insurance cover assured
		06/01	Recommend development of form for distribution of Thalidomide ("Indemnity & Responsibility agreement")	
	Antiseptic products need to be rationalised	04/01	Products to be removed after current supplies ceased listed	
		04/01	Chlorhexidine 0.5% in 70% alcohol tinted red to be changed to formulation tinted pink	
		04/01	Chlorhexidine 0.05% Aq 30ml to be replaced by 100ml packsize	

		06/01		Changes implemented
		06/01	Biopatch in ITU & Rec for a 3-month trial before putting on to formulary	
		07/01		Imprest lists updated
		07/01		Notification via email news
		07/01		Rationalisation completed
	TB medications and Directly observed treatments in outpatients	03/01	Charts available unsuitable, and no prescriber allocated to write up orders	
		04/01	DTC will follow-up re: • Appropriate person to write up charts/changesto outpt charts	
2	New Drugs: Gatifloxacin vs moxifloxacin	04/01	Added to formulary as restricted A/B requireing microbiology approval	
2	New Drugs: Avian Tuberculin PPD	04/01	Added to formulary for use by Chest Clinic for Diagnosis of immunosuppressed pts	
		04/01	DTC needs more info re: impact on patient management issues (eg drug use/additional investigations required)	
4	Need policy for Heparin infusion	04/01	Heparin infusion policy written and signed off by DTC following review and minor changes	
		01/02	Heparin policy revised to include dose of heparin when used with tenecteplase	
1	Medication incidents: Omitted doses a problem	06/01	4th Year Pharmacy student project to investigate problem	
		12/01		Pharmacy student project completed, report to be submitted to DTC
		03/02	Reports that further omission problems caused by problems accessing drugs after hours – to be followed-up	
2	New drugs: Tenacteplase	06/01	Added to formulary to replace r-TPA for acute MI	
		06/01	Need education campaign prior to change over	
		07/01	Alteplase still to be used for PE	
		07/01	Letter of endorsement to be sent to appropriate Drs	
		08/01		Letters to appropriate Drs written
		09/01		2 of the Drs written to endorsed change

		09/01	Education campaign planned for nursing, medical, pharmacy staff in ED, cardiac Cath lab, Acute & subacute coronary care, ACCA and CH12	
		11/01	Information sheet prepared and circulated to DTC members and MIC for comment	
		11/01	Change to tenetaplase planned for 01/03	
		11/01	Memo re: changeover from alteplase to be circulated	
		11/01	Drug company rep to be contacted to train re: prep and admin of tenectaplase	
		11/01	Pharmacist to be contacted re: education re: formulary guidelines	
		12/01		Inservices for pharmacy and ED staff organised
		01/02		Changeover taken place (see heparin policy update)
3	IPU: Recominant Factor VIIa for Haemotology pt	06/01	Approved for use	
	DUE of Low Molecular Weight Hep in elderly patients and those with renal failure at SVH	06/01	Pharmacy Graduate's project planned	
		07/01		Data collected and report pending
	DUE of COX2-I initiated in hospital and pts on COX2-I's on admission	06/01	Pharmacy Graduate's project planned	
		07/01		Data collected and report pending
2	New drugs: Mirtazapine	06/01	Added to formulary	
2	New drugs: Dysport Botulinium Toxin	06/01	Added to formulary for S100 indications only Botox still kept for non-S100 indications	
		06/01	Prescribing guidelines to be developed	
2	New drugs: Zoledronic Acid	06/01	Added to formulary for trial period of 6 months for hypercalcaemia of malignancy	
		06/01	Review of use and costs after 6 months to decide if it should be added permanently to formulary	
	Pioglitazone – PBS listing not obtained yet	06/01	Similar arrangement to rosiglitazone set up with drug company to supply free stock to patients until PBS listed	
	2 options of purchase deals for pamidronate to be considered	06/01	Purchase of pamidronate from Novartis (as per option 2) from July 2001 to June 2002	
2	New drugs: Tramadol	07/01	Added to formulary: • for use in theatre for the elderly, obese and those at risk of respiratory depression	

		08/01	Added to formulary: • for use in ITU for pts in whom narcotics cause respiratory distress	
		07/01 09/01	Formulary gudielines need to be written and circulated via DTC bulletin	
		11/01		Draft guidelines circulated for discussion
		11/01		Draft guidelines circulated to other local opinion leaders
		12/01	Development of guidelines (incorporating views of local opinion leaders) - Use of NSWTAG Tramadol Position Statement to ammend SVH guidelines	
		01/02	NSWTAG position statement reviewed. Confirmed SVH guidelines endorsed are in-line with NSWTAG statement	
		05/02	Guidelines to be circulated via DTC bulletin	
		05/02		1 week DUE of Tramadol use showed increased use since last snapshot (together with consistent use of Panadeine Forte)
	Terms of reference 2001 need to be updated	07/01	Circulate to members with meeting papers	
		07/01	Circulate to members via email	
		08/01		T of R ratified and attached to papers
		09/01		Final draft ratified and endorse
3	IPU request: Mycophenolate for pt with pyoderma gangrenosum	07/01	Approved for 3 month trial	
	Process for supply and labelling of insulin in the diabetes day centre outlined	07/01	Processes ratified and documented	
	ADR survey re: hospital reporting systems	08/01	Student project to start soon	
	DUE – use of A/B prophylaxis in vascular surgery	08/01	Student project to start soon	
	PPIs on formulary need to be revisited	09/01	Not the same drug on formulary for IV (pantoprazole) and oral (omeprazole) PPI	
		09/01	Plan to contact gastroenterologist re: opinion of which PPI to be on formulary	
		09/01	Need to get PPI costing from suppliers	
		07/02		Omeprazole selected for IV and oral use
		09/02	Esomeprozole may be more cost effective than omeprazole. ??need to review PPIs again??	
1	Medication incidents: Pholcodine Linctus administered via central line	08/01	Medication Incidents Committee to educate staff re: administration of drugs	

		08/01	Planned drug bulletin on administration of drugs	
		08/01	Planned memorandum on preferred administration requirements of oral liquids	
		08/01	SVH policy re: admin of oral liquids need to be revisited	
		09/01	Memorandum to all wards needed re: • all oral liquids to be administered immediately after preparation • oral liquids administered via medicine cup or 30mL syringe • S8 small volume oral liquids need double checking and immediate administration	
		12/01	Purchase of orange-coloured syringes labelled "for oral use" (initial trial on 2 wards)	
1	Medication incidents: Blood not signed for	08/01	Need education program re: administration of blood products	
		08/01 09/01	Need MI Committee's input on how to educate staff	
		09/01		Clinical Practice Committee working with Dr Dodds re: procedures for blood products
1	Medication incidents: Preparation for abdominal CT given to wrong patient	08/01	Advice needed on: • prevention future incidents • labelling of scanning fluid outside radiology • processes to record administration of scanning fluids	
2	New drugs: Biodone Forte	08/01	Added to formluary	
		08/01	Recommendation that before patients prescribed methadone, need to check if they had been on methadone syrup	
1	Medication incidents: Patients from theatres returning to wards with unflushed IV lines	08/01	Memo to be sent to theatre staff to flush pts' lines before returning to wards	
3	IPU request: Infliximab for Behcet's Disease (pt HC)	08/01	Request approved for maintenance, not reinduction	
		08/01	Strict monitoring required & 3-monthly feedback to DTC required	
	Allergy Alert systems review following memo from NSW Health	08/01	Follow-up RNSH system of allergy/ADR recording	

		09/01	Seprate allergy sheet not to be implemented	
		09/01	Allerdy stickers on every page not practical	
		09/01	Work with NSWTAG to improve ADE reporting (includes allergy reporting)	
		09/01		SVH allergy alert system summary to be prepared for B Kotze
2	New drugs: Rofecoxib	09/01	Added to formulary	
4	NSW Health Circular 2001/64: Policy of the Handling of Medications in NSW Public Hospitals	09/01	Plan to set up working groups to review and update current SVH policies	
		11/01	Clinical Practice Committee to set up group review and update policies to ensure compliance with circular	
		11/01	Clinical Practice Committee to set up schedule for review of other policies on medication handling	
		11/01	Policies to be sent to DTC for sign off when ready	
		11/01	Monthly progress report required until full implementation	
4	Medical gasses are listed as S4 in Poisons Reg	09/01	Current SVH practice needs to be followed-up to ensure compliance with regulations	
		11/01		Group set up to develop policies on handling medical gasses
1	Medication Incidents (and errors) need to be communicated to prescribers	08/01	MI to be a topic in DTC bulletin	
		11/01		DTC bulletin on MI's produced
		11/01	DTC bulletin on MI's to be placed on DTC website	
		11/01 04/02	Education summary attached to doctors' pay sheet each month to increase awareness	
		04/02	Intern teaching sessions to educate doctors about prescribing issues which have caused problems	
1	Medication Incidents: Oxycontin & MS Contin looking similar	11/01	Letter to be written Pharmacy Board, Manufacturer, TGA and ADRAC to raise concern and highlight potential of ADE	
		04/02		Drug company seeking SVH DTC comments on proposed changes to tablet appearance
2	New drugs: Erythropoietin pre-filled syringes (new strength)	11/01	6000 Units and 8000 Units added to formulary	
2	New drugs:	11/01	Added to formulary as S100 benefit only	

	Darbepoetin α pre-filled syringes	11/01	?? need for both erythropoietin and darbepoetin on formulary?? E Savdie opinion to be sought	
2	New drugs: Oxycodone	11/01	Added to formulary for SHH use only	
2	New drugs: Methotrimeprazine	11/01	Added to formulary for SHH use only	
		11/01	Prescribing guidelines to be developed	
		11/01	DUE to be conducted in 6 months (and update guidelines if necessary)	
2	New drugs: Basiliximab	11/02 01/02	More information needed before addition to formulary	
		11/02	Separate application for induction therapy for transplant needed	
		03/02		Application withdrawn
3	IPU: ↑ dose of MS Contin for patient ND	11/01	Approved increase in dose	
	Abbott's proposal for supply of vaporisers	11/01	Proposal accepted for 1 year, revisit decision after time period	
4	IPU ratification process/SAS drug use procedures some have bypassed both DTC and Ethics Committee	11/01 12/01	DTC/Ethics subgroup need to be formed to develop policies/guidelines	
		12/01	Subgroup to develop consent form for all patients on clinical trails/EAP	
		01/02		IPU subcommittee/High Cost Drugs Committee set up
		01/02		Executive bulletin re: use of developed consent form for all patients on clinical trials and EAPs receiving free drugs from drug companies
		06/02		High Cost Drug committee has prepared memo (endorsed by CEO) outlining patient eligibility criteria and procedures for obtaining high cost drugs
		06/02		Memo circulated as Executive Bulletin
		06/02	More information re: moral/ethical issues to be prepared	
		06/02	Draft consent form for SAS/EAP drugs for comments	
		07/02		Final draft approved to be sent to forms committee
		09/02		Forms approved by forms committee. Now bring printed

	Imatinib (Glivec) Expanded Access Programme (EAP) for CML pts	11/01	Need to develop guidelines with assistance from Haematologists for treatment of CML patients at SVH	
		11/01	From now on, enrolment of any SVH patient in any EAP or Clinical Trial needs endorsement by Ethics Committee	
		11/01	All consent forms given to SVH patients must go through Ethics Committee	
		11/01	Development of policy (with help from NSWTAG) for patient enrolment into EAPs and Clinical Trials	
		11/01	Letter to SESAHS to seek response to this issue Presentation at Hospital Board re: Strategic Planning for High Cost Drugs	
		11/01	Working Party to be formed to action items above	
		11/01	2nd working party needed to develop guidelines for handling clinical trials/EAP for SVH pts referred to other hospitals	
		11/01	2nd Working party to develop draft consent form with paragraph specifying what happens to supply of drugs at the end of trial/EAP (send to forms committee for approval and printing)	
		11/01	Treatment should not be discontinued	
		11/01	No new non-PBS eligible pts to start Glivec	
		11/01	Drug company to be asked to supply info submitted to PBAC	
		11/01	Need to find $$$ to support this situation	
		11/01	Need to decide what to tell pts	
		12/01	Group formed to oversee use and expenditure of Glivec (progress report to DTC every 3 months)	
		12/01	Letter to be sent to drug company requesting continuation of free supply of Glivec to these CML pts	
		01/02		Form informing patients re: supply of drug post trials/EAP periods approved and used
		01/02		Drug company responded that free supply of drug will not continue
		01/02	DTC member to meet with drug company to negotiate deals for supply of drug	

2	New drugs: Movicol (Macrogol 3350)	12/01	Added to formulary for Palliative Care	
		12/01	Protocol for use needs to be developed	
		12/01	Education program needs to be organised for staff	
2	New drugs: Valaciclovir for patient with post tx lymphoproliferative disease	12/01	Not sufficient evidence for this indication	
		12/01	Pharmacy to produce stock movement report of number of patients on valaciclovir post transplant	
		12/01	For uncontrolled EBV pts, IPUs could be submitted to DTC	
2 4	New drugs: Buprenorphine	12/01	Development of policies and procedures for use to comply with NSW Health Circular 2001/84 (NSW Policy for use of Buprenorphine in the treatment of opoid dependence)	
		12/01 03/02	Policy to be developed in line with NSW Health circular 2001/84	
		01/02	Policy to include indications, practical guidelines for use (eg after hours arrangements for prescribing/accessing supply, prescribing of analgesia in pts requiring unscheduled surgery)	
		03/02	Policies to be made accessible to medical, nursing and pharmacy	
		03/02	Policies and guidelines re: prescribing to be posted on DTC website and Pharmacy website	
		03/02		Acute Pain Team and Drug and Alcohol Team to manage inpatients requiring buprenorphine
		03/02		After hours access to be similar to that of methadone
		03/02		Elective surgery patients to change to methadone 1 week before planned admission
		03/02	Added to formulary Use limited to Drug and Alcohol pts	
3	IPU: Infliximab for pt BO with RA unresponsive to strandard drug therapy	12/01	Approved for 3 months – symptoms monitored and report to DTC before approval for ongoing therapy	
	Indications for pamidronate and mycophenolate have changed considerably	01/02	Current guidelines need to be reviewed (involve local opinion leaders in development of new guidelines)	
		01/02	DUEs planned	

		03/02		Lit review for pamidronate DUE done
		04/02		DUE pamidronate to start 05/02
		05/02		DUE pamidronate started
		06/02	Guidelines to be updated and reviewed according to results of pamidronate DUE	
		09/02		DUE of Non-S100 pamidronate use completed
		09/02	Results to be circulated to prescribers	
		10/02	Guidelines to be updated	
1	Medication incidents: S4D & S8 errors	01/02	Audits to focus on ensuring current patient receives correct dose of correct narcotic	
1	Medication incidents: IV contrast administration	01/02	Recommendation that IV contrasts administered be recorded on drug chart	
		01/02	Referred to CPC	
		04/02		CPC recommends: • IV/oral contrast to be prescribed in med chart (stat section)
		05/02		Letter written to support CPC recommendations. Letter to be circulated to Med Imaging Dept, MI Committee
		07/02		Letter sent to CPC, Med Imaging Dept, and MI Committee
		09/02	Legislation needed to be provided to prescriber indicating necessity of writing up contrasts	
		09/02 10/02	Letter to be written to prescriber addressing pt safety issues and regulatory requirements and to be forwarded to prescriber	
		12/02	Letter to Christ Jones (cc Kerry Stubbs) re: request to work out practical solution to recording and administration of contrast media	
1	Reporting of MI's	01/02	Could it be reported as drug class and outcomes? Referred to MI Committee	
		03/02		MI Committee recommends: • Space for outcomes section to be incorporated • Better to report by drug than by drug class
		03/02		Reporting format changed

1	Medication incidents: Unsure if patients are fully informed (& debriefed) when incidents (or ADRs) occur	01/02	Position statement to be developed based on the National Disclosure Act and Health Care Complaints Committee Statement	
		01/02	Refer to patient safety committee	
		01/02	Follow-up with Gosford Hosp re: their process of informing pts who have experienced ADR's	
		01/02	Need MI Committee input	
2	New drugs: Olanzapine IM	01/02	Added to formulary for use in psychiatry only	
2	New drugs: Candesartan/Hydrochlorothiazide 16/12.5mg	01/02	Added to formulary	
2	New drugs: Perindopril/Indapamide 4/1.25 mg	01/02	Added to formulary	
2	New drugs: Enalapril/hydrochlorothiazide 20/6mg	01/02	Added to formulary	
2	New drugs: Amprenavir	01/02	Added to formulary for pts who have failed/experienced toxicity with other protease inhibitors	
3	IPU: Infliximab for active inflammatory psoriatic arthritis	01/02	Approved for 3 months, report of therapy to DTC before approval of any subsequent treatment	
	Consumers concerned that untrained medical personnel are administering medications in nursing homes	01/02	To organise brief presentation on Medication Administration in Nursing Homes - Use of local opinion leader (JB)	
4	Surgical Management of Primary Dental Care Patients on Warfarin	01/02	Guidelines sent to NSWTAG & haematologists for review	
		03/02		Haematologists suggest shortened version incorporating SVH indications and INR ranges used at SVH
		03/02	Haematologists suggestions to be incorporated – final document to be placed on DTC website and Pharmacy website	
	Target Controlled Infusion Pump Delivery System in ED	01/02	Trial of target controlled infusion pump in ED	
		03/02	Anaes to meet with ED staff specialist	
		03/02	Trial protocol to be submitted to Ethics Committee	
2	New drugs: Atgam (anti-thymocyte globulin)	03/02	Transplant group interested in using Atgam instead of Basiliximab	
		03/02 04/02 05/02	Need protocol and indication for use	

1	Medication incidents: Some wards have very low reporting rates	01/02	Mechanism for interacting with poo reporters needed	
		03/02		Medication Incidents Committee have approached NUMs to appoint a champion to encourage wards to increase rate of reporting
1	Medication incidents: ??	03/02		Education program re: prescribing IV potassium targeted at new Drs in ITU
1	Medication incidents: Folinic Acid/Folic Acid confusion	03/02 07/02	Folinic Acid to be charted as calcium leucovorin	
		07/02	MI relating to same problem again	
		09/02	Education for staff needed	
	Use of one brand of warfarin only	03/02	Support proposal of Melb teaching Hosp Drug Usage Group: Boots produce only one brand of warfarin	
4	Drug reps paging junior doctors and giving nursing inservices without contacting Nursing Education	03/02	Need review of policies and procedures for Pharmaceutical Representatives - Policy to be disseminated at SVH, to APMA and to Pharmaceutical Companies	
		04/02		Policy amended and approved
		04/02	Appointment of SVH point of contact for registrar and JMO education sessions Appointment of SVH point of contact for Nursing Inservice Education Appointment of SVH point of contact for Pharmacy education sessions	
		04/02	Policy to be circulated via Executive Bulletin, and via points of contact to staff	
		04/02	Consultants to receive updated policy via senior medical staff mailing	
		04/02	Lunches provided by Drug companies can still continue	
		05/02		Policy and Procedures for Pharmaceutical Representatives reviewed, updated and approved
		05/02		Policy circulated as per decided
	Drug budget information	03/02	Report to DTC of top 50 drugs and drugs costing >$5000.00 per month	
		04/02		Presented

2	New drugs: Glicazide Modified Release Tablets (Glicazide 30mg HR)	04/02	Added to formulary	
2	New drugs: Fentanyl Citrate Lozenges	04/02	Added to formulary only for use in palliative care for breakthrough pain in patients using fentanyl patches or have difficulty with alternate opiate rescue analgesia at SHH	
		04/02	Need patient and staff education re: administration of lozenges, ways to overcome SEs, precautions (eg keep out of reach of children)	
3	IPU: Linezolid for patient with MRSA	04/02	Approved for supply only one month at a time Ongoing monitoring required	
3	IPU: Supply patient ND with daily supervised Kapanol	04/02	Approved for administration at Rankin Court until stable enough then transfer to Community Pharmacy for supervised dosing	
		07/02		Rankin Court no longer responsible for prescribing Kapanol for pt
	Botulinium Toxin vials are multi-dosed in EPS Clinic	04/02	Explore options of Pre-load syringes	
		04/02	Current practice not in line with NSW Health Guidelines Circular 2001/64 or TGA approved PI Assistance from NSWTAG needed to address issue	
		05/02	Botox policy need review in line with Dept of Health Circular 99/87 – Infection Control Policy	
		05/02	Guidelines to be rewritten and included in SVH Clinical Practice Manual and SVH Infection Control Manual	
		05/02	Baxter to fractionate vials for SVH use	
		07/02		Baxter unable to pre-load syringes for use
		07/02	Pharmaceutical services need to be contacted for advise	
		09/02		Pharmaceutical Services says current practice seem to be in-line with Infection Control Policy
		09/02	Current SVH policy to be updated and disseminated	
	Hospital Purchasing Agreement Proposal with GSK (for Zofran, Fortum and Timentin)	04/02	1 yr agreement to be acceptted for 07/02 to 07/03. Review at end of period	

	Lignocaine infusions for migraine on ward	04/02	pts to be monitored when receiving lignocaine infusions	
		04/02	Lignocaine blood levels to be taken after 24 hours	
		04/02	Need to set up meeting to communicate these decisions to staff affected by this change	
		04/02	Letters re: DTC decision to be sent to Dr (neurologist), NUMs, CH20 staff, CCU staff, ED – staff have opportunity to discuss the matter further with reps from DTC if required	
		07/02		Letters sent
	Supply of antiretrovirals to medicare ineligible patients in a clinical trial	04/02	Issues such as these must be considered in the trial set-up phase	
		04/02	Patients need to be told re: supply of future supplies	
		04/02	Ethical concerns re: enrolling pt in trial and then withdrawing supply need to be addressed	
	Need to increase timeliness and effectiveness of Drug Committee Bulletin	06/02	4-page bulletin every 3-4 months to be replaced with 1-2 page document produced each month after DTC meeting	
		06/02	Bulletin to be circulated via email news	
		12/02		Bulletin available on DTC website
1	Medication incidents: Incorrect amounts of heparin were placed in vascaths. The incorrect amounts were injected into patients	06/02	• Patient Safety Committee recommendations: ➢ Red plugs placed in vascath ports to block ports ➢ Warning sticker placed adjacent to ports ➢ Education sessions organised by Clinical Practice Committee to advise staff on accessing clinical practice policies and procedures (esp for policy relating to heparin in vascaths)	
	Reduce number of heparin strengths and concentrations on formulary	06/02	DUE Pharmacist to consider possibility of rationalising strengths/concentrations of heparin	

	Staff need to be aware of medication incidents	02/01	Medication Incidents Awareness Week (MIAW) to be held. Includes: • Grand Rounds presentation (video & presentations) • Competitions to spot medication/prescribing errors on chart • Inservices	
		03/01		MIAW conducted. Successful
		06/02	MIAW to be held in 07/02. Includes: • Posters • Grand rounds presentation • JMO presentations • Ward inservices	
2	New drugs: Acamprosate	06/02	Added to formulary for use by Drug and Alcohol Team	
2	New drugs: Amisulpride	06/02	Added to formulary for use by Dept of Mental Health to treat resistant Schizophrenia where 2/3 other agents have been ineffective	
2	New drugs: Caspofungin	06/02	Added to formulary as restricted agent requiring Microbiology approval	
2	New drugs: Cefuroxime	06/02	Added to formulary to replace cefaclor	
3	IPU: Valaciclovir for pt with Vaicella post lung tx	06/02	Approved	
3	IPU: Sandoglobulin for patient not eligible for Intragam	06/02	Not approved	
	Request for nurse initiated parenteral analgesia (morphine) in ED	06/02	DTC member to meet with ED staff specialist to get more details	
		07/02	Endorsed for 3 months	
		07/02	Interim report required after 3 months	
		07/02	Audit in ED at 3 months	
		11/02		3 month audit presented at DTC
		11/02	Follow-ups every 3 months from now on	
	Local Anaesthetic Wound Irrigations at SVH	06/02	DTC agree weith proposal to commence Local Anaes wound irrigations at SVH. There are more issues which need to be sorted out. But, would like anaesthetist input	
		07/02		Awaiting Anesthetist input
		11/02	More information still needed	

4	Medication guidelines for delirium	06/02 09/02	Delirium policy need to be revised in consultation with psychiatrists	
		10/02		Delirium policy updated and ready for circulation
		12/02	Policy to CPC for correction of altered data	
1	Medication Incidents: Fluids hung with no orders	07/02	MI Committee to follow-up	
	Residents would like to stagger rewriting of med charts	07/02	At this stage, no reason to change recharting practice	
1	Medication incidents: Overcoagulation of patients	07/02	Treatment of overcoagulation need to be highlighted in next DTC bulletin	
1	Medication incidents: Incorrect charting of drug by medical student not picked up by resident signing order	07/02	Issue to be raised with campus Education Committee	
		07/02	Suggest Rep from Campus Education Committee will speak to JMO's re: incident and need for more direct supervision of medical students charting drugs	
3	New drugs: Indapamide (Natrilix SR)	07/02	Added to formulary	
3	New drugs: Sirolimus	07/02	Clear guidelines for use needed, and not enough evidence for use	
		09/02	Heart and Lung Tx teams to approach drug company to undertake clinical trial	
		10/02	In the meantime, DTC to work with tx group to achieve QUM – support of 10 pts at any one time	
		11/02	Heart Lung Tx patients on sirolimus to be tracked by DUE Pharmacist	
3	New drugs: Bio-patch for CVCs	07/02	Audit comparing Bio-patch to chlorhexidine shows not statistically significant advantage More information required	
		07/02	Microbiologists needed to consult on matter	
1	Medication incidents: Errors with infusion pumps	09/02		Memo sent to NUMs to remind staff to double check when infusion rates are changed
1	Medication incidents: Errors with sliding scale insulin	09/02	Nursing Education to set up education campaign on wards	
		09/02	Article on insulin sliding scale to be in DTC bulletin	
		12/02	More reports of MI's with insulin	

		12/02	Reps from Diabetes Centre, MI Committee and DTC work together to develop strategy to minimise recurrence of insulin incidents	
1	New drugs: Reboxetine	09/02	Added to formulary for severe resistant depression or SSRI failure – restricted to psychiatrists' use	
		09/02	Review of use in 6 months	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
1	New drugs: Tramadol SR	09/02	Added to formulary for use in subacute setting for inpatients with chronic pain – restricted to specialist medical officers in rehab, pain and palliative care	
		09/02	DUE in 6 months	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
1	New Drugs: Lyclear to replace Quellada Lotion	09/02	ED and Head of Dermatology to be consulted	
		10/02		Head of Dermatology & ED supported change
		10/02	change in formulary approved	
		10/02	Change in formulary when current stock runs out	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
3	IPU: Tacrolimus for vitiligo	09/02	More evidence required	
		10/02	Not approved	
4	Guidelines needed for use of activated protein C	09/02		Draft guidelines prepared by intensivists
		09/02	To be piloted and limited to 10 pts/yr	
		09/02	Audit in 6 months	
	Role of TDM in HIV therapy	10/02	SVH usage of TDM in HIV reviewed	
1	Medication incidents: Ketamine & Morphine prescribed in combination	10/02	Should Ketamine be withdrawn from wards?	
		10/02	Refer to Pt Safety Committee	
		10/02	Anaesthetists to consult	
1	Medication incidents: Different pethidine concentrations in pumps	10/02	Pumps to be labelled with standard Pethidine concentrations used in SVH	
		10/02	Referred to Pt Safety Committee	

1	Medication incidents: Typos on computer generated discharge prescriptions	10/02	Referred to Pt Safety Committee	
1	Medication incidents: Problems with blood and stem cell administration	10/02	referred to SVH transfusion Committee	
		10/02	Referred to Pt Safety Committee	
2	New drugs: Variconazole	10/02	Added to formulary as restricted antibiotic requiring Microbiology approval	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
		12/02		Microbiology reported success in resricting use following closure of compassionate use program
2	New drugs: Dexmedetodine	10/02	Approved use of short dated supply provided free by drug company for limited groups of post-surgical patients	
		10/02 11/02	Outcomes to be reported to DTC	
		11/02	Referred to Ethics Committee	
2	New drugs: Tenofovir	10/02	Added to formulary for use in combination with other antiretrovirals for pts who have failed/experience treatment-lijmiting toxicity with current regimens	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
2	New drugs: Esomeprazole	10/02	Not approved	
		10/02	Review after State Contract for Pharmaceuticals in Jan 03	
2	New drugs; Prep Kit C	10/02	Added to formulary to be used in place of Picolax Dual Pack	
		11/02		DTC Bulletin highlighting changes in formulation. Available on Pharmacy and DTC homepages
3	IPU: Mycophenolate for psoriasis (Pt PB)	10/02	Approved for 3 months use. Outcome report to DTC for continual supply	
	Faulding deal for compounding fee for Anzatax	10/02	Not accepted	
	SAS Consent forms need to be developed	10/02	Forms need to be developed and sent to Forms Committee for approval and printing	
		11/02		Consent forms circulated

		11/02	Planned Executive Bulletin to address: • Availability • Content • Requirements of when to use (esp for EAP patients)	
		11/02	Education program needed. Targeting: Pharmacists, consultants, HIV/Rheumatology Unit Meetings, CSUs, Chairpersons of key committees (eg Ethics, Clinical Practice Research)	
1	Medication incidents: MS Contin wrong strength prescribed	11/02	Problem with electronic prescribing. Follow-up with Chris Conn	
1	Medication incidents: Naropin + Fentanyl – wrong concentration used	11/02	Education program highlighting changed nomenclature to be undertaken in areas using this product	
2	New drugs: Rocuronium to include use in ED	11/02	Strict criteria needed	
		11/02	Guidelines need to be developed	
		11/02	Anaesthetists to meet with ED staff to discuss issue	
		12/02	Anaesthetists, Intensivists and ED staf to meet for further discussion. Recommendations to be reported back to DTC	
	Supply of OTC medications to Gorman house residents	11/02	S4s and OTCs will not be stocked on imprest anymore	
	Community nurses administering high Vitamin C (IV) doses prescribed by GPs in community	11/02	Formal submission addressing safety, effectiveness, stability and evidence to be sibmitted to DTC, in the meantime these are to be obtained from private clinics	
	Terms of Reference need to be reviewed for 2003	11/02	Terms of reference circulated. Awaiting feedback	
	Generic cyclosporin	12/02	Cysporin – new generic of Neoral. Need to discuss which brand to use	
		12/02	Prescribers to be involved re: preferences and negotiations	
2	New drugs: Dysport for spasticity	12/02	More information required	
2	New drugs: Enoxaparin for prophylaxis of Venous Thromboembolism in medical patients	12/02	Such use already occurring at SVH – letters to M McGrath & A Glanville to rectify situation	
		12/02	After ratification, recommendations to be placed on DTC website	

		12/02	Use NSW TAG position statement on " Use of LMWH in acute Medical illness and atrial fibrillation" to be available as reference	
3	IPU: Temozolomide for relapsed/refractory acute leukaemia for up to 5 patients	12/02	HCD committee approved use	
		12/02	Report of use to be provided by prescriber to HCD committee	
3	IPU: Linezolid for MRSA	12/02	Commenced for 1 patient intolerant of rifampicin	
		12/02	Microbiology suggested that Pristinamycin may be cheaper alternative for linezolid, but SAS Scheme will cease soon and drug may need to be imported	
4	Chemical Restraint Policy	12/02	Delirium policy and Chemical Restraint Policy should be coordinated to use the same drugs	
		12/02	B Murnion & P Nair to follow-up and come up with consesus re: IV diazepam or IM Midazolam	
4	Self-medication policy	12/02	SHH self-medication forms (trialled succesfully at SHH) considered	
		12/02	Approval for use but need annotation "Forms for Sacred Heart Rehabilitation Service, only applicable to Sacred Heart" in bold	
		12/02	Forms not to be used in SVH	
		12/02	SVH patients must not proceed to Stage 3 (self-medication without medical supervision)	
	Pharmacy discharge prescriptions	12/02	Memo by Pharmacy Dept re: streamlining discharge process supported by DTC	
	Formulary updates	12/02	Difficult keeping formulary and guideline to prescribing up to date without funding or project officer	
		12/02	Some mechanism should be put into place so that SVH formulary is regularly updated	
2	New drugs: Nabilone	12/02	For nausea & vomiting not responsive to currently available agents for treatment for anorexia in terminal cancer secondary to AIDS related illness at SHH – approved for use	

Appendix 5.1

Invitation to participate in focus group discussions

The University of Sydney
ST VINCENT'S HOSPITAL SYDNEY LIMITED
A.C.N. 054 038 872
UNDER THE CARE OF THE SISTERS OF CHARITY

«Title» «First_name» «Surname»
«Job_Title»
«Address_1»
«Address_2»
«Suburb» «State» «Postcode»

23rd September 2003

Dear «Title» «Surname»,

Invitation to participate in a focus group discussion

Medication use is a large part of care delivery, particularly in a hospital setting. It is therefore important for hospitals to have a model for maximising drug use. Currently, the institutional Drug and Therapeutics Committee (DTC) is a pivotal feature of this model. DTCs are advocates of rational drug therapy within their local institutions.

In recent years, the roles of DTCs have begun to embrace the principles of Quality Use of Medicines (QUM). Nonetheless, DTCs continue to maintain economic and formulary management responsibilities. Whilst DTCs may make important decisions that could affect the quality of clinical practice and patient care outcomes, the methods in which DTC decisions are implemented (and their effectiveness) remains undocumented. A tool could be developed to evaluate the effectiveness of DTC intervention strategies. But, in order for this tool to be useful, it has to be developed based on literature and guided by stakeholders' opinions. You have been invited to participate in a focus group discussion to qualitatively document stakeholders' perceptions of intervention strategies.

This invitation has been extended to all members of the reference group formed to guide the study. Members of the St Vincent's Hospital DTC have also been invited. Focus group discussions will be held at St Vincent's Hospital, Darlinghurst. The discussion will be led by a trained facilitator. It is anticipated that this will take about an hour. You will only need to attend the focus group once only. Focus group discussions will be held on:

- Thursday, 16th October 2003 at 5:00pm
- Monday, 20th October 2003 at 5:00pm
- Tuesday, 21st October 2003 at 2:00pm
- Thursday, 23rd October 2003 at 11:00am
- Friday, 24th October 2003 at 3:00pm

If you would be interested in attending a focus group discussion, please send an email to eelyn@mail.usyd.edu.au or call Ee Lyn Tan on 02-83822199; by **29th September 2003** to let us know which **one of the above times** is convenient for you. Participant information will be forwarded to you prior to the focus group discussion.

Yours sincerely,

Ee Lyn TAN BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Member of Drug and Therapeutics Committee, St Vincent's Hospital, Sydney

This study has been approved by the Human Research Ethics Committee (HREC) of the University of Sydney and St Vincent's Hospital, Sydney. Any persons with concerns or complains about the conduct of a research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811; or the Executive Officer for the Research Office, St Vincent's Hospital, Sydney on 02-83822075.

Appendix 5.2

Focus group reminder letter

The University of Sydney
ST VINCENT'S HOSPITAL SYDNEY LIMITED
A.C.N. 054 038 872
UNDER THE CARE OF THE SISTERS OF CHARITY

«Title» «First_name» «Surname»
«Job_Title»
«Address_1»
«Address_2»
«Suburb» «State» «Postcode»

16th October 2003

Dear «Title» «Surname»,

Drug and Therapeutics Committee focus group discussion

Thank you registering to participate a focus group discussion. The details of the focus group discussion which you have agreed to attend are as follows:

Venue: Conference Room 1, Fred Street Conference Centre
Level 4, Xavier Building
St Vincent's Hospital, Darlinghurst
(go up the escalators to Lvl 4, turn right at the lifts)
Date: <<Date>> (<<Day>>)
Time: Focus group discussions start at <<time>>
Refreshments will be served from <<arrival_time>>
We anticipate the discussions will be for about an hour

A copy of the Participant Information Sheet and Consent Forms is enclosed. Could we request that you please read the Participant Information Sheet **before** coming to the focus group discussion. You will be given an opportunity to ask questions about the study at the start of the discussions. If you have no further enquiries or concerns with regard to the study, please sign the **2 copies** (1 copy to be brought along to the group discussions, and 1 copy for your own records) of the enclosed consent forms.

We look forward to seeing you at the focus group. We trust that it will be a stimulating and enjoyable discussion.

Thank you once again for your participation in the study.

Yours sincerely,

Ee Lyn TAN BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Member of Drug and Therapeutics Committee, St Vincent's Hospital, Sydney

This study has been approved by the Human Research Ethics Committee (HREC) of the University of Sydney and St Vincent's Hospital, Sydney. Any persons with concerns or complains about the conduct of a research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811; or the Executive Officer for the Research Office, St Vincent's Hospital, Sydney on 02-83822075.

Appendix 5.3

Focus group reminder email

On Wed, 15 Oct 2003 11:39:36 +1100, Ee Lyn Tan <etan@pharm.usyd.edu.au> wrote:

Dear <<Title>> <<Surname>>,
You have agreed to participate in a focus group discussion about Drug and Therapeutics Committees (DTCs). The details of the focus group discussion you have chosen to attend are as follows:

Venue: Conference Room 1
Level 4, Xavier Building
St Vincent's Hospital, Darlinghurst
Date: <<Date>> (<<Day>>)
Time: Focus group discussions start at <<Time>>
Refreshments will be served from <<Arrival_time>>
We anticipate the discussions will be for about an hour

If you have any problems, please do not hesitate to contact me on 02-83822199.

Looking forward to seeing you there!
Ee Lyn

--
Ee Lyn Tan
BPharm BPharmSci(Hons)
Faculty of Pharmacy
(Pharmacy Practice Research)
The University of Sydney & St. Vincent's Hospital
Tel: +612-83822199
Fax: +612-83822686

This message was sent using IMP, the Internet Messaging Program.

Appendix 5.4

Focus group schedule

4pm-4.30pm – Set up

4.30pm-5.00pm – Arrive & refreshments

5.00pm-6.00pm – Discussions & close

Introduction (4.45pm)
- Welcome
- You would have received a copy of the "Participant Information Sheet" & "Consent Forms". Are there any questions/concerns?
- If not, please sign both copies of consent form – one copy to us, the other for your records
- If didn't bring them, we have extra copies
- Distribute "Participant Information Sheet" and "Consent Forms"

Discussion (5pm)
- Purpose of tonight's discussion
    - To discuss the ways in which DTC decisions/policies are implemented
    - To seek your opinions re: methods of policy implementation (from literature) and how these can be applied to DTC decisions
- Ground rules
    - audio-taping so that we don't miss out any important information
    - one person speaking at a time
    - please say name before speaking, whenever possible
    - try to speak up (loud and clear)
    - when speaking, please do not disclose any identifying information
    - deidentified, so no names will be used in the reporting of the study
    - negative and positive views wanted
    - please do not discuss specifics of the focus group discussion outside the group
- Jo (??) & myself, will be taking notes during our discussion and this will assist with the transcribing work

****start recording****

- ask people to say their name and which department they are from when the recording starts for voice recognition (e.g. "my name is John Smith, I work in the Emergency Department")
- Discussion of issues (from list)

5.05pm	**Understanding of DTCs**

(10 mins)	
	To start off the discussions tonight, let's take 10 mins to briefly comment on your understanding of what a DTC is.
If no response	Perhaps, you'd like to comment on what the DTC's roles are, who are the people who are a part of the committee and how that contributes to the way they make decisions?
5.15pm (15 mins)	**Current implementation strategies**
	Drawing from your own experiences, how have the DTC decisions been communicated/disseminated/implemented? (ie what are the strategies you have come across?)
If no response	Give us an example of a decision your DTC has made at its last meeting, do you know/remember if or how it has been implemented? Tell us about a DTC decision that have affected the way you practiced, and how (a) it has been communicated to you and (b) how you knew that it was a DTC decision
	Some of you may/may not have talked about this tonight, but what are some of the barriers/hindrances in applying these strategies in day-to-day practice?
	Practically, can you think of some ways to overcome these barriers?
If no response	OK, let's look at one of the barriers some of you have brought up tonight (eg there is not enough staff), how would we go about solving this problem?
5.30pm (30mins)	**Effectiveness of implementation strategies**
	Now, I'd like to direct your attention to some implementation strategies from the literature. Considering the evidence for their effectiveness, how do you think these could be practically applied to DTC decisions? a) academic detailing b) use of local opinion leaders c) published/printed materials (bulletins, letters, memoranda, electronic??) d) continuing education Any others you would like to mention/discuss??
	Which strategies do you think are necessary if the we need to change ppl's behaviour/practice? What if the goal of a decision is only to create an awareness of a certain issue, is it enough to use published/printed mats?
6.00pm (10 mins)	Closing
	Before I close the discussion tonight, there's just a few concluding questions that I would like to ask. Firstly, is there any else that you would like to add? Anything that we haven't covered? Or any important issues you would like to discuss?
	Finally the last thing that I would like us to do is to go around the table and I'd like each of you to comment on what sort of things would you like to see happen with regards to the way DTC decisions are implemented in the future.

	Your opinions are very important in helping us improve the ways in which DTC decisions are implemented. Thank you for your participation. I'll stop the recording now.

Demographic data

- The last thing to do before you leave tonight….
- to fill in 1-page "questionnaire"
  - Purpose: to collect demographic data
  - Help us to interpret collected data
  - Information on form cannot be traced back to you
  - Please circle responses applicable to you (pens provided if need one)
  - Please hand back forms to me before you leave tonight.

Appendix 5.5

Data collection form (Demographic details)

Thank you for your participation in this focus group discussion. We would like to collect some demographic data of focus group attendees, in order to have an accurate interpretation of the data we will be collecting. All data collected on this form will not be able to be traced back to you. Please **circle** the appropriate response as would be applicable to you.

Age group
1 - <25 years
2 - 26-35 years
3 - 36-45 years
4 - 46-55 years
5 - >55 years

Gender
1- Male 2 - Female

Professional representation
1 – Hospital administrator
2 – General practitioner
3 – Junior medical staff
4 – Registrar
5 – Senior medical staff
6 – Consultant physician
7 – Nurse
8 – Hospital pharmacist
9 – Community pharmacist
10 – Consumer
11 – Other: _____

Have you ever been a member of a Drug at Therapeutics Committee (at St Vincent's Hospital or elsewhere)?
1 – Yes (Go to question 5) 2 – No (Go to question 7)

Are you currently a member of a Drug and Therapeutics Committee (at St Vincent's Hospital or elsewhere)?
1 – Yes (Go to question 6) 2 – No (Go to question 7)

How many years have you had membership of a Drug and Therapeutics Committee?
1 - <1 year
2 - 1-2 years
3 - 2-5 years
4 - >5 years

If you are not currently a member of a Drug and Therapeutics Committee, have you had any contact with a Drug and Therapeutics Committee (eg requested the addition of a drug to formulary, written a guideline/policy in consultation with the drug committee, presented a protocol for consideration at the drug committee etc.) in the last 12 months?
1 – Yes 2 – No
Please return the completed form to one of the investigators at the end of the focus group discussion. Thank you.

Appendix 5.6

Participant information sheet

The University of Sydney

ST VINCENT'S HOSPITAL SYDNEY LIMITED

A.C.N. 054 038 872

UNDER THE CARE OF THE SISTERS OF CHARITY

Participant information sheet

Putting evidence into practice – Implementing DTC policy

This focus group discussion is conducted in order to collect your opinions and advice about implementation strategies used by the DTCs to influence clinical practice with regard to medication use in the hospital.

Medication use is a large part of care delivery in the hospital setting. It is therefore important for hospitals to have a model for maximising drug use. Currently, a pivotal feature of this model is the Drug and Therapeutics Committee (DTC). The roles and expertise represented by DTCs gives them a unique opportunity to be a major influence on prescribing practices and patient care. Whilst DTCs may make important evidence-based decisions, these need to be appropriately implemented into day-to-day practice to have an impact on patient care.

There are a variety of strategies used to implement of programs and guidelines. Evidence from published reviews of intervention strategies in relation to practice change indicated that these intervention strategies may have differing levels of effectiveness. Unless, and until research-based evidence is integrated, the DTCs efforts invested in improving the quality of patient care will be wasted. The implementation of evidence may necessitate changes in long-held patterns of behaviour. Your opinions could serve as an important "diagnostic analysis" of factors likely to influence this process of change.

If you agree to be involved, you will be participating in a group discussion led by a trained facilitator. It is estimated that this will take around about an hour. You will only need to attend the focus group once only. The focus group discussion will be audiotaped to enable us to be able analyse issues that have been discussed. A researcher will also be present to take notes whilst the discussion is ongoing. Your identity will not be recorded or revealed. All your opinions will be held in strict confidence.

This study is being conducted to as part of a PhD project in the Pharmacy, under the supervision of Professor Jo-anne Brien of the Faculty of Pharmacy at the University of Sydney.

Your rights

Participation in this study is voluntary. You will be given an opportunity to ask questions regarding this study and can expect clear and understandable answers in return. You may withdraw from the study at any time you wish. Withdrawal from the study will not jeopardise your work, your working environment or your chances of professional development. Your name will not be used in any reports or publications arising from the study, to protect your privacy. This study has been approved by the Human Ethics Committees of The University of Sydney and St Vincent's Hospital.

Any person with concerns or complains about the conduct of a research study may contact the Manager for Ethics Administration, University of Sydney on (02) 93514811; or Executive Officer for the Research Office, St Vincent's Hospital, Sydney on (02) 83822075.

16th September 2003

Participant information sheet: Page 1 of 1

Appendix 5.7

Consent form

The University of Sydney

ST VINCENT'S HOSPITAL SYDNEY LIMITED

A.C.N. 054 038 872

UNDER THE CARE OF THE SISTERS OF CHARITY

Consent form

Putting evidence into practice – Implementing DTC policy

_____ has discussed this study with me. I have had the opportunity to ask questions about this study and I have received answers that are satisfactory to me. I understand that I can withdraw from this study at any time. I understand that my participation in this study will have no effect on my work, working environment or professional development.

I consent to the publishing of the results of this study provided my identity is not revealed. I have read the attached *Participant Information Sheet* and understand the general purposes and methods of the study. I agree to participate in this study. I hereby give permission to the researchers to use audiotapes in this focus group discussion to record discussions and understand that my personal information will remain confidential. I have received my own copy of this document.

PARTICIPANT'S NAME: _____
Please print

PARTICIPANT'S SIGNATURE: _____ **DATE:** _____

WITNESS'S NAME: _____
Please print

WITNESS'S SIGNATURE: _____ **DATE:** _____

The University of Sydney

ST VINCENT'S HOSPITAL SYDNEY LIMITED
A.C.N. 054 038 872

UNDER THE CARE OF THE SISTERS OF CHARITY

Consent form

Putting evidence into practice – Implementing DTC policy

_____ has discussed this study with me. I have had the opportunity to ask questions about this study and I have received answers that are satisfactory to me. I understand that I can withdraw from this study at any time. I understand that my participation in this study will have no effect on my work, working environment or professional development.

I consent to the publishing of the results of this study provided my identity is not revealed. I have read the attached *Participant Information Sheet* and understand the general purposes and methods of the study. I agree to participate in this study. I hereby give permission to the researchers to use audiotapes in this focus group discussion to record discussions and understand that my personal information will remain confidential. I have received my own copy of this document.

PARTICIPANT'S NAME: _____
Please print

PARTICIPANT'S SIGNATURE: _____ **DATE:** _____

WITNESS'S NAME: _____
Please print

WITNESS'S SIGNATURE: _____ **DATE:** _____

****This copy of the consent form is to be retained for your own records.**

Appendix 6.1

Questionnaire used in national survey

DTC decision survey

Please **circle** ONE appropriate option unless otherwise indicated.

Membership of a Drug and Therapeutics Committee (DTC)
1 – Yes, I currently have membership of a DTC
2 – No, I've never had membership of a DTC (Go to question C)
3 – I used to be a member of a DTC, but I'm currently not a member (Go to question C)

How many years have you been a DTC member?
1 - <1 year
2 – 1-2 years
3 – 3-5 years
4 - >5 years

Professional representation
1 – Hospital administrator
2 – General practitioner
3 – Junior medical staff / Registrar
4 – Senior medical staff / Consultant
5 – Nurse
6 – Hospital pharmacist
7 – Community pharmacist
8 – Other: _____

What domain(s) would make a DTC decision important?
(please circle ALL options which apply)
1 – Ensures patient safety
2 – Relates to cost
3 – Ensures the practice of evidence based medicine within the institution
4 – Ensures practice is according to legislative requirements
5 – Urgency
6 – Others: _____

Question E) to Question L) are set out as follows:

- *Saturday is the best day of the week* *SA A N D SD*

Where:
***SA** = Strongly agree;*
***A** = Agree;*
***N** = Neither agree nor disagree;*
***D** = Disagree;*
***SD** = Strongly disagree*

*For the following statements, please only circle **ONE** option which best represents your personal opinion.*

****PLEASE TURN OVER – THERE ARE MORE QUESTIONS OVER THE PAGE****

For office use only:

Survey no:

Form no:

Some DTC decisions are more important than others	SA	A	N	D	SD
There are domains (elements) of a decision that make a decision important	SA	A	N	D	SD
Important decisions involves at least ONE of the domains listed in question D) (on the previous page)	SA	A	N	D	SD
Given constraints on time and resources, the option of prioritising decisions for implementation should be considered	SA	A	N	D	SD
Prioritisation of decisions enables the important decisions to be implemented effectively	SA	A	N	D	SD
Prioritisation of decisions may allow the less important decisions to be **NOT** implemented	SA	A	N	D	SD
All DTC decisions are equally important	SA	A	N	D	SD
Decisions of low priority should not be implemented	SA	A	N	D	SD

Can DTC decisions be proritised for implementation? Yes / No / Maybe

If yes, then **how** can DTC decisions be prioritised for action?

Other comments:

Thank you for your participation.
Completed surveys could be returned, using the envelope enclosed, or by fax to 02-83824219 before 16th July 2004 (Friday).

Appendix 6.2

Invitation to participate in survey

The University of Sydney
ST VINCENT'S HOSPITAL SYDNEY LIMITED
A.C.N. 054 038 872
UNDER THE CARE OF THE SISTERS OF CHARITY

Dr Potential Participant
Department of XXX
Address line 1
Address line 2
Address line 3

29th June 2004

Dear Dr Participant,

We are documenting the effectiveness of intervention strategies employed by the Drug and Therapeutics Committee (DTC) at St Vincent's Hospital under the supervision of Prof Jo-anne Brien. This survey is part of a Quality Use of Medicines doctoral research study. We would appreciate it if you could take a few minutes to fill in the attached questionnaire. Thank you for considering this request.

Drug and Therapeutics Committees optimise use of medicines so that health outcomes will be improved. DTCs are advocates of rational drug therapy within the hospital. Their decisions may impact quality use of medicines and patient care outcomes. When the DTC makes a decision on drug use policy or guidelines, it cannot be assumed that it will be automatically implemented into routine practice. In fact, it is unknown if these decisions have been effectively communicated to stakeholders on the coal-face of clinical practice.

This questionnaire will be sent to stakeholders (eg clinicians, clinical pharmacologists, pharmacists, nurses, DTC members and hospital administrators) likely to be involved in, or affected by, decisions made by the Drug and Therapeutics Committee.

Completed questionnaires can be returned **via email** to eelyn@mail.usyd.edu.au or **by fax to 02-83822686** before **16th July 2004.** If we do not hear from you by this time, we will send you another reminder letter and another copy of the same questionnaire. An electronic copy of the questionnaire could be obtained by sending an email to eelyn@mail.usyd.edu.au

The information provided by you in this survey will be kept confidential. Participation in this survey is voluntary. Non-participation in this study will not jeopardise your work, your working environment or your chances of professional development. All data will be de-identified.

If you would be interested in the results of this survey, please include your contact details at the end of the questionnaire. Thank you, once again, in advance for your invaluable participation. Your opinions and views are important to help us improve the ways in which DTC decisions could be implemented.

Yours sincerely,

Ee Lyn TAN BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Member of Drug and Therapeutics Committee, St Vincent's Hospital, Sydney
Any questions or queries regarding this survey can be directed to the investigators: Prof Jo-anne Brien (☎02-83822605) or Ms Ee Lyn Tan (☎02-83822199).

This study has been approved by the Human Research Ethics Committee (HREC) of the University of Sydney and St Vincent's Hospital, Sydney. Any persons with concerns or complains about the conduct of a research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811.

Appendix 6.3

Follow-up letter for non-responders

The University of Sydney
ST VINCENT'S HOSPITAL SYDNEY LIMITED
A.C.N. 054 038 872
UNDER THE CARE OF THE SISTERS OF CHARITY

Dr Potential Participant
Department of XXX
Address line 1
Address line 2
Address line 3

Date of follow-up mail

Dear Dr Participant,

Three weeks ago, a questionnaire about decisions Drug and Therapeutics Committees (DTCs) have been sent to you. You have been invited to participate in this survey because we value the opinions of stakeholders likely to be involved in, or affected by, these decisions.

We have not received your response to date. We would appreciate if you could complete the questionnaire (copy attached) and return it to us. It is important that your responses to this questionnaire could be included in the results of the study so that DTC decisions can be effectively and efficiently implemented into clinical practice. This can have an impact on rational drug use and patient care outcomes within the hospital.

Completed questionnaires can be returned **via email to** eelyn@mail.usyd.edu.au or by **fax to 02-83824219** by the end of this week (Friday, 30th of July 2004). An electronic copy of the questionnaire is attached.

Information provided by you in this survey will be kept confidential. Please be reminded that participation in this survey is voluntary. Non-participation in this study will not jeopardise your work, your working environment or your chances of professional development. All data will be de-identified.

If you would be interested in the results of this survey, please include your contact details at the end of the questionnaire. Thank you, once again, in advance for your invaluable participation. Your opinions and views are important to help us improve the ways in which DTC decisions could be implemented.

Yours sincerely,

Ee Lyn TAN BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Member of Drug and Therapeutics Committee, St Vincent's Hospital, Sydney
Any questions or queries regarding this survey can be directed to Prof Jo-anne Brien (☎02-83822605) or Ms Ee Lyn Tan (☎02-83822053).

This study has been approved by the Human Research Ethics Committee (HREC) of the University of Sydney. Any persons with concerns or complains about the conduct of a research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811.

Appendix 7.1

Form used in pilot study to collect stakeholders' opinions on how questionnaire could be improved

For pilot study

Please estimate the time taken to complete this questionnaire

☐☐ Minutes

If you have any comments about the questionnaire, please let us know by filling in the space below:

Thank you for taking time to complete this questionnaire.

Appendix 7.2

Final survey questionnaire

IMPLEMENTING

DRUG AND THERAPEUTICS COMMITTEE (DTC)

POLICY STUDY

Please read prior to completing this survey

- **This questionnaire contains TWO sections:**
  Section 1: Collects your opinions about some scenarios
  Section 2: Collects some information about you

- **Please complete BOTH sections of the questionnaire**

- **You should not take longer than 10 minutes to complete this questionnaire**

- Please complete ALL questions in all sections

In Section 1:

- **You are described a hypothetical Drug and Therapeutics Committee (DTC)**

- **You will be presented with FIVE scenarios. Based on examples of types of DTC decisions, please read each scenario carefully and choose the most appropriate responses. There are no right or wrong answers**

- Please accept the DTC decisions at face value and respond to each scenario as it has been described (not necessarily according to what you/your DTC would have done)

- At the end of each scenario, you will be asked to assign the priority to the scenario. The definitions for these are as follows:

  High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision

  Medium priority: this decision should be implemented with remaining resources (time, manpower, money) after other decisions of high priority are implemented

  *Low priority: this decision can be implemented only if possible after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not implement this decision)*

In Section 2:

- Some information about you will be collected
- The data collected in this section cannot be traced back to you

Section 1:

You are the chairperson of the Drug and Therapeutics Committee (DTC) at St Elsewhere Hospital. There are no resources assigned to the operations of the DTC you chair. The DTC at St Elsewhere comprises of 2 pharmacists (the director of the pharmacy department who is also secretary to the DTC, and a clinical pharmacist), a nurse, and 4 senior medical officers (from clinical pharmacology, microbiology, cardiology and intensive care respectively).

Scenario 1

Your DTC received an application for a "me-too" proton pump inhibitor (PPI) to be included on the hospital formulary. Currently another PPI is on the hospital formulary. The new PPI is an isomer of the one currently on formulary. There was no evidence of clinical and/or economic benefit of the new PPI over the PPI currently used in the hospital. After discussions at a DTC meeting, the request for the addition of the "me-too" PPI was denied. Guidelines are needed for patients admitted to the hospital on the new PPI (ie started in community, or at another facility).

1. What is the domain (issue) relating to this decision?
*(choose only **ONE** domain which you consider to be the major issue in this decision)*
□ Ensures patient safety
□ Relates to cost
□ Ensures the practice of evidence-based medicine within the institution
□ Ensures practice is according to legislative requirements
□ Urgency
□ Other: _____

2. This is a very important decision

1	2	3	4	5
Strongly agree				Strongly disagree

3. This decision is of
(choose ONE option only)
□ High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
□ Medium priority: this decision should be implemented with remaining resources (time manpower, money) after other decisions of high priority are implemented
□ Low priority: this decision can be implemented only if possible, after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)

Scenario 2

The state health department has issued a circular about the prescribing of paracetamol. Your DTC reviewed the circular and agreed that the current practices with regard to paracetamol prescribing within your hospital were not in accordance with the health department recommendations detailed in this circular. At a DTC meeting it was decided that new guidelines for paracetamol prescribing were to be implemented. Implementation may need to include communication to staff (medical, nursing, pharmacy), staff education and possibly audits.

1. What is the domain (issue) relating to this decision?
*(choose only **ONE** domain which you consider to be the major issue in this decision)*
□ Ensures patient safety
□ Relates to cost
□ Ensures the practice of evidence-based medicine within the institution
□ Ensures practice is according to legislative requirements
□ Urgency
□ Other: _____

2. This is a very important decision

1	2	3	4	5
Strongly agree				Strongly disagree

3. This decision is of
(choose ONE option only)
□ High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
□ Medium priority: this decision should be implemented with remaining resources (time manpower, money) after other decisions of high priority are implemented
□ Low priority: this decision can be implemented only if possible, after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)

Scenario 3

The Head of the Pain and Palliative Care Department at St Elsewhere Hospital, Dr Pain, wrote a letter to the DTC requesting a review of the hospital's prescribing guidelines for pethidine. After an extended discussion, the DTC is supportive of Dr Pain's proposal. The clinical pharmacist was requested to report on the usage patterns of pethidine in the last 6 months at the next DTC meeting. A Pethidine Working Party was formed to review the hospital's prescribing guidelines. The redrafted guidelines must address occasions when pethidine may be used, as well as issues regarding morphine allergy. Redrafted guidelines must be circulated to clinical staff for feedback. An educational campaign targeting interns, residents, registrars, nurses as well as pharmacists needs to be conducted.

1. What is the domain (issue) relating to this decision?
*(choose only **ONE** domain which you consider to be the major issue in this decision)*
□ Ensures patient safety
□ Relates to cost
□ Ensures the practice of evidence-based medicine within the institution
□ Ensures practice is according to legislative requirements
□ Urgency
□ Other: _____

2. This is a very important decision

1	2	3	4	5
Strongly agree				Strongly disagree

3. This decision is of
(choose ONE option only)
□ High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
□ Medium priority: this decision should be implemented with remaining resources (time manpower, money) after other decisions of high priority are implemented
□ Low priority: this decision can be implemented only if possible, after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)

Scenario 4

A medication was supplied for patients free of charge through an expanded access program. A small number of patients from St Elsewhere were supplied with this medication through this program. The DTC and the Ethics Committee at St Elsewhere were unaware of this program. This medication is now marketed and the Drug Company will no longer make this medication available to patients free of charge. The costs for maintaining these patients on this medication is expected to be about $200,000 per annum. The DTC decided that it was not ethical to stop this treatment for these patients. However, the DTC decided that no new patients could be commenced on this medication. Guidelines with regard to the use of this medication need to be developed, with input from the relevant specialist prescribers. A policy regarding the enrolment of patients from St Elsewhere in trials and access programs needs to be developed. A letter needs to be written to the Drug Company to seek support with regard to the supply of this medication for existing patients. The Executive of the hospital needs to be consulted regarding ways to cover the cost of this medication for these patients.

1. What is the domain (issue) relating to this decision?

*(choose only **ONE** domain which you consider to be the major issue in this decision)*

□ Ensures patient safety
□ Relates to cost
□ Ensures the practice of evidence-based medicine within the institution
□ Ensures practice is according to legislative requirements
□ Urgency
□ Other: _____

2. This is a very important decision

1	2	3	4	5
Strongly agree				Strongly disagree

3. This decision is of

(choose ONE option only)

□ High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
□ Medium priority: this decision should be implemented with remaining resources (time manpower, money) after other decisions of high priority are implemented
□ Low priority: this decision can be implemented only if possible, after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)

Scenario 5

The DTC was reviewing medication incident reports at the meeting. DTC members present were concerned about the number of incidents relating to insulin. One of the senior medical officers present noted that these were not isolated as similar incidents have been reported. The DTC decided that a strategy to prevent the recurrence of insulin-related errors need to be developed. Representatives from the hospital's Endocrinology Department and Diabetes Clinic were invited to provide recommendations. Prescribers, pharmacists and nurses should be educated with regard to the types of insulin available and how these should be used.

1. What is the domain (issue) relating to this decision?
*(choose only **ONE** domain which you consider to be the major issue in this decision)*
□ Ensures patient safety
□ Relates to cost
□ Ensures the practice of evidence-based medicine within the institution
□ Ensures practice is according to legislative requirements
□ Urgency
□ Other: _____

2. This is a very important decision

1	2	3	4	5
Strongly agree				Strongly disagree

3. This decision is of
(choose ONE option only)
□ High priority: essential to implement this decision; resources/manpower are to be allocated to the implementation of this decision
□ Medium priority: this decision should be implemented with remaining resources (time manpower, money) after other decisions of high priority are implemented
□ Low priority: this decision can be implemented only if possible, after implementing decisions of high and medium priority (**note that given the lack of resources, the DTC may not get to implement this decision)

Section 2:

Please fill in details or tick ☑ the appropriate response

1. Sex
   □ Male
   □ Female

2. Age group
   □ <25 years
   □ 26-35 years
   □ 36-45 years
   □ 46-55 years
   □ >55 years

3. Membership of a Drug and Therapeutics Committee (DTC)
   □ Yes, I am currently a member of a DTC (Go to Question 4)
   □ No, I have never been a DTC member (Go to Question 5)
   □ I used to be a DTC member, but I'm currently not a member (Go to Question 4)

4. How many years have you been a DTC member?
   _____ Years

5. Professional representation
   □ Hospital administrator
   □ General practitioner
   □ Junior medical staff/Registrar
   □ Senior medical staff/ Consultant
   □ Nurse
   □ Hospital pharmacist
   □ Community pharmacist
   □ Other: _____

Appendix 7.3

Invitation to participate in survey

Dear Potential Participant,

You have been sent this email because you are either a member of a Drug and Therapeutics Committee (DTC) or have a working knowledge of DTCs. We are exploring the ways in which stakeholders may prioritise DTC decisions. This is a follow-up of a previous study in which you may have participated. This survey is part of a Quality Use of Medicines doctoral research study supervised by Prof Jo-anne Brien and Prof Ric Day. We would appreciate it if you could fill in a questionnaire. It should take you no longer than **10 minutes** to fill in this questionnaire. This questionnaire is available online at www.dtcsurvey.com Alternatively, a hard-copy of the survey may be downloaded via links on the website. If you require a hard copy of the questionnaire, please send an email to etan@pharm.usyd.edu.au with your contact address. Completed questionnaires could be returned **electronically to etan@pharm.usyd.edu.au** or **by fax to 02-83824219** by **15th November 2004**. The attached participant information letter is also available online.

The information provided by you in this survey will be kept confidential. Participation is voluntary. Non-participation in this study will not jeopardise your work, your working environment or your chances of professional development. All data will be de-identified. This study has been approved by The Human Research and Ethics Committee at The University of Sydney.

We would like to emphasise that we are interested in your opinion as an individual stakeholder, rather than the committee's opinion.

Thank you for considering this request.

Ee Lyn Tan
PhD Candidate
Clinical Pharmacy Research Group
Faculty of Pharmacy
The University of Sydney

The University of Sydney

Faculty of Pharmacy

NSW 2006 AUSTRALIA

Facsimile: (02) 9351 4391
Telephone: (02) 9351 2320

Dear potential participant,

We are exploring the ways in which stakeholders may prioritise Drug and Therapeutics Committee (DTC) decisions. This is a follow-up of a previous study in which you may have participated. This survey is part of a Quality Use of Medicines doctoral research study supervised by Prof Jo-anne Brien and Prof Ric Day. We would appreciate it if you could fill in a questionnaire which will inform this study. It should take you no longer than **10 minutes** to fill in this questionnaire. Thank you for considering this request.

DTCs function within the health care system to promote rational use of medicines within their institutions. Their decisions may have an impact on clinical and economic outcomes of drug use. In a previous study, DTC stakeholders suggested that current DTC decisions and policies may not be being implemented effectively. This was thought to be associated with the resource-poor environment. Stakeholders also suggested that DTC decisions should be prioritised for implementation so that available resources could be directed to effectively implement the decisions and policies of high priority. The attached questionnaire investigates the kinds of DTC decisions which could be assigned priority for implementation.

Stakeholders likely to be involved in, or affected by, decisions made by the DTC will be invited to participate in this study. This questionnaire is available online. If you require a hard copy of the questionnaire, please send an email to etan@pharm.usyd.edu.au with your contact address. Completed questionnaires could be returned **electronically to etan@pharm.usyd.edu.au** or **by fax to 02-83824219** by **15th November 2004**.

The information provided by you in this survey will be kept confidential. Participation in this survey is voluntary. Non-participation in this study will not jeopardise your work, your working environment or your chances of professional development. All data will be de-identified.

If you would be interested in the results of the survey, please send an email to etan@pharm.usyd.edu.au stating interest in the results of this survey, as well as your contact details. We will send you an email when the results become available. You do not have to participate in the survey to have access to the results.Thank you, once again, for your invaluable participation. Your opinions and views are important to help us improve the ways in which DTC decisions and policies could be implemented.

Yours sincerely,

Ee Lyn Tan BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Any questions or queries regarding this survey can be directed to the investigators: Prof Jo-anne Brien (Tel: 02-83822605) or Ms Ee Lyn Tan (Tel: 02-83822199).

This study has been approved by the Human Research Ethics Committee of The University of Sydney. Any persons with concerns or complaints about the conduct of the research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811.

Appendix 7.4

Interactive CD

- The interactive CD attached requires Windows XP, or Windows 2000 operating systems
- The CD is not compatible with Apple Macintosh computers
- The *.pdf links on this CD are not operational. If you would like to access *.pdf links, please visit the survey website at: www.dtcsurvey.com
- The CD is attached to the back (hard cover) of this thesis

Appendix 7.5

Follow-up reminder letter

The University of Sydney
Faculty of Pharmacy
NSW 2006 AUSTRALIA
Facsimile: (02) 9351 4391
Telephone: (02) 9351 2320

Dear Potential Participant,

A few weeks ago, an invitation to participate in a survey about the prioritisation of Drug and Therapeutics Committee (DTC) decisions was sent to you. You have been invited to participate in this survey because we value the opinions of stakeholders of these decisions.

If you have already completed and returned the questionnaire to us, please accept our sincere thanks. If not, could you please complete the questionnaire and return it to **etan@pharm.usyd.edu.au** or **by fax to 02-83824219.** A copy of the questionnaire is available online at www.dtcsurvey.com. Alternatively, send an email to me at etan@pharm.usyd.edu.au to request a copy of the questionnaire. Please complete and return the questionnaire to us by **Friday, 19th November 2004.**

Your responses to this questionnaire will be included in the results of the study which aims to improve the way DTC decision can effectively and efficiently be implemented into clinical practice. This may have an impact on rational drug use and patient care outcomes.

Information provided by you in this survey will be kept confidential. Please be reminded that participation in this survey is voluntary. Non-participation will not jeoparise your work, your working environment or professional development. All data will be de-identified.

We are looking forward to hearing from you soon.

Yours sincerely,

Ee Lyn Tan BPharm BPharmSci(Hons)
PhD candidate, The University of Sydney
Any questions or queries regarding this survey can be directed to the investigators: Prof Jo-anne Brien (Tel: 02-83822605) or Ms Ee Lyn Tan (Tel: 02-83822199).

This study has been approved by the Human Research Ethics Committee of The University of Sydney. Any persons with concerns or complaints about the conduct of the research study may contact the Manager for Ethics Administration, University of Sydney on 02-93514811.

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