A needs-based approach to patient-relevant information delivery

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ADDENDUM

Page 6, after “and sedative burden tools such as the Drug Burden Index(77) and CPG...” ADD: “Electronic tools which assist in clinical decision making are known as clinical decision support systems (CDSS).[1] CDSS encompass a variety of different tools, from diagnosis to treatment management and imaging; all of which can influence patient outcomes.[2] The type of CDSS can also vary widely, from simple, single user systems focusing on one aspect of the care process to multi-user or even multi-hospital all-encompassing systems.[3]

Some CDSS provide *solicited* information where health professionals (HPs) actively seek advice from the system. Examples of this type of system include MYCIN, which recommends both diagnosis and treatment for infectious diseases based on patient symptom input, and QMR, which assists with diagnosis of diseases in internal medicine.[2, 4] Other systems deliver *unsolicited* information during usual care processes, such as prescribing or dispensing, including alerts for suggested tests or usual doses.[3] Unlike CDSS that provide unsolicited information, systems that provide solicited information can be standalone systems, whereas both can be integrated into other computer systems used in health such as computerised physician order entry (CPOE) or dispensing software.[3] Some of the primary benefits of using CDSS to help improve clinical decision making is that they are able to simplify complex disease state management guidelines and assist in individualisation of patient care and potentially improve patient outcomes.[3] How effectively CDSS can improve patient outcomes is difficult to determine and needs to be evaluated on a case-by-case basis;[3] however, there has been some considerable work evaluating individual systems and reasons for their successes and failures (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

Overall it seems that CDSS are able to change practitioner behaviour by improving overall practitioner performance[5] and adherence to evidence-based practice,[6, 7] decreasing medication errors and reducing adverse drug reactions [8] and potentially decreasing treatment costs.[9] There is also some evidence that CDSS can improve medication dosing and frequency choice, compliance with local guidelines, decrease pharmacist interventions due to inappropriate medication choice, and improve patient satisfaction and outcomes, [6, 10-13] although there are some difficulties described concerning interpretation of CDSS effectiveness, due to poor study reporting and lack of publication guidelines, as well as difficulty making comparisons because of vast differences in CDSS purpose and design .[5, 8, 14] Despite difficulties in evaluating and comparing CDSS effectiveness, broad areas required for successful CDSS have been defined, such as developing user friendly CDSS, ensuring workflow integration and high quality data use in knowledge base (Chapter 4: Ingredients

of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).[15, 16]"

Page 6, after "…however they have been criticised for being difficult to use…" ADD: "The exponential growth in health data means that the use of CDSS as an essential tool during clinical decision making is inevitable;[15] however, discussion of the types of information that should be used and displayed to best improve clinical decisions appears to be lacking."

References

1. Wang, J. and D.J. Radosevich, *Decision Support Systems*, in *Encyclopedia of Information Technology Curriculum Integration* L.A. Tomei, Editor. 2008, IGI Global: Hershey. p. 197-208.
2. Armoni, A., *The Use of Artificial Intelligence Techniques and Applications in the Medical Domain* in *Healthcare Information Systems: Challenges of the New Millennium* A. Armoni, Editor. 2000, IGI Global: Hershey. p. 129-148.
3. Pusic, M. and J.M. Ansermino, *Clinical Decision Support Systems.* British Colombia Medical Journal, 2004. **46**(5): p. 236-239.
4. Carter, J.H., *Chapter 4: Design and Implementation Issues*, in *Clinical Decision Support Systems: Theory and Practice*, E.S. Berner, Editor. 1999, Springer: Birmingham. p. 64-98.
5. Garg, A.X., et al., *Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review.* Journal of the American Medical Association, 2005. **293**(10): p. 1223-1238.
6. Jamal, A., K. McKenzie, and M. Clark, *The impact of health information technology on the quality of medical and health care: a systematic review.* Health Information Management, 2009. **38**(3): p. 26-37.
7. Shiffman, R.N., et al., *Computer-based Guideline Implementation: A Systematic Review of Functionality and Effectiveness.* Journal of the American Medical Informatics Association, 1999. **6**(2): p. 104-114.
8. Ammenwerth, E., et al., *The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review.* Journal of the American Medical Informatics Association, 2008. **15**(5): p. 585-600.
9. Chaudhry, B., et al., *Systematic review: impact of health information technology on quality, efficiency, and costs of medical care.* Annals of Internal Medicine, 2006. **144**(10): p. 742-752.
10. Donyai, P., et al., *The Effects of Electronic Prescribing on the Quality of Prescribing.* British Journal of Clinical Pharmacology, 2007. **65**(2): p. 230-237.

11. Ozel, D., et al., *A web-based intensive care clinical decision support system: From design to evaluation.* Informatics for Health and Social Care, 2013. **38**(2): p. 79-92.
12. Seto, E., et al., *Developing healthcare rule-based expert systems: case study of a heart failure telemonitoring system.* International Journal of Medical Informatics, 2012. **81**(8): p. 556-565.
13. Buntin, M.B., et al., *The benefits of health information technology: a review of the recent literature shows predominantly positive results.* Health Affairs, 2011. **30**(3): p. 464-471.
14. Kaplan, B., *Evaluating informatics applications—clinical decision support systems literature review.* International Journal of Medical Informatics, 2001. **64**(1): p. 15-37.
15. Sittig, D.F., et al., *Grand challenges in clinical decision support.* Journal of Biomedical Informatics, 2008. **41**(2): p. 387-392.
16. Johnson, C.W., *Why did that happen? Exploring the proliferation of barely usable software in healthcare systems.* BMJ Quality and Safety in Health Care, 2006. **15**(Supp 1): p. i76-81.

Page 102 paragraph 5 after "…Conversely, if the CDSS is more comprehensive, in order to answer specific practitioner queries, an opt-in or "plug in" that utilises patient data in the CPOE may be more appropriate." Add "The level of information displayed should reflect CDSS purpose and HP requirements and should be designed in consolidation with HP end-users."

Page 162 paragraph 1 after "multiple evaluation techniques" add "(post demonstration questionnaire and focus group)"

Page 162, after "system purpose and study rationale…" add "A case vignette was used to demonstrate the features of the system and how the information is presented to the user. Questions from the audience were answered throughout the demonstration in order to clarify any areas of confusion."

ERRATA

Page 176 after CONCLUSION change "The tested system…" to "The demonstrated system…"

“Somewhere, something incredible is

waiting to be known”

-Carl Sagan

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List of Abbreviations

ACOVE	Assessing Care of Vulnerable Elders
ACSOM	Advisory Committee on the Safety of Medicines
ADL	Activities of Daily Living
ADR	Adverse Drug Reactions
AME	Adverse Medication Events
AMH	Australian Medicines Handbook
ANN	Artificial Neuronal Network
AOU	Assessment of Underutilisation
AVE	Average Variance Extracted
CAMs	Complementary and Alternative Medication
CDSS	Clinical Decision Support System
CI	Confidence Interval
COI	Conflict of Interest
CPG	Clinical Practice Guidelines
CPOE	Computer Physician Order Entry
CSUQ	Computer Software Usability Questionnaire
DBI	Drug Burden Index
DBMS	Database Management System
DSS	Decision Support Systems
EBM	Evidence Based Medicine
EHR	Electronic Health Record
EMR	Electronic Medicines Record (interchangeable with EHR)
GA	Genetic Algorithms
GP	General Practitioner
HIT	Health Information Technology
HMR	Home Medication Review
HP	Health professional
IADL	Independent Activities of Daily Living
IPET	Improving Prescribing in the Elderly Tool
IQR	Interquartile range
ISTA	International Sociotechnical Analysis
IT	Information Technology

MAI	Medication Appropriateness Index
mCSUQ	Modified Computer Software Usability Questionnaire
MedManAGE	Medication Management in the Aged
MRPs	Medication Related Problems
NASA	National Aeronautics and Space Administration
NHMRC	National Health and Medical Research Council
NORGEP	Norwegian General Practice
NPS	National Prescribing Service
PBS	Pharmaceutical Benefits Scheme
PD	Pharmacodynamic
PIM	Potentially Inappropriate Medications
PJC	Peter James Centre
PK	Pharmacokinetic
PRN	As required
PSA	Pharmaceutical Society of Australia
PSSUQ	Post-Study System Usability Questionnaire
QUM	Quality Use of Medications
RCT	Randomised Control Trial
RPBS	Repatriation Pharmaceutical Benefits Scheme
SD	Standard Deviation
START	Screening Tool to Alert doctors to Right Treatment
STOPP	Screening Tool of Older Person's Prescriptions
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

Definitions

Accredited Pharmacist

A registered pharmacist that has the necessary qualifications to provide pharmacy consultations such as home medication reviews.

Adverse Drug Reaction

A response to a drug that is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function; for example, an allergic reaction to a drug at normal dosing.

Clinical Decision Support System

A decision support system that is used during the provision of health care.

Code

Any collection of computer instructions using human-readable computer language.

Drug

A substance that has a physiological effect when introduced into the body.

Decision Support System

A system that utilises one or more computers in order to assist in decision making through the provision of information.

Geriatrician

A registered medical practitioner holds a specialist registration in geriatric care.

General Practitioner

A registered medical practitioner who holds a specialist registration in general practice.

Medical Practitioner

Those who are studying or are already registered to practice medicine under the Australian Health Practitioner Regulation Agency.

Pharmacist

Those who are studying or are already registered to practice pharmacy under the Australian Health Practitioner Regulation Agency.

Pharmacological agent

See drug

System

Any large software or program.

Statement of Originality

In accordance with Monash University Doctorate Regulation 17.2 Doctor of Philosophy and Research Master's regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

I declare no conflicts of Interest.

Signature: 

Date: 20/06/2014

Declaration for thesis based or partially based on conjointly published or unpublished work

In accordance with Monash University Doctorate Regulation 17.2 Doctor of Philosophy and Research Master's regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes three original papers published in peer reviewed journals and two unpublished publications. The core theme of the thesis is "**a needs-based approach to patient-relevant information delivery**". The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the candidate, working within the **Centre for Medicine Use and Safety, Monash University** under the supervision of Adjunct A/Prof Jennifer Marriott, Prof Peteris Darzins, and Dr. Ahmet Sekercioglu.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of chapters one, three, four and six my contribution to the work involved the following:

Thesis chapter	Publication title	Publication status	Nature and extent of candidate's contribution
1	Identifying Inappropriate Prescribing for Older People	PUBLISHED	Contributed to structure of manuscript; identification and review of relevant literature; collaborative preparation of draft and final manuscripts.
	A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People	PUBLISHED	Conducted literature search, reviewed articles, preparation of first and final drafts of manuscripts
3	Chapter 3: Resources for disease state management – what do health professionals want?	PUBLISHED	Conceived idea, developed interview guide, prepared ethics approval submission, conducted interviews, analysed data, prepared first and final drafts of manuscripts.
4	Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing	SUBMITTED	Conducted literature search, reviewed articles, design and development of system requirements, database, interface design, business rules, data acquisition and database population, development of testing scenario, conducting of talk-aloud usability testing and data analysis, and preparation of first and final drafts of manuscripts.
6	Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation	SUBMITTED	Conceived idea, developed modified Computer System Usability Questionnaire and focus group discussion guide, prepared ethics approval submission, conducted questionnaire demonstration session, conducted focus group, analysed data, prepared first and final drafts of manuscripts.

I have included manuscripts in their original format either as they appear in the respective journal or as they were submitted to the respective journal.

I have clearly stated the contribution of others to my thesis as a whole, including study design, data collection and analysis, editorial advice, and any other original research work used or reported in my thesis. I acknowledge that copyright of all material contained in my thesis resides with the copyright holder of that material.

Signature: 

Date: 20/06/2014

Journal Publications

1. Marriott J, **Stehlik P**. A critical analysis of the methods used to develop explicit clinical criteria for use in older people. Age and Ageing 2012;**41**(4):441-50

2. **Stehlik P**, Dārziņš P, Marriott J. Resources for medication management in the aged – what do health professionals want? eJHI 2014;**8**(1):e4

3. Elliott R, **Stehlik P**. Identifying Inappropriate Prescribing for Older People. JPPR 2013;**43**(4):312-19

4. **Stehlik P**, Bahmanpour A, Sekercioglu YA, Dārziņš P, Marriott J. Features for Successful Clinical Decision Support Systems: Results from Design, Development and Usability Testing (unpublished work), eJHI, 2014.

5. **Stehlik P**, Marriott J. Provision of patient relevant information during complex clinical decision-making - Usability evaluation (unpublished work), JAMIA, 2014.

Conference Presentations

1. **Stehlik P**, Bahmanpour A, Sekercioglu, YA, Dārziņš P, Marriott JL (Oral presentation). National Medicines Symposium (Brisbane) 2014: *"MedManAGE": A novel medication management decision support system for aged patients with complex needs*.
2. **Stehlik P**, Marriott JL, Dārziņš P, Bahmanpour A, Sekercioglu, YA, (Poster Presentation). International Pharmaceutical Federation (FIP) (Dublin) 2013: *"MedManAGE": A novel medication management decision support system for aged patients with complex needs.*
3. **Stehlik P**, Marriott JL, Dārziņš P (Oral presentation) Joint ASCEPT-APSA 2012 Conference (Sydney) 2012: Key Health Professionals' views of prescribing resources for older patients
4. **Stehlik P**, Marriott JL, Dārziņš P (Oral presentation). International Pharmaceutical Federation (FIP) (Amsterdam) 2012: *Geriatricians', General Practitioners', and Accredited Pharmacists' views of prescribing guidelines for older patients.*
5. **Stehlik P**, Marriott JL, Dārziņš P (Poster presentation). International Social Pharmacy Workshop (Phuket) 2012: *Geriatricians', General Practitioners', and Accredited Pharmacists' views of medication management resources: A qualitative study.*
6. **Stehlik P**, Marriott JL, Dārziņš P (Poster presentation). National Medicines Symposium (Sydney) 2012: *Geriatricians' views of medication management resources: A qualitative study.*

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To everyone – my deepest gratitude.

Abstract

The plethora of medical studies that are published annually leaves many health professionals (HPs) overwhelmed with new health information. To assist HPs, information from research is often summarised and presented in a practice ready fashion through disease specific guidelines, drug monographs, and up-date newsletters. Although these have been effective in improving the quality of medical care, criticisms of these resources are focused on their inability to deal with complex patients such as those with comorbidities and the aged. Resources tailored specifically to the aged are either simplistic and do not take into account all issues surrounding complex patient management, drug therapy individualisation and end of life care or are impractical to use at the point of care. The hypothesis of this research was that HPs' information needs were not currently being met and would require the identification, development and testing of an information delivery framework that would address their needs.

The overall aim of this research was to identify HP information needs when delivering healthcare to complex patients, such as the aged, and was conducted in three phases.

The **first phase** of this research used fifteen personal interviews with key HPs (geriatricians, GPs and accredited pharmacist) from the Melbourne metropolitan area to explore whether they felt currently available information resources meet their needs during complex patient healthcare delivery. Specifically it explored what HPs consider when making a clinical decision during healthcare delivery, what resources they use to assist in decision making and what features they desire in an information resource. Findings suggested that currently available resources did not meet HPs information needs. Issues identified included exclusion of complex patients from the literature, lack of relevance to the Australian environment and inability to access the literature due to lack of time to search for appropriate information and costs associated with subscriptions. Other identified hurdles included HPs inability to interpret and contextualise the literature and incomplete patient information that would otherwise influence their management choices. Features that were thought to make an information resource useful included clear formatting, simplicity, use of peer-reviewed evidence-based recommendations, local relevance and ready access via an easy to use electronic interface.

A new framework for delivering disease state management information to HPs that took into account all the complexities of care but did not jeopardise clinical autonomy was designed and developed in the **second phase** of this research. Past successes and failures of other electronic systems were identified to inform the basis of system design. These fundamental elements included

adherence to usability guidelines when developing user interface, provision of recommendations based on up-to-date reputable information sources accompanied by rationale and additional information links or references, identification of all important interactions clearly identifiable by level of importance, good integration into workflow and HP involvement throughout the design and development process. In order to take into account all of the complexities of appropriate care, the clinical decision making process was modelled by reviewing Australian and international literature regarding quality prescribing, medication review, disease state management and drug monographs. Features common across all sources included making a correct diagnosis, making a decision whether to treat a patient with non-pharmacological or pharmacological treatment, documenting care, and reviewing progress. Common considerations that influence treatment choice can be divided into patient characteristics and drug attributes. The clinical decision making model developed was used to design the system framework. Issues with updating the system knowledge and subsequent retesting were overcome by developing a business rule engine rather than coding decision making algorithms. Clinical autonomy was maintained by allowing HPs to choose the guideline for the system to use as the basis of decision support, as well as display of recommendations and associated potential issues based on patient data rather than providing absolute recommendations.

The usefulness of the way in which information is provided by the system was evaluated in **phase three** using 'think out aloud', questionnaire and focus group techniques.

Five pharmacy academics were asked to think-out aloud while using the system to make decisions regarding the management of newly diagnosed osteoarthritis in a complex patient in order to give insight into the usability, aesthetics and usefulness of information presentation. Although there were some minor issues identified, overall participants found the way in which information was displayed useful.

A validated modified computer system usability questionnaire (mCSUQ) was used to gain feedback from pharmacists and medical practitioners regarding system usefulness after a demonstration of the programme. The 17 question mCSUQ used a 7-point scale (1 = strongly disagree, 7 = strongly agree) and allows for open-ended feedback to measure user satisfaction with the system overall, its usefulness, the information and interface quality. When validated it demonstrated good internal consistency and congruent validity. Fifty-two HPs completed the mCSUQ and were invited to participate in focus group feedback. The system scored well on all domains: overall usability (mean 5.05, SD 1.07), system usefulness (mean 5.06, SD 1.11), interface quality (mean 4.84, SD 1.25) and highest on information quality (mean 5.09, SD 1.24). Two HPs were successfully recruited for focus group feedback. Results were used to confirm findings from open-ended question answers.

Participants felt that the system interface was simple, clear and could be easy to learn but required colour to help identify important issues. Positive aspects to the system included linking information to patient data and the comprehensive nature of the information given. Additional information desired included statistical information on treatment efficacy and provision of medication review and deprescribing guidance. Major determinants to using the system included ability to integrate with electronic health records (EHR) and use of high quality information within the knowledge base. Barriers identified to CDSS implementation in general included lack of access to accurate and complete patient information and inconsistent medical terminology use among HPs.

This research defines the types of information required during clinical decision-making as well information delivery preferences of HPs. It has resulted in the development of a new framework for delivering the information HPs need when requiring guidance during complex patient healthcare delivery. The framework developed is universal as the clinical decision making model is based on local and international literature. Only alterations to knowledge are required, rather than changes to code, to reflect local practice and drug availability. Future work could expand system knowledge, develop EHR integration capability, implement identified desired features and further evaluate the usability of the system and whether it is able to improve quality of prescribing.

Chapter 1: Introduction

Advances in medical care have improved the quality of life and extended the average life span by preventing and curing disease, or at the very least alleviating symptoms, and decreasing morbidity and mortality resulting from untreated disease states.(1) Part of this care includes the use of pharmacologically active agents, or medications, and there are thousands of options on the market, with more under development or awaiting approval by governing bodies.(2, 3) In addition to medications, there are non-pharmacological treatment choices to use in place of, or to augment, pharmacological therapy.(4) With so many choices available for any given problem, which treatment is best? How do health professionals (HPs) ensure quality use of medications (QUM)? How can HPs know that their choice is appropriate?

The Australian QUM National Health policy suggests an appropriate medication is one where the following have been taken into account:(5)

- "The individual;
- The clinical condition;
- Risks and benefits;
- Any co-existing conditions;
- Other therapies;
- Monitoring considerations;
- Costs for the individual, the community and the health system as a whole."

The World Health Organization defines appropriate medication use as "when patients receive the appropriate medicines, in doses that meet their own individual requirements, for an adequate period of time, at the lowest cost for both them and the community… (*Inappropriate*) use of medicines is when one or more of these conditions is not met."(6) Inappropriate prescribing can be grouped under two main headings: polypharmacy or overprescribing and underprescribing.

1. **Polypharmacy and Overprescribing**

   Polypharmacy can be defined as the use of more than one medication in a given patient.(7) Overprescribing can be considered as polypharmacy that is inappropriate,(8) although the two terms are often used interchangeably. Risk factors for overprescribing include the prescribing cascade, multiple health care providers, and failure to remove medications when they are no longer indicated.(7, 9, 10)

Whether appropriate or not, polypharmacy is an independent risk factor for a number of adverse outcomes. Drug-drug interaction risk increases with number of medications from 6% with two medications, to 50% with five medications and 100% with eight or more daily medications.(10, 11) Polypharmacy is also an independent risk factor for adverse drug reactions (ADR) due to inappropriate prescribing and for inappropriate prescribing itself.(12-16) Other than adverse patient outcomes, overprescribing increases government spending due to the unnecessary medication cost, hospitalisation and other health care costs associated with ADR and medication mismanagement.(16)

2. **Underprescribing**

   Underprescribing can be defined as "errors of omission of drug therapy likely to be beneficial to the patient which occur for ageist or irrational reasons",(17) and is commonly overlooked by clinicians.(9, 18-20) Underprescribing of indicated medications increases health expenditure due to hospital admissions and readmissions and contributes to patient morbidity, disability and mortality.(21, 22)

QUM is one of Australia's National Medicines Policy central objectives.(5) QUM can be defined as selecting management that considers pharmacological and non-pharmacological options, choosing a suitable medication when necessary and using medications safely and effectively.(5) The goal of the National Strategy for QUM is to "make the best possible use of medicines to improve health outcomes for all Australians".

Despite the involvement of numerous stakeholders including the government, health educators, health care practitioners, providers and supplies, medicines industry, consumers and the media, the prevalence of medication errors and preventable ADR remains high. A 2009 Australian literature review of "Medication Safety in the Community" undertaken by Easton et al., reported that medication errors occurred in up to 88% of people receiving care and ADR occurred in up to 25% patients, with up to 73% being potentially preventable.(23) Outcomes of ADR include general practitioner (GP) practice visits, emergency department visits, hospitalisation or readmission, or death.(23) Patient characteristics that increased ADR risk included female gender, advanced age, multiple medication use (or polypharmacy), medications with a high risk of ADR, and multiple co-morbidities.(23) High risk medications included cardiovascular, antithrombotic, antidepressant, antiepileptic and chemotherapeutic agents.(23)

These findings are not unique to Australia. Thomsen et al. conducted a systematic review of studies regarding preventable ADR prior to 2007 primarily from the USA but also including UK, France,

Northern Ireland, Australia, and Denmark.(24) They found that drug classes most likely to cause ADR included those with high prescription rates (e.g. cardiovascular, analgesic drugs) and those with narrow therapeutic index (e.g. digoxin, hypoglycaemic agents).(24) Most notably, they found medication related errors resulting in preventable ADR were more likely to occur during the prescribing and monitoring phases of health care.(24) Targeting these stages of the health care process can potentially decrease the likelihood of preventable ADR.

Patient complexity is a way of describing patient health status that not only takes into account genetics, biological decline due to age and number of comorbidities, but also cultural, socioeconomic, environmental, behavioral and medical system factors that impact on patient health.(25) These are major determinants of patient care and the complexity of that care.(25, 26) **Complex patients** are more vulnerable to poorer quality of care, including inappropriate prescribing, due to health care fragmentation and associated medical costs, such as hospitalisation.(23, 27) Due to accumulation of disease,(28) increasing number of medication use,(29) and age related changes in PK and PD,(15, 30-32) the **aged** can be thought of as surrogates for "complex patients". They frequently also have other attributes of patient complexity including decreased adherence to medications due to diminished cognitive function or disability.(33, 34)

In addition, **frailty** can adversely affect health outcomes of the aged. Although not clearly defined, frailty is generally accepted as a syndrome involving "multisystem impairment" distinct from the normal ageing process.(35) It has been is associated with increased risk of ADR(36) potentially due to decreased metabolism and conjugation reactions.(37) Frailty has also been associated with poor clinical outcomes(35) including increased risk of falls, mobility loss, functional decline, dementia, disability, hospital admission and death.(35, 38) It is considered a better predictor for biological age than chronological age, and in some cases more useful when making clinical discussions regarding treatment.(39)

As complex patients such as the aged are at the highest risk of inappropriate care and subsequent adverse outcomes, optimisation of therapy in this population group is imperative. In order to assist with therapy choice, or measure its appropriateness, practice-ready tools have been developed including guidelines, indicators, drug monographs, clinical decision support systems (CDSS) and other miscellaneous tools.

The remainder of this chapter discusses sources of information used to guide therapy choice in complex or aged patients and is divided into four sections:

1. Practice Ready Sources that Inform Clinical Decisions
2. Identifying Inappropriate Prescribing for Older People (published paper)
3. A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People (published paper)
4. Summary, Thesis Hypothesis, Aims and Objectives

2.1 Practice Ready Sources that Inform Clinical Decisions

In order to inform clinical decisions and choose an appropriate therapy, HPs are expected to practice evidence-based medicine (EBM), a concept formally presented in 1996 as “a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice”.(40) It is estimated that over 75 trials and 11 systematic reviews are being published daily; with the quantity of medical literature published, keeping up-to-date with the “best external evidence” is almost impossible.(41) Practice ready sources have been developed in order to assist HP in providing evidence-based care to their patients including drug monographs, clinical practice update newsletters and clinical practice guidelines.(42)

Clinical practice guidelines (CPG) are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances”.(43) They have a well-established role in providing practice-ready recommendations to HPs and are an effective way of improving compliance with evidence-based recommendations.(44) The population group a guideline addresses is dependent on the scope and purpose of the guideline – some may be specific to the aged, others may incorporate age-specific considerations/recommendations within the guideline.(45-48) Although each CPG needs to be judged on its own terms, they have been shown to improve the quality of care, reduce inappropriate medication use, improve risk/benefit ratio of treatment offered to patients and improve treatment economy.(46) Despite their appeal, implementation of CPG has not been widespread. Although the level of CPG adherence in Australia has proven difficult to estimate,(49) ten years of guideline development and dissemination experience in the Netherlands reported by Grol, suggested that the average level of adherence was around 67%, depending on type of CPG and its recommendations.(50)

Most criticisms of CPG have surrounded their “cookbook” nature: that they do not take into account individual patient needs and lack guidance regarding complex patients, such as those that are aged,

have multiple disease states, are taking multiple medications or require end of life care.(51-55) CPG generally focus on single disease management, despite the high prevalence of multi-morbidity.(28, 33, 55) A study by Hughes et al involved the application of the UK NICE guidelines to two hypothetical comorbid patients, one with five comorbidities and the other with two.(52) When applied, the first patient was prescribed a minimum of 11 medications with up to 10 others that are routinely recommended, the second patient was prescribed five medications with potentially eight additional medications.(52) Application of CPG that are focused on a single-disease state promote polypharmacy and complex medication regimens which may lead to more harm than benefit.(52)

These frustrations are echoed among HPs caring for complex patients. Calderon et al interviewed Spanish GPs to identify barriers to using EBM in general practice.(56) Their findings suggested that GPs, who equated EBM with following CPG, felt that in addition to time associated with finding, accessing and interpreting appropriate information, that CPG did not allow for therapy individualisation nor did they provide patient type specific information.(56) A focus group study with Irish GPs and pharmacists explored their views on managing patients with multi-morbidity.(57) HPs felt ill-equipped to manage multi-morbid patients and that the single-disease state focus of CPG encouraged polypharmacy which they felt could potentially result in patient harm.(57) Another focus group study of Dutch GPs managing patients with multi-morbidity also suggested that these HPs felt the rigid nature of disease orientated CPG do not allow for patient considerations.(58)

The single disease state orientation of CPG may stem from the evidence available in the literature; exclusion criteria of randomised controlled trials (RCT) indicates that high quality evidence stems from participants who do not have co-morbidities, are not aged, and are not complex.(59) More guidance on how to apply CPG to complex patients is being advocated.(28, 52, 55) Suggestions include electronic cross-referencing of CPG, use of economic modelling techniques to estimate the benefit and harm of treatments and to provide guidance from clinical experts where the evidence base is lacking that is clearly distinguishable from recommendations based on published data.(4, 52)

2.1.1 Aged Specific Tools

There are three major types of tools used to guide or measure quality prescribing specifically tailored to aged patients: explicit criteria, implicit criteria, and miscellaneous (indicators, guidelines, etc.). Below are a description, brief summary and analysis of the types of tools available. These tools are discussed in further detail in the publications forming sections 2 and 3 of this Introduction, in the form of a general overview of these tools and their place in practice and research (1.2 Identifying Inappropriate Prescribing for Older People), and a critical analysis of the most commonly cited tools

in the literature, explicit criteria, and the methods used to develop them (1.3 A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People).

Explicit criteria involve the provision of concise recommendations that do not rely on clinical judgment for implementation.(60) A literature review is often used to generate recommendations upon which experts subsequently are asked to agree. Commonly cited examples of explicit criteria include the Beers' Criteria(61) and STOPP/START criteria although there are other less-well cited examples. (32, 62-69) Using a definitive list of appropriate or inappropriate medications is a simple way of identifying potentially inappropriate medications (PIMs); however, it is that very simplicity for which explicit criteria have been criticised.(70, 71) A recent Australian study reporting interviews with 21 GPs stated that dichotomous methods for identifying PIMs such as explicit criteria were not a useful measure of prescribing appropriateness as they do not take into account the complex interactions between patient, disease state and medication choice.(70)

Implicit criteria involve prompting the user with a series of questions in order to evaluate the appropriateness of a medication; in contrast to explicit criteria, the user is required to use their clinical judgment when coming to a final decision.(60) The most cited example is the Medication Appropriateness Index.(72) Depending on the questions used to prompt the user, implicit criteria are able to address both under- and over-prescribing.(9, 73)

Miscellaneous tools that do not fit into either category include indicators such as ACOVE,(74-76) anticholinergic and sedative burden tools such as the Drug Burden Index(77) and CPG.

CDSS can be successful in improving quality of prescribing measured through adherence to evidence based practice or CPG, (78, 79) decreasing patient harm and improving outcomes;(78, 80-84) however they have been criticized for being difficult to use.(85, 86) Most CDSS are not specific to the aged and contain information primarily applicable the general population.(85) One system developed in Australia assists in medication review and is described below (1.2 Identifying Inappropriate Prescribing for Older People).

Despite shortcomings, CPG and some explicit criteria can help guide choices where indicated and decrease underprescribing. Other aged specific tools mentioned can help identify overprescribing and drug candidates for **deprescribing**. Deprescribing involves the review of all medications a patient is taking, selecting those that require removal or change in dose, and planning the deprescribing process in conjunction with the patient and prescriber.(16, 87) Discontinuation of unnecessary medication is generally not associated with adverse effects or disease recurrence and reportedly results in improved mood and functional status as well as decreased negative outcomes such as

mortality, cognitive impairment, and hospital admission.(88-92) A systematic review of deprescribing trials using different interventions concluded that the clinical effectiveness of deprescribing interventions and their sustainability is conflicting or lacking.(92) Larger high quality studies such as RCTs are required to establish the best method to guide deprescribing although there is some data regarding which medications are likely to cause withdrawal effects and which should be tapered rather than stopped.(92) Although no comprehensive deprescribing guidelines have been developed, there are general guides to assist practitioners on the deprescribing process.(89, 93-96) In addition, Farrell et al. have begun the development, implementation and evaluation of more comprehensive guides for deprescribing in overmedicated aged patients, but have only published case studies thus far.(97-99) Results from the evaluation of these guides will go toward understanding the best way to deprescribe medications.

2.2 Identifying Inappropriate Prescribing for Older People

2.2.1 Author declaration

Declaration by candidate for paper 1 entitled:

Identifying Inappropriate Prescribing for Older People

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from the date indicated below:

Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University
Victoria, Australia

Date: 20/06/2014

The nature and extent of candidate's contribution to the work was:

Nature of contribution	**Extent of contribution**
Contributed to structure of manuscript; identification and review of relevant literature; collaborative preparation of draft and final manuscripts.	45%

Candidate's signature: **Date**: 20/06/2014

The contributions of co-authors to the work were:

Name of co-author	**Nature of Contribution**
Rohan A Elliott	Lead role dictating manuscript structure; identification and review of relevant literature; collaborative preparation of draft and final manuscripts.

Co-author signature: **Date:** 20/06/2014

2.2.2 Manuscript

Identifying Inappropriate Prescribing for Older People

Rohan A Elliott, Paulina Stehlik

ABSTRACT

Older people are at risk of polypharmacy, inappropriate prescribing and adverse drug reactions. Reasons include comorbidities, altered pharmacodynamics and pharmacokinetics, and limited evidence to guide drug therapy decisions, especially for people aged > 75 years. Tools to assist with identifying inappropriate prescribing for older people have been developed. The most well known is the Beers criteria, a list of medications that an expert panel agreed should usually be avoided. Criticism of the Beers criteria and limited applicability outside of North America, led to the development of other tools and a major revision of the Beers criteria in 2012. Since 2008, the Screening Tool of Older Persons' Prescriptions and the Screening Tool to Alert doctors to Right Treatment have gained popularity. Australian indicators and electronic decision support systems have also been developed. This article provides an overview of the tools for identifying (and avoiding) inappropriate prescribing and their application in clinical practice and research.

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BACKGROUND

Prescribing for older people can be challenging and complex. They are more likely to have comorbidities and require multiple medications, increasing the risk of drug–disease and drug–drug interactions. Physiological and pathological changes, such as renal and hepatic impairment, decreased muscle to body fat ratio and decreased homoeostatic reserve impact the pharmacokinetics and pharmacodynamics of medications. There is often limited evidence to guide drug therapy decisions, due to exclusion of older people or people with comorbidities from clinical trials. These factors make older people vulnerable to potentially inappropriate prescribing and increase the risk of adverse drug reactions (ADRs).[1]

Over the last 20 years there has been a focus on identifying inappropriate prescribing for older people. The most well known tool for identifying potentially inappropriate prescribing is the Beers criteria published in 1991.[2] Since then, other tools have been developed and the Beers criteria underwent a major revision in 2012.

This article provides an overview of the tools for identifying (and avoiding) inappropriate prescribing and their application in clinical practice and research.

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DEFINING INAPPROPRIATE PRESCRIBING

The terms 'inappropriate prescribing' and 'inappropriate medication' refer to the use of a medication that is associated with significant risk of an ADR when there is an equal or more effective and lower risk alternative available (including prescribing no drug).[3] Often these terms are prefaced by the word 'potentially', i.e. potentially inappropriate medication (PIM). This reflects limitations of the methods used to identify inappropriate prescribing and that 'appropriateness' of a medication for a patient is often a subjective construct that depends on the quality and relevance of the evidence, viewpoints of the clinician and patient, and the patient's circumstances and treatment goals.

The prevalence of PIM use in older people ranges from 15% to 44%, depending on the criteria used to define PIMs and the population studied.[4] Australian studies have reported similar levels of PIM use (range 19% to 50%).[5-11]

Sometimes a broad definition of 'inappropriate prescribing' is used, which includes failure to prescribe a medication when clinically indicated, failure to prescribe the most suitable and practical dose or dose form, and failure to monitor medication outcomes.[3] When these are included, the prevalence of inappropriate prescribing in older people can be over 90%.[12,13]

IDENTIFYING INAPPROPRIATE PRESCRIBING

There are two methods for identifying inappropriate prescribing: implicit review and explicit criteria (Table 1).

Implicit Review

Implicit review is a patient-specific assessment of the appropriateness of a medication by a clinician with expert knowledge of pharmacotherapeutics in the aged, considering its indication, effectiveness, dosage, drug–drug and drug–disease interactions. Limitations of this method are that it can be time consuming, requires a clinician and access to clinical data, and may have low inter-rater reliability.

Medication Appropriateness Index

The Medication Appropriateness Index (MAI) was developed to standardise implicit review and improve reliability (Table 2).[14,15] The MAI provides operational definitions and instructions for evaluating each aspect of a prescription, but requires expert knowledge and clinical judgement. A score can be generated for each medication and medication regimen, serving as a quantitative measure of prescribing appropriateness. The original MAI did not assess under-prescribing, so the developers created the 'Assessment of Underutilisation' (AOU) tool which can be used in conjunction with the MAI (Table 2).[16] Inter- and intra-rater reliability of the MAI and AOU are reported to be moderate to excellent, depending on the expertise and experience of the reviewers.[14-19]

Table 1. Methods for identifying inappropriate prescribing

Method	Some tools to identify inappropriate prescribing	Advantages	Disadvantages
Implicit (judgment-based)	Medication Appropriateness Index	Addresses all medications	Requires expertise in geriatric medicine
		Addresses multiple aspects of prescribing	Variable inter-rater reliability
		Does not require regular updating	Time consuming (10 min per medication)
Explicit (criterion-based)*	Basger criteria Beers criteria STOPP/START	Relatively quick to use	Need regular updating
		Some criteria do not require clinical data and can be applied to large prescribing databases	Address a limited range of medications
		Can be used as indicators of quality of care	Do not address all aspects of prescribing, e.g. duration of therapy
		Can be integrated into decision support software	Do not take into account patient's clinical situation, e.g. life expectancy
			Significant variation between the different tools (Table 4)
			May not be easily transferable between countries

START = Screening Tool to Alert doctors to Right Treatment. STOPP = Screening Tool of Older Person's Prescriptions.

*Although explicit criteria are often used in research and quality assessments without patient-specific (implicit) review, they are generally designed to be used in combination with implicit review in clinical practice settings.

Table 2. Medication Appropriateness Index*

	Questions	Appropriate 1	Marginally appropriate 2	Inappropriate 3
1	Is there an indication for the drug?	Indicated		Not indicated
2	Is the medication effective for the condition?	Effective		Ineffective
3	Is the dosage correct?	Correct		Incorrect
4	Are the directions correct?	Correct		Incorrect
5	Are the directions practical?	Practical		Impractical
6	Are there clinically significant drug-drug interactions?	Insignificant		Significant
7	Are there clinically significant drug-disease interactions?	Insignificant		Significant
8	Is there unnecessary duplication with other drugs?	Necessary		Unnecessary
9	Is the duration of therapy acceptable?	Acceptable		Not acceptable
10	Is this drug the least expensive alternative compared with others of equal utility?	Least expensive		Most expensive
11	Is there an omission of a needed drug for an active disease or condition?	No drug omitted		Drug omitted

*Original 10-item Medication Appropriateness Index (MAI) plus additional item (question 11) to assess under-utilisation of medication.[14-16] Questions 1 to 10 are answered for each medication and question 11 for each active disease/condition. A rating of: 1 = appropriate medication use; 2 = marginally appropriate medication use; and 3 = inappropriate use. In the original MAI, if question 1 is rated as inappropriate, then 9 and 10 are automatically rated as inappropriate. Modifications to the MAI and its scoring method have been made to improve usability and validity.[13,16-18,21,82]

Although the MAI has good face validity, there has been limited evaluation of its predictive validity (ability to predict adverse outcomes).[12,15] The developers reported an association between MAI scores and health outcomes, but did not control for potential confounders.[20] One study suggested that high MAI scores (poor appropriateness of prescribing) were associated with poor quality of life after adjusting for confounders.[21] Another reported no association between standard MAI scores and self-reported ADRs after adjusting for confounders, but an a priori analysis of a modified (6–item) version of the MAI with greater weighting applied to factors likely to be associated with ADRs (e.g. drug–disease interactions) found a significant association.[13]

Another method that can be used to improve the validity of implicit medication review is to use independent expert clinicians to assess cases of potentially inappropriate prescribing using a validated assessment tool; this tool is time consuming process with variable reliability.[22-24]

Explicit Criteria

Explicit criteria, typically developed by a process of expert consensus, are lists of medications or drug classes that should usually be avoided in older people because of limited effectiveness or the risk of ADR. Some explicit criteria also include statements about appropriate care, such as avoidance of under-prescribing medications with strong evidence for beneficial outcomes and appropriate monitoring of therapy. Advantages of explicit criteria are that they are simple, quick to apply, objective and do not require clinical expertise. Due to their ease of use, several explicit criteria tools have been developed and widely used in studies exploring the prevalence of PIM use (Table 3).[4]

Beers Criteria

The most commonly used of these tools, the Beers criteria, was developed in 1991 by a panel of geriatricians and pharmacists in the USA.[2] The original Beers criteria were designed to guide medication selection in nursing home

Table 3. Some explicit criteria for identifying inappropriate prescribing in older people

Tool and year published	Country of origin	No. of PIM criteria	No. of prescribing omission criteria	No. of monitoring criteria	Size of expert consensus panel	Criteria referenced	Strength of evidence provided
Basger criteria 2012[36]	Australia	18	17	6	15	Some	No
Beers criteria 2012[27]	USA	53	0	0	11	Yes	Yes
French consensus criteria 2007[44]	France	34	0	0	15	No	No
McLeod criteria 1997[43]	Canada	38	0	0	32	No	No
NORGEP criteria 2009[42]	Norway	36	0	0	57	Yes	No
PRISCUS criteria 2010[46]	Germany	32	0	0	26	Yes	No
STOPP and START 2008[32]	Ireland/UK	65	22	0	18	Yes	No
ACOVE-3 2007[60,61]*	USA	16	17	7	12	Yes	No

ACOVE-3 = Assessing Care of Vulnerable Elders, version 3. NORGEP = Norwegian General Practice. PIM = potentially inappropriate medication. START = Screening Tool to Alert doctors to Right Treatment. STOPP = Screening Tool of Older Person's Prescriptions.

*Also includes process indicators (e.g. all vulnerable elders should have an annual medication regimen review) and implicit indicators (e.g. all prescribed drugs should have a clearly defined indication)

residents.[2] These were revised in 1997 and 2003 to facilitate general use.[25,26] The 2003 criteria were divided into two classes: medications that are inappropriate regardless of diagnosis/condition and medications that are inappropriate in the presence of specific disease/conditions.[26]

In 2012, the American Geriatrics Society sponsored a major revision and update of the Beers criteria.[27] The revised criteria differ from earlier versions in several ways. A more robust evidence-based approach, similar to that used for developing practice guidelines, was employed. Draft criteria were released for comment, ratings of the quality of evidence were added, along with strength of each recommendation and summaries of the studies the expert panel used to grade and rate the medications were made available. The revised criteria also include a list of medications that should be used with caution in older people.[27]

The 2012 criteria include 53 medications or drug classes. Medications that are no longer available in the USA, e.g. propoxyphene, and several other medications, e.g. stimulant laxatives, have been removed and new medications, e.g. zolpidem, have been added. Other notable additions include glibenclamide, benztropine, metoclopramide, prazosin, sliding scale insulin, glitazones with heart failure, acetylcholinesterase inhibitors with a history of syncope, and serotonin reuptake inhibitors with falls and fractures. Dabigatran has been listed to be used with caution in people aged > 75 years or with renal impairment.[27]

Criticisms of the Beers criteria and similar 'medications to avoid' lists have been raised, such as:[3,28-31]

- inclusion of drugs that may have a role in older people despite ADR concerns, e.g. amiodarone
- inclusion of drugs that are not available or infrequently used outside the USA
- failure to address other types of inappropriate prescribing, such as under-use of clinically indicated medications, dosing of renally cleared drugs, duration of therapy and drug therapy monitoring
- omission of drugs that are responsible for a significant proportion of ADRs and unplanned hospital admissions, e.g. warfarin.

These issues led to the development of new criteria for identifying inappropriate prescribing in older people. Criteria that are most relevant to the Australian context are the Screening Tool of Older Persons' Prescriptions (STOPP), Screening Tool to Alert doctors to Right Treatment (START) and Australian indicators.[32-36]

STOPP and START Criteria

STOPP comprises 65 criteria addressing commonly used PIMs and drug–drug and drug–disease interactions.[32] It shares a minority of criteria with the Beers criteria: 29 of the 65 STOPP criteria (45%) are common or similar to the 2012 Beers criteria.[37] As well as medications that are usually inappropriate, STOPP includes criteria related to medications that have a valid indication in older people but are frequently associated with adverse medication events (AMEs), e.g. warfarin, opiates.

START comprises 22 criteria identifying medications that are clinically indicated but often under-used, e.g. beta-blockers in chronic stable angina, metformin in type 2 diabetes and warfarin in chronic atrial fibrillation.[32]

The STOPP/START criteria published in 2008 were validated using a consensus process with experts in geriatric pharmacotherapy from Ireland and the UK.[32] The criteria are organised according to body systems or pharmacological groups. Each criterion is referenced but strength of evidence is not provided.

Australian Indicators

The need in Australia for locally developed tools to improve the quality of prescribing for older people has been raised.[38] Based on the UK criteria, prescribing indicators to detect inappropriate prescribing in older hospital inpatients were published in 2001.[33,34,39] These indicators addressed under- and over-prescribing but covered a narrow range of medications. These have not been further developed or updated.

In 2008, Basger et al.[35] published 48 criteria addressing medications frequently prescribed in Australia and common reasons that older Australians seek health care. The criteria were based on Australian references and guidelines but there was no expert consensus process. Some criteria had questionable relevance to the 'oldest old' (aged > 80 years), who are at greatest risk of ADRs. In 2012, these indicators were refined and subjected to a multidisciplinary consensus process that led to removal of 9 criteria, modification of 25 criteria and addition of 2 criteria.[36] Additional information was added for some criteria to assist with their application in the oldest old.

The 41 Basger criteria identify PIMs, under-prescribing and suboptimal monitoring. Although the criteria are explicit, some require clinical judgment (e.g. target blood pressure for patients prescribed antihypertensives) and the authors emphasise that they are intended to be used by health

professionals.[36] The criteria have had limited uptake.[40,41] A study by the developers, using the 2008 version, reported that an average of 18 of the 48 indicators were applicable to 126 patients discharged from a private hospital in Sydney, and that there was an average of seven instances of potentially inappropriate prescribing per patient.[40]

Limitations of Consensus-Derived Criteria

Explicit criteria are usually developed using variations of the Delphi technique, with multiple rounds of survey to achieve consensus among experts on statements about medication use derived from the literature.[2,25-27,32,42-46] A limitation of the Delphi technique is that it yields varying results depending on the number and type of experts, number of rounds of consultation and the way consensus is defined.[4,47] This is one of the reasons for the substantial variation between the explicit criteria published over the years (Table 4).[4,48,49] Other reasons include different patient populations, different methodologies used to select statements for the Delphi survey, and regional differences in medication availability and prescribing patterns.[4] These differences also mean that explicit criteria are often not transferable between practice settings or countries.[8,11,30,37] The overlap of medications included in different explicit criteria is as low as 25%.[29,37,50] This was illustrated in a Tasmanian study that compared the Beers and McLeod criteria in 2345 nursing home residents.[11] Potentially inappropriate prescribing was identified in 38% of patients based on the Beers criteria versus 19% of patients based on the McLeod criteria; only 10% of patients fulfilled both criteria.[11] A comparison of seven explicit criteria tools reported that only long-acting benzodiazepines and tricyclic antidepressants were included in all the criteria.[4] Application of six explicit criteria tools at a geriatric outpatient clinic in Taiwan found that the prevalence of PIM use varied between tools from 24% to 73%.[51]

Other limitations of consensus-derived criteria are that potential conflicts of interest of panel members are rarely declared, and strength of evidence supporting each criterion is usually not provided.[47] (Only the 2012 Beers criteria provided this information.) Most tools do not provide recommendations for safer or more effective alternatives when a PIM is identified, although a recent study addressed this issue for some of the Beers criteria.[52]

Reliability and Validity

To be used in research or clinical practice, tools for identifying inappropriate prescribing need to be reliable and valid.[12] It is assumed that explicit criteria will have excellent reliability because they do not require judgement. However, some criteria require information about the disease or problem being treated or contraindications, and the extraction and interpretation of these data may lead to variability. For most criteria reliability has not been tested. The inter-rater reliability of the STOPP/START tool is reported to be very good, however reliability has only been assessed by the tools' developers.[50]

Explicit criteria developed using consensus processes, such as the Delphi technique will inherently have face and content validity (at least for the country and setting for which they were developed), however the predictive validity of most explicit criteria is uncertain.[29,47] Some studies have reported positive associations between inappropriate prescribing identified by the Beers criteria and mortality, use of health services, AMEs and quality of life, whereas others reported no association.[4,12] Most studies had limitations, such as no assessment of the temporal relationship between prescribing and adverse outcomes and no adjustment for confounders, e.g. polypharmacy.[12]

Explicit criteria tend to have poor sensitivity and specificity when compared to implicit review by an expert. Steinman et al. compared the 2003 Beers criteria with individualised expert review and found poor agreement (kappa = 0.14, a level of agreement slightly better than chance).[48] Another study by the same research team compared three commonly used measures of inappropriate prescribing: 2003 Beers criteria, MAI and polypharmacy (defined as > 8 medications) and reported poor agreement between these measures.[49] Nearly half (46%) of the medications considered inappropriate by the Beers criteria were rated as appropriate by a clinician using the MAI, and only 16% of medications rated as inappropriate using the MAI were considered inappropriate according to the Beers criteria.[49] A recent study reported similar findings.[53] In two Australian studies most patients prescribed amitriptyline (included in the Beers criteria) had a potentially valid indication (neuropathic pain).[10,11]

The STOPP criteria may have better sensitivity and predictive validity. Comparisons between the STOPP and Beers criteria suggest that STOPP identifies more instances of inappropriate prescribing and medication-related hospital admissions, at least in Europe.[50] A prospective study of 600 patients admitted to an Irish hospital found that the STOPP criteria were significantly associated with avoidable ADR-related hospitalisation but the Beers criteria were not.[54] A prospective evaluation in hospitalised patients in Ireland found that the STOPP criteria PIMs were more likely to be the cause of ADR-related hospital admissions than Beers criteria PIMs (91% vs 48%).[55] A prospective study of hospitalised older patients in India found that the Beers criteria were more likely to detect PIM use than the STOPP criteria, but most ADRs were caused by drugs not included in either tool, e.g. insulin, statins, frusemide.[56]

The ability of the STOPP/START criteria to prevent inappropriate prescribing and improve patient outcomes has been tested.[57] Hospitalised patients (n = 400) were randomised to receive usual care (control) or screening by a research physician using the STOPP/START criteria with recommendations provided to attending physicians (intervention). The intervention group had significant improvements in MAI and AOU scores at discharge and 6 months, but there were no significant differences in secondary outcomes (mortality, frequency of hospital readmission or falls).[57] The Beers criteria have been similarly used to prevent inappropriate prescribing.[58] Community pharmacists telephoned prescribers when dispensing software alerted them that a Beers criteria PIM had been prescribed. The PIM was changed to another medication in 24% of cases.

Other Tools

ACOVE Indicators

The Assessing Care of Vulnerable Elders (ACOVE) indicators were developed by the RAND corporation in 2000 and updated for the third time in 2007 (ACOVE-3).[59] It includes almost 400 indicators, of which 70 relate to medication use.[60,61] This tool differs from those discussed above because it focuses on care processes. It also includes explicit criteria related to PIMs, under-prescribing and monitoring drug therapy. The ACOVE indicators were developed by a process of literature evaluation and expert

Table 4. Comparison of some criteria from selected explicit prescribing tools

PIMs	Tool	Statements*
Anticholinergic medications	Beers 2012	-Avoid with delirium, dementia or cognitive impairment -Avoid with chronic constipation -Avoid in men with lower urinary tract symptoms, including benign prostatic hyperplasia, unless used for urinary incontinence -Avoid first-generation antihistamines, antiparkinsonian drugs, antispasmodics (except in short-term palliative care to decrease oral secretions), tricyclic antidepressants
	STOPP 2008	-Avoid anticholinergic antispasmodic drugs with chronic constipation -Avoid to treat extrapyramidal side effects of neuroleptic medications
	Basger 2012	-Patient is not taking medication with significant anticholinergic activity -Patient with dementia is not receiving anticholinergic medication -Patient taking a proton pump inhibitor is not taking a medication that may cause dyspepsia (including anticholinergics) unless prescribed for gastro protection
	ACOVE-3 2007	-No VE should be prescribed medications with strong anticholinergic effects if alternatives are available
Benzodiazepines	Beers 2012	-Avoid for treatment of insomnia, agitation or delirium -Avoid with delirium, dementia or cognitive impairment -Avoid with a history of falls unless safer alternatives are not available
	STOPP 2008	Avoid long-term (> 1 month) use of long-acting benzodiazepines (chlorazepate, chlordiazepoxide, fluazepam, nitrazepam) and benzodiazepines with long-acting metabolites (diazepam)
	Basger 2012	-Patient has not been taking benzodiazepine for > 4 weeks -Patient with chronic obstructive pulmonary disease is not taking benzodiazepines -Patient with a history of falls is not taking psychotropic medications
	ACOVE-3 2007	-If a VE is taking a benzodiazepine (> 1 month), then there should be annual documentation of discussion of risks and attempt to taper and discontinue the benzodiazepine -If a VE reports a history of 2 or more falls (or 1 fall with injury) in the previous year and is taking a benzodiazepine, then there should be documentation of a discussion of related risks and assistance offered to reduce or discontinue benzodiazepine use
Non-benzodiazepine hypnotics (e.g. zopiclone, zolpidem)	Beers 2012	-Avoid chronic use (> 90 days) -Avoid in older adults with dementia or cognitive impairment -Avoid in older adults with a history of falls unless safer alternatives are not available
	STOPP 2008	-Not included
	Basger 2012	-Not included
	ACOVE-3 2007	-Not included
Nitrofurantoin	Beers 2012	-Avoid for long-term suppression; avoid in patients with creatinine clearance < 60 mL/min
	STOPP 2008	-Not included
	Basger 2012	-Patient with a UTI is not receiving nitrofurantoin for prophylaxis or acute treatment
	ACOVE-3 2007	-Not included
Statins	Beers 2012	-Not included
	STOPP 2008	-Not included
	Basger 2012	-Patient with risk factors for statin-induced myopathy is not taking a high dose of a high-potency statin
	ACOVE-3 2007	-Not included
Sulfonylureas	Beers 2012	-Avoid glibenclamide/chlorpropamide
	STOPP 2008	-Avoid glibenclamide/chlorpropamide
	Basger 2012	-Not included
	ACOVE-3 2007	-Not included
Metoclopramide, prochlorperazine	Beers 2012	-Avoid metoclopramide unless for gastroparesis -Avoid prochlorperazine/metoclopramide with parkinsonism -Avoid prochlorperazine with delirium, dementia, cognitive impairment, chronic constipation, lower urinary tract symptoms, including benign prostatic hyperplasia in men
	STOPP 2008	-Avoid prochlorperazine/metoclopramide with parkinsonism
	Basger 2012	-Avoid prochlorperazine
	ACOVE-3 2007	-Not included
Under-prescribing	**Tool**	**Statements**
Atrial fibrillation	START 2008	-Warfarin in the presence of chronic AF, or aspirin where warfarin is contraindicated
	Basger 2012	-Patient with AF is taking an oral anticoagulant or an antiplatelet drug, depending on stroke risk and bleeding risk
	ACOVE-3 2007	-If VE has chronic AF and is at medium- to high-risk for stroke, then anticoagulation should be offered -If VE has chronic AF, medium- to high-risk for stroke, and has a contraindication to anticoagulation, then antiplatelet therapy should be prescribed

continued next page

Table 4. Comparison of some criteria from selected explicit prescribing tools contd

Under-prescribing	Tool	Statements
Statins	START 2008	-Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, where the patient's functional status remains independent for activities of daily living and life expectancy is > 5 years -Statin therapy in diabetes mellitus if coexisting major cardiovascular risk factors present
	Basger 2012	-Patient at high risk of a recurrent cardiovascular event is taking a statin
	ACOVE-3 2007	-If VE with ischaemic heart disease has an LDL-C > 100 mg/dL, then they should be offered cholesterol-lowering medication
Osteoporosis	START 2008	-Bisphosphonates in patients taking maintenance corticosteroid therapy
	Basger 2012	-Patient with osteoporosis is receiving appropriate antiosteoporotic medication
	ACOVE-3 2007	-Not included
Monitoring	**Tool**	**Statements**
ACE inhibitors, diuretics	ACOVE-3 2007	-If VE is prescribed a loop diuretic, then they should have electrolytes checked within 2 weeks after initiation and at least yearly thereafter. -If VE is prescribed an ACE inhibitor, then they should have serum creatinine and potassium monitored within 2 weeks after initiation of therapy and at least yearly thereafter
	Basger 2012	-Not included
Antipsychotics	ACOVE-3 2007	-If VE is started on an antipsychotic drug, then there should be documentation of an assessment of response within 1 month
	Basger 2012	-Not included
Thyroxine	ACOVE-3 2007	-Not included
	Basger 2012	-Patient taking thyroid hormone replacement therapy has had a serum thyroid stimulating hormone measurement within the previous 12 months

ACOVE = Assessing Care of Vulnerable Elders, version 3. PIMs = potentially inappropriate medications. START = Screening Tool to Alert doctors to Right Treatment. STOPP = Screening Tool of Older Person's Prescriptions. VE = vulnerable elder.

*Some statements have been reworded to facilitate comparison

consensus review.[59] There has been little evaluation of their reliability and predictive validity. A number of indicators refer to medications that are not available or rarely used in Australia (e.g. ticlopidine) but there are indicators that would be relevant in most countries. The ACOVE indicators were modified for use in hospital inpatients in the Netherlands and demonstrated excellent inter-rater reliability.[62]

Anticholinergic and Sedative Burden Tools

Medications with anticholinergic or sedative effects have been consistently associated with increased risk of adverse effects in older people. Several tools have been developed to assist with classifying medications according to their anticholinergic and sedative burden.[63-65] Drug burden measured using some of these tools has been associated with adverse outcomes.[63] However, a recent study reported poor agreement between three anticholinergic burden tools and highlighted that these tools require regular updating.[66] Another limitation of these tools and most explicit criteria is that they do not take into account the medication dose.

The drug burden index (DBI) is a novel tool based on the principles of dose–response and cumulative effect.[67] It generates a score based on the dosages of anticholinergic and sedative medications used by the patient relative to the maximum recommended doses for those medications. Medications are included if they have clinically significant anticholinergic or sedative effects documented in the product information, hence the DBI does not require regular updating. The DBI does not provide information about the appropriateness of medications, but several studies have reported that high DBI scores are associated with poor physical performance and cognition in older people.[67-71]

Electronic Decision Support

Decision support systems (DSSs) within prescribing, dispensing or medication review software can assist with identifying potentially inappropriate prescribing.[58,72] Advantages of DSS are that they can incorporate multiple inappropriate prescribing tools and trigger alerts when they are likely to be relevant based on patient data.

An Australian DSS to assist with identifying medication-related problems (MRPs), including inappropriate prescribing, during medication reviews has been developed and commercialised.[73-75] The software uses rules created by an experienced clinical pharmacist to assess patients' medication regimens in the context of their medical history and laboratory data, and flag potential MRPs.[73,74] It has been reported to identify more MRPs than unassisted pharmacist review and the STOPP/START tool.[75,76] However, it does not detect all MRPs and some flagged MRPs are not applicable or clinically relevant to individual patients, so it must be used in conjunction with implicit (expert) review.[75,76] Reliability and predictive validity have not been assessed, and the evidence and strength of evidence underpinning each alert or MRP is not provided.

Another DSS prototype is under development based on evaluation of the needs of prescribers for older people.[77] It aims to assist with prescribing by displaying treatment recommendations for a given disease or symptom, and flagging potential problems based on patient data, including inappropriate or high-risk medications or combinations and problems related to patient factors, e.g. poor dexterity.

APPLICATION OF PRESCRIBING TOOLS

Ideally, a tool used to identify inappropriate prescribing should be easy to use, reliable, based on the most up-to-date evidence, evaluate all aspects of prescribing and be able to predict (and prevent) AMEs. Although no existing tool fulfils all of these requirements, the tools described in this article can be useful in clinical practice and research.[4]

The MAI and AOU have been used to evaluate the impact of interventions to improve quality of prescribing.[57,78,79] However, the time required to use these can be a barrier. The MAI and AOU can also be used by inexperienced clinicians to guide prescribing and medication review, as they provide a clear structure for assessing appropriateness of prescribing, with definitions, instructions and examples. However, because expert knowledge is required, clinicians may need to refer concurrently to resources, such as explicit criteria, clinical guidelines and other decision support tools.

Although explicit criteria are not highly sensitive or specific, they can highlight potentially inappropriate or high-risk prescribing in a patient or in a population. A study reported that patients who were prescribed a Beers PIM were more likely to have other inappropriate prescribing (identified using the MAI) than patients who did not receive a Beers PIM, suggesting that explicit criteria may also have a role as a screening tool to identify patients who may benefit from a medication review.[53] Explicit criteria can also assist prescribers avoid initiating PIMs or high-risk medications. However, explicit criteria cannot replace clinical knowledge, experience and judgment in determining the most appropriate medication for patients.

The Beers criteria (2012) and the Basger criteria (2012) are the most up-to-date explicit criteria, and the revised versions have addressed some of the criticisms of earlier versions. Although several medications have been removed from the 2012 Beers criteria, there are still some that are not used in Australia.[57] The Basger criteria have the advantages of not requiring adaptation and having a focus on commonly treated medical problems and commonly used medications. They also address a range of prescribing problems, such as under-prescribing and monitoring. Limitations of the Basger criteria are that the level of evidence supporting each recommendation is not provided, and they have not been widely used, so usability, reliability and predictive validity are uncertain.

The STOPP/START criteria (2008) are less current, but have some strengths. They are the only explicit criteria for which reliability has been assessed, and they have better predictive validity than the Beers criteria, at least in European countries. They include a broad range of medications, are organised according to body systems or pharmacological groups and address under-prescribing as well as over-prescribing. They appear to have good usability, having been used by investigators in several countries and settings.

The ACOVE indicators (2007) are also less current. They are organised according to disease, cover a range of care processes, including non-drug aspects of disease management and provide a summary of supporting evidence for each indicator. While they have good face and content validity, there is no information about their predictive validity or reliability.

The DBI does not require regular updating and appears to have good predictive validity. A limitation is that it only addresses the use of two drug classes.

Given the small overlap of prescribing criteria included in the various tools, it may be beneficial to combine tools. Incorporating criteria into electronic audit tools or DSS can enhance their usability and efficiency and lead to improved prescribing.[52,58,72,80,81]

CONCLUSION

Tools have been developed to identify potentially inappropriate prescribing in older people. No tool provides an absolute measure of inappropriate prescribing and each has unique strengths and limitations that need to be considered when used in clinical practice and research, and when interpreting studies utilising these tools. Explicit criteria need to be supplemented with clinical judgement when used in clinical practice.

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References

1. Hilmer SN, McLachlan AJ, Le Couteur DG. Clinical pharmacology in the geriatric patient. Fundam Clin Pharmacol 2007; 21: 217-30.
2. Beers MH, Ouslander JG, Rollingher I, Reuben DB, Brooks J, Beck JC. Explicit criteria for determining inappropriate medication use in nursing home residents. Arch Intern Med 1991; 151: 1825-32.
3. Gallagher P, Barry P, O'Mahony D. Inappropriate prescribing in the elderly. J Clin Pharm Ther 2007; 32: 113-21.
4. Chang CB, Chan DC. Comparison of published explicit criteria for potentially inappropriate medications in older adults. Drugs Aging 2010; 27: 947-57.
5. Beer C, Hyde Z, Almeida OP, Norman P, Hankey GJ, Yeap BB, et al. Quality use of medicines and health outcomes among a cohort of community dwelling older men: an observational study. Br J Clin Pharmacol 2011; 71: 592-9.
6. Roughead EE, Anderson B, Gilbert AL. Potentially inappropriate prescribing among Australian veterans and war widows/widowers. Intern Med J 2007; 37: 402-5.
7. King MA, Roberts MS. The influence of the Pharmaceutical Benefits Scheme (PBS) on inappropriate prescribing in Australian nursing homes. Pharm World Sci 2007; 29: 39-42.
8. Pattanaworanate W, Emmerton L, Pulver L, Winckel K. Comparison of prescribing criteria in hospitalised Australian elderly. Pharm Pract 2010; 8: 132-8.
9. Somers M, Rose E, Simmonds D, Whitelaw C, Calver J, Beer C. Quality use of medicines in residential aged care. Aust Fam Physician 2010; 39: 413-16.
10. Widagdo IS, Nyfort-Hansen K, Kowalski S. Prevalence of potentially inappropriate medication use in elderly hospitalised patients. J Pharm Pract Res 2011; 41: 122-5.
11. Stafford AC, Alowayan MS, Tenni PC. Inappropriate prescribing in older residents of Australian care homes. J Clin Pharm Ther 2011; 36: 33-44.
12. Spinewine A, Schmader KE, Barber N, Hughes C, Lapane KL, Swine C, et al. Appropriate prescribing in elderly people: how well can it be measured and optimised? Lancet 2007; 370: 173-84.
13. Lund B, Carnahan RM, Egge JA, Chrischilles EA, Kaboli P. Inappropriate prescribing predicts adverse drug events in older adults. Ann Pharmacother 2010; 44: 957-63.
14. Hanlon JT, Schmader KE, Samsa GP, Weinberger M, Uttech KM, Lewis IK, et al. A method for assessing drug therapy appropriateness. J Clin Epidemiol 1992; 45: 1045-51.
15. Samsa GP, Hanlon JT, Schmader KE, Weinberger M, Clipp EC, Uttech KM, et al. A summated score for the medication appropriateness index: development and assessment of clinimetric properties including content validity. J Clin Epidemiol 1994; 47: 891-6.
16. Jeffery S, Ruby C, Twersky J, Hanlon JT. Effect of an interdisciplinary team on suboptimal prescribing in a long-term care facility. Consult Pharm 1999; 14: 1386-91.
17. Fitzgerald LS, Hanlon JT, Shelton PS, Landsman PB, Schmader KE, Pulliam CC, et al. Reliability of a modified medication appropriateness index in ambulatory older persons. Ann Pharmacother 1997; 31: 543-8.
18. Kassam R, Martin LG, Farris KB. Reliability of a modified medication appropriateness index in community pharmacies. Ann Pharmacother 2003; 37: 40-6.
19. Bregnhoj L, Thirstrup S, Kristensen MB, Sonne J. Reliability of a modified medication appropriateness index in primary care. Eur J Clin Pharmacol 2005; 61: 769-73.
20. Schmader KE, Hanlon JT, Landsman PB, Samsa GP, Lewis IK, Weinberger M. Inappropriate prescribing and health outcomes in elderly veteran outpatients. Ann Pharmacother 1997; 31: 529-33.
21. Olsson IN, Runnamo R, Engfeldt P. Medication quality and quality of life in the elderly, a cohort study. Health Qual Life Outcomes 2011; 9: 95-103.
22. Elliott RA, Woodward MC. Assessment of risk associated with medication-related problems in elderly outpatients. J Pharm Pract Res 2009; 39: 109-13.
23. Krass I, Smith C. Impact of medication regimen reviews performed by community pharmacists for ambulatory patients through liaison with general medical practitioners. Int J Pharm Pract 2000; 8: 111-20.
24. Sorensen L, Grobler MP, Roberts MS. Development of a quality use of medicines coding system to rate clinical pharmacists' medication review recommendations. Pharm World Sci 2003; 25: 212-17.
25. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. Arch Intern Med 1997; 157: 1531-6.
26. Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US Consensus Panel of Experts. Arch Intern Med 2003; 163: 2716-24.

27. American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society updated Beers criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc 2012; 50: 616-31.
28. Roth MT, Weinberger M, Campbell WH. Measuring the quality of medication use in older adults. J Am Geriatr Soc 2009; 57: 1096-102.
29. Levy HB, Marcus EL, Christen C. Beyond the Beers criteria: a comparative overview of explicit criteria. Ann Pharmacother 2010; 44: 1968-75.
30. Scott I, Jayathissa S. Quality of drug prescribing in older patients: is there a problem and can we improve it? Intern Med J 2010; 40: 7-18.
31. O'Mahony D, Gallagher P. Inappropriate prescribing in the older population: need for new criteria. Age Ageing 2008; 37: 138-41.
32. Gallagher P, Ryan C, Byrne S, Kennedy J, O'Mahony D. STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Int J Clin Pharmacol Ther 2008; 46: 72-83.
33. Elliott RA, Woodward MC, Oborne CA. Indicators of prescribing quality in elderly hospital inpatients. Aust J Hosp Pharm 2001; 31: 19-25.
34. Elliott RA, Woodward MC, Oborne CA. Quality of prescribing for elderly hospital inpatients at nine hospitals in Victoria, Australia. J Pharm Pract Res 2003; 33: 101-5.
35. Basger BJ, Chen TF, Moles RJ. Inappropriate medication use and prescribing indicators in elderly Australians: development of a prescribing indicators tool. Drugs Aging 2008; 25: 777-93.
36. Basger BJ, Chen TF, Moles RJ. Validation of prescribing appropriateness criteria for older Australians using the RAND/UCLA appropriateness method. BMJ Open 2012; 2.
37. Dalleur O, Boland B, Spinewine A. 2012 updated Beers criteria: greater applicability to Europe? J Am Geriatr Soc 2012; 60: 2188-9.
38. Bell J, Le Couteur DG, McLachlan AJ, Chen TF, Moles RJ, Basger BJ, et al. Improving medicine selection for older people – do we need an Australian classification for inappropriate medicines use? Aust Fam Physician 2012; 41: 9-10.
39. Oborne CA, Batty GM, Maskrey V, Swift CG, Jackson SH. Development of prescribing indicators for elderly medical inpatients. Br J Clin Pharmacol 1997; 43: 91-7.
40. Basger BJ, Chen TF, Moles RJ. Application of a prescribing indicators tool to assist in identifying drug-related problems in a cohort of older Australians. Int J Pharm Prac 2012; 20: 172-82.
41. Garcia-Gollarte F, Baleriola-Julvez J, Ferrero-Lopez I, Cruz-Jentoft AJ. Inappropriate drug prescription at nursing home admission. J Am Med Dir Assoc 2012; 13: e9-e15.
42. Rognstad S, Brekke M, Fetvelt A, Spigset O, Wyller TB, Straand J. The Norwegian General Practice criteria for assessing potentially inappropriate prescriptions to elderly patients. Scand J Prim Health Care 2009; 27: 153-9.
43. McLeod PJ, Huang AR, Tamblyn RM, Gayton DC. Defining inappropriate practices in prescribing for elderly people: a national consensus panel. CMAJ 1997; 156: 385-91.
44. Laroche ML, Charmes JP, Merle L. Potentially inappropriate medications in the elderly. Eur J Clin Pharmacol 2007; 63: 725-31.
45. Naugler CT, Brymer C, Stolee P, Arcese ZA. Development and validation of an improving prescribing in the elderly tool. Can J Clin Pharmacol 2000; 7: 103-7.
46. Holt S, Schmiedl S, Thürmann PA. Potentially inappropriate medications in the elderly: the PRISCUS List. Dtsch Arztebl Int 2010; 107: 543-51.
47. Marriott J, Stehlik P. A critical analysis of the methods used to develop explicit clinical criteria for use in older people. Age Ageing 2012; 41: 441-50.
48. Steinman M, Rosenthal G, Landefeld CS, Bertenthal D, Kaboli P. Agreement between drugs-to-avoid criteria and expert assessments of problematic prescribing. Arch Intern Med 2009; 169: 1326-32.
49. Steinman MA, Rosenthal GE, Landefeld CS, Bertenthal D, Sen S, Kaboli PJ. Conflicts and concordance between measures of medication prescribing quality. Med Care 2007; 45: 95-9.
50. Lam MP, Cheung BM. The use of STOPP/START criteria as a screening tool for assessing the appropriateness of medications in the elderly population. Expert Rev Clin Pharmacol 2012; 5: 187-97.
51. Chang CB, Chen JH, Wen CJ, Kuo HK, Lu IS, Chiu LS, et al. Potentially inappropriate medications in geriatric outpatients with polypharmacy: application of six sets of published explicit criteria. Br J Clin Pharmacol 2011; 72: 482-9.
52. Hume AL, Quilliam BJ, Goldman R, Eaton C, Lapane KL. Alternatives to potentially inappropriate medications for use in e-prescribing software: triggers and treatment algorithms. BMJ Qual Saf 2011; 20: 875-84.
53. Lund BC, Steinman MA, Chrischilles EA, Kaboli PJ. Beers criteria as a proxy for inappropriate prescribing of other medications among older adults. Ann Pharmacother 2011; 45: 1363-70.
54. Hamilton H, Gallagher P, Ryan C, Byrne S, O'Mahony D. Potentially inappropriate medications defined by STOPP criteria and the risk of adverse drug events in older hospitalized patients. Arch Intern Med 2011; 171: 1013-19.
55. Gallagher P, O'Mahony D. STOPP: application to acutely ill elderly patients and comparison with Beers' criteria. Age Ageing 2008; 37: 673-9.
56. Vishwas HN, Harugeri A, Parthasarathi G, Ramesh M. Potentially inappropriate medication use in Indian elderly: comparison of Beers' criteria and Screening Tool of Older Persons' potentially inappropriate Prescriptions. Geriatr Gerontol Int 2012; 12: 506-14.
57. Gallagher P, O'Connor M, O'Mahony D. Prevention of potentially inappropriate prescribing for elderly patients: a randomised controlled trial using STOPP/START criteria. Clin Pharmacol Ther 2011; 89: 845-54.
58. Monane M, Matthias DM, Nagle BA, Kelly MA. Improving prescribing patterns for the elderly through an online drug utilization review intervention: a system linking the physician, pharmacist, and computer. JAMA 1998; 280: 1249-52.
59. Wenger NS, Roth CP, Shekelle P; ACOVE Investigators. Introduction to the assessing care of vulnerable elders-3 quality indicator measurement set. J Am Geriatr Soc 2007; 55 (suppl 2): S247-S252.
60. Anon. Assessing care of vulnerable elders; 3 quality indicators. J Am Geriatr Soc 2007; 55 (suppl 2): S464-S487.
61. Shrank WH, Polinski JM, Avorn J. Quality indicators for medication use in vulnerable elders. J Am Geriatr Soc 2007; 55 (suppl 2): S373-S382.
62. Wiersma P, Klopotowska J, Smorenburg S, van Kan H, Bijleveld Y, Dijkgraaf M, et al. Quality indicators for in-hospital pharmaceutical care of Dutch elderly patients. Drugs Aging 2011; 28: 295-304.
63. Karimi S, Dharia S, Flora D, Slattum P. Anticholinergic burden: clinical implications for seniors and strategies for clinicians. Consult Pharm 2012; 27: 564-82.
64. Linjakumpu T, Hartikainen S, Klaukka T, Koponen H, Kivelä SL, Isoaho R. A model to classify the sedative load of drugs. Int J Geriatr Psychiatry 2003; 18: 542-4.
65. Parsons C, Haydock J, Mathie E, Baron N, Machen I, Stevenson E, et al. Sedative load of medications prescribed for older people with dementia in care homes. BMC Geriatr 2011; 11: 56.
66. Lertxundi U, Domingo-Echaburu S, Hernandez R, Peral J, Medrano J. Expert-based drug lists to measure anticholinergic burden: similar names, different results. Psychogeriatrics 2013; 13: 17-24.
67. Hilmer SN, Mager DE, Simonsick EM, Cao Y, Ling SM, Windham BG, et al. A drug burden index to define the functional burden of medications in older people. Arch Intern Med 2007; 167: 781-7.
68. Cao YJ, Mager DE, Simonsick EM, Hilmer SN, Ling SM, Windham BG, et al. Physical and cognitive performance and burden of anticholinergics, sedatives, and ACE inhibitors in older women. Clin Pharmacol Ther 2008; 83: 422-9.
69. Gnjidic D, Cumming RG, Le Couteur DG, Handelsman DJ, Naganathan V, Abernethy DR, et al. Drug burden index and physical function in older Australian men. Br J Clin Pharmacol 2009; 68: 97-105.
70. Gnjidic D, Le Couteur DG, Abernethy DR, Hilmer SN. Drug burden index and Beers criteria: impact on functional outcomes in older people living in self-care retirement villages. J Clin Pharmacol 2012; 52: 258.
71. Gnjidic D, Hilmer SN, Blyth FM, Naganathan V, Cumming RG, Handelsman DJ, et al. High-risk prescribing and incidence of frailty among older community-dwelling men. Clin Pharmacol Ther 2012; 91: 521-8.
72. Yourman L, Concato J, Agostini JV. Use of computer decision support interventions to improve medication prescribing in older adults: a systematic review. Am J Geriatr Pharmacother 2008; 6: 119-29.
73. Bindoff IK, Tenni PC, Peterson GM, Kang BH, Jackson SL. Development of an intelligent decision support system for medication review. J Clin Pharm Ther 2007; 32: 81-8.
74. Bindoff I, Stafford A, Peterson G, Kang BH, Tenni P. The potential for intelligent decision support systems to improve the quality and consistency of medication reviews. J Clin Pharm Ther 2012; 37: 452-8.
75. Curtain CM, Bindoff IK, Westbury JL, Peterson GM. An investigation into drug-related problems identifiable by commercial medication review software. Australas Med J 2013; 6: 183-8.
76. Curtain C, Bindoff I, Westbury J, Peterson G. Validation of decision support software for identification of drug-related problems in home medicines reviews [abstract]. Proceedings of the 11th National Conference of Emerging Researchers in Ageing; 2012 Nov 19-20; Brisbane, Queensland. Brisbane: The University of Queensland; 2012; 94-7
77. Stehlik P, Marriott JL, Dürnigl P. Geriatricians', general practitioners', and accredited pharmacists' views of medication management resources: a qualitative study [abstract]. Res Social Adm Pharm 2012; 8: e48-e49.
78. Hanlon JT, Weinberger M, Samsa GP, Schmader KE, Uttech KM, Lewis IK, et al. A randomized, controlled trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy. Am J Med 1996; 100: 428-37.
79. Crotty M, Halbert J, Rowett D, Giles L, Birks R, Williams H, et al. An outreach geriatric medication advisory service in residential aged care: a randomised controlled trial of case conferencing. Age Ageing 2004; 33: 612-17.
80. Buck MD, Atreja A, Brunker CP, Jain A, Suh TT, Palmer RM, et al. Potentially inappropriate medication prescribing in outpatient practices: prevalence and patient characteristics based on electronic health records. Am J Geriatr Pharmacother 2009; 7: 84-92.
81. Smith DH, Perrin N, Feldstein A, Yang X, Kuang D, Simon SR, et al. The impact of prescribing safety alerts for elderly persons in an electronic medical record: an interrupted time series evaluation. Arch Intern Med 2006; 166: 1098-104.
82. Hanlon JT, Schmader KE. The Medication Appropriateness Index at 20: where it started, where it has been, and where it may be going. Drugs Aging 2013; 30: 893-900.

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2.3 A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People

2.3.1 Author declaration

Declaration by candidate for paper 2 entitled:

A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from the date indicated below:

Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University
Victoria, Australia

Date: 20/06/2014

The nature and extent of candidate's contribution to the work was:

Nature of contribution	**Extent of contribution**
Conducted literature search, reviewed articles, preparation of first and final drafts of manuscripts	90%

Candidate's signature: **Date**: 20/06/2014

The contributions of co-authors to the work were:

Name of co-author	**Nature of Contribution**
Adjunct A/Prof Jennifer L Marriott	Advised on literature and assisted with manuscript preparation

Co-author signature: **Date:** 20/06/2014

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REVIEWS

A critical analysis of the methods used to develop explicit clinical criteria for use in older people

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Abstract

Older people are the biggest users of medications and with the majority of the population ageing it is important to ensure that their medications are managed properly. Many have developed explicit criteria in order to assist in making appropriate drugs choices in the older population. This paper explores whether the methods used to develop the currently available explicit criteria for appropriate prescribing in older people are applied appropriately, and if not, whether this invalidates the criteria themselves. The wide spread use of the Delphi technique to develop medical criteria indicates that the technique itself should be evaluated for its suitability in the development of criteria in older people before the criteria are themselves evaluated. A number of criteria have been reviewed and none fulfils the requirements for appropriate development. There is a need for new criteria, with transparent referencing of recommendations and rigorous final evaluation.

Keywords: *clinical practice guideline, Delphi technique, criteria development, older people*

Introduction

Medication use and misuse in older patients is an important issue in medicine due to an ageing population [1], high rates of medicine use in older people [2], an apparent lack of clinical evidence for safe, effective and appropriate medication use in older people [3] or a combination of these. Many have tried to formulate explicit clinical criteria to assist practitioners in making appropriate medication choices. Evidence-based criteria developed specifically for an older population is problematic as they are commonly excluded from well-designed clinical trials [3]. To overcome this, some criteria have been developed using the Delphi technique, a survey technique intended to find consensus among 'experts' [4–8], to assist with formulation of recommendations on suitable treatments in older people. In 2008, O'Mahony and Gallagher [9] published a commentary criticising some of the criteria available at the time for their lack of usability, inability to be generalised and incompleteness including omission of some known instances of inappropriate prescribing and no mention of under-prescribing, drug–drug interactions and duplicate drug therapy. Issues with currently available explicit criteria go much deeper and lie with the development methodology itself. Of interest is the lack consistency between recommendations despite similar development methods [10]. Therefore the question this paper attempts to address is—are the methods used to develop the currently available explicit criteria for appropriate prescribing in older people applied correctly, and if not, is their widespread use justified?

Guidelines, criteria and indicators

Quality assurance is important in health care as it minimises inappropriate prescribing. There is an increasing global demand for clinical guidelines to assist practitioners in delivering the best care for their patients according to the most up-to date evidence [11], and to evaluate their current practices for potential improvement [12]. It is clear that guidelines, medical review criteria and prescribing indicators have different applications in clinical practice (Supplementary

data are available in *Age and Ageing* online, eBox 1), but their development is almost identical—in fact, medical review criteria, including prescribing criteria, (referred to simply as criteria) can be developed specifically to evaluate the appropriateness of medical care, or be derived from explicit clinical guidelines developed to improve the quality of care [13]. How a clinical guideline should be developed is described below; these same principles *should* be applied to the formulation of criteria.

Methods

Search strategy

Prescribing criteria were identified by searching Medline, EMBASE and International Pharmaceutical Abstracts databases using the following terms:

> prescribing appropriateness' or 'medication appropriateness' or 'inappropriate prescribing' or 'inappropriate medication' AND 'screening tool' or 'quality indicator' AND 'elderly' or 'aged' or 'geriatric

Articles were considered if they were written in English, described the development and/or evaluation (validity or reliability) of explicit criteria or evaluated medication appropriateness using a specific explicit criteria tool (subsequent searches were performed to find articles describing the development of the criteria if the development was not found in the original search) regardless of publication date. Criteria developed for a specific setting were excluded (e.g. hospital specific, etc…) for consistency in evaluation and as they are less likely to be widely used. Criteria which were local modifications of identified criteria were not included as this was considered redundant; however, all three versions of the Beers criteria were included due to their widespread reference in the literature.

Subsequent searches were conducted using the same search engines with the 'search term' AND 'validity' or 'reliability (Table 1).

Quality assessment of identified criteria

Processes used in the formulation of clinical criteria

There are three main phases to criteria development; initially there is a need for *a review of scientific literature* and *formulation of the criteria* [11]. Once the criteria have been disseminated and implemented, a final step involves *criteria evaluation* [11]. In this review, we will examine these key sections to evaluate the appropriateness of the methods used to develop explicit criteria.

Literature review

Review of the current scientific evidence is the foundation for producing high quality and acceptable criteria and is preferred to the consensus of expert panels [11].

The evidence should be classified according its power, quality and relevance and therefore whether or not there is strong (or otherwise) evidence for a recommendation given in the criteria; it is generally recommended that this be presented within the criteria as an evidence table [11]. Notably there is no 'gold standard' classification system [14] which may cause confusion for readers. It is therefore important to indicate which system of classification was used.

Formulation of the criteria

The Delphi technique is used in the formulation of explicit criteria to address an area where there is a lack of agreement or where there is incomplete knowledge on the subject matter [11]. Because of the widespread reported use of the Delphi technique to develop criteria, the technique itself should be evaluated for its suitability for the development of criteria before these criteria are themselves evaluated.

An analysis of the Delphi technique

The Delphi technique does not have one set method and has been modified in a variety of ways to suit researcher's aims and objectives [5]. There seems to be no agreement on some key aspects of the Delphi technique, even within each 'version' including the definition of an expert, number of experts used, the number of rounds and the consensus level [5]. The Delphi technique has some advantages over other qualitative research techniques. The most commonly mentioned advantage is the lack of discussion domination by any one panel member, which can occur during conventional face-to-face encounters such as focus groups or brain storming sessions [8]. By using anonymous mail survey participants are not swayed to change their opinion in the presence of a more dominant or 'superior status' panel member and can also change their views in subsequent rounds without 'losing face' [15]. Others argue that panel members may feel pressured to conform to the group's view [6, 16] or that the anonymity of the Delphi technique may give the panel members a lack of accountability for their answers [16–18].

The Delphi technique can potentially result in the production of large quantities of difficult to analyse data [19]; how data are handled should therefore be decided beforehand. If every statement raised by the expert panel members is added for analysis in the subsequent round, the questionnaire could become overly long; however, generalising the statements into categories may result in statements which have considerably deviated from the original intention [5].

The expert must be defined by the researcher *a priori* and as there is no universal definition of an expert, this can prove difficult [5, 17]. There is no guidance on the ideal number of expert panel members required [5]. It has been suggested that the use of a heterogeneous group of experts helps to eliminate the potential for skewed results [4] and selecting panel members through methods other than acquaintance minimises bias [16]. Conflict of interest (COI)

Table 1. Search results of validity and reliability studies

Criteria name	Search term	MedLine		Embase		IPA	
		Total number of articles	Useful articles	Total number of articles	Useful articles	Total number of articles	Useful articles
Beers criteria [31–33]	Beers criteria	5	3	4	No new articles	2	0
STOPP/START [38]	STOPP	21	5	32	1	2	No new articles
	START	575	None	6	No new articles	1	None
McLeod's criteria [34]	McLeod	4	1	992	1	10	None
	McLeod's criteria	0	N/A	99	No new articles	0	N/A
	Canadian Criteria	1	None	0	N/A	0	N/A
NORGEP [30]	NORGEP	0	N/A	125	None	0	N/A
Australian prescribing indicators tool [35]	Australian prescribing indicators tool	0	N/A	0	N/A	0	N/A
	APIT	1	None	1	None	0	N/A
Zhan [52]	Zhan	0	N/A	1	None	0	N/A
French consensus panel list [37]	French consensus panel list	0	N/A	53	None	0	N/A
PRISCUS list [40]	PRISCUS	2	None	2	None	0	N/A
Preventable drug-related morbidity in older adults [39]	Preventable drug-related morbidity in older adults	0	N/A	2	0	0	N/A
Clinically important drug–disease interactions and their prevalence in older adults [53]	Clinically important drug–disease interactions and their prevalence in older adults	0	N/A	1	0	0	N/A
	Clinically important drug–disease interactions	0	N/A	0	N/A	0	N/A
Improving prescribing in the elderly tool (IPET) [36]	IPET	2	No new articles	0	N/A	0	N/A
	Improving prescribing in the elderly tool	1	No new articles	2	No new articles	0	N/A

also needs to be considered, not only for those conducting the Delphi study, but also participating 'experts'. Many panel members do not disclose any COI despite its prevalence [20, 21].

The use of expert opinion in the formulation of criteria can be criticised as the findings may be overstated [5]. Using an expert potentially assumes that the *opinion* of an expert is equivalent to scientific evidence. Although there is a need for peer review, there should be a clear distinction between recommendations derived from a consensus on what scientific evidence means in practice and recommendations derived from personal opinion.

The number of rounds undertaken during development can be influenced by the amount of time it takes to reach consensus [5] although an increased number of rounds may lead to a decreased response rate from panel members [5, 6]. This, or any other reason for the lack of response, can create biased results [19] and alter the validity of the findings [15].

The meaning of consensus should also be established in advance as there is no universally accepted definition; often it is decided *ad hoc* [22]. Consensus can be anywhere from 51 to 100% agreement among panel members, others do not even set a target but suggest that consensus can be 'implied' from the results [16]. Ideally the panel members should come to a consensus, however, if there are time, practical or financial constraints, achieving consensus may not be possible. It is therefore important to ask: what is done with the statements for which no consensus is reached?

The 'test-retest' reliability or precision of an experiment or study design describes the extent that results are reproducible when the study is repeated under the same conditions [19, 23]. The Delphi technique has been criticised for its lack of proven reliability [24]. The results produced from the same initial survey vary depending on the experts chosen and are therefore not reproducible [7, 8].

The Delphi technique is far from a scientific method, with a number of inconsistencies and areas with the potential for bias. More importantly, the information gained from a Delphi technique is not fact. Where data are lacking it is merely a consensus among chosen experts about a given practice at a specific point in time, and does not replace scientific evidence. Jones and Hunter [25] point out the danger of using a consensus of expert opinions in place of science:

> The existence of a consensus does not mean that the "correct" answer has been found – there is the danger of deriving collective ignorance rather than wisdom [25]

Evaluation

Generally, evaluation of criteria refers to evaluation of their 'validity'—does the method used measure whatever it is

intended to measure [23]? As there are a number of types of validity (Supplementary data are available in *Age and Ageing* online, eBox 2), whether or not results obtained using the Delphi technique are 'valid' depends on which type of validity is being considered. The Delphi technique, by definition, assesses face and content validity [23]. However, it is a *consensus* technique and therefore does not ensure that the 'right answer' has been found—it does not measure internal validity of a proposed criteria or prescribing tool. Unless the findings of the consensus can be validated by scientific methods, such as well designed prospective studies, knowing whether or not the 'right' answer has been reached cannot be established [25]. This final part of any criteria formulation, evaluation of whether or not the criteria have achieved their primary goal [11, 14, 26–28], is commonly omitted.

Search results

The MEDLINE search yielded 17 results, of which 2 were appropriate to the review. One was a comparative overview [29] of explicit criteria published in 2010; nine criteria [30–38] were identified from this article. One was the development of Australian indicators [35] also identified in the comparative overview. One other criteria [39] was identified from the references cited by one the Australian indicators. To expand this search, a second search was performed with the following terms: 'inappropriate medications' or 'inappropriate prescribing' or 'medication appropriateness' AND 'elderly' or 'aged' AND 'evaluation' or 'tool' or 'criteria'; this new search yielded 60 results. From this only one additional criterion [40] was identified. Nine [36, 41–48] articles were deemed useful regarding 'validity' and 'reliability'.

The EMBASE search yielded 32 results of which 18 were deemed useful. One identified article was the RASP criteria [49]; however, this was a modified STOPP-list criteria and was therefore not included in the review. Seventeen additional articles described medication appropriateness evaluation with prescribing criteria but used already identified tools. Two [50, 51] articles were deemed useful regarding 'validity' and 'reliability'.

The International Pharmaceutical Abstracts search yielded 282 results. Two new criteria [52, 53] were identified that were not identified in previous searches. No articles were deemed useful regarding 'validity' and 'reliability'.

In total, 14 criteria (Table 2) were identified for quality assessment in this article, and 11 articles (Table 1) were identified regarding validity and reliability.

Discussion

Quality assessment

Literature review

None of the criteria identified by the authors for this critique present their evidence graded according to strength of evidence and presented in an evidence table (Table 2). The STOPP/START tool [38] references their recommendations, but provides no strength of evidence. The NORGEP [30] has some recommendations referenced but they not are categorised according to strength of evidence. The PRISUS List [40] give an example of how the information in the preliminary list was presented to their expert panel, which did list references used; however, this was just an example and not the full list, and no strength of evidence was assigned, nor were any of the final recommendations referenced. All of the other identified criteria (Table 2) merely mention that a literature review was conducted, but give no supporting references [31, 32, 33, 34, 37, 53].

Three criteria give 'severity ratings' or 'significance rating' for the likelihood the listed drug is going to cause a clinically significant problem [32–34]; however, these ratings are based on 'expert consensus' rather than scientific evidence and should be viewed as opinion rather than fact. Beers *et al.* [31] argued, in contrast to current recommendations, that consensus methods 'have several advantages over literature review'; it is noteworthy that they base their initial recommendations on a literature review and then use consensus to conclude which statements from the literature are applicable. None of these recommendations are referenced, nor were the surveys presented to their expert panel. The Australian Prescribing Indicators tool [35] have referenced all of their recommendations, but on closer analysis of the references themselves, they are other explicit criteria for prescribing in older people (many of which have not yet been 'validated'), text books, indicators for quality prescribing and minimal primary literature. The Zhan Criteria [52] used the Beers criteria [32] in order to formulate their own list, forgoing any literature search whatsoever; the IPET tool [36] did the same using McLeod's criteria [34].

The lack of transparency on the literature used calls into question the validity of most of these criteria—are they based on sound evidence or simply informed opinion, and is this acceptable?

Formulation of the criteria

Of the identified criteria (Table 2), the reason for using the Delphi technique is not stated, with three exceptions [36, 38, 39], that state they used this technique to test the face and content validity of their recommendations, and one [30] which states that the Delphi technique is a validation method. Others mentioned that the Delphi technique is a consensus method [32, 33, 37, 53], but none justified the need for it. One research group [40] justifies their use of the Delphi technique because it 'was done for the PIM [*potentially inappropriate medications*] lists that were generated in other countries'—perhaps an argument from popularity. The Beers criteria [31], as mentioned above, suggest that a consensus is more useful in formulation of criteria than a literature review alone because of the different results arising from the literature and narrow application nature of stringent trials.

Table 2. Summary of the methodology used in identified explicit clinical criteria for appropriate prescribing in the elderly

Criteria name	Literature review sources	Sources graded?	Were new recommendations allowed by panel members?	Were accompanying references required?	Were the recommendations referenced?	Number of Delphi rounds?	Number of experts in expert panel?	Heterogeneous group of experts in expert panel? (number of professional types?)	Consensus level?
Beers criteria 1991 [31]	Published guidelines Primary literature Review articles Textbooks	No	Yes	No	No	2	13	Yes (6)	During round 1, a mean score of the Likert scale[a] had to be below 3 with a 95[b] CI[c] to be included in the criteria For round 2, a mean score of the Likert scale[a] had to be above 4.5 with a 95[b] CI[c] to have no limit to dose, duration or frequency of therapy
Beers criteria 1997 [32]	Literature from 1991 Beers criteria [31] Guidelines for used of medications in elderly persons Review articles Opinion articles Controlled trials	No	Yes	No	No	2	6	Yes (2)	Mean score of the Likert scale[a] had to be below 3 with a 90[b] CI[c] to be included in the criteria, a mean score of 3 meant they were resubmitted to the expert panel
Beers criteria 2003 [33]	Primary literature? (unclear)	No	Yes	Yes	No	2 + additional round asking about severity of the potential medication problem	12	Yes (5)	Mean score of the Likert scale 1 had to be below 3 with a 95[b] CI[c] to be included in the criteria, a mean score of 3 meant they were resubmitted to the expert panel
McLeod's criteria [34]	Beers criteria 1991 [31] Standard textbooks Quarterly expert review of drug interactions	No	Yes	No	No	2 (not a true Delphi technique as consensus was not required)	32	Yes (4)	Used a 4 point scale (1 = not significant; 4 = highly significant) to state agreement/disagreement with proposed alternatives from round 1; consensus was not required

Continued

Table 2. Continued

Criteria name	Literature review sources	Sources graded?	Were new recommendations allowed by panel members?	Were accompanying references required?	Were the recommendations referenced?	Number of Delphi rounds?	Number of experts in expert panel?	Heterogeneous group of experts in expert panel? (number of professional types?)	Consensus level?
STOPP/START [38]	British National Formulary	No	Yes	Yes	Yes (most)	2	18	Yes (5)	Mean score of the Likert scale1 had to be below 3 with a 95[b] CI[c] to be included in the criteria, a mean score of 3 meant they were resubmitted to the expert panel
	Text books of geriatric pharmacotherapy								
	Primary literature								
	Reviews including Cochrane reviews								
	Expert consensus or consensus statements								
	Published guidelines								
NORGEP [30]	Beers criteria [31–33]	No	Yes	No	Yes (most)	3	57 first round	Yes (3)	If the IQR[d] fell in the upper third of the VAS[e] then there was agreement that the criteria was relevant and should be included in the criteria, if it was in the lower third of the scale then it was excluded
	Swedish prescribing indicators						50 s round		
	Norwegian-based review							NOTE: one group includes 'random group of GP Norwegian specialists'	
	Other reviews						47 completed all three rounds, hence only data from these panellists was included		
	Primary literature								
	Established textbooks								
	Personal experience								
Australian prescribing	Expert review of evidence	No	N/A	N/A	Yes (most)	N/A	N/A	N/A	N/A
	Reference textbooks								

indicators tool [35][f]	International literature Australian consensus documents Clinical practice guidelines for medication use in the elderly Other prescribing criteria								
Zhan [52]	None	N/A	No	N/A	No	2	7	Yes (3)	Not defined
French Consensus panel list [37]	Prescribing criteria and guidelines for prescribing in the elderly	No	Yes	No	No	2	15	Yes (5)	Mean score of the Likert scale[a] of 1–2 meant the criteria were included, 4–5 meant they were excluded, 3 meant they were resubmitted to the expert panel
PRISCUS list [40]	Prescribing criteria developed by other countries	No	Yes	No	Yes in list provided to panel members	2	38	Yes (8)	Mean score of the Likert scale[a] had to be below 3 with a 95[b] CI[c] to be included in the criteria; a mean score of 3 meant they were resubmitted to the expert panel
	Primary literature Reviews including Cochrane reviews				No in final list				
Preventable drug-related morbidity in older adults [39]	Peer-reviewed medical and pharmacy articles Referenced texts	No[b]	Yes	No	No	2	7	Yes (2)	4/7 members had to agree on the position statement
Clinically important drug–disease interactions and their prevalence in older adults [53]	Primary literature Reviews Textbooks Personal experience	No	Yes	No	No	2	9	Yes (2)	Mean score of the Likert scale[g] had to be above 4 with a 95[b] CI[c] to be included in the criteria; a mean score of 3–4 meant they were resubmitted to the expert panel
Improving prescribing in the elderly tool (IPET) [36][f]	None	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A

[a]Likert scale: 1, strongly agree; 5, strongly disagree; 3, equivocal (STOPP/START included 0, unable to offer an opinion).
[b]Concise inclusion criteria for references to be used was listed.
[c]CI, confidence interval.
[d]IQR, inter-quartile range,
[e]Visual analogue scale: a 100 mm scale where 0, highly irrelevant, 100, highly relevant.
[f]IPET and the Australian prescribing indicators tool did not use the Delphi technique to develop their tool.
[g]Likert scale: 1, definitely not serious; 5, definitely serious.

There are a few issues that appear in the identified literature in the application of the Delphi technique. The Beers criteria 1997 [32] and 2003 [33] used face-to-face meetings as their second round to arrive at a consensus, which removed any anonymity. Management of data such as additional recommendations proposed by the expert panel was handled differently—some added *all* the statements gathered from the expert panel [30, 32, 33], others did not specifically mention, or were ambiguous about, how they dealt with the data collected [30, 32, 34]. The definition of consensus also greatly varied among the identified criteria and whether consensus was reached during all studies is not entirely clear (Table 2). Some reached a full consensus by the conclusion of the study [30, 37–39], some do not explicitly state if they reached a consensus on all of the statements [32, 53], some stated that a consensus was not reached and seem to exclude the statements altogether [52], while others listed them separately so it was clear that a consensus could not be reached [31, 34, 40]. Also, many of the identified criteria did not give a COI statement [31, 32, 34, 36, 39, 52, 53], some made a COI statement on behalf of the researchers [30, 33, 35, 37, 40], none gave a COI statement on behalf of the experts involved.

Evaluation

The majority of the identified criteria have not undergone any formal evaluation. The authors of the STOPP/START tool [38] have, however, shown that the STOPP/START criteria have good inter-rater reliability among 9 physicians from 6 European countries [48] and among 10 pharmacists from both hospital and community settings [46]. O'Mahony *et al.* [51] conducted a prospective randomised controlled trial using the STOPP/START criteria to evaluate the medications of 200 hospitalised aged patients and make subsequent recommendations with respect to medication changes, while the other 200 received usual hospital care. The outcome of this trial was a significant improvement in the medication appropriateness index (MAI) and assessment of underutilisation of medication scores in the STOPP/START arm. As this trial did not measure patient outcomes and the ability of the MAI to predict adverse outcomes has not been fully established [50], it cannot be conclusively stated that the STOPP/START criteria have internal validity.

The Beers criteria have been used to analyse medication use in number of health care settings to evaluate the relationship between adverse drug reactions (and associated outcomes such as hospitalisation, morbidity, death, etc ...) and potentially inappropriate medication (PIM) use; so far only a correlation between the two can be established [42, 54, 55]. Notably, explicit criteria are commonly used for retrospective evaluation of the prevalence of PIMs in a variety of settings [29]; however, none of the criteria (to date) has been validated to show that they are capable of identifying *all* PIMs. Therefore the prevalence of PIMs in a given situation measured using explicit criteria can be skewed depending on which criteria are used. This has been demonstrated by Steinman *et al.* [56] who compared the types of PIMs identified by the Beers criteria, Zhan criteria and their own expert pharmacist-physician panel—they concluded that there was a wide variety of PIMs identified by all three measures indicating that no one measure was capable of identifying all PIMs. These types of results were already demonstrated in another study by Steinman *et al.* [57] where the group compared the number of PIMs identified using the Beers criteria, MAI and polypharmacy (≥9 medications as a marker of PIM).

Conclusion

There are a number of issues with the methods used in the development of criteria for prescribing in older people. The main issues concern the presentation of results from the Delphi technique with no distinction between consensus on the 'scientific literature' and 'expert opinion', a lack of COI reporting on behalf of the expert panel members, and a lack of final evaluation of the published explicit criteria. This analysis of the methods used in development suggests that widespread use of most criteria may not be justified.

Key points

- Clinical criteria development needs to be reviewed to ensure the validity of information presented.
- The Delphi technique is used in the development of most clinical criteria but the findings are not presented appropriately.
- There is a need for a new criteria, with a transparent methodology, well referenced recommendations, an evidence table, and subsequent evaluation.

Conflicts of interest

None declared.

Supplementary data

Supplementary data mentioned in the text is available to subscribers in *Age and Ageing* online.

References

1. Australian Bureau of Statistics. Population by age and sex, Australian states and territories. Canberra: Australian Government, June 2010.
2. McLennan W. National Health Survey: use of medications, Australia. In: Bo A, ed. Statistics. Canberra: Australian Bureau of Statistics, 1995.
3. Van Spall HGC, Toren A, Kiss A, Fowler RA. Eligibility criteria of randomized controlled trials published in high-impact general medical journals. JAMA 2007; 297: 1233–40.

4. Grant JS, Kinney MR. Using the Delphi technique to examine the content validity of nursing diagnoses. Nurs Diagn 1992; 3: 12–22.
5. Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. Aust J Adv Nurs 2006; 53: 205–12.
6. Keeney S, Hasson F, McKenna HP. A critical review of the Delphi technique as a research methodology for nursing. Int J Nurs Stud 2001; 38: 195–200.
7. McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs 2000; 32: 1008–15.
8. Williams PL, Webb C. The Delphi technique: a methodological discussion. Aust J Adv Nurs 1994; 19: 180–6.
9. O'Mahony D, Gallagher P. Inappropriate prescribing in the older population: need for new criteria. Age Ageing 2008; 37: 138–41.
10. Chang C-B, Chan D-C. Comparison of published explicit criteria for potentially inappropriate medications in older adults. Drugs Aging 2010; 27: 947–57.
11. National Health and Medical Research Council. A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines. Canberra: National Health and Medical Research Council, 1998; 1–88.
12. Field MJ, Lohr KN, eds. Clinical Practice Guidelines. Washington, DC: National Academy Press, 1990.
13. Grimshaw J, Russell I. Achieving health gain through clinical guidelines. I: developing scientifically valid guidelines. Qual Health Care 1993; 2: 243–8.
14. Culleton B. Development and limitations of clinical practice guidelines. In: Parfrey P, Barrett B, eds. Clinical Epidemiology: Practice and Methods. New York: Humana Press, 2009; 1–11.
15. Beretta R. A critical review of the Delphi technique. Nurse Res 1996; 3: 79–89.
16. Powell C. The Delphi technique: myths and realities. Aust J Adv Nurs 2003; 41: 376–82.
17. Goodman CM. The Delphi technique: a critique. Aust J Adv Nurs 1987; 12: 729–34.
18. McKenna HP. The Delphi technique: a worthwhile research approach for nursing? Aust J Adv Nurs 1994; 19: 1221–5.
19. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. Aust J Adv Nurs 2000; 32: 1008–15.
20. Williams MJ, Kevat DAS, Loff B. Conflict of interest guidelines for clinical guidelines. Med J Aust 2011; 195: 442–5.
21. Neuman J, Korenstein D, Ross JS, Keyhani S. Prevalence of financial conflicts of interest among panel members producing clinical practice guidelines in Canada and United States: cross sectional study. Br Med J 2011.
22. Bowles N. The Delphi technique. Nurs Stand 1999; 13: 32–6.
23. Fitzner K. Reliability and validity: a quick review. Diabetes Educat 2007; 33: 775–80.
24. Sackman H. Delphi Critique: Expert Opinion, Forecasting, and Group process. MA: Lexington Books, 1975.
25. Jones J, Hunter D. Consensus methods for medical and health services research. Br Med J 1995; 311: 376–80.
26. Harris JS. Development, use, and evaluation of clinical practice guidelines. J Occup Environ Med 1997; 39: 23–34.
27. Roche N, Durieux P. Clinical practice guidelines: from methodological to practical issues. Intensive Care Med 1994; 20: 593–601.
28. Miller M, Kearney N. Guidelines for clinical practice: development, dissemination and implementation. Int J Nurs Stud 2004; 41: 813–21.
29. Levy HB, Marcus E-L, Christen C. Beyond the Beers criteria: a comparative overview of explicit criteria. Ann Pharmacother 2010; 44: 1968–75.
30. Rognstad S, Brekke M, Fetveit A, Spigset O, Wyller TB, Straand J. The Norwegian General Practice (NORGEP) criteria for assessing potentially inappropriate prescriptions to elderly patients. Scand J Prim Health Care 2009; 27: 153–9.
31. Beers MH, Ouslander JG, Rollingher I, Reuben DB, Brooks J, Beck JC. Explicit criteria for determining inappropriate medication use in nursing home residents. UCLA division of geriatric medicine. Arch Intern Med 1991; 151: 1825–32.
32. Beers MH. Explicit criteria for determining potentially inappropriate medication use by the elderly. An update. *Arch Intern Med* 1997; 157: 1531–6.
33. Fick DM, Cooper JW, Wade WE, Waller JL, Maclean JR, Beers MH. Updating the Beers criteria for potentially inappropriate medication use in older adults: results of a US consensus panel of experts. Arch Intern Med 2003; 163: 2716–24.
34. McLeod PJ, Huang AR, Tamblyn RM, Gayton DC. Defining inappropriate practices in prescribing for elderly people: a national consensus panel. Can Med Assoc J 1997; 156: 385–91.
35. Basger BJ, Chen TF, Moles RJ. Inappropriate medication use and prescribing indicators in elderly Australians: development of a prescribing indicators tool. Drugs Aging 2008; 25: 777–93.
36. Naugler CT, Brymer C, Stolee P, Arcese ZA. Development and validation of an improving prescribing in the elderly tool. Can J Clin Pharmacol 2000; 7: 103–7.
37. Laroche M-L, Charmes J-P, Merle L. Potentially inappropriate medications in the elderly: a French consensus panel list. Eur J Clin Pharmacol 2007; 63: 725–31.
38. Gallagher P, Ryan C, Byrne S, Kennedy J, O'Mahony D. STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation. Int J Clin Pharmacol Therapeut 2008; 46: 72–83.
39. Mackinnon N. Preventable drug-related morbidity in older adults 1. Indicator development. J Manag Care Pharm 2002; 8: 365–71.
40. Holt S, Schmiedl S, Thrmann P. Potentially inappropriate medications in the elderly: the PRISCUS list. Dtsch Ärztebl Int 2010; 107: 543–51.
41. Barnett K, McCowan C, Evans JMM, Gillespie ND, Davey PG, Fahey T. Prevalence and outcomes of use of potentially inappropriate medicines in older people: cohort study stratified by residence in nursing home or in the community. Qual Health Care 2011; 20: 275–81.
42. Jano E, Aparasu RR. Healthcare outcomes associated with Beers' criteria: a systematic review. Ann Pharmacother 2007; 41: 438–47.
43. Fillenbaum G, Hanlon J, Landerman L *et al*. Impact of inappropriate drug use on health services utilization among representative older community-dwelling residents. Am J Geriatr Pharmacother 2004; 2: 92–101.
44. Hamilton H, Gallagher P, Ryan C, Byrne S, O'Mahony D. Potentially inappropriate medications defined by STOPP criteria and the risk of adverse drug events in older hospitalized patients. Arch Intern Med 2011; 171: 1013–9.

45. Gallagher P, O'Connor MN, O'Mahony D. Prevention of potentially inappropriate prescribing for elderly patients: a randomized controlled trial using STOPP/START criteria. Clin Pharmacol Therapeut 2011; 89: 845–54.
46. Ryan C, O'Mahony D, Byrne S. Application of STOPP and START criteria: interrater reliability among pharmacists. Ann Pharmacother 2009; 43: 1239–44.
47. Gallagher P, O'Mahony D. STOPP (Screening Tool of Older Persons potentially inappropriate Prescriptions): application to acutely ill elderly patients and comparison with Beers' criteria. Age Ageing 2008; 37: 673–9.
48. Gallagher P, Topinkova E, Maldova P *et al*. Inter-rater reliability of STOPP (Screening Tool of Older Persons' Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment) criteria amongst physicians in six European countries. Age Ageing 2009; 38: 603–6.
49. Van Der Linden LR, De Keulenaer J, Quanten A *et al*. RASP criteria. Content validation and inter-rater variability among Belgian pharamcists. Int J Clin Pharm 2011; 33: 426.
50. Lund B, Carnahan RM, Egge JA, Chrischilles EA, Kaboli P. Inappropriate prescribing predicts adverse drug events in older adults. Ann Pharmacother 2010; 44: 957–63.
51. O'Mahony D, Gallagher P, Ryan C *et al*. STOPP and START criteria: a new approach to detecting potentially inappropriate prescribing in old age. Eur Geriatr Med 2010; 1: 45–51.
52. Zhan C, Sangl J, Bierman AS *et al*. Potentially inappropriate medication use in the community-dwelling elderly. J Am Med Assoc 2001; 286: 2823–9.
53. Lindblad C, Hanlon J, Gross C *et al*. Clinically important drug-disease interactions and their prevalence in older adults. Clin Therapeut 2006; 28: 1133–43.
54. Chang C-M, Liu P-YY, Yang Y-HK, Yang Y-C, Wu C-F, Lu F-H. Use of the Beers criteria to predict adverse drug reactions among first-visit elderly outpatients. Pharmacotherapy 2005; 25: 831–8.
55. Harugeri A, Joseph J, Parthasarathi G, Ramesh M, Guido S. Potentially inappropriate medication use in elderly patients: a study of prevalence and predictors in two teaching hospitals. J Postgrad Med 2010; 56: 186–91.
56. Steinman M, Rosenthal G, Landefeld CS, Bertenthal D, Kaboli P. Agreement between drugs-to-avoid criteria and expert assessments of problematic prescribing. Arch Intern Med 2009; 169: 1326–32.
57. Steinman MA, Rosenthal GE, Landefeld CS, Bertenthal D, Sen SKaboli PJ. Conflicts and concordance between measures of medication prescribing quality. Med Care 2007; 45: 95–9.

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2.4 Summary, Thesis Hypothesis, Aims and Objectives

Pharmacological and non-pharmacological therapies are able to prevent, cure or alleviate the symptoms of disease. Appropriate choice of therapy will depend on the individual, the condition being treated and available options. Choice can be complicated by patient complexity such as multi-morbidity, age and frailty. EBM should be used to guide clinical decision-making regarding the best therapy for a given patient; however, the amount of new evidence being published makes keeping up-to-date with published literature an almost impossible task for HPs.

Tools have been developed that put published literature into practice-ready forms. CPG have proven effective at improving health outcomes when implemented, but have been criticised for their single-disease state focus that is not compatible with the level of multi-morbidity seen in practice. Aged specific tools have also been developed and can be used to identify PIMs, safe and effective medications that can be used in the aged, or to measure quality of prescribing. Explicit criteria are quick and simple to use due to their explicit nature, but only cover medications examined by the developers. Most do not address aspects that dictate appropriateness of prescribing, such as drug-drug interactions, drug-disease interactions, monitoring requirements and affordability. More importantly the consensus method is used to develop most explicit criteria, without referencing and strength of evidence of recommendations and lack of conflict of interest statements for those on the consensus panel, call into question the reliability and validity of the recommendations[1]. Implicit criteria, on the other hand, are able to address all medications and factors missed by explicit criteria but are time consuming to use and rely on user knowledge to answer the questions they pose.

In general, tools that are simple do not cover all the complexities considered when choosing an 'appropriate' medication, whereas those that are comprehensive are impractical to use at the point of care. CDSS are able to overcome some of these barriers by simplifying comprehensive tools so that only relevant information is displayed or are able to take into account patient complexity such as multi-morbidity; however, at the time of writing, systems that address complex patients, such as the aged, are limited number and scope.

The **overall aim** of this research was to identify HP information needs when delivering healthcare to complex patients, such as the aged.

[1] The 2012 Beers' Criteria, published after the"A Critical Analysis of the Methods Used to Develop Explicit Clinical Criteria for Use in Older People" manuscript acceptance, has addressed many of these concerns.

The **specific aims** of this research are:

1. To determine satisfaction with currently available information sources;
2. To explore the requirements of an information delivery framework that would meet HPs needs, as defined by key HPs (geriatricians, GPs and accredited pharmacists);
3. To develop the information delivery framework based on additional requirements defined by;
    a. Exploring past successes and failures;
    b. Examining the clinical decision making process;
4. To pilot test the developed information delivery framework and
    a. Define areas for improvement;
    b. Further define requirements for an information delivery framework that assists HPs in making clinical decisions in complex patients, such the aged.

The **hypothesis** of this research was that HPs' information needs were not currently being met and would require the identification, development and testing of an information delivery framework that would address their needs.

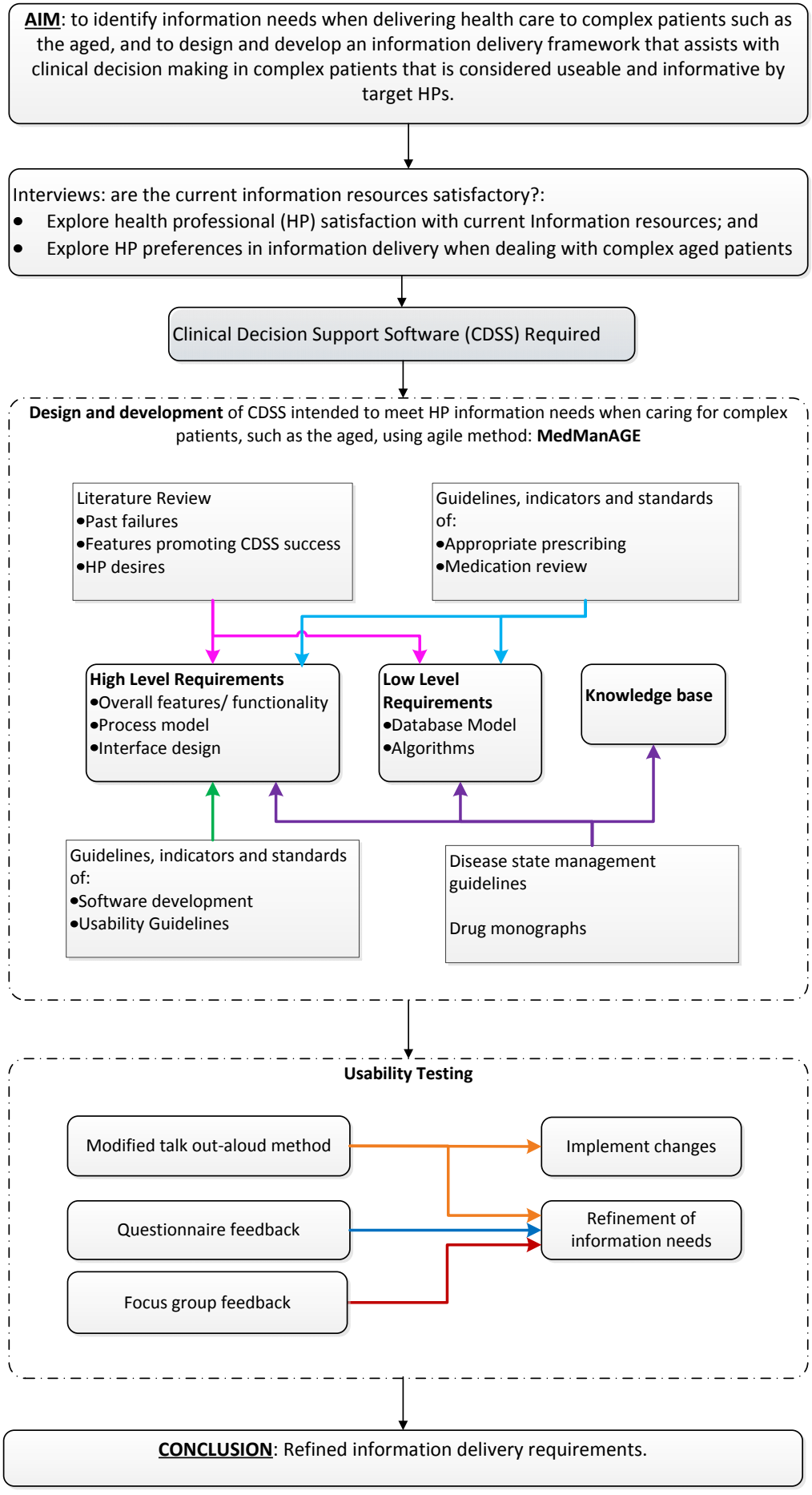
The research consisted of three phases with the following objectives:

Phase 1: Definition of information delivery framework requirements based on HP interviews and literature review;

Phase 2: Information delivery framework development, including detailed design and knowledge acquisition;

Phase 3: Information delivery framework usability evaluation by potential users and requirement refinement.

2.5 Research Overview



2.6 References

1. Bunker JP. The role of medical care in contributing to health improvements within societies. International Journal of Epidemiology. 2001;30(6):1260-3.
2. Vaughan G. The Australian drug regulatory system. Australian Prescriber. 1995;18(5):124-7.
3. Therapeutic Goods Administration. Australian Register of Therapeutic Goods. World Wide Web: Australian Government Department of Health; 2013 [updated 9th April 2014; cited 2014]; Available from: http://www.tga.gov.au/industry/artg.htm.
4. Guthrie B, Payne K, Alderson P, McMurdo ME, Mercer SW. Adapting clinical guidelines to take account of multimorbidity. Br Med J. 2012;345(e6341).
5. Department of Health and Ageing. The National Strategy for Quality Use of Medicines: Plain English Edition. Canberra: Commonwealth of Australia; 2002.
6. Holloway K, van Dijk L. Rational use of medicines. The world medicines situation 2011. 3rd ed. Switzerland: World Health Organization; 2011.
7. Salazar JA, Poon I, Nair M. Clinical consequences of polypharmacy in elderly: expect the unexpected, think the unthinkable. Expet Opin Drug Saf. 2007;6(6):695-704.
8. Zarowitz BJ. Medication overuse and misuse. Geriatr Nurs. 2006;27(4):204-6.
9. Hanlon JT, Schmader KE, Ruby CM, Weinberger M. Suboptimal prescribing in older inpatients and outpatients. J Am Geriatr Soc. 2001;49(2):200-9.
10. Wooten J, Galavis J. Polypharmacy. Keeping the elderly safe. RN. 2005;68(8):44-50.
11. Lai S-W, Liao K-F, Liao C-C, Muo C-H, Liu C-S, Sung F-C. Polypharmacy correlates with increased risk for hip fracture in the elderly: a population-based study. Medicine. 2010;89(5):295-9.
12. Perri M, 3rd, Menon AM, Deshpande AD, Shinde SB, Jiang R, Cooper JW, et al. Adverse outcomes associated with inappropriate drug use in nursing homes. Ann Pharmacother. 2005;39(3):405-11.
13. Chang C-M, Liu P-YY, Yang Y-HK, Yang Y-C, Wu C-F, Lu F-H. Use of the Beers criteria to predict adverse drug reactions among first-visit elderly outpatients. Pharmacotherapy. 2005;25(6):831-8.
14. Fialova D, Topinkova E, Gambassi G, Finne-Soveri H, Jonsson PV, Carpenter I, et al. Potentially Inappropriate Medication Use Among Elderly Home Care Patients in Europe. J Am Med Assoc. 2005;293(11):1348-58.
15. Le Couteur DG, Hilmer SN, Glasgow N, Naganathan V, Cumming RG. Prescribing in older people. Aust Fam Physician. 2004;33(10):777-81.
16. Woodward MC. Deprescribing:achieving better health outcomes for older people through reducing medications. J Pharm Pract Res. 2003;33(3):323-8.
17. Gallagher P, Ryan C, Byrne S, Kennedy J, O'Mahony D. STOPP (Screening Tool of Older Person's Prescriptions) and START (Screening Tool to Alert doctors to Right Treatment). Consensus validation. Int J Clin Pharmacol Therapeut. 2008;46(2):72-83.
18. Rochon PA, Gurwitz JH. Prescribing for Seniors: Neither Too Much nor Too Little. J Am Med Assoc. 1999;282(2):113-5.
19. McLeod PJ. A complex conspiracy against the elderly: inappropriate prescribing. Can J Clin Pharmacol. 2000;7(2):85-6.
20. Lang PO, Hasso Y, Drame M, Vogt-Ferrier N, Prudent M, Gold G, et al. Potentially inappropriate prescribing including under-use amongst older patients with cognitive or psychiatric co-morbidities. Age Ageing. 2010;39(3):373-81.
21. Halczli A, Woolley AB. Medication Underdosing and Underprescribing: Issues That May Contribute to Polypharmacy, Poor Outcomes. Formulary Journal. 2013;48(6):193-5.
22. Cherubini A, Corsonello A, Lattanzio F. Underprescription of beneficial medicines in older people: causes, consequences and prevention. Drugs Aging. 2012;29(6):463-75.
23. Easton K, Morgan T, Williamson M. Medication Safety in the Community: A Review of the Literature. Sydney: National Prescribing Service; 2009.

24. Thomsen LA, Winterstein AG, Søndergaard B, Haugbølle LS, Melander A. Systematic review of the incidence and characteristics of preventable adverse drug events in ambulatory care. Ann Pharmacother. 2007;41(9):1141-426.
25. Safford MM, Allison JJ, Kiefe CI. Patient Complexity: More Than Comorbidity. The Vector Model of Complexity. J Gen Intern Med. 2007;22(Supp 3):382-90.
26. Sieben-Hein D, Steinmiller EA. Working with Complex Care Patients. J Ped Nurse. 2005;20(5):389-95.
27. Australian Medical Association. AMA Chronic Disease Plan: Improving Care for Patients with Chronic and Complex Care Needs – Revised 2012. World Wide Web: 2010.
28. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study. Lancet. 2012;380(9836):37-48.
29. Morgan TK, Williamson M, Pirotta M, Stewart K, Myers S, Barnew J. A national census of medicines use: a 24-hour snapshot of Australians aged 50 years and older. Med J Aust. 2012;196(1):50-3.
30. Corsonello A, Pedone C, Antonelli Incalzi R. Age-related pharmacokinetic and pharmacodynamic changes and related risk of adverse drug reactions. Curr Med Chem. 2010;17(6):571-84.
31. Cusack BJ. Pharmacokinetics in older persons. Am J Geriatr Pharmacother. 2004;2(4):274-302.
32. McLeod PJ, Huang AR, Tamblyn RM, Gayton DC. Defining inappropriate practices in prescribing for elderly people: a national consensus panel. Can Med Assoc J. 1997;156(3):385-91.
33. Australian Bureau of Statistics. Disability, Ageing and Carers, Australia: Summary of Findings, 2012: Older People - Long term health conditions. Canberra: Australian Government; 2012 [updated 16 April 2014; cited 2014 11 May]; Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/682B6E1F8ACC3D5DCA257C21000E5085?opendocument.
34. Australian Bureau of Statistics. Disability, Ageing and Carers, Australia: Summary of Findings, 2012: Older People - Assistance. Canberra: Australian Government; 2012 [updated 16 April 2014; cited 2014 11 May]; Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/2BD5F57AD992C66CCA257C210011AD70?opendocument.
35. van Kan GA, Rolland Y, Houles M, Gillette-Guyonnet S, Soto M, Vellas B. The Assessment of Frailty in Older Adults. Clin Geriatr Med. 2010;26(2):275-86.
36. Routledge PA, O'Mahony MS, Woodhouse KW. Adverse drug reactions in elderly patients. Br J Clin Pharmacol. 2004;57(2):121-6.
37. Kinirons MT, O'Mahony MS. Drug metabolism and ageing. Br J Clin Pharmacol. 2004;57(5):540-4.
38. Gobbens RJ, Luijkx KG, Wijnen-Sponselee MT, Schols JM. Toward a conceptual definition of frail community dwelling older people. Nurs Outlook. 2010;58(2):76-86.
39. Slaets JPJ. Vulnerability in the elderly: frailty. Med Clin North Am. 2006;90(4):593-601.
40. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. Br Med J. 1996;312(7023):71-2.
41. Bastian H, Glasziou P, Chalmers I. Seventy-Five Trials and Eleven Systematic Reviews a Day: How Will We Ever Keep Up? PLoS Med. 2010;7(9).
42. Therapeutic Goods Administration. Market research: stage one - qualitative research report. World Wide Web: Australian Government Department of Health; 2014 [updated 25th February 2014; cited 2014]; Available from: http://www.tga.gov.au/about/tga-communication-market-research-qualitative-report-04-sources.htm.
43. Lawrence M, Olesen F. Indicators of Quality in Health Care. Eur J Gen Pract. 1997;3(3):103-8.

44. Grimshaw JM, Thomas RE, MacLennan G, ., Fraser C, Ramsay CR, Vale L, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technol Assess. 2004;8(6):1-72.
45. Roche N, Durieux P. Clinical practice guidelines: From methodological to practical issues. Intensive Care Med. 1994;20(8):593-601.
46. National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. In: National Health and Medical Research Council, editor. Canberra1998. p. 1-88.
47. Culleton B. Development and Limitations of Clinical Practice Guidelines. In: Parfrey P, Barrett B, editors. Clinical Epidemiology: Humana Press; 2009. p. 1-11.
48. Qaseem A, Snow V, Owens DK, Shiekelle P. The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods. Ann Intern Med. 2010;153(3):194-9.
49. Australian Commission on Safety and Quality in Health Care. Annual Report 2012/13. Sydney: ACSQHC, 2013.
50. Grol R. Successes and Failures in the Implementation of Evidence-Based Guidelines for Clinical Practice. Med Care. 2001;39(8):II46-II54.
51. O'Mahony D, O'Connor M. Pharmacotherapy at the End-of-Life. Age Ageing. 2011;40(4):419-22.
52. Hughes LD, McMurdo MET, Guthrie B. Guidelines for people not for diseases: the challanges of applying UK clinical guidelines to people with multimorbidity. Age Ageing. 2013;42(1):62-9.
53. Hayward RSA. Clinical practice guidelines on trial. Canadian Medical Association. 1997;156(12):1725-7.
54. Harding J. Practice guidelines. Cookbook medicine. Physician Exec. 1994;20(8):3-6.
55. Tinetti ME, Bogardus J, Agostini JV. Potential pitfalls of disease-specific guidelines for patients with multiple conditions. N Engl J Med. 2004;351(27):2870-4.
56. Calderón C, Sola I, Rotaeche R, Marzo-Castillejo M, Louro-González A, Carrillo R, et al. EBM in primary care: a qualitative multicenter study in Spain. BMC Fam Pract. 2011;12(84).
57. Smith SM, O'Kelly S, O'Dowd T. GPs' and pharmacists experiences of manageing multimorbidity: a 'Pandora's box'. Br J Gen Pract. 2010;60(576):e285-e94.
58. Luijks HD, Loeffen MJ, Largo-Janssen AL, Van Weel C, Lucassen PL, Schermer TR. GPs' considerations in multimorbidity management: a qualitative study. Br J Gen Pract. 2012;62(600):e503-e10.
59. Van Spall HGC, Toren A, Kiss A, Fowler RA. Eligibility criteria of randomized controlled trials published in high-impact general medical journals: A systematic sampling review. J Am Med Assoc. 2007;297(11):1233-40.
60. Shelton PS, Fritsch MA, Scott MA. Assessing medication appropriateness in the elderly: a review of available measures. Drugs Aging. 2000;16(6):437-50.
61. American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropraite Medication Use in Older Adults. J Am Geriatr Soc. 2012;50(4):616-31.
62. Rognstad S, Brekke M, Fetveit A, Spigset O, Wyller TB, Straand J. The Norwegian General Practice (NORGEP) criteria for assessing potentially inappropriate prescriptions to elderly patients. Scand J Prim Health Care. 2009;27(3):153-9.
63. Basger BJ, Chen TF, Moles RJ. Inappropriate medication use and prescribing indicators in elderly Australians: development of a prescribing indicators tool. Drugs Aging. 2008;25(9):777-93.
64. Zhan C, Sangl J, Bierman AS, Miller MR, Friedman B, Wickizer SW, et al. Potentially Inappropriate Medication Use in the Community-Dwelling Elderly. J Am Med Assoc. 2001;286(22):2823-9.
65. Laroche M-L, Charmes J-P, Merle L. Potentially inappropriate medications in the elderly: a French consensus panel list. Eur J Clin Pharmacol. 2007;63(8):725-31.

66. Holt S, Schmiedl S, Thrmann P. Potentially inappropriate medications in the elderly: the PRISCUS list. Dtsch Ärztebl Int. 2010;107(31-32):543-51.
67. Mackinnon N. Preventable drug-related morbidity in older adults 1. Indicator development. J Manag Care Pharm. 2002;8(5):365-71.
68. Lindblad C, Hanlon J, Gross C, Sloane R, Pieper C, Hajjar E, et al. Clinically important drug-disease interactions and their prevalence in older adults. Clin Therapeut. 2006;28(8):1133-43.
69. Naugler CT, Brymer C, Stolee P, Arcese ZA. Development and validation of an improving prescribing in the elderly tool. Can J Clin Pharmacol. 2000;7(2):103-7.
70. Magin P, Goode S, Pond D. GPs, medications and older people: A qualitative study of general practitioners' approaches to potentially inappropriate medications in older people. [*Early view*]. Australas J Ageing. 2014.
71. Roth MT, Weinberger M, Campbell WH. Measuring the Quality of Medication Use in Older Adults. J Am Geriatr Soc. 2009;57(6):1096-102.
72. Hanlon JT, Schmader KE, Samsa GP, Weinberger M, Uttech KM, Lewis IK, et al. A method for assessing drug therapy appropriateness. J Clin Epidemiol. 1992;45(10):1045-51.
73. Jeffery S, Ruby C, Twersky J, Hanlon JT. Effect of an Interdisciplinary Team on Suboptimal Prescribing in a Long-Term Care Facility. The Consultant Pharmacist. 1999;14(12):1386-91.
74. Wenger NS, Roth CP, Shekelle P, ACOVE Investigators. Introduction to the Assessing Care of Vulnerable Elders-3 Quality Indicator Measurement Set. J Am Geriatr Soc. 2007;55(Supp 2):s247-52.
75. Assessing Care of Vulnerable Elders-3 Quality Indicators. J Am Geriatr Soc. 2007;55(Supp 2):s464-87.
76. Shrank WH, Polinski JM, Avorn J. Quality Indicators for Medication Use in Vulnerable Elders. J Am Geriatr Soc. 2007;55(Supp 2):s373-82.
77. Hilmer SN, Mager DE, Simonsick EM, Cao Y, Ling SM, Windham BG, et al. A drug burden index to define the functional burden of medications in older people. Arch Intern Med. 2007;167(8):781-7.
78. Jamal A, McKenzie K, Clark M. The impact of health information technology on the quality of medical and health care: a systematic review. Health Inform Manag. 2009;38(3):26-37.
79. Shiffman RN, Liaw Y, Brandt CA, Corb GJ. Computer-based Guideline Implementation: A Systematic Review of Functionality and Effectiveness. J Am Med Inform Assn. 1999;6(2):104-14.
80. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review. J Am Med Inform Assn. 2008;15(5):585-600.
81. Donyai P, O'Grady K, Jacklin A, Barber N, Franklin BD. The Effects of Electronic Prescribing on the Quality of Prescribing. Br J Clin Pharmacol. 2007;65(2):230-7.
82. Ozel D, Blige U, Zaim N, Cengiz M. A web-based intensive care clinical decision support system: From design to evaluation. Inform Health Soc Care. 2013;38(2):79-92.
83. Seto E, Leonard K, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Developing healthcare rule-based expert systems: case study of a heart failure telemonitoring system. Int J Med Inform. 2012;81(8):556-65.
84. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health Aff. 2011;30(3):464-71.
85. Spinewine A, Schmader KE, Barber N, Hughes C, Lapane KL, Swine C, et al. Appropriate prescribing in elderly people: how well can it be measured and optimised? Lancet. 2007;370(9582):173-84.
86. Johnson CW. Why did that happen? Exploring the proliferation of barely usable software in healthcare systems. Qual Health Care. 2006;15(Supp 1):i76-81.
87. Thompson W, Farrell B. Deprescribing: what is it and what does the evidence tell us? Can J Hosp Pharm. 2013;66(3):201-2.

88. Beer C, Loh P-k, Peng YG, Potter K, Millar A. A pilot randomized controlled trial of deprescribing. Ther Adv Drug Saf. 2011;2(2):37-43.
89. Garfinkel D, Mangin D. Feasibility Study of a Systematic Approach for Discontinuation of Multiple Medications in Older Adults: Addressing Polypharmacy. Arch Intern Med. 2010;170(18):1648-54.
90. Hanlon JT, Shimp LA, Semla TP. Recent advances in geriatrics: drug-related problems in the elderly. Ann Pharmacother. 2000;34(3):360-5.
91. Iyer S, Naganathan V, McLachlan AJ, Le Couteur DG. Medication Withdrawal Trials in People Aged 65 Years and Older. Drugs Aging. 2008;25(12):1021-31.
92. Gnjidic D, Le Couteur DG, Kouladjian L, Hilmer SN. Deprescribing Trials: Methods to Reduce Polypharmacy and the Impact on Prescribing and Clinical Outcomes. Clin Geriatr Med. 2012;28(2):237-53.
93. Hilmer SN, Gnjidic D, Le Couteur DG. Thinking through the medication list - appropriate prescribing and deprescribing in robust and frail older patients. Aust Fam Physician. 2012;14(12):924-8.
94. Scott IA, Gray LC, Martin JH, Pillans PI, Mitchell CA. Deciding when to stop: towards evidence-based deprescribing of drugs in older populations. Evid Based Med. 2013;18(4):121-4.
95. Scott IA, Gray LC, Martin JH, Mitchell CA. Minimising Inappropriate Medications in Older Populations: A 10-step Conceptual Framework. Am J Med. 2012;125(6):529-37.
96. Holmes HM, Hayley DC, Alexander GC, Saches GA. Reconsidering medication appropriateness for patients late in life. Arch Intern Med. 2006;166(6):605-9.
97. Cross C. Introducing deprescribing into culture of medication. Can Med Assoc J. 2013;185(13):E606.
98. Farrell B, Merkley VF, Thompson W. Managing polypharmacy in a 77-year-old woman with multiple prescribers. Can Med Assoc J. 2013;185(4):1240-5.
99. Farrell B, Merkley VF, Thompson W. Revisiting medicaiton use in a frail 93-year-old man experiencing possible adverse effects. Can Med Assoc J. 2014;186(6):445-9.

Chapter 2: Methodology

This chapter has been divided into three sections describing the major areas in this thesis:

1. Qualitative Research Techniques – Eliciting User Requirements
2. System Development
3. Usability Evaluation

Sample size and recruitment techniques are discussed at the end of this chapter as they are relevant to all experimental components of this research.

A summary of the methods used and brief rationale for each phase of this research is provided at the end of this chapter.

3.1 Qualitative Research Techniques – Eliciting User Requirements

Qualitative research describes research which involves information that is predominantly, but not always, non-quantitative in nature.(1) It is commonly used to explore social phenomena such as human experiences, social interactions and reflection on a given topic.(1, 2) Qualitative research has traditionally been used in the social science field,(3) but has been successfully employed in health research to describe both practitioner and patient experiences,(3, 4) as well as usability evaluation of information technology (IT) systems.(5, 6) Qualitative methods are most valuable to *explore* topics where the literature is sparse.(7) There are three main methods that can be used to elicit this type of information:(7)

1. Observational Techniques
2. Personal Interviews
3. Focus Groups

This doctoral research required the use of qualitative techniques to explore the views and attitudes of key consumer groups regarding information requirements during clinical decision making when caring for complex patients, whether currently available resources met these requirements (Chapter 3: Resources for disease state management – what do health professionals want?) and to evaluate the information resource developed as a result of this research (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation).

3.1.1 Observational Techniques

Observational techniques involve the researcher (observer) observing people (participants) in their usual environments,(8) and is also known as "field research".(7) Participants can either be unaware (observation) or aware (participant observation) that they are being observed.(8)

This type of research is generally used to observe natural behaviours that may not be highlighted during focus group or interview techniques because participants are either unaware of the behaviours or are unwilling to discuss them.(7-9) These techniques are not suited for gathering non-observable data such as thought processes(9) and was not considered appropriate to explore health professional (HP) information needs.

Although observational methods can be useful for usability evaluation and gain insight into how systems are used in real life,(5) it requires a working system suitable to the work environment. As this research resulted in the development of a prototype system not suited to the work environment, observational techniques were not used during the system evaluation phase of this research.

3.1.2 Personal Interviews

Personal interviews are usually conducted face to face with an interviewer asking questions of an interviewee in an attempt to collect information on a research topic.(10) One way to know if personal interviews should be used is if all other qualitative methods have been eliminated as inappropriate.(10)

It is generally recommended that interactions are video or audio recorded and transcribed *verbatim* as this allows the interviewer to engage with the interviewee, rather than be distracted by taking notes.(7, 11) It is also recommended that the interviewer make notes on general observations of the interviewee (e.g. body language) after the interview concludes.(7)

Interviews can be practical to conduct as they can be organised at a time and place of both the interviewee's and the interviewer's convenience;(7) however, they are generally time-consuming and potentially expensive if remuneration is offered to interviewees.(7) Interviews also lack any social pressures to conform to a group view or discussion domination that can occur in other methods such as focus groups (2.1.3 Focus Groups). As interviews are conducted face-to-face, some interviewees may be reluctant to answer truthfully; this can be resolved by taking measures to assure confidentiality.(2, 10)

Interviewer bias can influence the results of any interview.(10) Giving clues to the participant about the interviewers preconceived attitudes, motivations and expectations can potentially bias the

responses from the participant.(10) This can be avoided by remaining non-directive during an interview, while keeping the interview focused on the issue being explored by:(11)

- Knowing the purpose of the interview;
- Asking appropriate questions in order to gain the information required; and
- Giving appropriate verbal and non-verbal feedback to the interviewee.

Interview skills may take time to develop and it is therefore recommended that the interviewer is well rehearsed prior to starting interview based research.(10)

3.1.2.1 Interview methods

There are three basic formats that describe interview methods, each of which serve a particular purpose.

3.1.2.1.1 Structured Interviews

This type of interview represents a verbal questionnaire, and is usually used where a questionnaire or survey would be impractical to administer,(10) and for this reason is considered more of a quantitative rather than qualitative research method.(7) The questions are administered in a standardised manner and usually require a fixed answer – e.g. *"is your health good, fair, or poor?"*.(11) This also means that questions and answers must be decided *a priori* and are of little use in an exploratory study; therefore, structured interviews were not chosen for the first phase of this research.

3.1.2.1.2 Unstructured Interviews

This type of interview typically cover one or two topics, but in great detail, and are therefore also known as *in depth* interviews.(10, 11) They usually begin with open-ended questions allowing the interviewee to answer freely, and not be confined to set answers.(10, 11) In addition, the interviewers job is to encourage the interviewee to talk liberally and fully answer the question at hand, and explore topics brought up by asking additional questions.(10) Although the amount and type of data collected from unstructured interviews can be vast and complex, it was not considered appropriate for the first phase of this research as this technique allows for the exploration of only a few topics at a time.

3.1.2.1.3 Semi-structured Interviews

This type of interview is somewhere between structured and unstructured interviews. As the name suggests, the interviewee follows an interview guide, but also has the liberty of asking probing questions in order to explore additional ideas raised during the interview.(7, 10, 11) Unlike structured interviews, semi-structured interviews allow for evolution of the question guide in light of

new ideas, questions and topics raised in prior interviews.(8) Both unstructured and semi-structured interviews allow for clarification of the interviewees response, improving the accuracy of the data collected.(10) Interviews can be used in the initial stages of information system design and development in order to generate ideas, or to collect data on user perception and feedback of the system and specific functions.(5, 6, 12-14) It is for these reasons semi-structured interviews were chosen for the first phase of this research to explore HP information needs and generate ideas for system design (Chapter 3: Resources for disease state management – what do health professionals want?).

3.1.3 Focus Groups

Some types of focus groups can be thought of as group interviews which exploit group dynamics in order to collect data on a focused topic.(8, 15) They are typically conducted with 4-8 participants per group, where too few participants may result in discussion domination and too many may result in an uncontrolled discussion.(7) The number of groups required will depend on the purpose of the research; any one project may consist of 3-6 to over 50 groups, depending on the desired outcome.(15) Sampling should be purposive (2.5 Recruitment Techniques) to allow for homogenous groups where variables that could influence a study are uniform within each group.(7, 15)

Discussions during focus groups are, as the name suggests, focused and require a clear goal for discussion with a set questions that can be used as a discussion guide.(16) Questions should be short, clear, easy to say, open ended and evoke discussion.(16) As with personal interviews, focus groups should be video or audio recorded and transcribed *verbatim* for analysis, while researchers may also take additional notes to help with transcript analysis or to highlight key points identified during the session.(16)

Focus groups are quick and relatively simple to conduct, meaning that they are also potentially less expensive than other qualitative methods;(7) however, researchers may have difficulty in interpreting the focus group recordings during data analysis.(8) Group interaction can be used to deepen discussion as participants bounce ideas off one another and new issues are brought up that individuals may not have thought of during personal interviews.(7, 15) Focus groups are advantageous where group interactions and common language need to be explored.(8) Some suggest that they can be used to explore attitudes towards sensitive topics,(15) while others suggest that sensitive topics are poor candidates.(7) Other disadvantages include compromise in confidentiality or anonymity (c.f. personal interviews) or aggressive participants resulting in others holding back information or changing their ideas to suit the group's majority view.(8, 15) There are also logistical issues with finding an appropriate space and time to conduct focus groups.(7)

Focus groups were not used to explore HP information needs in the first phase of this research (Chapter 3: Resources for disease state management – what do health professionals want?) due to potential confidentiality compromise, peer judgment regarding personal prescribing practices and inability to discuss a wide range of topics. They were used during the usability evaluation phase of this research to supplement questionnaire data (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation and 2.3.2.1 Questionnaires) as they can gauge in-depth information regarding the prototype interface and its perceived usefulness and how it can be improved, HPs' reasoning behind these opinions and additional requirements that may not have been generated during interviews (2.1.2 Personal Interviews) or questionnaire feedback.(7, 15, 16)

3.1.4 Qualitative Data analysis

Data analysis tends to occur alongside data collection during qualitative research.(17) Unlike quantitative analysis where there is a "manipulation of numerical data", qualitative analysis is "characterised by the development and manipulation of concepts".(4)

There are two main methods for analysing qualitative data:

1. **Inductive** analysis is where the data is analysed and themes and theories emerge as a result; an example of this type of analysis is the grounded theory approach.(17)
2. **Deductive** analysis uses more of a "frame work approach", where anticipated themes are used as a starting point for analysis.(17)

In order to ensure reliability of qualitative data interpretation, it is generally recommended that two or more researchers independently analyse the data.(2) Qualitative research can produce large quantities of data which can be difficult to analyse; however, there are a number of programs developed specifically to help researches make sense of qualitative data.(17)

As themes were anticipated prior to qualitative research conducted, deductive analysis was used during data analysis of interviews (Chapter 3: Resources for disease state management – what do health professionals want?), qualitative component of the questionnaire and focus group feedback (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation).

3.2 System Development

3.2.1 Decision Support Systems and Types of Logic

Information technology (IT) is widely used in healthcare in a broad range of areas including decision support for diagnosis and evidence based medicine, Electronic Health Records (EHR), communication, and imaging.(18)

Decision support systems (DSS) are computer based systems used to assist in decision making processes.(19) These systems have been employed in a wide variety of fields including marketing, finance, and health.(19) In the medical field, DSS or clinical decision support systems (CDSS) can be used to assist practice with diagnosis and medication management.(20) They can be broadly categorised into two basic design strategies: non-knowledge based systems and knowledge based systems.(21)

Non-knowledge based systems use “artificial intelligence”, allowing the computer to learn from past experiences and/or pattern recognition.(21) Artificial Neural Networks (ANN), a type of non-knowledge based DSS, uses pattern recognition from examples input into the system in order to form connections between things such as symptoms and diagnoses.(21) Genetic algorithms (GA), another non-knowledge based DSS, are based on Darwin’s concept of “survival of the fittest” where a number of algorithmic combinations are constructed in an attempt to find the best possible solution to a given problem and repeated until the right solution is found.(21) In health, ANN are most commonly used in diagnostic DSS, whereas GA are commonly avoided due to a lack of reasoning transparency.(21)

A non-knowledge based CDSS was not considered appropriate for this research for one primary reason: during the first phase of this research (Chapter 3: Resources for disease state management – what do health professionals want?) we found that HPs want peer-reviewed, evidence-based resources. Unlike knowledge bases systems, non-knowledge based systems do not use data from the scientific literature or expert opinion.(21) Therefore, in order to deliver a transparent resource that would meet the needs of HPs, a knowledge-based CDSS was considered more appropriate.

3.2.1.1 Knowledge Based Systems

Knowledge based systems are also known as **expert systems** because their intention is to mimic the problem-solving thought processes of a human expert.(22)

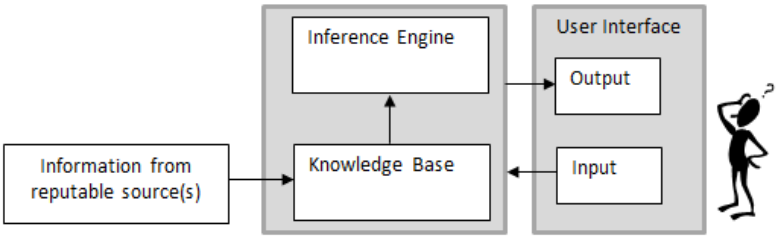


Figure 1: DSS Model

A knowledge based system has three basic components (Figure 1):(21)

1. Knowledge base
2. Inference or reasoning engine
3. Interface

Information needs to be built into the system (knowledge) and rules use used to extrapolate information in order to give the user the information they require (inference engine).(21) Finally there needs to be some way the system communicates with the user (interface).(21) Patient data input may be manual or automatic/electronic, depending on whether or not the system is integrated with any EHR.(21) Output may be in the form of alerts, recommendations, or other notifications and can be displayed on screen or as a printable report.(21)

3.2.2 Limitations to Expert Systems

Expert systems have some limitations. Each aspect of human reasoning, including aspects which may seem "common sense", need to be included within the system itself and some aspects of human reasoning cannot be described using logical reasoning.(22) Updating expert systems with new information can be difficult and time consuming.(22) How these limitations have been overcome is outlined later in this thesis (2.2.3.1.4 Database Architecture, Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine).

3.2.3 System Development Lifecycle

System development methodologies can be split into agile and non-agile, or iterative and formal/ linear methods.(23) Agile methods use continual testing to produce feedback, resulting in changes to system components (Figure 2).(23-25) This means that unlike formal methods where testing occurs towards the implementation stage of system development, agile methodology can discover and rectify issues early in the design and development process.(26) Agile methods have been shown to be more effective and successful in providing usable systems and are preferable for system development where the interface is the major component of the system;(27, 28) therefore, the agile

method was chosen for this research (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

The National Aeronautics and Space Administration (NASA) describes a system development lifecycle characterised by:(28)

1. Requirement definition and analysis, defining what the system must do in order to meet user needs;
2. Preliminary design: database architecture, object functionality and interface design begins in order to meet requirements;
3. Detailed design: detailed specifications not defined in preliminary design;
4. Implementation or coding of system;[2]
5. System Testing;
6. Acceptance Testing or usability evaluation; and
7. Maintenance and Operation.

Although this process appears linear, all phases may continue throughout the development lifecycle; requirements may change and therefore design, making the development process iterative in nature.(28) This process was used for prototype system development (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

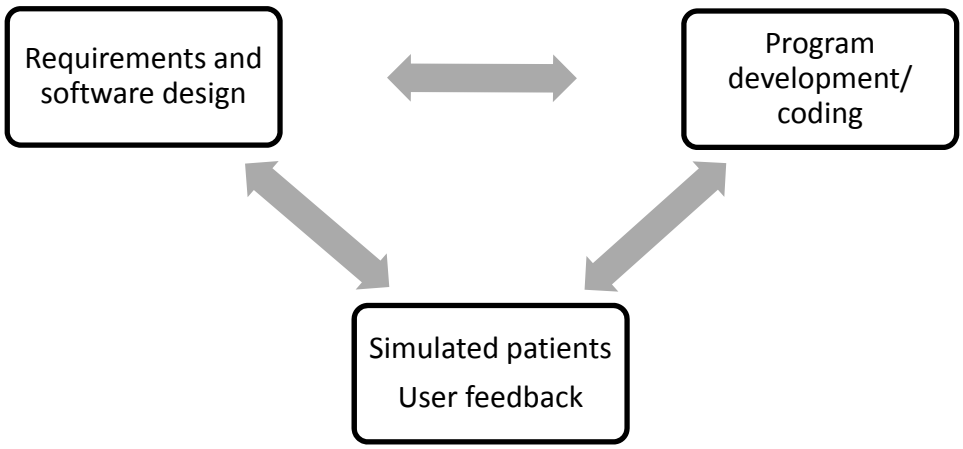


Figure 2: Iterative system development

[2] Coding of system was conducted by a software programmer. All other aspects (steps 1-6, step 7 is not applicable during this research) were managed by the PhD candidate.

3.2.3.1 High and Low Level Requirements

High and low level system requirements need to be defined as part of the design and development process, where high level requirements can be defined as the system overview and its components (such as process model, interface, etc.), and low level requirements can be defined as the database architecture and algorithms.(28)

3.2.3.1.1 Input/output – User Interface

This is how the program interacts with the user – i.e. the interface. The user interface design will depend on system requirements.(28) Usability guidelines and principals should be adhered to when designing the user interface.(29-31)

The interface was designed using MS Power Point®(32) and used as the fundamental design for the programmer to use during coding. The basic interface design can be found on the CD-ROM provided with this thesis.

3.2.3.1.2 Process Model Design

The process model provides the overview of what the program will do and what information is required which assists with database design. Process modelling was initially established as a tool for organisational design that describes responsibilities or object flow.(33) With respect to system development, the process model describes flow of information and data storage, processes and practices.(33) This is the foundation for any system as it describes the overall design.

MS Visio®(34) was used to design the process model. Details of the development of the process model can be found in Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing.

3.2.3.1.3 Inference Engine

This is where rules put in place in the knowledge base are programmed in such a way that they are capable of mimicking human reasoning; this has been most successfully done with a **rule-based** or **logic-based** approach,(22, 35) where "each rule specifies that if certain conditions can be established as true, then certain conclusions can be regarded as valid" (Figure 3).(22) This can also be thought of as a procedural knowledge representation of the knowledge base.(35) The inference engine rules are based on business rules or algorithms and can be thought of as the logic within a system.

IF not allergic to penicillin
THEN use amoxycillin
IF allergic to penicillin
THEN use roxithromycin

Figure 3: Example of rule-based knowledge representation

One example of this type of inference engine is MYCIN, an expert system built to recommend both diagnosis and treatment for infectious diseases based on patient symptom input.(20, 35) Other diagnostic examples include the INTERNIST-1 system (diagnosis of diseases in internal medicine), CASNET system (diagnosis of various glaucomas), the PIP system (diagnoses of kidney diseases),(20) and the ESP system (diagnosis and treatment of poisoning).(36)

MS Word®(37) was used to document the business rules. Details of the development of the business rules can be found in Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine.

3.2.3.1.4 Database Architecture

The knowledge of an expert system needs to be stored in a database that has been appropriately designed.(22) For instance, if a system is to identify that amoxicillin is inappropriate for a patient because they have a penicillin allergy, the information that states that amoxicillin *is* a penicillin antibiotic must to be within the knowledge base or database.

Databases not only store data or information, but also describe the relationship between the data, while allowing the user to store information without being concerned with how it is physically stored.(38) Databases are managed using database management systems (DBMS), including creating database structure and associated relationships, extraction and modification of data, and limiting access to data through the use of usernames and passwords.(38) There are a number of different database models describing how the data is stored, including, file processing systems, hierarchical, network, object orientated database management systems, and relational database management systems.(39) Which model is used will depend on the nature of the data that needs to be stored.(40-42) The most commonly used are the hierarchical (e.g. XML) and relational models; the differences in these databases are described in Table 1.

Table 1: Comparison of XML and relational database model.(42)

XML	Relational
Data is hierarchical	Data can be represented by logical relationships
Data is self-describing	Data is not self-describing
Data has an inherent “order”	Data does not have an inherent order

Other CDSS developers have used XML or non-relational database archetypes due to the hierarchical nature of diseases and symptoms.(43-47) However, the clinical decision-making process is non-

hierarchical, has no inherent order and can be easily represented by logical relationships between data (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

In order to overcome issues with updating the system developed as part of this research, a business rule engine was developed. Business rule engines have business rules built into the database, which simplifies system development as the rules are independent of code.(48) This also allows for changes to the business rules without code modification.(48)

Database design depends on the process model, the business rules, and system requirements. Terminology used should be standardised within the database in order to minimise confusion and error.(49)

MS Access®(50) DBMS was used to design the database and was converted to MS SQL server®(51) for a multi-user environment. Details of the database design and development can be found in Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine.

3.2.3.1.4.1 Knowledge Acquisition

The knowledge used to develop this expert system was gathered from peer-reviewed evidence-based guidelines and position statements, government websites and documents and reference books developed by reputable Australian sources. Where this information was lacking, peer-reviewed evidence-based guidelines from countries similar to Australia, such as the UK or USA, were used, focusing only on therapies relevant to, and available in, Australia. If further information was required, peer-reviewed evidence-based guidelines from other sources, or primary literature, were used where appropriate. Keeping in line with the National Health and Medical Research Council requirements,(52) all sources used were clearly referenced within the expert system.

The primary disease chosen for the prototype was type 2 diabetes and its two commonly associated co-morbidities: hyperlipidaemia and osteoporosis. These conditions encompass three of the eight national health priority areas.(53) The drugs included in the system are those used to treat the aforementioned diseases, as well as those used by simulated patients/ case vignettes used for system testing.

These decisions are based on information gathered from HPs interviews during the first phase of this research and on the features associated with success as described in Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing. Details of knowledge acquisition can be found in Chapter 4: Ingredients of a Successful

Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine.

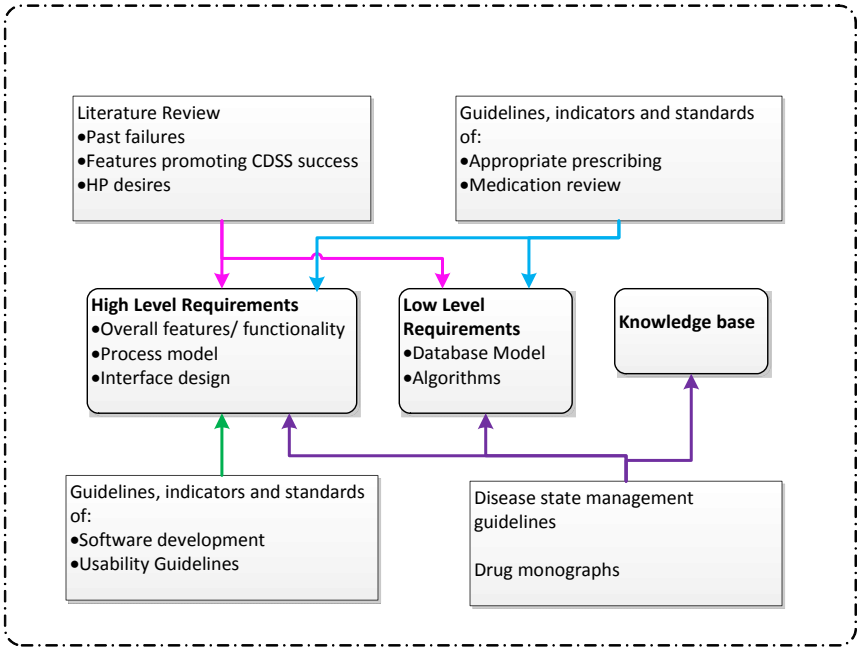


Figure 4: Summary of information sources used to influence various components of the system

3.3 Usability Evaluation

The purpose of usability evaluation is to decrease system errors with use and improve user satisfaction and productivity.(54) Factors that affect usability include efficiency, understandability, error prevention, accuracy, attractiveness and learnability.(54-56) Factors examined during usability evaluation depend on the technique used; no single technique describes all usability issues and it is therefore best to use a combination of techniques to identify the majority of issues prior to use in real settings.(56, 57)

Usability evaluation techniques can be formative or summative.(54) Formative techniques are used during the design and development process and are more qualitative in nature, whereas summative techniques are intended to validate the system towards the end of the development process.(54) This research aimed to define the requirements of an information delivery framework for complex patients and to build and test a *prototype* system; therefore, summative techniques were not considered appropriate at this stage of system development.

Formative evaluation techniques can be grouped under three major headings:(5)

1. Inspection Methods

2. Usability Inquiry
3. Usability Testing

These can be further subdivided. The following sections will briefly describe the techniques, their strengths and weaknesses, and rationale for use/non-use.

Table 2: Usability evaluation techniques

Evaluation technique	Advantages	Disadvantages
	Inspection techniques	
Heuristic Evaluation	Relatively quick Cost-effective Can be used early on with interface story boards or prototype systems	Need multiple expert evaluators
Cognitive Walkthrough	Can be used early on with interface story boards or prototype systems	Need multiple expert evaluators Time consuming to conduct
	Usability Inquiry	
Field observation	Allows for insight into how a system is used in real life	Unable to explore user's thoughts and views
Interviews	Relatively inexpensive Allows for detailed insight	Qualitative data requires time consuming data evaluation
Questionnaires	Inexpensive Relatively quick to administer and evaluate Can be administered remotely Good for subjective measures	Inappropriate for objective measures Inappropriate for exploratory studies unless supplemented by qualitative techniques Potential for ambiguity of questions and written responses
Focus Groups	Quick to conduct Relatively cheap to conduct Able to gain in depth information on one topic Able to generate more ideas than interviews	Time consuming data analysis May be logistically difficult as participants need to be in one room Not appropriate for sensitive topics
	Usability Testing	
Usability testing	Gains insight into actual user interaction with the system in a controlled environment Information or insights gained can be implemented immediately	Potentially expensive Requires recording equipment Participants may not feel "natural" due to controlled testing environment

3.3.1 Inspection Methods

Inspection methods require usability experts and other professionals, such as software developers or users, to examine the proposed user interface or prototype to identify usability related issues with the use of a guide.(5, 55) Occasionally, inspection methods will attach a severity level to identified issues in order to help prioritise the order in which they should be resolved.(57-59) Inspection

techniques should be used in conjunction with other evaluation techniques to identify missed issues.(57) These methods are inexpensive and faster to perform than other usability evaluation techniques.(6, 55)

Heuristic evaluation requires evaluators to judge whether or not an interface meets the criteria of a set of usability principals or "heuristics", and can be applied early in the design and development process including on interface story boards.(57, 60) Heuristic evaluation is best used early in the design process to allow for early identification and resolution of user interface issues.(5) They are capable of finding approximately 42% of all major and 32% of all minor user interface issues, although they should be supplemented by severity rating of identified issues and other usability evaluation techniques.(61) The most famous set of heuristics are "Nielson's Heuristics",(31) which consist of 10 general principles for interface design. Other heuristics have been developed and cover similar principles including consistency, error management, adaptability, user control and freedom, low memory load and compatibility with real world.(62, 63) Heuristic evaluations require multiple evaluators to examine the system independently; 75% of all usability issues can be uncovered with approximately 5 evaluators.(5, 64) Although usability novices can identify usability problems using heuristics, experts are generally recommended as the number of issues found by usability experts is comparable to usability testing (2.3.3 Usability Testing).(60, 65)

Cognitive walkthrough involves one, or a group of, usability experts using a description of a simulated user and inspecting the interface in order to assess the learnability of the system.(5, 60, 66) Evaluators can use a set of questions to help assess system learnability, for example:(59, 60, 66, 67)

1. What effect was the user trying to achieve by selecting this action?
2. How did the user know that this action was available?
3. Did the selected action achieve the desired effect?
4. When the action was selected, could the user determine how things were going?

Like heuristic evaluation, cognitive walkthroughs can be used early in the design and development process without the need for a working prototype.(67) They can be time consuming to conduct, however, and require extensive evaluator training, making them costly to researchers if evaluators are not usability experts.(59, 60)

As access to usability experts was not available, inspection methods were not used, however, Nielson's Heuristics(31) were used as a guide during design and development of the system prototype. In addition, learnability questions listed above were used during usability testing in order

to help gauge how easily participants learnt to use the system (2.3.3 Usability Testing and Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

3.3.2 Usability Inquiry

Usability inquiry techniques are qualitative in nature and are intended to gain information regarding the users' experiences during system interaction.(5) Many of the basic principles have been discussed at the beginning of this chapter (2.1 Qualitative Research Techniques – Eliciting User Requirements); additional details are presented below.

User satisfaction does not correlate well with some measures of usability, such as effectiveness and efficacy,(54) however, it is still an important component of system design and development, especially in the early stages, as user involvement during this stage has been shown to increase CDSS success.(14, 68-70)

There are four main methods used during usability inquiry:

1. Observational Techniques;
2. Interviews;
3. Focus groups; and
4. Questionnaires

Observational techniques, Interviews and Focus Groups have been discussed previously under Qualitative Research Techniques in sections 2.1.1, 2.1.2 and 2.1.3. Questionnaires can be qualitative and quantitative and are discussed below.

3.3.2.1 Questionnaires

Questionnaires research is used as an objective method to collect subjective data such as people's knowledge, beliefs, attitudes, and behaviour.(5, 71) They are practical to use as they can be administered online or through email links and if access to the internet is unavailable, a hard copy can be given to, or mailed to, participants.(5)

Questionnaires are not appropriate in all situations, particularly during exploratory stages of research, as answers tend to be predetermined unless open ended.(56, 71) They are also inappropriate as absolute measures of objective information, such as usual practice (e.g. usual prescribing practices by medical practitioners, usual diet, smoking and drug taking habits, etc.) or in "needs assessment" studies unless supplemented by other qualitative research methods.(71) Closed ended questions allow quick completion, clear responses and simple analysis as answers are already

provided and data is already standardised.(71) Open ended questions or free text is recommended at the end of questionnaires, or after particular questions or sections, in order to enrich the data collected.(71) In order for qualitative data to be meaningful, instructions on how to answer appropriately should be used to avoid vague or overly broad answers.(56, 71)

The usability evaluation phase of this research aimed to provide feedback from HPs on whether the system prototype had the potential to meet their needs and to further explore system requirements. Therefore, the usability evaluation phase of this study used questionnaires to gain subjective feedback from potential users regarding the system prototype developed, using closed questions combined with open-ended questions to enrich information (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). The results obtained from questionnaires were supplemented by focus groups (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation).

3.3.2.1.1 Choice of Questionnaire

Questionnaires can be developed *de novo* or previously developed questionnaires can be used as a template or in their entirety.(2) The advantages of using a previously developed questionnaire is that its reliability and validity will have already been established - namely face, construct, criterion, and content validity.(2) However, if a template is used, the questionnaire must be re-evaluated to ensure that any changes in the question wording have not altered the validity of the survey.(2) If a new or altered questionnaire is developed, face and content validity can be assessed using appropriate experts and consumers.(72) After face and content validity testing, internal validity testing can be conducted by piloting the questionnaire.(2) Ideally this should occur at least twice, some weeks apart, in order to evaluate reliability of the questionnaire.(2) Things which can affect the reliability of a questionnaire include ambiguous wording and inability of respondents to give accurate information.(2)

In order to save time and resources it is desirable to choose a previously developed questionnaire. When choosing a questionnaire, researchers need to consider the following: questionnaire validity, reliability, and purpose.(71)

3.3.2.1.1.1 Validity and Reliability

There are different types of validity, each of which needs to be established before using a questionnaire.

External validity refers to how generalizable results are to the rest of the target population.(73) External validity will be affected by the sample used to complete a questionnaire, the environment in which the study was completed and the time in which it was completed.(74)

Face validity is "a *subjective* judgement of whether the tool... is a good measure or not", whereas **content validity**: "an exhaustive review by an *expert panel* to decide whether the types of questions (items) adequately cover the behaviour that you are interested in measuring".(73) Researchers choosing a questionnaire should ensure that appropriate experts have assessed the face and content validity.(73)

Construct validity refers to how much agreement there is between the theoretical concept being measured and a specific measuring device or procedure.(73) In other words, how well the questionnaire actually measures what it intends to measure.(75) The construct validity of a questionnaire evaluating usability will be determined by what aspect of usability is being measured – e.g. work load, efficiency, appeal, etc. Similar to construct validity is **internal validity**, which concerns itself with a causal relationship between two things.(74) For example, implementation of a "healthy eating program" that includes a meal *and* exercise plan may have internal validity in that improves overall health, but does not have construct validity as it may have been exercise or other components that have also improved health.(74) With regard to a usability questionnaire, internal validity is not required as there is no causal relationship between the questionnaire and an outcome.

Questionnaires aim to address certain over-arching issues. The explicit nature of questionnaires means that questionnaire developers must consider all potential aspects within the issue being addressed. Without this consideration, vital information which deepens our understanding may be missed and introduce misconceptions.(76) Within a given issue, there are primary domains that address the complexities that can influence a person's attitudes or practices. Each of these primary domains needs to be addressed in order to establish construct validity.

Primary domains can be further subdivided into secondary domains, which in-turn can be described by a number of factors. The factors within a secondary domain need to be unidirectional in nature in that they address the same domain, giving the questionnaire **internal consistency**. The internal consistency can be measured using Cronbach's alpha[3] (a co-efficient of reliability; where Cronbach

[3] Cronbach alpha: $$\alpha = \frac{k}{k-1}\left(1 - \frac{\Sigma s_i^2}{s_T^2}\right)$$ where k is the number of items or factors, s^2_i is the variance of the i^{th} item, and s^2_T is the variance of the total score from all the items.(77.)

alpha $\in [0,1]$), where a value greater than 0.7 is considered to demonstrate consistency.(2) Note that internal validity only refers to closed-ended questions.

Domains can be established from a literature search or where the literature is lacking or incomplete, they can be extrapolated from in depth interviews; alternatively a mixture of both methods can be used. For example, McKinney et al developed their "measurement of Web-Customer satisfaction" survey construct directly from the literature,(78) whereas Bailey and Pearson in their development of "a tool for measuring and analysing computer user satisfaction" used both a literature review and subsequent interviews to develop their survey construct.(72)

Questions that are developed must be appropriate, meaning that they cannot be "loaded" or "leading" questions which can bias response, or double-barrelled questions which can lead to confusion.(76) The order in which questions are delivered can lead to *order bias* and can be avoided by giving two or more versions of the same questionnaire during piloting.(78)

Closed answer questions must be responded to with pre-determined answers, which can be on a scale, dichotomous, or use multiple answers where the responses are not mutually exclusive.(76) When developing scales, careful consideration needs to be applied to number of intervals, whether there are an odd or even number of intervals and whether numbers or words are used to describe scale intervals.(2) Inappropriate scale use for can lead to biased answers.(76) Answers, in the same way as the questions themselves, need to be tested for face, content and construct validity, and reliability.

Finally, questionnaires need to be tested for **test-retest reliability**, to ensure the same results are achieved over time.(73)

3.3.2.1.1.2 Questionnaire Purpose and Choice of Questionnaire

This phase of the research aimed to measure HP satisfaction with the way in which information was presented by the prototype system developed. Questionnaires administered during usability evaluation are commonly developed locally without the standard development rigour found in the social and health sciences; many studies provide minimal information regarding questionnaire development or details of the questions themselves.(79) Standard questionnaires have been developed in order to examine different aspects that contribute to user satisfaction and examine various aspects of usability to varying degrees of detail, including overall satisfaction, and perceived work load, efficacy, efficiency and usefulness.(55) For example, the NASA Task Load Index measures subjective mental workload for completing a task,(80) whereas System Usability Scale measures overall subjective satisfaction with task completion.(81)

For the usability evaluation phase of this research IBMs Computer Software Usability Questionnaire (CSUQ), a slightly modified version of the Post-Study System Usability Questionnaire (PSSUQ), has been chosen to evaluate HPs satisfaction with the system prototype (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). Both questionnaires measure overall usability, system satisfaction, information quality and interface quality.(82) CSUQ and PSSUQ have good reliability overall and within the subscales.(82) In addition, the PSSUQ has been shown as a good predictor of other usability indicators such as successful task completion.(82, 83) Due to the similarities between CSUQ and PSSUQ, the two questionnaires are can be considered interchangeable with regard to reliability and validity.(82) One limitation of questionnaire research is inappropriate response or non-response to questions,(84) however, the CSUQ is designed to be used on a variety of systems, where not all questions may be relevant.(82) In order to manage non-responses, developers of CSUQ instruct questionnaire users to average the score of *answered* questions.(82)

The CSUQ is designed to be administered after system use.(82) Direct interaction with the system by potential users (pharmacists and medical practitioners) was initially planned; however, the recruitment strategy used was unsuccessful (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). Therefore potential users evaluated the system after a demonstration (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). As the participants did not have direct interaction with the system, minor modification of the CSUQ wording was necessary; for example “it is simple to use this system” was changed to “I would find it simple to use [*the system*]”. As a result, the modified CSUQ was revalidated (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation).

3.3.2.1.2 Data analysis

Questionnaire data is primarily quantitative in nature, unless open-ended questions are used; in this case, usual qualitative data analysis techniques should be used (2.1.4 Qualitative Data analysis).

The type of data analysis used will depend on the study question and type of data collected. For research with no hypothesis, no statistical tests are required and descriptive statistics are an adequate way to illustrate results.(85) Questionnaire research methods are not robust methods for hypothesis testing as they are subjective and do not give temporal data; however, they are useful in hypothesis generation from resulting associations and correlations.(86)

If researchers wish to test a hypothesis or find correlations, the type of statistical test will depend on the type of data collected (paired, unpaired, nominal, ordinal, discrete, categorical) and how the

data is distributed (normal versus non-normal).(85) Choice of statistical test should be made in consultation with a statistician.

As no hypothesis was tested during the usability evaluation of this study, descriptive statistics were used to describe questionnaire data and establish correlations between participant characteristics and overall usability (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). As the CSUQ uses a 7-point scale (when averaged is a continuous variable) choice of correlation test was dependent on the nature of the participant characteristic data.(82)

3.3.3 Usability Testing

Usability testing requires representative users to use the system in order to complete typical tasks.(5, 6) There are multiple usability testing methods but all have the same general concepts with slight variations regarding:(5)

- Environment – where the study is conducted: real life, laboratory, remotely;
- Study question – learnability of the system, task completion correctness or efficiency; and
- Equipment used – eye tracking devices, screen capture, video recording.

Usability testing is used early in the development process to allow for identification of major issues before it becomes too difficult and expensive to fix them.(5)

The **think-out-aloud** method can be used to evaluate the learnability of a system.(87) As the name suggests, participants are asked to verbalise their thoughts while completing tasks using the system.(5, 87) Typically these sessions are audio or video recorded and screen capture is also required allowing for rich qualitative data describing the user cognitive process while using the system.(5, 87)

Usability testing is typically used early in the development process and is generally conducted after focus groups and questionnaires.(6) However, as it allows for immediate feedback, a modified “think aloud method” was used in this research to provide initial feedback and identification of major usability issues regarding a working prototype before demonstration to a wider audience (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing). As the aim of this phase was to identify major problems rather than an in-depth evaluation of the cognitive process when using the prototype, a set of standard questions (2.3.1 Inspection Methods) were used rather than audio recording and screen capture. As a result this

study can also be thought of as a "non-expert cognitive walkthrough"; such studies have been shown to identify as many interface issues as when usability experts are used.(5, 88, 89)

3.4 Sample Size

As it is both unreasonable and potentially unethical to test an entire population, studies gathering quantitative data require testing a sample of the population in question.(85, 90) A sample size calculation is used to ensure that the sample reflects the population;(90) for this research it asks how many HPs are required to provide feedback in order to reflect the opinion of the entire population of HPs. There are numerous mathematical formulas that can be used to calculate an appropriate sample size;(86) a commonly used formula (recommended by the statistician consultant) is: $n = \frac{Z_{\alpha/2}\,\sigma^2}{d^2}$ where n = sample size,α = type I error, σ = standard deviation and d = anticipated effect size.

In contrast, during qualitative studies *n* is not statistically calculated, but is dependent on the number of participants (i.e. interviewees, focus group participants, etc.) it takes until "data saturation" is reached, where data saturation is considered to be the point where no new themes or ideas are being contributed by subsequent interviews or focus groups.(7)

3.5 Recruitment Techniques

Purposive sampling involves selecting participants based on their characteristics; for instance choosing women with breast cancer in order to explore their views of breast cancer treatment.(2) This type of sampling is most appropriate in qualitative research because it ensures that the participants have a depth of knowledge of the research topic.(7, 8)

Convenience sampling involves asking people who are known to the researcher to participate in the study.(2) This type of sampling can introduce biases which the researcher may be unaware of and may also be unrepresentative of the general/target population.(2) However, it can be appropriate in exploratory studies in early fieldwork.(2, 91) **Snowballing** sampling methods, where participants suggest new participants to be involved,(8) is considered a sub-set of convenience sampling.(2)

A combination of these methods was used in the first phase of this research (Chapter 3: Resources for disease state management – what do health professionals want?). Convenience sampling was used to recruit participants for initial usability testing (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing) whereas

purposive sampling was employed during subsequent usability evaluation (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation).

Finally, **theoretical** sampling is commonly employed in grounded theory, where the researcher collects and evaluates data simultaneously, and changes what data to collect next in light of emerging theories in order to examine, expand and refine them.(92) This was not used in the present research as it was not designed to evaluate emerging theories or concepts.

3.6 Summary of Research Methods

Table 3 summarises the methods that were used during this research and the rationale for their use.

Table 3: Summary of research methods used

Phase	Chapter	Method Used	Brief rationale	Sampling Method
1: Identifying HP information requirements	Chapter 3	Semi structured personal one-on-one-Interviews (2.1.2.1.3 Semi-structured Interviews).	Exploration of information needs required thorough exploration of the prescribing process, without fear of judgement from other participants.	Purposive convenience augmented by snowballing
2: Prototype system design and development	Chapters 4 and 5	Agile methodology (2.2.3 System Development Lifecycle)	More efficient at producing successful and usable systems.	N/A
3: Usability evaluation	Chapter 6	Questionnaire (2.3.2.1 Questionnaires)	Able to gain qualitative and quantitative feedback from a large group of participants and measure perceived system usability and usefulness and identify areas of improvement.	Purposive
		Focus group (2.1.3 Focus Groups)	Intended to augment questionnaire results. Allows for in-depth exploration of system usefulness and further identification of areas of improvement and potential solutions.	Purposive

3.7 References

1. Saldana J. Fundamentals of Qualitative Research. New York: Oxford University Press; 2011.
2. Smith F. Research Methods in Pharmacy Practice. London: Pharmaceutical Press; 2002.
3. Pope C, Mays N. Chapter 1: Qualitative Methods in Health Research. In: Pope C, Mays N, editors. Qualitative research in health care. 3rd ed. Malden: Blackwell Publishing Ltd.; 2006. p. 1-11.
4. Fitzpatrick R, Boulton M. Qualitative methods for assessing health care. Qual Health Care. 1994;3(2):107-13.
5. Zhang Z. Usability Evaluation. In: Zaphiris P, Kurnaiwan S, editors. Human Computer Interaction Research in Wed Design and Evaluation. Hershey USA: Idea Group Inc; 2007. p. 209-28.
6. Bernhaupt R. Usability and User Experience Evaluation Methods. In: Mourlas C, Germanakos P, editors. Mass Customization for Personalized Communication Environments: Integrating Human Factors. Athens, Greece: IGI Global; 2009.
7. Cline RR. Chapter 9: Data Collection Methods. In: Aparasu RR, editor. Research Methods for Pharmaceutical Practice and Policy. London: Pharmaceutical Press; 2011. p. 143-59.
8. Hansen EC. Successful Qualitative Health Research. Crows Nest: Allen & Unwin; 2006.
9. Barker KN. Chapter 13: Observations. In: Nelson AA, editor. Research in Pharmacy Practice: Priniciples and Methods. Columbia: Bethesda, MD : American Society of Hospital Pharmacists 1981. p. 83-91.
10. Purohit AA. Chapter 12: Personal Interviews. In: Nelson AA, editor. Research in Pharmacy Practice: Priniciples and Methods. Columbia: Bethesda, MD : American Society of Hospital Pharmacists 1981. p. 77-82.
11. Britten N. Chapter 2: Qualitative Interviews. In: Pope C, Mays N, editors. Qualitative research in health care. 3rd ed. Malden: Blackwell Publishing Ltd.; 2006. p. 12-20.
12. Trafton J, Martins S, Michel M, Lewis E, Wang D, Combs A, et al. Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic, noncancer pain by primary care providers. Pain Med. 2010;11(4):575-85.
13. Grossman JM, Gerland A, Reed MC, Fahlman C. Physicians' Experiences Using Commercial E-Prescribing Systems. Health Aff. 2007;26(3):w393-404.
14. Abramson EL, Patel V, Malhotra S, Pfoh ER, Osorio SN, Cheriff A, et al. Physician experiences transitioning between an older versus newer electronic health record for electronic prescribing. Int J Med Inform. 2012;81(8):539-48.
15. Kitzinger J. Chapter 3: Focus groups. In: Pope C, Mays N, editors. Qualitative research in health care. 3rd ed. Malden: Blackwell Publishing Ltd.; 2006. p. 21-31.
16. Krueger RA, Casey MA. Focus Groups: A practical gude. 4th ed. Knight V, Connelly S, Habib L, Virding A, Suqinsky P, editors. Los Angeles, London, New Delhi, Singapore, Washington DC: SAGE; 2009.
17. Pope C, Ziebland S, Mays N. Qualitative research in health care: Analysing qualitative data. Br Med J. 2000;320(7227):114-6.
18. Rocha A. Evolution of Information Systems and Technologies Maturity in Healthcare. Int J Healthc Inform Syst Informat. 2011;6(2):28-36.
19. Wang J, Radosevich DJ. Decision Support Systems. In: Tomei LA, editor. Encyclopedia of Information Technology Curriculum Integration Hershey: IGI Global; 2008. p. 197-208.

20. Armoni A. The Use of Artificial Intelligence Techniques and Applications in the Medical Domain In: Armoni A, editor. Healthcare Information Systems: Challenges of the New Millennium Hershey: IGI Global; 2000. p. 129-48.
21. Berner ES, La Lande TJ. Chapter 1: Overview of Clinical Decision Support Systems. In: Berner ES, editor. Clinical Decision Support Systems: Theory and Practice. 2nd ed. Birmingham: Springer; 1999. p. 3-22.
22. Changchit C. Expert Systems. In: Tomei LA, editor. Encyclopedia of Information Technology Curriculum Integration Hershey: IGI Global; 2008. p. 316-22.
23. Shankarmani R, Pawar R, Mantha SS, Babu V. Agile Methodology Adoption: Benefits and Constraints. Int J Comput Appl. 2012;58(15):31-7.
24. Black S, Boca PP, Bowen JP, Gorman J, Hinchey M. Formal versus Agile: Survival of the Fittest. Computer. 2009;42(9):37-45.
25. Kumar G, Bhatia PK. Impact of Agile Methodology on Software Development Process. Int J Comput Technol Electronics Eng. 2012;2(4):46-50.
26. Barkstrom BR. The Standard Waterfall Model for Systems Development. World Wide Web: NASA; 2014 [cited 2013 30th April].
27. Schwaber K, editor. SCRUM Development Process. 10th Annual ACM Conference on Object Oriented Programming Systems, Languages, and Applications; 1995; Texas, USA: ACM.
28. Landis L, Waligora S, Mcgarry F, Pajerski R, Stark M, Johnson KO, et al. Recommended Approach to Software Development: Maryland, USA; 1992.
29. Bailey RW, Barnum C, Bosley JC, Barbara, Dumas J, Ivory MY, John B, et al. Research-Based Web Design & Usability Guidelines. Washington: U.S. Government Printing Office; 2006.
30. Ambler SW. User Interface Design Tips, Techniques, and Principles - Ambysoft. Ambysoft Inc.; 2014 [cited 2014 10 February].
31. Nielsen J. 10 Usability Heuristics for User Interface Design. online: NN/g Nielsen Normal Group; 2005 [cited 2013 18 June]; Available from: http://www.nngroup.com/articles/ten-usability-heuristics/.
32. Microsoft PowerPoint 2010. Microsoft Corporation; 2010.
33. Mendling J, Reijers H, van der Aalst WM. Seven process modeling guidelines (7PMG). Inform Software Tech. 2008;52(2):127-36.
34. Microsoft Visio. Microsoft Corporation; 2010.
35. Carter JH. Chapter 4: Design and Implementation Issues. In: Berner ES, editor. Clinical Decision Support Systems: Theory and Practice. 2nd ed. Birmingham: Springer; 1999. p. 64-98.
36. Batista-Navarro RTB, Bandojo DA, Gatapia MAJK, Santos RNC, Marcelo AB, Panganiban LCR, et al. ESP: An expert system for poisoning diagnosis and management. Inform Health Soc Care. 2010;35(2):53-63.
37. Microsoft Word. Microsoft Corporation; 2007.
38. Harrington JL. The Database Environment. Relational Database Design and Implementation: Clearly Explained. 3rd ed. Massachusetts, USA: Morgan Kaufmann; 2009.
39. Harrington JL. Historical Antecedents. Relational Database Design and Implementation: Clearly Explained. 3rd ed. Massachusetts, USA: Morgan Kaufmann; 2009.
40. IBM. Database management systems on z/OS. World Wide Web: IBM Corporation; 2010 [cited 2013 5 April]; Available from: http://publib.boulder.ibm.com/infocenter/zos/basics/index.jsp?topic=/com.ibm.zos.zmiddbmg/zmiddle_46.htm.
41. Nicola M. XML versus Relational Database Performance. World Wide Web2011; Available from: https://www.ibm.com/developerworks/community/blogs/xmldatabase/entry/xml_versus_relational_database_performance17?lang=en.

42. IBM. Comparison of the XML model and the relational model. World Wide Web: IBM Corporation; 2008 [cited 2013 5 April]; Available from: http://publib.boulder.ibm.com/infocenter/db2luw/v9/index.jsp?topic=%2Fcom.ibm.db2.udb.apdv.embed.doc%2Fdoc%2Fc0023811.htm.
43. Kuo K-L, Fuh C-S. A rule-based clinical decision model to support interpretation of multiple data in health examinations. J Med Syst. 2011;35(6):1359-73.
44. Wright A, Sittig DF. A four-phase model of the evolution of clinical decision support architectures. Int J Med Inform. 2008;77(10):641-9.
45. Tu SW, Campbell JR, Glasgow J, Nyman MA, McClure R, McClay J, et al. The SAGE Guideline Model: Achievements and Overview. J Am Med Inform Assoc. 2007;14(5):589-98.
46. Grandi F, Mandreoli F, Martoglia R. Efficient management of multi-version clinical guidelines. J Biomed Inform. 2012;45(6):1120-36.
47. Bindoff IK, Tenni PC, Peterson GM, Kang BH, Jackson SL. Development of an intelligent decision support system for medication review. J Clin Pharm Therapeut. 2007;23(1):81-8.
48. Lieberman BA. Requirements for rule engines: Capture and communication of complex business rules. World Wide Web: IBM; 2009 [updated 6 November 2012].
49. Slee A, Lewis K. Design for patient safety: guidelines for the safe on-screen display of medication information: National Patient Safety Agency; 2010. Available from: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=66713.
50. Microsoft Access. 2008 Microsoft Corporation; 2007.
51. Microsoft SQL Server. Microsoft Corporation; 2012.
52. National Health and Medical Research Council. A guide to the development, implementation and evaluation of clinical practice guidelines. In: National Health and Medical Research Council, editor. Canberra1998. p. 1-88.
53. Department of Health and Ageing. Chronic Disease. 2010 [updated 31 March 2011]; Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/chronic.
54. Belden JL, Grayson R, Barnes J. Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating. Healthcare Information and Management Systems Society, 2009.
55. Shafinah K, Selamat MH, Abdullah R, Muhamad AMN, Noor AGA. System Evaluation for a Decision Support System. Inform Technol J. 2010;9(5):889-98.
56. Horsky J, McMolgan K, Pang JE, Melnikas AJ, Linder JA. Complementary methods of system usability evaluation: Surveys and observations during software design and development cycles. J Biomed Inform. 2010;43(5):782-970.
57. Nielsen J. Usability Inspection Methods. Conference companion on Human factors in computing systems: ACM; 1994. p. 413-4.
58. Nielsen J. Severity Ratings for Usability Problems. World Wide Web: Nielsen Norman Group; 1995 [cited 2014 21 Feb]; 1995]. Available from: http://www.nngroup.com/articles/how-to-rate-the-severity-of-usability-problems/.
59. Mack R, Nielsen J. Usability Inspection Methods. ACM SIGCHI Bulletin. 1993;25(1):28-33.
60. Woolrych A, Hindmarch M. Understanding and Improving Usability Inspection Methods. In: Potter M, editor. Encyclopedia of Human Computer Interaction. Hershey, PA, USA: Idea Group Inc; 2006. p. 641-7.
61. Nielsen J. Characteristics of Usability Problems Found by Heuristic Evaluation. World Wide Web: Nielsen Norman Group; 1995 [cited 2014 21 Feb]; Available from: http://www.nngroup.com/articles/usability-problems-found-by-heuristic-evaluation/.
62. Masip L, Granollers T, Olivia M. A heuristic evaluation experiment to validate the new set of

usability heuristics. The 2011 Eighth International Conference on Information

Technology: New Generations; Las Vegas, NV: IEEE Computer Society; 2011. p. 429-34.
63. Beuscart-Zéphir M-C, Leroy N, Alao O, Darmoni S. Usability assessment study of a web site displaying medical resources on line: the CISMeF. Stud Health Technol Inform. 2002;90:133-7.
64. Nielsen J. How to Conduct a Heuristic Evaluation. World Wide Web: Nielsen Norman Group; 1995 [cited 2014 21 Feb]; Available from: http://www.nngroup.com/articles/how-to-conduct-a-heuristic-evaluation/.
65. Jeffries R, Desurvire H. Usability Testing vs. Heuristic Evaluation: Was there a contest? ACM SIGCHI Bulletin. 1992;24(4):39-41.
66. Wharton C, Rieman J, Lewis C, Polson P. The Cognitive Walkthrough Method: A Practitioner's Guide. In: Nielsen J, editor. Usability inspection method. New York, NY, US: John Wiley & Sons, Inc.; 1994. p. 105 - 40.
67. Allendoerfer KR, Aluker S, Panjwani G, Proctor JM, Sturtz D, Vukovic M, et al., editors. Adapting the cognitive walkthrough method to assess the usability of a knowledge domain visualization. IEEE Symposium on Information Visualization; 2005; Minneapolis, MN, USA.
68. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving Clinical Practice Using Clinical Decision Support Systems: a Systematic Review of the Trials to Identify Features Critical to Sucess. Br Med J. 2005;330(7494):765-8.
69. Ash JS, Sittig DF, Guappone KP, Dykstra RH, Richardson J, Carpenter J, et al. Recommended Practices for Computerized Clinical Decision Support and Knowledge Management in Community Settings: A Qualitative Study. BMC Med Informat Decis Making. 2012;12(6).
70. Scanlon M. Computer physician order entry and the real world: we're only humans. Jt Comm J Qual Patient Saf. 2004;30(6):342-6.
71. Boynton PM, Greenhalgh T. Hands-on guide to questionnaire research: Selecting, designing, and developing your questionnaire. Br Med J. 2004;328(7451):1312-5.
72. Bailey JE, Pearson SW. Development of a Tool for Measuring and Analyzing Computer User Satisfaction. Manag Sci. 1983;29(5):530-45.
73. Fitzner K. Reliability and validity: a quick review. Diabetes Educat. 2007;33(5):775-80.
74. Trochim WMK. The Research Methods Knowledge Base. World Wide Web2006. Available from: http://www.socialresearchmethods.net/kb/.
75. de Laat FA, Rommers GM, Geertzen JH, Roorda LD. Construct Validity and Test-Retest Reliability of the Questionnaire Rising and Sitting Down in Lower-Limb Amputees. Arch Phys Med Rehabil. 2011;92(8):1305-10.
76. Zelnio RN. Chapter 11: Mail Questionnaires. In: Nelson AA, editor. Research in Pharmacy Practice: Priniciples and Methods. Columbia: Bethesda, MD : American Society of Hospital Pharmacists 1981. p. 70-6.
77. Bland JM, Altman D. Statistics notes: Cronbach's alpha. Br Med J. 1997;314(7080):572.
78. McKinney V, Yoon K, Zahedi FM. The Measurement of Web-Customer Satisfaction: An Expectation and Disconfirmation Approach. Inform Syst Res. 2002;13(3):296-316.
79. Yen P-Y, Bakken S. Review of health information technology usability study methodologies. J Am Med Inform Assoc. 2014;19(3):413-22.
80. Cao A, Chintamani K, Pandya A, Ellis R. NASA TLX: software for assessing subjective mental workload. Behav Res Methods. 2009;41(1):113-7.
81. Brooke J. SUS - A quick and dirty usability scale. In: W. Jordan P, Thomas B, McClelland IL, Weerdmeester B, editors. Usability evaluation in industry. London, England: Published by CRC Press; 1996.
82. Lewis JR. IBM computer usability satisfaction questionnaires: psychometric evaluation and instructions for use. Intl Journal of Human–Computer Interaction. 1995;7(1):57-78.

83. Lewis JR. Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies. Intl Journal of Human–Computer Interaction. 2002;14(3&4):463-88.
84. Gillham B. Developing a Questionnaire. Great Britian: Continuum; 2000.
85. Swinscow TDV. Study design and choosing a statistical test. In: Campbell MJ, editor. Statistics at Square One. 9th ed. World Wide Web: BMJ Publishing Group; 1997.
86. Jekel JF, Katz DK, Elmore JG, DWild DMG. Epidemiology, Biostatistics, and Preventative Medicine. 3rd ed. Merritt J, DiCicco N, editors. Philadelphia, USA: Saunders Elsevier Inc.; 2007.
87. Jaspers MWM. The Think Aloud Method and User Interface Design. In: Claude G, editor. Encyclopedia of Human Computer Interaction. 7th ed. World Wide Web: ale Virtual Reference Library; 2006. p. 597-602.
88. usability.gov. Recruiting Usability Test Participants. Washington: U.S. Department of Health & Human Services,; 2014 [cited 2014 21 Feb]; Available from: http://www.usability.gov/how-to-and-tools/methods/recruiting-usability-test-participants.html.
89. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. J Biomed Inform. 2004;37(1):56-76.
90. Swinscow TDV. Populations and samples. In: Campbell MJ, editor. Statistics at Square One. 9th ed. World Wide Web: BMJ Publishing Group; 1997.
91. Anderson C. Presenting and Evaluating Qualitative Research. Am J Pharmaceut Educ. 2010;74(8).
92. Coyne IT. Sampling in qualitative research. Purposeful and theoretical sampling; mergin or clear boundaries? Aust J Adv Nurs. 1997;26(3):632-0.

Chapter 3: Resources for disease state management – what do health professionals want?

(Phase 1)

4.1 Preamble

Before developing a framework for information delivery, understanding the perceptions of health professionals (HPs) regarding information needs and delivery preferences when caring for complex patients is required. This required an exploration of:

- Usual clinical decision making process as described by practicing HPs caring for complex patients;
- What information sources HPs used to inform their clinical decisions; and
- Whether or not currently available information sources meet HP needs when providing care to complex patients.

Despite extensive literature on potential issues with current information resources and their ability to inform complex patient care, little is known about HP preferences regarding delivery of required information. In order to provide an in-depth understanding of the topic, personal semi-structured interviews were conducted with key HP: geriatricians, general practitioners (GPs), and accredited pharmacists. These HPs are commonly responsible for the care of complex patients, such as the aged, and are able to provide the valuable insight into considerations taken into account when providing care, what information sources are currently available or used in practice and whether they are adequate.

The aim of this study was to determine HPs level of satisfaction with currently available resources and to explore the requirements for an information resource that HPs can use to assist in disease state management that takes into account all complexities of patient care, or at the very least, old age and multi-morbidity.

The specific objectives of this study were to elicit:

- What considerations are taken into account when making a clinical decision in complex patients;

- The information hurdles to providing optimal care to complex patients;
- Which information resources HPs currently use to inform their clinical decisions and their strengths and weaknesses as perceived by HPs;
- What features an information resource should have in order to assist in clinical decision making in a practical and useful way.

This information will partially fulfil the objectives of Phase 1: to define the requirements of an information delivery framework based on HP interviews and literature review (1.4 Summary, Thesis Hypothesis, Aims and Objectives).

What this manuscript adds to the current knowledge

To the best of the candidate's knowledge, this was the first study to investigate HPs preferences regarding information delivery when managing complex patients such as the aged. This study provides information on how HP manage complex patients and methods they use to inform their clinical decision-making. Ultimately it provides information on the fundamental features of an information delivery framework as desired by practising HP including format, design, and information display and requirements.

As the participants primarily discussed these features in the context of an electronic information resource, the open access online **electronic Journal of Health Informatics** appropriately targets an audience involved in electronic health resource development.

4.2 Author Declaration

Declaration by candidate for paper 3 entitled:

Resources for disease state management– what do health professionals want?

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from the date indicated below:

Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University
Victoria, Australia

Date: 20/06/2014

The nature and extent of candidate's contribution to the work was:

Nature of contribution	**Extent of contribution**
Conceived idea, developed interview guide, prepared ethics approval submission, conducted interviews, analysed data, prepared first and final drafts of manuscripts.	90%

Candidate's signature: **Date**: 20/06/2014

The contributions of co-authors to the work were:

Name of co-author	**Nature of Contribution**
Adjunct A/Prof Jennifer L Marriott	Advised on study and interview guide design and assisted with manuscript preparation.

Co-author signature: **Date:** 20/06/2014

Prof Pēteris Dārziņš	Advised on study design, provided contacts for convenience sampling, and assisted with manuscript preparation.

Co-author signature: **Date:** 20/06/2014

4.3 Manuscript

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Resources for disease state management– what do health professionals want?

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Abstract
Objectives: Many medication management resources aim to improve the quality of prescribing, but simple resources naively do not address potential interactions when there are many diseases and many medications, while complex ones seem impractical to use during consultations. Limited work has explored health professional preferences regarding information resources for complex patients. This study aimed to explore the requirements for an information resource that HPs can use to assist in disease state management that takes into account all complexities of patient care, or at the very least, old age and multi-morbidity.
Methods: Purposive convenience sampling was used to recruit geriatricians, general practitioners and accredited pharmacists for one hour, individual, semi-structured interviews through August 2011 to April 2012. Recruitment continued until data saturation. Nine geriatricians, one GP and five accredited pharmacists from the Melbourne metropolitan area were interviewed. Thematic analysis was conducted using NVivo9 software.
Results: Study participants reported current resources do not assist with complex patient prescribing and lack relevance to the Australian setting. Difficulty in timely access to appropriate information and with contextualising vast amounts of new health information were identified hurdles in healthcare delivery, as were incomplete health care records. Key features which make resources useful include clear formatting, simplicity, use of peer-reviewed evidence-based recommendations, and ready access via an easy to use electronic interface.
Conclusion: Current resources do not meet health professionals' needs when they seek practical assistance when prescribing to complex patients. Future resources need to address identified hurdles to providing optimal care and incorporate desired features.

Keywords: Decision Support; Resource; Information; Health Professional; eHealth; Aged Care

1 Introduction

The plethora of medical studies published leaves many health professionals (HPs) overwhelmed. To assist HPs, information from research has been summarised and presented in a practice ready fashion through disease specific guidelines, drug monographs, and up-date newsletters. These information resources primarily aim to inform HPs on the most appropriate way to manage patient disease states. However, these resources may not be sufficient to meet HPs needs as many fail to take into account patients with multi-morbidity, drug therapy individualisation, and end of life care. [1-4] The aged are affected by these shortcomings. A recent large descriptive study of patients in General Practices in Scotland across all age groups showed that approximately one quarter of all patients had more than one health care condition, and the proportion of people with more than one health condition increased with increasing age.[5] Indeed multi-morbidity amongst older people is the norm, rather than the exception.[5-8]

Disease state management is multifaceted, usually

requiring both pharmacological (i.e.: medications) and non-pharmacological treatments. Pharmacological therapy can cure diseases, decrease symptoms of disease and improve quality of life, or help prevent undesired end-points such as heart attack or stroke; not using proven pharmacological therapy could be considered unethical medical practice. However, of increasing concern is inappropriate medication use,[9] whether the medication is not indicated, given at an inappropriate dose, or the medication itself may be inappropriate for the patient due to past allergies, adverse drug events or potential for drug or disease interactions. Inappropriate medication use leads to avoidable adverse drug events, to which the aged are especially vulnerable, leading to unnecessary medication use, general practitioner (GP) visits, hospitalisations, residential care admission, and even death.[10] Inappropriate medication use also leads to increase medical costs arising from provision of additional health care and drug use, both to treat adverse outcomes and expenditure on inappropriate medications themselves[11]. The 2009 National Prescribing Service literature review of medication safety in the community suggested that up to 30.4% of hospital admissions in the aged were attributable to adverse drug events, almost 70% of which were potentially preventable.[7]

Health services are increasingly challenged by the needs of complex patients, those who have complex medical needs, including those with multiple conditions and that are aged. New initiatives that communicate best practice to clinicians that take into account complex patient needs are required, but how to design these is not clear. Qualitative studies of General Practitioners' (GPs') and pharmacists' experiences of managing multimorbidity show that guidance when managing complex aged patients is lacking.[12, 13] Explicit criteria, expert consensus lists of appropriate and inappropriate medications in the aged, are cited as time efficient tools but lack transparency regarding the creation of recommendations, of final evaluation, and many do not address the question of multi-morbidity, limiting their use.[14]

Few studies have examined HP preferences regarding prescribing guidelines [15], or computerised decision support tools.[16, 17] Despite many post-hoc evaluations of information resources,[18] to our knowledge, none have explored HP preferences regarding prescribing resources for aged and/or multi-morbid patients, nor have they explored how best to deliver prescribing resources in general.

We wish to create an information resource that HPs can use to assist them in appropriate management of disease states that takes into account all complexities of patient care, or at the very least, old age and multimorbidity. This study was undertaken to explore the requirements of such an information resource.

2 Methods

Face to face semi-structured interviews were conducted with geriatricians, GPs and accredited pharmacists, as it was postulated that these HPs would have the greatest insight to geriatric specific resources available for medication management. Interviews lasted for up to one hour, were audio recorded, and transcribed verbatim. Ethics approval was granted by the Monash University Human Research Ethics Committee. Geriatrician interviews were conducted first; GP and pharmacist interviews were used to validate the insights gained from the geriatrician interviews. Purposive convenience sampling was used to recruit geriatricians and was planned for the GPs and pharmacists, but, as there was no remuneration to participants, difficulties were experienced when recruiting GPs and accredited pharmacists. Accordingly, a snowballing technique was used where GPs and accredited pharmacists who took part were asked to pass on study information to colleagues inviting them to participate in the study. This method helped recruit pharmacists, but only one GP was able to be recruited for this study. The interview schedule had three parts:

1. Exploration of what HPs do when they manage a geriatric patient, to:

   a) Explore what matters they take into account when making therapeutic decisions; and

   b) Provide insights into the hurdles to providing optimal care.

2. Exploration of what resources HPs use to assist them in therapeutic decision making, to:

   a) Explore why they use or do not use particular resources so that features which make a resource useful (or not) could be identified; and

   b) Provide insight into hurdles to providing optimal care that stem from currently available resources.

3. Exploration of features desired in a medication management resource to help therapeutic decision-making for older people.

Data were analysed using NVivo 9®[19] with both deductive and inductive approaches. Anticipated nodes were based on interview questions and new nodes were added as the data were analysed. Interviews with geriatricians were conducted until data saturation.

3 Results

Nine geriatricians, one GP and five accredited pharmacists from the Melbourne metropolitan area were interviewed between August 2011 and April 2012 (see Table 1). Data were analysed and grouped into three major themes: features which influence geriatric medication management choice, hurdles to providing optimal care in the aged, and desired features of a medication management resource.

3.1 Features which Influence Geriatric Medication Management Choices

The primary principle to choosing drug therapy identified in this study was goal of care. Participants based goal of care on factors such as trading off quantity versus quality of life, their patients' or their patients' family's wishes, the stage of disease, and the ability of patients to tolerate recommended disease management strategies. Choice of therapy was also based on the available evidence for efficacy and lack of harm – the Hippocratic Oath's "do no harm" was often quoted.

> *"Whether that's end of life care, whether that's preventative medicine or whether it's symptomatic care. Because I think that then flows on and it's the major crux behind any prescribing in an older person." G4*

> *"Okay. I think the other thing that's really important is the quality of life of the person. So what are their goals in life? Do they want a prolonged life . . . and / or do they want a quality of life. Not that they are exclusive, they can have both." P3*

Medical, functional and social characteristics also influenced choice. Medical characteristics considered included co-morbidities, medication history including failed therapies, allergies, and stage of disease. Functional characteristics such as the ability to swallow, to administer medication, to remember to take medications as prescribed, etc. . . were taken into account when making therapeutic choices. Social characteristics considered included continuity of care when discharged from hospital to community, as well as support to manage aspects of therapy such as administration and recognition of possible adverse effects. Social support in the community was seen as being of utmost importance for those with cognitive impairment, physical disability or those considered frail.

> *"The other big issue apart from the medication itself to me would be is this person going to take it? And how?" G6*

> *"Flag the potential for non-compliance, and difficulty with compliance, not so much non-compliance, and what are the things to look for, vision, dexterity, swallowing tablets." P5*

> *"The social support and social network of the patients who could provide the medications on a regular basis and ensure that there is no intolerance of side effects of the medication" G3*

Finally, HPs weighed the financial burden and risks of additional pharmacotherapy to patients against potential benefits before making therapeutic decisions.

> *"We do have to consider the economics as well for our patients in terms of can they afford it" G1*

> *"Even though they may have a fairly benign side effect profile they potentially are just adding to the burden of polypharmacy and can have side effects." G6*

3.2 Identified Hurdles to Providing Optimal Care in the Aged

Two major hurdles in providing optimal care were identified: 1) patient information relevant to making therapeutic choices was commonly missing from health records, and 2) literature that claimed to provide information about medication use in the aged was commonly inadequate or difficult to access in a timely manner. Good health records ensure critical patient characteristics are not missed when choosing an appropriate therapy. Some HPs found that patient information was often not adequately communicated from one HP to another, which not only translated to inappropriate medication choice in some cases, but also a waste of time and money for all stake holders – medical practitioners, patients, and funding bodies. Medical practitioners may need time to clarify information from other HPs, or may need to spend time conducting repeat examinations. Patients may need to spend time and money on unnecessary medical visits, medications, and examinations. Funding bodies are also affected; for example, each home

HP Type and Number	Gender	Age	HP experience (yrs)	Years of specialist practice
G1	F	40-49	17	7
G2	M	30-39	10	1.5
G3	M	40-49	20	6
G4	M	30-39	12	3.5
G5	M	30-39	12	5
G6	F	40-49	25	18
G7	F	40-49	19	11
G8	M	40-49	22	13
G9	F	50-59	33	22
GP1	M	60-69	40	37
P1	F	50-59	32	3
P2	F	60-69	40	11
P3	F	50-59	33	14.5
P4	M	40-49	27	14
P5	F	60-69	40	12

Table 1: Demographic Data; Key: G = Geriatrician; GP=General Practitioner; P = Accredited Pharmacist

medication review (HMR) conducted by an accredited pharmacist costs the Australian government $194.07; if accredited pharmacists do not have all the appropriate patient information they cannot conduct an effective review.[20] Money spent on such HMRs may be considered wasted. Additionally, inappropriate therapy choices stemming from incomplete medical records can lead to additional GP visits, hospital and residential care admissions.

> *"They give you terrible scribble that's often unreadable… Abbreviations are a real problem, because whoever wrote it might know what they mean, but often between the nine GPs in my practice we can't figure out what they mean, so I have to ring them up." GP1*

> *"If I don't have all the information it's a huge hindrance… I get very superficial information from most doctors… To give… a good comprehensive review… with the outcome to improve quality of life, you need as much information as possible… Then I… get feedback from the doctor, they say well you know, we tried this and they ended up in hospital because of this. And I wasn't told that. I don't know why you chose this unusual drug… I didn't know that you had tried this. I haven't been given an insight." P5*

According to the study participants, a major hurdle to providing optimal care is the paucity of aged-specific information and even less information that is applicable to the complex and frail patients commonly encountered in practice. Participants found it time consuming to identify available information. Some reported foregoing any searches due to time constraints. Indeed, a wide variety of resources was used to find answers to clinical questions, including peer experience, soft (electronic) and hard copy text books, decision-support software, and information retrieved by medical and general search engines, including guidelines and criteria published in the primary literature, hospital databases or by other reputable groups.

> *"Now as far as going online and researching and reading the product information I honestly don't have time. And I can't dissect it" G6*

When apparently appropriate primary literature was found, some HPs commented that they felt they did not have the skills to put the identified information into the clinical context, especially if there were competing results or opinions.

> *"The choice of drug therapy has to be guided by evidence and we have to extrapolate evidence from research that has occurred mainly in an adult average age population rather than looking at evidence to support the use or safety of a drug in the older population… It's a bit of guess work I guess." P3*

Finally, community based HPs were concerned about the cost of access to resources. Subscriptions available to HPs in large institutions are too expensive for small practices or for individuals, thus limiting access to relevant information.

> *"I mean it just costs too much, we can't afford to buy multiple copies, [the references are] not cheap, see that's an issue, cost is an issue" GP1*

> *"Actually the primary literature is limited for independent pharmacists because you can't always access the ... full study. So you are at the mercy of abstracts which is a really poor way to practice ... But we are just battling and flying in the dark now because we just don't have that access. You can't be subscribing to all the primary journals." P3*

3.3 Desired Features of a Medication Management Resource

Participants were asked what features they felt were "positive" or "useful" in a resource, what features they felt were "negative", and what features they thought were important to include in a medication management resource. Two general themes were identified:

3.3.1 Information Quality

HPs felt that answers to *simple* clinical questions were readily available from many current resources; however, they felt a medication management resource that can give answers to complex clinical questions is lacking. They felt the ideal resource would link both disease state and drug information to assist in therapy individualisation.

> *"The problem with the guidelines is that they are not individualised for elderly patients. So we need to then ... try and individualise them." P3*

> *"I think all the references they use are just based on the drugs. But... when I write up my report I consider a drug disease interactions quite a bit. I would like to have both [drug and disease focus]" P5*

The HPs interviewed felt recommendations made by resources should be based on peer-reviewed evidence that puts primary information into a context with accompanying rationale. The level of evidence should be described and primary sources or references provided for transparency. The recommendations should also be relevant to local practice, wherever that practice is located.

> *"Level of evidence is very important. Two points: firstly... there is still some level of evidence from trials conducted in the elderly... Secondly the recommendations should be formulated by a panel of experts ... It is very important to have both." G3*

> *"[Having] references... That's very important... Because I want to be able to have a look at that myself... why is this particular book recommending it? I want to go back to the source" P5*

When asked about international literature, some felt that it was applicable, while others felt that international resources are not always appropriate due to differences in practice, drug availability and costs.

> *"Yeah, the American ones are fairly translatable, and the philosophy seems to be the same." G2*

> *"I think there's a need more Australian based [guidelines]... what is appropriate for America, or third world countries, may not be appropriate for Australia." G8*

Finally, HPs were generally more likely to use resources in which they had confidence. To be used resources should be up-to-date and produced or endorsed by a reputable organisation.

> *"I think it's important that you... have confidence in the guideline... A reputable creator or a reputable source" G5*

3.3.2 Format

Simple suggestions such as attention to font, smart use of colours, and clear layout were at the heart of making a resource useful. The right balance between simplicity

and detail needs to be found; too much text can be difficult to read, but oversimplifying is to be avoided.

> *"Sensible use of colour, font, formatting so that it's readable... If it's not absolutely readable the likelihood is that you won't bother using it..." G5*

> *"I like [the AMH] because it's always got the little section points to consider... and it's in dot form and it just mentions the relevant things in a nutshell that you might need to consider" P1*

All but one participant (P1) suggested that the easiest resources to use are electronic, as they are generally more time efficient to use, and easy to update.

> *"Well certainly the electronic guidelines are really easy to use because just text word searching is fantastic rather than just flicking through a book... it does save time..." P3*

> *"So you have got to be able to update it frequently because it is changing all the time... [Referring to electronic resources] it's the only way to update things." P2*

4 Discussion

This study was undertaken to explore the requirements for an information resource that HPs can use to assist in appropriate management of disease states that takes into account all complexities of patient care, or at the very least, old age and multi-morbidity. Hurdles to providing appropriate care and positive or negative features of medication information resources were noted.

4.1 Summary of findings

Hurdles to providing optimal patient care included poor communication among HPs resulting in inadequate knowledge of all relevant patient information, and issues with finding best-practice information. Poor communication of relevant patient information has been identified in other research looking at experiences of primary HPs when caring for multi-morbid patients.[12, 13] Difficulties in finding clinical information resources stem from the huge volume of potentially relevant materials, their wide dispersion, and lack of time to perform extensive searches needed to identify appropriate information. HPs not part of large institutions faced an additional hurdle, namely financial constraints, meaning that they were unable to pay for subscriptions and memberships that provided access to some resources. Finally, some HPs struggled to apply the available information to their patients especially with competing information or opinions. Sometimes the retrieved information lacked relevance to their patients or to local practice. Desirable features of an information resource reflected the identified hurdles and the need to fit in with the "usual care" process. Ideally information within resources would use up-to-date, patent-group-specific, peer-reviewed evidence, that is relevant to local practice, that provides patient-centric answers to complex clinical questions. The ideal resource would provide concise answers to complex questions in a time efficient manner, with the option of providing in-depth information regarding the rationale and references behind any recommendations. Preferably, the resource would be electronic.

4.2 How do our findings fit in with current literature?

Others have had similar findings regarding information resources for HPs. Hayward et al conducted a survey looking at "preferences [*of internists*] for how guidelines are presented".[15] Aspects deemed "important"[15] largely match the observations of our research, including peer and organisation endorsement, use of algorithms, concise summaries of recommendations and supporting evidence. In contrast to our study, computer based systems were not deemed useful except for those who commonly used online resources; however, the study by Hayward was conducted in 1992, when computer support systems were not commonplace in health care. Ahearn and Kerr[16] conducted 3 focus groups with Australian GPs in 2003 looking at their perceptions of decision support tools within prescribing software. They reported similar characteristics that made decision support easy to use, such as providing concise and relevant information to the patient being treated with the option of expanding on that information, the marriage of drug and disease information, and use of evidence-based guidelines to provide recommendations within the software. [16] A 2010 Australian study used a modified Delphi technique to examine desired features of electronic prescribing software, including decision support features and their impact across four domains – patient safety, quality of care, utility to clinicians and utility to patients.[17] Decision support features deemed

to have high impact on patient safety and quality of care matched those found in our study, including use of up-to-date, evidence-based information relevant to local practice, and display of only that information relevant to particular patients.[17] Up-to-date, simple and easy to read information that is relevant to the patient in question are repeated themes across HP and resource medium type.

The major limitation of this study is the sampling method. Resources were not available to provide remuneration to participants, which limited the sampling method to using medical practitioners and pharmacists known to the investigators, augmented by snowballing. This sampling method risks recruiting like-minded study participants and potentially results in narrow views that are not in accord with the views of the wider population. Further, there was only one GP. Although data saturation was reached when all HPs were analysed as a group, interviewing more GPs may have uncovered new themes. However, the validity of our results is bolstered by the fact that they mirror other studies with GPs, both regarding requirements for information resources and hurdles identified to providing optimal care to aged or multi-morbid patients.[12, 13, 16, 17] Although we set out to define what resource health professionals want when treating aged or complex patients specifically, our findings indicate that the basic requirements for an information resource will remain the same irrespective of the population group they are targeting or the health professionals that use them.

4.3 Author recommendations

The following are recommendations by the authors for how to meet the requirements for disease management information resources for HP use. Our results suggest that HPs want an electronic information sources in the form of decision support software.

4.3.1 Providing the Patient Context

Information provided to users (i.e.: HPs) needs to be put into patient context. This requires comprehensive, up-to-date disease state management information and complete patient health records. Both need to be addressed simultaneously. One solution to proving complete patient health records is the electronic health records (EHRs). A number of countries have or are developing patient EHRs that store patient information in a central database and can be accessed by all treating HPs.[21] We believe that patient EHRs need to be integrated with intelligent decision support software. Information resources could list every possible scenario where a recommendation may or may not be appropriate in given patients – e.g.: listing *all* drug-drug interactions, *all* drug-disease interactions, *all* patient groups which may not be able to tolerate recommended drugs (for example, metformin is the drug of choice in most type 2 diabetes patients, but is not recommended in those with marked renal dysfunction) – but this solution would not be practical at the point of care. Instead, we recommend that information resources use data available in patient EMRs and only display information relevant to the patient in question. This means that EMR developers need to be able to capture all patient information relevant in clinical decision making, such as swallowing and dexterity difficulties, life expectancy, social status, etc… in addition to simple medical records, and information resource developers need to be able to utilise this information.

4.3.2 Providing Up-To-Date and Relevant Information

Our study suggests that HPs not only find it difficult to search through information resources such a primary literature due to time and financial constraints, but they also find it difficult to put what little available relevant literature there is into context. Developers should use "local" experts in a given medical field to update the data within the information resource. Experts are equipped with skills that allow them review the primary literature and translate it to practice ready recommendations for disease state management. To update information within the resource, developers should provide an easy to use template that integrates any new information with existing information.

4.3.3 Design

Our results suggest that the most user friendly resources use sensible colours, fonts, and layout, and do not provide too much information at any one time. We did not gather details on what is considered "sensible colours, fonts, and layout" as there has been considerable research in this area;[22, 23] however, it is interesting to note that design impacted interviewed HPs willingness to use an information resource and so must be considered carefully by developers. Provision of succinct information, without over simplification can be achieved by giving brief recommendations, with links to further detail. Future research should elicit exactly how much detail should be given so that HPs are able to use the information provided without the need for further clarification on most occasions. The authors are in the final stages of developing a working prototype of

4

[4] EMR should read EHR

an information resource with these recommendations – MedManAGE. Issues such as missing patient information, abundance of different information resources and formats, lack of skills interpreting evidence, lack of time to find appropriate information, and cost of resources are expected to be improved by use of MedManAGE.

5 Conclusion

HPs struggle under the pressure of keeping up to date with the latest medical literature while managing increasingly more complex patients. Despite the proliferation of medical literature limited information resources specifically address complex patients. New approaches that communicate relevant information to HPs in a timely and user-friendly fashion are needed. Results from this study have begun to define of the requirements of such a resource.

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Conflicts of Interest

No conflicts of interest declared.

References

1. Gokula M, Holmes HM. Tools to reduce polypharmacy. Clinics in Geriatric Medicine. 2012. 28(2): 323-41.

2. O'Mahony D, O'Connor M. Pharmacotherapy at the end-of-life. Age and Ageing. 2011. 40(4): 419-22.

3. Hughes LD, McMurdo MET, Guthrie B. Guidelines for people not for diseases: The challenges of applying UK clinical guidelines to people with multimorbidity. Age and Ageing. 2013. 42(1): 62-9.

4. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical practice guidelines and quality care for older patients with multiple comorbid diseases: Implications for pay for performance. Journal of the American Medical Association. 2005. 294(6): 716-24.

5. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: A cross-sectional study. Lancet. 2012. 380(9836): 37-48.

6. Australian Institute of Health and Welfare. Older Australians at a glance: 4th edition, Department of Health and Ageing, Ed. 2007; AIWH: Canberra.

7. Easton K, Morgan T, Williamson M. Medication safety in the community: A review of the literature, National Prescribing Service, Ed. 2009: Sydney.

8. Salisbury C. Multimorbidity: Redesigning health care for people who use it. Lancet. 2012. 380(9836): 7-9.

9. Hanlon JT, Schmader KE, Ruby CM, Weinberger M. Suboptimal prescribing in older inpatients and outpatients. Journal of the American Geriatrics Society. 2001. 49(2): 200-9.

10. Department of Health and Ageing. The national strategy for quality use of medicines: Executive summary. 2002; Commonwealth of Australia: Canberra.

11. Rochon PA, Gurwitz JH. Optimising drug treatment for elderly people: The prescribing cascade. British Medical Journal. 1997. 315(7115): 1096-9.

12. Smith SM, O'Kelly S, O'Dowd T. GPs' and pharmacists experiences of manageing multimorbidity: A 'pandora's box'. British Journal of General Practice. 2010. 60(576): e285-e94.

13. Luijks HD, Loeffen MJ, Largo-Janssen AL, Van Weel C, Lucassen PL, Schermer TR. GPs' considerations in multimorbidity management: A qualitative study. British Journal of General Practice. 2012. 62(600): e503-e10.

14. Marriott J, Stehlik P. A critical analysis of the methods used to develop explicit clinical criteria for use in older people. Age and Ageing. 2012. 41(4): 441-50.

15. Hayward RSA, Wilson MC, Tunis SR, Guyatt GH, Moore K-A, Bass EB. Practice guidelines: What are internists looking for? Journal of General Internal Medicine. 1996. 11(3): 176-8.

16. Ahearn MD, Kerr SJ. General practitioners' perceptions of the pharmaceutical decision-support tools in their prescribing software. Medical Journal of Australia. 2003. 179(1): 34-7.

17. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, Snowdon T. Identification of features of electronic prescribing systems to support quality and safety in primary care using a modified delphi process. BMC Medical Informatics and Decision Making. 2010. 10(21).

18. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: A systematic review of the trials to identify features critical to success. British Medical Journal. 2005. 330(7494): 765-8.

19. Nvivo9. 2010; QSR International.

20. Medicare. Home medicines review (HMR). 2013 Available from: http://www.medicareaustralia.gov.au/provider/pbs/fourth-agreement/hmr.jsp#N100BA.

21. Boonstra A, Broekhuis M. Barriers to the acceptance of electronic medical records by physicians from systematic review to taxonomy and interventions. BMC Health Services Research. 2010. 10(231).

22. Slee A, Lewis K. Design for patient safety: Guidelines for the safe on-screen display of medication information. 2010; National Patient Safety Agency.

23. Yu KH, Sweidan M, Williamson M, Fraser A. Drug interaction alerts in software - what do general pracitioners and pharmacists want? Medical Journal of Australia. 2012. 195(11): 676-80.

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Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing

(Phase 1 continued and Phase 2 and Phase 3)

5.1 Preamble

Interviews (Chapter 3: Resources for disease state management – what do health professionals want?) with health professionals (HPs) suggested that they feel current resources were not adequate in assisting clinical decision making in complex patients such as the aged and that a new resource is needed that addresses identified hurdles, has a usable electronic interface, and provides patient relevant information using up-to-date locally applicable evidence.

The results of these interviews indicated that HPs desired a clinical decision support system (CDSS) with specific features (Chapter 3: Resources for disease state management – what do health professionals want?). This only partially fulfilled the objectives of Phase 1: to define the requirements of an information delivery framework based on HP interviews and literature review (1.4 Summary, Thesis Hypothesis, Aims and Objectives). A literature review of previously developed CDSS further informed the requirements of an *electronic* information delivery framework. Building a CDSS involves design and development of a database, business rules, process model, interface and acquisition of knowledge to populate the database (2.2 System Development). This information was used to design and develop the information delivery framework. Evaluation of the framework is vital in order to determine whether or not it is useful to practicing HPs and how information delivery can be improved.

The aim of this study was to define the fundamental elements of an information delivery framework applicable to any CDSS.

The specific objectives of this study were to:

- Identify elements of successful CDSS by exploring past successes and failures;

- Define the clinical decision making process;
- Design, develop and test the usability a prototype system that meets the needs of HPs, encompasses identified elements of CDSS success and considers all the aspects of clinical decision making.

This information completes the objectives of Phase 1 (to define the requirements of an information delivery framework based on HP interviews and literature review) and Phase 2 (develop an information delivery framework including detailed design and knowledge acquisition), and partially completes the objective of Phase 3 (to evaluate usability of the information delivery framework with potential users and further refine information delivery requirements) (1.4 Summary, Thesis Hypothesis, Aims and Objectives).

What this manuscript adds to the current knowledge

HPs have suggested that current information resources are not adequate during complex patient clinical decision-making. This framework for delivering information to HP based on their needs may be able to overcome the identified hurdles to providing optimal care. The results of this study:

- Informs the general principals of CDSS success;
- Provides a universally applicable system model; and
- Defines the patient, drug and disease state management data capture required to allow for meaningful information use and provision of decision support recommendations.

This study is has been submitted for publication in the peer-reviewed open-access online **electronic Journal of Health Informatics** which appropriately targets an audience involved in electronic health resource development. Additional details of the business rule engine development have been provided as a traditional chapter in this thesis (Chapter 5: Developing the Business Rule Engine).

The system (MedManAGE) is provided on CD-ROM. Review of the program will provide a clearer understanding of the system and context for the results of this chapter

5.2 Author Declaration

MONASH University

Declaration by candidate for paper 4 entitled:

Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from the date indicated below:

Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University
Victoria, Australia

Date: 20/06/2014

The nature and extent of candidate's contribution to the work was:

Nature of contribution	**Extent of contribution**
Conducted literature search, reviewed articles, design and development of system requirements, database, interface design, business rules, data acquisition and database population, development of testing scenario, conducting of talk-aloud usability testing and data analysis, and preparation of first and final drafts of manuscripts.	90%
Candidate's signature: 	**Date**: 20/06/2014

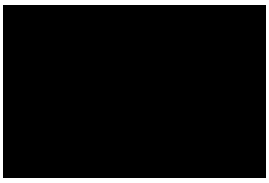
The contributions of co-authors to the work were:

Name of co-author	**Nature of Contribution**
Adjunct A/Prof Jennifer L Marriott	Advised on literature, system design, and assisted with manuscript preparation

Co-author signature: **Date:** 20/06/2014

Mr Amirhossein Bahmanpour	Coded the software and assisted with manuscript preparation

Co-author signature: **Date:** 20/06/2014



Dr. Y. Ahmet Sekercioglu	Supervision of student programmer, and assisted with manuscript preparation

Co-author signature: **Date:** 20/06/2014

Prof. Pēteris Dārziņš	Assisted with manuscript preparation

Co-author signature: **Date:** 20/06/2014

5.3 **Manuscript**

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Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing

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We describe a new clinical decision support system (CDSS) that delivers patient-relevant disease-state management information to health professionals seeking guidance. Traditional forms of communicating best practice disease state management do not adequately support appropriate prescribing in patients with complex needs, such as those with multi-morbidities or aged patients. An effective solution is the use of clinical decision support systems. Here, we present a new CDSS framework for healthcare information delivery tailored for health professional use. Concepts described in this article could be used to as the foundation for other CDSS and to inform electronic medical record design.

Keywords: clinical decision support system; decision support system; requirements; database architecture; usability

1 Introduction

Clinical practice guidelines have been used to improve and standardise clinical practice. Despite potential benefits, clinical guidelines have been criticised for failing to take into account patients with multi-morbidity, drug therapy individualisation and end of life care, and because they can be time consuming to use.[1-4] Other barriers to clinical guideline use include health professionals (HP) feeling that their clinical autonomy is under threat, a lack of awareness of or time to search for guidelines and difficulties in individualisation of recommendations.[5-7] Multi-morbidity is the norm rather than the exception in ageing people[8-11] and as the average age of the population increases[12, 13] there is an increasing need for effective delivery of evidence based information to assist in management of complex patients. Decision support systems (DSS) also known as expert systems, can help overcome barriers with clinical practice guidelines. DSS intend to mimic human experts[14] and aim to assist users through alerts and messages, providing definite answers where such are available or by displaying other information that may influence the user's decisions.

The primary purpose of DSS in medicine, or clinical decision support system (CDSS), is to improve the quality of patient-care. CDSS are able to improve practitioner performance[15], adherence to evidence-based practice,[16, 17] decrease medication errors and reduce adverse drug reactions[18] and potentially decrease costs.[19] There is also some evidence that CDSS can improve medication dosing

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and frequency choice, compliance with local guidelines, decrease pharmacist intervention due to inappropriate medication choice, and improve patient satisfaction and outcomes.[16, 20-23]

CDSS with varying degrees of sophistication are commonly integrated into computer physician order entry (CPOE) systems, dispensing or other patient information documentation systems with automatic alerts, reminders, and recommendations. Despite the potential benefits of CDSS, there have been numerous barriers to their use in practice, including type of information displayed and its quality, as well as non-adherence to basic rules of system development, and lack of overall structure and data standardisation within the e-Health industry.[24-27] Unlike in other information-driven fields, such as accounting and business, medicine lacks effective and usable solutions.[28]

Previous work reviled that new information resource is required that assists in the disease state management of complex patients by display of patient relevant information.[6] To meet this need, and to better define what constitutes an effective and useful CDSS, a prototype system was developed and tested. Therefore, this paper aims to describe fundamental elements applicable to any CDSS by:

1. Exploring past CDSS successes and failures;
2. Examining the clinical decision making process;
3. Describing the development and initial usability testing of a prototype system (MedManAGE).

2 Part 1: Past Successes and Failures

Aims

This section aims to explore reasons for past failures of CDSS and determine what features are significant in improving CDSS usability and success.

Method:

MedLine (1966-2013) was searched for relevant studies by using the search terms: ["*Computer Physician Order Entry*" OR "*Clinical Decision Support*"] AND ["*usability*" OR "*implementation*" OR "*lessons*" OR "*testing*"]. The searches were restricted to English language. The reference lists were reviewed to identify additional articles.

Articles that described the design, development, or evaluation of medication management CDSS, where a CDSS was defined as a system designed specifically to assist HPs during the clinical decision-making process regarding treatment of disease states were included. Articles that described CDSS that were administrative in nature, for example that dealt with appointments, diagnostic test results, and laboratory result alerts, were excluded from the review. Focus was kept on "clinical" rather than "administrative" CDSS as features that make one type of CDSS successful or unsuccessful may not be applicable to other types.[29] Articles were included if information pertaining to reasons for success or failure of CDSS or discussion of CDSS data requirements was provided.

Results

The search of MedLine yielded 105 results. Sixty-one articles met the inclusion criteria.

Lessons from the past – Contributors to technology induced errors

The majority of technology-induced errors stem from inappropriate integration of the CDSS into usual workflow and unusable system interfaces.

A mixed method study, conducted in 2005, in major urban tertiary care teaching hospitals in the USA involved interviews, focus groups, observations and surveys that aimed to "identify and quantify the role of CPOE in facilitating prescription error risks" highlighted that medication errors predominately stemmed from information errors as well as workflow and interface issues.[30] Information errors included using pharmaceutical warehouse information rather than clinical guidelines. Interface sources of error relevant to decision support included legibility issues related to the font size and colour, lack of easy "one screen fit" for patient information and an inflexible system regarding medication order entry (including non-formulary and modified formulation items).[30] Many of the sources of error came from what seems to be an incomplete understanding of usual workflow, for example, failure to provide medications after surgery, antibiotic renewal failure, and charting difficulties.[30] Further errors arose from malfunctions such as sending medications to the wrong rooms when the system shuts down.[30]

The Children's Hospital of Pittsburgh conducted a retrospective study examining the mortality rates of admitted children before and after CPOE implementation.[31] The study period, October 2001 to March 2003, encompassed 13 months without, and 5 months with, a CPOE system. Analysis revealed an unexpected increase in mortality rates after the introduction of the CPOE system. The primary reason for the increase in mortality was that the CPOE interfered with usual workflow resulting in delayed vital medication ordering, decreased patient-practitioner face-to-face interaction, unwanted duplication of tasks, and inefficient use of HPs. Although some of the issues that arose may have been due to inexperience with the CPOE, most would not have been rectified with experience.[31] This study inspired a commentary describing eight lessons learnt from this experience, from the number of clicks required when using the system to the overall CPOE implementation strategy. [32]

A study that investigated the number of medication errors and pharmacist interventions during two four-week periods, before and after the implementation of CPOE in a UK hospital, found that there was a lower rate of medication errors (absolute reduction of 1.8% CI 0.9-2.7%) and a decreased number of pharmacist interventions (absolute reductions of 1.1% CI 0.2-2%) after implementation.[20] This decrease was not due to decision support however, as the only decision support provided was default doses. There were some general lessons from this study as unexpected errors arose due to order entry that can be seen as relevant to all health information technology (HIT). Selection of inappropriate medication, omission of drugs, excessively frequent dosing of "PRN" drugs, selection of incorrect dosing frequency, selection of inappropriate formulation were errors deemed to be due to the system itself. [20] These types of "data input" errors can potentially be minimised with interface solutions such the use of appropriate font size and colours, and autocomplete boxes rather than selecting items from lists.[33]

A Canadian study specifically examined what features of interface designs contribute to adverse events.[34] Seven emergency department physicians were observed using four different CDSS.[34] The number and types of events were recorded.[34] Errors that could potentially contribute to patient harm included inability to record patient data accurately because terms were not predefined, inappropriate screen layout, prompts to indicate patient data or order entry fields were missed, and automatic screen population of data fields (e.g. providing a standard dose rather than requiring manual dose entry). [34]

Previous successes

Many of the components that make CPOE successful are relevant to CDSS; key features are summarised in Table 1.

Gadd et al. in 1998 identified properties that improve usability and acceptance of internet-based DSS. These include clear viewing screen set out, flagging of potential problems and easy identification of problem importance, and the provision of the rationale for DSS recommendations with ready access to more information if desired by users.[35] Numerous studies since then have identified the desired features have not changed.[6, 36-50] A multi-method observational study involving developers, users and managers of the systems in US hospitals and medical clinics that used CPOE and CDSS identified some additional desired features. These concerned workflow integration and separate CDSS components, up-to-date high quality content, work flow integration, feedback mechanisms after implementation and involvement of HPs during development of the systems.[36]

Sweidan et al. determined what features of electronic prescribing systems support high quality and safe use of medications in primary care.[37] The features were initially identified using an extensive literature review, key informant interviews and expert panel member recommendations resulting in 114 features, ten of which were considered "aspirational". Twelve experts with backgrounds in general practice, public health, quality and safety, health informatics, pharmacy and consumer health issues, then rated the features according to impact across four domains (patient safety, quality of care, useful to clinician, useful to patient) using a three round modified Delphi technique. Although these features were developed with electronic prescribing system in mind, many are relevant to CDSS. Similar themes were identified by an exploratory study that used three GP focus groups (Sydney, Melbourne and rural NSW) to explore the strengths and weaknesses of prescribing software.[38] Kawamoto et al conducted a systematic review of the literature and identified CDSS features that were considered crucial for improving clinical practice.[51] Of the 71 reviewed CDSSs, 48 significantly improved clinical practice.[51] Other studies exploring user satisfaction, preferences, expectations, or lessons learnt from HIT implementation have mirrored these findings.[6, 39-50]

Table 1: Summary of Features Associated with CDSS Success: Desired Features

General Features
• Use of a computer to generate decision support.[6, 51] • Fast system.[51]
Clinician-system interaction features

• Saves clinician time or requires minimal time to use.[51]
• Clear and intuitive user interface adhering to usability guidelines and developed using human factor engineering methods.[6, 35, 40, 41, 43, 46, 49, 51]
• Key information can be seen all on the one screen.[41, 43, 49]
• Keyword based search rather than menu-based search.[20, 52]
• Any CPOE and CDSS must fit into the usual workflow of the organisation.[36, 49]
  ○ Integration with charting and order entry system.[51]
  ○ Provision of decision support at time and place of decision making.[51]
  ○ Automatic provision of decision support as part of workflow.[51]
  ○ No need for additional data entry.[44, 46, 51]
• Documentation of actions: [6, 35, 45, 51]
  ○ Request documentation of rationale for not following CDSS recommendations.[6, 35, 51]
  ○ Recommendations executed by noting agreement.[35, 51]
• Have methods to stop "easily overriding" important alerts.[38]

CDSS Capabilities
• Provides patient individualised recommendations.[6, 37, 46] • Flag all important interactions including drug-disease interactions, duplicate drug, etc...[35, 37, 38, 50] while avoiding "alert fatigue".[43, 44, 50] • Alerts are prioritised and distinguishable by importance/severity, potentially with the use of colours and positioning.[6, 35, 37, 38, 40, 45, 46, 50] • Allergies need to be highlighted; it should be extremely difficult to prescribe a medication if the patient is potentially allergic.[37, 38, 44]

- Monitoring of laboratory results and alerts where indicated.[37]
- A medications list should be producible from the stored patient information that lists current medication by diagnosis/condition and current/past medication.[6, 37, 38, 41, 44]
- Inclusion of dosage, renal function, etc... calculators.[37, 38]
- Easy sending of information to the local body in charge of collecting information on adverse drug reactions; for example in Australia this would be the Advisory Committee on the Safety of Medicines (ACSOM).[37, 38]

Communication content features

- Knowledge base should:
  - Contain high quality local data.[6, 36, 37]
  - Appropriate procedures need to be in place to ensure the knowledge base is kept up to date.[36, 37, 44]
- Use standard vocabulary and database architecture to allow for easy understanding and information exchange with other systems.[36, 37, 40, 41, 43]
- Assessments and recommendations are accurate.[51]
- Provision of key information, with access to further information if required.[6, 40, 42, 45, 50]
- Provision of a recommendation, not just assessment.[6, 39, 51]
  - Justification of decision support via provision of reasoning.[6, 35, 51]
  - Justification of decision support via provision of research evidence.[6, 35, 51]
  - Users should be able to access the resource used to give a recommendation; at the very least, the recommendation should be referenced.[6, 35, 38]
  - Decision support needs to be based on clinical guidelines and independent drug information other than approved drug monograph.[35, 37, 38, 46]
  - Avoidance of default dose for DSS within CPOE systems is recommended.[34, 43]
- Provision of key counselling points.[37]
- Promotion of action rather than inaction.[51]

Other

- Local or end user involvement in development and evaluation process.[36, 43, 49, 51]
- Active involvement of local opinion leaders.[51]
- Alignment of decision support objective with organisational proprieties and with the beliefs and financial interests of individual clinicians.[44, 51]
- System developed through iterative refinement process.[51]
  - CDS should be tested on real users before implementation.[36]
  - After implementation, avenues for receiving and acting upon user feedback should be established.[36, 43, 49, 51]
- CDSS accompanied with conventional education.[51]
- Ability to personalise system.[41]
- Provision of decision support results to patients as well as providers.[51]

A follow up study to Sweidan et al.[37], using test scripts, evaluated the presence of the features that were thought to have a high impact of safety or quality of care, excluding "aspirational" features, in seven commonly used general practice electronic prescribing software packages .[53] Only 34-62% of the 50 evaluated features were fully implemented across the seven evaluated programs. Although most had important safety features such as drug-drug interactions, allergy alerts, and pathology reminders, the following CDSS-specific shortfalls were identified:

1. There was little or no decision support for harmful dosage regimens, and safety warning issued by the Therapeutic Goods Administration;
2. None had information from the key Australian drug and clinical information sources: the Australian Medicines Handbook (AMH)[54] and Therapeutic Guidelines[55];
3. Systems provided limited drug information and used only approved product information;
4. Linking indications to prescribed medications was optional providing incomplete information given to other health care professionals;

5. Drug selection was made difficult by the use of small and cramped lists with similar named products placed in close proximity;
6. The patients' current and past medications were poorly defined;
7. Medication lists produced for patients were inappropriate – many included abbreviations, Latin terms, and omitted crucial information such as indication;
8. Some systems did not have allergy warnings for potential cross-sensitivities;
9. There was no standard way of recording non-pharmacological treatment initiated; in some cases they were not recorded at all; and
10. Many had minimal patient resources.

Conclusion: Part 1

Features that contribute to CDSS failure or, conversely, contribute to improved usability and success have been identified. These features should form the basis of overall system design. First, appropriate implementation is vital for success including a clear definition of CDSS purpose. Second, use of human factor methods, adherence to usability standards and end-user involvement throughout design and development are vital in order to make usable and effective system. End-user involvement not only gives insight into usability issues, but also helps developers ensure that HIT integrates well with workflow. To avoid repeated patient data entry CDSS should integrate with locally used CPOE or EHR systems. Information used to form clinical recommendations needs to be up to date, of high quality, and verified for accuracy. Summarised recommendations should be accompanied by rationale and access to supporting evidence. Finally, systems need to be thoroughly tested prior to implementation and periodically thereafter for continual improvement.

3 Part 2: Examining the Clinical Decision Making Process

Aims

To examine the clinical decision making process in order to describe a universally applicable model including associated data requirements.

Method

In order to identify the clinical decision-making process, Australian and international online publications regarding the medication review and quality prescribing process, including World Health Organization (WHO) and National Prescribing Service (NPS).

Australian approved drug monographs were used to identify drug attributes that influenced decision making. In addition, disease state management literature and guidelines for four disease states, five associated symptoms and numerous population types and subtypes were reviewed. Guidelines were used to describe the usual clinical decision making process, identify drug factors that affect pharmacological therapy choice, and for database population. Information sources included the National Health and Medical Research Council guidelines (NHMRC) and disease specific bodies such as the National Heart Foundation, Diabetes Australia, Diabetes Educators and Arthritis Australia.

Results

The World Health Organisation has released the "Guide to Good Prescribing" as an international standard.[56] They describe six core steps to rational prescribing:

1. "Defining the patient's problem."

- The correct diagnosis must be established prior to choosing an appropriate treatment.

2. "Specify the therapeutic objective."
   - Objectives may change under different circumstances. This process assists with minimising drug-overprescribing and later evaluation of treatment efficacy.
3. "Verify whether your P-treatment [*or available treatment*] is suitable for this patient."
   - Any treatment, whether pharmacological or non-pharmacological should be safe, effective and cost-effective for the patient. Choosing an appropriate drug requires taking into account patient and drug attributes.
4. "Start the treatment."
5. "Give information, instruction and warnings."
6. "Monitor (stop) the treatment."
   - Treatment failure generally results from three basic causes: 1) the treatment was ineffective, 2) the treatment was unsafe (e.g.: side effects), 3) the treatment was inconvenient to administer due to the nature of administration or dosing schedule. When choosing to re-treat with a new therapy, these need to be taken into consideration.

The NPS of Australia published a document entitled "Competences Required to Prescribe Medicines: Putting quality use of medicines into practice" that describes five areas of competency required for prescribing irrespective of the HP type that reflect core steps described by the WHO.[57] These overall principals for disease state management are echoed globally indicating that the clinical decision making *process* is the same irrespective of geographical location.[58-61]

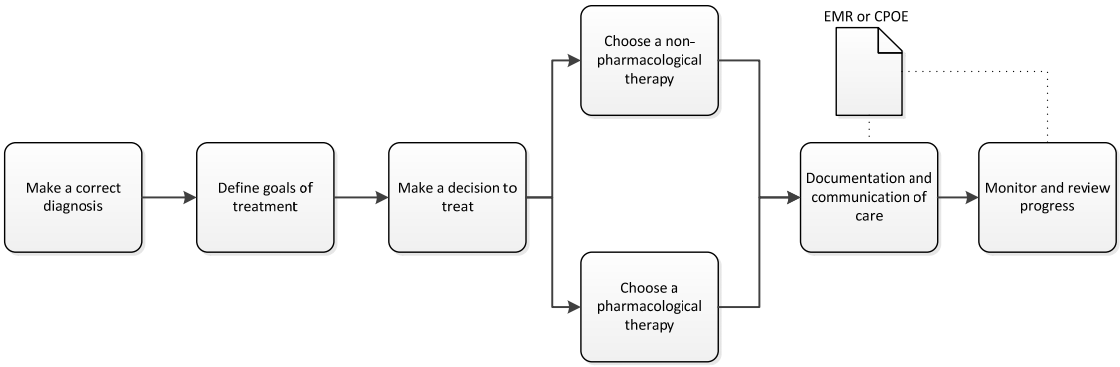

Figure 1: Summary of overall prescribing process

Disease state management guidelines were used to help identify disease specific considerations that may not have been identified otherwise.[54, 62-89] Common factors considered by all the guidelines reflected the overall prescribing process (*Figure 1*). This information was utilized to develop a universal model implemented in our prototype system (*Figure 2*).

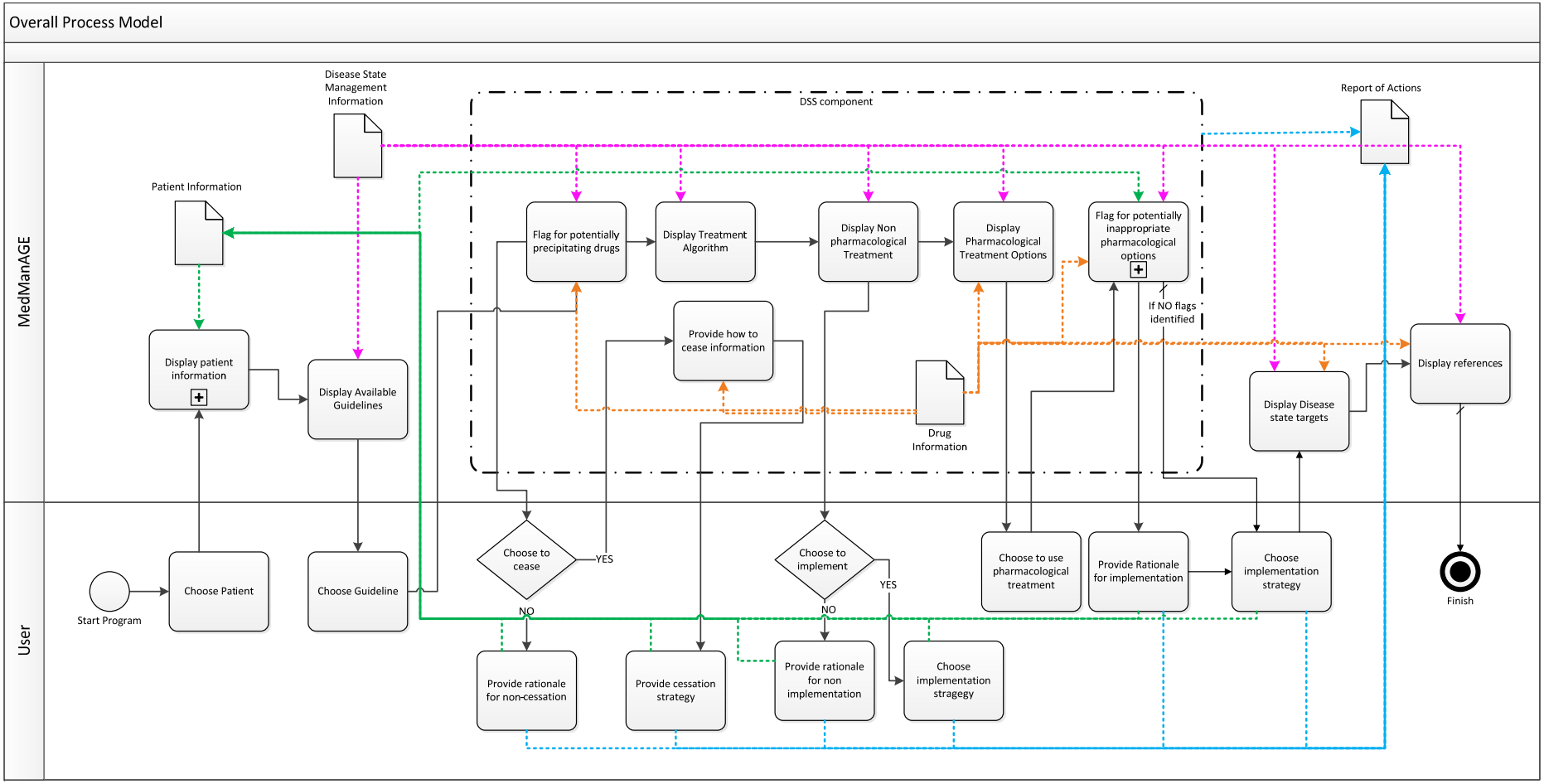

Figure 2: Universal clinical decision-making model implemented in MedManAGE

Patient physical and medical factors as well as patient preferences influence medication choice.[56, 57] Patient factors include, but are not limited to, past and present medication and medical history, laboratory results and other observations, adverse drug reactions, allergies, physical or mental impairment that may affect medication taking, and social status. In addition to these, pharmacogenomics will have a larger influence on drug choice as the body of information regarding genetic factors impacting pharmacokinetics (PK) and pharmacodynamics (PD) grows; these should be included in CDSS, electronic health record (EHR) and CPOE systems and populated with emerging information.[90, 91] Disease state management factors influencing treatment choice include evidence for effective pharmacological and non-pharmacological treatment and disease state targets such as blood pressure or blood glucose.[54, 62-89] Drug factors revolved around PK and PD properties, as well as local availablity and cost.[54, 62-89] The overall process of choosing pharmacological therapy is summarised in *Figure 4*.

'IF… THEN' algorithms can be developed based on these influences (*Figure 3*), as well as algorithms to identify drugs that may be precipitating presenting symptoms.

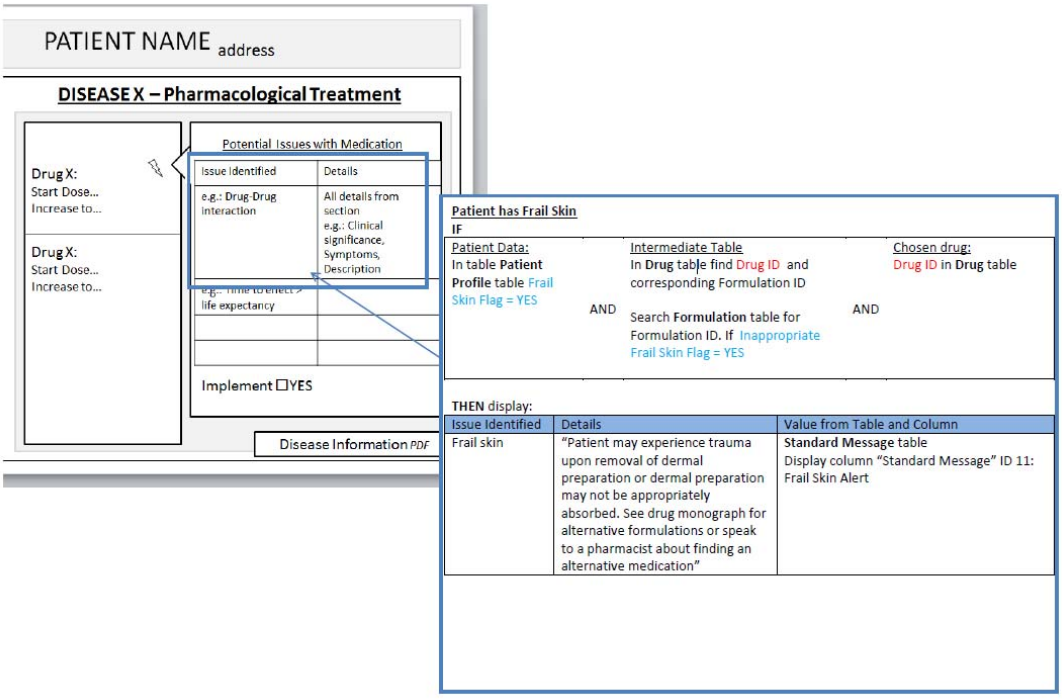

Figure 3: Example of IF-THEN algorithm for identifying potentially inappropriate pharmacological therapy due to patient frail skin used in MedManAGE

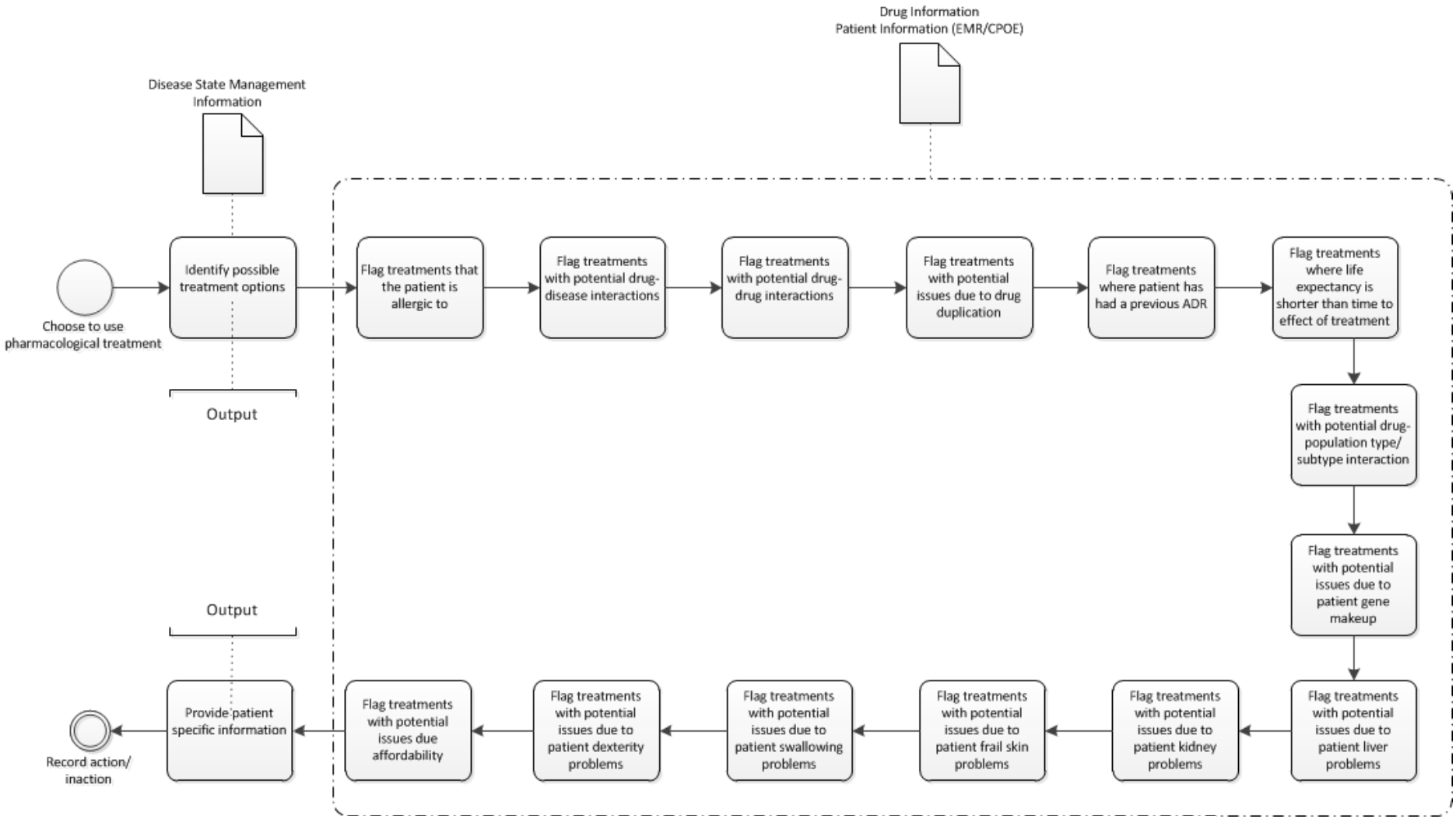

Figure 4: Overall pharmacological therapy choice process.

CDSS need to mimic the thought process of a HP in order to come to a similar conclusion regarding best patient care; therefore, factors discussed above that are considered during clinical decision making are the basis for the information CDSS needs to provide meaningful recommendations/alerts to users (*Table 2*).

Table 2: CDSS overall system design and corresponding data needed

System Design	Data needed		
	Patient information (EHR component)	**Drug information**	**Disease management information**
Documentation of Non-pharmacological therapy	Patient non-pharmacological therapy including what and implementation strategy		Non-drug therapy used for disease/symptom including what and rationale.
Documentation of action	Rationale for use/ comments section for each patient in drug or non-drug treatment history.		Drug therapy used for disease/symptom including dose, frequency, duration of treatment, and rationale.
Documentation of inaction	Rationale for non-use/ comments section in patient treatment history. If a drug is has been ceased, the reason for cessation needs to be stored.		
Warnings and alerts should be colour-coded to their severity.	Any interactions/ alerts should have a "severity code".		
Flag for all important alerts			
• Allergy	Patient drug or drug class or allergy class stored.	Drug class and allergy class stored for each drug.	
• Drug disease interactions	All diseases/ symptoms stored for each patient. Whether these are current, intermittent or past conditions.	Drug-disease/symptom interaction and a description of the interaction.	
• Drug-drug interactions	All patient drugs are stored in patient treatment history, including illicit drug use	Drug interactions and a description of the interaction.	

	and smoking status. Whether these are current (chronic or short term), intermittent or past medications is clear.		
• Previous adverse drug reaction (ADR); and easy sending of information to local governing bodies.	All drug-ADR stored in patient history including details of reaction as per local drug-ADR form (in Australia this is the Advisory Committee on the Safety of Medicines (ACSOM) form).	All ADR (disease/symptom a drug can cause) stored for each drug.	
• Drug-population type/subtype interaction	Patients can be part of a number of population types/subtypes. These include but are not limited to: • Age • Gender (male/female) • Pregnancy status and stage (if applicable) • Breastfeeding status (if applicable) • Frailty score • Race	Drug min and max age of use. Drug-gender interaction. Drug-pregnancy status/stage interaction. Drug-breastfeeding interaction. Drug-frailty score interaction. Drug-Race interaction. Descriptions of each interaction.	For each disease management guideline – what population types and subtypes they are relevant to.
• Drug-liver dysfunction interaction	Patient liver function.	Drug-liver function interaction severity, description and dose adjustment.	
• Drug-renal dysfunction interaction	Patient renal function.	Drug-renal function interaction severity, description and dose adjustment.	
• Drug-frail skin interaction	Patient skin frailty flag.	Drug inappropriate with frail skin flag.	
• Drug-swallowing difficulty interaction	Patient swallowing difficulty flag.	Drug inappropriate with swallowing difficulty flag, whether it is due to the drug itself or the formulation type.	
• Drug-dexterity problems	Patient dexterity problems flag.	Drug inappropriate with dexterity	

interaction		problems flag, whether it is due to the drug itself or the formulation type.	
• Drug-cost issues	Patient entitlements. For example, relevant to Australia is patient eligibility for: • Medicare • Concession • Safety net • Repat	Local cost requirements. For example, relevant to Australia: Whether the drug is subsidised by the Pharmaceutical Benefits Scheme (PBS) If the drug has any special requirements for subsidisation.	
• Pharmacogenetic factors impacting PK and PD	Patient allele type.	Gene affecting drug PK or PD and description of impact.	
Monitoring of laboratory results and alerts where indicated.	Patient monitoring results including what type measurement was taken, date and result.	Drug target for each disease/symptom and population type/subtype. Drug-monitoring interaction.	Disease/symptom targets (e.g.: blood pressure, etc…) for each population type/subtype.
Provision of key counselling points		Drug counselling points stored including ancillary labels.	

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Conclusion: Part 2

When choosing a safe, effective, and affordable medication, there is interplay between effective treatments available for use to manage a disease state in a patient, the patient's current and past medical history, their preferences, and drug PK and PD properties, as well as affordability and availability. All of these need to be considered in order to provide "appropriate" treatment. A universal clinical decision-making model was developed that can be utilized as the basis of CDSS process model, and associated algorithms and database architecture.

4 Part 3: System Development and Usability Testing

Aims

To develop a system that meets HPs' identified needs and perform usability testing to evaluate whether HPs find the way in which the system delivers information useful.

Method

System Development

Agile methodology was used to develop the system. Requirements for this CDSS were based on in Part 1 and 2 of this paper, as well as previously identified HP desires.[6] Visual Studio[92] C# language .4NET[93] was used to develop the system. Programming was undertaken by a final year computer science student (AB), in line with Monash University's collaborative policies. AB was given all system requirements including process model, populated database, basic interface design and business rules, which were modified during development as necessary.

Initial Usability Testing

Five pharmacy academics were asked to use the system to decide on the management of a patient's newly diagnosed osteoarthritis. Participants were asked to pretend to be a user with given attributes, rather than themselves (*Table 3*). The user's and patient's characteristics were based on real life where the user represented an average medical practitioner and the patient represented an aged and complex patient. The goal of the scenario was to use the system as it would be used in practice; specifically to:

1. Choose an appropriate treatment guideline
2. Implement treatment strategies
    a. Make a decision regarding precipitating drugs,
    b. Make a decision regarding non-pharmacological treatment,
    c. Make a decision regarding pharmacological treatment,

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d. View monitoring requirements.

Participants were asked to think aloud during the sessions and provide insight into usability, aesthetics, and overall usefulness in the way information is presented in the system. The sessions were observed by a researcher who took notes regarding usability issues, user likes and dislikes, and overall program issues. In order to establish the usability of each interface screen, the observer attempted to answer the following questions:[94]

1. What effect was the user trying to achieve by selecting this action?
2. How did the user know that this action was available?
3. Did the selected action achieve the desired effect?
4. When the action was selected, could the user determine how things were going?

Sessions took place over two consecutive days. Minor changes were made to the interface based on feedback after day one (3 participants) and the new interface was used for day two testing.

Table 3: User attributes

Education
Is a registered medical practitioner in Australia
Relevant work experience
Completed their medical degree 8 years ago Has been registered as a GP for 6 months.
Experience with DSS
Uses MIMS drug interaction identifier.
Operating Systems and Software Packages used Frequently (at least once a week)
Microsoft Windows 7 Microsoft Outlook Apple, iTunes, Microsoft Office (Word, Excel, etc…), Google Chrome, Adobe Reader, Skype, Internet Explorer Various prescribing software, MIMS, AMH, eTG
Experience with Complex Patients
Encounters complex patients as part of their role as a GP; at least 5 times a week for the past 6 months.

Results

Prototype system was successfully built within the allowed time fame, although not all features were implemented (*Table 4*).

Table 4: Summary of features associated with success (from Table 1) implemented in MedManAGE.

Desired Feature	Included	Rationale for exclusion
Clinician-system interaction features		
• Clear and intuitive user interface adhering to usability guidelines and developed using human factor engineering methods.[6, 35, 40, 41, 43, 46, 49, 51]	✓	
• Key information can be seen all on the one screen.[41, 43, 49]	✓	
• Keyword based search rather than menu-based search.[20, 52]	✓ and ×	Where appropriate, keyword base search was implemented
• Any CPOE and CDSS must fit into the usual workflow of the organisation.[36, 49] o Integration with charting and order entry system.[51] o Provision of decision support at time and place of decision making.[51] o Automatic provision of decision support as part of workflow.[51] o No need for additional data entry.[44, 46, 51]	✓ and ×	This system was developed as a prototype. Future development will include data integration properties.
• Documentation of actions: [6, 35, 45, 51] o Request documentation of reason for not following CDSS recommendations.[6, 35, 51] o Recommendations executed by noting agreement.[35, 51]	✓	
• Have methods to stop "easily overriding" important alerts.[38]	×	This system was developed as a prototype. Future development will include safety features such as this one.
CDSS Capabilities		
• Provides patient individualised recommendations.[6, 37, 46]	✓	
• Flag all important interactions, including drug-disease interactions, duplicate drug, etc...[35, 37, 38, 50] while avoiding "alert fatigue".[43, 44, 50]	✓	
• Alerts are prioritised and distinguishable by importance/severity, potentially with the use of colours and positioning.[6, 35, 37, 38, 40, 45, 46, 50]	✓	
• Allergies need to be highlighted; it should be extremely difficult to prescribe a medication if the patient is potentially allergic.[37, 38, 44]	✓ and ×	Allergies are highlighted. However, this system was developed as a prototype. Future development will include safety features such as this one.
• Monitoring of laboratory results and alerts where indicated.[37]	×	This was not intended as a review program. Therefore, review algorithms were not developed. However, database model was designed with the potential for expansion to review system in mind
• A medications list should be producible from the stored patient information that lists current medication by diagnosis/condition and current/past medication.[6, 37,	✓	

38, 41, 44]		
• Inclusion of dosage, renal function, etc... calculators.[37, 38]	×	This system was developed as a prototype. Future development will include features such as this one.
• Easy sending of information to the local body in charge of collecting information on adverse drug reactions; for example in Australia this would be the Advisory Committee on the Safety of Medicines (ACSOM).[37, 38]	✓ and ×	Relevant data is stored in database for easy extraction. As this system was developed as a prototype, sending capabilities have not yet been implemented.
Communication content features		
• Knowledge base should: o Contain high quality local data.[6, 36, 37]	✓	
• Use standard vocabulary and database architecture to allow for easy understanding and information exchange with other systems.[36, 37, 40, 41, 43]	×	New archetype was used for this system. Future development will include data integration properties.
• Provision of key information, with access to further information if required.[6, 40, 42, 45, 50]	✓	
• Provision of a recommendation, not just assessment.[6, 39, 51] o Justification of decision support via provision of reasoning.[6, 35, 51] o Justification of decision support via provision of research evidence.[6, 35, 51] o Users should be able to access the resource used to give a recommendation; at the very least, the recommendation should be referenced.[6, 35, 38] o Decision support needs to be based on clinical guidelines and independent drug information other than approved drug monograph.[35, 37, 38, 46] o Avoidance of default dose for DSS within CPOE systems is recommended.[34, 43]	✓ and ×	References are provided; however the referencing system is immature and needs further development.
• Provision of key counselling points.[37]	✓	
• Promotion of action rather than inaction.[51]	✓	
Other		
• Local or end user involvement in development and evaluation process.[36, 43, 49, 51]	✓	
• System developed through iterative refinement process.[51] o CDSS should be tested on real users before implementation.[36] o After implementation, avenues for receiving and acting upon user feedback should be established.[36, 43, 49, 51]	✓	
• Ability to personalise system.[41]		
• Provision of decision support results to patients as well as providers.[51]	✓ and ×	Report generated at end of session is targeted at HPs, but could be used for patients if modified by HP.

Initial Usability Testing

Only minor usability issues were identified during usability testing, the majority of which were associated with the "EHR" component of the system. Although the system was not developed as EHR system, information gained may be useful to developers.

Day one of testing indicated that labels and instructions caused the most confusion; these were changed to be more clear and concise. Comments were made regarding button position (such as save, view more information, etc…); it was agreed that they needed to be in an obvious or intuitive place, although opinions varied as to what was "intuitive". Participants also commented that they preferred drop-down combo boxes for short lists and autocomplete combo boxes for longer lists to assist in searching. Use of colours to separate sections of the screen was considered a useful way to guide users. No new categories of issues were identified on day two, although the same issues were identified in new areas of the interface that others had missed.

Participants had the most difficulty with the "choose the appropriate guideline" screen (*Figure 5*) and required explanation from the researcher. Once the screen concept was explained, participants were able to successfully select a guideline. Otherwise the way in which information that assists with making therapeutic choices was presented, was deemed useful and informative by participants.

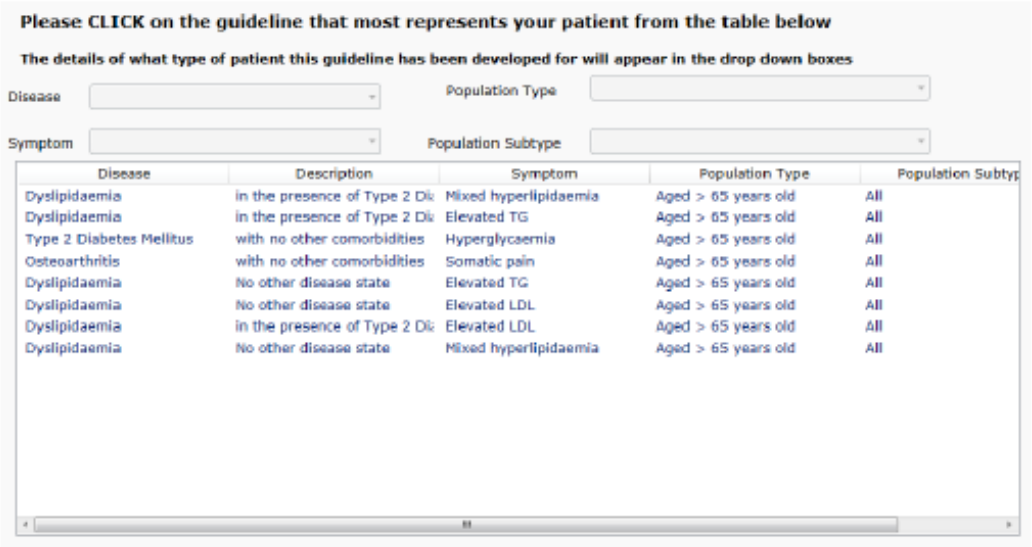

Figure 5: Choose the appropriate treatment guideline screen.

Overall, most participants stated that they would find the program easier to use with practice and suggested that an initial demonstration would be helpful for first time users.

Conclusion: Part 3

A prototype CDSS was successfully built although not all requirements were implemented. Initial usability testing suggests that overall the system is usable despite minor interface issues.

5 Overall Discussion

Overcoming Past CDSS Problems and Researcher Recommendations

A prototype system program was successfully built with most, but not all, previously features associated with CDSS success implemented. There were three major reasons for non-implementation. MedManAGE is a prototype and not intended for full scale use. Its purpose was to test whether or not the way in which information was presented to HPs was useful during clinical decision-making. Therefore, not all features were considered "vital" at this stage of development and testing. Additionally, a student programmer was used which put constraints on time and skill available during development. However, for the development of a prototype system, it was felt that a student programmer was adequate and appropriate. If further development were to occur, programmers with more experience would be involved.

Clinical autonomy is an important to clinicians using decision support, electronic or otherwise.[6, 7] Previous research also has demonstrated that HPs occasionally find guidelines selected by CDSS inappropriate for their patient. [6, 95, 96] Therefore to overcome this and to maintain clinical autonomy, we allowed HPs to view all available guidelines and choose the one they felt most closely represented their patient. However, this was the most problematic screen for participants. Although clinicians choose their own guidelines in practice this is a new concept in CDSS as most automatically choose the guideline for the user, and a possible explanation as to why participants found this page somewhat difficult to manage. Nevertheless, when the page was explained, participants easily understood the concept.

Relational model was used for the database design. Other CDSS have used XML or non-relational database archetypes due to the hierarchical nature of diseases and symptoms.[97-101] A relational model was chosen because flagging for inappropriate treatment options (e.g.: drug-disease interactions) is relational in nature. Although somewhat hierarchical in nature, disease/symptoms can be stored as relational data; use of hybrid database may be considered in future development of this or similar systems. Non-relational models are also used due to the complex branching of most disease state management guidelines. As algorithms are an effective format for displaying complex guidelines containing decision trees and are preferred by most HPs,[5, 6, 102] the issue of complex branching was overcome with the display an algorithm (picture) rather than coding for treatment guidelines.

While CDSS are able to improve patient outcomes and decrease health cost, currently available CDSS in common use in Australian medical practice do not yet meet the HP needs.[6, 24, 25, 27, 53] In order to improve the usability and increase the chances of CDSS success, the following should be considered:

1. Integration into Workflow

Any HIT needs to integrate into usual workflow and enhance work efficiency rather than hinder it. [36, 44, 46, 49, 51]Therefore, defining the exact purpose of the system before any other design begins is imperative.[25] For instance, if the CDSS is part of a CPOE, then the decision support should allow users to work effectively while only alerting them of high risk issues (e.g.: wrong dose, drug-drug interactions, etc…) to prevent alert fatigue. Conversely, if the CDSS is more comprehensive, in order to answer specific practitioner queries, an opt-in or "plug in" that utilises patient data in the CPOE may be more appropriate. In order to best define the purpose of HIT, and ensure appropriate design and integration into usual workflow, HPs should be involved in all stages of the design and development process.[103-105] Regardless of purpose, CDSS should be able to integrate with locally used CPOE or EHR systems to avoid repeat patient data entry.[44, 46, 51] Involvement in HIT design and development can also positively influence physicians' attitudes regarding HIT and improve perceived usefulness,[21, 43, 103] and is possibly why the most effective systems are developed locally.[16]

In addition to work flow and physician attitude, available human and technological resources need to be taken into consideration when creating HIT.[106] Resource poor developing countries are most likely to benefit from DSS as they may be lacking in appropriately trained physicians, but may also be lacking the infrastruc-

ture to support DSS.[104] These barriers must be considered when developing HIT and whether the appropriate hardware is available to support DSS.

2. Adherence to Usability Standards

Human factor methods such as ergonomics and human-computer interaction (HCI) techniques should be used when designing and evaluating HIT. HCI can improve the usability and efficacy of programs, as well as decrease re-engineering costs.[105] Numerous medical systems have been developed that have low usability, resulting in staff "working around" interface problems, inappropriate use of the system, ultimately putting patients at risk.[28] Harrison et al. have developed the Interactive Sociotechnical Analysis (ISTA) to be used during the design and development process. [107] Much like other analysis frameworks, ISTA is intended to identify unintended consequences of HIT but also takes into account the interplay between the HIT, workflow, clinicians and the organisation.[107]

Most of the identified usability issues surrounded the EHR component of the system. Although not the primary purpose of the system, the patient data entry section was necessary to allow for patient specific information to be displayed to users. However, usability issues identified echo other research; appropriate use of colours and font has been identified an simple way to guide users, add consistency to the system, and increase overall appeal.[6, 40, 46, 108] although it is suggested that interfaces be developed in black and white initially and tested for usability to account for colour blind users.[108] Use of autocomplete combo boxes or key word search seems is desired by users when a long list of possible responses are available (e.g.: drug name).[20, 52] Finally adherence to usability guidelines, including appropriate labeling and instruction on the interface screen, is imperative to avoid confusion and assist in system use. [6, 35, 40, 41, 43, 46, 49, 51]

3. Using the "Right" Data

An identified barrier to e-Health success is the lack of standardisation, including the minimal patient data that should be collected and utilised in a meaningful way.[27] Patient information required by CDSS described in this paper can serve as a guide for the minimal patient detail that should be captured by CPOE or EHR. Four disease states were reviewed when defining the clinical decision-making model and data attributes required for CDSS. As a result all disease specific considerations may not have been considered. However, other information sources were utilised during development, including Australian and international standards for quality prescribing and past CDSS success and failures. In addition, three of the researchers are qualified HPs and are familiar with the clinical decision making process. As a result, the majority of data attributes used to make clinical decisions accounted for and the clinical decision making model developed can be used as the foundation of other CDSS.

Website developers have found that although usability and aesthetics influence first and overall impressions, content has the greatest influence of users' intention to revisit, intention to recommend, and overall impression of a website.[109] The same is most likely true for CDSS content. The information in the knowledge base should come from sources that the HPs themselves would use – i.e.: clinical guidelines and reputable independent drug information sources other than approved drug information.[21, 30] Knowledge acquisition should be facilitated by experts in the field to ensure that information is of adequate quality.[35, 37, 38, 46] Any HIT needs to be thoroughly tested prior to implementation and periodically thereafter for continual improvement and to insure appropriate information output.[36, 43, 49, 51]

Limitations of usability testing

HPs were used during usability testing rather than usability experts. However, usability experts are not necessarily required as non-experts are able to provide quality insight into usability issues parallel to experts.[110] We only used five participants to test the usability of the system, all of whom were pharmacy academics. It has been suggested that for most usability studies five participants are sufficient to identify most major usability errors.[111, 112] Indeed, Nielsen argues that "discounted" usability testing such as this

one are valid, and at the very least, better than no testing.[113] However, further system testing with different HPs using a larger sample size to provide more robust usability results have already begun.

6 Conclusion

This paper describes a new framework for delivering information HPs need, giving guidance during complex patient healthcare delivery. General principles for successful CDSS have been described, including good workflow integration, use of usability standards and appropriate data usage. In addition, a universally applicable system model has been defined using Australian and international principles for quality prescribing.

When tested, data suggests that despite minor usability issues the system developed using this framework provides information to users in an informative and useful manner. Further studies will expand on this information and provide more insight into the effectiveness of this information delivery framework.

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Conflict of Interests

None of the authors has any conflict of interest in the manuscript. There were not any financial or other relations with relevant parties that could have affected the results and conclusions of the study.

References

1. Gokula M, Holmes HM. Tools to reduce polypharmacy. Clinics in Geriatric Medicine. 2012. 28(2): 323-41.
2. O'Mahony D, O'Connor M. Pharmacotherapy at the end-of-life. Age and Ageing. 2011. 40(4): 419-22.
3. Hughes LD, McMurdo MET, Guthrie B. Guidelines for people not for diseases: The challanges of applying uk clinical guidelines to people with multimorbidity. Age and Ageing. 2013. 42(1): 62-9.
4. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical practice guidelines and quality care for older patients with multiple comorbid diseases: Implications for pay for performance. Journal of the American Medical Association. 2005. 294(6): 716-24.
5. Sinuff T, Eva KW, Meade M, Dodek P, Heyland D, Cook D. Clinical practice guidelines in the intensive care unit: A survey of canadian clinicians' attitudes. Canadian Journal of Anasthesia. 2007. 54(9): 728-36.
6. Stehlik P, Dārziņš P, Marriott J. Resources for medication management in the aged – what do health professionals want? electronic Journal of Health Informatics. 2014. 8(1): e4.
7. Varonena H, Kortteistob T, Kailac M. What may help or hinder the implementation of computerized decision support systems (cdsss): A focus group study with physicians. Family Practice. 2008. 25(3): 162-7.
8. Australian Institute of Health and Welfare. Older australians at a glance: 4th edition, Department of Health and Ageing, Ed. 2007; AIWH: Canberra.
9. Easton K, Morgan T, Williamson M. Medication safety in the community: A review of the literature, National Prescribing Service, Ed. 2009: Sydney.
10. Barnett K, Mercer SW, Norbury M, Watt G, Wyke S, Guthrie B. Epidemiology of multimorbidity and implications for health care, research, and medical education: A cross-sectional study. Lancet. 2012. 380(9836): 37-48.
11. Salisbury C. Multimorbidity: Redesigning health care for people who use it. Lancet. 2012. 380(9836): 7-9.
12. Australian Bureau of Statistics. Population by age and sex, australian states and territories Jun 2011 Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Previousproducts/3101.0Feature%20Article1Jun%202011?opendocument&tabname=Summary&prodno=3101.0&issue=Jun%202011&num=&view=.
13. World Health Organisation. Interesting facts about ageing. Ageing and Life Course 2012.
14. Changchit C, Expert systems. In: Tomei LA, Ed. Encyclopedia of information technology curriculum integration 2008; IGI Global: Hershey. 316-22.
15. Garg AX, Adhikari NKJ, McDonald H, Rosas-Arellano MP, Devereaux PJ, Sam J, Haynes RB. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: A systematic review. Journal of the American Medical Association. 2005. 293(10): 1223-38.
16. Jamal A, McKenzie K, Clark M. The impact of health information technology on the quality of medical and health care: A systematic review. Health Information Management. 2009. 38(3): 26-37.

17. Shiffman RN, Liaw Y, Brandt CA, Corb GJ. Computer-based guidline implementation: A systematic review of functionality and effectiveness. Journal of the American Medical Informatics Association. 1999. 6(2): 104-14.
18. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The effect of electronic prescribing on medication errors and adverse drug events: A systematic review. Journal of the American Medical Informatics Association. 2008. 15(5): 585-600.
19. Chaudhry B, Wang J, Maglione M, Mojica W, Roth E, Morton SC, Shekelle PG. Systematic review: Impact of health information technology on quality, efficiency, and costs of medical care. Annals of Internal Medicine. 2006. 144(10): 742-52.
20. Donyai P, O'Grady K, Jacklin A, Barber N, Franklin BD. The effects of electronic prescribing on the quality of prescribing. British Journal of Clinical Pharmacology. 2007. 65(2): 230-7.
21. Ozel D, Blige U, Zaim N, Cengiz M. A web-based intnsive care clinical decision support system: From design to evaluation. Informatics for Health and Social Care. 2013. 38(2): 79-92.
22. Seto E, Leonard K, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Developing healthcare rule-based expert systems: Case study of a heart failure telemonitoring system. International Journal of Medical Informatics. 2012. 81(8): 556-65.
23. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: A review of the recent literature shows predominantly positive results. Health Affairs. 2011. 30(3): 464-71.
24. National Institute of Clinical Sudies. Electronic decision support systems action planning report, Informatics CfH, Ed. 2004: University of New South Wales.
25. Coiera E. Why e-health is so hard. Medical Journal of Australia. 2013. 198(4): 178-9.
26. Sweidan M, Reeve J, Dartnell J, Phillips S. Improving clinical decision support tools: Challenges and a way forward. Australian Family Physician. 2011. 40(6): 561-2.
27. Britt H, Miller G. The bettering the evaluation and care of health (beach) program: Where to from here? Medical Journal of Australia. 2013. 198(3): 125-6.
28. Johnson CW. Why did that happen? Exploring the proliferation of barely usable software in healthcare systems. BMJ Quality and Safety in Health Care. 2006. 15(Supp 1): i76-81.
29. Berlin A, Sorani M, Sim I. A taxonomic description of computer-based clinical decision support systems. Journal of Biomedical Informatics. 2006. 39(6): 656-67.
30. Koppel R, Metlay JP, Cohen A, Abaluck B, Localia AR, Kimmel SE, Storm BL. Role of computerized physician order entry systems in facilitating medication errors. Journal of the American Medical Association. 2005. 293(10): 1197-203.
31. Han YY, Carcillo JA, Venkataraman ST, Clark RSB, Watson RS, Nguyen TC, Bayir H, Orr RA. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. Pediatrics. 2005. 116(6): 1506-12.
32. Sittig DF, Ash JS, Zhang J, Osheroff JA, Shabot MM. Lessons from "unexpected increase mortality after implementation fo commercially sold computerized physician order entry system". Pediatrics. 2006. 118(2): 797-801.
33. Bailey RW, Barnum C, Bosley JC, Barbara, Dumas J, Ivory MY, John B, Miller-Jacobs H, Koyani SJ, Lewis JR, Page S, Ramey J, Redish JG, Scholtz J, Wigginton S, Wolfson CA, Wood LE, Zimmerman D. Research-based web design & usability guidelines, Department HaHS, Ed. 2006; U.S. Government Printing Office: Washington.
34. Graham TAD, Kushniruk AW, Bullard MJ, Hilroyd BR, Meurer DP, Rowe BH. How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events. AMIA Annual Symposium Proceedings. 2008: 257–61.
35. Gadd CS, Baskaran P, Lobach DF. Identification of design features to enhance utilization and acceptance of systems for internet-based decision support at the point of care. AMIA Annual Symposium Proceedings. 1998: 91-5.
36. Ash JS, Sittig DF, Guappone KP, Dykstra RH, Richardson J, Carpenter J, McMullen C, Shapiro M, Bunce A, Middleton B. Recommended practices for computerized clinical decision support and knowledge management in community settings: A qualitative study. BMC Medical Informatics and Decision Making. 2012. 12(6).

37. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, Snowdon T. Identification of features of electronic prescribing systems to support quality and safety in primary care using a modified delphi process. BMC Medical Informatics and Decision Making. 2010. 10(21).
38. Ahearn MD, Kerr SJ. General practitioners' perceptions of the pharmaceutical decision-support tools in their prescribing software. Medical Journal of Australia. 2003. 179(1): 34-7.
39. Cantor MN, Raucher BG. Measuring clinicians' expectations prior to emr implementation. AMIA Annual Symposium Proceedings. 2005: 911.
40. Murff HJ, Kanny J. Physician satisfaction with two order entry systems. Journal of American Medical Informatics Association. 2001. 8(5): 499-509.
41. Borbolla D, Otero C, Lobach DF, Kawamoto K, Gomez Saldano AM, Staccia G, Lopez G, Figar S, Luna D, Gonzalez Bernaldo de Quiros F. Implementation of a clinical decision support system using a service model: Results of a feasibility study. Studies in health technology and informatics. 2010. 160(Pt 2): 816-20.
42. Lamy J-B, Venot A, Ouvard P, Duclos C. Design of a graphical and interactive interface for facilitating access to drug contraindications, cautions for use, interactions and adverse effects. BMC Medical Informatics and Decision Making. 2008. 8(21).
43. Abramson EL, Patel V, Malhotra S, Pfoh ER, Osorio SN, Cheriff A, Cole CL, Bunce A, Ash JS. Physician experiences transitioning between an older versus newer electronic health record for electronic prescribing. International Journal of Medical Informatics. 2012. 81(8): 539-48.
44. Grossman JM, Gerland A, Reed MC, Fahlman C. Physicians' experiences using commercial e-prescribing systems. Health Affairs. 2007. 26(3): w393-404.
45. Trafton J, Martins S, Michel M, Lewis E, Wang D, Combs A, Scates N, Goldstein MK. Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic, noncancer pain by primary care providers. Pain Medicine. 2010. 11(4): 575-85.
46. Anderson JA, Willson P, Peterson NJ, Murphy C, Kent TA. Prototype to practice: Developing and testing a clinical decision support system for secondary stroke prevention in a veterans healthcare facility. CIN: Computers, Informatics, Nursing. 2010. 28(6): 353-63.
47. Ying-Jui C, Chirh-Yun T, Min-Li Y, Yu-Chuan L. Assessing the impact of user interfaces to the usability of a clinical decision support system. AMIA Annual Symposium Proceedings. 2003: 808.
48. Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Spurr C, Khorasani R, Tanasijevic M, Middleton B. Ten commandments for effective clinical decision support: Making the practice of evidence-based medicine a reality. Journal of American Medical Informatics Association. 2003. 10(6): 523-30.
49. Scanlon M. Computer physician order entry and the real world: We're only humans. Joint Commission Journal on Quality and Safety. 2004. 30(6): 342-6.
50. Yu KH, Sweidan M, Williamson M, Fraser A. Drug interaction alerts in software - what do general pracitioners and pharmacists want? Medical Journal of Australia. 2012. 195(11): 676-80.
51. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: A systematic review of the trials to identify features critical to sucess. British Medical Journal. 2005. 330(7494): 765-8.
52. . !!! INVALID CITATION !!!
53. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, Snowdon T. Evaluation of features to support safety and quality in general practice clinical software. BMC Medical Informatics and Decision Making. 2011. 11(27).
54. Australians medicines handbook 2013 [online]. 2013 Available from: https://www.amh.net.au/downloads/Referencing%20the%20AMH.pdf.
55. Etg complete. 2012 Available from: http://etg.tg.com.au.ezproxy.lib.monash.edu.au/conc/tgc.htm.
56. de Vries TPGM, Henning RH, Horgerzeil RV, Fresle DA. Guide to good prescribing - a practical manual 1994 Available from: http://apps.who.int/medicinedocs/pdf/whozip23e/whozip23e.pdf.
57. NPS: Better choices Better health. Competencies required to prescribe medicines: Putting quality use of medicines into practice. 2012; National Prescribing Service Limited: Sydney.
58. Medical Board of Australia. Good medical practice: A code of conduct for doctors in australia, AHPRA: Medical Board of Australia, Ed. 2010.
59. Medical Council of New Zealand. Good medical practice, Medical Council of New Zealand, Ed. 2013.

60. General Medical Council. Good practice in prescribing medicines and managing medicines and devices, General Medical Council, Ed. 2013.
61. American Society of Health-System Pharmacists. Ashp guidelines on a standardized method for pharmaceutical care. American Journal of Health-System Pharmacy. 1996. 53(14): 1713-6.
62. Cardiovascular Expert Group. Therapeutic guidelines: Cardiovascular. Version 6. Melbourne: Therapeutic Guidelines Limited; 2012.
63. National Vascular Disease Prevention Alliance (NVDPA). Absolute cardiovascular disease management. Quick reference guide for health professionals., © 2012 National Stroke Foundation, Ed. 2012.
64. World Health Organisation. Prevention of cardiovascular disease: Guidelines for assessment and management of cardiovascular risk. 2007.
65. He FJ, Campbell NRC, MacGregor GA. Reducing salt intake to prevent hypertension and cardiovascular disease. Revista Panamericana de Salud Pública. 2012. 32(4): 293-300.
66. Morey MC. Physical activity and exercise in older adults. 2012 Available from: http://www.uptodate.com/contents/physical-activity-and-exercise-in-older-adults?source=search_result&search=physical+activity+and+exercise+in+older+adults&selectedTitle=1~150.
67. Diabetes Australia, The Royal Australian Collage of General Pracitioners. Diabetes management in general practice. Seventeenth edition 2011/12. 2011. Available from: https://www.diabetesaustralia.com.au/PageFiles/763/Diabetes%20Management%20in%20General%20Practice%202011-12.pdf.
68. The Royal Australian Collage of General Pracitioners. Snap: A population health guide to behavioural risk factors in general practice. 2004.
69. National Vascular Disease Prevention Alliance (NVDPA). Guidelines for the management of absolute cardiovascular disease risk., © 2012 National Stroke Foundation, Ed. 2012.
70. National Heart Foundation of Australia (National Blood Pressure and Vascular Disease Advisory Committee). Guide to the management of hypertension 2008. Updated 2010. 2010.
71. National Vascular Disease Prevention Alliance (NVDPA). Australian absolute cardiovascular disease risk calculator. 2012 Available from: http://www.cvdcheck.org.au/.
72. National Heart Foundation of Australia. Salt and hypertension (professional paper). 2007.
73. Australian Diabetes Educators Association. Guidelines for the management and care of diabetes in the elderly. 2003; Australian Diabetes Educators Association: ACT, Australia.
74. National Heart Foundation of Australia. Position statement: Dietary fats and dietary sterols for cardiovascular health. 2009.
75. Mims online. 2013.
76. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National evidence based guidelines for the management of type 2 diabetes mellitus: Part 7 - lipid control in type 2 diabetes, National Health and Medical Research Council, Ed. 2004; Australian Government NHMRC.
77. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National evidence based guidelines for the management of type 2 diabetes mellitus: Part 2 - primary prevention of type 2 diabetes, National Health and Medical Research Council, Ed. 2001; Australian Government NHMRC.
78. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National evidence based guidelines for the management of type 2 diabetes mellitus: Part 2 - case detection and diagnosis of type 2 diabetes, National Health and Medical Research Council, Ed. 2001; Australian Government NHMRC.
79. Endocrinology Expert Group. Therapeutic guidelines: Endocrinology. Version 4. Melbourne: Therapeutic Guidelines Limited; 2009.
80. World Health Organisation, International Diabetes Federation. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: Report of a who/idf consultation. 2006.
81. World Health Organisation, International Diabetes Federation. Use of glycated haemoglobin (hba1c) in the diagnosis of diabetes mellitus: Abbreviated report of a who consultation. 2011.
82. Colagiuri S, Dickinson S, Girgis S. National evidence based guidelines for blood glucose control in type 2 diabetes. 2009; Diabetes Australia and the NHMRC: Canberra, Australia.

83. McCulloch DK, Munshi M. Treatment of type 2 diabetes mellitus in the elderly patient. 2012 Available from: http://www.uptodate.com/contents/treatment-of-type-2-diabetes-mellitus-in-the-elderly-patient?source=search_result&search=Treatment+of+Type+2+Diabetes+Mellitus+in+the+elderly+patient&selectedTitle=1~150.
84. American Geriatrics Society Panel on Exercise and Osteoarthrtitis. Exercise prescription for older adults with osteoarthritis pain: Consensus practice recommendations. Journal of American Geriatrics Society. 2012. 49(6): 808-23.
85. Rheumatology Expert Group. Therapeutic guidelines: Rheumatology. Version 2. Melbourne: Therapeutic Guideliens Limited; 2010.
86. Kalunian KC. Nonpharmacologic therapy of osteoarthritis. 2012 Available from: http://www.uptodate.com/contents/nonpharmacologic-therapy-of-osteoarthritis?source=search_result&search=nonpharmacologic+treatment+of+osteoarthritis&selectedTitle=1~150.
87. RACGP Osteoarthritis Working Group. Guideline for the non-surgical management of hip and knee osteoarthritis, National Health and Medical Research Council, Ed. 2009; The Royal Australian College of General Practitioners: Victoria, Australia.
88. Kalunian KC. Risk factors and possible causes of osteoarthritis. 2012 Available from: http://www.uptodate.com/contents/risk-factors-for-and-possible-causes-of-osteoarthritis?source=search_result&search=Risk+factors+and+possible+causes+of+osteoarthritis&selectedTitle=1~150.
89. Kalunian KC. Diagnosis and classification of osteoarthritis. 2012 Available from: http://www.uptodate.com/contents/diagnosis-and-classification-of-osteoarthritis?source=search_result&search=Diagnosis+and+classification+of+osteoarthritis&selectedTitle=1~150.
90. Mitchell JA. The impact of genomics on e-health. Studies in health technology and informatics. 2004. 106: 63-74.
91. Pulley JM, Denny JC, Peterson JF, Bernard GR, Vnencak-Jones CL, Ramirez AH, Delaney JT, Bowton E, Brothers K, Johnson K, Crawford DC, Schildcrout J, Masys DR, Dilks HH, Wilke RA, Clayton EW, Shultz E, Laposata M, McPherson J, Jirjis JN, Roden DM. Operational implementation of prospective genotyping for personalized medicine: The design of the vanderbilt predict project. Clinical Pharmacology and Therapeutics. 2012. 98(1): 87-95.
92. Microsoft visual studio. 2010; Microsoft Corporation.
93. Microsoft .Net framework. 2010; Microsoft Corporation.
94. Wharton C, Rieman J, Lewis C, Polson P, The cognitive walkthrough method: A practitioner's guide. In: Nielsen J, Ed. Usability inspection method. 1994; John Wiley & Sons, Inc.: New York, NY, US. 105 - 40.
95. Luijks HD, Loeffen MJ, Largo-Janssen AL, Van Weel C, Lucassen PL, Schermer TR. Gps' considerations in multimorbidity management: A qualitative study. British Journal of General Practice. 2012. 62(600): e503-e10.
96. Smith SM, O'Kelly S, O'Dowd T. Gps' and pharmacists experiences of manageing multimorbidity: A 'pandora's box'. British Journal of General Practice. 2010. 60(576): e285-e94.
97. Kuo K-L, Fuh C-S. A rule-based clinical decision model to support interpretation of multiple data in health examinations. Journal of Medical Systems. 2011. 35(6): 1359-73.
98. Wright A, Sittig DF. A four-phase model of the evolution of clinical decision support architectures. International Journal of Medical Informatics. 2008. 77(10): 641-9.
99. Tu SW, Campbell JR, Glasgow J, Nyman MA, McClure R, McClay J, Parker C, Hrabak KM, Berg D, Weida T, Mansfield JG, Musen MA, Abarbanel RM. The sage guideline model: Achievements and overview. Journal of American Medical Informatics Association. 2007. 14(5): 589-98.
100. Grandi F, Mandreoli F, Martoglia R. Efficient management of multi-version clinical guidelines. Journal of Biomedical Informatics. 2012. 45(6): 1120-36.
101. Bindoff IK, Tenni PC, Peterson GM, Kang BH, Jackson SL. Development of an intelligent decision support system for medication review. Journal of Clinical Pharmacy and Therapeutics. 2007. 23(1): 81-8.
102. Hayward RSA, Wilson MC, Tunis SR, Guyatt GH, Moore K-A, Bass EB. Practice guidelines: What are internists looking for? Journal of General Internal Medicine. 1996. 11(3): 176-8.

103. Weber S, Crago EA. Practitioner approaches to the integration of clinical decision support system technology in critical care. Journal of Nursing Administration. 2009. 39(11): 465-9.
104. Blank A, Prytherch H, Kaltschmidt J, Krings A, Sukums F, Mensah N, Zakane A, Loukanova S, Gustafsson LL, Sauerborn R, Haefeli W. "Quality of prenatal and maternal care: Bridging the know-do gap" (qualmat study): An electronic clinical decision support system for rural sub-saharan africa. BMC Medical Informatics and Decision Making. 2013. 13(44).
105. Saleem J, Patterson ES, Militello L, Asch SM, Doebbeling BN, Render ML. Using human factor methods to design a new interface for an electronic medical record. AMIA Annual Symposium Proceedings. 2007: 640-4.
106. Litvin CB, Ornstein SM, Wessell A, Nemeth L, Nietert PJ. Adoption of a clinical decision support system to promote judicious use of antibiotics for acute respiratory infections in primary care. International Journal of Medical Informatics. 2012. 81(8): 521-6.
107. Harrison MI, Koppel R, Bar-Lev S. Unintended consequences of information technologies in health care—an interactive sociotechnical analysis. Journal of American Medical Informatics Association. 2007. 14(5): 542-9.
108. Ambler SW. User interface design tips, techniques, and principles - ambysoft. 2014.
109. Thielsch MT, Blotenberg I, Jaron R. User evaluation of websites: From first impression to recommendation. Integrating with Computers. 2014. 26(1): 89-102.
110. Carroll C, Marsden P, Soden P, Naylor E, New JD, Tim. Involving users in the design and usability evaluation of a clinical decision support system. Computer Methods and Programs in Biomedicine. 2002. 69(2): 123-35.
111. usability.gov. Recruiting usability test participants. 2014 Available from: http://www.usability.gov/how-to-and-tools/methods/recruiting-usability-test-participants.html.
112. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. Journal of Biomedical Informatics. 2004. 37(1): 56-76.
113. Nielsen J. Discount usability: 20 years. 2009 Available from: http://www.nngroup.com/articles/discount-usability-20-years/.

Conflicts of Interest

None declared.

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Chapter 5: Developing the Business Rule Engine

(Phase 2)

The system (MedManAGE) is provided on CD-ROM. Review of the program will provide a clearer understanding of the system and context for the results of this chapter.

6.1 Summary

In order to develop a framework for patient-relevant disease state management information delivery, a business rule engine driven clinical decision support system (CDSS) was developed.

This chapter describes how the triangulation of findings from health professional (HP) interviews, review of past successes and failures of other CDSS, clinical decision-making models and pharmacological and disease state management information (Chapter 3: Resources for disease state management – what do health professionals want? and Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing) were used to develop system business rules and database architecture. In addition, this chapter describes the knowledge acquisition process.

6.2 Aims

The overall aim of this phase of the research was to develop a business rule engine that could be easily updated with new information without the need for system reprogramming. The specific aims were:

1. To identify literature to be used as knowledge within the system;
2. To identify common attributes that define disease state management, and drug and patient factors that influence pharmacological treatment choice and develop:
    a. A disease state management template,
    b. A drug monograph template,
    c. A list of patient information required to make a therapeutic choice; and
3. To develop and test the system's business rule engine.

6.3 Knowledge Acquisition and Identification of Patient, Disease State Management, and Drug Monograph Attributes

6.3.1 Method

Previous studies have shown that CDSS that lead to success contain high quality local data,(1-3) and have procedures in place to ensure the knowledge base is kept up to date.(1, 2, 4) With this in mind, a business rule engine was used to allow for disease state management and drug monograph information updates without changes to system code.(5) Templates were developed that can be completed by HPs who are experts in a given health field (e.g. management of diabetes) in order to update the system's knowledge. Others have used this method to successfully integrate and update guidelines within CDSS.(6, 7)

In order to develop the templates, all attributes that can affect disease state management needed to be identified and addressed. Therefore, treatment guidelines and drug monographs published by reputable sources were reviewed. Reputable sources were defined as Australian or international bodies responsible for delivery of practice ready healthcare information to HPs, or guidelines published in peer reviewed journals.

- Disease state management information sources used:
    - National Health and Medical Research Council (NHMRC)
    - National Prescribing Service (NPS)
    - World Health Organization (WHO)
    - Therapeutic Guidelines
    - Diabetes Australia
    - Diabetes Educators
    - National Heart Foundation
    - National Stroke Foundation
    - Arthritis Australia
    - The Royal Australian Collage of General Practitioners
    - Up-To-Date®
    - Primary literature: guidelines published in peer reviewed journals
- Drug information sources used in addition to information sources listed above:
    - Australian Medicines Handbook (AMH)
    - MIMs
    - Pharmaceutical Benefits Scheme (PBS)

Common attributes were identified in order to develop standard templates for disease state management and Drug monograph information and define patient information required.

6.3.2 Results

Thirty-one references were used to populate the system database (Table 1).

Table 1: References used for database population

What	References used
Disease State	
Hypertension in General patients	(8-19)
Dyslipidaemia in those over the age of 65 years old in the presence of no other co-morbidities	(8-10, 12-18, 20, 21)
Dyslipidaemia in those over the age of 65 years old in the presence of Type 2 Diabetes Mellitus	(8-10, 12-14, 16, 17, 20, 22, 23)
Type 2 Diabetes in the presence of in presence of no other co-morbidities	(12, 13, 24-30)
Osteoarthritis in those over the age of 65 years old in the presence of no other co-morbidities	(21, 23, 31-36)
Drug monographs	(in addition to above references) (21, 23, 37, 38)

6.3.2.1 Disease State Management

The overall clinical decision-making process (or prescribing process) had been described in detail (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing). Review of disease state management guidelines allowed for the expansion of each step in the clinical decision making process (Figure 1). Attributes described were used as part of the business rule engine unless otherwise stated.

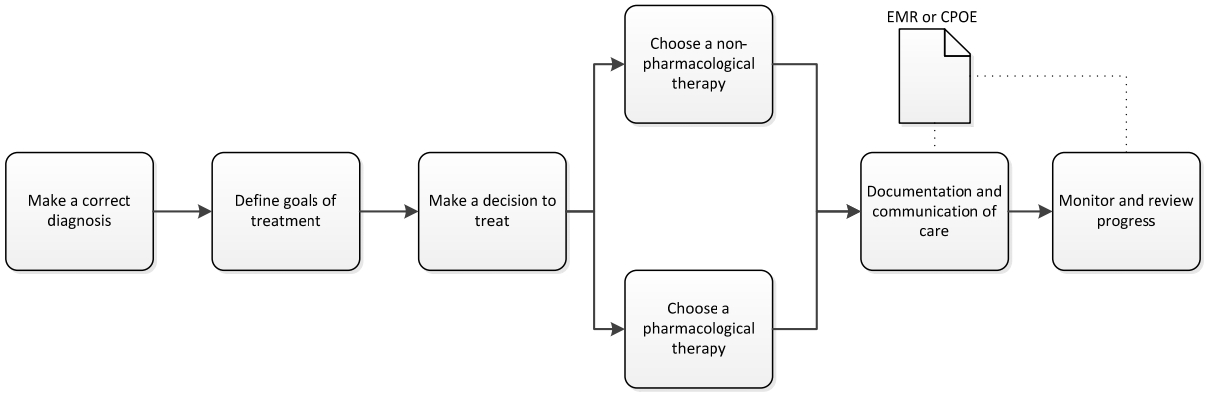

Figure 1: Summary of overall prescribing process

6.3.2.1.1 Making a Correct Diagnosis

One of the assumptions of this system is that the correct diagnosis has been made. Although the system's purpose was not to provide assistance in appropriate diagnosis, HPs desire the ability to gain additional information if needed.(3, 39, 40)

Other information required for appropriate diagnosis includes non-pharmacological and pharmacological risk factors. **Non-pharmacological risk factors** include diet, exercise, race, genetic predispositions and malformations, among others. These risk factors appear across guidelines for different disease states; therefore, for simplicity of template completion, standard non-pharmacological risk factors were developed. As with any other standard term, HP experts who update the system knowledge would be able to add new standard terms as appropriate. If the non-pharmacological risk factor is modifiable (e.g. inactivity), a description of how to modify the risk factor should be provided. Diagnosis information and non-pharmacological risk factor information was stored in the system to allow users access if they desired, but not used as part of the business rule engine.

Pharmacological risk factors include pharmacological agents (or drugs)[5] such as medications, herbs and vitamins that have a side effect or adverse drug reaction (ADR) that may cause the disease or symptom being treated or the pharmacological agent may interact and exacerbate the disease itself. This information is required to identify potential precipitators of the disease and prevent the prescribing cascade. If HPs wish to cease a potential precipitator, they need to know how to do so as some can be stopped abruptly, whereas others require weaning.

6.3.2.1.2 Define Goals of Treatment

As with diagnosis, the system assumes that the HP is aware of treatment goals. If they wish to view recommended goals this information is stored in the system, although treatment goals are not used as part of the business rule engine.

6.3.2.1.3 Make a Decision to Treat

The decision to treat will depend on the available treatment options, either non-pharmacological or pharmacological. Available options are commonly described as text, or in the preferred form, as an algorithm.(3, 41, 42)

6.3.2.1.3.1 Non-pharmacological Treatment

Non-pharmacological treatment is recommended for most disease state management either on its own or to accompany pharmacological treatment. The same types of non-

[5] Pharmacological agent and drug are used interchangeably

pharmacological treatment are common across disease states although the details generally differ – for example dietary recommendations for patients with diabetes may differ to recommendations for those with dyslipidaemia, and may differ again depending on the target population.

6.3.2.1.3.2 Pharmacological Treatment

Pharmacological treatment choice is influenced by evidence of efficacy, availability and affordability[6] and whether the treatment is likely to cause a patient harm and whether that harm outweighs the benefits of treatment. These considerations are common across all disease states. Circumstances in which a pharmacological treatment may cause a patient harm include, but are not limited to:

- Potential allergy;
- Potential ADR;
- Drug-disease interaction;
- Drug-drug interaction;
- Inability to administer treatment;
- Life expectancy of the patient is shorter than the time to effect of the pharmacological agent;
- Pharmacological agent not suited to population type;
- Pharmacokinetics (PK) of pharmacological agent may be altered due to liver or kidney dysfunction; and
- The pharmacological agent's PK or pharmacodynamics (PD) may be altered because of patient ethnicity or genetic polymorphism.

The same issue can commonly be identified in a number of different ways (Table 2).

HPs should be able to view recommended dose, duration and treatment rationale. Any additional information that may influence their choice, such as benefits of treatment and identification of treatments that are potentially inappropriate due to risk of harm or affordability issues, should also be available.

6.3.2.1.4 Documentation and Communication of Care

Documentation of care is an important part of the health care process. (3, 40, 43, 44) Previous work has indicated that communication between HPs is potentially inadequate and may lack vital information that may influence other HPs' therapy choices.(3, 45) In order to improve communication HPs should be prompted to record what action was taken, including how, and why, non-pharmacological and pharmacological therapies were implemented or ceased.

[6] In Australia, affordability is affected by PBS and patient entitlements.

6.3.2.1.5 Monitor and Review Progress

Disease state and drug targets are important in allowing HPs to gauge whether or not the treatment(s) implemented have made a positive impact, or whether the patient has deteriorated. Other reasons for monitoring are to make sure plasma concentrations are within the recommended therapeutic range, to ensure efficacy, that adverse effects have not developed or to prevent toxic effects.

Some laboratory tests can be affected by the presence of pharmacological agents and could potentially give HPs inaccurate information regarding patient progress. This information should be highlighted to HPs.

6.3.2.1.6 Ancillary information

In addition to information during the clinical decision making process, additional pharmacological and patient information may be required as it may influence the overall care process.

Additional patient information includes smoking status, activities of daily living and independent activities of daily living, mini mental-state exam score, living status and surgery history.(46) Additional pharmacological information includes special instructions for storage and administration.

Table 2: Factors that affect pharmacological therapy choice and required pharmacological agent or patient information.

Factor affecting pharmacological agent choice	Way of identifying factor	Pharmacological Information Required	Patient Information Required
Allergy	– Patient has an allergy to the same drug, a drug in the same class or same allergy class.	– Drug name, associated drug class and allergy class.	– Patient drug or allergy class allergies; – Severity of past reaction.
ADR	– Past ADR to the drug or a drug in the same class.	– Drug name and associated drug class; – Symptom caused by ADR.	– As per the Australian Advisory Committee on the Safety of Medicines ADR form. At the very least causative drug, onset of reaction, description of reaction, and outcome.
Drug-disease or event interaction	– Drug causes same event, disease or symptom patient is being treated for; and – Drug is known to interact with an event, disease or symptom patient is being treated for.	– Drug, associated ADR profile (i.e. symptoms caused), and risk of ADR; – Diseases which the drug interacts with, clinical importance of the interaction, symptom caused, and description of the interaction; – Event which the drug interacts with, clinical importance of the interaction and description of the interaction.	– Current medical history with clear identification of active disease states; – Acute events.

Factor affecting pharmacological agent choice	Way of identifying factor	Pharmacological Information Required	Patient Information Required
Drug-Drug interaction	– Interaction with other drugs the patient is on due to pharmacokinetic/pharmacodynamic interactions; or – The drug has the same side effect profile as another drug the patient is taking; or – Treatment duplication (same drug or same drug class).	– Drugs which the drug interacts with, clinical importance of the reaction, symptom caused, and description of the interaction; – Drug, associated ADR profile (i.e. symptoms caused), and risk of ADR; – Drug name, associated drug class.	– Current drug history.
Administration	– May be due to patient swallowing or dexterity issues or due to frail skin.	– Whether drug or associated formulation type are inappropriate in patients with swallowing or dexterity issues or those with frail skin.	– Flag for patients with swallowing or dexterity problems or those with frail skin.
Life expectancy of the patient is shorter than the time to effect of the pharmacological agent	– Life expectancy of the patient is shorter than the time to effect of the pharmacological agent	– Time to effect of the drug for a given disease state.	– Life expectancy of patient.

Factor affecting pharmacological agent choice	Way of identifying factor	Pharmacological Information Required	Patient Information Required
Population type	– Drug therapy may be inappropriate for the patient due to their age, gender, fertility status in women, pregnancy or breastfeeding status, and/or patient frailty.	– Min age of use of drug and associated description; – Max age of use of drug and associated description; – Flag for drugs inappropriate for a given gender, child-bearing women, in pregnancy including which trimester, during breastfeeding, in premenopausal or menopausal women, or in frail patients and associated description.	– Date of birth; – Gender: if female whether they are of child bearing age, pregnant including trimester, breastfeeding, premenopausal or menopausal; – Frailty status.
Pharmacokinetic or pharmacodynamic changes	– PK of drug may be altered due to liver or kidney dysfunction; or – PK or PD may be altered because of patient ethnicity or genetic polymorphism.	– At what level of liver or kidney dysfunction interaction occurs; consequences of taking the drug with liver or kidney dysfunction; and dose adjustment guide. – Known racial groups that may respond differently to the drug and a description of the difference in response; – Genetic polymorphs that may affect the drug and associated description.	– Liver function; – Renal function; – Patient race or heritage; – Polymorphs present.

Factor affecting pharmacological agent choice	Way of identifying factor	Pharmacological Information Required	Patient Information Required
Affordability	– Drug may not be listed on the PBS; or – Patient may need to meet the requirements for drug subsidy; or – Drug may only be subsidised for patients with given Medicare entitlements.	– Whether the drug is subsidised by the PBS or Repat PBS (RPBS); – Prescription subsidy requirements.	– Patient Medicare entitlements.

6.3.2.2 Template Development and Database Knowledge

Using the information above, disease state management and drug monograph templates were developed to allow for easy addition or alteration of system information. In addition, a "report" template was developed to allow for documentation of interactions with the system and that could be shared with other HPs. The disease state management and drug monograph templates were populated with information to form the knowledge within the system (Appendix 18and Appendix 19).

6.3.2.2.1 Disease State Management Template

Disease name: disease to which the guideline refers. [Standard value]

Description: description of what population group to which this disease state guideline refers. For example: in patients over the age of 65 years with no other co-morbidities, or pregnant women in the first trimester. The description was not standardised as the number of population groups a guideline can refer to is infinite. In addition, the descriptor only serves to help users identify which guideline would be most suited to their population group. [Free text]

Diagnosis: description of how to diagnose a patient with this disease. It may also include aims of care. [Free text]

Non-pharmacological risk factors: list of non-pharmacological risk [Standard value]	Description of how it increases the risk of disease. [Free text]	Is the risk factor modifiable?[Flag]	How to modify risk factor. [Free text]

Pharmacological risk factors: list of pharmacological agents that precipitate the disease. [Standard value]	Clinical importance of interaction illustrates the risk of disease precipitation. [Standard value]	Symptom caused by interaction. [Standard value]	Description. [Free text]

Review Process: this includes a description of patient review prior to and during treatment. [Free text]

Symptom: symptom to be treated (e.g. somatic pain). [Standard value]	**Treatment algorithm**: picture depicting the treatment algorithm for a particular symptom. [Picture]

Symptom: symptom to be treated (e.g. somatic pain). [Standard value]	**Non pharmacological treatment**: list of non-pharmacological treatments used to treat the symptom of the disease. [Standard value]	Description of why and how the non-pharmacological treatment should be implemented. [Free text]

Symptom: symptom to be treated (e.g. somatic pain). [Standard value]	**Pharmacological Treatment**: List of pharmacological treatments that can treat the symptom. [Standard value]	Dose				Duration of treatment. [Standard value]	Rationale for treatment [free text]	Time to effect		Additional information. [Free text]
		[Number]	Units [Standard value]	Frequency. [Standard value]	Whether the dose needs to be increased and how to increase it. [free text]			[Number]	Units [Standard value]	

Drug Monitoring: List of implemented pharmacological agents, used to treat the disease, that need to be monitored. [Standard value]	Monitoring name. [Standard value]	Frequency of testing. [Standard value]	Target		Can the results may be affected by another pharmacological agent? [Flag YES/NO]
			[Free text]	Unit [Standard value]	

Disease Monitoring: List of monitoring tests required used to monitor disease progress. [Standard value]	Frequency of testing. [Standard value]	Target		Can the results may be affected by another pharmacological agents? [Flag YES/NO]
		[Free text]	Unit [Standard value]	

References: List of references used.

6.3.2.2.2 Drug Monograph Template

Drug/Brand name: Although using generic names is preferable, some brands have specific properties that may affect clinical decision-making. [Free text]	If brand name, generic drug name is required. [Standard value]	**Drug class**: to which the drug belongs. [Standard value]	**Formulation Type**: [Standard value]	Duration of action: duration of time the drug of the specified formulation effective.	
				[Number]	Units [Standard value]

Allergy Class: list of allergy classes to which the drug belongs. [Standard value]

Indication: list of indications for the drug, either on or off label by disease and symptom. [Standard value]

ADR: list of symptoms	Clinical importance or risk of	Description of ADR:	Description of how to treat	Flag if drug cannot be

caused by ADR of drug. [Standard value]	ADR occurring. [Standard value]	describes how to identify ADR. [Free text]	the ADR once it has occurred. [Free text]	reinitiated if an ADR occurs. [Flag YES/NO]

Drug-Disease Interaction: list of disease states with which the drug interacts. [Standard value]	Symptom caused by interaction. [Standard value]	Clinical importance or risk of interaction occurring. [Standard value]	Description of interaction. [Free text]

Drug Event Interaction: list of acute events with which the drug interacts. [Standard value]	Clinical importance or risk of interaction occurring. [Standard value]	Description of interaction. [Free text]

Drug-Drug Interaction: list of drugs with which the drug interacts. [Standard value]	Symptom caused by interaction. [Standard value]	Clinical importance or risk of interaction occurring. [Standard value]	Description of interaction. [Free text]

Liver dysfunction interaction: level of liver dysfunction at which drug PK change. [Standard value]	Description of the consequence if used in patient with liver dysfunction. [Free text]	Description of how to adjust the dose. [Free text]

Renal dysfunction interaction: level of renal dysfunction at which drug PK change. [Standard value]	Description of the consequence if used in patient with renal dysfunction. [Free text]	Description of how to adjust the dose. [Free text]

Population type interaction	
MIN age of patient in whom drug should be used. [number]	Description of consequence if used in patient under the min age. [Free text]
MAX age of patient in whom drug should be used. [number]	Description of consequence if used in patient over the MAX age. [Free text]
Flag if the drug is inappropriate in frail patient. [Flag YES/NO]	Description of consequence if used in frail patient. [Free text]
Flag if the drug is inappropriate in breastfeeding. [Flag YES/NO]	Description of consequence if used in breastfeeding patient. [Free text]
Flag if the drug is inappropriate in a female patient of child bearing age. [Flag YES/NO]	Description of consequence if used in a female patient of child bearing age. [Free text]
Flag if the drug is inappropriate in a premenopausal female patient. [Flag YES/NO]	Description of consequence if used in a premenopausal female patient. [Free text]
Flag if the drug is inappropriate in a menopausal female patient. [Flag YES/NO]	Description of consequence if used in a menopausal female patient. [Free text]
Flag if the drug is inappropriate in male patient. [Flag YES/NO]	Description of consequence if used in a male patient. [Free text]
Pregnancy trimester in which the drug is considered unsafe to use. [Standard value]	Description of consequence if used in a pregnant female patient in a given trimester. [Free text]

Race interaction: List of racial groups that may respond differently to the drug. [Standard value]	Description of how the racial group responds differently.

Genetic polymorphism interaction: List of genetic polymorphs that may result in altered response to drug. [Standard value]	Description of consequence of polymorphism.

Drug Monitoring: List of monitoring tests used if drug is administered. [Standard value]	Disease guideline to which drug target is applicable. [Standard value]	Frequency of testing. [Standard value]	Target		Can the results may be affected by another drug. [Flag YES/NO]
			[Free text]	Unit [Standard value]	

Drug-monitoring interaction: List of monitoring tests the drug may affect. [Standard value]	Description of how the drug affects results. [Free text]

Special instructions: instructions that should be given to patients when prescribing the drug. [Standard value]	If this information refers to a brand, flag if these instructions override the generic drug instructions. [Flag YES/NO]	Detailed description of instructions. [Free text]

Flag if **PBS** subsidised. [Flag YES/NO]	Flag if **RPBS** subsidised. [Flag YES/NO]	Flag if PBS has specific **requirements** for subsidy. [Flag YES/NO]	Description of requirements. [Free text]

References: List of references used.

6.3.2.2.3 Report template

Date of interaction with system. [Date]
Name of Health Professional who interacted with the system. [Standard value/Log in name]

Presenting complaint: described by using disease and symptom addressed during interaction. [Standard value]

Actions taken

Pharmacological agent ceased: name of ceased pharmacological agents(s). [Standard value]	Description of how the pharmacological agent was ceased; OR if not ceased, rationale of why the pharmacological agent was not ceased. [Free text]

Non-pharmacological therapy: list of non-pharmacological therapy initiated. [Standard value]	Description of implementation strategy; OR rationale not implementing non-pharmacological therapy. [Free text]

Pharmacological therapy: list of pharmacological therapies initiated. [Standard value]	Dose			Whether the pharmacological therapy will be used chronically, acutely, or prn. [Standard value]	Rationale for implementation if it had been flagged as potentially inappropriate. [Free text]
	[Number]	Units. [Standard value]	Frequency. [Standard value]		

Current History

Medical History (sorted by current, intermittent or past)

Disease [Standard value]	Date of diagnosis. [Date]	Any comments regarding disease progress. [Free text]

Event [Standard value]	Date of event. [Date]

Surgery [Standard value]	Date of Surgery. [Date]

Allergies: drug or allergy class.[Standard value]	Severity of reaction. [Standard value]	Description of reaction. [Free text]

ADR: List of drugs patient had experienced an ADR with. [Standard value]	Description of how ADR was treated. [Free text]	Onset of reaction. [Date]	Outcome. [Standard value]	Date of outcome. [Date]

Non-pharmacological therapy: list of non-pharmacological therapy prescribed. [Standard value]	Indication described by disease and symptom. [Standard value]	Description of how non-pharmacological therapy has been implemented. [Free text]

Pharmacological therapy (sorted by current, PRN or past)

Drug. [Standard value]	Indication described by disease and symptom. [Standard value]	Dose			Date initiated. [Date]	Rationale for use. [Free text]
		[Number]	Units. [Standard value]	Frequency. [Standard value]		

Monitoring results: list of monitoring tests performed. [Standard value]	Date of result. [Date]	Result	
		[Number]	Units. [Standard value]

6.4 Business Rule Development and Testing

6.4.1 Method

IF… THEN business rules were developed using the clinical decision making process and formed the basis of the business rule engine (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and 5.3.2.1 Disease State Management). How the rules were linked to the user interface can be found in Appendix 20.

Implemented business rules were tested for face validity using the same base patient (Table 3) with *one* attribute change that would trigger a rule (Table 4). The "base" patient had attributes that would not trigger any patient dependent rules[7]. For business rules that were not coded for, database queries were used to test the database architecture and the face validity of the information that *would* appear on the user-interface screen once coded. Hyperglycaemia due to type 2 diabetes over 65 no other conditions guideline was used to test algorithms, unless otherwise stated.

Table 3: Base patient attributes

Attribute	Information stored
Name	Paulina X Stehlik
Gender	Male
Date of Birth	15-12-1987
Race	Caucasian
PBS eligibility	Eligible for Medicare but not repat or concession
Renal function	Normal
Liver function	Normal
Frailty status	Normal
Life expectancy	> 10 years
Swallowing difficulty	No
Dexterity difficulty	No
Frail skin	No
Other	No medical history (allergies, events, surgery, ADR, etc…) unless stated below.

[7] Pharmacological treatments that required requirements to be met for PBS subsidy or were not PBS subsidised triggered affordability rules.

Table 4: Test patients

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
1	Patient allergy – drug	Allergy to metformin	Add in patient information: allergy to Metformin (severe – anaphylaxis)	Appears in allergy History
				No precipitator
				Flag as issue with: Metformin Diabex XR - Metformin
2	Patient allergy – drug class	Allergy to Rosiglitazone	Add in patient information: allergy to Rosiglitazone (mild – rash)	Appears in allergy History
				No precipitator
				Flag as issue with: Pioglitazone Rosiglitazone
3	Patient allergy – allergy class	Sulfur	Add in patient information: allergy to Sulfur (moderate – uricaria)	Appears in allergy History
				No precipitator
				Flag as issue with: Gliclazide Diamicron MR - Gliclazide Glibenclamide Glimepiride Glipizide
4	Drug-disease interaction – precipitates disease chosen	Nicotinic Acid	Add in patient information: Nicotinic acid, current, 250mg tds – initiated 7/12/2002 – Not tolerating other lipid medication	Appear in Drug History
				Precipitator identified: Can cause hyperglycaemia; moderate risk
				Flag drug-drug interaction due to same ADR with: Acarbose

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
5	Drug-disease interaction – on drug page	Heart failure	Add in patient information: Heart failure, chronic, diagnosed 24/05/2010, patient does not want treatment	Appear in medical history No precipitator Flag drug-disease interaction with: Metformin Diabex XR - Metformin Pioglitazone Rosiglitazone
4	Drug-drug interaction – same ADR Precipitator drug due to drug-disease interaction + drug ADR	Nicotinic Acid	Add in patient information: Nicotinic acid, current, 250mg tds – initiated 7/12/2002 – Not tolerating other lipid medication	Appear in Drug History Precipitator identified: Can cause hyperglycaemia; moderate risk Flag for drug-drug interaction with due to SAME ADR with: Metformin Diabex XR - Metformin Gliclazide Diamicron MR - Gliclazide Glipizide Glibenclamide Glimepiride Acarbose Sitagliptin Exanatide

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
6	Drug duplication– same drug	Metformin	Add in patient information: Metformin; 500mg tds, initiated 12/05/2011, first line therapy	Appear in Drug History No precipitator Flag for same drug already prescribed with: Metformin Diabex XR - Metformin
7	Drug duplication – same class	Glipizide	Add in patient information: Glipizide, 2.5 mg d, initiated 24/09/2013 – Metformin not tolerated.	Appears in Drug History No precipitator Drug duplication with: Glipizide Flag as issue with (same class): Gliclazide Diamicron MR - Gliclazide Glibenclamide Glimepiride Glipizide
7	Drug-drug interaction			Flag for drug-drug interaction with due to SAME ADR: Metformin Diabex XR - Metformin Gliclazide Diamicron MR - Gliclazide Glibenclamide

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
				Glimepiride Acarbose Sitagliptin Exanatide Pioglitazone Rosiglitazone Insulin
				Flag Drug-Drug interaction Sitagliptin Exanatide
8	Previous ADR – drug	Metformin	Add in patient information: Metformin, ceased medication, 20-25/03/2013, laticacidosis, no sequale	Appears in ADR History
				No precipitator
				Flag for previous ADR with: Metformin Diabex XR- Metformin
9	Previous ADR – class	Glipizide	Add in patient information: Glipizide, ceased, 22/06 to 24/07/1999, Blood dyscrasia (Agranulocytosis), no sequalae, hospitalised	Appears in Drug History
				No precipitator
				Flag as issue with (same class) with: Gliclazide Diamicron MR - Gliclazide Glibenclamide Glimepiride Glipizide

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
10	Life expectancy shorter than time to effect	Life expectancy < 5	DRUG EXANATIDE: time to effect 7 years	Appears in "patient profile" No precipitator Flag time to effect > than life expectancy with: Exanatide
11	Drug-Liver interaction	Mild liver impairment	Add in patient information: mild liver impairment	Appears in "patient profile" No precipitator Flag liver function interaction with: Glibenclamide Pioglitazone Rosiglitazone
12	Drug kidney interaction	Mild renal function impairment	Add in patient information: mild renal function impairment	Appears in "patient profile" No precipitator Flag liver function interaction with: Metformin Diabex XR- Metformin Exanatide Glibenclamide Sitaglipin
13	Drug frail skin interaction	Frail skin	Add patient frail skin = yes	Appears in "patient profile" No precipitator Flag issue with frail skin with: Exanatide Insulin

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
14	Drug-Race interaction	Asian race	Patient information = race is Asian Choose Osteoarthritis	Appears in “patient profile” No precipitator Flag: Tramadol Tramal SR Durotram SR
15	Drug swallowing issues – DCC	Swallowing difficulty	Patient information swallowing issues = yes	Appears in “patient profile” No precipitator Flag issue with swallowing difficulty with: Diabex XR- Metformin Diamicron MR - Gliclazide Drug X
15	Drug swallowing issues – flagged on formulation (swallowing difficulty flag)	Swallowing difficulty	Patient information swallowing issues = yes	Appears in “patient profile” No precipitator Flag issue with swallowing difficulty with: Diabex XR- Metformin Diamicron MR - Gliclazide
16	Drug dexterity issues	Dexterity	Patient information dexterity issues = yes	Appears in “patient profile” No precipitator Flag issue with dexterity issues with: Exanatide Insulin

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
17	Affordability – drug not subsidised		Choose Osteoarthritis	Normal patient profile
				No precipitator
				Flag for drug affordability issue: Voltaren Emugel Zostrix Sulindac Durotram SR
18	Affordability – no Medicare	No Medicare	Patient info medicare = NO	Appears on “patient profile”
				No precipitator
				Flag for drug affordability issue: All recommended drugs for T2DM
19	Affordability – authority required			Appears on “patient profile”
				No precipitator
				Flag for drug affordability issue: Sitaglipin Exanatide Pioglitazone Rosiglitazone
21	Drug-Monitoring Interaction	Acarbose	Patient info = Acarbose, 50 mg bd, initiated 05/04/2011	Appears on patient profile
				No precipitator
				Flag for drug-monitoring interaction: Hb measurement affected in disease target

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
22	Frailty score	Moderately Frail	Patient info = moderately frail Choose Dyslipidaemia with no other disease	Appears on “patient profile” No precipitator Flag for issue with frail patients with: Simvastatin Pravastatin Fluvastatin Atorvastatin Rosuvastatin
23	Pregnant	Pregnant	Change to female Change to pregnant: First trimester Change to Fertile	Appears on “patient profile” No precipitator Flag for issue with pregnant patients with: Metformin Diabex XR- Metformin Gliclazide Diamicron MR - Gliclazide Glipizide Glibenclamide Glimepiride Acarbose Sitagliptin Exanatide Pioglitazone Rosiglitazone

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
24	Breastfeeding	Breastfeeding	Patient info: female; breastfeeding; fertile	Appears on “patient profile” No precipitator
				Flag for issue with breastfeeding patients with: Gliclazide Diamicron MR - Gliclazide Glipizide Glibenclamide Glimepiride Acarbose Sitagliptin Exanatide Pioglitazone Rosiglitazone
24	Fertile	Fertile	Patient info: female; fertile	Appears on “patient profile”
				No precipitator
				Flag for issue with fertile women with: Simvastatin Pravastatin Fluvastatin Atorvastatin Rosuvastatin

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
25	Age – Older than MAX age	Patient is > 65	Patient info: DOB 15/12/1925	Appears on “patient profile” No precipitator Flag for issue with patients older than 65 with: Metformin Diabex XR - Metformin Gliclazide Diamicron MR - Gliclazide Glipizide Glibenclamide Glimepiride
26	Age – Younger than MIN age	Patient < 12	Patient info: DOB 15/12/2007 Choose Dyslipidaemia with no other disease	Appears on “patient profile” No precipitator Flag for issue with patients younger than 12 with: Simvastatin Pravastatin Fluvastatin Rosuvastatin Ezetimibe Fenofibrate Questran Lite Colestid Fenofibrate Gemfibrozil

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
				Omacor Simvastatin Pravastatin Fluvastatin Rosuvastatin Fenofibrate Gemfibrozil Omacor
27	Premenopausal	Premenopausal	Patient info: female, premenopausal	Appears on “patient profile”
				No precipitator
				Flag for issue with premenopausal women with: Pioglitazone Rosiglitazone
All except: 23, 24, 27	Male	None	N/A	Appears on “patient profile”
				No precipitator
				Flag inappropriate in men with: DRUG X
28	Gene Polymorph	CYP2D6 ultra-fast metaboliser	Patient info: CYP2D6 ultra-fast metaboliser	Appears on “patient profile”
				No precipitator
				Flag as inappropriate due to gene polymorph with: DRUG X

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query
29	Drug-event interaction	Stroke	Patient info: myocardial infarction, 15/02/2013 Choose dyslipidaemia with no other comorbidities	Appears on patient profile No precipitator Flag as inappropriate due to past event: Nicotinic acid

In addition, a fabricated pharmacological agent was added to the database to test business rules that would not be triggered with the knowledge currently in the system (Table 5). This drug was added to disease and symptom pharmacological treatment table for Type 2 diabetes with no other co-morbidities (dose 500mg daily, time to effect 5 days).

Table 5: Fabricated pharmacological agent attributes

Attribute	Information stored	
Name	DRUG X	
Formulation	IR tablet	
Pharmacological Class	Other	
Duration of action	24 hours	
Inappropriate in:	Menopausal women	Description: BAD
	Men	Description: BAD
PBS Subsidised	YES	
Gene polymorph interaction	With CYP2D6 ultra rapid metaboliser Increased risk of ADR	
Ancillary labels	DCC	

6.4.2 Results

Initial code was created by a student programmer (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing); however, incorrect information appeared on the user interface screen. A senior programmer was consulted to rectify the identified problems, in addition to making interface modifications as identified in usability testing (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

All query results matched data put into the knowledge base suggesting good database architecture and face validity of information given.

Five business rules had been implemented at the conclusion of this research:

1. Identification of allergy risk due to allergy to the same drug;
2. Identification of allergy risk due to allergy to a drug in the same drug class;
3. Identification of allergy risk due to allergy to a drug in the same allergy class;
4. Identification of current medication that may be precipitating disease or symptom experienced by the patient; and
5. Identification of potential drug interaction with patient currently active disease.

All coded business rules displayed the expected information on the user interface (Table 6).

Table 6: Business rules coded in system

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query	Did expected result appear on user interface?
1	Patient allergy – drug	Allergy to metformin	Add in patient information: allergy to Metformin (severe – anaphylaxis)	Appears in allergy History	Yes
				No precipitator	Yes
				Flag as issue with: Metformin Diabex XR - Metformin	Yes
2	Patient allergy – drug class	Allergy to Rosiglitazone	Add in patient information: allergy to Rosiglitazone (mild – rash)	Appears in allergy History	Yes
				No precipitator	Yes
				Flag as issue with: Pioglitazone Rosiglitazone	Yes
3	Patient allergy – allergy class	Sulfur	Add in patient information: allergy to Sulfur (moderate – uricaria)	Appears in allergy History	Yes
				No precipitator	Yes
				Flag as issue with: Gliclazide Diamicron MR - Gliclazide Glibenclamide Glimepiride Glipizide	Yes
4	Drug-disease interaction – precipitates disease chosen	Nicotinic Acid	Add in patient information: Nicotinic acid, current, 250mg tds – initiated 7/12/2002 – Not tolerating other lipid medication	Appear in Drug History	Yes
				Precipitator identified: Can cause hyperglycaemia; moderate risk	Yes
				Flag drug-drug interaction due to same ADR with: Acarbose	Not implemented

Test Patient	Algorithm Tested	Patient info change	Data (patient, drug, disease)	Expected result as per database query	Did expected result appear on user interface?
5	Drug-disease interaction – on drug page	Heart failure	Add in patient information: Heart failure, chronic, diagnosed 24/05/2010, patient does not want treatment	Appear in medical history	Yes
				No precipitator	Yes
				Flag drug-disease interaction with: Metformin Diabex XR - Metformin Pioglitazone Rosiglitazone	Yes

6.5 Discussion

A business rule engine was successfully built using a relational database model. Rationale and the benefits of using a business rule engine and relational model have been discussed previously (2.2.3.1.4 Database Architecture and Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing). The database was populated with quality data gained from reputable sources, although the extent of knowledge within the system prototype is limited. Systems not using a rule-based engine require extensive testing after information updates.(47, 48) By using a business rule engine not only is development is simplified as rules are independent of software coding, but updates to business rules can occur without the need for interface recoding.(5) Information can be added to, or altered within, the system database using the disease state management and drug monograph templates without the need for reprogramming. This information should be handled by experts in respective fields, as is current practice for disease state management and drug information distribution and also expected by health professionals using electronic resources to guide practice.(1, 39, 40, 49)

Issues encountered during database development and population were primarily due to medical terminology. To overcome these issues during prototype development, terms such as “all” were used to identify clusters of diseases and symptoms (e.g. a pharmacological agent can cause “all” the symptoms of a given disease). This is not ideal and a major limitation of the system prototype. Future development of the system should use either medical terminology developed with the help of medical experts or utilise standard medical terminology to allow for easier disease and symptom clustering in addition to data exchange with dispensing and prescribing systems and other electronic health records.(1, 2, 50-52) Although numerous standard terminologies are available,(53) the Australian extension of SNOMED clinical terms should be used in Australia to allow for easy integration with the personally controlled e-health record system developed by the National E-Health Transition Authority.(54) Standard terminology was not used during the development of this system as large amounts of data conversion would be required and was not considered necessary for prototype development. Alternatively, artificial intelligence can be built into the database as part of the knowledge management to allow the system to learn new terminology, how terms are connected to each other and standard terminology used by other systems.(55, 56)

Some reprogramming will be required when these updates occur; however, the concepts regarding attributes required and processes for clinical decision-making described in this chapter are still applicable.

6.6 Conclusion

The findings from Chapter 3: Resources for disease state management – what do health professionals want? and Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing have influenced the design and development of a new framework for patient relevant disease state management information delivery in the form of a CDSS. Information attributes required for clinical decision-making remain the same irrespective of population type, disease state or pharmacological agent and were used to develop the business rules, define database attributes and construct templates for system knowledge updates. Previously encountered issues with updating system information were overcome by the use of a business rule engine and templates for data population.

The next chapter describes target user feedback regarding whether the developed system prototype meets HPs' information needs during health care delivery.

6.7 References

1. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, et al. Identification of Features of Electronic Prescribing Systems to Support Quality and Safety in Primary Care using a Modified Delphi Process. BMC Med Informat Decis Making. 2010;10(21).
2. Ash JS, Sittig DF, Guappone KP, Dykstra RH, Richardson J, Carpenter J, et al. Recommended Practices for Computerized Clinical Decision Support and Knowledge Management in Community Settings: A Qualitative Study. BMC Med Informat Decis Making. 2012;12(6).
3. Stehlik P, Dārziņš P, Marriott J. Resources for medication management in the aged – what do health professionals want? electronic Journal of Health Informatics. 2014;8(1):e4.
4. Grossman JM, Gerland A, Reed MC, Fahlman C. Physicians' Experiences Using Commercial E-Prescribing Systems. Health Aff. 2007;26(3):w393-404.
5. Lieberman BA. Requirements for rule engines: Capture and communication of complex business rules. World Wide Web: IBM; 2009 [updated 6 November 2012].
6. Batista-Navarro RTB, Bandojo DA, Gatapia MAJK, Santos RNC, Marcelo AB, Panganiban LCR, et al. ESP: An expert system for poisoning diagnosis and management. Inform Health Soc Care. 2010;35(2):53-63.
7. Lee J, Kim J, Cho I, Kim Y. Integrattion of Workflow and Rule Engines for Clinical Decison Support Services. Stud Health Technol Inform. 2010;160(pt 2):881-15.
8. Cardiovascular Expert Group. Therapeutic guidelines: cardiovascular. Version 6. Melbourne: Therapeutic Guidelines Limited; 2012.
9. National Vascular Disease Prevention Alliance (NVDPA). Absolute cardiovascular disease management. Quick reference guide for health professionals. In: © 2012 National Stroke Foundation, editor. 2012.
10. World Health Organisation. Prevention of Cardiovascular Disease: Guidelines for assessment and management of cardiovascular risk. Geneva, Switzerland: 2007.
11. He FJ, Campbell NRC, MacGregor GA. Reducing salt intake to prevent hypertension and cardiovascular disease. Rev Panam Salud Publica. 2012;32(4):293-300.
12. Morey MC. Physical activity and exercise in older adults. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/physical-activity-and-exercise-in-older-adults?source=search_result&search=physical+activity+and+exercise+in+older+adults&selectedTitle=1~150.
13. Diabetes Australia, The Royal Australian Collage of General Pracitioners. Diabetes Management in General Practice. Seventeenth edition 2011/12. 2011 July 2011. Report No.
14. The Royal Australian Collage of General Practitioners. SNAP: a population health guide to behavioural risk factors in general practice. Melbourne, Australia: 2004.
15. National Vascular Disease Prevention Alliance (NVDPA). Guidelines for the management of absolute cardiovascular disease risk. In: © 2012 National Stroke Foundation, editor. 2012.
16. National Heart Foundation of Australia (National Blood Pressure and Vascular Disease Advisory Committee). Guide to the management of hypertension 2008. Updated 2010. 2010.
17. National Vascular Disease Prevention Alliance (NVDPA). Australian absolute cardiovascular disease risk calculator. 2012 [cited 2013 05/03/2013]; Available from: http://www.cvdcheck.org.au/.
18. National Heart Foundation of Australia. Salt and Hypertension (Professional Paper). http://www.heartfoundation.org.au/sitecollectiondocuments/salt-and-hypertension.pdf,: 2007.
19. Australian Diabetes Educators Association. Guidelines for the Management and Care of Diabetes in the Elderly. ACT, Australia: Australian Diabetes Educators Association; 2003.

20. National Heart Foundation of Australia. Position statement: Dietary fats and dietary sterols for cardiovascular health. http://www.heartfoundation.org.au/SiteCollectionDocuments/Dietary-fats-position-statement-LR.pdf: 2009.
21. MIMS Online. online: MIMS Australia Pty Ltd.; 2013 [updated July 2013; cited 2013 05 July 2013].
22. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 7 - Lipid Control in Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2004.
23. Australians Medicines Handbook 2013 [online]. Adelaide: Australians Medicines Handbook Pty Ltd; 2013; Available from: https://www.amh.net.au/downloads/Referencing%20the%20AMH.pdf.
24. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Primary Prevention of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
25. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Case Detection and Diagnosis of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
26. Endocrinology Expert Group. Therapeutic guidelines: endocrinology. Version 4. Melbourne: Therapeutic Guidelines Limited; 2009.
27. World Health Organisation, International Diabetes Federation. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. Geneva, Switzerland: 2006.
28. World Health Organisation, International Diabetes Federation. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus: Abbreviated Report of a WHO consultation. Geneva, Switzerland: 2011.
29. Colagiuri S, Dickinson S, Girgis S. National Evidence Based Guidelines for Blood Glucose Control in Type 2 Diabetes. Canberra, Australia: Diabetes Australia and the NHMRC; 2009.
30. McCulloch DK, Munshi M. Treatment of type 2 diabetes mellitus in the elderly patient. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/treatment-of-type-2-diabetes-mellitus-in-the-elderly-patient?source=search_result&search=Treatment+of+Type+2+Diabetes+Mellitus+in+the+elderly+patient&selectedTitle=1~150.
31. American Geriatrics Society Panel on Exercise and Osteoarthrtitis. Exercise Prescription for Older Adults With Osteoarthritis Pain: Consensus Practice Recommendations. J Am Geriatr Soc. 2012;49(6):808-23.
32. Rheumatology Expert Group. Therapeutic guidelines: rheumatology. Version 2. Melbourne: Therapeutic Guideliens Limited; 2010.
33. Kalunian KC. Nonpharmacologic therapy of osteoarthritis. Waltham, MA, USA: UpToDate; 2012 [cited 2012 3 Dec 2012]; Available from: http://www.uptodate.com/contents/nonpharmacologic-therapy-of-osteoarthritis?source=search_result&search=nonpharmacologic+treatment+of+osteoarthritis&selectedTitle=1~150.

34. RACGP Osteoarthritis Working Group. Guideline for the non-surgical management of hip and knee osteoarthritis. In: National Health and Medical Research Council, editor. Victoria, Australia: The Royal Australian College of General Practitioners; 2009.
35. Kalunian KC. Risk factors and possible causes of osteoarthritis. Waltham, MA, USA: UpToDate; 2012 [cited 2012 01 Dec]; Available from: http://www.uptodate.com/contents/risk-factors-for-and-possible-causes-of-osteoarthritis?source=search_result&search=Risk+factors+and+possible+causes+of+osteoarthritis&selectedTitle=1~150.
36. Kalunian KC. Diagnosis and classification of osteoarthritis. Waltham, MA, USA: UpToDate; 2012 [cited 2012 27 November]; Available from: http://www.uptodate.com/contents/diagnosis-and-classification-of-osteoarthritis?source=search_result&search=Diagnosis+and+classification+of+osteoarthritis&selectedTitle=1~150.
37. Department of health and Ageing. Pharmaceutical Benefits Scheme (PBS). online: Australian Government; 2013 [cited 2013 01 July].
38. Pharmaceutical Society of Australia. Australian pharmaceutical formulary and handbook : the everyday guide to pharmacy practice. 22nd ed. ACT, Australia: Pharmaceutical Society of Australia 2012.
39. Ahearn MD, Kerr SJ. General Practitioners' Perceptions of the Pharmaceutical Decision-Support Tools in their Prescribing Software. Med J Aust. 2003;179(1):34-7.
40. Gadd CS, Baskaran P, Lobach DF. Identification of design features to enhance utilization and acceptance of systems for Internet-based decision support at the point of care. AMIA Annu Symp Proc. 1998:91-5.
41. Sinuff T, Eva KW, Meade M, Dodek P, Heyland D, Cook D. Clinical practice guidelines in the intensive care unit: a survey of Canadian clinicians' attitudes. Can J Anaesth. 2007;54(9):728-36.
42. Hayward RSA, Wilson MC, Tunis SR, Guyatt GH, Moore K-A, Bass EB. Practice Guidelines: What are Internists Looking For? J Gen Intern Med. 1996;11(3):176-8.
43. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving Clinical Practice Using Clinical Decision Support Systems: a Systematic Review of the Trials to Identify Features Critical to Sucess. Br Med J. 2005;330(7494):765-8.
44. Trafton J, Martins S, Michel M, Lewis E, Wang D, Combs A, et al. Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic, noncancer pain by primary care providers. Pain Med. 2010;11(4):575-85.
45. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, et al. Evaluation of Features to Support Safety and Quality in General Practice Clinical Software. BMC Med Informat Decis Making. 2011;11(27).
46. Sansoni J, Marosszeky J, Fleming G, Sansoni E. Selecting tools for ACAT Assessment: A Report for the Expert Clinical Reference Group, Aged Care Assessment Program, Department of Health and Ageing In: Cenre for Health Services Department University of Wollongong, editor. Canberra: Aged Care Assessment Program, Australian Govornment of Health and Ageing; 2010.
47. Bindoff IK, Tenni PC, Peterson GM, Kang BH, Jackson SL. Development of an intelligent decision support system for medication review. J Clin Pharm Therapeut. 2007;23(1):81-8.
48. Lyerla F. Design and Implementation of a Nursing Clinical Decision Support System to Promote Guideline Adherence. Comput Inform Nurs. 2008;26(4):227-33.
49. Anderson JA, Willson P, Peterson NJ, Murphy C, Kent TA. Prototype to practice: Developing and testing a clinical decision support system for secondary stroke prevention in a veterans healthcare facility. Comput Inform Nurs. 2010;28(6):353-63.

50. Murff HJ, Kanny J. Physician Satisfaction with Two Order Entry Systems. J Am Med Inform Assoc. 2001;8(5):499-509.
51. Borbolla D, Otero C, Lobach DF, Kawamoto K, Gomez Saldano AM, Staccia G, et al. Implementation of a clinical decision support system using a service model: results of a feasibility study. Studies in health technology and informatics. 2010;160(Pt 2):816-20.
52. Abramson EL, Patel V, Malhotra S, Pfoh ER, Osorio SN, Cheriff A, et al. Physician experiences transitioning between an older versus newer electronic health record for electronic prescribing. Int J Med Inform. 2012;81(8):539-48.
53. Wright A, Sittig DF. A four-phase model of the evolution of clinical decision support architectures. Int J Med Inform. 2008;77(10):641-9.
54. NEHTA. SNOMED CT-AU - NEHTA. World Wide Web2014; Available from: http://www.nehta.gov.au/our-work/clinical-terminology/snomed-clinical-terms.
55. Wu X. Building Intelligent Learning Database Systems. AI Magazine. 2000;21(3):61-7.
56. Cortes C, Mohri M, Weston J, editors. A General Regression Technique for Learning Transductions. 22nd International Conference on Machine Learning; 2005; Bonn, Germany.

Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation

(Phase 3)

7.1 Preamble

The previous chapters (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine) described the design, development and usability testing of a novel framework for information delivery to health professionals (HPs) in the form of a clinical decision support system (CDSS). The CDSS design was based on requirements identified from HP interviews (Chapter 3: Resources for disease state management – what do health professionals want?) and literature review of successes and failures of other CDSS, quality prescribing, disease state management guidelines and drug monographs (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine). The system was successfully developed, although not all requirements were implemented. Initial usability evaluation using a modified talk-out-aloud method suggested that the system was informative and usable despite minor interface issues (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing).

Business rule testing using simulated patients uncovered incorrect information display; as a result the system was recoded by a senior programmer using the same basic interface design (Chapter 5: Developing the Business Rule Engine). The five business rules implemented in the recoded system provided the expected information about the user interface. Further evaluation of the framework was required to determine whether or not the system is useful to a larger sample of practicing HPs and how the information delivery can be improved.

The aim of this study was to evaluate the usefulness and usability of the system and identify areas of improvement.

What this manuscript adds to the current knowledge

This study reinforces that the information delivery framework developed could be useful and usable in practice according to potential users and supports results of other studies identifying regarding desired information and system features. This study also validated a modified Computer System Usability Questionnaire (mCSUQ) that allows for usability evaluation in an indirect setting such as a demonstration. Finally areas of future development for evaluated system were identified in addition to cultural and technical barriers that need to be overcome for CDSS success.

This study has been submitted for publication in the peer-reviewed **Journal of the American Medical Informatics Association** that appropriately targets an audience involved in all aspects of health informatics including policy making, design, development and evaluation.

7.2 Author Declaration

Declaration by candidate for paper 5 entitled:

Provision of patient relevant information during complex clinical decision making: Usability evaluation

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from the date indicated below:

Centre for Medicine Use and Safety, Faculty of Pharmacy and Pharmaceutical Sciences, Monash University
Victoria, Australia

Date: 20/06/2014

The nature and extent of candidate's contribution to the work was:

Nature of contribution	**Extent of contribution**
Conceived idea, developed modified Computer System Usability Questionnaire and focus group discussion guide, prepared ethics approval submission, conducted questionnaire demonstration session, conducted focus group, analysed data, prepared first and final drafts of manuscripts.	90%

Candidate's signature: **Date**: 20/06/2014

The contributions of co-authors to the work were:

Name of co-author	**Nature of Contribution**
Adjunct A/Prof Jennifer L Marriott	Advised on study design, modified Computer System Usability Questionnaire and focus group discussion guide and assisted with manuscript preparation.

Co-author signature: **Date:** 20/06/2014

7.3 Manuscript

Title Page

Title: Provision of patient relevant information during complex clinical decision-making: Usability evaluation.

Key words

clinical decision support system; decision support system; complex patients; CSUQ; usability

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Abstract

Background

Traditional forms of communicating best practice do not adequately address all aspects of quality prescribing needs when managing complex patients. Electronic solutions in the health sector are often unusable. A new system for information delivery was developed in order to address identified shortcomings. This paper describes the usability evaluation of this information delivery system.

Method

The system was demonstrated to medical practitioners and pharmacists. Their feedback was provided through a modified Computer Software Usability Questionnaire (CSUQ) and focus group.

Results

A modified CSUQ for indirect system usability evaluation was validated. Overall the system usability was good (mean 5.05, SD 1.07). Minor changes to the functionality, information available and interface were suggested.

Conclusion

The system is considered potentially usable and useful by health professionals, although minor, easily implementable changes are required. Further testing with a fully developed prototype is now required.

BACKGROUND AND SIGNIFICANCE

Health professionals (HPs) are expected to use the most up to date evidence to guide their practice. The quantity of information published makes this almost impossible; on average 75 trials and 11 systematic reviews are being published every day.(1) In order to assist HPs, clinical guidelines have been developed as tools that summarise the evidence and inform practice; however they do not take into account important determinants of quality prescribing such as multi-morbidity, end of life and other contributors to patient complexity such as ageing.(2-5) Other tools have been developed to address these gaps, but HPs generally do not find them adequate or practical in assisting decision making in complex patients.(6) One possible way HPs can be provided with required information in an efficient and usable way is with the use of decision support systems (DSS).(6)

DSS mimic human experts(7) and aim to assist users through alerts and messages, providing definite answers, or display of other information, that may influence the user's actions or decisions. DSS used in health, or clinical decision support systems (CDSS), contribute to improving adherence to disease state management guidelines, decrease inappropriate prescribing and improve patient satisfaction and outcomes.(8-12) They are also able to improve practitioner performance(13), adherence to evidence based practice,(9, 14) decrease medication errors and adverse drug reactions (ADR)(15) and potentially decrease costs.(16) Usability influences the success of a CDSS and is affected by factors such as efficiency, understandability, error prevention, accuracy, attractiveness and learnability.(17-19) Unfortunately, the health sector lacks effective and usable CDSS.(20)

A prototype CDSS, MedManAGE, has been developed that displays patient relevant information to inform disease state management of complex patients.(21) System requirements were defined using HP interviews, literature outlining past successes and failures of CDSS, disease state management guidelines and drug monographs.(6, 21) Initial usability testing using a modified talk-out-aloud method indicated that MedManAGE was usable despite minor interface issues.(21) The system was originally coded by a student programmer; however, a senior programmer advised recoding the software to rectify identified issues. Other than minor changes recommended by usability testing, the interface design remained the same.

Usability testing throughout the design and development process is able to improve usability, user satisfaction and productivity and decrease remodelling costs;(18) however, no single evaluation technique is able to measure all factors that influence usability.(19, 22) This study aimed to gain insight from a larger sample size of likely end-users using multiple evaluation techniques to determine if the way in which MedManAGE presents information is considered informative and useable and how information delivery can be improved.

MATERIALS AND METHODS

This study used questionnaires to gather quantitative and qualitative data, which were augmented by focus group feedback. Questionnaires can be used to objectively collect subjective data such as people's knowledge, beliefs, attitudes, and behaviours.(23, 24) They are practical to administer and can gather feedback from a large number of people.(23, 24) Focus groups can be used during early development in order to gain in-depth understanding of the perceived usefulness of a prototype in addition to other insights that may not have been gathered with the use of questionnaires.(25-27) The study was approved by Monash University Research Ethics Committee.

Recruitment and Sample Size Calculation

Purposive sampling was used to recruit potential users to evaluate the system. Eligible participants were student, intern, or registered HPs (pharmacists or medical practitioners) as these are the target end-users of the system.

Questionnaire sample size calculation (accuracy=1, standard deviation (SD)=2, *p-value*=0.05, power=0.8) indicated that a minimum of eight participants per group were required for between group comparisons. Focus groups, a qualitative research method, do not require a sample size calculation as data is collected until saturation of themes.(25)

Questionnaire Evaluation

The system was demonstrated to participants in the metropolitan area of Melbourne (Australia) attending educational sessions held by the Pharmaceutical Society of Australia (PSA), Peter James Centre (PJC) hospital and the General Practitioner (GP) Reference Group at Medicare Local. The demonstration consisted of an introduction explaining why the system was created, system purpose and study rationale. At the time the system interface and major

functions had been coded, although not all decision algorithms had been implemented and no colour had been added to the system interface. Demonstration of the system enabled participants to see *how* the information would be displayed. Participants were also given a detailed description of what information would be displayed when all the decision algorithms are implemented.

The Computer Software Usability Questionnaire (CSUQ) was developed and validated by IBM in the 1990s to quantitatively measure overall satisfaction with the system, its usefulness, information quality and interface quality in addition to qualitative data collection.(28) It can be used to estimate overall satisfaction across different user groups and research settings.(28) The CSUQ is a slightly modified version of the Post-Study System Usability Questionnaire (PSSUQ). Both questionnaires measure overall usability, system satisfaction information quality, and interface quality.(28) CSUQ and PSSUQ have good reliability overall and within the subscales.(28) In addition, the PSSUQ has been shown as a good predictor of other usability indicators such as successful task completion.(28, 29) Due to the similarities between CSUQ and PSSUQ, the two questionnaires are considered interchangeable with regard to reliability and validity.(28)

As the CSUQ was intended to be completed by users who have directly interacted with the system, the wording was modified slightly to reflect a demonstration environment; for example “it is simple to use this system” was changed to “I would find it simple to use MedManAGE” In addition, some questions were removed as they could not be completed by participants. The modified CSUQ (mCSUQ) was revalidated using a pilot demonstration to ensure that the minor changes in wording did not affect questionnaire validity. The final questionnaire and omitted questions are shown in Table 1. Demographic data regarding clinical and computer experience was collected from participants.

After a demonstration of the system, participants were asked to complete the mCSUQ and an expression of interest form to participate in usability evaluation focus group. Questionnaire participants remained anonymous and return of questionnaires was considered informed consent.

Table 1: Comparison of mCSUQ to original CSUQ

Original Question	**Modified Question***	**Domains Covered**
Q1 Overall, I am satisfied with how easy it is to use this	Q1 Overall, I am satisfied with how easy it would be to	Overall satisfaction System usefulness

system.	use MedManAGE	
Q2 It is simple to use this system.	Q2 I would find it simple to use MedManAGE	
Q3 I can effectively complete my work using this system.	Q3 I could effectively complete tasks using MedManAGE	
Q4 I am able to complete my work quickly using this system.	Q4 I would be able to complete tasks using MedManAGE	
Q5 I am able to efficiently complete my work using this system.	Q5 I would be able to *efficiently* complete tasks using this MedManAGE	
Q6 I feel comfortable using this system.	Q6 I would feel comfortable using MedManAGE	
Q7 It was easy to learn to use this system.	Q7 It would be easy to learn to use MedManAGE	
Q8 I believe I became productive quickly using this system.	Q8 I believe I would become productive quickly using MedManAGE	
Q11 The information (such as on-line help, on-screen messages and other documentation) provided with this system is clear.	Q9 The information (such as on-screen messages, and other documentation) provided MedManAGE is clear	Overall satisfaction Information quality
Q12 It is easy to find the	Q10 It would be easy to find	

information I need.	the information I may need	
Q13 The information provided with the system is easy to understand.	Q11 The information provided for the system is easy to understand	
Q14 The information is effective in helping me complete my work.	Q12 The information would be effective in helping me complete the tasks and scenarios	
Q15 The organization of information on the system screens is clear.	Q13 The organization of information on MedManAGE screens is clear	
Q16 The interface of this system is pleasant.	Q14 The interface of MedManAGE is pleasant	Overall satisfaction Interface quality
Q17 I like using the interface of this system.	Q15 I would like using the interface of MedManAGE	
Q18 This system has all the functions and capabilities I expect it to have.	Q16 MedManAGE has all the functions and capabilities I expect it to have	
Q19 Overall, I am satisfied with this system.	Q17 Overall, I am satisfied with MedManAGE	Overall satisfaction
Unchanged questions		
List the most negative aspect(s) of MedManAGE: 1. 2. 3.		
List the most positive aspect(s) of MedManAGE:		

1. 2. 3.		
Additional comments:		
Omitted question	**Rationale for exclusion**	**Domains Covered**
Q9 The system gives error messages that clearly tell me how to fix problems.	These features were had not been implemented at time of demonstration	Overall satisfaction Information quality
Q10 Whenever I make a mistake using the system, I recover easily and quickly.		

*questions used a 7-point Likert scale (1 = strongly disagree; 7 = strongly agree; N/A)

Focus group feedback

Demonstration attendees who expressed interest were invited by phone or email to participate in the focus group. During the focus group the system was demonstrated again and a question guide developed by the researchers was used to explore participants' initial impressions of the system, positive and negative aspects, perceived usefulness and areas for improvement (Box 1). The focus group session was held at Monash University (Parkville) and lasted 90 mins. Written consent was obtained prior to conducting the focus group. The session was audio recorded and transcribed verbatim. In addition, field notes were taken to assist with transcript analysis.

Box 1: Focus group question guide

1. What was your initial impression of MedManAGE?
2. What are the positive aspects of MedManAGE? How are they positive?
3. What are the negative aspects of MedManAGE? How can these be improved? Including design, information and functionality
4. Do you feel that MedManAGE would provide you with useful information when deciding on disease state management options for complex patients? What additional information would you need?
5. Would you find MedManAGE useful in practice? Why or why not? How can it become useful?
6. Additional Remarks?

Data analysis

Internal consistency for the mCSUQ was calculated using Cronbach's alpha. Average variance extracted (AVE) was also calculated in order to assess convergent validity, a subtype of construct validity.(30) The overall score (Q1-17), system usability (Q2-8), information quality (Q9-13), and interface quality (Q14-16) were calculated by taking the average of answered questions. Skewness of results was measured by finding the median scores. Correlations between overall usability score and type of HP, years of registration, hours of practice per week, geriatric qualification and computer confidence were calculated using non-parametric tests. Qualitative questionnaire data and focus group feedback, including field notes, were evaluated using thematic analysis.

Quantitative data was managed in MS Access(31) and exported to SPSS(32) and MS Excel(33) for analysis. NVivo was used for all qualitative analysis.(34)

RESULTS

Fifty three educational session attendees were eligible to participate; 52 returned a completed questionnaire (Table 2). Of the returned questionnaires one had only three out of 17 questions completed, and one provided low scores despite positive comments suggesting that the participant had misread scale orientation; results were analysed excluding these participants. Of the 53 eligible participants, six returned focus group expression of interest forms. One participant did not provide a valid contact email or phone number, one did not respond to email invitation, one was unable to participate during scheduled focus group times and one declined at follow up; only two participants were successfully recruited for focus group feedback.

Table 2: Demographic Data (including two outlier participants)

Questionnaire Feedback	
Session	
PSA	42 out of 43 returned
Medicare local	2 out of 2 returned*
PJC	7 out of 7 returned
Type of Health Professional	
Undergraduate Medical Student †	3

Undergraduate Pharmacy Student [†]	1
Registered Medical Practitioner	7
Registered Pharmacist	36
Unknown	5
Registered in Australia	
Yes	46
No	6
Years of Registration	
Pharmacist	Mean: 30, Mode: 30; Range: 5-51
Medical Practitioner	Mean: 11, Mode: 2; Range: 2-29
Unknown	Mean: 23, Mode: 17; Range: 17-35
Hours of Practice	
> 40	11
30-40	17
20-30	6
10-20	6
<10	8
Not practising	4
Other Qualifications or Specialisations	
Geriatric	7
Computer	0
Computer Use	
Every day	47
Once a week	4
Once a month	1
Computer confidence	
Very confident	15
Confident	29
Little confidence	8

Focus Group Feedback

	Years of registration	Geriatric specialty	Computer specialty	Hours of practice per week	Computer use	Computer confidence

Pharmacist 1 (P1)	40	Yes	No	30-40	Every day	Very confident
Pharmacist 2 (P2)	50 (retired)	Yes	No	N/A	Every day	Confident

* Ten attendees were present, only two were eligible
† All undergraduate students were in their final year of study

mCSUQ validation

The mCSUQ exhibited good internal consistency with high Cronbach's alpha across all domains (Table 3). AVE scores show good correlation between domains and, as expected, more variation between domains than within domains, indicating that modification did not jeopardise convergent validity (Table 3).

Table 3: mCSUQ Cronbach Alpha and AVE

	Cronbach Alpha	**AVE**		
Overall usability	0.968	**System usefulness**	**Information quality**	**Interface quality**
System usefulness	0.949	0.72	-	-
Information quality	0.927	0.65	0.74	-
Interface quality	0.868	0.51	0.67	0.67

Descriptive statistics

Overall the system scored above neutral (mean 5.05, SD 1.07) (Table 4). The highest scoring domain was the information quality (mean 5.09, SD 1.09) demonstrating that HPs were most satisfied with the quality of information given. As the interface was not complete at the time of demonstration the domain relating to interface quality unsurprisingly scored the lowest (mean 4.84, SD 1.24). Question 14, “the interface of MedManAGE is pleasant” scored the lowest average score (mean 4.78, SD 1.38), whereas question 7 “it would be easy to learn to use MedManAGE” had the highest score (mean 5.55, SD 1.17) suggesting that the interface was clear and simple but perhaps scored lower than other domains due to a lack of colour and embellishments.

Table 4: mCSUQ score

	Mean (SD)	Median	Mode	Range
Overall usability	5.05 (1.07)	5.13	5.88	2.41-6.94
System usefulness	5.06 (1.11)	5.13	4.50	2.13-7
Information Quality	5.09 (1.09)	5.10	5	2.60-7
Interface Quality	4.84 (1.24)	5	5	1-7

There were no differences in overall usability score and type of HP (p=0.585), years of registration (p=0.880), having a geriatric qualification (p = 0.269), computer confidence (p=0.066) and hours of practice per week (p=0.679) (Table 5).

Table 5: Comparison between mean overall usability score and subject groups

	Overall Usability Score			**p-value (with unknown)**	**p-value (without unknown)**
Type of HP*	Medical (1) n=10	Pharmacy (2) n=35	Unknown (0) n=5	0.817	0.585
Years of registration	≤10 (1) † n=12	>10 (2) n=37	Unknown (0) n = 1 excluded	0.437	0.880
Hours of practice	≤20 hours a week (2) n=14	>20 hours a week n=32	Unknown‡ (0) n=4	0.685	0.679
Geriatric qualification	Yes (1) n=43	No (0) n=7	-	0.269	-
Computer Confidence	Very confident or confident (1) n=42	Little confidence (2) n=8	-	0.066	-

* including students

† Students were counted as zero years of registration

‡All students left this blank and were counted as zero hours of practice a week

Qualitative feedback

Qualitative feedback from questionnaires was grouped into two main themes: features that improve satisfaction with the demonstrated system and perceived barriers to CDSS implementation in general.

Positive aspects of the system identified by participants included being able to access required information from one system that is comprehensive and patient relevant.

"Quick method of acquiring information that is reliable." Pharmacist (ID 45)

"Very comprehensive program detailing information required for prescribing decisions" Pharmacy Student (ID 42)

"Positive aspect: completeness of decision based support." Medical Practitioner (ID 56)

"Positive aspect: all information is linked to individual patient folder" Pharmacist (ID 25)

Participants offered ideas on how to improve interface usability and software usefulness with additional information and functionality. Most participants commented positively about the interface; however, suggestions for improvement included addition of colour to highlight important information, larger headings and ability to see all patient information on one screen.

"Clear interface, appears user friendly and easy to navigate" Medical Student (ID 44)

"Interface is very uniform. Need more highlighting of important aspects" Pharmacist (ID 15)

"Not easy to see all information in 'one' go" Pharmacist (ID 24)

"It's great having [patient information] *on one page without having to fish for it on another page" P2 (Focus group)*

Suggestions for additional information included comprehensive review and deprescribing guidance and statistical data on therapy efficacy such as number needed to treat. Most frequently highlighted by participants was the need for high-quality up-to-date referenced information within the system.

"Danger of garbage in and garbage out if the decision support evidence is not verified or issued by authority" Pharmacist (ID 25)

"References where guidelines were taken from would be very important. Who will be screening the reliability of info entered into database?" Medical Practitioner (ID 55)

"I do marking for ACP on the case studies and the candidates come up with the most remarkable studies and things to say what they want to say… things from 1990 and they're not filtering their references… they've found something in

> *Pubmed so that's gospel… You need a filter going on as well… That latest thing you read in the Women's Weekly last week I really don't want to appear* [in the system]*."P1 (Focus group)*

Functionality suggestions included hyperlinks to references, a forward/back button at the bottom of the screen for faster navigation and addition of calculators that would standardise patient categorisation such as creatinine clearance and life expectancy calculators. An identified deterrent to system use was patient data entry due to the time taken to populate patient information. Compatibility with electronic health records (EHR) would improve their ability to use the system, such as with prescribing, dispensing or home medication review software.

> *"Negative aspect: The initial time involved to fill in all the required details" Pharmacist (ID 34)*

> *"May be time consuming to create patient profile" Pharmacist (ID 43)*

> *"Appears that it would take a long time to enter patient data." Medical Practitioner (ID 56)*

> *"I'd only like to enter* [patient information] *once… I'd like to enter it into and have* [my home medication review software] *populate your tool… Or the other way around right, either way I wouldn't want to be double entering everything" P1 (Focus Group)*

There were a number of barriers to CDSS use raised by participants that are applicable to decision support in general. A major barrier identified was the lack of accurate patient health records accessible by all HPs involved in patient care and concerns surrounding clinical autonomy and litigation if CDSS recommendations are followed.

> *"It seems to require a very comprehensive patient history - rarely available to clinical pharmacist" Pharmacist (ID 50)*

> *"I find that in my work most of the time I am working with incomplete information, I really don't know all the symptoms, so I read the progress notes, I read the referral, I write down what I have got, I talk to the nurse, she tells me some more, still don't have it all, so if the programme's depending on me knowing it all that's harder" P1 (Focus group)*

> *"*[I would feel comfortable] *using the software yes - but not sure of legal aspects of the information/ choices" Pharmacist (ID 34)*

Issues with poor patient record keeping were of concern, including use of medical terminology with varying meaning among clinicians. Participants highlighted a number of issues surrounding the way patient information was entered and maintained in current medical records. Several examples were provided, such as combining allergies and ADR, listing events such as stroke as a current medical condition and listing complementary and alternative medications (CAMs) such as herbal medications and vitamins as non-drug treatment.

> *"A lot of doctors leave in every drug that the person's ever had and they don't necessarily mark it as inactive so I'll still be there looking at the drug chart and finding out what's actually going on" P1 (Focus group)*

> *"Again you could probably combine… both* [allergies and adverse drug reactions]*… That's what's happening in practice, that's what on front of the drug chart"P1 (Focus Group)*

> *"And I'm assuming you've got under the non-drug treatment there that would include all the vitamins or whatever else they've got… I think the medical professional…* [are] *essentially interested in the orthodox medicine and the other drugs* [e.g. CAM] *do you separate the two out at all?" P2 (Focus group)*

DISCUSSION

This study examined HP satisfaction with a novel framework for information delivery during complex patient clinical decision-making. Despite the limitations of using a demonstration and limited recruitment for focus group feedback, the strength of this study lies in the overall sample size; sample size calculation indicated that eight participants per comparison group were required and a total of 52 (10 medical and 42 pharmacy) HPs were recruited for the questionnaire feedback, adding confidence to the results. The questionnaire sample size was large enough ($n \geq 16$) to draw conclusions regarding system useability. MedManAGE scored well on all domains: overall usability, system usefulness, interface quality, and scored highest on information quality. No differences in results were observed between type of health professional, years of registration, hours of practice per week, geriatric specialty and

computer confidence indicating that the system is considered usable by both types of HPs irrespective of clinical or computer experience. Qualitative feedback was positive with minor, easily-implementable recommendations to improve the system functionality, information and interface. These recommendations are in line with usability guidelines and studies regarding CDSS interface design.(35-40)

Major concerns encompassed quality of patient information and time taken to enter patient data where a possible solution alluded to by participants is integration with a range of currently utilised EHR. These results reflect known factors affecting CDSS acceptance. Shibl et al expanded on the UTAUT model of DSS acceptance by conducting in-depth interviews with 37 Australian GPs in order to describe factors that influenced DSS acceptance.(41) Similar to the UTAUT model, non-integration with local EHR systems hindered acceptance of DSS.(41) Newly identified enablers of DSS acceptance included trust in the knowledge base, where trust was gained if the knowledge came from a reputable source such as a medical expert.(41) These findings are echoed by other qualitative method studies,(6, 42, 43) and CDSS evaluations.(21, 44)

Beyond the scope of this system, two major changes were identified that need to occur for effective CDSS implementation. *First*, accurate recording of patient information using a consistent approach is required.(45-47) This includes appropriate classification of attributes such as allergies, ADR, events, medical conditions, and therapies. In the case of drug, CAM and non-drug classification, in order to overcome confusion the terms “non-pharmacological” and “pharmacological” were used in MedManAGE; despite this, focus group participants still equated “pharmacological” to “orthodox medicine”. One solution to this may be altering the interface so that therapies flagged as “CAM” are listed separately; however, use of the term “CAM” is may not be appropriate in itself:

> *“There are not two kinds of medicine, one conventional and the other unconventional, that can be practiced jointly in a new kind of ‘integrated medicine’. Nor… are there two kinds of thinking, or two ways to find out which treatments work and which do not. In the best kind of medical practice, all proposed treatments must be tested objectively. In the end, there will only be treatments that pass that test and those that do not, those that are proven worthwhile and those that are not.” Relman (48)*

How attributes such as these are classified needs to be agreed upon, and remain consistent, among HPs when documenting patient information.

Second, a central EHR to which all HP have access needs to be available to inform HP and CDSS decision making; these types of EHR have been successfully implemented in other countries, but have met with limited success in Australia.(46, 49)

Limitations

Results of this study may have been limited by lack of direct interaction of participants with the system. Ideally participants should use the system themselves in order to judge its usability; however, use of an online server was not feasible and local computers were unavailable for system installation. An initial recruitment strategy involved participant download and installation of the system for testing; no participants were recruited using this method possibly due to reluctance to download an unproven software application. Therefore the system was demonstrated to potential users in order to gain feedback. Comments by participants suggested that the demonstration might have misrepresented actual usability due to inability to see the projection screen properly and inability to explore the system themselves. In addition, the system used during demonstrations was not fully re-coded; not all of the decision algorithms or system features had been implemented, and the system interface was in black and white only. Some of these limitations were overcome by providing an introduction to the system, explanation of planned features yet to be implemented and by answering participant questions during demonstrations.

The focus group provided an opportunity for in-depth system discussion; however, as only 2 participants were able to attend and were similar in characteristics, the discussion was not as wide-ranging as intended and data saturation could not be reached. Lack of successful recruitment for both online testing and focus group feedback indicates that HPs may not consider providing usability feedback at early stages of system development worthwhile or within their capability; however, in order to provide useful, effective and usable systems to health care providers their involvement throughout development is imperative.(37, 39, 43, 50)

CONCLUSION

The tested system for patient-relevant information delivery during complex-patient disease state management was considered usable by potential HP users. Participants were most satisfied with disease state management therapy choice information provided by the system.

Major determinants of usefulness were integration with EHR currently in use by the HPs and quality of information within the system. Identified barriers to CDSS use included inconsistent classification of patient information attributes and access to accurate patient data. A modified CSUQ was also validated and may be useful to other researchers during indirect usability evaluation. Future work will involve usability evaluation with all decision algorithms implemented, a fully developed colour interface and additional features as identified in this study.

CONTRIBUTORS

PS contributed to the study conception and design, drafted and revised manuscript, and data collection, management and interpretation. JLM assisted with study design and data analysis and provided critical revisions to the manuscript

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COMPETING INTERESTS

None.

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ETHICAL APPROVAL

Ethical approval was granted by Monash University Research Ethics Committee.

REFERENCES

1. Bastian H, Glasziou P, Chalmers I. Seventy-Five Trials and Eleven Systematic Reviews a Day: How Will We Ever Keep Up? PLoS Med. 2010;7(9).
2. O'Mahony D, O'Connor M. Pharmacotherapy at the End-of-Life. Age Ageing. 2011;40(4):419-22.
3. Hughes LD, McMurdo MET, Guthrie B. Guidelines for people not for diseases: the challanges of applying UK clinical guidelines to people with multimorbidity. Age Ageing. 2013;42(1):62-9.
4. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical Practice Guidelines and Quality Care for Older Patients With Multiple Comorbid DIseases: Implications for Pay for Performance. J Am Med Assoc. 2005;294(6):716-24.
5. Ackermann E. Barriers to "appropriate care" in general practice. Med J Aust. 2012;197(2):76-7.
6. Stehlik P, Dārziņš P, Marriott J. Resources for medication management in the aged – what do health professionals want? electronic Journal of Health Informatics. 2014;8(1):e4.
7. Changchit C. Expert Systems. In: Tomei LA, editor. Encyclopedia of Information Technology Curriculum Integration Hershey: IGI Global; 2008. p. 316-22.
8. Donyai P, O'Grady K, Jacklin A, Barber N, Franklin BD. The Effects of Electronic Prescribing on the Quality of Prescribing. Br J Clin Pharmacol. 2007;65(2):230-7.
9. Jamal A, McKenzie K, Clark M. The impact of health information technology on the quality of medical and health care: a systematic review. Health Inform Manag. 2009;38(3):26-37.
10. Ozel D, Blige U, Zaim N, Cengiz M. A web-based intensive care clinical decision support system: From design to evaluation. Inform Health Soc Care. 2013;38(2):79-92.
11. Seto E, Leonard K, Cafazzo JA, Barnsley J, Masino C, Ross HJ. Developing healthcare rule-based expert systems: case study of a heart failure telemonitoring system. Int J Med Inform. 2012;81(8):556-65.
12. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: a review of the recent literature shows predominantly positive results. Health Aff. 2011;30(3):464-71.
13. Garg AX, Adhikari NKJ, McDonald H, Rosas-Arellano MP, Devereaux PJ, Sam J, et al. Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes: A Systematic Review. J Am Med Assoc. 2005;293(10):1223-38.
14. Shiffman RN, Liaw Y, Brandt CA, Corb GJ. Computer-based Guideline Implementation: A Systematic Review of Functionality and Effectiveness. J Am Med Inform Assn. 1999;6(2):104-14.
15. Ammenwerth E, Schnell-Inderst P, Machan C, Siebert U. The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review. J Am Med Inform Assn. 2008;15(5):585-600.
16. Chaudhry B, Wang J, Maglione M, Mojica W, Roth E, Morton SC, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med. 2006;144(10):742-52.
17. Shafinah K, Selamat MH, Abdullah R, Muhamad AMN, Noor AGA. System Evaluation for a Decision Support System. Inform Technol J. 2010;9(5):889-98.
18. Belden JL, Grayson R, Barnes J. Defining and Testing EMR Usability: Principles and Proposed Methods of EMR usability Evaluation and Rating. Healthcare Information and Management Systems Society, 2009.

19. Horsky J, McMolgan K, Pang JE, Melnikas AJ, Linder JA. Complementary methods of system usability evaluation: Surveys and observations during software design and development cycles. J Biomed Inform. 2010;43(5):782-970.
20. Johnson CW. Why did that happen? Exploring the proliferation of barely usable software in healthcare systems. Qual Health Care. 2006;15(Supp 1):i76-81.
21. Stehlik P, Bahmanpour A, Sekercioglu YA, Dārziņš P, Marriott J. Features for Successful Clinical Decision Support Systems: Results from Design, Development and Usability Testing (unpublished work). 2014.
22. Nielsen J. Usability Inspection Methods. Conference companion on Human factors in computing systems: ACM; 1994. p. 413-4.
23. Boynton PM, Greenhalgh T. Hands-on guide to questionnaire research: Selecting, designing, and developing your questionnaire. Br Med J. 2004;328(7451):1312-5.
24. Zhang Z. Usability Evaluation. In: Zaphiris P, Kurnaiwan S, editors. Human Computer Interaction Research in Wed Design and Evaluation. Hershey USA: Idea Group Inc; 2007. p. 209-28.
25. Cline RR. Chapter 9: Data Collection Methods. In: Aparasu RR, editor. Research Methods for Pharmaceutical Practice and Policy. London: Pharmaceutical Press; 2011. p. 143-59.
26. Kitzinger J. Chapter 3: Focus groups. In: Pope C, Mays N, editors. Qualitative research in health care. 3rd ed. Malden: Blackwell Publishing Ltd.; 2006. p. 21-31.
27. Krueger RA, Casey MA. Focus Groups: A practical gude. 4th ed. Knight V, Connelly S, Habib L, Virding A, Suqinsky P, editors. Los Angeles, London, New Delhi, Singapore, Washington DC: SAGE; 2009.
28. Lewis JR. IBM computer usability satisfaction questionnaires: psychometric evaluation and instructions for use. Intl Journal of Human–Computer Interaction. 1995;7(1):57-78.
29. Lewis JR. Psychometric Evaluation of the PSSUQ Using Data from Five Years of Usability Studies. Intl Journal of Human–Computer Interaction. 2002;14(3&4):463-88.
30. Trochim WMK. The Research Methods Knowledge Base. World Wide Web2006. Available from: http://www.socialresearchmethods.net/kb/.
31. Microsoft Access. 2008 Microsoft Corporation; 2007.
32. IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.
33. Microsoft Excel. Microsoft Corporation; 2010.
34. NVivo9. 9.0.204.0 ed: QSR International; 2010.
35. Bailey RW, Barnum C, Bosley JC, Barbara, Dumas J, Ivory MY, John B, et al. Research-Based Web Design & Usability Guidelines. Washington: U.S. Government Printing Office; 2006.
36. Yu KH, Sweidan M, Williamson M, Fraser A. Drug interaction alerts in software - what do general pracitioners and pharmacists want? Med J Aust. 2012;195(11):676-80.
37. Scanlon M. Computer physician order entry and the real world: we're only humans. Jt Comm J Qual Patient Saf. 2004;30(6):342-6.
38. Borbolla D, Otero C, Lobach DF, Kawamoto K, Gomez Saldano AM, Staccia G, et al. Implementation of a clinical decision support system using a service model: results of a feasibility study. Studies in health technology and informatics. 2010;160(Pt 2):816-20.
39. Abramson EL, Patel V, Malhotra S, Pfoh ER, Osorio SN, Cheriff A, et al. Physician experiences transitioning between an older versus newer electronic health record for electronic prescribing. Int J Med Inform. 2012;81(8):539-48.
40. Horsky J, Phansalkar S, Desai A, Bell D, Middleton B. Design of decision support interventions for medication prescribing. 82. 2013;6(492-503).
41. Shibl R, Lawley M, Debuse J. Factors influencing decision support system acceptance. Decis Support Syst. 2013;54(2):953-61.

42. Robertson J, Moxey AJ, Newby DA, Gillies MB, Williamson M, Pearson S-A. Electronic information and clinical decision support for prescribing: state of play in Australian general practice. Fam Pract. 2011;28(1):93-101.
43. Ash JS, Sittig DF, Guappone KP, Dykstra RH, Richardson J, Carpenter J, et al. Recommended Practices for Computerized Clinical Decision Support and Knowledge Management in Community Settings: A Qualitative Study. BMC Med Informat Decis Making. 2012;12(6).
44. Hoonakker P, Khunlertkit A, Tattersal M, Keevil J, Smith PD. Computer Decision Support Tools in Primary Care. Work. 2012;41(Supp 1):4474-8.
45. Britt H, Miller G. The Bettering the Evaluation and Care of Health (BEACH) program: where to from here? Med J Aust. 2013;198(3):125-6.
46. Boonstra A, Broekhuis M. Barriers to the acceptance of electronic medical records by physicians from systematic review to taxonomy and interventions. BMC Health Serv Res. 2010;10(231).
47. Henderson J, Britt H, Miller G. Extent and utilisation of computerisation in Australian general practice. Med J Aust. 2006;185(2):84-7.
48. Relman AS. A Trip to Stonesville. The New Republic. 1998;29(24):28-37.
49. Choong R. President's desk: GPs frustrated by floundering NeHTA Medicus. 2013;53(10):2.
50. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving Clinical Practice Using Clinical Decision Support Systems: a Systematic Review of the Trials to Identify Features Critical to Sucess. Br Med J. 2005;330(7494):765-8.

Chapter 7: Summary, Future Directions and Conclusion

8.1 Summary

Currently available information sources addressing complex patients, such as the aged, do not cover all aspects of care such as end of life, multi-morbidity and frailty; those that do are unpractical to use at the point of care due to their complexity.(1-4) One way to overcome this may be through the use of clinical decision support systems (CDSS); however, although there have been a number of studies identifying features that improve CDSS success, currently available systems are reported to be far from usable.(5-9) In addition, CDSS in use do not address many of aspects of providing care to complex patients.(10) The overall aim of this research was to identify health professionals' (HPs') information needs when delivering healthcare to complex patients and to develop and test a framework for information delivery that would address identified needs.

Key HPs that are regularly involved in complex patient clinical decision-making were interviewed to determine their information needs and to provide insight into how to deliver the required information in a way that is not only informative but also usable (Chapter 3: Resources for disease state management – what do health professionals want?). Findings indicated that currently available information sources did not meet HP needs. Timely access to relevant literature and difficulties in contextualising identified information were major hurdles to health care delivery. In addition, omitted patient health information prevented participants from making informed decisions regarding their patients' healthcare management. Desired features of information resources included providing locally relevant recommendations individualised to patient needs that are based on up-to-date high quality information accompanied by rationale and links to additional information. HPs interviewed focused not only on pharmacological aspects of disease state management, but also on non-pharmacological treatment options. Factors that guided treatment choice included patient medical and social history and how treatment choice would impact the patient's quality and quantity of life; information resources should take the same factors into account when providing recommendations. Participants preferred electronic delivery as it is quicker to navigate and can use patient information stored in prescribing or dispensing software or other electronic health records (EHR) to provide patient relevant recommendations. Finally,

attention to font, colour and layout, impacted on participants' willingness to use information resources.

These findings were augmented by review of Australian and international literature to inform system development (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine). Information requirements were defined in further detail as part of clinical decision-making process modelling (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine) and identification of features promoting CDSS success (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing) and were found to be universal irrespective of geographical location.

Information attributes that influence clinical decision-making can be categorised as disease state management, drug or patient information. Disease state management information included pharmacological and non-pharmacological treatment options, associated level and evidence of efficacy, recommended implementation strategy and drug and disease targets. Drug information included drug class, allergy class, formulation type and interactions with diseases, other drugs, events such as stroke or myocardial infarction, monitoring tests and population type. Pharmacokinetic or pharmacodynamic changes due to liver or kidney dysfunction, gene polymorphism or race were also influenced drug choice, as well as local availability and affordability. Patient information to consider encompassed medical, functional, social and miscellaneous factors. Current and past medical history included pharmacological or non-pharmacological treatments, events, comorbidities, allergies, adverse drug reactions and liver and kidney function status. Functional and social factors included dexterity, issues with swallowing, activities of daily living, independent activities of daily living and mini mental-state exam score, frailty status, skin integrity and eligibility for local drug subsidy. Miscellaneous patient factors include life expectancy, smoking status, genetic polymorphism, race, gender, fertility status in women (prepubescent, fertile, pregnancy, breastfeeding, premenopausal, menopausal) and monitoring results.

CDSS features that were associated with success and improved clinical efficacy and efficiency of health care delivery included integration into local EHR, use human-computer interaction techniques during user interface design and good workflow integration including documentation of action or inaction. Good workflow integration can be achieved by using

potential users during the development and evaluation process. CDSS capabilities that were associated with success involved provision of patient relevant recommendations and identification of all important issues with pharmacological treatment without contributing to alert fatigue. In order to maintain clinical autonomy, evidence based, locally relevant recommendations should be provided with rationale and associated evidence. These results echo findings in the first phase of this research (Chapter 3: Resources for disease state management – what do health professionals want?).

A prototype CDSS, MedManAGE, was developed to deliver required information to guide complex patient management based on the identified features for success and information required by HPs during clinical decision making (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 5: Developing the Business Rule Engine). Simulated patients were used to evaluate the system's business rule engine (Chapter 5: Developing the Business Rule Engine). Database query results confirmed the face validity of the business rule engine; however it was discovered that incorrect information was being displayed on the user-interface. On the advice of a senior programmer the system was recoded to rectify these issues.

Usability evaluation of the prototype system was conducted in three stages, providing both qualitative and quantitative feedback regarding system usability and perceived potential usefulness (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing and Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). These stages helped identify whether the prototype met HP information needs during clinical decision making in complex patients.

Think out aloud protocol (Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing) suggested that the original prototype system was generally useful and informative, despite minor interface issues. Participant comments reflected results from other studies regarding system usability evaluations: use of colour to guide the user, clear headings and labels indicating page or active button purpose, intuitive placement of active buttons, use of drop down lists for short lists and auto-complete boxes for long lists were all identified as features that improved system usability. The interface that was the least intuitive was the "choose disease state guideline" page. This was most likely due to the novelty of this page, as no other system that could be identified requires the user to choose the management guideline that will provide

the decision support. Once explained, participants were able to navigate around the page. Findings from this study were incorporated into the new prototype during system recoding.

A modified computer system usability questionnaire (mCSUQ) was used to evaluate the improved system usability after demonstration to participants (Chapter 6: Provision of patient relevant information during complex clinical decision making: Usability evaluation). The questionnaire was validated showing good internal consistency and congruent validity and could be used by other researchers assessing system usability in a demonstration or indirect evaluation environment.

The prototype system scored well on all domains of usability: overall usability 5.05 (SD 1.07), system usefulness 5.06 (SD 1.11), information quality 5.09 (SD 1.09) and interface quality 4.84 (SD 1.24). Unsurprisingly, as the prototype interface was incomplete and lacked colour, interface quality had the lowest score. The question "the interface of MedManAGE is pleasant" scored the lowest (mean 4.78, SD 1.38) and "it would be easy to learn to use MedManAGE" scored the highest of all questions (mean 5.55, SD 1.17) suggesting the lack of colour and embellishments were major determinants for interface dissatisfaction, rather than interface clarity. In addition, qualitative feedback from the questionnaire and focus group suggested that participants felt that the interface was clear and simple to follow. The information quality domain scored the highest indicating that participants were most satisfied with the quality of information given. Qualitative feedback indicated that participants liked the patient relevance and comprehensiveness of the information provided by the system.

Suggestions for improvements gathered from qualitative feedback included functionality changes such as addition of hyperlinks to references and a forward or back button and interface changes such as the addition of colour to highlight important information. Additional information requirements included information on medication review, comprehensive deprescribing guidance and additional statistical data regarding therapy efficacy.

Aspects impacting wiliness to use CDSS were integration with EHR and use of high quality data in the knowledge base. A major barrier to CDSS use beyond the scope of the system itself was access to accurate and complete patient data. These results are consistent with findings from Chapter 3: Resources for disease state management – what do health professionals want? and Chapter 4: Ingredients of a Successful Clinical Decision Support System: Results from Design, Development and Usability Testing.

8.2 Strengths and Limitations

This research has investigated important barriers and facilitators to disease state management information communication to HPs caring for complex patients, such as the aged. It has resulted in the development and usability testing of a new framework for delivering patient relevant information to HPs - MedManAGE. This framework has overcome many of the previously identified barriers HPs had in sourcing information by:

- Providing a method for data-pooling relevant guidelines into one database for easy access;
- Identifying guidelines as appropriate to a given patient through the use of a descriptor;
- Maintaining clinical autonomy by allowing HPs to choose the guideline most appropriate to their patient as the basis of the system's decision support and to make the ultimate decision regarding treatment options;
- Providing information on non-pharmacological treatment options;
- Providing information on pharmacological treatment and identifying any potential patient-relevant issues that may occur if it were prescribed; and
- Identifying of potential drug precipitators of disease or symptom and how to deprescribe the offending pharmacological agent.

In addition, this research has identified what information is needed to provide useful guidance to HPs regarding treatment options for their patients; namely patient, drug and disease information. This can be used to inform other systems such as EHR, computer physician order entry systems and other CDSS. Furthermore it has validated a modified CSUQ that can be used to evaluate usability in indirect evaluation settings such as demonstrations.

Initial interviews were only able to recruit one GP; feedback from practices indicated that lack of remuneration for their time was the primary reason for lack of participation, which is disappointing and limited available information from a large potential-user group. Initial coding of MedManAGE was done by a student programmer, in line with Monash University's collaborative policies; however, this constrained the time and skill available. Although the system was subsequently recoded by a senior programmer, not all the decision algorithms were in place at the time of usability testing, which may have adversely affected results from the questionnaire and focus group.

Due to repeated recruitment failure for online testing, a group demonstration option was chosen. Ideally participants should use the system themselves in order to judge its usability. Using a demonstration meant that participants could not get an accurate impression of how the system functions or how to interact with it and they may have misinterpreted the usefulness of the system information presentation. Despite the limitations of using a demonstration, results were strengthened by a large questionnaire feedback sample that was in agreement with qualitative feedback from initial talk-out-aloud usability testing, where participants were able to directly interact with the system, and subsequent focus group feedback.

8.3 Future Directions

Initial findings suggest that this new framework for patient relevant information delivery is considered useful and informative by HPs. This system was developed targeting complex patients such as the aged; by addressing complex patients this system is also able to provide useful information during clinical decision making in uncomplicated patients.

The prototype system included limited disease states and associated drug and management information. Future work will involve expanding this knowledge. In addition it will involve completion of system coding with a colour interface, implementation of additional features identified during usability evaluation and expansion of system capabilities by developing comprehensive medication review and deprescribing abilities. Aspects not currently implemented in the current system, which were identified as important to CDSS success, including a robust referencing system with hyperlinks and integration with EHR, should also be developed.

Use of templates for addition of disease state management and drug monograph information to system knowledge have not been tested, as working templates were not coded as part of the system prototype. The usability of these templates and accuracy of completion needs to be evaluated. In addition, medical terms can be added to the system and associations between terms established using artificial intelligence to overcome issues associated with integration with EHR and inconsistent medical terminology use.

Finally, recruitment failure for early system development usability evaluation suggests that HPs may not believe that their feedback is of value. Awareness should be raised among HPs that their involvement with health information technology development throughout all stages would greatly improve their usability and usefulness.

8.4 Conclusion

This research has identified HPs' information needs when delivering healthcare to complex patients and subsequently developed a new system for information delivery designed to meet those needs. The system developed, MedManAGE, although only a prototype, has addressed many of the shortcomings of other CDSS and has the potential to change the way in which disease state information is delivered to HPs. It sets up a new framework for health care information delivery to HPs while maintaining clinical autonomy and provides a standard mechanism for storing drug monographs and disease state management information tailored to specific population groups. The system makes efficient use of stored information to provide patient-relevant recommendations. Use of a business rule engine with built in universally-applicable algorithms means that this framework is applicable globally; only knowledge changes are required to suit the local environment.

Although further development and testing is required, this framework for information delivery has been deemed both useful and usable and has the potential to improve the quality of prescribing in complex patients by providing HPs with high-quality patient-relevant information during clinical decision making while maintaining clinical autonomy. Evaluation showed that this method of information delivery was acceptable to HPs and addressed previously unmet information and management needs for complex patients.

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8.5 References

1. Gokula M, Holmes HM. Tools to Reduce Polypharmacy. Clin Geriatr Med. 2012;28(2):323-41.
2. O'Mahony D, O'Connor M. Pharmacotherapy at the End-of-Life. Age Ageing. 2011;40(4):419-22.
3. Boyd CM, Darer J, Boult C, Fried LP, Boult L, Wu AW. Clinical Practice Guidelines and Quality Care for Older Patients With Multiple Comorbid DIseases: Implications for Pay for Performance. J Am Med Assoc. 2005;294(6):716-24.
4. Hughes LD, McMurdo MET, Guthrie B. Guidelines for people not for diseases: the challanges of applying UK clinical guidelines to people with multimorbidity. Age Ageing. 2013;42(1):62-9.
5. National Institute of Clinical Sudies. Electronic Decision Support Systems Action Planning Report. In: Informatics CfH, editor. University of New South Wales2004.
6. Coiera E. Why e-health is so hard. Med J Aust. 2013;198(4):178-9.
7. Sweidan M, Reeve J, Dartnell J, Phillips S. Improving Clinical Decision Support Tools: Challenges and a Way Forward. Aust Fam Physician. 2011;40(6):561-2.
8. Britt H, Miller G. The Bettering the Evaluation and Care of Health (BEACH) program: where to from here? Med J Aust. 2013;198(3):125-6.
9. Johnson CW. Why did that happen? Exploring the proliferation of barely usable software in healthcare systems. Qual Health Care. 2006;15(Supp 1):i76-81.
10. Sweidan M, Williamson M, Reeve J, Harvey K, O'Neill JA, Schattner P, et al. Evaluation of Features to Support Safety and Quality in General Practice Clinical Software. BMC Med Informat Decis Making. 2011;11(27).

Appendices

Appendix 1: Monash University Human Research Ethics Committee Approval Letter (Chapter 3)

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**20 June 2011**
Project Number:	**CF11/1662 – 2011000914**
Title:	**The need for Medication use improvement in the elderly**
Chief Investigator:	**Assoc Prof Jennifer Marriott**
Approved:	**From: 20 June 2011 To: 20 June 2016**

Terms of approval

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Prof Peteris Darzins, Ms Paulina Stehlik

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Appendix 2: Monash University Human Research Ethics Committee Amendment Approval Letter (Chapter 3)

From: MRO Human Ethics Team [mailto:muhrec@monash.edu]
Sent: Monday, September 19, 2011 11:05 AM
To: Jennifer Marriott
Subject: CF11/1662 – 2011000914: The need for medication use improvement in the elderly

PLEASE NOTE: To ensure speedy turnaround time, this correspondence is being sent by email only. MUHREC will endeavour to copy all investigators on correspondence relating to this project, but it is the responsibility of the first-named investigator to ensure that their co-investigators are aware of the content of the correspondence.

Dear Researchers

Thank you for submitting a Request for Amendment to the above named project.

This is to advise that the following amendments have been approved and the project can proceed according to your approval given on 20 June 2011:

1 Recruitment of GPs and Accredited pharmacists in accordance with the procedures, letters, explanatory statements and consent forms provided to the Committee by the researchers.

Thank you for keeping the Committee informed.

Professor Ben Canny
Chair, MUHREC

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Appendix 3: Interview Consent Form (Chapter 3)

Consent Form

Title: The need for Medication use improvement in the elderly

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

1. I agree to be interviewed by the researcher ☐ Yes ☐ No
2. I agree to allow the interview to be audio-taped ☐ Yes ☐ No
3. I agree to make myself available for a further interview if required ☐ Yes ☐ No

I understand that I will be given a transcript of data concerning me for my approval before it is included in the write up of the research.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw from the project without being penalised or disadvantaged in any way, however you will only be able to withdraw data prior to your approval of the interview transcript /prior to the publication of a report of the project.

I understand that any data that the researcher extracts from the interview for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

Participant's name

Signature

Date

Appendix 4: Interview Explanatory Statement: Geriatricians (Chapter 3)

MONASH University

3/06/2011

Explanatory Statement – Geriatrician Interviews

Title: The need for Medication use improvement in the elderly

This information sheet is for you to keep.

My name is Paulina Stehlik and I am conducting a research project with Dr Jennifer Marriott, an Associate Professor at the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University and Professor Pēteris Dārziņš, a Professor of Geriatric Medicine at Monash University, towards a PhD at Monash University. This means that I will be writing thesis.

You are invited to take part in this study. Please read this Explanatory Statement in full before making a decision.

Why did you choose this particular person/group as participants?
We are seeking the views of geriatricians as they are most responsible for the care of elderly people. You have been given this information by a colleague who believes you may be able to contribute your expertise to this project.

The aim/purpose of the research
The aim of this study is to elicit the opinions and preferences of practicing geriatricians with regard to the format of potential clinical practice guidelines that are to be used in assisting appropriate prescribing in the geriatric patient.

Possible benefits
Inappropriate prescribing in geriatric patients is a growing issue in Australia and globally. This project seeks to develop valid and usable guidelines in order to assist practitioners in making informed choices about appropriate medication use in their geriatric patients. In order for this to be successful, practitioners need to be accepting of these guidelines and need to find them of value. The opinions and preferences gathered in this study will assist in formulating clinical guidelines that meet the needs of prescribers.

What does the research involve?
The study involves an interview, which will be audio recorded, asking your views on the usability of proposed guideline format and seeking your opinion of possible alternative formats.

How much time will the research take?
The interview should take approximately one hour.

Inconvenience/discomfort
There is little to no risk of potential discomfort that could be caused by this study. Interviews will take place at a time and location of your choice. Your details will not be published and will be kept confidential, only the researchers will be able to access any of your details for the purposes of this study.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may withdraw from further participation at any stage but you will only be able to withdraw data prior to your approval of the interview transcript /prior to the publication of a report of the project.

Confidentiality

Transcripts and audio files will only be accessed by the researchers. Participants will not be named or able to be identified in any publication arising from this research.

Storage of data

Data collected will be stored in accordance with Monash University regulations, kept on University premises, in a locked filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

If you would like to be informed of the aggregate research finding, please contact **Paulina Stehlik on (03) 9903 9025 or email Paulina.Stehlik@monash.edu.**

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research **<insert your project number here>** is being conducted, please contact:
Associate Professor Jennifer Marriott **Director, Bachelor of Pharmacy Course** **Faculty of Pharmacy and Pharmaceutical Sciences** **Monash University** **381 Royal Parade** **Parkville 3052** **Telephone: (03) 9903 9533** **Fax: (03) 9903 9629** **Email: jennifer.marriott@monash.edu**	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Thank you.

Paulina Stehlik

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Email: **Paulina.Stehlik@monash.edu**

Appendix 5: Follow up Email to Initial Invite Sent to Geriatricians by their Colleague to Participate in Interviews (Chapter 3)

Dear

This is just a follow up email regarding to your invitation to participate interview I am conducting as part of my PhD project. If you are interested please feel free to contact me via [redacted] to organise a time as I am hoping to conclude interviews by mid-September. I have attached the explanatory statement and consent form.

If you are unable or unwilling to participate please let me know and also give a reason why you are unable to participate (e.g. too busy, uninterested, etc.) so that I can cease communication.

Kind Regards

Paulina Stehlik

Paulina Stehlik
PhD candidate, B.Pharm (Hons)
Faculty of Pharmacy and Pharmaceutical Sciences
Monash University
381 Royal Parade
Parkville 3052
[redacted]

Appendix 6: Interview Explanatory Statement: GPs (Chapter 3)

MONASH University

24/08/2011

Explanatory Statement – General Practitioner Interviews

Title: The need for Medication use improvement in the elderly

This information sheet is for you to keep.

My name is Paulina Stehlik and I am conducting a research project with Dr Jennifer Marriott, an Associate Professor at the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University and Professor Pēteris Dārziņš, a Professor of Geriatric Medicine at Monash University, towards a PhD at Monash University. This means that I will be writing thesis.

You are invited to take part in this study. Please read this Explanatory Statement in full before making a decision.

Why did you choose this particular person/group as participants?
We are seeking the views of general practitioners as they are most responsible for the care of elderly people. You have been given this information by a colleague who believes you may be able to contribute your expertise to this project.

The aim/purpose of the research
The aim of this study is to elicit the opinions and preferences of practicing general practitioners with regard to the format of potential clinical practice guidelines that are to be used in assisting appropriate prescribing in the geriatric patient.

Possible benefits
Inappropriate prescribing in geriatric patients is a growing issue in Australia and globally. This project seeks to develop valid and usable guidelines in order to assist practitioners in making informed choices about appropriate medication use in their geriatric patients. In order for this to be successful, practitioners need to be accepting of these guidelines and need to find them of value. The opinions and preferences gathered in this study will assist in formulating clinical guidelines that meet the needs of prescribers.

What does the research involve?
The study involves an interview, which will be audio recorded, asking your views on the usability of proposed guideline format and seeking your opinion of possible alternative formats.

How much time will the research take?
The interview should take approximately one hour.

Inconvenience/discomfort
There is little to no risk of potential discomfort that could be caused by this study. Interviews will take place at a time and location of your choice. Your details will not be published and will be kept confidential, only the researchers will be able to access any of your details for the purposes of this study.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may withdraw from further participation at any stage but you will only be able to withdraw data prior to your approval of the interview transcript /prior to the publication of a report of the project.

Confidentiality

Transcripts and audio files will only be accessed by the researchers. Participants will not be named or able to be identified in any publication arising from this research.

Storage of data

Data collected will be stored in accordance with Monash University regulations, kept on University premises, in a locked filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

If you would like to be informed of the aggregate research finding, please contact **Paulina Stehlik on (03) 9903 9025 or email Paulina.Stehlik@monash.edu.**

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research **<insert your project number here>** is being conducted, please contact:
Associate Professor Jennifer Marriott **Director, Bachelor of Pharmacy Course** **Faculty of Pharmacy and Pharmaceutical Sciences** **Monash University** **381 Royal Parade** **Parkville 3052** **Telephone: (03) 9903 9533** **Fax: (03) 9903 9629** **Email: jennifer.marriott@monash.edu**	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Thank you.

Paulina Stehlik

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Appendix 7: Letter of Invitation to GP divisions for GP Participation in Interviews (Chapter 3)

Dear

My name is Paulina Stehlik and I am currently doing my PhD with a focus on geriatric medication management; this email was passed on to be by Jess from your admin office.

I wish to get a GP perspective on what resources they use when coming to a therapeutic decision concerning geriatric patients, and what they think makes a resource useful. Eventually I hope to make a guideline/tool to assist in medication management in the elderly.

I wish to invite GP's in this division to participate in a one-off 1 hour interview, which can be conducted at a time and place of their convenience. If possible, could you send out the attached invite to the GPs in this division. If not, please let me know; any accompanying reasons would be much appreciated.

If you have any queries please feel free to contact me.

Kind regards,

Paulina Stehlik
Paulina Stehlik
PhD candidate, B.Pharm (Hons)
Faculty of Pharmacy and Pharmaceutical Sciences
Monash University
381 Royal Parade
Parkville 3052
[redacted]

Appendix 8: Letter of Invitation to GPs to Participate in Interviews (Chapter 3)

Dear General Practitioner

My name is Paulina Stehlik and I am currently doing my PhD at Monash University with a focus on geriatric medication management; my primary aim is to formulate a new Australian focused user-friendly guideline for appropriate medication use in the elderly.

I wish to conduct face-to-face interviews with 10-20 GPs such yourself in order to give me an insight into:

- What resources you use when choosing an appropriate medication for your geriatric patients
- If you feel that the currently available resources and guidelines are appropriate and fulfil your prescribing needs
- What you feel makes a user friendly guideline and the type of information that should be included
- If you feel that the formats that I have proposed are appropriate and in what ways they could be improved

As GPs play an important role in geriatric care your thoughts and views are important.

The interview should take approximately 1 hour and will be conducted at a time and place of your convenience. I hope to complete these interviews by the end of March 2012.

Information gathered from these interviews will be used as the basis for the format of my guideline.

If you wish to participate please contact me via email [redacted] and I will be able to send you an explanatory statement and answer any other questions you may have.

Looking forward to hearing from you

Yours sincerely

Paulina Stehlik ☺

Paulina Stehlik

PhD candidate, B.Pharm (Hons)

Faculty of Pharmacy and Pharmaceutical Sciences

Monash University

381 Royal Parade

Parkville 3052

[redacted]

Appendix 9: Letter of Invitation to AACP to Publish Flyer for Accredited Pharmacist's to Participate in Interviews (Chapter 3)

To whom it may concern,

My name is Paulina Stehlik and I am doing my PhD at Monash University with a focus on geriatric medication management. I wish to invite accredited pharmacists to participate in phase 1 of my project. Could you please publish the attached flyer your next fortnightly e-newsletter.

Kind Regards

Paulina Stehlik

Paulina Stehlik
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Faculty of Pharmacy and Pharmaceutical Sciences
Monash University
381 Royal Parade
Parkville 3052
[redacted]

Appendix 10: Interview Explanatory Statement: Accredited Pharmacists (Chapter 3)

MONASH University

24/08/2011

Explanatory Statement – Pharmacist Interviews

Title: The need for Medication use improvement in the elderly

This information sheet is for you to keep.

My name is Paulina Stehlik and I am conducting a research project with Dr Jennifer Marriott, an Associate Professor at the Faculty of Pharmacy and Pharmaceutical Sciences at Monash University and Professor Pēteris Dārziņš, a Professor of Geriatric Medicine at Monash University, towards a PhD at Monash University. This means that I will be writing thesis.

You are invited to take part in this study. Please read this Explanatory Statement in full before making a decision.

Why did you choose this particular person/group as participants?
We are seeking the views of pharmacists as they are highly involved in the care of elderly people. You have been given this information by a colleague who believes you may be able to contribute your expertise to this project.

The aim/purpose of the research
The aim of this study is to elicit the opinions and preferences of practicing pharmacists with regard to the format of potential clinical practice guidelines that are to be used in assisting appropriate prescribing in the geriatric patient.

Possible benefits
Inappropriate prescribing in geriatric patients is a growing issue in Australia and globally. This project seeks to develop valid and usable guidelines in order to assist practitioners in making informed choices about appropriate medication use in their geriatric patients. In order for this to be successful, practitioners need to be accepting of these guidelines and need to find them of value. The opinions and preferences gathered in this study will assist in formulating clinical guidelines that meet the needs of prescribers.

What does the research involve?
The study involves an interview, which will be audio recorded, asking your views on the usability of proposed guideline format and seeking your opinion of possible alternative formats.

How much time will the research take?
The interview should take approximately one hour.

Inconvenience/discomfort
There is little to no risk of potential discomfort that could be caused by this study. Interviews will take place at a time and location of your choice. Your details will not be published and will be kept confidential, only the researchers will be able to access any of your details for the purposes of this study.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may withdraw from further participation at any stage but you will only be able to withdraw data prior to your approval of the interview transcript /prior to the publication of a report of the project.

Confidentiality

Transcripts and audio files will only be accessed by the researchers. Participants will not be named or able to be identified in any publication arising from this research.

Storage of data

Data collected will be stored in accordance with Monash University regulations, kept on University premises, in a locked filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Results

If you would like to be informed of the aggregate research finding, please contact **Paulina Stehlik on (03) 9903 9025 or email Paulina.Stehlik@monash.edu.**

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research <**insert your project number here**> is being conducted, please contact:
Associate Professor Jennifer Marriott **Director, Bachelor of Pharmacy Course** **Faculty of Pharmacy and Pharmaceutical Sciences** **Monash University** **381 Royal Parade** **Parkville 3052** **Telephone: (03) 9903 9533** **Fax: (03) 9903 9629** **Email: jennifer.marriott@monash.edu**	**Executive Officer** **Monash University Human Research Ethics Committee (MUHREC)** **Building 3e Room 111** **Research Office** **Monash University VIC 3800** **Tel: +61 3 9905 2052 Fax: +61 3 9905 3831** **Email: muhrec@monash.edu**

Thank you.

Paulina Stehlik

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Email: **Paulina.Stehlik@monash.edu**

Appendix 11: Flyer Published in AACP Newsletter (Chapter 3)

Accredited Pharmacist participation required for research study

This is an invitation for accredited pharmacists to participate in an exploratory interview regarding medication management in the geriatric patient.

Paulina Stehlik is currently doing a PhD at Monash University Faculty of Pharmacy and Pharmaceutical Sciences with a focus on geriatric medication management; her primary aim is to formulate a new Australian focused user-friendly guideline for appropriate medication use in the elderly.

Paulina wishes to conduct face-to-face interviews with 10-20 Melbourne pharmacists such yourself in order to give her an insight into:

- What resources you use when choosing an appropriate medication for your geriatric patients
- If you feel that the currently available resources and guidelines are appropriate and fulfil your therapeutic decision making needs
- What you feel makes a user friendly guideline and the type of information that should be included
- If you feel that the formats that she has proposed are appropriate and in what ways they could be improved

As pharmacists play an important role in geriatric care your thoughts and views are important.

These interviews should take approximately 1 hour and will be conducted at a time and place of your convenience. Paulina hopes to complete these interviews by the end of October or mid November 2011. Information gathered from these interviews will be used as the basis for the format of her guideline.

If you wish to participate please contact Paulina via email [redacted] and she will be able to send you an explanatory statement and answer any other questions you may have.

Appendix 12: Letter of Invitation to Accredited Pharmacist's to Participate in Interviews (Chapter 3)

Accredited Pharmacist participation required for research study

My name is Paulina Stehlik and I am currently doing my PhD at Monash University with a focus on geriatric medication management; my primary aim is to formulate a new Australian focused user-friendly guideline for appropriate medication use in the elderly.

I wish to conduct face-to-face interviews with 10-20 Melbourne pharmacists such yourself in order to give me an insight into:

- What resources you use when choosing an appropriate medication for your geriatric patients
- If you feel that the currently available resources and guidelines are appropriate and fulfil your prescribing needs
- What you feel makes a user friendly guideline and the type of information that should be included
- If you feel that the formats that I have proposed are appropriate and in what ways they could be improved

As pharmacists play an important role in geriatric care your thoughts and views are important.

These interviews should take approximately 1 hour and will be conducted at a time and place of your convenience. I hope to complete these interviews by the end of October 2011.

Information gathered from these interviews will be used as the basis for the format of my guideline.

If you wish to participate or find out more please contact me via email

(

Yours sincerely

Paulina Stehlik ☺

Paulina Stehlik

PhD candidate, B.Pharm (Hons)

Faculty of Pharmacy and Pharmaceutical Sciences

Monash University

381 Royal Parade

Parkville 3052

Appendix 13: Interview Guide: Geriatricians (Chapter 3)

1. What sorts of issues do you think are most important to consider when it comes to prescribing for the geriatric population?
2. Do you find it difficult choosing an appropriate drug therapy for an elderly (aged >75yrs old) patient?
    a. What do you aspects do you find difficult when choosing a drug therapy for an elderly patient?
3. Do you use any resources when trying to determine if a medication is appropriate for an elderly patient?
    a. If you use a resource/s, which one/s and why? (e.g. Primary literature, pharmacist, other health care professionals, hospital protocols, guidelines, reference books etc…)
4. Do you know of, or use, any clinical guidelines specifically tailored to appropriate prescribing in the elderly patient?
    a. If yes, do you think these guidelines are appropriate for the Australian elderly patients?
    b. Do you feel that these guidelines are adequate enough to meet your needs as a prescriber?
5. Of the clinical guidelines that you know of or use, what do you think are positive and negative aspects of these guidelines?
6. If new clinical guidelines were formulated, what are the features you think are important to include? For example: level of evidence of recommendations?
7. We have formulated two different proposed formats for presenting our guidelines. Of these two, do you have a preference of either one? Would you like something different from either of these?
    a. Which aspects do you like?
    b. Which aspects would you change?
8. What disease topics do you think are most important to cover in a geriatric guideline?
9. Are there any additional comments you would like to add?

Appendix 14: Interview Guide: GPs (Chapter 3)

1. What sorts of issues do you think are most important to consider when it comes to prescribing for the geriatric population?
2. Do you find it difficult choosing an appropriate drug therapy for an elderly (aged >75yrs old) patient?
    a. What do you aspects do you find difficult when choosing a drug therapy for an elderly patient?
3. How do you manage the following?
    a. Post hospital admission – are there any follow up procedures that you follow? Are there any problems with communication between the hospital and yourself?
    b. Non-adherence. How do you identify potential non-adherence?
    c. Adverse effects? How do you monitor for adverse effect especially when initiating a new medication? How are these adverse effects managed?
    d. Polypharmacy? When do you cease medications? Do you feel there are difficulties in ceasing medications?
4. Do you use any resources when trying to determine if a medication is appropriate for an elderly patient?
    a. If you use a resource/s, which one/s and why? (e.g. Primary literature, pharmacist, other health care professionals, hospital protocols, guidelines, reference books etc…)
5. What clinical guidelines do you know of, or use, that are specifically tailored to appropriate prescribing in the elderly patient?
    a. If yes, do you think these guidelines are appropriate for the Australian elderly patients?
    b. Do you feel that these guidelines are adequate enough to meet your needs as a prescriber?
6. Of the clinical guidelines that you know of or use, what do you think are positive and negative aspects of these guidelines?
7. If new clinical guidelines were formulated, what are the features you think are important to include? For example: level of evidence of recommendations?
8. We have formulated two different proposed formats for presenting our guidelines. Of these two, do you have a preference of either one? Would you like something different from either of these?
    a. Which aspects do you like?
    b. Which aspects would you change?
9. In what format would you be most likely to use a resource – i.e. web based, iPhone/iPad application or similar, computer program, hard copy?
10. What disease topics do you think are most important to cover in a geriatric guideline?
11. Are there any additional comments you would like to add?

Appendix 15: Interview Guide: Accredited Pharmacists (Chapter 3)

1. What sorts of issues do you think are most important to consider when it comes to making a therapeutic decision for the geriatric
2. Do you find it difficult trying to make an appropriate drug therapy recommendation for an elderly (aged >75yrs old) patient?
    a. What do you aspects do you find difficult when trying to make a drug therapy recommendation for an elderly patient?
3. What sorts of recommendations do you make, or how to you manage, the following:
    a. Non-adherence? What methods do you use to identify potentially non-adherent patients?
    b. Adverse effects? How do you monitor for or identify potential adverse effects?
    c. How do you manage poly pharmacy? Do you feel there are difficulties in ceasing medications?
    d. If you recommend ceasing medications, what resources do you use in recommending a ceasing-medication schedule?
4. Do you use any resources when trying to determine if a medication is appropriate for an elderly patient?
    a. If you use a resource/s, which one/s and why? (e.g. Primary literature, pharmacist, other health care professionals, hospital protocols, guidelines, reference books etc…)
5. What clinical guidelines do you know of, or use, that are specifically tailored to appropriate prescribing in the elderly patient?
    a. If yes, do you think these guidelines are appropriate for the Australian elderly patients?
    b. Do you feel that these guidelines are adequate enough to meet your needs as a pharmacist?
6. Of the clinical guidelines that you know of or use, what do you think are positive and negative aspects of these guidelines?
7. If new clinical guidelines were formulated, what are the features you think are important to include? For example: level of evidence of recommendations?
8. We have formulated two different proposed formats for presenting our guidelines. Of these two, do you have a preference of either one? Would you like something different from either of these?
    a. Which aspects do you like?
    b. Which aspects would you change?
9. In what format would you be most likely to use a resource – i.e. web based, iPhone/iPad application or similar, computer program, hard copy?
10. What disease topics do you think are most important to cover in a geriatric guideline?
11. Are there any additional comments you would like to add?

Appendix 16: Guideline Format - Option 1 (Chapter 3)

Potentially Inappropriate Medications

Recommendation	Evidence for recommendation			Deprescribing		Evidence for deprescribing	
	Reference	Grade	Clinical significance	Process	When to re-initiate	Reference	Grade
What drug and/or dose shouldn't be used – try to specify in what situation it would or would not be appropriate e.g. Do not use digoxin dose > 125mcg d unless already stabilised and not experiencing any adverse effects.	[ref]	Level according to GradePRO	Expert opinion or according to the literature. Which source is used is clearly stated.	How to actually reduce the dose safely	What signs and/or symptoms indicate that therapy should be reinitiated? What could be used instead of the PIM(is there a better option)?	[ref]	Level according to GradePRO

Potentially Omitted Medications

Recommendation	Evidence for recommendation		
	Reference	Grade	Clinical significance
What drug and/or dose should be used – try to specify in what situation it would or would not be appropriate e.g. Use of warfarin in patients with AF with a $CHADS_2$ score ≥2 aiming for an INR 2-3 who do not have a contraindication to anticoagulation	[ref]	Level according to GradePRO	Expert opinion or according to the literature. Which source is used is clearly stated.

Appendix 17: Guideline Format - Option 2 (Chapter 3)

Disease to be managed (e.g. AF) Statement of what the disease is and how it presents in elderly patients

Treatment options

Scenario	Recommendations	Explanatory notes
A specific scenario which describes the patient situation. **e.g.**	A list of drugs for which there is evidence of use in elderly patients	Why this drug is or is not recommended – these statements are referenced The clinical significance of the recommendation is also included – these statements are referenced. If it is not recommended, an explanation of how to deprescribe the drug is included – these statements are referenced
	A list of drug for which there is no evidence of benefit or for which there is evidence of harm	
AF with no other complications and < 70 yrs old	Drug X	Drug X decreases the risk of stroke [ref] The benefit of using this drug outweighs the risk of harm [ref]
	Drug Y	Drug Y has not been shown to decrease the risk of stroke in this population [ref] It has been shown to increase the risk of adverse effects in this population such as …. [ref]
AF with no other complications and > 70 yrs old	Etc…	Etc…
AF with complications and < 70 yrs old		
AF with complications and > 70 yrs old		

Reference table:

The references used within each "disease to be managed" section will be at the end of each section.

Reference	Evidence level
[1]	A statement of the level of evidence is given according to GradePRO program.

Appendix 18: Disease State Management Guideline SAMPLE (Chapters 4 and 5)

Full detail of disease state guidelines included in the system is on the CD-ROM provided

Type 2 Diabetes

In the presence of:

With no other comorbidities for patients over the age of 65

Non-drug Risk Factors

Risk Factor	Description	Is the risk factor modifiable? If so, how (brief)?	
Diet	High fat diet increases the risk of insulin resistance and T2DM. (1) High saturated fat intake increases the risk of insulin resistance and T2DM. (1) High glycaemic index (GI) diet increases risk of especially when associated with low cereal fibre intake.	Yes	Reduce dietary fat <30% of energy intake Reduce saturated fat to <10% energy intake Consume a low energy diet Eat a wide range of food high in dietary fibre and with low GI
Exercise	Low cardiovascular fitness in men increases the risk of IGT and T2DM. (1) Physical inactivity increases the risk of IGT and T2DM. (1) Physical activity level can be measured using: (1) • Movement recorders – e.g. pedometer • Questionnaires focussing on leisure time activities Heart rate monitoring	Yes	Increase exercise to 3-5 times a week • Can reduce DM related mortality *At least* 150mins of exercise per week.(2, 3) Increase resistance training.(2)
Obesity	The more obese a person is and the longer the duration of obesity the higher the risk of T2DM development. (1) Abdominal obesity is an important indicator of T2DM risk(1)	Yes	Most adults require ongoing weight loss programs that provide diet, exercise and social support. • Weight loss can be achieved during supervised periods of programs but usually regained in unsupervised periods – weight should be monitored at every HP visit Long term effectiveness requires further

	• This applies to all ethnic groups; however, grading systems are primarily applicable in Europeans and should be applied to other ethnicities with caution Central fat distribution predisposes patients to T2DM. (1) • Waist circumference should be used in conjunction with BMI and body weight to identify people for weight loss • Europeans ≥40 years old : Men >100cm; Women >90cm • Lower thresholds for aged population • Threshold does not apply to other ethnicities but general principals do Impaired glucose tolerance and impaired fasting glucose risk increases especially in those with central adiposity.(2, 4, 5)		investigation
Smoking		Yes	Advise on risks of smoking.(2) Offer smoking cessation.
ATSI > 35 yrs old	All patients in this category are considered at high risk of developing T2DM and should be screened. (2, 4, 5)	No	
Pacific Islanders	Certain non-English speaking people >35 years old are at high risk of developing T2DM and should be screened.(2, 4, 5)	No	
Indian subcontinent	Certain non-English speaking people >35 years old are at high risk of developing T2DM and should be screened.(2, 4, 5)	No	
Chinese	Certain non-English speaking	No	

origin	people >35 years old are at high risk of developing T2DM and should be screened.(2, 4, 5)		
Aged >45 yrs old	With first degree relative with T2DM.(2, 4, 5) The net clinical or economic benefit of screening this population for T2DM is yet to be determined.(4) With either or both:(4, 5) * • Obesity (BMI ≥30) • Hypertension (HT) All patients in this category are considered at high risk of developing T2DM and should be screened. (2, 4, 5)	No	
Aged > 55 yrs old	The net clinical or economic benefit of screening this population for T2DM is yet to be determined.(2, 4, 5)	No	
Impaired glucose tolerance	Risk of developing IGT and IFG include: (2, 4, 5) • Over 40 • Overweight especially if central adiposity is present • High BP • Known CVD • Family history of DM • History of gestational diabetes	Yes	Control of glucose levels through diet and exercise
Impaired fasting glucose	Risk of developing IGT and IFG include: (2, 4, 5) • Over 40 • Overweight especially if central adiposity is present • High BP • Known CVD • Family history of DM • History of gestational diabetes	Yes	Control of glucose levels through diet and exercise
History of	The net clinical or economic	No	

gestational diabetes	benefit of screening this population for T2DM is yet to be determined.(2, 4, 52)		
Polycycstic Ovary Syndrome	In women who are obese(4, 5) All patients in this category are considered at high risk of developing T2DM and should be screened. (2, 4, 5)	No	
Presence of clinical CVD	All people with clinical CVD:(2, 4, 5) * • Myocardial infarction • Angina • Stroke • Peripheral vascular disease All patients in this category are considered at high risk of developing T2DM and should be screened. (2, 4, 5)	No	

Drug Risk Factors

Drug	Clinical Significance	Causes (Symptom)	Description

Diagnosis

What is it?

Characterised by insulin resistance.(2)

Other characteristics include:(2)

- Patient is usually middle aged and overweight
- Slow onset
- Strong family history
- Not prone to ketosis

Symptoms

Generally not symptomatic – this means that glucose dysfunction may have been present for years before detected.

Symptoms of **glucosuria**:(2)

- Polyuria
- Polydipsia
- Polyphagia
- Weight loss
- Nocturia

Symptoms of **hyperglycaemia**:(2)

- Malaise or fatigue
- Altered vision

Lab Measures

Type of sample

- Capillary blood glucose with glucose monitor is ok only if confirmed with venous plasma measurement.(2)
- Venous plasma glucose measurements are the preferred sample method and should be used wherever possible to test for undiagnosed T2DM.(4, 6)
- Laboratory measurement is preferred over a glucose machine measurement.(4)
- Fasting sample is preferred over a random sample; however, a random plasma sample can be used.(4)

Diagnosis needs to be confirmed on a subsequent day unless unequivocal hyperglycaemia with acute metabolic depression or obvious symptoms.(2, 4)

Oral glucose tolerance test (OGTT) is *not* required if unequivocally elevated fasting or random plasma glucose.(2)

HbA_{1c} is an appropriate diagnostic tool for diabetes provided that:(7)

- Stringent quality assurance is in place
- Assays are standardised to criteria aligned to international reference values
- No conditions which can affect HbA_{1c} results are present

Aims of Care

<u>Summary</u>

Short term

- Relief of symptoms(2, 5)

- Relief of acute complications(2)

Long term – overall long term goal is to prevent long term complications(5) by:

- Optimising:(2)
  - Glucose control
  - Dyslipidemia
  - BP
- Reduce risk factors(2)
- Identify and treat T2DM complications(2)
- Maintain other preventative activities(2)

Review Process

Baseline and ongoing review(2, 5):

- Weight (refer to DIETICIAN): BMI; waist circumference
- CVD: BP (standing and lying down); peripheral, neck and abdominal vessels
- Eyes (refer to OPTHAMILIGIST or OPTOMETRIST): visual activity (without correction); cataracts; retinopathy (examine with pupil dilation)
- Feet (Refer to PODIATRIST): sensation and circulation; skin condition; pressure areas; inter-digital problems; abnormal bone structure
- Peripheral nerves: tendon reflex; sensation (touch and vibration)
- Urinalysis: albumin; ketones; nitrates and/or leucocytes
- Renal function: plasma creatinine; micro-albuminuria
- Lipids: LDL-C; HDL-C; total cholesterol; triglycerides
- Glycaemia: HbA_{1c}
- Other: ECG if > 50 yrs old; microurine if in high risk group; thyroid function text if there is a family history or clinical suspicion.

Also to be reviewed yearly:(5)

- Management goals
- Smoking status
- Healthy eating plan
- Physical activity
- Self-care education
- Medications
- Immunisation status

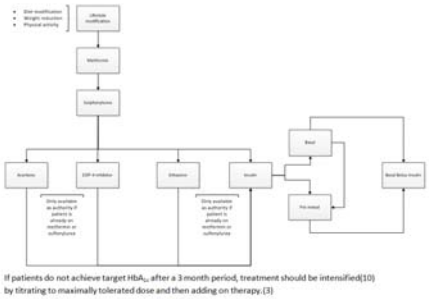
Self-Monitoring Blood Glucose

All patients with T2DM should be recommended self-monitoring of blood glucose (SMBG), the frequency of which needs to be individualized based on patient needs,(8) physical and cognitive function.(9)

SMBG may not be required in elderly patients especially in those who:(9)

- Diet-treated T2DM
- Medications which do not cause hypoglycemia

Symptom Treatment Algorithms

Symptom to be treated	Treatment algorithm
Hyperglycaemia	

Non-Drug Treatment

Symptom to be treated	Non-Drug Treatment	Details
Hyperglycaemia	Healthy Diet	Reduce dietary fat <30% of energy intake.(1) Reduce saturated fat to <10% energy intake.(1) Consume a low energy diet with a wide range of food high in dietary fibre and with low GI.(1) Fish may have a protective effect in the development of T2DM • May also decrease TG levels, decrease platelet aggregation and protect against thrombosis in diseased blood vessels if >5g fish oil per day (2) Oils to use:(2) • Monosaturated and seed sourced polyunsaturated fats o Will help lower LDL-C o E.g. olive oil, canola oil Use:(2) • Low fat milk • Light margarine, especially with plant sterols to help decrease cholesterol absorption • Low fat ricotta or cottage cheese as an alternative spread • Lean meat – ask local butcher • Low salt or no added salt foods • Sweeteners instead of sugar • Low alcohol beer (c.f.: diet or ordinary beer) o Alcohol intake should be ≤2 standard drinks or 20g alcohol per day for both men and women **Patient and Practitioner resources** Diabetes Australia – Eating well (10) Referral to dietician
Hyperglycaemia	Exercise	Increase exercise to 3-5 times a week.(1) • Can reduce DM related mortality

		At least 150mins of exercise per week.(2, 3) *Up to 300mins per week for obese patients with dietary modification to assist weight control.(3)* Resistance training will:(2) • Insulin sensitivity • Decreases insulin levels in people with hyperinsulinaemia • Improves dyslipidaemia • Decreases blood pressure (BP) Increased physical activity in the aged can benefit them by:(3) • Improving conditioning, strength, flexibility and overall fitness level • Improving mobility • Reducing risk of: o CVD o Thromboembolic stroke o HT o T2DM o OP o Obesity o Colon cancer o Breast cancer o Anxiety o Depression o Cognitive decline • Reducing falls risk and associated injuries Exercise can be split up into four categories:(3) 1. Aerobic exercise o Involves the use of large muscle groups (e.g. brisk walk, swimming, etc.) in addition to normal activities of daily living o Recommendation (minimum requirement): ▪ 30mins moderate intensity 5 times a week ▪ 20mins vigorous intensity 3 times a week o Patients with chronic diseases may not be able to achieve this; maximally achievable physical activity that does

		not cause harm is recommended. o Intensity effort should be based on a "relative" scale due to large range of individual functional capacity. 2. Muscle strengthening o Activities that maintain or increase muscle strength (e.g. weight and resistance training, etc…) o Recommendation (minimum requirement): ▪ 2 non consecutive days a week ▪ Target 8-10 muscle groups ▪ Strive for 10-15 repetitions of each exercise at moderate-high intensity and slowly increase over time 3. Flexibility o Paramount to achieve activities of daily living such as putting on shoes, and turning around to reverse car. o Recommendations (minimal requirement): ▪ At least twice a week for 10mins ▪ Slowly stretch, without bouncing, and hold for 10-30 seconds ▪ Best done after aerobic or muscle strengthening exercises 4. Balance o Are especially important for patients with a history of falls (e.g. tai chi, etc…) **OA**: (3) Aerobic exercise that minimises joint stress. Begin at low intensity and increase slowly. Avoid during periods of flare-up. **Cognitive Impairment**:(3) Same recommendations apply May need assistance **OP**:(3) Same recommendations apply; however, more emphasis on strengthening and weight bearing exercises, as well as balance training. Consult an exercise specialist if a fracture has occurred to relieve pain and regain mobility **Patient and Practitioner resources** Go4Life website (U.S. based; aged specific, pictures and video available) http://go4life.nia.nih.gov/about/health-professionals

		Referral to exercise professional can be claimed under the Enhanced Primary Care Program as part of the Team Care Arrangement (MBS item number 723).(2)
Hyperglycaemia	Smoking cessation	Advise on risks of smoking Offer smoking cessation **Patient and Practitioner Resources** Quit Website http://www.quit.org.au/
Hyperglycaemia	Weight loss/control	Most adults require ongoing weight loss programs that provide diet, exercise and social support. • Weight loss can be achieved during supervised periods of programs but usually regained in unsupervised periods – weight should be monitored at every HP visit Long term effectiveness requires further investigation Aged patients with T2DM can benefit from caloric restriction and increased physical activity with a weight loss of approximately 5% body weight.(9) Note: Aged patients are also at risk of under-nutrition which can increase morbidity and mortality.(9) Any weight loss needs to be assessed during medical nutritional evaluation.(9) General principles for preventing weight regain after weight loss • Decrease TV watching time – increased TV watching is positively associated with weight gain • Consume low energy low fat diet. Exercise is important in preventing weight re-gain • Therapist contact may aid with weight maintenance after weight loss • Education on diet and exercise may help reduce waist circumference in men for up to 2 years **Patient and Practitioner Resources** Elderly patients should receive medical nutritional evaluation.(9) Referral to dietician may be warranted.

Drug Treatment

Symptom to be treated	Drug	Dose	Does the dose need to be increased? If so, how?		Duration of treatment	Rationale for Treatment	Time to effect	Other information
Hyperglycaemia	Metformin	250 mg bd	YES	Increase slowly by 500mg per week to a MAX of 1g tds	Long Term	Insulin sensitizer. (5) No risk of hypoglycemia if used on own. (5) However, there is a risk if used in combination with insulin or secretagogues. (5) Helps with weight loss.	[Number][Units]	Always take immediately after food to prevent gastrointestinal intolerance. Ensure adequate renal function – see "Metformin information sheet" Increased risk of lactic acidosis in aged as they are more predisposed to conditions that decrease renal function or cause lactic acidosis:(9) • Myocardial infarction • Stroke • Cardiac failure • Pneumonia
Hyperglycaemia	Metformin XR	500 mg evening	YES	Increase slowly by 500mg per week to a MAX of 2g daily	Long Term	Insulin sensitizer. (5) No risk of hypoglycemia if used on own. (5) However, there is		*Always take* immediately after food to prevent gastrointestinal intolerance. *Ensure adequate renal function* – see "Metformin information sheet"

						a risk if used in combination with insulin or secretagogues. (5) Helps with weight loss. Slow release product can produce more stable blood glucose in some patients.		Increased risk of lactic acidosis in aged as they are more predisposed to conditions that decrease renal function or cause lactic acidosis:(9) • Myocardial infarction • Stroke • Cardiac failure • Pneumonia
Hyperglycaemia	Glicazide	40 mg d	YES	Can initially be d or bd Increase to a maximum dose of 320mg d, where doses over 160mg are given as divided doses	Long Term	Insulin secretagogue.		Always take with food to prevent hypoglycemia.
Hyperglycaemia	Glicazide SR	30 mg mane	YES	Increase to a maximum dose of 120mg d	Long Term	Insulin secretagogue.		Always take with food to prevent hypoglycemia.

Hyperglycaemia	Glipizide	2.5 mg d	YES	Can initially be d or bd Increase to a maximum dose of 20mg d, where doses over 10mg are given as divided doses	Long Term	Insulin secretagogue. Glipizide is the sulfonylurea of choice has the shortest duration of action and lowest risk of hypoglycaemia in aged patients.(9)		Always take with food to prevent hypoglycemia. Avoid long acting sulphonylureas especially in patients with renal dysfunction as severe prolonged hypoglycemia can occur.
Hyperglycaemia	Glibenclamide	2.5 mg d	YES	Can initially be d or bd Increase to a maximum dose of 20mg d, where doses over 10mg are given as divided doses	Long Term	Insulin secretagogue.		Always take with food to prevent hypoglycemia. **Is the longest acting sulphonylurea.** Avoid long acting sulphonylureas especially in patients with renal dysfunction as severe prolonged hypoglycemia can occur.
Hyperglycaemia	Glimepiride	1 mg d	YES	Increase to a maximum dose of 4mg d	Long Term	Insulin secretagogue.		Always take with food to prevent hypoglycemia. Avoid long acting sulphonylureas especially in patients with renal dysfunction as severe prolonged

								hypoglycemia can occur.
Hyperglycaemia	Acarbose	50 mg tds	YES	Can be 50-100mg tds initially	Long Term	α-glucosidase inhibitor.		Hypoglycaemia is possible if used in combination with insulin or secretagogues. If hypoglycemia occurs use **glucose** rather than sucrose. Not tested widely in the elderly, but most likely safe.(9)
Hyperglycaemia	Sitagliptin	100 mg d	NO		Long Term	Attractive choice for aged patients as monotherapy because:(9) • No risk of hypoglycemia • Weight neutral		DPP-4 Inhibitor Dose needs to be adjusted in renal failure
Hyperglycaemia	Exenatide	5 mcg BD	YES	Give before morning and evening meal for the first month Increase to 10mcg BD if needed to meet glycaemic	Long Term	Incretin mimetic		

				targets				
Hyperglycaemia	Pioglitazone	15 mg d	YES	Up to 45mg daily	Long Term	Insulin sensitizer. Are well tolerated in aged patients, can be given to those with renal dysfunction and do not cause hypoglycaemia.(9)		As it may take 6-8 weeks for full effect, dose should not be increased before this time. If on full dose for >2months with no improvement in HbA_{1c} then cease. Can be considered in some aged patients especially those with lower HbA_{1c} values with a contraindication to sulphonylureas and unable to unwilling to take insulin.(9) Are well tolerated in aged patients, can be given to those with renal dysfunction and do not cause hypoglycaemia.(9) However there are a number of concerns with this class (see "glitazones information sheet")
Hyperglycaemia	Rosiglitazone	2mg d	YES	Up to 4mg d	Long Term	Insulin sensitizer. Are well tolerated in aged patients, can be given to		As it may take 6-8 weeks for full effect, dose should not be increased before this time.

						those with renal dysfunction and do not cause hypoglycaemia.(9)		If on full dose for >2months with no improvement in HbA_{1c} then cease. Can be considered in some aged patients especially those with lower HbA_{1c} values with a contraindication to sulphonylureas and unable to unwilling to take insulin.(9) Are well tolerated in aged patients, can be given to those with renal dysfunction and do not cause hypoglycaemia.(9) However there are a number of concerns with this class (see "glitazones information sheet")
Hyperglycaemia	Insulin		YES	**Mono therapy** Intermediate acting insulin (~40% total daily insulin requirement) subcutaneously before bed; OR Long acting insulin (~40%	Long Term			**Insulin added to oral anti-diabetic medications** Is the **preferred** regimen and is usually added to metformin and/or sulfonyurea as it is less likely to cause weight gain than insulin alone. May need higher starting dose if higher body weight or FBG

				total daily insulin requirement) subcutaneously at the same time each day **PLUS** Short acting insulin (~60% total daily insulin requirement) subcutaneously divided into 3 doses given 20-30mins before meals; OR Very short acting insulin (~60% total daily insulin requirement) subcutaneously divided into 3 doses given immediately				If once daily basal insulin does not achieve glycemic target, specialist advice should be sought to help guide therapy. Options include: • Twice daily premixed insulin • Twice daily basal insulin • Bolus insulin at each meal as intensive regimen For more information see "insulin information sheet" Quality of life can improve with the use of basal insulin.(9) Considerations before giving insulin to elderly:(9) • Is the patient physically cognitively able to: o Administer insulin o Recognise the symptoms of hypoglycemia and treat appropriately o Monitor blood glucose o Insulin requirements are lower in renal failure (GFR <

				before meals **OR** **Insulin added to oral anti-diabetic medications** Intermediate or Long acting insulin 10-12 Units subcutaneously at bed time as initial dose **PLUS** Oral anti-diabetic (metformin and/or sulfonyurea) Increase dose of basal insulin slowly each week by 2 to 4 Units (i.e. 10-				50mL/min)

				20% if the current insulin dose) until pre-breakfast blood glucose is 4-6mmol/L				

Drug Monitoring

Drug or Brand Name	Monitoring Type	Frequency	Target	Are the results affected by other drugs?
			[Number][Units]	[Tick box]

Disease Monitoring

Aged > 65 yrs old	All	Fasting Blood Glucose Level		4-6 mmol/L (2) These targets may be higher for elderly people.(5)	
Aged > 65 yrs old	All	HbA_{1c}	Every 3-6 months.(2, 9)	≤ 7% (2) Frail with medical and functional comorbidities and life expectancy less than 10 years: ≤ 8%(9) Individualised goals for very elderly can be even higher – need to preserve quality of life and avoid hypoglycemia and related complications(9)	YES
Aged > 65 yrs old	All	LDL-C	Every 6 months (5)	Primary prevention < 2.5 mmol/L (5)	

				Secondary Prevention < 1.8mmol/L (5)	
Aged > 65 yrs old	All	Total Cholesterol	Every 6 months (5)	< 4.0 mmol/L (2)	
Aged > 65 yrs old	All	HDL-C	Every 6 months (5)	> 1.0 mmol/L (2)	
Aged > 65 yrs old	All	TG	Every 6 months (5)	< 1.5 mmol/L (2)	
Aged > 65 yrs old	All	BP	Every 3 months (5)	No proteinuria: ≤ 130/80 mmHg(5) Proteinuria > 1g/day: < 125/80mmHg(5)	
Aged > 65 yrs old	All	BMI	Every 3 months (5)	< 25 kg/m^2 where appropriate (2)	
Aged > 65 yrs old	All	Urinary Albumin Excretion – Timed overnight collection		< 20 µg/min (2)	
Aged > 65 yrs old	All	Urinary Albumin Excretion – Spot Collection		< 20 mg/L (2)	
Aged > 65 yrs old	All	Urinary Albumin Excretion – Albumin: Creatinine Ratio		Women < 3.5 mg/mmol (2) Men < 2.5 mg/mmol (2)	
Aged > 65 yrs old	All	Cigarette consumption	Yearly (5)	Nil (2)	
Aged > 65 yrs old	All	Alcohol Intake		< 2 standard drinks (20g) per day (2)	
Aged > 65 yrs old	All	Physical Activity	Yearly (5)	Minimum TOTAL: 150 mins/week (2) Minimal requirement: 30 mins or more of walking (or equivalent) 5 or more days a week (2)	

References

Symptom to be treated	References
Hyperglycaemia	

1. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Primary Prevention of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
2. Diabetes Australia, The Royal Australian Collage of General Pracitioners. Diabetes Management in General Practice. Seventeenth edition 2011/12. 2011 July 2011. Report No.
3. Morey MC. Physical activity and exercise in older adults. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/physical-activity-and-exercise-in-older-adults?source=search_result&search=physical+activity+and+exercise+in+older+adults&selectedTitle=1~150.
4. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Case Detection and Diagnosis of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
5. Endocrinology Expert Group. Therapeutic guidelines: endocrinology. Version 4. Melbourne: Therapeutic Guidelines Limited; 2009.
6. World Health Organisation, International Diabetes Federation. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. Geneva, Switzerland: 2006.
7. World Health Organisation, International Diabetes Federation. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus: Abbreviated Report of a WHO consultation. Geneva, Switzerland: 2011.
8. Colagiuri S, Dickinson S, Girgis S. National Evidence Based Guidelines for Blood Glucose Control in Type 2 Diabetes. Canberra, Australia: Diabetes Australia and the NHMRC; 2009.
9. McCulloch DK, Munshi M. Treatment of type 2 diabetes mellitus in the elderly patient. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/treatment-of-type-2-diabetes-mellitus-in-the-elderly-patient?source=search_result&search=Treatment+of+Type+2+Diabetes+Mellitus+in+the+elderly+patient&selectedTitle=1~150.

1. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Primary Prevention of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
2. Diabetes Australia, The Royal Australian Collage of General Pracitioners. Diabetes Management in General Practice. Seventeenth edition 2011/12. 2011 July 2011. Report No.
3. Morey MC. Physical activity and exercise in older adults. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/physical-activity-and-exercise-in-older-adults?source=search_result&search=physical+activity+and+exercise+in+older+adults&selectedTitle=1~150.
4. the Australian Centre for Diabetes Strategies Prince of Wales Hospital Sydney for the Diabetes Australia Guideline Development Consortium. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus: Part 2 - Case Detection and Diagnosis of Type 2 Diabetes. In: National Health and Medical Research Council, editor.: Australian Government NHMRC; 2001.
5. Endocrinology Expert Group. Therapeutic guidelines: endocrinology. Version 4. Melbourne: Therapeutic Guidelines Limited; 2009.
6. World Health Organisation, International Diabetes Federation. Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia: report of a WHO/IDF consultation. Geneva, Switzerland: 2006.
7. World Health Organisation, International Diabetes Federation. Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus: Abbreviated Report of a WHO consultation. Geneva, Switzerland: 2011.
8. Colagiuri S, Dickinson S, Girgis S. National Evidence Based Guidelines for Blood Glucose Control in Type 2 Diabetes. Canberra, Australia: Diabetes Australia and the NHMRC; 2009.
9. McCulloch DK, Munshi M. Treatment of type 2 diabetes mellitus in the elderly patient. Waltham, MA, USA: UpToDate; 2012 [cited 2012 17 Oct]; Available from: http://www.uptodate.com/contents/treatment-of-type-2-diabetes-mellitus-in-the-elderly-patient?source=search_result&search=Treatment+of+Type+2+Diabetes+Mellitus+in+the+elderly+patient&selectedTitle=1~150.

Appendix 19: Drug Monograph SAMPLE(Chapters 4 and 5)

Full detail of drug monographs included in the system is on the CD-ROM provided

Highlight indicates fabricated data for the purposes of business rule testing

Acarbose

Is this the brand name? No

If YES, what is the generic name?

Formulation type: Immediate release tablet

Duration of action: [Number][Units}

Drug class: Alpha-glucosidase Inhibitor

Allergy Class

Allergy Class

Indication

Disease	Symptom
Type 2 Diabetes Mellitus	Hyperglycaemia

Adverse Drug Reactions

ADR	ADR Frequency	Description of ADR	Treatment	Never reinitiate if ADR occurs?
Flatulence	Common	GI adverse effects are dose-dependent; increased by taking sucrose.(1)	Can be reduced by starting on low dose and titrating slowly; improve as treatment continues.(1) Unlikely to be alleviated by taking an antacid.(1)	
Diarrhoea	Common	GI adverse effects are dose-dependent; increased by taking sucrose.(1)	Can be reduced by starting on low dose and titrating slowly; improve as treatment continues.(1)	

			Unlikely to be alleviated by taking an antacid.(1)	
Abdominal pain	Common	GI adverse effects are dose-dependent; increased by taking sucrose.(1)	Can be reduced by starting on low dose and titrating slowly; improve as treatment continues.(1) Unlikely to be alleviated by taking an antacid.(1)	
Distension	Common	GI adverse effects are dose-dependent; increased by taking sucrose.(1)	Can be reduced by starting on low dose and titrating slowly; improve as treatment continues.(1) Unlikely to be alleviated by taking an antacid.(1)	
Increased aminotransferase	Infrequent	More common in in underweight people and with high doses.(1)	Decrease dosage if aminotransferases elevated; monitor weekly until aminotransferase concentrations return to normal; stop treatment if elevations persist.(1)	
Ileus	Rare			
Hepatotoxicity	Rare			
Skin reactions	Rare			
Anaemia	Rare			
Oedema	Rare			

Drug Monitoring

Does this Drug need monitoring?

Monitoring Targets

Disease	Monitoring Type	Monitoring Frequency	Target	Are results affected by other drugs?
			[Number][Units]	

Drug Monitoring Interactions

Monitoring Type	Description
Hb	Small reductions in haematocrit occurred more often in acarbose treated patients than in placebo treated patients but were not associated with reductions in haemoglobin.(2) Low serum calcium and low plasma vitamin B_6 levels were associated with acarbose therapy but were thought to be either spurious or of no clinical significance.(2)

Drug- Disease Interaction

Disease	Clinical Significance	Symptom of interaction	Description
Chron's Disease	High	All	Contraindicated.(1, 2)
Ulcerative Colitis	High	All	Contraindicated.(1, 2)
All	High	Bowel Obstruction	Contraindicated.(1, 2)
All	High	Major hernia	Contraindicated.(1, 2)
All	High	Malabsorption	Contraindicated.(1, 2)

Drug Renal Function Interaction

Renal Function	Consequence	Dose Adjustment
Moderate Impairment	Unknown – limited experience in this patient group.(1)	Avoid use.(1)
Severe Impairment	Unknown – limited experience in this patient group.(1)	Avoid use.(1)

Drug Liver Function Interaction

Liver Function	Consequence	Dose Adjustment

Drug- Drug Interaction

Interacting Drug	Clinical Significance	Symptom of interaction	Description
Colestyramine	Low	Hypoglycaemia	Cholestyramine may enhance acarbose's effect; monitor blood glucose as may need to decrease acarbose dosage. In non-diabetic subjects a rebound rise in postprandial insulin concentration occurred when both drugs were stopped together.(1)
Digoxin	Medium	Decreased efficacy	Acarbose may decrease absorption of digoxin; give acarbose and digoxin at about the same times each day to standardise this effect; monitor digoxin concentration and increase

			digoxin dose if necessary.(1)
Warfarin	Medium	Changed INR	Combination with warfarin occasionally may increase or decrease INR; monitor INR and adjust warfarin dose as necessary.(1)
Atenolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1) Less likely because beta-1 selective.(1)
Bisoprolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1) Less likely because beta-1 selective.(1)
Carvedilol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1)
Esmolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1)
Labetolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms

			and increase incidence and severity of hypoglycaemia but data are conflicting.(1)
Metoprolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1) Less likely because beta-1 selective.(1)
Nebivolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1) Less likely because beta-1 selective.(1)
Oxprenolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1)
Pindolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1)
Propranolol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are

			conflicting.(1)
Sotalol	High	Hypoglycaemia	*Beta-blockers* may mask some hypoglycaemic warning symptoms and increase incidence and severity of hypoglycaemia but data are conflicting.(1)

Drug- Population Type and Subtype Interaction

Population Type	Description
Pregnancy (all trimesters)	Avoid use; category B3.(1)
Breastfeeding	Very low bioavailability, should be safe to use.(1)

Drug- Race Interaction

Race	Description

Drug Gene polymorph Interaction

Gene Polymorph	Description

Drug Instructions

Special Instructions	Override Generic Instructions?	Description
IAF		Swallow whole with liquid immediately before a meal or chew with the first few mouthfuls of food.(1)

PBS Information

Is this drug PBS Subsidised? YES

Is this drug RPBS Subsidised? YES

Does this drug require an Authority script? NO

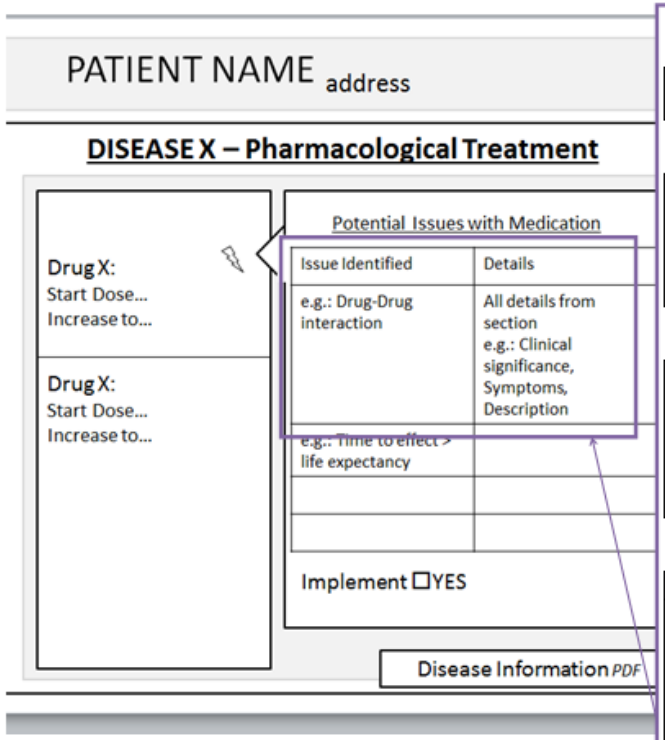
If so, what are the requirements?

References

1. Australians Medicines Handbook 2013 [online]. Adelaide: Australians Medicines Handbook Pty Ltd; 2013; Available from: https://www.amh.net.au/downloads/Referencing%20the%20AMH.pdf.
2. MIMS Online. online: MIMS Australia Pty Ltd.; 2013 [updated July 2013; cited 2013 05 July 2013].

Appendix 20: Database-Interface Connection and Business Rule SAMPLE (Chapters 4 and 5)

Full database-interface connection and business rule documentation is on the CD-ROM provided



Allergy

IF allergy has been caused by the same drug

Patient Data:	=	Chosen drug:
In table **Patient Allergies** Drug ID		Drug ID in **Drug** table

OR by a drug in the same class

Patient Data:	=	Chosen drug:
In table **Patient Allergies** find Drug ID in **Drug** table.		Drug ID in **Drug** table
Find the Drug Class ID		Find the Drug Class ID

OR by a drug in the same allergy class

Patient Data:	=	Chosen drug:
In table **Patient Allergies** Allergy Class ID		Allergy Class ID Search column: Allergy Class ID from **Drug-Allergy Class** table for chosen Drug ID, use corresponding Allergy Class ID value.

THEN display:

Issue Identified	Details	Value from Table and Column
Allergy	"Patient has had a previous allergic reaction to this or a similar medication. Please choose an alternative medication"	**Standard Message** table. Display column "Standard Message" ID 6: Previous Allergy Alert
	Previous allergy drug, severity and description	**Patient Allergies** table. Display column: "Drug ID" OR "Allergy Class ID" "Allergy Severity ID" "Description"

Appendix 21: Monash University Human Research Ethics Committee approval letter: International Study (Chapter 6)

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**1 July 2013**
Project Number:	**CF13/1806 – 2013000955**
Project Title:	**Usability testing of the intelligent decision support software "MedManAGE"**
Chief Investigator:	**Assoc Prof Jennifer Marriott**
Approved:	**From: 1 July 2013 To: 1 July 2018**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, MUHREC

cc: Ms Paulina Stehlik, Prof Pēteris Dārziņš, Dr Ahmet Sekercioglu

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 3831
Email muhrec@monash.edu www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

Appendix 22: Monash University Human Research Ethics Committee approval letter: Melbourne Study (Chapter 6)

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**29 July 2013**
Project Number:	**CF13/1984 – 2013001041**
Project Title:	**Usability testing of the intelligent decision support software "MedManAGE" - Melbourne Study**
Chief Investigator:	**Assoc Prof Jennifer Marriott**
Approved:	**From: 29 July 2013** **To: 29 July 2018**

Terms of approval

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.**
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from MUHREC. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Nip Thomson
Chair, MUHREC

cc: Ms Paulina Stehlik, Prof Pēteris Dārziņš, Dr Ahmet Sekercioglu

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 3831
Email muhrec@monash.edu http://www.monash.edu.au/researchoffice/human/
ABN 12 377 614 012 CRICOS Provider #00008C

Appendix 23: Online Testing International Recruitment Poster (Chapter 6)

"MedManAGE": A novel medication management decision support system for aged patients with complex needs

Stehlik P[1], Marriott JL[1], Dārziņš P[2], Bahmanpour A[3], Sekercioglu, YA[3]

[1] Centre for Medicine Use and Safety, Monash University (Parkville campus), Parkville, Australia;
[2] Faculty of Medicine, Nursing and Health Sciences , Monash University (Eastern Health Clinical School campus), Forest Hill, Australia
[3] Faculty of Engineering, Monash University (Clayton Campus), Clayton, Australia

Background:
Increasing age brings an increase in chronic disease and subsequent increase in complexity of care and health sector burden, however current resources inadequately support appropriate prescribing in complex aged patients. The development of decision support software (DSS) that aims to assist appropriate prescribing in this population group is required.

Method:
Agile method was used in the development of MedManAGE using C# language with Visual Studio Integrated Development Environment in .Net 4 Framework and SQL server express 2008 to allow for multiuser capability. Process flow, business rules and database design was based on a literature review of qualities of appropriate prescribing, medication review and clinical decision making processes. Included data were based on disease and drug literature reviews. Interface design was based on health informatics developer guidelines, previous e-Health software evaluation studies, and studies regarding health professional preferences when using software and/or resources..

Results:

A DSS was developed that meets pre-defined requirements.

- Acts as a data-pool of current disease state management information,
- Contextualizes information based on patient information,
- "Aged specific" information is easily distinguished from that intended for the general or younger population,
- Relevant to the Australian environment,
- Easily updated without the need for programming knowledge,
- Simple to use interface with ability to access more detailed information.

Future Directions: Usability testing

If you wish to be participate in the MedManAGE usability study, please take a booklet or speak to Paulina Stehlik about participating.

Thank you!

Correspondence email: Paulina.Stehlik@monash.edu

MONASH University

Appendix 24: Online Testing Melbourne Recruitment Email (Chapter 6)

MEDMANAGE

To interested health professionals,

We would like to invite you to participate in the MedManAGE usability study. MedManAGE is a prototype software that displays patient specific decision support information.

This study is the usability assessment of *MedManAGE;* it does NOT assess your clinical knowledge. You will NOT be identifiable from any of the data collected. It should take you no more than 20 minutes to complete the pilot testing.

Please click on the following link to participate:

https://www.dropbox.com/sh/6rra9nwyn9uv8qp/_79tRDCI8L

Please feel free to pass this email on to your health professional (pharmacist or medical practitioner) colleagues.

Kind Regards,

A/Prof Jennifer Marriott (Chief Investigator)
Department of Pharmacy Practice
[redacted]

Ms Paulina Stehlik (Co-Investigator, PhD Candidate)
Department of Pharmacy Practice
[redacted]

Prof Peteris Darzins (Co-Investigator)
Eastern Health Clinical School
[redacted]

Dr Ahmet Sekercioglu Darzins (Co-Investigator)
Department of Electrical and Computer Systems Engineering, Electrical and Computer Systems Engineering
[redacted]

Appendix 25: Online Testing Case Study Booklet (Chapter 6)

Usability testing of the intelligent decision support software "MedManAGE"

Monash University

EXPLANATORY STATEMENT

(Pharmacists and Medical Practitioners)

Project: Usability testing of the intelligent decision support software "MedManAGE"

A/Prof Jennifer Marriott (Chief Investigator)
Department of Pharmacy Practice
Phone AUSTRALIA: (03) 9913 8100
email: Jennifer.Marriott@monash.edu

Ms Paulina Stehlik (Co-Investigator, PhD Candidate)

Department of Pharmacy Practice
Phone AUSTRALIA : (03) 9903 9170
email: Paulina.Stehlik@monash.edu

Prof Peteris Darzins (Co-Investigator)
Eastern Health Clinical School
Phone AUSTRALIA: (03) 8804 2750
email: Peteris.Darzins@monash.edu

Dr Ahmet Sekercioglu Darzins (Co-Investigator)
Department of Electrical and Computer Systems Engineering, Electrical and Computer Systems Engineering
Phone AUSTRALIA: (03) 99053503
email: Ahmet.Sekercioglu@monash.edu

My name is Paulina Stehlik and I am conducting a research project towards a PhD at Monash University.

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to ask the researchers directly or contact the researchers via the phone numbers or email addresses listed above.

What does the research involve?

This study involves the assessment of the usability of software developed by the researchers, called *MedManAGE*. You will be asked to use MedManAGE online to work through the case study provided. This will involve the completion of certain tasks and provision of feedback via an online survey on how easy you found the program to use. Please note that this study is NOT an assessment of your clinical knowledge, but an assessment of the computer program's usability.

You will NOT be identifiable from any of the data collected. It should take you no more than 20 minutes to complete the pilot testing.

Why were you chosen for this research?

We wish to assess the usability of MedManAGE. We anticipate that users will be pharmacists or medical practitioners. We feel that these people will most benefit from the software and will have greatest insight into potential usability issues.

For the purposes of this study you need to be a pharmacist or medical practitioner, fluent in English, over 18 years old, and have access to the internet. If you do not meet these criteria you are ineligible to participate in this study.

Consenting to participate in the project and withdrawing from the research

As this study is voluntary you are under no obligation to consent to participate in this study. Provision of information to the researchers will be considered as consent to participate in this study. Should you wish, you are able to withdraw from the study at any time, however, as you will remain anonymous during this study, after you complete the online surveys it will not be possible to withdraw your information from the study.

Possible benefits and risks to participants

This study will help inform software developers on usable software design that meet the needs of pharmacists and medical practitioners. This will potentially result in better and more efficient care of patients.

There is little to no risk of potential discomfort that could be caused by this study. Your personal details will not be collected.

Confidentiality

You will not be identifiable from any of the data collected. All data will only be accessible by the researchers.

Storage of data

All data collected must be stored in accordance with Monash University regulations. This means that data collected will be stored in accordance with Monash University regulations, kept on University premises, in a locked filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

The data collected from this study will be used to:

- Improve the current software
- Inform other medication management decision support software developers of the requirements for a usable software

Results

If you would like to be informed of the aggregate research finding, please contact Paulina Stehlik on (03) 9903 9170 or email Paulina.Stehlik@monash.edu

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Building 3e
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,

Jennifer Marriott (Chief Investigator)

Step 1: Installing MedManAGE

Please download MedManAGE from the following Dropbox URL:

https://www.dropbox.com/sh/6rra9nwyn9uv8qp/_79tRDCI8L

You will need a Windows operating system to run MedManAGE.

We suggest also looking at:

1. How to install MedManAGE; and
2. Introduction to MedManAGE

WARNING

Some of the information found in MedManAGE is fictional and is not intended for use in real patients.

DO NOT use this software for the care of real patients.

Once you have finished this study, please uninstall MedManAGE.

Once you have finished installing MedManAGE, open the program.

Step 2: Completing Patient 1 Scenario

Mary Jane Do (lives at 123 Fake St, Fakeville 0000), is one of your regular patients. She has come to your clinic for a follow up consultation.

You have received some laboratory results indicating that Mrs Do has **elevated LDL** predominant **dyslipidaemia**. You also decide that she is in the "High Cardiovascular Risk" category.[1] As Mrs Do is a complex patient you decide to use MedManAGE to help you make an appropriate treatment choice.

Please use MedManAGE to decide how to treat Mary Jane Do.

[1] For more information regarding cardiovascular risk stratification please see: http://www.cvdcheck.org.au/

Step 3: Completing the Survey

Go to http://paulinastehlik.polldaddy.com/s/medmanage-usability-study-1 to complete the usability survey.

WARNING

Some of the information found in MedManAGE is fictional and is not intended for use in real patients.

DO NOT use this software for the care of real patients.

Once you have finished this study, please uninstall MedManAGE.

Step 4: Uninstalling MedManAGE

Once you have submitted your survey, please uninstall MedManAGE.

To uninstall or change a program

1. Open Programs and Features by clicking the Start button, clicking Control Panel, clicking Programs, and then clicking Programs and Features.
1. Select a program, and then click Uninstall. Some programs include the option to change or repair the program in addition to uninstalling it, but many simply offer the option to uninstall. To change a program, click Change or Repair. If you're prompted for an administrator password or confirmation, type the password or provide confirmation.

For more information on how to uninstall a program go to:

http://windows.microsoft.com/en-us/windows/uninstall-change-program#uninstall-change-program=windows-7

Thank you for participating in the MedManAGE usability study.

Appendix 26: Monash University Human Research Ethics Committee amendment approval letter (Chapter 6)

PLEASE NOTE: To ensure speedy turnaround time, this correspondence is being sent by email only. MUHREC will endeavour to copy all investigators on correspondence relating to this project, but it is the responsibility of the first-named investigator to ensure that their co-investigators are aware of the content of the correspondence.

Dear Researchers

Thank you for submitting a Request for Amendment to the above named project.

This is to advise that the following amendments have been approved:

Changes to Recruitment

- Participants will be recruited through educational sessions aimed at target groups.

- Participants will also be invited to participate in a focus group discussion of the program to provide further feedback.

Changes to Procedures

- Participants will be given an explanatory statement and a booklet with demographic data form and Modified Computer System Usability Questionnaire (CSUQ).

- Participants will be guided through the program using two case studies.

- At the focus group session, the participants will be given the same explanatory statement and asked to complete a consent form. The software will be shown to participants again and focus group discussion will be stimulated using the IBM After Scenario Questionnaire. Total session time is expected to be 30-45 mins. The session will be audio recorded and transcribed verbatim.

Approved Documents

- Explanatory Statement - Health Professionals

- Expression of Interest - Health Professionals

- Consent Form - Health Professionals

Thank you for keeping the Committee informed.

Professor Nip Thomson
Chair, MUHREC

Human Ethics
Monash Research Office

Our aim is exceptional service

Monash University
Level 1, Building 3e, Clayton Campus
Wellington Rd
Clayton VIC 3800, Australia

Telephone: +61 3 9905 5490
Email: muhrec@monash.edu
Website: http://www.monash.edu.au/researchoffice/human
ABN 12 377 614 012 CRICOS Provider No 00008C

Appendix 27: Questionnaire Explanatory Statement (Chapter 6)

EXPLANATORY STATEMENT

(Health Professionals)

Project: Usability testing of the intelligent decision support software "MedManAGE"

A/Prof Jennifer Marriott (Chief Investigator)

Department of Pharmacy Practice
Phone AUSTRALIA: (03) 9913 8100
email: Jennifer.Marriott@monash.edu

Ms Paulina Stehlik (Co-Investigator, PhD Candidate)

Department of Pharmacy Practice
Phone AUSTRALIA : (03) 9903 9170
email: Paulina.Stehlik@monash.edu

Prof Peteris Darzins (Co-Investigator)
Eastern Health Clinical School
Phone AUSTRALIA: (03) 8804 2750
email: Peteris.Darzins@monash.edu

Dr Ahmet Sekercioglu (Co-Investigator)
Department of Electrical and Computer Systems Engineering, Electrical and Computer Systems Engineering
Phone AUSTRALIA: (03) 99053503
email: Ahmet.Sekercioglu@monash.edu

My name is Paulina Stehlik and I am conducting a research project towards a PhD at Monash University.
You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to ask the researchers directly or contact the researchers via the phone numbers or email addresses listed above.

What does the research involve? This study involves the assessment of the usability of software developed by the researchers, called *MedManAGE*. You will be asked to watch a demonstration of how MedManAGE is used after which you will be asked to complete an anonymous questionnaire regarding the usability of MedManAGE.

If you wish to provide further feedback, you are also invited to participate in a short focus group discussion regarding whether MedManAGE would assist you in your everyday practice as a health professional. If you wish to be contacted regarding further discussions, please fill out the "expression of interest" form or contact Paulina Stehlik directly. With your consent, the focus group session will be audio recorded and should take no more than 30-45 mins to complete. Light refreshments will be provided.

Why were you chosen for this research?
We wish to assess the usability of MedManAGE. We anticipate that users will be pharmacists or medical practitioners. We feel that these people will benefit most from the software and will have greatest insight into potential usability issues.

For the purposes of this study you need to be a pharmacist or medical practitioner, fluent in English, over 18 years old. If you do not meet these criteria you are ineligible to participate in this study.

Consenting to participate in the project and withdrawing from the research
As this study is voluntary you are under no obligation to consent to participate in this study. Return of the survey booklet will be considered consent to participate in this study. Should you wish, you are able to withdraw from the study at any time, however, as you will remain anonymous during this study, after you complete the survey it will not be possible to withdraw your questionnaire results from the study.

Expressions of interest to participate in the short focus group discussion will be followed up by the researchers. You are under no obligation to participate in the focus group discussion even if interest has been expressed. Consent to participate in the focus groups will be assumed only after you have signed and returned the consent form given out at the session. You may request the removal your discussion results any time prior to publication of results.

Possible benefits and risks to participants
This study will help inform software developers on usable software design that meet the needs of pharmacists and medical practitioners. This will potentially result in better and more efficient care of patients.

There is little to no risk of potential discomfort that could be caused by this study. Your personal details will not be collected , other than contact details associated with expressions of interest in focus group participation.

Confidentiality
All data will only be accessible by the researchers.

Storage of data
All data collected must be stored in accordance with Monash University regulations. This means that data collected will be stored in accordance with Monash University regulations, kept on University premises, in a locked filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

The data collected from this study will be used to:

- Improve the current software
- Inform other medication management decision support software developers of the requirements for a usable software

Results

If you would like to be informed of the aggregate research finding, please contact Paulina Stehlik on (03) 9903 9170 or email Paulina.Stehlik@monash.edu

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer
Monash University Human Research Ethics Committee (MUHREC)
Room 111, Building 3e
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052 Email: muhrec@monash.edu Fax: +61 3 9905 3831

Thank you,

Jennifer Marriott (Chief Investigator)

Appendix 28: Modified CSUQ used for Usability Feedback (Chapter 6)

MedManAGE Usability Questionnaire

Demographic Data

Please complete the following demographic information.

Are you currently studying in to be, or are already registered as, a pharmacist or medical practitioner in Australia?

☐ Yes ☐ No

What is your current status in Australia? If you answered "no" above, what is your current status in your country of study/practice?

☐ Undergraduate medical student ☐ Undergraduate pharmacy student

☐ Medical Intern ☐ Pharmacy Intern

☐ Registered medical practitioner ☐ Registered pharmacist

If you are an undergraduate student currently studying to be a pharmacist or medical practitioner what year of study are you in?

☐ Year: _____ out of _____

If you are a registered pharmacist or medical practitioner for how many years have you been registered?

☐ Years:_____

Are you an accredited pharmacist or do you have any formal specialisations in geriatric medicine? (e.g.: geriatric pharmacology, geriatrics, etc…)

☐ Yes ☐ No

Do you have any computer related qualifications? (e.g.: Bachelor of Computer Science, programming background, etc…)

☐ Yes ☐ No

If you are an intern or registered health professional, on average how many hours a week do you practice as a pharmacist/ medical practitioner?

☐ > 40 hrs ☐ 30-40 hrs ☐ 20-30 hrs ☐ 10-20 hrs ☐ < 10 hrs

How experienced are you with using computers?

☐ Every day ☐ Once a week ☐ Once a month ☐ Less than once a month

How would you rate your confidence in using computers?

☐ Very confident ☐ Confident ☐ Little confidence ☐ No confidence

Modified Computer System Usability Questionnaire (CSUQ)

This questionnaire gives you an opportunity to express your satisfaction with the usability of MedManAGE. Your responses will help us understand what aspects of the system you are particularly concerned about and the aspects that satisfy you.

To as great a degree possible, think about all the tasks that may do with the system while you answer these questions.

Please read each statement and indicate how strongly you agree or disagree with the statement. If the statement does not apply to you, select **N/A**.
Whenever appropriate please write comments to explain your answers.

Please try to respond to all the items.

1. **Overall, I am satisfied with how easy it would be to use MedManAGE**

   Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

   Comments:

2. **I would find it simple to use MedManAGE**

   Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

   Comments:

3. **I could effectively complete tasks using MedManAGE**

   Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

   Comments:

4. **I would be able to complete tasks using MedManAGE**

St Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

5. **I would be able to *efficiently* complete tasks using this MedManAGE**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

6. **I would feel comfortable using MedManAGE**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

7. **It would be easy to learn to use MedManAGE**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

8. **I believe I would become productive quickly using MedManAGE**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

9. **The information (such as on-screen messages, and other documentation) provided MedManAGE is clear**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

10. **It would be easy to find the information I may need**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

11. **The information provided for the system is easy to understand**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

12. **The information would be effective in helping me complete the tasks and scenarios**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

13. **The organization of information on MedManAGE screens is clear**

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

The interface includes those items that you use to interact with the system. For example, some components of the interface are the keyboard, the mouse, the screens (including their use of graphics and language).

14. The interface of MedManAGE is pleasant

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

15. I would like using the interface of MedManAGE

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

16. MedManAGE has all the functions and capabilities I expect it to have

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

17. Overall, I am satisfied with MedManAGE

Strongly Disagree 1 2 3 4 5 6 7 Strongly Agree N/A

Comments:

List the most **negative** aspect(s) of MedManAGE:

1.

2.

3.

List the most **positive** aspect(s) of MedManAGE:

1.

2.

3.

Additional Comments:

Appendix 29: Invitation to Health Professionals to Participate in Focus Group Feedback (Chapter 6)

Expression of Interest

(Health Professionals)

Project: '*Usability testing of the intelligent decision support software "MedManAGE" – Melbourne Study*'

Chief Investigator: Jennifer Marriott

I wish to be contacted via regarding participation in focus group discussions of MedManAGE.

Name of Participant _____

Contact (email and/or phone number): _____

Appendix 30: Focus Group Feedback Consensus Form (Chapter 6)

MONASH University

CONSENT FORM

(Health Professionals)

Project: *'Usability testing of the intelligent decision support software "MedManAGE"*
Chief Investigator: Jennifer Marriott

I have been asked to take part in the Monash University research project specified above. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
Audio recording during the interview / focus group	☐	☐
Take part in a focus group of up to 8 people	☐	☐
I agree to make myself available for a further interview if required	☐	☐

I understand that I will be given a transcript of data concerning me for my approval before it is included in the write up of the research.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw from the project without being penalised or disadvantaged in any way, however you will only be able to withdraw data prior to your approval of the session transcript /prior to the publication of a report of the project.

I understand that any data that the researcher extracts from the session for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

Name of Participant _____

Email of Participant for Transcripts: _____

Participant Signature _____ Date _____

Appendix 31: Focus Group Discussion Guide (Chapter 6)

1.	What is your initial impression of MedManAGE?	1 sentence summary from each participant
2.	What are the positive aspects of MedManAGE – how are they positive?	5 mins
3.	What are the negative aspects of MedManAGE – how can these be improved, including design, information and functionality?	10 mins
4.	Do you feel that MedManAGE would provide you with *useful* information when deciding on *disease state management options* for complex patients? What additional information would you need?	10 mins
5.	Would you find MedManAGE useful in practice – why or why not? How can it become useful?	10 mins