Improving the quality of prescribing in elderly hospital inpatients: evaluating the effect of a clinical pharmacist on ward rounds

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Abstract

Introduction: Elderly patients are at increased risk of adverse medication events (ADEs) and potentially inappropriate medicines (PIMs). The STOPP START tool has been validated to assess medications of elderly patients for potentially inappropriate prescribing. There is little data on prescribing patterns for elderly Australian hospital inpatients. This Thesis aims to describe changes in prescribing as measured by the STOPP START tool in elderly patients throughout a hospital admission including admission and discharge from a specialised geriatric evaluation management (GEM) unit. This Thesis also assessed the effect of inclusion of a pharmacist on a physician-led ward round on the quality of prescribing in elderly hospitalised patients. The number of medications prescribed for each patient on admission to hospital, on transfer to the GEM unit and at discharge from the GEM unit for both the pre-intervention and post-intervention group were also compared.

Method: This Thesis used an observational retrospective design to study the quality of prescribing in two groups of patients, pre- and post-intervention, using the STOPP START tool at three points during hospital stay; admission to hospital, transfer to a specialised geriatric unit and discharge from hospital. Data was collected over 4 months pre- and post-introduction of a pharmacist to a physician-led ward round. Demographic and clinical data, including total number of medications and STOPP START criteria met, were collected. The number of STOPP START criteria at the different time points, was compared between the pre- and post-intervention groups to determine whether there was a change in potentially inappropriate prescribing after the intervention of a pharmacist participating on the ward round. The mean number of STOPP START criteria (the total number of criteria met divided by number of patients) at each time point were compared pre- and post-introduction of a pharmacist using a Mann-Whitney U test. The mean number of criteria for each time point within both the pre- and post-intervention groups were compared using a paired Wilcoxon test.

Results: The demographics of the participants in the pre- and post-intervention groups were similar. In the ninety-six pre-intervention group patients, 58 (60.4%) were female, the median age was 83 [IQR 76-87] years and the mean number of co-morbidities was 5.10. The post-intervention group had one hundred patients, 55 (55%) were female and the median age was 84 [IQR 78-89]. The post-intervention group had 21% less STOPP START criteria at discharge, mean 1.18 (SD 1.37) compared to the pre-intervention group 1.50 (SD 1.41), $p=0.07$. The pre-intervention group had no significant change in the criteria from admission 1.78 (SD 1.57) to geriatric unit transfer 1.72 (SD 1.54) ($p=0.37$)
however there was a significant 13% decrease from geriatric unit transfer 1.72 (SD 1.54) to discharge 1.50 (SD 1.41) ($p=0.02$). The post-intervention group had a 26% decrease in criteria from hospital admission 2.30 (SD 1.91) to geriatric unit transfer 1.59 (SD 1.60) ($p<0.01$) and again to discharge 1.18 (SD 1.37) ($p<0.01$).

The total number of medications prescribed per patient in the pre-and post-intervention groups were not significantly different between the groups at admission (median 7 [IQR 5-10] vs 8 [IQR 5-10], $p=0.4$) or discharge (median 8 [IQR 6-11] vs 9 [IQR7-11], $p=0.5$). However, in the individual groups, the number of medications increased from admission to discharge (pre-intervention group 7 [IQR 5-10] to 8 [IQR 6-11], $p<0.01$), (post-intervention group 8 [IQR 5-10] to 9 [IQR 7-11], $p<0.01$).

**Conclusion:** This Thesis found that prescribing quality changed for elderly patients during admission to an Australian hospital. During the acute hospital stay potentially inappropriate prescribing did not change significantly for the pre-intervention group however a decrease in STOPP START criteria was seen in the post-intervention group. This Thesis found that after admission to the GEM unit prescribing quality improved, as measured by less STOPP START criteria on discharge in both the pre- and post-intervention groups. We observed that whilst the number of prescribed medicines per patient increased, potentially inappropriate prescribing was reduced during the hospital stay. The lesser amount of STOPP START criteria for the post-intervention group on discharge compared to the pre-intervention group is evidence that pharmacist participation on physician ward rounds can improve prescribing quality and supports pharmacist participation on ward rounds as a valuable addition to the pharmaceutical care provided by clinical pharmacists.
Declaration by author

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

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Publications during candidature


Publications included in this thesis


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| Kelly Mulvogue (Candidate) | Idea and conception of the manuscript (30%)  
|                         | Literature review (80%)                                         |
|                         | Preparation of the manuscript (100%)                              |
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Contributions by others to the thesis

- Kelly Mulvogue: All data collection and analysis for Chapters 3 and 4 (the two submitted papers) was undertaken by the candidate, Kelly Mulvogue. All chapters and papers were drafted and written by Kelly Mulvogue under the guidance of the other co-authors. Assisted with study design and prepared ethics submissions.
- Jason A. Roberts: Study design, assistance with data analysis and review of written material prior to submission.
- Ian Coombes: Study design, expert pharmacist input and review of written material prior to submission.
- Neil Cottrell: Study design, assistance with data analysis and review of written material prior to submission.
- Shanthi Kanagarajah: Study design, expert physician advice and review of written material prior to submission.
- Alesha Smith: Study design and review of written material prior to submission.

Statement of parts of the thesis submitted to qualify for the award of another degree

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Inappropriate prescribing, STOPP START, pharmacist ward rounds, prescribing quality, elderly

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List of Abbreviations Used

ACE: acute care for elders
ADE: adverse drug event
ADR: adverse drug reaction
DMR: discharge medication record
GDP: gross domestic product
GEM: geriatric evaluation and management
GP: general practitioner
ICU: intensive care unit
IPET: improved prescribing in the elderly
IQR: interquartile range
LOS: length of stay
MAI: medication appropriateness index
MAP: medication action plan
NIMC: national inpatient medication chart
NSAID: non-steroidal anti-inflammatory drug
PBS: pharmaceutical benefits scheme
PIM: potentially inappropriate medicine
PPI: proton pump inhibitor
QUM: quality use of medicines
RBWH: Royal Brisbane and Womens Hospital
SD: standard deviation
START: screening tool to alert to the right treatment
STOPP: screening tool of older persons’ potentially inappropriate prescriptions
TCA: tricyclic antidepressant
Chapter 1: Literature Review

Prescribing for elderly patients can be particularly challenging due to changes in pharmacokinetics, pharmacodynamics and multiple co-morbidities. As such, elderly patients are at increased risk from adverse drug effects (ADEs) and potentially inappropriate medicines (PIMs). Whilst the risks of medication misadventure, such as falls, ADEs and hospitalisation are well documented, there has been less evidence of effective interventions to improve prescribing and decrease these risks.

There are also gaps in the published literature around current patterns in prescribing for elderly patients throughout a hospital admission, including admission to a specialised geriatric unit. The impact of a pharmacist participating in a physician-led ward round in a geriatric unit has also not been previously studied.

This Thesis aims to describe changes in prescribing as measured by the STOPP START tool in elderly patients throughout a hospital admission including admission and discharge from a specialised geriatric evaluation management (GEM) unit. This Thesis will also assess the effect of inclusion of a pharmacist on a physician-led ward round on the quality of prescribing in elderly hospitalised patients and the number of medications prescribed for each patient.

1.1 Elderly Population

The Australian population over 65 years old is increasing in both number and proportion. Those aged over 65 are expected to make up 25% of the Australian population in 2056\(^1\). In 2013, they represented 3.3 million people (14.4% of the population)\(^2\).

The total expenditure on health as a percentage of gross domestic product (GDP) in Australia has increased from 7.8% in 1999 to 8.7% in 2008\(^3\). In the same time period, the per capita expenditure on pharmaceuticals and other medical non-durables has increased from $290(US) in 1999 to $503(US) in 2008\(^3\). These statistics demonstrate a trend of increasing health and pharmaceutical spending. As more medication becomes available and longevity increases, the use of medication by the elderly will increase further\(^4\). Data from the USA suggests that while the population over 65 accounts for 13% of the total population, it also accounts for the largest per capita consumers of prescription medications\(^5,6\). Trend analysis into Government expenditure on medications funded by the Pharmaceutical Benefits Scheme (PBS) in Australia showed that persons aged 65 years and over
contributed to over half of all Government expenditure and nearly two-thirds of all the growth in PBS expenditure in the time period analysed (2006-2011)\textsuperscript{7}. 

Elderly patients also consume a disproportionate amount of healthcare resources with 35% of hospital admissions in 2004-2005 for patients over 65\textsuperscript{8}. Growing population numbers and healthcare spending will reach a point of unsustainability. Judicious use of healthcare resources is important from both a fiscal and quality use of medications perspective.

1.2 Potentially Inappropriate Prescribing

Quality Use of Medicines (QUM) is one of the central objectives of Australia’s National Medicines Policy\textsuperscript{9}.

QUM means:
- Selecting management options wisely;
- Choosing suitable medicines if a medicine is considered necessary;
- Using medicines safely and effectively; and
- Maintaining a viable pharmaceutical industry\textsuperscript{9}.

The definition of QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population\textsuperscript{9}. The term ‘medicine’ includes prescription, non-prescription and complementary medicines\textsuperscript{9}. The optimisation of prescribing for elderly patients by reducing potentially inappropriate prescribing follows the principles of QUM.

Despite the best intentions of treating medical practitioners, there can be cases of suboptimal prescribing for individual elderly patients. The term potentially inappropriate prescribing is frequently used in the literature to encompass the use of medicines that introduce a significant risk of an adverse drug-related event where there is evidence for an alternative, equally or more effective, or associated with a lower risk, to treat the same condition\textsuperscript{4,10}. Potentially inappropriate prescribing may lead to a significant risk of an ADE\textsuperscript{10}. Potentially inappropriate prescribing also includes the use of medications at a higher frequency and for longer than clinically indicated, the use of medicines that have recognised, clinically significant drug-drug interactions or drug-disease interactions, and also the underuse of beneficial medicines that are clinically indicated but not prescribed despite evidence based medicine\textsuperscript{4}. 

2
1.3 Medication Use in Elderly Patients

Regulatory bodies usually consider older people to be those aged 65 years and older\textsuperscript{11}. Despite the wide intra-group variability, this age delineation is well-recognized and this group of older or elderly patients has the potential to have different physiological properties to the general adult population. These differences can raise challenges in prescribing. Pharmacological treatment is an important component of medical care for the elderly and whilst potentially beneficial it also has the potential to decrease morbidity and mortality and increase quality of life\textsuperscript{12}. Problems associated with pharmacological treatment are frequent among elderly hospitalised patients and for a significant number of patients it can lead to a medication-related hospital admission\textsuperscript{12}.

There are age related changes to pharmacokinetics and pharmacodynamics of medicines that lead to a reduction in physiological reserves, as outlined in Table 1\textsuperscript{13}. Additionally differences in receptor numbers and binding affinities, changes in target organ responses and impaired compensatory reflexes also result in less predictable outcomes\textsuperscript{13}. Cytochrome P450 oxidation declines with ageing and drug-drug interactions involving these enzymes are important to recognise\textsuperscript{14,15}.
Table 1: Pharmacokinetic and pharmacodynamics changes in the elderly\textsuperscript{13}

<table>
<thead>
<tr>
<th>Action</th>
<th>With ageing</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absorption/first pass</td>
<td>Unchanged absorption</td>
<td>Same amount of medication absorbed, but increased bioavailability of some drugs (e.g. metoprolol, nortriptyline)</td>
</tr>
<tr>
<td></td>
<td>Reduced first pass metabolism (reduced liver mass, reduced blood delivery to liver)</td>
<td></td>
</tr>
<tr>
<td>Volume of distribution</td>
<td>Increased body fat in proportion to lean muscle</td>
<td>Prolonged half-life of fat soluble drugs (e.g. diazepam)</td>
</tr>
<tr>
<td></td>
<td>Decreased body water</td>
<td>Increased serum concentrations of water soluble drugs (e.g. digoxin, paracetamol)</td>
</tr>
<tr>
<td>Protein binding</td>
<td>Lower serum albumin concentration in frail or unwell elderly</td>
<td>Increased free concentrations of highly protein bound drugs (e.g. warfarin, phenytoin)</td>
</tr>
<tr>
<td>Metabolism</td>
<td>Reduced oxidative metabolism (liver)</td>
<td>Prolonged half-life, higher steady state concentrations of some drugs (e.g. diazepam, metoprolol, phenytoin)</td>
</tr>
<tr>
<td></td>
<td>Unchanged conjugative metabolism (liver)</td>
<td></td>
</tr>
<tr>
<td>Excretion</td>
<td>Reduced with decreased glomerular filtration rate (GFR) and tubular excretion</td>
<td>Prolonged half-life, higher steady state concentrations of some drugs or metabolites (e.g. digoxin, cephalaxin, morphine)</td>
</tr>
</tbody>
</table>
1.3.1 Adverse Drug Events

The prevalence of adverse drug events (ADEs) is increased in older patients and reactions are generally more severe\(^1\). A large prospective UK study identified 6.5% of hospital admissions were due to ADEs and 72% were avoidable\(^1\). Patients with ADEs were also significantly older (median age 76) compared to those without (median age 66)\(^1\). A German population-based study reported that drug-related hospitalisation was five times higher in the elderly\(^1\). In an Australian study using data from 1988-2001, drug-related problems were responsible for up to 30% of all hospital admissions for patients over 75 years and it was estimated that three quarters of these admissions were avoidable\(^1\). At least 40,000 older Australians are hospitalised each year as a result of medication related problems, representing 20-30% of unplanned hospital admissions in this age group\(^1\).

ADEs can be difficult to detect in elderly patients as they often exhibit non-specific symptoms such as lethargy, confusion, light-headedness, falls, constipation and depression\(^4\). The ADE rate in the elderly is at least three times that of the general population\(^4\). Additionally up to 20% of re-admissions in geriatric patients were found to be medication related\(^2\). It was estimated that 75% of these admissions could have been prevented if medications had been used more appropriately\(^2\).

1.3.2 Polypharmacy

Polypharmacy is usually defined as taking five or more medications, including prescribed, over the counter and complementary medications\(^2\). There is an extensive use of medications in older people given that increasing age is a major risk factor for disease, disability and co-morbidity\(^1\). The prevalence of chronic diseases, for which one or more medications may be indicated, increases with age\(^2\). Concurrent use of several medications may be justifiable in the treatment of multiple chronic diseases. Polypharmacy is known to dramatically increase the risk of ADRs, drug-drug and drug-disease interactions\(^5\). The risk of a potential ADRs increases with the number of medications prescribed, rising from an incidence of 13% if two drugs are prescribed, to 38% with four drugs prescribed and to 82% if seven or more drugs are prescribed\(^4\). Elderly patients use an average of two to five medications on a regular basis and polypharmacy is present in 20-40% of elderly patients\(^2\). Polypharmacy may also occur when additional medications are prescribed to treat the adverse effects of another medication, known as the prescribing cascade\(^2\).

Polypharmacy and inappropriate medicine use correlates with increasing age, co-morbidity, disability and number of medications\(^2\). It is also associated with the likelihood of nursing home placement, impaired mobility, morbidity, hospitalisation and death\(^2\). The increased risk of falls is associated with polypharmacy, partly due to the chronic diseases for which multiple medications are
prescribed\textsuperscript{22}. The increased use of specific classes of medication, especially centrally-acting and cardiovascular medications, is also likely to be a risk factor in increasing the falls risk\textsuperscript{28}.

Polypharmacy has also been associated with under-prescribing\textsuperscript{29}. The probability of under-prescription increases with an increase in the number of medications used, common examples were the omission of laxatives for patients prescribed opioids or beta blockers following myocardial infarction. As the number of medications prescribed increases, it is possible prescribers are reluctant to start new medications, including those which could be of benefit for the patient. Polypharmacy alone is not a clinically useful independent marker of the quality use of medicines\textsuperscript{22}. The medication type and dose, rather than the number of medications, can determine more meaningful clinical outcomes\textsuperscript{30}. An increased number of medications may be appropriate if prescribing quality is maintained and all medications prescribed are appropriate for the individual patient. There is also evidence that prescribing quality can influence quality of life\textsuperscript{31}. There is validity supported by the literature in the basic principle of prescribing quality, the more appropriate the medication, the better quality of life for the patient\textsuperscript{29,31}.

1.4 Tools for Identifying Potentially Inappropriate Prescribing
Assessment of prescribing quality or potentially inappropriate prescribing can be assessed using implicit (judgement-based) or explicit (criteria-based) methods\textsuperscript{32}. Each medication is assessed individually and a potentially inappropriate medication (PIM) can be flagged. PIMs have limited effectiveness in older adults and have been associated with serious ADEs such as delirium, gastrointestinal bleeding, falls and fractures\textsuperscript{33,34}.

Implicit criteria, such as the Medication Appropriateness Index (MAI) are used to assess each medication prescribed for a patient considering its indication, effectiveness, dosage, correct direction, cost and other clinical information required to determine appropriateness\textsuperscript{35}. The reviewer is required to have a comprehensive knowledge of medications to confidently perform this assessment\textsuperscript{32} and there is a degree of subjectivity.

An alternative method of identifying PIM in the elderly is to use validated screening tools that incorporate explicit prescribing indicators\textsuperscript{4}. Explicit PIM criteria have been developed by a consensus panel using the modified Delphi method\textsuperscript{32}. The research group constructs criteria or statements about the appropriateness of specific medication use on the basis of a review of the literature\textsuperscript{32}. Selected experts are asked to rate their agreement with statements about these
medications using a Likert scale. Statements with high degree of agreement are circulated for a second or third rating. Consensus is reached for the PIMs that generate a high level of agreement amongst the experts. An example of a criteria from the STOPP tool (explicit tool) is “digoxin at a long-term dose >125 microgram per day with impaired renal function”.

There have been several explicit criteria developed, in different settings and countries, each with its own advantages.

1.4.1 Beers Criteria

Beers criteria were first published in 1991, are an explicit list of PIMs for nursing home residents. A modified Delphi technique was used to derive consensus opinion on prescribing indicators from a panel of 13 experts in geriatric medicine, long-term care, geriatric and psychogeriatric pharmacology and pharmacoepidemiology. The expert panel produced a list of 30 medications to be avoided in nursing home residents. There were subsequent revisions in 1997 and 2003 to include all settings of geriatric care.

The latest update published in 2012 used a comprehensive systematic review and grading of the evidence on drug-related problems and adverse drug events in older adults. There are 53 medications or medication classes divided into three categories: PIMs and classes to avoid in older adults, those to avoid in older adults with certain diseases and syndromes and medications to use with caution in older adults. It is proposed that application of the criteria will allow for closer monitoring of drug use, application of real-time e-prescribing and interventions to decrease ADEs in older adults and to obtain improved patient outcomes. Observational studies have shown a strong link between the medications listed in Beers criteria and poor patient outcomes including ADEs, hospitalisation and mortality.

Criticism of the Beers Criteria has been that as the list was developed in the USA, it reflects medications that are used there and may be not used in other countries, particularly Europe and Australia. Beers criteria have significant limitations when applied in Australia as it contains many medications which have never been available in Australia, some that have been withdrawn from use in Australia and medications which are used infrequently. These limitations have led many researchers to attempt to adapt the Beers criteria to reflect their own healthcare settings and this limits the transferability of results.
Additionally, it does not include all causes of potentially inappropriate prescribing, for example, drug-drug interactions are not included\(^4\). Controversy also exists over some of the medications considered inappropriate by Beers, eg. amitriptyline (a tricyclic antidepressant) which is useful in a broad range of pain syndromes at varying doses\(^4\). The criteria also only consider the prescribing of PIMs and not the under-prescribing of clinically indicated drugs and other drug-management issues\(^4\). The criteria are not organised according to physiological systems\(^48\) and the 2012 revision has resulted in a tool that is quite cumbersome to use as there are several sections to consider.

1.4.2 Improved Prescribing in the Elderly Tool (IPET)

The IPET was first published in 2000\(^49\) as an attempt to update McLeod’s criteria which were developed based on a Canadian medication formulary\(^50\). IPET was developed as a quick tool comprising of 14 questions representing potentially inappropriate prescribing, for example “beta-blocker in patient with chronic obstructive airways disease or asthma”\(^49\). It has several deficiencies; it is not based on physiological systems and the criteria are not comprehensive. There are also outdated questions, such as the avoidance of beta-blockers in heart failure, which are now accepted as clinically appropriate.

1.4.3 Australian Prescribing Indicators

An Australian group published a suggested a list of prescribing indicators in 2008 based on frequent medical conditions which elderly patients consult their general practitioner for and cross-referenced these conditions with common prescribed medications by volume\(^47\). This resulted in a list of 48 prescribing indicators, which included 45 explicit criteria\(^47\). There is also a supplementary table of contraindications and precautions to consider before commencing medications that may be suggested by the tool\(^47\). This tool has been used by pharmacists to successfully identify drug related problems in elderly patients\(^51\). The resulting tool and supplement are quite cumbersome to use, and the tool has a mix of medications that should be used and medications that should not be used interspersed through the table. Whilst it was produced using local, relevant information this also limits the tools ability to be compared to international data.

1.4.4 Other Criteria

There have been several other criteria developed internationally that have been less popular in the literature. Developed by a team of geriatricians in Canada, the Rancourt criteria has four categories: medications, duration, dosage and drug-drug interactions\(^52\). The Laroche Criteria include a set of 36 criteria published in France for use in patients aged 75 years or older\(^53\). The first Asian PIM criteria (Winit-Watajana), developed in Thailand, includes 77 statements divided into high-risk medications
with potential ADRs, high risk medications with drug-disease interactions and high risk medications with drug-drug interactions⁵⁴. They also regrouped the medications/medication classes into drugs which should be avoided, drugs that are rarely appropriate, drugs with some indications for older patients and unclassified drugs⁵⁴. The usefulness of this tool is limited by 70% of drugs being in the unclassified group³². Thirty-six medications or medication classes were considered potentially inappropriate based on Norwegian expert consensus the NORGEP criteria for patients over 70 years⁵⁵. There were no statements for drug-drug interactions or alternatives³².

1.4.5 STOPP START

STOPP (Screening Tool of Older Persons’ potentially inappropriate Prescriptions) and START (Screening Tool to Alert to the Right Treatment) are two validated tools comprising of 65 and 22 explicit criteria respectively³⁶. The validity was first established through a Delphi consensus process involving 18 experts in geriatric pharmacotherapy from Ireland and the United Kingdom, including geriatric physicians, senior hospital pharmacists with an interest in geriatric pharmacotherapy, senior academic primary care physicians and a specialist geriatric psychiatrist³⁶. The criteria are organised by body system for ease of use and are designed to be used together to ensure a comprehensive assessment of older persons’ medications.

The STOPP START tools have been used to describe rates of potentially inappropriate prescribing in a range of international settings across Europe, Asia and northern America⁶⁶.

The STOPP tool has been shown to detect more PIMs than Beers criteria (2003 revision) and almost twice as many PIMs with a causal or contributory relationship to hospital admission⁵⁷. STOPP START criteria medications have been significantly associated with ADEs, unlike Beers criteria 2003⁵⁸. The STOPP START criteria has also been shown to predict hospitalisations due to potentially inappropriate prescribing⁵⁹. The STOPP START criteria have been found to be associated with a significant number of acute hospital admissions in frail older persons⁵⁹. Fall-induced osteoporotic fracture was the most frequent cause of hospital admission related to inappropriate prescribing⁵⁹. STOPP START criteria used as an intervention to improve prescribing during hospitalisation for an acute illness was effective in improving medication appropriateness with an effect lasting 6 months post discharge⁶⁰. In a further study applying STOPP START criteria to individual patients within 72 hours of admission to hospital significantly reduced ADRs and reduced average length of stay (LOS)⁶¹.
The STOPP START tool version 2 was published in 2014, updating and expanding the original list of criteria\textsuperscript{61}. The new version has been validated only by Delphi consensus panel\textsuperscript{61}, and there is yet to be published data on its practical and clinical application, however the list of criteria appear promising.
1.5 Comparison of Criteria

Some of the newer criteria are limited by the lack of published studies in English\textsuperscript{32}. It has been proposed that there are several criteria to consider when deciding on which tool is more appropriate\textsuperscript{62}. These are shown below in table 2, adapted from Chang\textsuperscript{32} and the seven criteria described by O’Mahoney and Gallagher are listed as the criteria for assessment in the column on the left of table 2.

Table 2: Evaluation of the seven criteria against the principles of optimal explicit criteria for potentially inappropriate medications (PIMs)

<table>
<thead>
<tr>
<th></th>
<th>Beers</th>
<th>McLeod/IPET</th>
<th>Ranceur</th>
<th>Laroche</th>
<th>STOPP</th>
<th>Winit-Watjana</th>
<th>NORGEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisation based on physiological systems and rapid applicability in daily practice</td>
<td>-</td>
<td>-</td>
<td>+/-</td>
<td>+/-</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Inclusion of common prescribing errors</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
</tr>
<tr>
<td>Generalisability to a global community of physicians &amp; pharmacists</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
</tr>
<tr>
<td>Ease of interface with computer records of patients and drug lists</td>
<td>-</td>
<td>-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>+</td>
</tr>
<tr>
<td>Ability to reduce the prevalence of PIMs</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>NS</td>
<td>+</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Ability to reduce the incidence and negative impact of ADRs</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Ability to predict ADEs and/or hospitalisation</td>
<td>+</td>
<td>-</td>
<td>NS</td>
<td>NS</td>
<td>+</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS = no studies; + indicates fully met; +/- indicates partially met; - indicates not met.

The STOPP/START tool has been selected for use in this Thesis as it was the tool which came closest to meeting the ideal tool\textsuperscript{32}. For this Thesis the choice of criteria had to be supported by literature demonstrating effectiveness in measuring prescribing, be practical to apply and useful in the Australian hospital environment. The combination of STOPP with START, gives a set of explicit
criteria which are easy to apply and has been validated to assess for prescribing quality in the elderly. The medication classes and treatment recommendations are congruent with the Australian setting and the tool has been validated for minimal variability between users. This led to STOPP START being the tool chosen to measure the prescribing quality of Australian elderly hospital patients in this study. STOPP START was chosen as a practical method of measuring the effect of an intervention to improve prescribing quality (Appendix D).

STOPP START was designed for prescribers or clinicians to guide or assess their potential prescribing against a set of explicit criteria and to guide better choices. In the setting of this Thesis, the STOPP START tool will be used as a de facto measure of prescribing quality. Using the tool as a quality measure is an extension of the original design as an assessment tool, however it enables the comparison of two models of care.

1.6 Interventions to Improve Prescribing

There have been numerous interventions studied to assess for impact on prescribing quality or polypharmacy. These interventions have been in several different settings and are often multi-faceted which makes comparison of effect difficult. Whilst the settings may be varied, numerous studies and reviews are described below to provide background. Also, the small study numbers and multiple approaches make conclusive, outcome based results difficult to obtain, so considering different study designs and settings could identify directions to guide future studies.

A Cochrane review conducted in 2014 concluded that it was unclear whether interventions to reduce inappropriate polypharmacy had a clinically significant improvement however these interventions, which often included pharmaceutical care, appear beneficial in terms of reducing inappropriate prescribing. Pharmaceutical care was complex to assess, as it was often multi-faceted as an intervention. Pharmaceutical care often reflected a systematic approach that ensures the patient receives the correct medication, at an appropriate dose for an appropriate indication and often involves a collaborative approach between the pharmacist, physician and patient. In 2016 a separate Cochrane review found that several interventions improved medication appropriateness, the identification and resolution of medication-related problems, a slower decline in health-related quality of life and fewer days in hospital in older patients from care homes.

Individual studies into interventions to improve prescribing include educational interventions, medication reviews, geriatricians’ services, multidisciplinary teams, computerised support systems,
regulatory policies and multi-faceted approaches\textsuperscript{10}. These interventions are displayed below in Table 3, adapted from Kaur\textsuperscript{10}. The studies listed as successful interventions, are those which demonstrated a significant improvement in prescribing, based on each study’s definition \textsuperscript{10}. There were encouraging results for multidisciplinary teams, interventions from a pharmacist, computerised support for the physician or pharmacist and some regulatory policies.
Table 3: Types of interventions used to reduce inappropriate prescribing, adapted from Kaur

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Unsuccessful</th>
<th>Successful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Educational Interventions</td>
<td>Audit results and guidelines mailed to GPs&lt;sup&gt;57&lt;/sup&gt;</td>
<td>Small group workshop, use of decision tree or both&lt;sup&gt;68&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Feedback about prescribing and evidence mailed to GPs&lt;sup&gt;69&lt;/sup&gt;</td>
<td>Three-step approach of quarterly reports, biannual onsite visits and annual meetings&lt;sup&gt;70&lt;/sup&gt;</td>
</tr>
<tr>
<td>Regulatory Policies</td>
<td>Inclusion of list of inappropriate medications in drug use protocol&lt;sup&gt;71&lt;/sup&gt;</td>
<td>PBS restriction of inappropriate drugs for elderly patients&lt;sup&gt;72&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mandated pharmacy services in nursing homes&lt;sup&gt;73&lt;/sup&gt;</td>
</tr>
<tr>
<td>Multi-Faceted Approach</td>
<td>Combining age-specific computerised alerts with academic detailing&lt;sup&gt;74&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>Computerised Support System</td>
<td></td>
<td>Medication alert to pharmacist when dispensing&lt;sup&gt;75&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Computerised alerts triggering telephone call to physician by pharmacist&lt;sup&gt;76&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Computerised decision support system for physician&lt;sup&gt;77&lt;/sup&gt;</td>
</tr>
<tr>
<td>Pharmacist Interventions</td>
<td></td>
<td>Medication review&lt;sup&gt;78-80&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacist coordinated transition from hospital to long-term care facilities&lt;sup&gt;81&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacist consultation to patients and physicians&lt;sup&gt;82,83&lt;/sup&gt;</td>
</tr>
<tr>
<td>Multidisciplinary Teamwork</td>
<td></td>
<td>Pharmaceutical care provided by a pharmacist with direct contact with unit&lt;sup&gt;84&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Case conferences&lt;sup&gt;85&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presentation of feedback of internal audit at multidisciplinary staff meetings&lt;sup&gt;86&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Educational interventions were varied and had different results. An interactive workshop combined with a treatment algorithm had more impact on prescribing non-steroidal anti-inflammatory drugs (NSAIDS) to elderly patients than presenting a patient with a treatment algorithm\(^{68}\). However an intervention that focused on discussing the results of an audit of proton pump inhibitors (PPIs) prescribing with general practitioners (GPs) had no impact on the rates of PPI prescribing\(^{67}\). Passive approaches such as mail outs or listing inappropriate medications in a protocol manual did not produce a change\(^{69}\). A three-step approach involving quarterly reports, biannual onsite visits and annual network meetings showed that always inappropriate and sometimes inappropriate medication use decreased\(^{70}\).

Computerised support systems have had success as an intervention to improve prescribing\(^{66}\). A computerised pharmacy alert system to the pharmacist then collaboration between healthcare professionals decreased PIM use in elderly patients\(^{75}\). Another study showed that computer-based access to a complete medication profile combined with alerts to potential prescribing problems to the pharmacist followed by a call to the physician reduced the number of some PIMs\(^{76}\). When the physician was provided with a computerised decision support system the number of new PIM prescriptions was lowered\(^{77}\). Computerised support systems integrated into e-Prescribing could support the prescriber to consider assessing or changing “high-risk” medications and serve as a good reminder of contra-indications such as age or disease state.

Pharmacist intervention has been successful in improving prescribing\(^{10}\), however the definition of pharmacist intervention is varied. Medication review and written recommendation to the physician decreased the MAI number\(^{87}\), inappropriate prescribing\(^{80}\) and PIM\(^{83}\). Medication review at discharge from hospital and follow-up with the patient by a pharmacist was also successful at improving prescribing\(^{79,81}\). An acute care for elders (ACE) pharmacist who consulted on all patients decreased the prevalence of Beers criteria on discharge compared to admission of a hospital stay for elderly patients\(^{82}\). Several studies have used an intervention model in acute care, or hospital based patients that involves a pharmacist performing a medication history on admission, medication reviews and individual patient counselling during admission and communication with the patient and primary care provider on discharge\(^{88}\). A study conducted in Belgium found that pharmacist intervention increased the medication appropriateness, as measured by MAI and under-prescribing criteria and showed a trend toward decreased mortality and emergency department visits\(^{84}\). A Swedish study found that pharmacist intervention in patients over the age of 80 admitted to hospital had morbidity benefits; decreased emergency department visits, hospital visits and drug-related readmissions\(^{89}\). In a second
Swedish study, multidisciplinary input on medications which included a pharmacist showed a decrease in drug-related hospital visits and MAI score\textsuperscript{12}. 
1.7 Pharmacist Interventions on Ward Rounds

There is evidence that the addition of a pharmacist to the healthcare team can help to improve the quality of medicine use and reduce patient risk in a range of hospital settings. For example, a senior pharmacist decreased the incidence of adverse drug events (ADEs) when they participated as a full member of the patient care team, making rounds with the physicians in an ICU setting\textsuperscript{\textsuperscript{92}}. The rate of preventable ADEs due to prescribing errors decreased by 66% and the pharmacist made 366 prescribing interventions, of which 362, or 99%, were adopted\textsuperscript{92}.

A pharmacist added to a rounding team in a general medical unit has been shown to reduce preventable ADEs by 78\%\textsuperscript{93}. Another study identified 150 interventions by a pharmacist on a ward round, of which 147 were adopted\textsuperscript{94}. A pharmacist on a post-take ward round has been shown to have a range of quantitative benefits leading to optimised treatment for individual patients\textsuperscript{95}. They improved the accuracy of drug history documentation, reduced prescribing costs and decreased the potential risk to patients\textsuperscript{95}. Recommendations regarding a specific drug, modifying the drug dose and reviewing the need for drug treatment were the most common interventions out of a total of 109 interventions for 53 patients\textsuperscript{95}. Most interventions were rated as minor or moderate and there were 4 interventions rated as major relating to potential problems that could result in permanent harm to the patient\textsuperscript{95}.

It was felt these results were promising evidence that the addition of a pharmacist to the physician led ward round would lead to an improvement in the quality of prescribing. The high adoption rate of recommendations or interventions is evidence that this would be an optimal setting to ensure effective communication of treatment recommendations. The effect of a pharmacist on ward rounds in a specialised geriatric unit has not yet been studied.

1.8 Chapter Conclusion

Elderly patients are particularly at risk of a medication related adverse event. Changes in metabolism, increased co-morbidities and increasing frailty make prescribing particularly challenging. Prescribing quality can be measured using a specifically designed tool, such as STOPP START. It is proposed that STOPP START is appropriate for assessing prescribing patterns and measuring the effect of an intervention, specifically the addition of a pharmacist to a physician-led ward round.
Chapter 2 – Aim and Methods

2.1 Aim

The aim of this study is to assess the effect of pharmacist ward round participation on prescribing quality as assessed by the STOPP-START tool in hospitalised elderly patients.

2.2 Specific Aims

1. Describe the current pattern of prescribing for geriatric patients at several points of hospital admission at the Royal Brisbane and Women’s Hospital (RBWH) using the STOPP START tool.
2. Describe the number of regular medications prescribed for geriatric patients at several points of hospital stay at the RBWH.
3. Evaluate the impact of pharmacist participation on physician-led ward rounds on prescribing quality in an interventional phase of the study.
4. Explore the impact a pharmacist has on clinical decision making around prescribing

2.3 Hypotheses

Prescribing quality will be improved after the addition of a pharmacist to physician-led ward rounds (post-intervention) in the GEM unit. Specifically:

1. Patients in the post-intervention group will have fewer STOPP START criteria met on discharge from the GEM unit compared to the pre-intervention group.
2. Patients in the post-intervention group will have fewer STOPP START criteria met on discharge from the GEM unit compared to admission to hospital and admission to the GEM unit.
2.4 Method

2.4.1 Study Design
This study was a retrospective analysis of two data periods a pre- and a post-intervention phase. The pre-intervention phase was from April – August 2012. The post-intervention phase included data from September 2012 to February 2013.

2.4.2 Setting
The study was conducted in the Geriatric Evaluation and Management (GEM) Unit in the Department of Internal Medicine at the Royal Brisbane and Women’s Hospital (RBWH). The RBWH is a 929 bed tertiary referral teaching hospital located at Herston, Brisbane. The RBWH is in the Metro North Health District of Queensland Health. It is a key provider of health care services providing high quality care over a large range of specialities including medicine, surgery, orthopaedics, obstetrics, gynaecology, neonatal intensive care and trauma services. It is the largest tertiary referral hospital in Queensland and provides more than one tenth of all patient services in Queensland. It also serves patients in northern New South Wales and the Pacific Rim.

The GEM Unit is a 28 bed ward located on the Herston campus of the RBWH. The GEM unit was established in April 2012. This geriatric service specializes in optimizing independence and functional outcomes for the frail older person. The GEM model of care aims to return elderly patients to their achievable or maximal level of independence.

GEM patients are usually over the age of 65 and have specific treatment or assessment goals that can benefit from time in the specialised unit such as a need to increase mobility to return home or comprehensive psychological assessment to best determine treatment options in cognitive decline. The GEM team aims to provide a holistic, multi-disciplinary team approach. The medical team is led by a geriatrician, specialised nursing staff, senior pharmacist and specialist allied health team including physiotherapists, occupational therapists, speech pathologists, dieticians, clinical psychologists, neuropsychologists, social workers and allied health assistants. There are a complex series of assessments and patient reviews to ensure each patient receives tailored treatment aimed at meeting their needs. The team meet regularly to review each patient’s progress and report back to the patient and/or carer. The patient journey through the RBWH and GEM unit is presented in figure 1.
In the pre-intervention phase (i.e. before clinical pharmacist presence on ward round) the clinical pharmacist service was restricted to providing a medication review on admission to the unit, daily chart reviews to advise on dose, duration and route of medications, discharge planning and participation in the multi-disciplinary case meetings, but not ward rounds. This was representative of how most of the clinical pharmacist services were delivered at this hospital for general medical and surgical wards at this time. In September 2012, when the post-intervention data collection commenced, the pharmacist had commenced participating on the physician-led ward rounds up to twice each week. At this time the pharmacist stopped attending the multi-disciplinary case meetings and received advice on the outcomes of these meetings from the discharge facilitator.
Figure 1 Patient journey through RBWH GEM unit

Patient admitted to RBWH through emergency department or outpatient clinic → Treatment for acute medical or surgical issue

Referral to GEM unit and assessment for suitability

Admission to GEM unit and treatment by multidisciplinary team

Post-Intervention Phase
Usual pharmacist review + participation on physician-led ward rounds

Pre-Intervention Phase
Usual pharmacist review

Discharge options:
- Discharge home with or without formal community supports
- Discharge to alternative community accommodation
- Discharge to a Transition Care Program
- Interim placement awaiting bed in residential care facility
- Discharge to a residential care facility
2.4.3 Assessment of Intervention Choice

When assessing which intervention to assess for potential to improve prescribing in elderly patients, it is imperative to consider the standard care already provided and what measures are being used to evaluate the quality of prescribing. The term “pharmaceutical care” or “pharmacist review” can have multiple meanings and often involves multi-faceted interventions\textsuperscript{66}. The standard clinical pharmacist care in our setting (outlined in chapter 3) already includes several of the potential interventions described in the above section.

Pharmacist review by an ACE Pharmacist using the Beers criteria as an intervention and prompt can lead to a reduction in the number of Beers criteria met\textsuperscript{82}. An enhanced pharmacist model has been shown to improve the appropriateness of prescribing for Swedish hospital patients as demonstrated by decreased mean STOPP and START criteria and decreased MAI score\textsuperscript{90}. The enhanced service included medication reconciliation and review, drug-related problems were discussed by the pharmacist with the physician in charge and follow-up was provided to the primary care physician and patient\textsuperscript{90}. There is evidence from a Belgium study that admission to a geriatric unit with a pharmacist can improve medication appropriateness \textsuperscript{84}. When the specialised clinical pharmacist is involved in the collaborative review of the patient with direct contact with the geriatric team the appropriate use of medications improved during the hospital stay and at discharge compared to patients who received a more limited pharmacist review\textsuperscript{84}. These studies describe a model of care that is already utilised within our Australian metropolitan hospital setting.

There is evidence that physicians do not review the medication chart for every patient on each ward round\textsuperscript{91} and may not view the pharmacists written recommendations. This would be likely for any written communication, as evidenced by a low uptake rate in the study which used faxed recommendations\textsuperscript{80}. There is however promising evidence that when a pharmacist discusses medication issues verbally with the physician in charge, that patient scores can decrease for STOPP START, and prescribing appropriateness could improve\textsuperscript{90}.

With the low potential for written, didactic recommendations to improve appropriateness of prescribing, and improved outcomes when oral communication is direct with the physician, this study aims to place the intervention closer to the point of prescribing decision making, on the physician-led ward round.
2.4.4 Ethics

The pre-intervention phase was granted ethics exemption by the RBWH Human Research Ethics Committee (HREC/12/QRBW/115) see Appendix A. The post-intervention phase was approved by the RBWH Human Research Ethics Committee (HREC/15/QRBW/212) see Appendix B.

2.4.5 Patients:

Inclusion Criteria:
- All patients aged 65 years and older on admission to the GEM Unit

Exclusion Criteria:
- Patients assessed as suitable for end of life care by the palliative care team
- Patients transferred from the GEM unit to another specialty acute or rehabilitation team other than the GEM unit

2.4.6 Design

Pre-Intervention:
Data was collected from all eligible patients admitted over a period of four months from April to August 2012 with an initial target of 100 patients. Patients were identified prospectively and data collected throughout their admission. The data was collected and evaluated by the candidate. Standard clinical pharmacy services were provided by a clinical pharmacist who was experienced in the care of hospital inpatients, including the elderly, performing a daily clinical review including admission review of medication, advice provided on dose, duration and route, discharge planning and participation in the multi-disciplinary case meetings. Most communication regarding medication was with a junior medical officer or communicated in a written manner on a medication action plan (MAP).

Intervention:
After the pre-intervention period a change was made to the model of care in the GEM unit. A clinical pharmacist was included on physician-led ward rounds, providing advice on optimising patient’s individual medication regimens and documenting suggestions on the MAP. This advice was communicated directly with either the physician or registrar. The major point of difference to the pre-intervention group is the communication was directed at a different level of medical prescriber.
This is a model of care that has been successfully used in other clinical areas including intensive care and general medical wards to improve prescribing outcomes\textsuperscript{96-99}. There were different clinical pharmacists involved in the GEM unit during the data collection periods, with two different primary pharmacists involved. There was a pharmacist staff change between the pre and post-intervention groups. The primary pharmacists involved had similar levels of hospital clinical pharmacist experience with a specific interest in geriatrics. Further analysis of the differences between pharmacists and prescribers was not conducted as part of this Thesis.

In the absence of local data to enable a formal sample size calculation, an a priori target patient inclusion target of 100 eligible patients was used as had been chosen in similar studies using an intervention model\textsuperscript{78,100,101}.

2.4.7 Data Collection
Data collection was consistent for both phases of the study. Patient demographic information, presenting complaint, presenting diagnosis, co-morbidities, medications and pathology were recorded on a data collection tool (Appendix C). A complete list of the patient’s medication was also collected from the patient’s current National Inpatient Medication Chart (NIMC), MAP, discharge medication record (DMR) and/or the discharge prescription. PIMs and potential prescribing omission criteria were identified using the data collection tool, consisting of the STOPP START tool as a proxy measure of prescribing quality (see Appendix D). Medical notes were consulted to ensure that all factors regarding appropriateness were considered. If medication was ceased or commenced, details regarding the change will be recorded on the data collection tool.

Identified patients were followed longitudinally across the admission with data collection occurring:
- Stage 1 – on admission to hospital, after review by a clinical pharmacist and the admitting consultant. Any medication discrepancies between the NIMC and MAP at this point were investigated to determine if changes were intentional, and this information was noted on the data collection tool.
- Stage 2 - on admission to the GEM unit
- Stage 3 – on discharge from the GEM unit

2.4.8 Outcome Measures
The primary outcome measure was the mean number of STOPP START criteria identified at each timepoint (mean number of criteria = total number of criteria identified divided by total number of
patients). Secondary outcome measures were the total number of medications and individual STOPP START criteria identified.

All outcome measures were compared within each group (pre-intervention or post-intervention) and between the two groups.

2.4.9 Data Analysis

The data were analysed using Microsoft Excel (Microsoft Office 2011; Redmond, WA) and GraphPad Prism 6 (GraphPad Software 2015; La Jolla, CA).

Data are presented as median [interquartile range] or mean (standard deviation) as appropriate. To assess the primary outcome the Mann-Whitney U test was used to analyse the differences in the number of criteria identified at each time-point between the pre- and post-intervention groups.

To analyse the differences in the number of STOPP START criteria within each group between time-points to assess where any change to prescribing quality may have occurred a paired Wilcoxon test was used. In this analysis admission was compared to transfer to the geriatric unit and transfer to geriatric unit was compared to discharge for both groups.

To compare the number of medicines prescribed at each of the three time-points within each group a paired Students t-test was used; with admission to hospital compared to transfer to the geriatric unit and transfer to geriatric unit compared to discharge from hospital. To compare the proportion of patients that met each individual STOPP START criteria at the three time-points within each group and the proportion of patients that met at least one STOPP or START criteria at each time-point the Chi-Square test was used.

An unpaired Students t-test was used to compare continuous data between the pre- and post-intervention groups. A Chi-square test was used to compare categorical data between the pre- and post-intervention groups. A $p$-value <0.05 was considered statistically significant for all analyses.
Chapter 3: Submitted manuscript: An evaluation of prescribing using STOPP START criteria throughout a hospital admission - does a geriatric management unit improve prescribing in elderly patients?

The manuscript titled “An evaluation of prescribing using STOPP START criteria throughout a hospital admission – does a geriatric management unit improve prescribing in elderly patients.” Has been submitted to the journal, Drugs – Real World Outcomes, in December 2016.

The manuscript is included as submitted except tables have been inserted into the text. The numbering of pages, figures and tables and references have been adjusted for overall continuity.

KEYWORDS: STOPP START, geriatric, pharmacy, inappropriate prescribing

3.1 Chapter Introduction

This chapter aims to describe the current patterns of prescribing for Australian hospital inpatients using the STOPP START tool. This is a significant addition to the published literature. Additionally, it provides a comparison of the STOPP START tool at three time-points to allow comparison of the prescribing quality across a hospital admission, including a stay in a specialised geriatric unit. The chapter begins to describe the first two of the Thesis’ specific aims; describe the current pattern of prescribing for geriatric patients at several points of hospital admission at the Royal Brisbane and Womens Hospital (RBWH) using the STOPP START tool and describe the number of regular medications prescribed for geriatric patients at several points of hospital stay at the RBWH. The group described in this chapter form the pre-intervention group and provide the baseline data set for this Thesis.
3.2 Introduction

The elderly population is commonly defined as those over 65 years. In Australia, this population is an extremely diverse group\(^1\) that is increasing in both number and proportion. In 2013, they represented 3.3 million people (14.4% of the population)\(^2\). Elderly patients consume a disproportionate amount of healthcare resources accounting for 38% of hospital admissions in 2010-11 and 48% of inpatient days\(^8\).

The incidence and severity of adverse drug-related events (ADEs) is increased in the elderly patients\(^1\). At least 40,000 elderly Australians are hospitalised each year as a result of medication-related problems, representing 20-30% of unplanned hospital admissions in this age group, many of which are avoidable\(^10\)\(^32\)\(^64\). Given these healthcare challenges, specialist geriatric units that maximize independence and functional outcomes for the elderly are increasing in size and number throughout Australia.

The term inappropriate prescribing is frequently used to encompass a use of a medicine that increases the risk of an ADE where there is evidence for an equally or more effective alternative, or associated with a lower risk, to treat the same condition\(^4\)\(^10\). It can also include the use of a medication for an unapproved indication, for no indication, for an inappropriate duration or treatment that is unnecessarily expensive. Inappropriate prescribing also includes the failure to prescribe appropriate therapy.

Potentially inappropriate prescribing can be assessed using implicit (judgement-based) or explicit (criteria-based) methods\(^32\). There are a number of validated tools that can be used to assess potentially inappropriate prescribing in the elderly. STOPP (Screening Tool of Older Persons’ Potentially inappropriate Prescriptions) and START (Screening Tool to Alert to the Right Treatment) are two validated tools comprising of 65 and 22 explicit criteria respectively\(^36\).

The STOPP tool may be favoured over Beers criteria (2003 revision) as the STOPP tool detects more potentially inappropriate prescribing that has a causal or contributory temporal relationship to hospital admission\(^59\). STOPP START has also been shown to predict hospitalisations due to potentially inappropriate prescribing\(^59\). The STOPP START criteria have been found to be associated with a significant number of acute hospital admissions in frail older persons\(^59\).

There is evidence that admission to a geriatric unit with input from a pharmacist can improve medication appropriateness\(^84\). When a pharmacist performs a medication history close to admission
including reconciliation and review, discussion of medication problems with the physician and
follow-up with the patient and primary care physician the appropriateness of prescribing has been
shown to improve, demonstrated by decreased mean STOPP and START criteria and decreased MAI
score\textsuperscript{90}. There has been a lack of published literature describing the patterns of prescribing quality
for patients throughout their hospital admission.

The primary aim of this single-centre study is to describe current prescribing patterns as measured by
the STOPP START tool in elderly patients throughout a hospital admission including admission to a
specialised geriatric unit.

3.3 Methods

3.3.1 Setting
The setting for this study was a specialised 28 bed geriatric unit within a 950-bed public Australian
tertiary hospital. In this unit, patients are referred from inpatient medical and surgical teams and
\(>95\%)\) are over 65 years. This unit accepts referrals for patients with functional goals that require
expert geriatric staff, including physiotherapists, occupational therapists, psychologists, dieticians,
social workers, speech pathologists, pharmacists and a specialist geriatrician. The aim of the unit is
to rehabilitate patients to enable them to become sufficiently functional to return home. A clinical
pharmacist service was also present providing admission review of medication, advice on dose,
duration and route of medications, discharge planning and participation in the multi-disciplinary case
meetings. Prior to admission the general pharmacist service included medication reconciliation
performed shortly after admission to hospital, regular (every 1-3 days) clinical pharmacist review and
input in the multidisciplinary team.

3.3.2 Patients
Data were collected from all eligible patients admitted over a period of four months from April to
August 2012 with an initial target of 100 patients. Patients were prospectively assessed for eligibility
according to the following criteria:

Inclusion Criteria:
- All patients aged 65 years and older on admission to the specialised geriatric unit

Exclusion Criteria:
3.3.3 Data Collection and Design
Identified patients were followed longitudinally throughout the entire hospital admission with data collection occurring at three stages:
1. On admission to hospital
2. On transfer to the specialised geriatric unit
3. On discharge from the specialised geriatric unit

Patient demographic information, presenting complaint, presenting diagnosis, co-morbidities and pathology was collected from the patient’s medical notes and hospital pathology provider. A complete list of the patient’s medication was also collected from the inpatient medication chart and other medication records, discharge medication record and/or the discharge prescription. Potentially inappropriate medication and potential prescribing omission alerts were identified using the STOPP START tool.

This study used an observational, retrospective design. The same group of patients were compared at three timepoints to assess for any changes in prescribing quality. The primary outcome measure was the mean number of STOPP START criteria identified at each timepoint (mean number of criteria = total number of criteria identified divided by total number of patients). Secondary outcome measures were the total number of medications and individual STOPP START criteria identified.

3.3.4 Analyses
In the absence of local data to enable a formal sample size calculation, an a priori target patient inclusion target of 100 eligible patients was used as had been chosen in similar studies using an intervention model90. Data are presented as mean (standard deviation) or median [interquartile range] as appropriate.

To assess the primary outcome; the mean number of STOPP START criteria identified at each timepoint (admission to hospital, transfer to the specialised geriatric unit, discharge from the specialised geriatric unit), a Wilcoxon matched-pairs signed rank test was used. The mean number of criteria from admission was compared to geriatric unit transfer and the mean number of criteria from geriatric unit transfer was compared to hospital discharge. A Wilcoxon matched-pairs signed rank
test was also used to compare the mean number of medicines prescribed at the three different timepoints in the same manner.

The proportion of patients with at least one STOPP or START criteria at each timepoint was compared using a Chi-square test. The presence of individual STOPP START criteria at the three different timepoints was also compared using a Chi-square test. Each Chi-square test compared the data from two individual timepoints to assess for any change.

\( p<0.05 \) was considered statistically significant.

### 3.3.5 Ethics

This study was granted ethics exemption by the Royal Brisbane and Womens Hospital Human Research Ethics Committee (HREC/12/QRBW/115).

### 3.4 Results

Ninety-six patients were eligible for inclusion. The demographic and clinical characteristics of the patients are described in Table 4. Most of the patients lived at home prior to hospital admission. Less than half of those patients returned home after hospital discharge (Table 4). Patients had been referred to the specialised geriatric unit from a variety of surgical, medical and oncology speciality teams. The leading causes of hospital admission for these patients were falls in 34 (35.4\%) patients, infections (n=9, 9.4\%), difficulty coping at home (n=9, 9.4\%) and the requirement for specialised care during cancer treatment (n=9, 9.4\%). Included patients had a mean number of co-morbidities of 5.10 conditions per patients. The most prevalent co-morbidities are listed (Table 4) and had a broad range of affected organ systems including cardiovascular, falls, endocrine and gastrointestinal.
Table 4: Demographic and clinical data for patients evaluated

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>38 (39.6%)</td>
<td>58 (60.4%)</td>
</tr>
<tr>
<td>Age</td>
<td>83 [IQR 76-87]</td>
<td></td>
</tr>
<tr>
<td>Accommodation Type</td>
<td>Pre-Hospital</td>
<td>After Discharge</td>
</tr>
<tr>
<td>Home</td>
<td>82 (85.4%)</td>
<td>35 (36.5%)</td>
</tr>
<tr>
<td>Independent Living; e.g. retirement home</td>
<td>5 (5.2%)</td>
<td>3 (3.1%)</td>
</tr>
<tr>
<td>Aged Care Facility</td>
<td>9 (9.4%)</td>
<td>41 (42.7%)</td>
</tr>
<tr>
<td>Transition Care Program</td>
<td>0</td>
<td>17 (17.6%)</td>
</tr>
<tr>
<td>Mean number of co-morbidities per patient</td>
<td></td>
<td>5.10</td>
</tr>
<tr>
<td>Prevalent co-morbidities, number of patients (%)</td>
<td>Hypertension: 56 (58.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased falls risk: 33 (34.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Osteoporosis: 31 (32.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Atrial fibrillation: 30 (31.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interstitial heart disease: 30 (31.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increased cholesterol: 27 (28.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gastro-oesophageal reflux disease: 25 (26.0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Osteoarthritis: 25 (26.0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diabetes: 24 (25%)</td>
<td></td>
</tr>
</tbody>
</table>

Patients had a mean hospital length of stay of 39.5 (20.2) days of which 22.2 (16.7) days were in the specialised geriatric unit. The mean number of medications prescribed per patient showed a significant increase from admission 7.3 (4.3) to discharge 8.8 (4.6), p<0.01.

At hospital admission 55 patients (57.3%) met one or more STOPP criteria for a potentially inappropriate medication prescribed and 48 patients (50%) had at least one START criteria for a medication that may have been inappropriately omitted. On hospital discharge 55 patients (57.3%) met at least one STOPP criteria for a potentially inappropriate medication prescribed and 41 patients (42.7%) had at least one START criteria for a medication that may have been inappropriately omitted. These proportions were not significantly different (p=1 for STOPP and p=0.3 for START).
The mean number of STOPP START criteria (total number of criteria divided by number of patients) decreased from hospital admission 1.78 (1.57) to geriatric unit admission 1.72 (1.54) and again to discharge 1.50 (1.41). The decrease in mean number of criteria from geriatric unit transfer to hospital discharge was significant, $p=0.02$. The decrease in mean number of criteria from hospital admission to discharge was also significant, $p=0.02$.

The five most common STOPP alerts are described in Table 5. The most common START criteria are described in Table 6. The changes between time-points for each individual criteria were not significantly different.

Table 5: The five most prevalent STOPP criteria (for the pre-intervention group)

<table>
<thead>
<tr>
<th>Criteria Description</th>
<th>Admission</th>
<th>Geriatric unit transfer</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPI for peptic ulcer disease at full therapeutic dosage for $&gt; 8$ weeks</td>
<td>29 (30.2%)</td>
<td>30 (31.2%)</td>
<td>26 (27.1%)</td>
</tr>
<tr>
<td>Loop diuretic for dependent ankle oedema only (i.e. no clinical signs of heart failure)</td>
<td>11 (11.6%)</td>
<td>9 (9.4%)</td>
<td>8 (8.3%)</td>
</tr>
<tr>
<td>Drugs that adversely affect those prone to falls ($&gt;1$ fall in the past 3 months) – benzodiazepines</td>
<td>12 (12.5%)</td>
<td>9 (9.4%)</td>
<td>7 (7.3%)</td>
</tr>
<tr>
<td>Long-term long-acting benzodiazepines</td>
<td>9 (9.4%)</td>
<td>5 (5.2%)</td>
<td>4 (4.2%)</td>
</tr>
<tr>
<td>Drugs that adversely affect those prone to falls – neuroleptic drugs</td>
<td>4 (4.2%)</td>
<td>5 (5.2%)</td>
<td>4 (4.2%)</td>
</tr>
</tbody>
</table>
Table 6: The five most prevalent START criteria alerts (for the pre-intervention group)

<table>
<thead>
<tr>
<th>Criteria description</th>
<th>Number of Patients that met criteria (% of all patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium and vitamin D supplement in patients with known osteoporosis</td>
<td>Admission: 14 (14.6%) Geriatric unit transfer: 16 (16.7%) Discharge: 13 (13.5%)</td>
</tr>
<tr>
<td>Antiplatelet therapy in diabetes with one or more cardiovascular risk factors</td>
<td>Admission: 11 (11.5%) Geriatric unit transfer: 10 (10.4%) Discharge: 7 (7.3%)</td>
</tr>
<tr>
<td>Warfarin in the presence of chronic atrial fibrillation OR aspirin if warfarin is contra-indicated</td>
<td>Admission: 6 (6.3%) Geriatric unit transfer: 5 (5.2%) Discharge: 5 (5.2%)</td>
</tr>
<tr>
<td>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</td>
<td>Admission: 5 (5.2%) Geriatric unit transfer: 6 (6.3%) Discharge: 4 (4.2%)</td>
</tr>
<tr>
<td>ACE Inhibitor or angiotensin receptor blocker in diabetes with neuropathy or microalbuminuria</td>
<td>Admission: 6 (6.3%) Geriatric unit transfer: 5 (5.2%) Discharge: 5 (5.2%)</td>
</tr>
</tbody>
</table>

3.5 Discussion

We observed a significant decrease in mean number of STOPP START criteria met by patients after a stay in a specialised geriatric unit. There was a 13% reduction, or 0.22 criteria per patient in the number of STOPP START criteria identified after the stay in the specialised geriatric unit. There was also an overall decrease, or 16% in STOPP START criteria met from hospital admission to discharge from the geriatric unit. The overall decrease is largely influenced by the significant change during the geriatric unit admission, however there was also a small trend of decrease during the acute hospital admission.

Interestingly, we observed a significant increase in the number of medications prescribed on admission to hospital (7.3 per patient) to that prescribed on discharge, (8.8 per patient). Indeed, the risk of medication misadventure increases for each additional prescribed medication above 5 medications\textsuperscript{102}, suggesting that this increase has clinically significant consequences, although
polypharmacy alone should not be considered a clinically useful marker of the quality use of medicines\textsuperscript{22}. To this end, the medication type and dose, rather than the number of medications, can determine more meaningful clinical outcomes\textsuperscript{30}. The decrease in potentially inappropriate prescribing, as measured using STOPP START criteria, during the hospital admission would suggest that the slight increase in number of medications could indicate more appropriate prescribing. In this present study, this result suggests that the increases in prescribed medications were appropriate.

The results from our study are similar with previous international data. On admission to hospital 57\% of patients met at least one STOPP criteria and 50\% met at least one START criteria. A similar study of Australian hospital inpatients identified 60\% of patients had at least one STOPP criteria upon admission to hospital\textsuperscript{63}. Irish studies have identified rates of STOPP criteria between 34\%-50\% in hospital patients and 60\% in nursing home patients\textsuperscript{62}. Studies across six European countries (Switzerland, Spain, Ireland, Czech Republic, Italy and Belgium) found an overall rate of 51.3\% for STOPP criteria and 59.4\% for START criteria for hospital patients\textsuperscript{56}.

The leading STOPP criteria, PPI therapy for peptic ulcer disease at full therapeutic dosage for > 8 weeks (27.1\% of patients on discharge), is consistent with other study data that showed that PPI use within the wider patient group is very common\textsuperscript{103}. Chronic PPI use is associated with increased rates of community acquired pneumonia, increased Clostridium difficile-associated diarrhoea, malabsorption resulting in vitamin B12 deficiency and possibly higher fracture rates\textsuperscript{103}. Recent evidence suggests that PPI use is associated with an increased risk of developing dementia and avoidance of PPI medication could contribute to the prevention of dementia\textsuperscript{104}. These risks are particularly relevant to older patients and are all important reasons why all prescribers should carefully review the use and duration of PPI therapy. The small decrease in inappropriate PPI use from geriatric unit transfer to hospital discharge indicates appropriate deprescribing in this patient group. Deprescribing, or the trial withdrawal of specific classes of medications that may be inappropriate for the individual patient can lead to a reduction in ADEs\textsuperscript{105}. There can also be decreased medication costs to the patient and healthcare system, improved medication adherence and improved patient satisfaction from taking fewer medications\textsuperscript{105}. There is evidence that multi-disciplinary review by a pharmacist and physician can reduce the rate of potentially inappropriate prescribing in an outpatient clinic setting by targeting deprescribing\textsuperscript{106}.

The number of patients prescribed benzodiazepines decreased from 12.5\% patients on admission to 7.3\% on discharge. This reduction is considered appropriate as use of benzodiazepines has been associated with an increased risk of falls\textsuperscript{28}. 
The START alerts were also high in these patients and may represent missed opportunities to increase the appropriate use of medications. There were a high proportion of patients, 13.5% on discharge, that were not prescribed calcium and vitamin D despite a diagnosis of osteoporosis. Calcium and vitamin D co-supplementation for the treatment of osteoporosis are well accepted in literature and guidelines\textsuperscript{107} \textsuperscript{108}. This study period was before concerns were raised in the literature regarding the safety of calcium supplementation\textsuperscript{109}. A relatively high number of patients (5.2% at discharge) had a diagnosis of atrial fibrillation (AF) and were not receiving aspirin or warfarin for secondary stroke prevention, despite evidence of effect\textsuperscript{108} and no documented contra-indication. Statin use was also lower than expected, with 4.2% patients at discharge with a history of coronary, cerebral or peripheral vascular and independent in daily living activities that were not prescribed a statin.

The results described above, summarized as an increase in the number of medications prescribed per patient and a modest decrease in the mean number of START STOPP criteria was less significant than hypothesized. There could be numerous reasons why these results were seen. During a hospital admission, particularly for this patient group, there are numerous treatment goals. Many of these are focused on ensuring the patient can meet the functional goals required to return home. A recent Australian study of specific geriatrician review of medications for new nursing home patients did not show significant change to high risk medications\textsuperscript{110}. This was thought to be suggestive of the medications being appropriate on balance for the specific patient or, because of other factors, such as an unwillingness to change medications\textsuperscript{110}. Pharmacotherapeutics may not be considered a high priority for patients in the geriatric unit and may be overlooked in place of other therapy goals or social concerns.

These patients had quite a lengthy admission to hospital, with the mean total admission to hospital approaching 40 days, 22 of which were spent within the specialised geriatric unit. A long period of hospital admission especially within a specialised geriatric unit does provide a sufficient opportunity for medical and pharmacy staff to completely review and tailor individual medication regimens. There is some evidence that admission to a geriatric unit with a pharmacist can improve medication appropriateness\textsuperscript{84}. When the specialised clinical pharmacist is involved in the collaborative review of the patient with direct contact with the geriatric team the appropriate use of medications improved during the hospital stay and at discharge compared to patients who received a more limited pharmacist review\textsuperscript{84}. A specialised geriatric unit may allow for the controlled trial of new medications or trial of medication withdrawal under close observation with easy access to pathology and other services.
These results have some limitations as they represent the findings from a single centre study. The services provided in a large, metropolitan hospital may not be available at all sites so may not be able to be duplicated at other sites. Additionally, the STOPP START tools were initially described to guide prescribing and may lack sensitivity to accurately described prescribing changes.

3.6 Conclusion
This study has described the current pattern of prescribing for elderly hospital inpatients in a tertiary referral centre with a specialised geriatric unit. We observed that the overall quality of prescribing did improve after admission to a geriatric unit however the number of medications prescribed did increase during the hospital admission. Further work is required to investigate the effects of interventions designed to further improve prescribing quality for this important group of older patients.

3.7 Chapter Summary
This chapter has described the current pattern of prescribing quality for elderly hospitalised patients that have a stay in a specialised geriatric unit, summarised as an overall improvement in prescribing quality despite an increase in the overall number of prescribed medications. This group of patients form the pre-intervention group for the Thesis and will form the baseline data for comparison with the post-intervention group in the next chapter, Chapter 4.
Chapter 4: Accepted Manuscript: The effect of pharmacists on ward rounds measured by the STOPP START tool in a specialised geriatric unit

The manuscript titled “The effect of pharmacists on ward rounds measured by the STOPP START tool in a specialised geriatric unit” has been accepted for publication by the Journal of Clinical Pharmacy and Therapeutics, 13th November 2016, DOI: 10.1111/jcpt.12489.

The manuscript is included as submitted except tables have been inserted into the text. The numbering of pages, figures and tables and references have been adjusted for overall continuity.

KEYWORDS:
Inappropriate prescribing, STOPP START, pharmacist ward rounds, prescribing quality, elderly
4.1 Chapter Introduction

This chapter continues to describe patterns in prescribing quality for elderly hospitalised patients. The results from the pre-intervention group, as described in chapter 3, are compared to new results from the post-intervention group using a before and after study design in two groups of elderly patients. The aim of this Thesis is to assess the effect of pharmacist ward round participation on prescribing quality as assessed by the STOPP-START tool in hospitalised elderly patients. Additionally, this chapter also addresses the four specific aims:

1. Describe the current pattern of prescribing for geriatric patients at several points of hospital admission at the RBWH using the STOPP START tool.
2. Describe the number of regular medications prescribed for geriatric patients at several points of hospital stay at the RBWH.
3. Evaluate the impact of pharmacist participation on physician-led ward rounds on prescribing quality in an interventional phase of the study.
4. Explore the impact a pharmacist has on clinical decision making around prescribing.

These aims are assessed using the outcome measures first discussed in Section 2.4.8 Outcome Measures. The primary outcome measure was the mean number of STOPP START criteria identified at each timepoint (mean number of criteria = total number of criteria identified divided by total number of patients). Secondary outcome measures were the total number of medications and individual STOPP START criteria identified.

All outcome measures were compared within each group (pre-intervention or post-intervention) and between the two groups.
4.2 Background

The incidence and severity of adverse drug-related events (ADEs) is increased in elderly patients\textsuperscript{11}, commonly defined as individuals 65 years of age or older. Medication-related problems are a frequent cause of unplanned hospital admissions in this age group, many of which are avoidable\textsuperscript{10,32,64}. The term inappropriate prescribing is frequently used to encompass the use of a medication that increases the risk of ADEs where there is evidence for an equally or more effective alternative, or associated with a lower risk, to treat the same condition\textsuperscript{4,10}. It can also include the use of a medication for an unapproved indication, for no indication, for an inappropriate duration or treatment that is unnecessarily expensive\textsuperscript{4} or the failure to prescribe appropriate therapy\textsuperscript{36}.

The original STOPP (Screening Tool of Older Persons’ Potentially inappropriate Prescriptions) and START (Screening Tool to Alert to the Right Treatment) tools comprise of 87 validated, explicit criteria\textsuperscript{36}. A previous systematic review has described that the combined STOPP START tool has been used as a measure of prescribing quality\textsuperscript{111}. The use of the criteria has been shown to decrease falls, delirium episodes, hospital length of stay, care visits (primary and emergency) and medication costs\textsuperscript{111}. STOPP START criteria have also been shown to predict hospitalisations due to potentially inappropriate prescribing\textsuperscript{59}. The STOPP START tool is therefore used as an accepted measure for potentially inappropriate prescribing, or prescribing quality. Previous work has used the STOPP START criteria to measure the effect of an enhanced pharmacist service on prescribing in elderly hospital patients\textsuperscript{90}.

The addition of a pharmacist to the physician-led ward round has provided evidence of improved prescribing quality in other clinical settings. A pharmacist added to the physician-led rounding team has been shown to reduce preventable ADEs by 78\% in a general medical unit\textsuperscript{99} and 66\% in an intensive care unit\textsuperscript{92}. The presence of a pharmacist on a physician-led general medical ward round shortly after admission has also been shown to improve the accuracy of drug history documentation, reduce prescribing costs and decrease the potential risk to patients\textsuperscript{96}. Recommendations regarding drug choice, dose and need for drug treatment were the most common interventions leading to optimisation of treatment for individual patients\textsuperscript{96}. There is evidence that suggestions made by a pharmacist on a ward round are adopted, in two studies the rate was 98\%\textsuperscript{98} and 99\%\textsuperscript{92}. No published data currently exists for whether addition of a specialised clinical pharmacist to a physician-led geriatric ward round can improve the appropriate use of medications during the hospital stay and at discharge.
This study aimed to assess the effect of inclusion of a pharmacist on a physician-led ward round on potentially inappropriate prescribing in hospitalised elderly patients.

4.3 Methods

4.3.1 Design
This was an observational cohort study to assess changes in prescribing quality using the STOPP START tool (2008 version) that occurred pre- and post- addition of a clinical pharmacist to a physician-led ward round in a specialised geriatric unit. The first cohort, or pre-intervention group, consisted of patients admitted to the specialised geriatric unit between April to August 2012. The second cohort, or post-intervention group, consisted of patients admitted from September 2012 to February 2013 at which stage a pharmacist had been added to physician ward rounds. The addition of the clinical pharmacist to the ward round was considered the only change to the model of care at this time, however there were changes to the pharmacist and medical staff during this time.

4.3.2 Setting
This study was conducted in a 28-bed specialised geriatric unit within a 950-bed tertiary referral hospital in Australia. The specialised geriatric unit patients are referred from inpatient medical and surgical teams. The role of the unit is to optimise treatments that can enable the patient to become sufficiently functional to return home or to community based care.

Multi-disciplinary clinical care (includes physiotherapists, occupational therapists, psychologists, dieticians, social workers, speech pathologists) led by a specialist geriatrician is provided in the unit as standard practice. Pre-intervention, the clinical pharmacist service included providing a medication review on admission to the unit, daily chart reviews to advise on dose, duration and route of medications, discharge planning and participation in the multi-disciplinary case meetings, but not ward rounds. General pharmacist service (prior to admission to the specialised geriatric unit) included medication reconciliation performed shortly after admission to hospital, regular (every 1-3 days) clinical pharmacist review and input in the multidisciplinary team. In September 2012, when the post-intervention data collection commenced, the pharmacist began participating on the twice-weekly physician-led ward rounds. Pharmacist tasks on the physician-led ward round included participating in discussion about medication appropriateness, dose and duration of treatment. At this time, the pharmacist stopped attending the multi-disciplinary case meetings and received advice on the outcomes of these meetings from the discharge facilitator. The mean length
of stay of over 20 days for each group enabled the pharmacist to regularly review each patient as part of the twice weekly ward rounds (post-intervention) or ward meetings (pre-intervention).

4.3.3 Patients
All patients admitted to the specialised geriatric unit were retrospectively assessed for eligibility according to the following criteria:

Inclusion Criteria:
- Patients aged 65 years and older on admission to the specialised geriatric unit

Exclusion Criteria:
- Patients transferred from the geriatric unit to:
  - An acute medical, surgical or rehabilitation team or unit
  - A palliative care team or unit

4.3.4 Data Collection
In the pre- and post-interventions groups, patients were identified and followed longitudinally across the entire hospital admission with data collection at three stages:

1. On admission to the hospital
2. On transfer to the specialised geriatric unit
3. On discharge from the specialised geriatric unit

Patient demographic and clinical information was collected from the patient’s medical notes and hospital pathology provider, including presenting complaint, co-morbidities and pathology. The patient’s complete medication list was also collected from the inpatient medication chart and other medication records. The STOPP START tool was used to identify potentially inappropriate medication and potential prescribing omission criteria. Medical notes were reviewed to ensure that all factors regarding appropriateness were considered.

The primary outcome was the differences between the pre- and post-intervention groups for changes to the number of STOPP START criteria at the times of; hospital admission, transfer to the geriatric unit and hospital discharge. The secondary outcomes were the longitudinal differences in prescribing within the pre- and post-intervention groups. We also evaluated the total number of medications prescribed and the most common individual STOPP START criteria identified in both groups.
4.3.5 Analyses

Data are presented as mean (standard deviation) or median [interquartile range] as appropriate. A Mann-Whitney U test was used to analyse the primary outcome, the differences in the number of criteria identified at each time-point between the pre and post-intervention groups.

A paired Wilcoxon test was used to analyse the differences in the number of STOPP START criteria within each group between time-points to assess where any change to prescribing quality may have occurred; admission was compared to transfer to the geriatric unit and transfer to geriatric unit was compared to discharge for both groups.

A paired Students t-test was used to compare the number of medicines prescribed at the three different time-points within each group; with admission to hospital compared to transfer to the geriatric unit and transfer to geriatric unit compared to discharge from hospital. The Chi-Square test was used to compare the proportion of patients that met each individual STOPP START criteria at the three time-points within each group and the proportion of patients that met at least one STOPP or START criteria at each time-point.

An unpaired Students t-test was used to compare continuous data between the pre- and post-intervention groups. A Chi-square test was used to compare categorical data between the pre- and post-intervention groups. A $p$-value <0.05 was considered statistically significant for all analyses.

4.3.6 Ethics

This study was granted low risk ethics approval by the RBWH Human Research Ethics Committee (HREC/15/QRBW/212).

4.4 Results and Discussion

Ninety-six patients were included in the pre-intervention group and 100 in the post-intervention group, a flowchart describes the total number of patients and exclusions in figure 2. As described in Table 7, there were no significant differences between the two groups in their demographic and clinical characteristics.
Pre-Intervention Group

Total number of patients in study period = 109 patients

- Excluded due to age < 65 = 7 patients
- Excluded due to transfer to palliative care unit or acute treatment unit = 6 patients

Included in study group = 96 patients

Post-Intervention Group

Total number of patients in study period = 112 patients

- Excluded due to age < 65 = 3 patients
- Excluded due to transfer to palliative care unit or active treatment unit = 9 patients

Included in study group = 100 patients

Figure 2: Flowchart of patients admitted during the pre- and post intervention study periods
Table 7: Demographic characteristics of pre- and post intervention groups

<table>
<thead>
<tr>
<th></th>
<th>Pre-intervention group</th>
<th>Post-intervention group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>96</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Sex - % male</td>
<td>39.6%</td>
<td>45%</td>
<td>0.39</td>
</tr>
<tr>
<td>Age</td>
<td>83 [IQR 76.25-87]</td>
<td>84 [IQR 78-88.75]</td>
<td>0.19</td>
</tr>
<tr>
<td>Mean total length of stay</td>
<td>40 (20)</td>
<td>42 (34)</td>
<td>0.52</td>
</tr>
<tr>
<td>Mean length of stay (days) in specialised geriatric unit</td>
<td>22 (17)</td>
<td>25 (21)</td>
<td>0.29</td>
</tr>
<tr>
<td>Median number of medications - admission</td>
<td>7 [IQR 5-10]</td>
<td>8 [IQR 5-10]</td>
<td>0.41</td>
</tr>
<tr>
<td>Median number of medications – transfer to geriatric unit</td>
<td>9 [IQR 7-13]</td>
<td>10 [IQR 7-12]</td>
<td>0.26</td>
</tr>
<tr>
<td>Median number of medications - discharge</td>
<td>8 [IQR 7-11]</td>
<td>9 [IQR 7-10]</td>
<td>0.47</td>
</tr>
<tr>
<td>Proportion of patients living at home pre-hospital (own home, home with family or independent living unit)</td>
<td>91%</td>
<td>92%</td>
<td>0.80</td>
</tr>
<tr>
<td>Leading causes of hospital admission</td>
<td>Falls (35%)</td>
<td>Falls (43%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infection (9%)</td>
<td>Infection (17%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Difficulty coping at home (9%)</td>
<td>Neurological cause (17%)</td>
<td></td>
</tr>
</tbody>
</table>

The results of the mean number of criteria met by the two groups, pre- and post-intervention, at the three time-points, admission to hospital, transfer to the geriatric unit and discharge from hospital, are described in Table 8.
Table 8: Summary of changes to mean number of STOPP START criteria at each time point

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>$p$ value of difference between admission and geriatric unit transfer</th>
<th>Geriatric unit transfer</th>
<th>$p$ value of difference between geriatric unit transfer and discharge</th>
<th>Discharge</th>
<th>Decrease from geriatric unit transfer to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention</td>
<td>1.78 (1.57)</td>
<td>0.37*</td>
<td>1.72 (1.54)</td>
<td>0.02*</td>
<td>1.50 (1.41)</td>
<td>13%</td>
</tr>
<tr>
<td>Post-Intervention</td>
<td>2.30 (1.91)</td>
<td>&lt;0.01*</td>
<td>1.59 (1.60)</td>
<td>&lt;0.01*</td>
<td>1.18 (1.37)</td>
<td>26%</td>
</tr>
<tr>
<td>$p$ value of difference between groups (pre- and post intervention groups)</td>
<td>0.09^</td>
<td>0.36^</td>
<td>0.07^</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*paired Wilcoxon test

^Mann Whitney U-test
The pre-intervention group did not have a significant change in the mean number of STOPP START criteria from hospital admission to geriatric unit transfer however there was a significant 13% decrease from geriatric unit transfer to discharge. In the post-intervention group, the mean number of STOPP START criteria significantly decreased from hospital admission to geriatric unit transfer and again to discharge. The decrease from geriatric unit transfer to discharge represented a 26% reduction in the mean number of STOPP START criteria.

The proportion of patients who met at least one STOPP or START criteria at each time-point are described in Table 9. There was no significant difference found between each group at each of the three time-points or between each time-point within the pre- and post-intervention group. There was an overall decreasing trend in the post-intervention group, with less patients meeting at least one STOPP or START criteria at geriatric unit transfer compared to admission, and less again on discharge, however this change was not found to be significant. The high proportion of patients that met at least one criteria at discharge in the post-intervention group (42% STOPP and 35% START) could have contributed to the lack of significance for the primary aim, even though these proportions are numerically less than the pre-intervention group (54% STOPP and 42% START).

Table 9: Summary of changes to proportion patients that met at least one STOPP and START criteria at each time point for the pre- and post-intervention groups

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Geriatric unit transfer</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Intervention STOPP Criteria</td>
<td>57%</td>
<td>58%</td>
<td>54%</td>
</tr>
<tr>
<td>Pre-Intervention START Criteria</td>
<td>50%</td>
<td>49%</td>
<td>42%</td>
</tr>
<tr>
<td>Post-Intervention STOPP Criteria</td>
<td>64%</td>
<td>53%</td>
<td>42%</td>
</tr>
<tr>
<td>Post-Intervention START Criteria</td>
<td>58%</td>
<td>44%</td>
<td>35%</td>
</tr>
</tbody>
</table>
The most prevalent STOPP and START criteria for both groups are described in Table 10 and Table 11 respectively. For the pre-intervention group, there were no significant differences between the proportions of patients meeting each of these criteria at each time-point. For the post-intervention group, there were some significant differences in changes to the proportions of patients meeting individual criteria between time-points for selected STOPP and START criteria.
<table>
<thead>
<tr>
<th>Criteria Description</th>
<th>Pre-Intervention Group</th>
<th>Post-Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Admission</td>
<td>Geriatric unit transfer</td>
</tr>
<tr>
<td>PPI for peptic ulcer disease at full therapeutic dosage for &gt; 8 weeks</td>
<td>29 (30.2%)</td>
<td>30 (31.2%)</td>
</tr>
<tr>
<td>Loop diuretic for dependent ankle oedema only (no diagnosis of heart failure, pulmonary oedema or hypertension)</td>
<td>11 (11.6%)</td>
<td>9 (9.4%)</td>
</tr>
<tr>
<td>Drugs that adversely affect those prone to falls (&gt;1 fall in the past 3 months) – benzodiazepines</td>
<td>12 (12.5%)</td>
<td>9 (9.4%)</td>
</tr>
<tr>
<td>Calcium channel blockers with constipation</td>
<td>3 (3.1%)</td>
<td>3 (3.1%)</td>
</tr>
<tr>
<td>Drugs that adversely affect fallers - long term opiates</td>
<td>3 (3.1%)</td>
<td>4 (4.2%)</td>
</tr>
<tr>
<td>TCAs with an opiate or calcium channel blocker</td>
<td>3 (3.1%)</td>
<td>3 (3.1%)</td>
</tr>
</tbody>
</table>

**p=0.04 (between admission and transfer to the specialised geriatric unit within the post-intervention group)

^^p=0.03 (between admission and transfer to the specialised geriatric unit within the post-intervention group)

^^^p=0.05 (between admission and transfer to the specialised geriatric unit within the post-intervention group)
### Table 11: Comparison of prevalent START criteria for each group

<table>
<thead>
<tr>
<th>Criteria Description</th>
<th>Pre-Intervention Group</th>
<th>Post-Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Admission</td>
<td>Geriatric unit transfer</td>
</tr>
<tr>
<td>Calcium and vitamin D supplement in patients with known osteoporosis</td>
<td>14 (14.6%)</td>
<td>16 (16.7%)</td>
</tr>
<tr>
<td>Antiplatelet therapy in diabetes with one or more cardiovascular risk factors</td>
<td>11 (11.5%)</td>
<td>10 (10.4%)</td>
</tr>
<tr>
<td>Warfarin OR aspirin in the presence of chronic atrial fibrillation*</td>
<td>6 (6.3%)</td>
<td>5 (5.2%)</td>
</tr>
<tr>
<td>Statin therapy with a history of coronary, cerebral or peripheral vascular disease (functionally independent patient)</td>
<td>5 (5.2%)</td>
<td>6 (6.3%)</td>
</tr>
<tr>
<td>Aspirin or clopidogrel with a history of atherosclerotic coronary, cerebral or peripheral vascular disease in patients with sinus rhythm</td>
<td>9 (9.4%)</td>
<td>4 (4.2%)</td>
</tr>
</tbody>
</table>

**p=0.002 (between transfer to the specialised geriatric unit and discharge within the post-intervention group)

* novel oral anticoagulants and low molecular weight heparin was also accepted in this study as an alternative to warfarin for this patient group

For the secondary outcomes, the total number of medications prescribed per patient in the pre-intervention and intervention groups were not significantly different between the groups at admission (median 7 [5-10] vs 8 [5-10], p=0.4) or discharge (median 8 [6-11] vs 9 [7-11], p=0.5).
However, in the individual groups, the number of medications increased from admission to discharge (pre-intervention group 7 [5-10] to 8 [6-11], \( p < 0.01 \)), (post-intervention group 8 [5-10] to 9 [7-11], \( p < 0.01 \)).

On admission to hospital the post-intervention group had numerically more STOPP START criteria identified on admission to hospital, 2.30 (1.91) compared to the pre-intervention group 1.78 (1.57), \( p = 0.09 \). The mean number of STOPP START criteria upon transfer to the specialised geriatric unit was not found to be significantly different between the pre-intervention group, 1.72 (1.54) and the post-intervention group, 1.59 (1.60), \( p = 0.36 \). For the primary outcome, at hospital discharge, the post-intervention group had numerically less STOPP START criteria 1.18 (1.37) compared to the pre-intervention group 1.50 (1.41), \( p = 0.07 \). The post-intervention group had a 21\% fewer mean number of criteria, or 0.32 less criteria per patient at discharge when compared to the pre-intervention group. The post-intervention group had a larger decrease (26\%) in the mean number of criteria from geriatric unit transfer to discharge compared to the pre-intervention group (13\%).

In this study, we found that inclusion of a pharmacist on a physician-led ward round in a specialised geriatric unit was associated with a numerical improvement in prescribing quality compared to the existing clinical pharmacist service. Both groups had a significant decrease in the number of STOPP START criteria met at discharge when compared to geriatric unit transfer, however this decrease was larger in the post-intervention group. The lower number of criteria in the post-intervention group is encouraging for the involvement of the pharmacist on the physician-led ward round in a specialised geriatric unit and may have clinical significance, but requires testing in a larger cohort of patients.

STOPP START is a validated tool for assessing the appropriateness of prescribing. STOPP criteria have been associated with avoidable ADEs that cause or contribute to hospitalisation in elderly patients\(^{58}\). Previous studies have shown that a pharmacist on physician-led ward rounds can reduce ADEs\(^{92,99}\), improve accuracy of medication histories, reduce prescribing costs and decrease potential risk to patients\(^{96}\). This study has demonstrated that the mean number of STOPP START criteria met by each patient did decrease after a stay in a specialised geriatric unit, and that this decrease is larger when the pharmacist is included on the physician-led ward round. The inclusion of the pharmacist on the physician-led ward round placed the pharmacist where prescribing decisions are made with access to the medication chart. The standard methods of the pharmacist reviewing the medication chart, identifying a potential issue and then discussing with the medical team had numerous barriers – the medication charts were not at the team meetings and outside the
meeting it was often the more junior medical officers available on the ward and they may feel unable to make changes to a patient’s medication without consultant input. The use of STOPP START criteria as a measure of prescribing quality can enable practitioners to assess the value in changes to the model of care. As such, the decrease in STOPP START criteria was an objective measure of a change to the pharmacist model of care. The results of this study add to the literature that pharmacist participation in physician-led ward rounds can improve prescribing quality as measured using STOPP START.

We found that both the pre- and post-intervention groups showed a significant decrease in STOPP START criteria from the time of intra-hospital transfer to the geriatric unit to hospital discharge. The post-intervention group also showed a decrease in STOPP START criteria from hospital admission to transfer to the geriatric unit suggesting that the acute care provided on the medical and surgical wards was associated with a reduction in potentially inappropriate prescribing. It is unclear why the pre-intervention group had no significant decrease in STOPP START criteria during the acute care phase as there were no known differences in the approach to prescribing over the study periods. One explanation could be that the two groups had other, unidentified, differences which influenced the baseline number of STOPP START criteria which were met on admission to hospital. Our observations of the decrease in STOPP START criteria in the geriatric unit is consistent with international results that support the collaboration of a pharmacist and geriatrician to improve prescribing in an inpatient geriatric unit.

The most frequent START criteria observed in both the pre- and post-intervention groups was the use of calcium and vitamin D supplement in patients with known osteoporosis. Calcium and vitamin D supplementation in the treatment of osteoporosis are well accepted in literature and international guidelines and this study period was before concerns were raised regarding the safety of calcium supplementation. During the pre-intervention phase there was no significant change in patient proportions at the different timepoints. In contrast, this amount was significantly different in the post intervention group, there were 28 patients on transfer to the geriatric unit with a diagnosis of osteoporosis with no calcium and vitamin D supplementation which then decreased to 11 at discharge, a considerable improvement in prescribing.

The small but significant decrease in inappropriate benzodiazepine use in the post-intervention group demonstrates potentially appropriate deprescribing in these patients. Deprescribing, or the trial withdrawal of specific classes of medications that may be inappropriate for the individual patient is associated with a reduced incidence of ADEs. Previous data has highlighted multi-
disciplinary medication review by a pharmacist and physician can reduce the rate of potentially inappropriate prescribing in an outpatient clinic setting by targeted deprescribing. The most prevalent STOPP criteria for both groups; proton pump inhibitor (PPI) use for peptic ulcer disease at full therapeutic dosage for > 8 weeks, did not change significantly in either group. There are multiple risks associated with chronic PPI use including an association with a higher fracture rate and increased risk of developing dementia. These risks are particularly relevant to older patients and the high proportions seen in our results represent a potentially missed opportunity for appropriate deprescribing.

An unexpected finding in this study was a significant increase in the median number of medications prescribed between hospital admission and hospital discharge. Both the pre- and post-intervention groups increased the median number of medications per patient by one over this timeframe. Indeed, such increases in ‘appropriate’ prescribing are likely to be advantageous for patients, but in many cases, the prescription of each additional medication above 5 medications per patient increases the risk of medication misadventure. Of course polypharmacy alone is not a clinically useful marker of the quality use of medicines. The medication type and dose, rather than the number of medications, would be more predictive of clinical effects including potential ADEs. In both groups the increased number of medications may be offset by a decrease in the number of STOPP START criteria and improved prescribing quality. An example is the increased number of patients prescribed calcium and vitamin D supplements if they have osteoporosis in the post-intervention group. In the post intervention group there appeared to be an increase in several medications, specifically the prescribing of calcium channel blockers (CCB) (Table 4) this could be due to an increase in patients requiring further control of their blood pressure and increased use of tricyclic antidepressants and opioids for pain (Table 5).

Small sample numbers may have limited the statistical power to detect changes in prescribing quality using the STOPP START criteria. The generalizability of these results is also a study limitation, these results were achieved in a large, metropolitan tertiary hospital with a specialist geriatric team. There were also staff changes to the pharmacist and medical staff during the study period. The experience, communication skills and competencies of the individual pharmacists and prescribers were not investigated during this study however the effect of individual pharmacist or prescriber competencies compared with clinical interventions would be an interesting area of further research.
4.5 Conclusion

In this study, the improved appropriateness of prescribing, as measured by reduced STOPP START criteria in the post-intervention group, are encouraging for pharmacist participation on physician-led ward rounds. We also observed that the collaborative, multi-disciplinary model of care in the specialised geriatric unit also improved prescribing quality for both groups in comparison to the changes made to prescribing within the acute care wards. In conclusion, pharmacist participation on ward rounds has potential to support appropriateness of prescribing in a specialised geriatric unit.
Chapter 5: Thesis Discussion and Conclusion

5.1 Introduction

This Thesis describes the current patterns of potentially inappropriate prescribing in elderly patients who had a hospital admission, before and after the inclusion of a pharmacist on the physician-led ward round in a specialised geriatric unit. The STOPP START tool was used to assess medication prescribing across a patient’s hospital admission, from admission, to transfer to the specialised geriatric or GEM unit and on hospital discharge. The results of these cohort studies are suggestive of a model that supports improved prescribing quality for geriatric patients by combining a collaborative, multi-disciplinary GEM team with pharmacist participation on physician-led ward rounds. This chapter reflects on the key findings of this thesis, limitations of this work and directions for future research before reaching the thesis conclusion.

5.2 Summary of the Key Findings

The aim of this Thesis was to assess the effect of pharmacist ward round participation on prescribing quality as assessed by the STOPP-START tool in hospitalised geriatric patients. A pre- and post-intervention, observational cohort study was used to assess the effect of the addition of the clinical pharmacist to the physician ward round. The STOPP START criteria were applied at three time-points (admission to hospital, transfer to the GEM unit, and on hospital discharge) to assess whether any changes in prescribing quality were present across the hospital admission for both the pre- and post-intervention group. Analysis of the medication prescribing patterns in 196 patients (96 patients in the pre-intervention group and 100 patients in the post-intervention group) identified key trends of potentially inappropriate prescribing as described below.

5.2.1 Description of Prescribing Patterns for Patients Through-out a Hospital Admission

Chapter 3 demonstrated that prescribing quality improves after patient admission to a specialised geriatric unit as there was a decrease in STOPP START criteria between transfer to the geriatric unit and discharge for both this pre-intervention group. The specialised geriatric unit at RBWH has a collaborative multi-disciplinary model including a pharmacist and geriatric physician. Chapter 4 further demonstrated that the post-intervention group also had a decrease in potentially inappropriate prescribing from GEM unit transfer to hospital discharge. This is consistent with previous research
that has showed that a collaborative physician-pharmacist approach to prescribing and medication review in an inpatient geriatric unit led to improved medication appropriateness\textsuperscript{84}.

The pre-intervention group did not show a significant change in prescribing quality from hospital admission to transfer to the GEM unit. The post-intervention group had a significant decrease in mean number of STOPP START criteria from hospital admission to transfer to the GEM unit, however this research did not focus on why this may have occurred.

Our data was also compared with previously published Australian and international data, as detailed in chapter 3. As most of the published data reported a proportion of patients that met at least one criteria this was also evaluated. When the prescribing pattern was reviewed in this manner there was no significant change in prescribing from admission to discharge in the proportions for this group. In the pre-intervention group on admission to hospital, 57% of patients met at least one STOPP criteria and 50% met at least one START criteria and these rates were similar on transfer to the specialised geriatric unit it was 58% and 49% respectively and at discharge was 54% for STOPP criteria and 42% for START criteria. A similar study of Australian hospital inpatients identified 60% of patients had at least one STOPP criteria upon admission to hospital\textsuperscript{63}. Irish studies have identified rates of STOPP criteria between 34-50% in hospital patients and 60% in nursing home patients\textsuperscript{62}. Studies across six European countries (Switzerland, Spain, Ireland, Czech Republic, Italy and Belgium) found an overall rate of 51.3% for STOPP criteria and 59.4% for START criteria for hospital patients\textsuperscript{56}. As this was the first study to follow prescribing across transitions of care using STOPP START, it is hard to make direct comparisons, however these rates appear similar. The post-intervention group did show a trend of decreased proportion of patients meeting at least one STOPP criteria at each time-point; from 64% at admission to 53% on transfer to the specialised geriatric unit to 42% at discharge. Similar proportions were seen for START criteria with 58% of patients meeting at least one START criteria on admission, 44% on transfer to the specialised geriatric unit and 35% at discharge.

A Swedish study found a mean number of STOPP START criteria of 1.85 on hospital admission\textsuperscript{90}. In this Thesis, the mean number of criteria on discharge were 1.0 for the post-intervention group and 2.2 for the pre-intervention group\textsuperscript{90}. These results are similar to the mean number of criteria found in this study; on hospital admission 1.78 for the pre-intervention group and 2.30 for the post-intervention group and on discharge 1.5 for the pre-intervention group and 1.18 for the post-intervention group.
5.2.2 Description of the Number of Medications Prescribed Throughout a Hospital Admission for Elderly Patients

Interestingly, we observed a significant increase in the mean number of medications prescribed on admission (7.3 per patient in the pre-intervention group, 7.9 per patient in the post-intervention group) to that prescribed on discharge, (8.8 per patient in the pre-intervention group, 9.3 per patient in the post-intervention group) for the pre- and post-intervention groups, \( p < 0.01 \). Whilst the number of medications prescribed seems high, polypharmacy alone should not be considered a clinically useful marker of the potentially inappropriate prescribing\(^{22}\). The increased prescribing quality as indicated by a decrease in potentially inappropriate prescribing, as measured using STOPP START criteria, during the hospital admission would suggest that the slight increase in number of medications could indicate more appropriate prescribing.

5.2.3 Evaluation of the Impact of Pharmacist Participation on Physician-led Ward Rounds on Prescribing Quality

Prescribing patterns, namely the mean number of STOPP START criteria met at each time-point in each cohort, were compared between the pre and post intervention group. It was evident that there were less criteria met on discharge for the post-intervention group compared to the pre-intervention group. Whilst this decrease did not reach statistical significance it is likely to be clinically significant. A mean decrease of 0.32 criteria for the post-intervention group compared to the pre-intervention group could translate clinically, for every 3 patients there would be 1 less criteria for potentially inappropriate prescribing. This is likely to be significant as each criteria represents a prescribing situation which has been identified as likely to cause an ADE in this patient population. This is encouraging that pharmacist participation on the physician-led ward round may decrease the amount of potentially inappropriate prescribing. Previous literature had suggested that pharmacist involvement on physician led ward rounds can decrease ADEs in intensive care units\(^{92}\) and general medical units\(^{93,95}\). The decrease in potentially inappropriate prescribing described in Chapter 4, supports a model of care that includes the pharmacist on the physician-led ward round in a specialised geriatric unit.

5.2.4 Comments on Individual Criteria

The most prevalent STOPP criteria for both groups; PPI prescription for peptic ulcer disease at full therapeutic dosage for > 8 weeks is consistent with other study data that showed that PPI use within the wider patient group is very common\(^{103}\). The Royal Australian College of General Practitioners have made the statement: “Don’t use PPIs long term in patients with uncomplicated disease without regular attempts at reducing dose or ceasing” as their leading statement as part of the Choosing Wisely

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Australia initiative\textsuperscript{113}. There are significant risks associated with chronic PPI use including an association with a higher fracture rate\textsuperscript{103}, increased risk of community acquired pneumonia, gastrointestinal infection, interstitial nephritis and nutritional deficiencies\textsuperscript{114} in addition to an increased risk of developing dementia\textsuperscript{104}. These are important reasons why all prescribers should carefully review the use and duration of PPI therapy. The lack of significant change could be viewed as a missed opportunity during the hospital admission for both patient groups.

The small decrease in inappropriate benzodiazepine use in both groups demonstrates appropriate deprescribing in this patient group. The trial withdrawal of specific classes of medications that may be inappropriate for the individual patient, also known as deprescribing, can lead to an improvement in ADEs\textsuperscript{105}. There can also be decreased medication costs to the patient and healthcare system, improved medication adherence and improved patient satisfaction from taking fewer medications\textsuperscript{105}. There is evidence that multi-disciplinary review by a pharmacist and physician can improve the rate of potentially inappropriate prescribing in an outpatient clinic setting by targeting deprescribing\textsuperscript{106}. Of note, the Canadian Deprescribing Group are targeting both benzodiazepines and PPIs to improve prescribing in elderly patients\textsuperscript{115}. Primary Health Tasmania have also included benzodiazepines and PPIs in their deprescribing targets\textsuperscript{116}.

For both the pre- and post-intervention groups the most frequent START criteria was the use of calcium and vitamin D supplement in patients with known osteoporosis. The pre-intervention group showed no significant change in patient proportions at the different time-points. The post-intervention group had a significant decrease from 28 patients on geriatric unit transfer to 11 at discharge, a significant change in prescribing. Calcium and vitamin D supplementation in the treatment of osteoporosis are well accepted in literature and guidelines\textsuperscript{107, 108} and this study period was before concerns were raised in the literature regarding the safety of calcium supplementation\textsuperscript{109}. Such a significant change in prescribing is encouraging and there was anecdotal evidence in the medical notes that the assessment of vitamin D serum levels was prompted by the pharmacist on the ward rounds in a large number of patients.

5.3 Recommendation for Future Research

5.3.1 Expanding Pharmacists on Ward Rounds in Other Clinical Areas
This thesis presents evidence that the inclusion of a pharmacist on ward rounds can lead to potentially increased prescribing quality and less ADEs for patients in a specialised geriatric unit. This adds to
evidence that pharmacist inclusion on ward rounds can improve pharmacotherapy in intensive care units\textsuperscript{92} and general medical units\textsuperscript{93 95}. Future research work would be required to establish if this improved prescribing quality and potential decreased risk of ADEs can be translated to other clinical areas. Also it would be of value to perform qualitative studies to describe why a pharmacist on a ward round confers these apparent benefits. This is especially pertinent as participating on a ward round can be a time consuming and would represent a change in model of care for most clinical pharmacists. Indeed, such benefits may not be realised in all other specialties or clinical areas that do not have the same focus on medications. It would also be of value to further investigate the nature of the communication that occurs during the ward round that makes this setting conducive to making decisions around better prescribing. An extension of this direction could be further qualitative work in evaluating patient preferences around the prescribing decision making, ensuring the patient is the centre of any decision regarding their health.

5.3.2 Decision-Making Around Prescribing Decisions
During the data collection periods it was noted that there were occasions where a pharmacist had suggested a change in prescribing that did not occur, but if it had it may have improved prescribing quality. This suggestion was often communicated through the medication action plan (MAP) or in the patient’s medical notes. The ward rounds occurred once or twice a week and these suggestions may not have been timed to allow their discussion on that ward round. There was also anecdotal evidence during the data collection that indicated the junior medical doctors did not feel empowered to change a patient’s medications, as that decision may have been made by a more senior doctor. Time constraints meant that further qualitative work to investigate the nature of prescribing decision-making was not investigated as part of this thesis but work in this area would provide further direction on how to target interventions to improve prescribing.

With the advances of computer technology towards a paperless hospital with electronic prescribing, it will be of interest to assess the role of computerised medication management support. There is work underway to have STOPP START integrated into a computerised decision support tool to guide more appropriate prescribing, and results of such interventions will be of interest\textsuperscript{61}. Common criteria identified by these results, and other similar studies, could be used to guide targeted interventions on high-profile criteria or medications.

5.3.4 Pharmacist Prescribing
A further interesting future direction would be exploring the impact of pharmacist prescribing on medication appropriateness. In some Canadian provinces where pharmacists can prescribe the
evidence is promising. A pharmacist prescribing model for hypertension resulted in better clinical outcomes, with the intervention group having a greater proportion of patients reach the blood pressure target and the pharmacist prescribing group showed a significant decrease in systolic and diastolic blood pressure. Of interest, the pharmacist prescribing group had more medication changes, pharmacists initiated more hypertension and cardiovascular medications, ceased more medications and had more dose changes than the control group. Similar clinical improvements have been achieved in Canada for pharmacist interventions in cholesterol lowering and pharmacist management of insulin initiation in type 2 diabetes patients. As pharmacist prescribing expands its scope of practice it will be interesting to evaluate if pharmacists can further impact the quality of prescribing in other areas. Clinical improvements are a promising start to more appropriate prescribing and future work could also analyse how this model (pharmacist prescribing) compares to traditional medical, and other non-medical, prescribing in geriatric patients.

5.3.5 Deprescribing

The process of reviewing a patient’s medications; which spans therapy initiation, dose titration, changing or adding drugs, and switching or ceasing drug is part of the good prescribing continuum but may have suffered from a lack of identity. The term “deprescribing” has been proposed as the process of tapering or stopping drugs, aimed at minimizing polypharmacy and improving patient outcomes. A five stage process has been proposed by an Australian network and consists of:

1. Ascertain all drugs the patient is currently taking and the reasons for each one;
2. Consider overall risk of drug-induced harm in individual patients in determining the required intensity of deprescribing intervention;
3. Assess each drug in regard to its current or future benefit potential compared with current or future harm or burden potential;
4. Prioritize drugs for discontinuation that have the lowest benefit-harm ratio and lowest likelihood of adverse withdrawal reactions or disease rebound syndromes;
5. Implement a discontinuation regimen and monitor patients closely for improvement in outcomes or onset of adverse effects.

When this process was applied to patients admitted to an acute medical ward in a large, Australian, tertiary hospital a significant decrease was achieved in the median number of medications with an overall decrease of 34.3%. Whilst the results suggest a positive patient outcome, there was no measure of medication appropriateness or clinical outcomes.

The outlined deprescribing process is consistent with decreasing potentially inappropriate prescribing and improving prescribing quality however the term has been slow to gain traction in the literature.
and in practice. This could be in part due to a lack of familiarity with the term\textsuperscript{123}, however there have been more publications recently in international literature\textsuperscript{121} and Canada has a deprescribing network\textsuperscript{115}. Future research into “deprescribing” as the process is outlined above should give further insight into how the relationship between evidence based medicine and individual patients continues to evolve.

5.4 Limitations

Time and feasibility ensured that data was collected for a total of 196 patients. The end analysis of the primary aim resulted in a non-statistically significant result. Larger patient numbers may have increased the power of this study to demonstrate a significant result.

This Thesis used a retrospective, observational comparison of two groups. It is possible that data may have been missed, particularly as the data collection was passive and did not impact on prescribing at the time. It would be of value to observe the prescribing patterns of the physician-led ward round “live” and explore the nature of the interactions between prescribers, pharmacists, nurses and the patient.

The data collection and analysis of the individual patient’s medication and conditions with the STOPP START criteria was performed by the author and could be a potential source of bias. The STOPP START tool was designed to be explicit and the criteria are written in a way that ensures ease of use. STOPP START has also been shown to have a large degree on inter-user reliability\textsuperscript{64}.

This was a novel topic to examine and there were limited examples in the literature of similar work. To answer the aims of this Thesis, the STOPP START tool was used to measure prescribing quality, not simply detect potentially inappropriate prescribing. The STOPP START tool was designed to be a set of criteria to detect potentially inappropriate prescribing. As a tool, STOPP START may lack the sensitivity required to detect a change in prescribing quality.

The generalisability of these results is also a limitation, as these studies were collected in a large, metropolitan tertiary hospital in Australia with a specialist geriatric team led by consultant geriatricians. Clinical pharmacists in Australia are already involved in many aspects of medication management, such as medication review and reconciliation, and are often working collaboratively with prescribers. Other healthcare settings may differ and as such results may differ if a similar model or intervention is used.
As this Thesis was conducted in a busy healthcare environment there could be other factors that changed during the study that could have affected the results. This could include, but is not limited to, staffing changes, adaptation and more familiarity with models of care and unit management, prescriber changes such as prescribers becoming more competent later in the year with more experience and subtle differences in patient populations that could influence prescribing patterns.

5.5 Conclusion

Specialised geriatric unit admission improves prescribing quality, as measured by less STOPP START criteria on discharge compared to transfer to the geriatric unit for both our cohort groups. Within the geriatric unit patients received multi-disciplinary care with a collaborative approach including a geriatric physician and a pharmacist. This model appears effective in improving prescribing quality. The lesser amount of STOPP START criteria for the post-intervention group is evidence that pharmacist participation on physician ward rounds can improve prescribing quality. This Thesis supports pharmacist participation on ward rounds as a valuable addition to the pharmaceutical care provided by clinical pharmacists. This Thesis provides encouraging evidence that a model of care that combines multi-disciplinary, expert geriatric care in an specialised inpatient unit with the pharmacist directly participating on the physician-led ward round leads to improved medication appropriateness.
References


91. Looi KL, Black PN. How often do physicians review medication charts on ward rounds? BMC Clinical Pharmacology 2008;8(9).


112. Gnijdic D, Hilmer SN, Blyth FM, et al. Polypharmacy cutoff and outcomes: five or more medicines were used to identify community-dwelling older men at risk of different adverse outcomes. Journal of Clinical Epidemiology 2012;65(9):989-95.


Appendix A – Ethics Approval for Pre-Intervention Study

Office of the Human Research Ethics Committee

Enquiries to: Olena Petrun Coordinator
Phone: 07 3646 5419
Fax: 07 3646 5418
Our Ref: HREC/12/QRBW/115
E-mail: RWHM.ethics@health.qld.gov.au

Ms Kelly Mulvogue
Pharmacist
Royal Brisbane & Women’s Hospital

Dear Ms Mulvogue

Re: HREC/12/QRBW/115 DOES Admission to the Geriatric Evaluation And Management Unit Improve the Quality of Prescribing

On behalf of the Royal Brisbane & Women’s Hospital Human Research Ethics Committee, I reviewed the above project on 11.04.12. The Committee is duly constituted, and operates and complies with the National Health and Medical Research Council’s ‘National Statement on Ethical Conduct in Human Research’ 2007.

I have no objections and confirm that this project does not meet the National Statement definition of research and is approved as an audit. As such, a full Committee review is not required.

This project is exempt from full ethical review subject to the following conditions:

- If the project has not commenced within 3 months, please advise the Coordinator, HREC.
  This exemption is valid for 12 months from 11.04.13.

- The project must be carried out in accordance with the National Statement on Ethical Conduct in Human Research 2007.

- Please provide a report on the outcomes of this project on 01.07.13.

- If the results of your project are to be published, please include an appropriate acknowledgment of the relevant department/s who have supported this project.

- The HREC may audit the conduct of any project reviewed under NHMRC guidelines. This may include consultation with the Principal Investigator and/or a visit to the research site by members of the HREC.

The Royal Brisbane & Women’s Hospital Human Research Ethics Committee is constituted and operates according to the NHMRC’s National Statement on Ethical Conduct in Human Research (2007).

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<td>Herston 4029</td>
<td>Queensland 4029 Australia</td>
<td>352 - 617 3495 1490</td>
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I would like to offer you every success for the outcome of the project.

Should you have any queries please contact the Research Ethics office on 07 3646 5490.

Yours sincerely

Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North DISTRICT
11.04.2012
Appendix B – Ethics Approval for Post-Intervention Study

Royal Brisbane & Women’s Hospital
Human Research Ethics Committee

Dear Ms Mulvogue,

Re: Ref No: HREC/15/QRBW/212: Improving the quality of prescribing in elderly hospital inpatients – evaluating the effect of a clinical pharmacist on ward rounds

Thank you for submitting the above research project for single ethical review. This project was received by the Royal Brisbane & Women’s Hospital Human Research Ethics Committee (HREC) (RC101172) on 01 May 2015 and was considered by a sub-Committee of the HREC.

I am pleased to advise that the sub-Committee has approved of this low risk project which will be noted by the RWHH Human Research Ethics Committee at its 15 June 2015 meeting. A further letter will be sent after that meeting.

The manner of consent and breach of the Australian Privacy Principles were considered justified in accordance with National Statement 23.10 and are approved.

For information on submitting a Public Health Act (PHTA) application for the release of confidential health information for research purposes, please visit the Health and Medical Research website at:

The nominated participating site for this project is:

- Royal Brisbane and Women’s Hospital, Qld
Appendix C: Data Collection Tool – Impact of Pharmacist STOPP START

Patient Identification ________________

Age (years): ______________

Sex: Male O Female O

Data Collection Date: _____________

Dates for:
RBWH Admission __________ Admission to GEM unit __________ Discharge __________

Length of Stay (days) Acute: __________ GEM __________

Weight: _______ Height: _______ LBW: _______

Cr: __________ CrCl: _______

Presenting Complaint: _______________________________________________________________

Medical History: _________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________
______________________________________________________________________________

Allergies: ________________________________________________________________

Admission Residence: Home O Independent Living O Carer’s Home O Hostel O Nursing Home O

Number of Medications:
Admission: ___________ GEM Admission ___________ Discharge _____________
### Admission:

**STOPP Medications Identified**

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### GEM Admission

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Comments (if a medication is stopped or started describe who initiated the change)

________________________________________________________________________________
________________________________________________________________________________
__________________

**Discharge Destination:**
- Residential Transition Care O
- Community Transition Care O
- Home O
- Independent Living O
- Carer’s Home O
- Independent Living O
- Hostel O
- Nursing Home O

Medication Cost ($):
- Admission_________________
- GEM Admission_________________
- Discharge_________________

**30 day readmission:** Yes O  No O
Appendix D: STOPP: Screening Tool of Older People’s potentially inappropriate prescriptions.

The following drug prescriptions are potentially inappropriate in persons aged 65 years.

A Cardiovascular system
1. Digoxin at a long-term dose >125 mg day⁻¹ with impaired renal function*.
2. Loop diuretic for dependent ankle oedema only, i.e. no clinical signs of heart failure.
3. Loop diuretic as first-line monotherapy for hypertension.
4. Thiazide diuretic with a history of gout.
5. Noncardioselective b-blocker with chronic obstructive pulmonary disease (COPD).
6. b-Blocker in combination with verapamil.
7. Use of diltiazem or verapamil with New York Heart Association Class III or IV heart failure.
8. Calcium channel blockers with chronic constipation.
9. Use of aspirin and warfarin in combination without histamine H2 receptor antagonist (except cimetidine because of interaction with warfarin) or proton pump inhibitor (PPI).
11. Aspirin with a past history of peptic ulcer disease without histamine H2 receptor antagonist or PPI.
12. Aspirin at dose >150 mg day⁻¹.
13. Aspirin with no history of coronary, cerebral or peripheral vascular symptoms or occlusive event.
14. Aspirin to treat dizziness not clearly attributable to cerebrovascular disease.
15. Warfarin for first, uncomplicated deep venous thrombosis for >6 months’ duration.
16. Warfarin for first uncomplicated pulmonary embolus for >12 months’ duration.
17. Aspirin, clopidogrel, dipyridamole or warfarin with concurrent bleeding disorder.

*Serum creatinine >150 mmol l⁻¹, or estimated glomerular filtration rate (GFR) <50 ml min⁻¹.

B Central nervous system and psychotropic drugs
1. Tricyclic antidepressants (TCAs) with dementia.
2. TCAs with glaucoma.
3. TCAs with cardiac conductive abnormalities.
4. TCAs with constipation.
5. TCAs with an opiate or calcium channel blocker.
6. TCAs with prostatism or prior history of urinary retention.
7 Long-term (i.e. >1 month), long-acting benzodiazepines, e.g. chlordiazepoxide, flurazepam, nitrazepam, chlorazepate and benzodiazepines with long-acting metabolites, e.g. diazepam.
8 Long-term (i.e. >1 month) neuroleptics as long-term hypnotics.
9 Long-term neuroleptics (>1 month) in those with parkinsonism.
10 Phenothiazines in patients with epilepsy.
11 Anticholinergics to treat extrapyramidal side-effects of neuroleptic medications.
12 Selective serotonin re-uptake inhibitors (SSRIs) with a history of clinically significant hyponatraemia.
13 Prolonged use (>1 week) of first-generation antihistamines, i.e. diphenhydramine, chlorpheniramine, cyclizine, promethazine.

C Gastrointestinal system
1 Diphenoxylate, loperamide or codeine phosphate for treatment of diarrhoea of unknown cause.
2 Diphenoxylate, loperamide or codeine phosphate for treatment of severe infective gastroenteritis, i.e. bloody diarrhoea, high fever or severe systemic toxicity.
3 Prochlorperazine (Stemetil) or metoclopramide with parkinsonism.
4 PPI for peptic ulcer disease at full therapeutic dosage for >8 weeks.
5 Anticholinergic antispasmodic drugs with chronic constipation.

D Respiratory system
1 Theophylline as monotherapy for COPD.
2 Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate–severe COPD.
3 Nebulized ipratropium with glaucoma.

E Musculoskeletal system
1 Nonsteroidal anti-inflammatory drug (NSAID) with history of peptic ulcer disease or gastrointestinal bleeding, unless with concurrent histamine H2 receptor antagonist, PPI or misoprostol.
2 NSAID with moderate–severe hypertension.
3 NSAID with heart failure.
4 Long-term use of NSAID (>3 months) for symptom relief of mild osteoarthritis.
5 Warfarin and NSAID together.
6 NSAID with chronic renal failure*.
7 Long-term corticosteroids (>3 months) as monotherapy for rheumatoid arthritis or osteoarthritis.
8 Long-term NSAID or colchicine for chronic treatment of gout where there is no contraindication to allopurinol.
*Serum creatinine >150 mmol l⁻¹, or estimated GFR 20–50 ml min⁻¹.

F Urogenital system
1 Bladder antimuscarinic drugs with dementia.
2 Antimuscarinic drugs with chronic glaucoma.
3 Antimuscarinic drugs with chronic constipation.
4 Antimuscarinic drugs with chronic prostatism.
5 a-Blockers in men with frequent incontinence, i.e. one or more episodes of incontinence daily.
6 a-Blockers with long-term urinary catheter in situ, i.e. >2 months.

G Endocrine system
1 Glibenclamide or chlorpropamide with Type 2 diabetes mellitus.
2 b-Blockers in those with diabetes mellitus and frequent hypoglycaemic episodes, i.e. >1 episode per month.
3 Oestrogens with a history of breast cancer or venous thromboembolism.
4 Oestrogens without progestogen in patients with intact uterus.

H Drugs that adversely affect fallers
1 Benzodiazepines.
2 Neuroleptic drugs.
3 First-generation antihistamines.
4 Vasodilator drugs with persistent postural hypotension, i.e. recurrent >20 mmHg drop in systolic blood pressure.
5 Long-term opiates in those with recurrent falls.

I Analgesic drugs
1 Use of long-term powerful opiates, e.g. morphine or fentanyl as first-line therapy for mild–moderate pain.
2 Regular opiates for >2 weeks in those with chronic constipation without concurrent use of laxatives.
3 Long-term opiates in those with dementia unless indicted for palliative care or management of moderate–severe chronic pain syndrome.
Duplicate drug classes
Any duplicate drug class prescription, e.g. two concurrent opiates, NSAIDs, SSRIs, loop diuretics, ACE inhibitors.

START: Screening Tool to Alert doctors to Right, i.e. appropriate, indicated but often omitted treatments.

These medications should be considered for people >65 years of age with the following conditions, where no contraindication to prescription exists.

A Cardiovascular system
1 Warfarin in the presence of chronic atrial fibrillation (AF).
2 Aspirin in the presence of chronic AF, where warfarin is contraindicated, but not aspirin.
3 Aspirin or clopidogrel with a documented history of atherosclerotic coronary, cerebral or peripheral vascular disease in patients with sinus rhythm.
4 Antihypertensive therapy where systolic blood pressure consistently >160 mmHg.
5 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.
6 Angiotensin converting enzyme (ACE) inhibitor with chronic heart failure.
7 ACE inhibitor following acute myocardial infarction.
8 beta-Blocker with chronic stable angina.

B Respiratory system
1 Regular inhaled b2 agonist or anticholinergic agent for mild to moderate asthma or chronic obstructive pulmonary disease (COPD).
2 Regular inhaled corticosteroid for moderate–severe asthma or COPD, where predicted forced expiratory volume in 1 s <50%.
3 Home continuous oxygen with documented chronic type 1 respiratory failure (pO2 < 8.0 kPa, pCO2 < 6.5 kPa) or type 2 respiratory failure (pO2 < 8.0 kPa, pCO2 > 6.5 kPa).

C Central nervous system
1 L-DOPA in idiopathic Parkinson’s disease with definite functional impairment and resultant disability.
2 Antidepressant drug in the presence of moderate–severe depressive symptoms lasting at least 3 months.

D Gastrointestinal system
1 Proton pump inhibitor with severe gastro-oesophageal acid reflux disease or peptic stricture requiring dilation.
2 Fibre supplement for chronic, symptomatic diverticular disease with constipation.

E Musculoskeletal system
1 Disease-modifying antirheumatic drug with active moderate–severe rheumatoid disease lasting >12 weeks.
2 Bisphosphonates in patients taking maintenance corticosteroid therapy.
3 Calcium and Vitamin D supplement in patients with known osteoporosis (previous fragility fracture, acquired dorsal kyphosis).

F Endocrine system
1 Metformin with Type 2 diabetes metabolic syndrome (in the absence of renal impairment*).
2 ACE inhibitor or angiotensin receptor blocker in diabetes with nephropathy, i.e. overt urinalysis proteinuria or microalbuminuria (>30 mg per 24 h) serum biochemical renal impairment*.
3 Antiplatelet therapy in diabetes mellitus with co-existing major cardiovascular risk factors (hypertension, hypercholesterolaemia, smoking history).
4 Statin therapy in diabetes mellitus if coexisting major cardiovascular risk factors present.
* Serum creatinine > 150 mmol l-1, or estimated GFR < 50 ml min-1.