Perioperative Medication Management–Expanding the Role of the Pre Admission Clinic Pharmacist in a Single Centre, Randomised Controlled trial of Collaborative Prescribing

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-003027.R1
Article Type:	Research
Date Submitted by the Author:	24-May-2013
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Surgery, Health services research
Keywords:	Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Adult surgery < SURGERY

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Keywords: Allied health, Pharmacy, Non-medical prescribing, Pharmacist prescribing, Safe prescribing

Word Count :

Abstract 271

Main text 3182

Article Summary

Article Focus

- A doctor-pharmacist collaborative prescribing model provides as least as high a quality of care as usual care, with regards to safety, access, appropriateness, effectiveness, efficiency and consumer participation
- Workforce shortages are prompting a review of the way that the current workforce is utilised, and whether different roles could be taken on by healthcare professionals to alleviate some of the pressures within the system.
- Research on non medical prescribing so far is predominantly qualitative in nature. Our study has analysed quantitative data on safety, accuracy and appropriateness of prescribing to try and assess whether this model is at least as good as usual care.

Key Messages

- Pharmacists' skills in medication management are currently underutilised, and with appropriate training and education they could be contributing to medication management much more effectively by taking on a prescribing role.
- The prescribing is collaborative, and driven by guidelines and under the supervision of a medical team. Diagnosis is not within the scope of practice of the prescribing pharmacist.
- This model of care has been proved to be highly effective in this study, with an increased accuracy, safety and appropriateness of prescribing within the intervention arm

Strengths and Limitations

- The results, with regards to accuracy and safety of medication charts produced in the study are emphatic and statistically significant.
- The intervention is reproducible in other setting with a pharmacist of appropriate experience, training and education.

- The study assessed one pharmacist prescriber versus a cohort of medical prescribers. While this has been accounted for in the analysis, this reflects what usual practice would be in a model care such as this. The authors recognise and acknowledge it as a limitation.

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ABSTRACT

Objectives: Current evidence to support non-medical prescribing is predominantly qualitative, with little evaluation of accuracy, safety and appropriateness. Our aim was to evaluate a new model of service for the Australia healthcare system, of inpatient medication prescribing by a pharmacist in an elective surgery pre admission clinic (PAC) against usual care, using an endorsed performance framework.

Design: Single centre, randomised controlled, two arm trial

Setting: Elective surgery pre admission clinic in Brisbane based tertiary hospital

Participants: Four hundred adults scheduled for elective surgery were randomised to intervention or control.

Intervention: A pharmacist generated the inpatient medication chart to reflect the patient's regular medication, made a plan for medication perioperatively and prescribed VTE prophylaxis.

In the control arm, the medication chart was generated by the Resident Medical Officers (RMO).

Outcome Measures: Primary outcome was frequency of omissions and prescribing errors when compared against the medication history. The clinical significance of omissions was also analysed.

Secondary outcome was appropriateness of VTE prophylaxis prescribing.

Results: There were significantly less unintended omissions of medications: 11 of 887 (1.2%) intervention orders compared with 383 of 1217 (31.5%) control (p<0.001).

There were significantly less prescribing errors involving selection of drug, dose or frequency: 2 in 857 (0.2%) intervention orders compared with 51 in 807 (6.3%) control (p<0.001).

Orders with at least one component of the prescription missing, incorrect or unclear occurred in 208 of 904 (23%) intervention orders and 445 of 1034 (43%) control (p<0.001).

VTE prophylaxis on admission to the ward was appropriate in 93% of intervention patients and 90% control (p=0.29).

Conclusion: Medication charts in the intervention arm contained fewer clinically significant omissions, and prescribing errors, when compared to control.

There was no difference in appropriateness of VTE prophylaxis on admission between the two groups.

Trial Registration: Registered with ANZCTR – ACTR Number ACTRN12609000426280

INTRODUCTION

Prescribing involves four stages; information gathering, clinical decision making, communication of decision and monitoring.[1] Taking a medication history, continuing, ceasing and withholding of medications, and initiating new medications are critical components of prescribing associated with an admission for surgery. Medication errors are common, occur most often at the time of prescribing, and frequently on the day of hospital admission, resulting in discrepancies between regular medications and admission orders.[2-4] A small, but significant, proportion of errors result in adverse drug events (ADEs).[5] Errors have been defined as when when there is "*a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.*"[6] To be able to communicate a clinical decision safely and effectively in the form of a written prescription, it is necessary for selection of the correct drug, together with the route, form, dose, frequency and duration.[7] Multiple interventions have been suggested in an attempt to improve prescribing, with suggestions that increased training of the individual, a controlled environment and a change in organisational culture are necessary.[8]

Within hospital, the medication chart provides instructions for safe medication supply and administration, and ensures patient access to medications as an inpatient. It is an integral part of communication between doctors, pharmacists and nurses about prescribing decision and is used as the primary source of information regarding medications on discharge. The pharmacy service in Princess Alexandra Hospital (PAH) PAC began in 1998, to provide timely, accurate and comprehensive information about medication as patients crossed between healthcare settings. It ensured accurate transfer of information at admission, during the inpatient stay and at discharge, the benefits of which were a reduction in both readmissions and contact with community healthcare providers post discharge.[9] The importance of accurate transfer of information across the whole surgical care pathway from preadmission to discharge, including information about medications, has been highlighted in a recent study that reported communication failures led to patient morbidity and mortality. Standardisation and systemisation of communication processes, along with other interventions targeted at the entire surgical pathway were recommended, with a view to improving information transfer and quality of care.[10]

Pharmacists in pre admission clinics (PAC) have been shown to improve the accuracy of medication histories and medication orders, when compared to standard care, and the efficacy of prescribing

perioperatively in line with recognised guidelines.[11,12] Only with an accurate history of medication usage can decisions be made safely regarding management of medications perioperatively. Medication histories are elicited from a variety of sources of information; patient's own medications, the patient or carer, GP summaries, community pharmacies, previous hospital admissions and nursing home records. A number of sources may be consulted to build an accurate record of medication that the patient is taking, both regularly and occasionally.

The range of prescribers has been expanded in a number of countries, with changes in legislation to allow for extension of prescribing privileges to non-medical professionals, including pharmacists.The objective of this was to make greater use of the skills and specialisation of pharmacists so that a more flexible system for the prescribing, supply and administration of medicines could be developed, whilst maintaining safe and appropriate access to medicines .[13,14]

In response to documented workforce shortages in Australia, Brooks *et al* described possible solutions, including 'task substitution', and a focus has been placed recently on non-medical prescribers within the healthcare system.[15-19] Pharmacists, with training in pharmacology and therapeutics, are potentially well placed to undertake prescribing roles. An Australian study identified the main driver behind pharmacist prescribing as the desire to work collaboratively with medical and nursing staff to:

• provide consumers with improved, responsible and safe access to prescription medicines

• optimise use of pharmacists' and doctors' skills and time

• reduce inefficient use of health resources.[20]

Evidence to support non-medical prescribing so far has been mainly qualitative, with minimal evaluation of access, safety and appropriateness. One recent review concluded acceptability of non-medical prescribing services is based on the perceived value to the health service.[21] This lack of evidence has led to calls to prove the safety and effectiveness of non-medical prescribing services in Australia.[22] The aim of the data analysis discussed in this paper was to compare a doctor – pharmacist collaborative prescribing model with usual care, with regards to safety, access, appropriateness and effectiveness; the null hypothesis being that no difference exists between the two models of care.[23]

METHODS

The study was conducted between June to September 2009 in the surgical PAC at PAH, a 750 bed tertiary teaching hospital in Queensland.

Ethics approval was obtained from the PAH Human Research Ethics Committee.

The definition of error used in the study was:

"*a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.*"[3]

All patients who attended PAC and could provide written, informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery (see Figure 1)

Patients were approached on arrival at clinic and written consent was obtained. After consent, patients were randomised using a computer generated randomisation list, in blocks of ten (Microsoft Excel). Sealed envelopes (not prepared by the recruiting researcher) contained a zero or one as per the computer list; the next envelope was opened after consent to determine whether a patient entered the control or intervention arm respectively. If a patient had been randomised, and surgery cancelled during PAC, the patient was removed from the study and not replaced.

A previous pilot study in PAC showed an error rate of 1**2**% of orders.[24] Using an expected error rate of 8% in the intervention arm a sample size of 932 orders per group was calculated to be required for a power of 80%. Assuming an average of 5 orders per patient, approximately 200 patients per arm would be required.

Only one pharmacist in PAC, with three years' experience as a hospital pharmacist and having a postgraduate diploma in clinical pharmacy, was trained to be a prescriber. The pharmacist attended a prescribing course which was accredited by the General Pharmaceutical Council, UK as an Independent Pharmacist Prescribing Course.[25]

Training included a minimum of 12 days of 'period of learning in practice' under a 'designated medical practitioner' (DMP), who was the consultant anaesthetist for PAC. The training included case studies and sessions on venous thromboembolism (VTE) prophylaxis with a consultant vascular physician and the clinical nurse consultant (CNC) for VTE prophylaxis at PAH. The DMP endorsed the pharmacist's competency to prescribe before the study could commence.

For the pilot, an amendment was facilitated to the *Queensland Health (Drugs and Poisons) Regulation 1996* to allow 'Pharmacists registered in Queensland who are employed or contracted to Queensland Health and working in the Pharmacist Prescribing Pilot' to prescribe controlled drugs, restricted drugs and Schedule 2 and 3 poisons.

Intervention Cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients had to be seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a countersignature of the pharmacist prescriptions, a site requirement.

The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the medication chart. The scope of prescribing was continuing or withholding regular medications and prescribing VTE prophylaxis according to local and national guidelines, following a risk and contraindication assessment.[26]

Directors of surgery were consulted prior to commencement of the trial for permission to include patients in prescribing of VTE prophylaxis, according to their specific unit guidelines, which had been defined in advance in collaboration with the CNC for VTE prophylaxis at PAH. Urology and renal transplant patients were excluded (N=43 control, N=34 intervention) from VTE prophylaxis prescribing as the director of urology was unavailable to confirm the scope of the project, and the director for transplant requested exclusion on the grounds that VTE prophylaxis in these patients being more consultant discretion as opposed to guideline driven.

Control Cohort

Patients were seen by all four health care professionals in clinic, in no particular order, as per usual care. Either pharmacist in the clinic saw control patients for documentation of medication history. The prescribing of the medication chart was the responsibility of the RMO. In both arms, review and monitoring was undertaken, both by the RMOs in clinic at countersignature and by RMOs and clinical pharmacists at a ward level once the patient was admitted. Changes made by RMOs to intervention patient medication charts in clinic were recorded.

Outcome Measures

The primary endpoint for the study was the accuracy of medication charts, with regards to concordance of the medication chart with the medication history, the plan for medications perioperatively and the quality of the individual orders related to legality and safety for administration purposes. The secondary endpoint was the appropriateness of prescribing for both chemical and mechanical VTE prophylaxis according to local and national guidelines.[26]

Analysis of scanned copies of medication charts, for the primary outcomes of omissions and errors, was conducted in tandem by two assessors;one member of the research team and one external assessor, both trained in use of the validated audit tools[1] and blinded to randomisation. Any ambiguities were clarified by consensus.

Appropriateness of VTE prophylaxis prescribed in both arms in clinic was analysed, using scanned copies of medication charts, in tandem by two assessors; one member of the research team and the Clinical Nurse Consultant (CNC) for VTE prophylaxis at PAH. Prescribing was also assessed on admission to the ward to ensure VTE prophylaxis was appropriate.

An expert panel, comprising of a surgeon, clinical pharmacologist, anaesthetist, RMO, pharmacist and a nurse, was convened to assess the clinical significance of omissions in a randomly selected 5% sample of the total cohort of patients from both arms (N=10 control, N=9 intervention). Panel members were blinded to randomisation.

Tables 1 and 2 describe the collection methods and definitions of these endpoints.

Table 1 – Analysis to assess accuracy and safety of medication charts generated in the study

Measure	Definition	Method	Assessing
Omissions	Medication in	Every	Whether or not

	patient's medication history not prescribed on medication chart, with no reason documented in patient chart	medication in patient's medication history checked against medication chart - omissions from medication chart noted	medication is prescribed
Prescribing Errors	Anomaly in drug name, strength, dose, frequency or route, with no documentation in patient chart	Every medication in patient's medication history checked against medication chart – anomalies noted	Whether or not prescription is accurate in terms of drug name, strength, dose, frequency and route
Communication Errors	Unclear prescription in terms of name, route, dose, frequency, slow release medication notification or intermittent order prescribing	Every prescription written checked using validated tool – unclear prescribing noted, as agreed by both researchers	Whether or not prescription is safe for administration purposes

Table 2 – Analysis to assess accuracy of VTE risk and contraindication assessments and appropriateness of VTE prescribing

Measure	Definition	Method	Assessing
VTE Risk Assessment	Patient categorised in to low or high risk for VTE, as per guidelines	Every patient medical record checked for a documented VTE risk assessment	Risk assessment documented Y/N Risk assessment correct Y/N
VTE Contraindication Assessment	Patient highlighted as inappropriate for mechanical or chemical prophylaxis, as per guidelines	Every patient medical record checked for a documented contraindication assessment	Contraindication assessment documented Y/N Contraindication assessment correct Y/N
VTE prescribing	Whether patient prescribed mechanical and/or chemical VTE prophylaxis, as per guidelines	Prescribing of mechanical and chemical VTE prophylaxis checked against agreed local and national guidelines	VTE prescribing appropriate according to guidelines and individual patient factors Y/N

Categorical data was compared using chi-square tests for independence. When any one cell had a count of less than tenFisher's exact test was substituted. . Logistic regression was used to analyse the overall omissions between the two groups. The number of regular and 'prn' medications the patient was currently taking was included as an explanatory variable in the model as it was deemed more likely an individual medication would be omitted in a patient taking a large number of medications. Logistic regression was also used to analyse the overall communications prescribing errors between the two groups. The assumption of independence between observations is clearly violated as multiple observations exist for most subjects. As such, robust standard errors clustered by patient were calculated. No other covariates were adjusted for. All reported p values are two-sided using a level of significance of 0.05. All statistical analysis and sample size calculations was conducted using Stata 11.2 (StataCorp, College Station, Tx).

RESULTS

Table 3 Characteristics of Study Population

The demographics of the patients randomised in to the trial were similar, except for the higher number of medications taken by patients in the control arm (See Table 3)

	Control	Intervention
Total Patients	190	194
Age ‡	57.6 [18-89]	55.8 [18-86]
Male (%)	58%	59%
*Regular Medications†	4[0-16]	3[0-18]
#When Required 'PRN' Medications†	2[0-7]	1[0-4]
Complementary and Alternative Medicines (CAM) †	(0)[0-9]	(0)[0-6]
Over The Counter (OTC) Medications†	(0)[0-2]	(0)[0-2]
Total Medications	1364	983
Total medications (regular and prn only)	1217	887
Medication Charts Prescribed	161 (85%)	194 (100%)

‡ mean [range]

† median [range]

*Regular medications are defined as medications prescribed with the intent to be taken on a regular basis

#Pro Re Nata (PRN) medications are defined as medications prescribed with the intent to be taken only when required

Omissions

Total unintentional medication omissions from medication charts was higher for control patients (31.5%) compared to intervention (1.2%) The odds ratio for an order in the control group to be omitted, compared to the intervention group was 41.0 (95% CI 20.6 – 81.8) (p<0.001 logistic regression) after adjusting for the number of medications the patient was currently taking. (see Table

4 and Figure 2) There were 59 prescribers in the control arm, 54 of whom reviewed patients who were currently taking regular or PRN medications at home, and as such had the opportunity to omit a patient's medication. Out of these 54 prescribers, the median percentage of medications that were omitted per prescriber in the control arm was 21 (range 0 - 100).

Table 4: Medication omissions from medication chart

Type of Medication and Perioperative Plan	Control (N)[%]	Intervention(N)[%]
Regular		
Continue	179 (805)[22.2]	3 (620)[0.5]

Withhold prior to surgery	46(75)[7.4]	0(48)
Withhold on morning of surgery	21(54)[38.9]	0(39)
Adjust dose	1(5)[20.0]	0(5)
Review	1(7)[14.2]	0(6)
Cease	0(1)	0(2)
PRN		
Continue	128(248)[51.6]	6(142)[4.2]
Withhold prior to surgery	7(12)[58.3]	2(13)[15.4]
Adjust dose	0(2)[20.0]	0(1)
Review	0(8)[14.3]	0(11)
Total Omissions	383(1217)[31.5]	11(887)[1.2]
***Complementary and Alternative Medicines (CAMs)**	126	87
***Over The Counter Medications (OTC)**	21	9

*CAM and OTC medications were not classed as omissions in either arm if not prescribed on the inpatient medication chart

Clinical Significance of Omissions

Omissions from a randomly selected 5% of the total cohort were evaluated for clinical significance. Out of 89 regular medication in the patients' medication histories in the control arm, 25 (28%) were omitted from the medication charts, compared to 1 out of 55 (2%) in the control arm . When asked to assess the severity of omission, the average across the panel showed 52% of omissions in the control arm had the potential for patient harm or ward inconvenience (see Figure 3) Only one reviewer thought the omission in the intervention arm was significant.

Prescribing Errors Related to Drug, Dose and Frequency Selection

Overall, 53 errors were identified where the drug strength, dose or frequency prescribed did not match the medication history or perioperative plan (see Figure 4). This equates to 4.9% of control orders compared to 0.2% of intervention orders ($p<0.001$, Fisher's exact).

Communication Errors

Communication errors, where prescriptions were rated as ambiguous or unclear, were significantly higher in the control arm compared to the intervention arm. The odds ratio for an order in the control arm to have a communication error compared to an order in the intervention arm was 2.52 (95%CI 1.96 – 3.27) (logistic regression $p<0.001$). As there were multiple orders per patient, robust standard errors, clustered by patient were utilised(see Table 5). Individually, communication errors were significantly higher in the control arm for all types of error except route of administration ($p=0.57$ chi-square).

From the control arm prescribers, 44 of them prescribed medication on the medication charts, with a median number of orders of 21 (range 1 - 85). The median percentage of orders in the control arm that contained at least one communication error per prescriber was 38 (range 0 - 100).

Table 5: Prescribing errors with an ambiguity in at least one component of the prescription

	Control Number of errors (% of total orders)	Intervention Number of errors (% of total orders)	P value
Total Orders	1034	904	
Orders with at Least One Communication Error	445(43)	208(23)	<0.001 Π †
Prescribing Communication Errors	667	229	
Prescribing Communication Errors			

Drug name	23 (2.1)	0	<0.001‡
Route	79 (7.6)	76 (8.4)	0.57†
Dose	48 (4.6)	5 (0.6)	<0.001‡
Frequency	190 (18.4)	96 (10.6)	<0.001‡
Administration times incorrect or missing	117 (14.9) (781 orders)	4 (0.5%) (762 orders)	<0.001‡
prn max dose missing	178 (74.5) (241 orders)	47 (32.6) (142 orders)	<0.001‡
Slow Release not specified	15 (30.0) (50 orders)	1 (1.5) (66 orders)	<0.001‡
Intermittent order not specified	17 (57.5) (30 orders)	0 (38 orders)	<0.001‡

Π Logistic regression

† Chi-Square

‡ Fisher's Exact

Venous Thromboembolism (VTE) Prophylaxis

Patients in the intervention arm were significantly more likely than controls to have appropriate VTE prophylaxis prescribed on the medication chart in PAC and to have documented VTE assessment (see Figure 5). On admission to the ward, approximately 90% of both intervention and control patients were prescribed appropriate VTE prophylaxis.

DISCUSSION

This study has built on the findings from previous research of pharmacist prescribing in PAC settings, which have found improved accuracy of information gathered, and improved prescribing according to

guidelines.[9,27] Similar studies of pharmacist interventions in different settings have shown improvements in clinical endpoints such as blood pressure control, increased appropriateness of prescribing and reductions in adverse drug events, such as warfarin associated bleeds.[28,29]

The traditional scope of practice for the PAC pharmacist consists of taking a medication history, using guidelines, clinical judgement and referral to the surgical team to suggest a plan for medications perioperatively, and providing this information for the RMOs to generate the medication charts. This scope has been extended in our study by providing an appropriately trained pharmacist to generate the medication chart and prescribe VTE prophylaxis, which has led to a significant reduction in omissions and prescribing errors, ensuring patients get the correct medication whilst in hospital. The evaluation of VTE prophylaxis prescribing was essential to assess the safety and appropriateness of initiation of a new medication, within guidelines, by the prescribing pharmacist. The results from this study have shown the prescribing to be as appropriate as usual care at the time the patient is admitted to the ward. Issues still remain with the prescribing, especially with the use of inappropriate abbreviations.[30] For example, a large proportion of communication errors in the intervention arm were due to the use of s/c to indicate subcutaneous, which has informed the researchers on future educational requirements of prescribers, especially with regards to safe prescribing.

Electronic prescribing may be one solution to such errors involving legibility and inappropriate abbreviations, but studies have shown the systems introduce errors of their own.[31] These errors need to be fully assessed and appreciated if the quality of prescribing is to be improved by the introduction of computerised prescribing in to the healthcare system.

The results presented in this paper are part of a larger study, further work is required to assess the appropriateness of prescribing of medication charts and consumer participation of this new model of care.[23]There are a number of limitations. Even though the trial was randomised, the total number of medications patients were taking was higher in the control arm (1364) compared to the intervention arm (983). The explanation for this is unknown but may in part be due to large randomisation block sizes, possibly meaning a number of consecutive patients were randomised to the control arm during clinic sessions where patients were more likely to have a higher burden of medication, for example during a vascular surgery clinic. There was more opportunity for omissions from the control arm as a result of more medications needing to be continued, and this was allowed for in the analysis.

RMOs in clinic during the study were aware of the intervention pharmacist's role, which may have led to an increased number and quality of medication charts prescribed in the control arm. Even with this potential effect, the study still showed a significant improvement in the safety and accuracy of medication charts.

Review of medication orders is not a role a RMO routinely undertakes. All RMOs were educated with regards to the requirement for a countersignature of pharmacist orders, and to amend anything as required prior to sign off. In the trial, 10 charts were amended – 5 changes were minor, 3 were addition of analgesics out of the pharmacist's prescribing scope and two changes actually resulted in inappropriate VTE prophylaxis. Despite the legislative changes, countersignature of pharmacist orders was a local requirement owing to the concern that junior doctors may become deskilled as a result of being removed from the prescribing process. However, the authors suggest that having an appropriately trained prescribing pharmacist in clinic, for the RMOs to use as guidance and to feedback on any prescribing errors, may increase the effectiveness of the learning environment.

Only having one pharmacist prescribing in the intervention arm, and multiple RMOs prescribing in the control arm is a potential source of bias, unavoidable where individual knowledge, skills and capabilities determine the quality of prescribing. It has been suggested medical undergraduate training may not prepare graduates to prescribe, which if addressed, may reduce this individual variance.[32] The model of care tested in our study was successful as we were able to reduce the variance within a group by training one individual pharmacist to manage medications perioperatively, within a set scope of practice, and to include prescribing. It could be argued that the same results may have been obtained by providing the RMOs with extra prescribing training, and the improved performance may not necessarily be solely down to the introduction of a new professional discipline. The authors acknowledge the improved results may well be multi-factorial, but would also suggest that the underlying competencies of an experienced, 'advanced level' pharmacist, plus the prescribing training provided, have ensured appropriate competencies to prescribe in the model of care in which the prescribing took place.[33]

The order of consultation in the intervention arm was set by trial design. The order in the control arm was not set, which is a true reflection of usual care, where the patient could see the RMO prior to the pharmacist. This may have impacted on quality of control medication charts prescribed by the RMO, without information available from the pharmacist history. Whilst this could be classed as a limitation,

this does reflect usual care in PAC and highlights the collaborative nature of the existing model of care.

The prescribing pharmacist was able to see control patients for usual care duties of a medication history, which may be perceived as introducing bias. However, as both pharmacists have received the same undergraduate and general level pharmacist training, the quality of medication history gathered for the RMO to use to prescribe the medication chart would be the same.

Another limitation is the potential sustainability of the model of care, and capacity to train pharmacists as prescribers. This was only one pharmacist, in one hospital who had received special training to be able to prescribe. Evaluation of the requirements of non-medical prescribing courses is underway, but substantial further thought needs to be applied to ensure reproducibility of these results, in a larger sample, and consistent production of safe and effective prescribers.[34]

Further work is required to address the actual and perceived medico-legal implications for both doctors and pharmacists in such collaborations.

CONCLUSION

Medication charts in the intervention arm were significantly safer and more accurate with regards to the patients' regular medications, than medication charts in the control arm.

There was no difference in appropriateness of VTE prophylaxis prescribing between arms on admission to the ward.

Our study has shown the pharmacist in PAC was able to effectively gather all the information required to collaboratively formulate a clinical decision in clinic within an agreed scope of practice, and communicate the decisions safely and accurately onto the medication chart.

A collaborative doctor – pharmacist prescribing model in a PAC was as safe and accurate as usual care, in ensuring that patients were prescribed the medication required on admission for elective surgery.

Acknowledgements

The authors would like to acknowledge the following people, without whom the study would not have been possible.

Professor Stephen Lynch, Chair of Surgery, Princess Alexandra Hospital

A/Prof Lynette Loy, Director of Pharmacy, Princess Alexandra Hospital

Ms Ching-Ting Hung, Senior Pharmacist, Princess Alexandra Hospital
Ms Renea Collins, Clinical Nurse Consultant, VTE Prophylaxis, Princess Alexandra Hospital
All of the staff in Pre Admission Clinic

Competing Interests

There are no competing interests to be declared for any of the authors

Funding

There was no external funding received for the study.

Contributorship

Contributorship and guarantorship are concepts that were applied first to original research papers, and are sometimes hard to define for other articles. Each contributorship statement should make clear who has contributed what to the planning, conduct, and reporting of the work described in the article, and should identify one, or occasionally more, contributor(s) as being responsible for the overall content as guarantor(s)

Andrew Hale, Ian Coombes, Julies Stokes, Karen Whitfield, Elizabeth Maycock and Lisa Nissen contributed to project concept and study design. Andrew Hale collected all data and was responsible for the running of the study.

Andrew Hale, Ian Coombes, Julie Stokes, Lisa Nissen were evaluation of data. Andrew Hale and David Mcdougall were responsible for database design, data evaluation and statistical reporting.

All authors contributed significantly to write up of the project. All authors have read and approved the final manuscript.

Data sharing

"Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.81tr1."

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Figure legends:

Figure 1 - Randomisation Flowchart

Figure 2 - Percentage of Medications Omitted

Figure 3 - Assessment of Clinical Significance of Omissions

Figure 4 - Numbers of Prescribing Errors

Figure 5 - VTE Prophylaxis Assessments and Prescribing

Perioperative Medication Management–Expanding the Role of the Pre Admission Clinic Pharmacist in a Single-Centre, Randomised Controlled Trial of Collaborative Prescribing

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Keywords: Allied health, Pharmacy, Non-medical prescribing, Pharmacist prescribing, Safe prescribing

Word Count :

Abstract 271

Main text 3182

Article Summary

Article Focus

- A doctor-pharmacist collaborative prescribing model provides as least as high a quality of care as usual care, with regards to safety, access, appropriateness, effectiveness, efficiency and consumer participation
- Workforce shortages are prompting a review of the way that the current workforce is utilised, and whether different roles could be taken on by healthcare professionals to alleviate some of the pressures within the system.
- Research on non medical prescribing so far is predominantly qualitative in nature. Our study has analysed quantitative data on safety, accuracy and appropriateness of prescribing to try and assess whether this model is at least as good as usual care.

Key Messages

- Pharmacists' skills in medication management are currently underutilised, and with appropriate training and education they could be contributing to medication management much more effectively by taking on a prescribing role.
- The prescribing is collaborative, and driven by guidelines and under the supervision of a medical team. Diagnosis is not within the scope of practice of the prescribing pharmacist.
- This model of care has been proved to be highly effective in this study, with an increased accuracy, safety and appropriateness of prescribing within the intervention arm

Strengths and Limitations

- The results, with regards to accuracy and safety of medication charts produced in the study are emphatic and statistically significant.
- The intervention is reproducible in other setting with a pharmacist of appropriate experience, training and education.

- The study assessed one pharmacist prescriber versus a cohort of medical prescribers. While this has been accounted for in the analysis, this reflects what usual practice would be in a model care such as this. The authors recognise and acknowledge it as a limitation.

Perioperative Medication Management–Expanding the Role of the Pre Admission Clinic Pharmacist in a Single Centre, Randomised Controlled Trial of Collaborative Prescribing

ABSTRACT

Objectives: Current evidence to support non-medical prescribing is predominantly qualitative, with little evaluation of accuracy, safety and appropriateness. Our aim was to evaluate a new model of service for the Australia healthcare system, of inpatient medication prescribing by a pharmacist in an elective surgery pre admission clinic (PAC) against usual care, using an endorsed performance framework.

Design: Single centre, randomised controlled, two arm trial

Setting: Elective surgery pre admission clinic in Brisbane based tertiary hospital

Participants: Four hundred adults scheduled for elective surgery were randomised to intervention or control.

Intervention: A pharmacist generated the inpatient medication chart to reflect the patient's regular medication, made a plan for medication perioperatively and prescribed VTE prophylaxis.

In the control arm, the medication chart was generated by the Resident Medical Officers (RMO).

Outcome Measures: Primary outcome was frequency of omissions and prescribing errors when compared against the medication history. The clinical significance of omissions was also analysed.

Secondary outcome was appropriateness of VTE prophylaxis prescribing.

Results: There were significantly less unintended omissions of medications: 11 of 887 (1.2%) intervention orders compared with 383 of 1217 (31.5%) control (p<0.001).

There were significantly less prescribing errors involving selection of drug, dose or frequency: 2 in 857 (0.2%) intervention orders compared with 51 in 807 (6.3%) control (p<0.001).

Orders with at least one component of the prescription missing, incorrect or unclear occurred in 20826 of 904 (235%) intervention orders and 445667 of 1034 (4364.5%) control (p<0.001).

VTE prophylaxis on admission to the ward was appropriate in 93% of intervention patients and 90% control (p=0.29).

Conclusion: Medication charts in the intervention arm contained fewer clinically significant omissions, and prescribing errors, when compared to control.

There was no difference in appropriateness of VTE prophylaxis on admission between the two groups.

Trial Registration: Registered with ANZCTR – ACTR Number ACTRN12609000426280

INTRODUCTION

Prescribing involves four stages; information gathering, clinical decision making, communication of decision and monitoring.[1] Taking a medication history, continuing, ceasing and withholding of medications, and initiating new medications are critical components of prescribing associated with an admission for surgery. Medication errors are common, occur most often at the time of prescribing, and frequently on the day of hospital admission, resulting in discrepancies between regular medications and admission orders.[2-4] A small, but significant, proportion of errors result in adverse drug events (ADEs).[5] Errors have been defined as when when there is "*a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.*"[6] To be able to communicate a clinical decision safely and effectively in the form of a written prescription, it is necessary for selection of the correct drug, together with the route, form, dose, frequency and duration.[7] Multiple interventions have been suggested in an attempt to improve prescribing, with suggestions that increased training of the individual, a controlled environment and a change in organisational culture are necessary.[8]

Within hospital, the medication chart provides instructions for safe medication supply and administration, and ensures patient access to medications as an inpatient. It is an integral part of communication between doctors, pharmacists and nurses about prescribing decision and is used as the primary source of information regarding medications on discharge. The pharmacy service in Princess Alexandra Hospital (PAH) PAC began in 1998, to provide timely, accurate and comprehensive information about medication as patients crossed between healthcare settings. It ensured accurate transfer of information at admission, during the inpatient stay and at discharge, the benefits of which were a reduction in both readmissions and contact with community healthcare providers post discharge.[9] The importance of accurate transfer of information across the whole surgical care pathway from preadmission to discharge, including information about medications, has been highlighted in a recent study that reported communication failures led to patient morbidity and mortality. Standardisation and systemisation of communication processes, along with other interventions targeted at the entire surgical pathway were recommended, with a view to improving information transfer and quality of care.[10]

Pharmacists in pre admission clinics (PAC) have been shown to improve the accuracy of medication histories and medication orders, when compared to standard care, and the efficacy of prescribing

perioperatively in line with recognised guidelines.[11,12] Only with an accurate history of medication usage can decisions be made safely regarding management of medications perioperatively. Medication histories are elicited from a variety of sources of information; patient's own medications, the patient or carer, GP summaries, community pharmacies, previous hospital admissions and nursing home records. A number of sources may be consulted to build an accurate record of medication that the patient is taking, both regularly and occasionally.

The range of prescribers has been expanded in a number of countries, with changes in legislation to allow for extension of prescribing privileges to non-medical professionals, including pharmacists. ~~.~~ ~~T~~the objective of this~~which~~ was to make greater use of the skills and specialisation of pharmacists so that a more flexible system for the prescribing, supply and administration of medicines could be developed, whilst maintaining safe and appropriate access to medicines ~~improve access to medicines in the light of healthcare workforce shortages~~.[13,14]

In response to ~~similar~~ documented workforce shortages in Australia, Brooks *et al* described possible solutions, including 'task substitution', and a focus has been placed recently on non-medical prescribers within the healthcare system.[15-19] Pharmacists, with training in pharmacology and therapeutics, are potentially well placed to undertake prescribing roles. An Australian study identified the main driver behind pharmacist prescribing as the desire to work collaboratively with medical and nursing staff to:

• provide consumers with improved, responsible and safe access to prescription medicines

• optimise use of pharmacists' and doctors' skills and time

• reduce inefficient use of health resources.[20]

Evidence to support non-medical prescribing so far has been mainly qualitative, with minimal evaluation of access, safety and appropriateness. One recent review concluded acceptability of non-medical prescribing services is based on the perceived value to the health service.[21] This lack of evidence has led to calls to prove the safety and effectiveness of non-medical prescribing services in Australia.[22] The aim of the data analysis discussed in this paper was to compare a doctor – pharmacist collaborative prescribing model with usual care, with regards to safety, access, appropriateness and effectiveness; the null hypothesis being that no difference exists between the two models of care.[23]

METHODS

The study was conducted between June to September 2009 in the surgical PAC at PAH, a 750 bed tertiary teaching hospital in Queensland.

Ethics approval was obtained from the PAH Human Research Ethics Committee.

The definition of error used in the study was:

"*a failure to communicate essential information; the use of drugs or doses is inappropriate for the individual patient; and transcription error.*"[3]

All patients who attended PAC and could provide written, informed consent were considered for participation. Patients were excluded if they were under 18 years of age, unable to communicate due to language difficulties or undergoing day surgery (see Figure 1)

Patients were approached on arrival at clinic and written consent was obtained. After consent, patients were randomised using a computer generated randomisation list, in blocks of ten (Microsoft Excel). Sealed envelopes (not prepared by the recruiting researcher) contained a zero or one as per the computer list; the next envelope was opened after consent to determine whether a patient entered the control or intervention arm respectively. If a patient had been randomised, and surgery cancelled during PAC, the patient was removed from the study and not replaced.

A previous pilot study in PAC showed an error rate of 12% of orders.[24] Using an expected error rate of 8% in the intervention arm a sample size of 932 orders per group was calculated to be required for a power of 80%. Assuming an average of 5 orders per patient, approximately 200 patients per arm would be required.

Only one pharmacist in PAC, with three years' experience as a hospital pharmacist and having a postgraduate diploma in clinical pharmacy, was trained to be a prescriber. The pharmacist attended a prescribing course which was accredited by the General Pharmaceutical Council, UK as an Independent Pharmacist Prescribing Course.[25]

Training included a minimum of 12 days of 'period of learning in practice' under a 'designated medical practitioner' (DMP), who was the consultant anaesthetist for PAC. The training included case studies and sessions on venous thromboembolism (VTE) prophylaxis with a consultant vascular physician

and the clinical nurse consultant (CNC) for VTE prophylaxis at PAH. The DMP endorsed the pharmacist's competency to prescribe before the study could commence.

For the pilot, an amendment was facilitated to the *Queensland Health (Drugs and Poisons) Regulation 1996* to allow 'Pharmacists registered in Queensland who are employed or contracted to Queensland Health and working in the Pharmacist Prescribing Pilot' to prescribe controlled drugs, restricted drugs and Schedule 2 and 3 poisons.

Intervention Cohort

Patients were seen by a nurse, prescribing pharmacist, Resident Medical Officer (RMO) and anaesthetist. Patients had to be seen by the pharmacist before they were seen by the RMO to allow usual RMO duties and a countersignature of the pharmacist prescriptions, a site requirement.

The pharmacist undertook all pharmacist duties as per usual care, as well as prescribing medications on the medication chart. The scope of prescribing was continuing or withholding regular medications and prescribing VTE prophylaxis according to local and national guidelines, following a risk and contraindication assessment.[26]

Directors of surgery were consulted prior to commencement of the trial for permission to include patients in prescribing of VTE prophylaxis, according to their specific unit guidelines, which had been defined in advance in collaboration with the CNC for VTE prophylaxis at PAH. Urology and renal transplant patients were excluded (N=43 control, N=34 intervention) from VTE prophylaxis prescribing as the director of urology was unavailable to confirm the scope of the project, and the director for transplant requested exclusion on the grounds that VTE prophylaxis in these patients being more consultant discretion as opposed to guideline driven.

Control Cohort

Patients were seen by all four health care professionals in clinic, in no particular order, as per usual care. Either pharmacist in the clinic saw control patients for documentation of medication history. The prescribing of the medication chart was the responsibility of the RMO. In both arms, review and monitoring was undertaken, both by the RMOs in clinic at countersignature and by RMOs and clinical pharmacists at a ward level once the patient was admitted. Changes made by RMOs to intervention patient medication charts in clinic were recorded.

Outcome Measures

The primary endpoint for the study was the accuracy of medication charts, with regards to concordance of the medication chart with the medication history, the plan for medications perioperatively and the quality of the individual orders related to legality and safety for administration purposes. The secondary endpoint was the appropriateness of prescribing for both chemical and mechanical VTE prophylaxis according to local and national guidelines.[26]

~~Appropriateness of VTE prophylaxis prescribed in both arms in clinic was reassessed on admission to ensure prescribing was still appropriate.~~

Analysis of scanned copies of medication charts, for the primary outcomes of omissions and errors~~Audits were~~, was conducted in tandem by two assessors~~:~~, one member of the research team and one external assessor, both trained in use of the validated audit tools[1] and blinded to randomisation. Any ambiguities were clarified by consensus.

Appropriateness of VTE prophylaxis prescribed in both arms in clinic was analysed, using scanned copies of medication charts, in tandem by two assessors; one member of the research team and the Clinical Nurse Consultant (CNC) for VTE prophylaxis at PAH. Prescribing was also assessed on admission to the ward to ensure VTE prophylaxis was appropriate.

An expert panel, comprising of a surgeon, clinical pharmacologist, anaesthetist, RMO, pharmacist and a nurse, was convened to assess the ~~appropriateness of prescribing and~~ clinical significance of omissions in a randomly selected 5% sample of the total cohort of patients from both arms (N=10 control, N=9 intervention). Panel members were blinded to randomisation.

Tables 1 and 2 describe the collection methods and definitions of these endpoints.

Table 1 – Analysis to assess accuracy and safety of medication charts generated in the study

Measure	Definition	Method	Assessing
Omissions	Medication in patient's medication history not prescribed on medication chart, with no reason documented in patient chart	Every medication in patient's medication history checked against medication chart - omissions from medication chart noted	Whether or not medication is prescribed
Prescribing Errors	Anomaly in drug name, strength, dose, frequency or route, with no documentation in patient chart	Every medication in patient's medication history checked against medication chart – anomalies noted	Whether or not prescription is accurate in terms of drug name, strength, dose, frequency and route
Communication Errors	Unclear prescription in terms of name, route, dose, frequency, slow release medication notification or intermittent order prescribing	Every prescription written checked using validated tool – unclear prescribing noted, as agreed by both researchers	Whether or not prescription is safe for administration purposes

Table 2 – Analysis to assess accuracy of VTE risk and contraindication assessments and appropriateness of VTE prescribing

Measure	Definition	Method	Assessing
VTE Risk Assessment	Patient categorised in to low or high risk for VTE, as per guidelines	Every patient medical record checked for a documented VTE risk assessment	Risk assessment documented Y/N Risk assessment correct Y/N
VTE Contraindication Assessment	Patient highlighted as inappropriate for mechanical or chemical prophylaxis, as per guidelines	Every patient medical record checked for a documented contraindication assessment	Contraindication assessment documented Y/N Contraindication assessment correct Y/N
VTE prescribing	Whether patient prescribed mechanical and/or chemical VTE prophylaxis, as per guidelines	Prescribing of mechanical and chemical VTE prophylaxis checked against agreed local and national guidelines	VTE prescribing appropriate according to guidelines and individual patient factors Y/N

~~Continuous variables were compared using Wilcoxon rank-sum tests due to the non-parametric nature of the data.~~ Categorical data was compared using chi-square tests for independence. When any one cell had a count of less than ten ~~or~~ Fisher's exact test~~s where appropriate~~ was substituted. ~~All reported p-values are two sided using a level of significance of 0.05~~. Logistic regression was used to analyse the overall omissions between the two groups. The number of regular and 'prn' medications the patient was currently taking was included as an explanatory variable in the model as it was deemed more likely an individual medication would be omitted in a patient taking a large number of medications. Logistic regression was also used to analyse the overall communications prescribing errors between the two groups. The assumption of independence between observations is clearly violated as multiple observations exist for most subjects. As such, robust standard errors clustered by patient were calculated.~~Odds ratios for patient to have one or greater omissions where calculated using the Mantel – Haenszel method of stratification. Patients where stratified according to~~

~~the total number of medications on their complete medication history as it was deemed more likely that an omission would occur in a patient taking a larger number of medications.~~ No other covariates were adjusted for. All reported p values are two-sided using a level of significance of 0.05. All statistical analysis and sample size calculations was conducted using Stata 11.2 (StataCorp, College Station, Tx).

RESULTS

Table 3 Characteristics of Study Population

The demographics of the patients randomised in to the trial were similar, except for the higher number of medications taken by patients in the control arm (See Table 3)

	Control	Intervention
Total Patients	190	194
Age ‡	57.6 [18-89]	55.8 [18-86]
Male (%)	58%	59%
*Regular Medications†	4[0-16]	3[0-18]
#When Required 'PRN' Medications†	2[0-7]	1[0-4]
Complementary and Alternative Medicines (CAM) †	(0)[0-9]	(0)[0-6]
Over The Counter (OTC) Medications†	(0)[0-2]	(0)[0-2]
Total Medications	1364	983
Total medications (regular and prn only)	1217	887
Medication Charts Prescribed	161 (85%)	194 (100%)

‡ mean [range]

† median [range]

*Regular medications are defined as medications prescribed with the intent to be taken on a regular basis

#Pro Re Nata (PRN) medications are defined as medications prescribed with the intent to be taken only when required

Omissions

Total unintentional medication omissions from medication charts was ~~significantly~~ higher for control patients (31.5%) compared to intervention (1.2%) ~~(p<0.001, chi-square)~~ The odds ratio for an order in the control group to be omitted, compared to the intervention group was 41.0 (95% CI 20.6 – 81.8) (p<0.001 logistic regression) after adjusting for the number of medications the patient was currently taking. (see Table 4 and Figure 2) There were 59 prescribers in the control arm, 54 of whom reviewed patients who were currently taking regular or PRN medications at home, and as such had the opportunity to omit a patient's medication. Out of these 54 prescribers, the median percentage of medications that were omitted per prescriber in the control arm was 21 (range 0 - 100).

Table 4: Medication omissions from medication chart

Type of Medication and Perioperative Plan	Control (N)[%]	Intervention(N)[%]
Regular		
Continue	179 (805)[22.2]	3 (620)[0.5]
Withhold prior to surgery	46(75)[7.4]	0(48)
Withhold on morning of surgery	21(54)[38.9]	0(39)
Adjust dose	1(5)[20.0]	0(5)
Review	1(7)[14.2]	0(6)
Cease	0(1)	0(2)
PRN		
Continue	128(248)[51.6]	6(142)[4.2]
Withhold prior to surgery	7(12)[58.3]	2(13)[15.4]
Adjust dose	0(2)[20.0]	0(1)
Review	0(8)[14.3]	0(11)
Total Omissions	383(1217)[31.5]	11(887)[1.2]
***Complementary and Alternative Medicines (CAMs)**	126	87
***Over The Counter Medications (OTC)**	21	9

*CAM and OTC medications were not classed as omissions in either arm if not prescribed on the inpatient medication chart

~~The crude odds ratio for a patient in the control arm to have one or greater omissions was 37.5 (95% CI 16.9 – 93.1, p<0.001). After randomisation control patients had a larger number of medications on their history compared to the intervention patients and therefore the crude odds ratio could be misleading. Stratifying the patients into 4 groups, based on total number of medications in the complete history and utilising the Mantel-Haenszel method to control for potential confounding, the adjusted odds ratio for a patient in the control arm to have one or greater omissions was 31.7 (95% CI 14.7 – 68.3, p<0.001).~~

Clinical Significance of Omissions

Omissions from a randomly selected 5% of the total cohort were evaluated for clinical significance. Out of 89 regular medication in the patients' medication histories in the control arm, 25 (28%) were omitted from the medication charts, compared to 1 out of 55 (2%) in the control arm ~~(p<0.001, exact)~~. When asked to assess the severity of omission, the average across the panel showed 52% of omissions in the control arm had the potential for patient harm or ward inconvenience (see Figure 3) Only one reviewer thought the omission in the intervention arm was significant.

Prescribing Errors Related to Drug, Dose and Frequency Selection

Overall, 53 errors were identified where the drug strength, dose or frequency prescribed did not match the medication history or perioperative plan (see Figure 4). This equates to 4.9% of control orders compared to 0.2% of intervention orders (p<0.001, Fisher's exact).

Communication Errors

Communication errors, where prescriptions were rated as ambiguous or unclear, were significantly higher in the control arm compared to the intervention arm. The odds ratio for an order in the control arm to have a communication error compared to an order in the intervention arm was 2.52 (95%CI 1.96 – 3.27) (logistic regression p<0.001). As there were multiple orders per patient, robust standard errors, clustered by patient were utilised ~~(p<0.001, chi-square)~~ (see Table 5). Individually, communication errors were significantly higher in the control arm for all types of error except route of administration (p=0.57 chi-square).

From the control arm prescribers, 44 of them prescribed medication on the medication charts, with a median number of orders of 21 (range 1 - 85). The median percentage of orders in the control arm that contained at least one communication error per prescriber was 38 (range 0 - 100).

Table 5: Prescribing errors with an ambiguity in at least one component of the prescription

	Control Number of errors (% of total orders)	Intervention Number of errors (% of total orders)	P value
Total Orders	1034	904	
Orders with at Least One Communication Error	445(43)	208(23)	<0.001 Π †
Prescribing Communication Errors	667 ~~(64.5)~~	229 ~~(25.0)~~	~~<0.001†~~
Prescribing Communication Errors			
Drug name	23 (2.1)	0	<0.001‡
Route	79 (7.6)	76 (8.4)	0.57†
Dose	48 (4.6)	5 (0.6)	<0.001‡
Frequency	190 (18.4)	96 (10.6)	<0.001‡
Administration times incorrect or missing	117 (14.9) (781 orders)	4 (0.5%) (762 orders)	<0.001‡
prn max dose missing	178 (74.5) (241 orders)	47 (32.6) (142 orders)	<0.001‡
Slow Release not specified	15 (30.0) (50 orders)	1 (1.5) (66 orders)	<0.001‡
Intermittent order not specified	17 (57.5) (30 orders)	0 (38 orders)	<0.001‡

Π Logistic regression

† Chi-Square

‡ Fisher's Exact

Venous Thromboembolism (VTE) Prophylaxis

Patients in the intervention arm were significantly more likely than controls to have appropriate VTE prophylaxis prescribed on the medication chart in PAC and to have documented VTE assessment (see Figure 5). On admission to the ward, approximately 90% of both intervention and control patients were prescribed appropriate VTE prophylaxis.

DISCUSSION

This study has built on the findings from previous research of pharmacist prescribing in PAC settings, which have found improved accuracy of information gathered, and improved prescribing according to guidelines.[9,27] Similar studies of pharmacist interventions in different settings have shown improvements in clinical endpoints such as blood pressure control, increased appropriateness of prescribing and reductions in adverse drug events, such as warfarin associated bleeds.[28,29]

The traditional scope of practice for the PAC pharmacist consists of taking a medication history, using guidelines, clinical judgement and referral to the surgical team to suggest a plan for medications perioperatively, and providing this information for the RMOs to generate the medication charts. This scope has been extended in our study by providing an appropriately trained pharmacist to generate the medication chart and prescribe VTE prophylaxis, which has led to a significant reduction in omissions and prescribing errors, ensuring patients get the correct medication whilst in hospital. The evaluation of VTE prophylaxis prescribing was essential to assess the safety and appropriateness of initiation of a new medication, within guidelines, by the prescribing pharmacist. The results from this study have shown the prescribing to be as appropriate as usual care at the time the patient is admitted to the ward. Issues still remain with the prescribing, especially with the use of inappropriate abbreviations.[30] For example, a large proportion of communication errors in the intervention arm were due to the use of s/c to indicate subcutaneous, which has informed the researchers on future educational requirements of prescribers, especially with regards to safe prescribing.

Electronic prescribing may be one solution to such errors involving legibility and inappropriate abbreviations, but studies have shown the systems introduce errors of their own.[31] These errors need to be fully assessed and appreciated if the quality of prescribing is to be improved by the introduction of computerised prescribing in to the healthcare system.

The results presented in this paper are part of a larger study, further work is required to assess the appropriateness of prescribing of medication charts and consumer participation of this new model of care.[23]

There are a number of limitations. Even though the trial was randomised, the total number of medications patients were taking was higher in the control arm (1364) compared to the intervention arm (983). The explanation for this is unknown but may in part be due to large randomisation block sizes, possibly meaning a number of consecutive patients were randomised to the control arm during clinic sessions where patients were more likely to have a higher burden of medication, for example during a vascular surgery clinic. There was more opportunity for omissions from the control arm as a result of more medications needing to be continued, and this was allowed for in the analysis.

RMOs in clinic during the study were aware of the intervention pharmacist's role, which may have led to an increased number and quality of medication charts prescribed in the control arm. Even with this potential effect, the study still showed a significant improvement in the safety and accuracy of medication charts.

Review of medication orders is not a role a RMO routinely undertakes. All RMOs were educated with regards to the requirement for a countersignature of pharmacist orders, and to amend anything as required prior to sign off. In the trial, 10 charts were amended – 5 changes were minor, 3 were addition of analgesics out of the pharmacist's prescribing scope and two changes actually resulted in inappropriate VTE prophylaxis. Despite the legislative changes, countersignature of pharmacist orders was a local requirement owing to the concern that junior doctors may become deskilled as a result of being removed from the prescribing process. However, the authors suggest that having an appropriately trained prescribing pharmacist in clinic, for the RMOs to use as guidance and to feedback on any prescribing errors, may increase the effectiveness of the learning environment.

Only having one pharmacist prescribing in the intervention arm, and multiple RMOs prescribing in the control arm is a potential source of bias, unavoidable where individual knowledge, skills and capabilities determine the quality of prescribing. It has been suggested medical undergraduate training may not prepare graduates to prescribe, which if addressed, may reduce this individual variance.[324] The model of care tested in our study was successful as we were able to reduce the variance within a group by training one individual pharmacist to manage medications perioperatively,

within a set scope of practice, and to include prescribing. It could be argued that the same results may have been obtained by providing the RMOs with extra prescribing training, and the improved performance may not necessarily be solely down to the introduction of a new professional discipline. The authors acknowledge the improved results may well be multi-factorial, but would also suggest that the underlying competencies of an experienced, 'advanced level' pharmacist, plus the prescribing training provided, have ensured appropriate competencies to prescribe in the model of care in which the prescribing took place.[33]

The order of consultation in the intervention arm was set by trial design. The order in the control arm was not set, which is a true reflection of usual care, where the patient could see the RMO prior to the pharmacist. This may have impacted on quality of control medication charts prescribed by the RMO, without information available from the pharmacist history. Whilst this could be classed as a limitation, this does reflect usual care in PAC and highlights the collaborative nature of the existing model of care.

The prescribing pharmacist was able to see control patients for usual care duties of a medication history, which may be perceived as introducing bias. However, as both pharmacists have received the same undergraduate and general level pharmacist training, the quality of medication history gathered for the RMO to use to prescribe the medication chart would be the same.

Another limitation is the potential sustainability of the model of care, and capacity to train pharmacists as prescribers. This was only one pharmacist, in one hospital who had received special training to be able to prescribe. Evaluation of the requirements of non-medical prescribing courses is underway, but substantial further thought needs to be applied to ensure reproducibility of these results, in a larger sample, and consistent production of safe and effective prescribers.[34~~2~~]

Further work is required to address the actual and perceived medico-legal implications for both doctors and pharmacists in such collaborations.

CONCLUSION

Medication charts in the intervention arm were significantly safer and more accurate with regards to the patients' regular medications, than medication charts in the control arm.

There was no difference in appropriateness of VTE prophylaxis prescribing between arms on admission to the ward.

Our study has shown the pharmacist in PAC was able to effectively gather all the information required to collaboratively formulate a clinical decision in clinic within an agreed scope of practice, and communicate the decisions safely and accurately onto the medication chart.

A collaborative doctor – pharmacist prescribing model in a PAC was as safe and accurate as usual care, in ensuring that patients were prescribed the medication required on admission for elective surgery.

Acknowledgements

The authors would like to acknowledge the following people, without whom the study would not have been possible.

Professor Stephen Lynch, Chair of Surgery, Princess Alexandra Hospital

A/Prof Lynette Loy, Director of Pharmacy, Princess Alexandra Hospital

Ms Ching-Ting Hung, Senior Pharmacist, Princess Alexandra Hospital

Ms Renea Collins, Clinical Nurse Consultant, VTE Prophylaxis, Princess Alexandra Hospital

All of the staff in Pre Admission Clinic

Competing Interests

There are no competing interests to be declared for any of the authors

Funding

There was no external funding received for the study.

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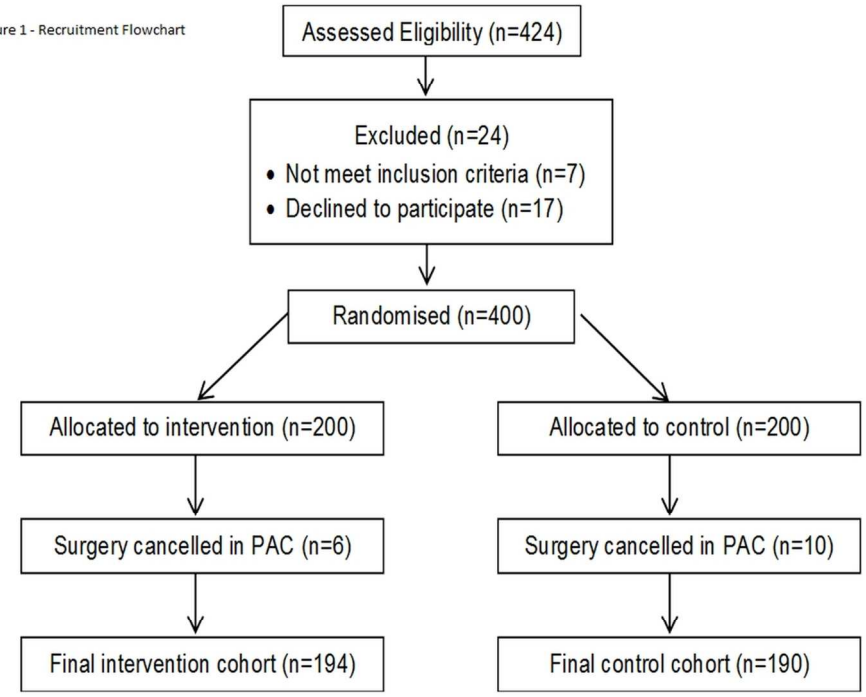
CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
		Introduction	
Background and objectives	2a	Scientific background and explanation of rationale	3
	2b	Specific objectives or hypotheses	4
		Methods	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	N/A

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12
		Results	
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	10
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11,12
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
		Discussion	
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14,15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	15
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14,15
Other information			
Registration	23	Registration number and name of trial registry	17
Protocol	24	Where the full trial protocol can be accessed, if available	17
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	N/A

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Figure 1 - Recruitment Flowchart



Randomisation Flowchart
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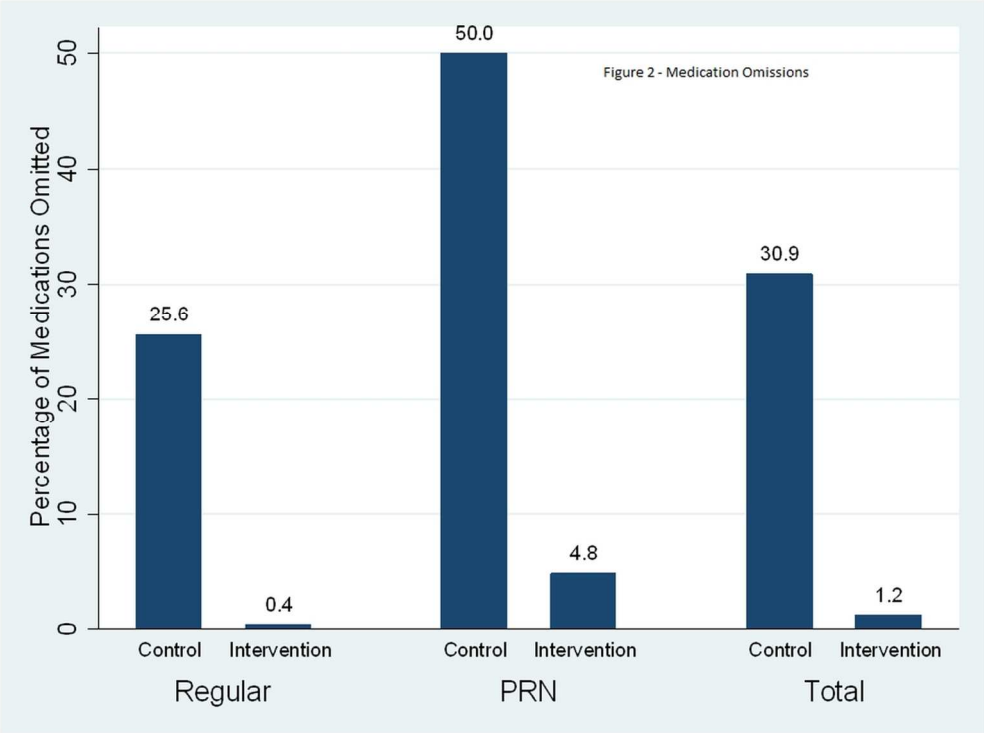

Percentage of Medications Omitted
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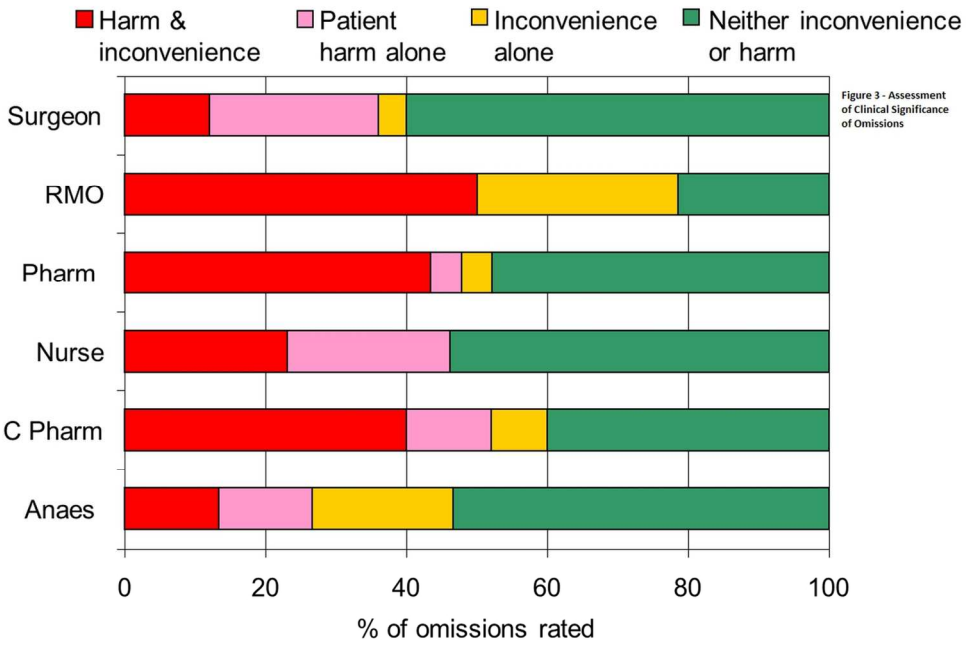

Assessment of Clinical Significance of Omissions
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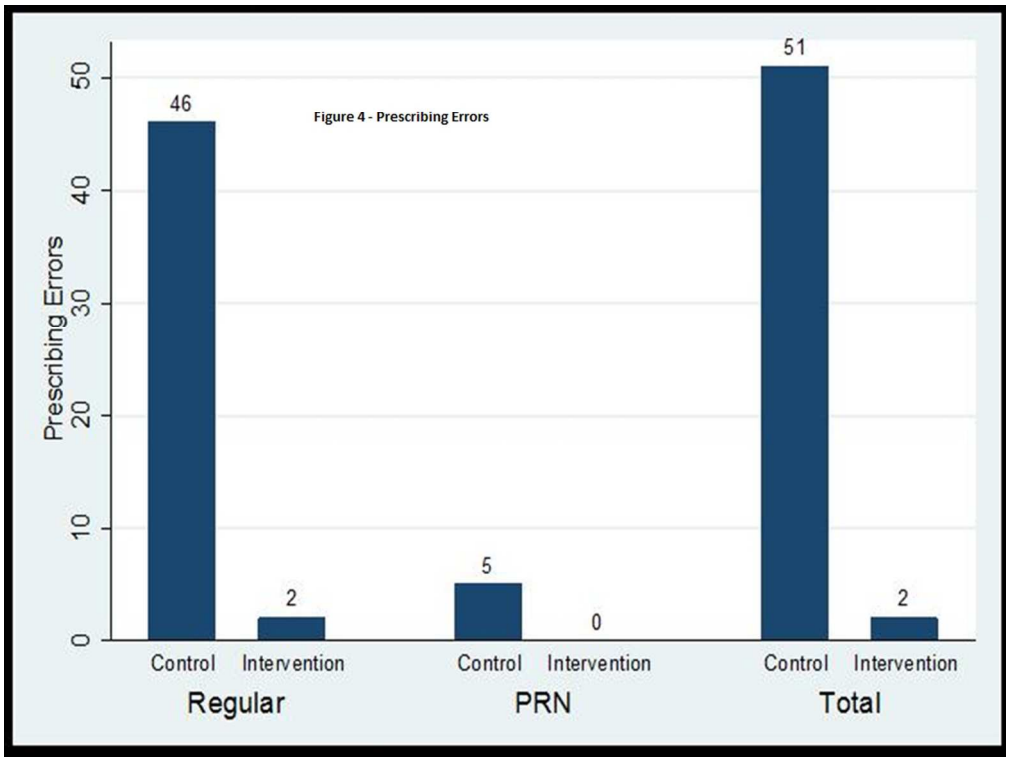

Numbers of Prescribing Errors
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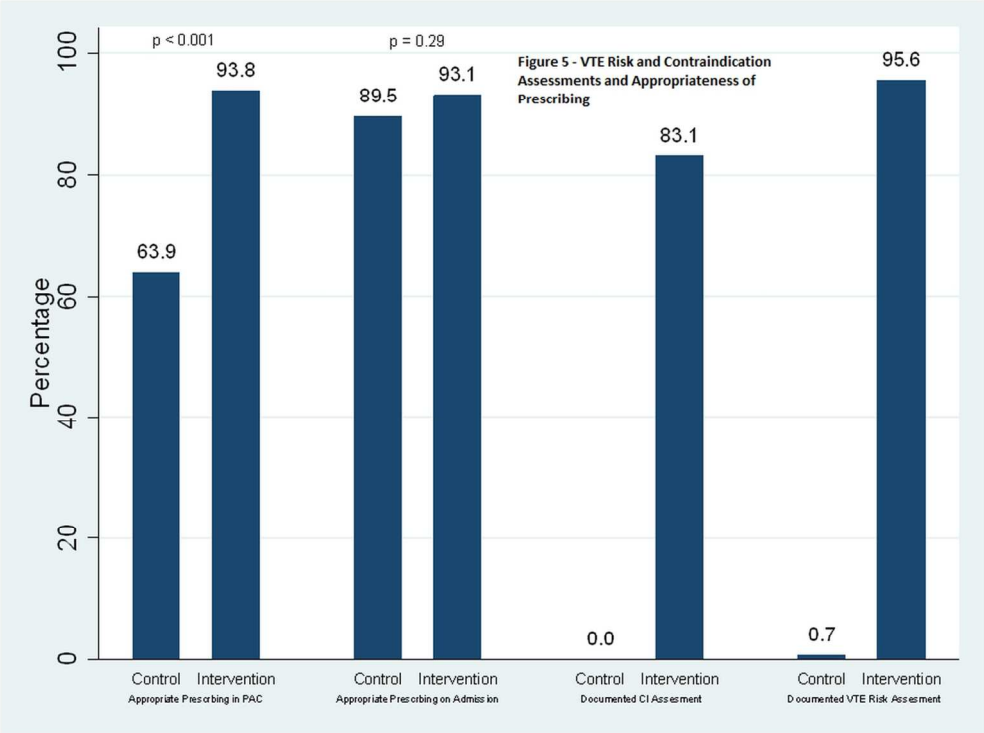

VTE Prophylaxis Assessments and Prescribing
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