

**Clinical audit of
dosing omissions among surgical patients in a hospital electronic
prescribing and medicine administration (HEPMA) system**

A research project

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Abstract

Background: Medication errors are a national concern, and even small changes can make a real difference in reducing harm to patients. Dose omissions are one of the medication errors causing harm, and it is a recommendation for NHS organisations to periodically audit all omissions to help target where improvements can be performed to prevent these errors.

Aim and objectives: The aim of the project was to collect numbers of frequency, reasons and the relative risk of causing harm to patients for dose omissions in surgical settings at The Ayr Hospital. From the results the aim was also to create guidelines to help inform ward staff about medicines that should not be omitted in the peri-operative period.

Methods: A prospective study was performed in a hospital electronic prescribing and medicine administration (HEPMA) system to study dose omission patterns for a period of three weeks at two surgical wards. Clinical information was collected from patients suffering from dose omissions that were included in the study by giving their consent. An expert group of 4 pharmacists evaluated the omitted doses after a new assessment for scoring clinical significance, and guidelines were developed from the findings.

Results: The total numbers of dose omissions in both settings were 10.1% and 6.0%, and there were several differences between the two settings. Of all omitted doses evaluated for clinical significance 41.2% were scored as possible to cause a disturbance to the patient's symptom control in some degree.

Discussion: The different outcomes at the two wards can possibly be explained by the frequency of surgeries performed in each ward, turnover of patients and use of different medicine supply systems. Scoring of clinical significance of omissions would possibly vary by the selection of patients because there are many important individual aspects.

Conclusion: Dose omissions are common and many of them are possible to cause disturbance to patients symptom control when omitted in the peri-operative period.

Abbreviations

95% CI	95 % Confidence Interval
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
EPMA	Electronic Prescribing and Medicine Administration
HEPMA	Hospital Electronic Prescribing and Medicine Administration
MRSA	Methicillin- Resistant <i>Staphylococcus Aureus</i>
NBM	Nil By Mouth
NHS	National Health Service
NSAID	Non Steroidal Anti Inflammatory Drug
OSD	One Stop Dispensing
POD	Patient's Own Drugs
POE	Prescription Order Entry
PRN	Pro Re Nata (as required)
SSI	Surgical site infections
VTE	Venous thromboembolism

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1 Introduction

1.1 *Medicine incidents causing harm*

Although most medicines are prescribed and used safely, sometimes things go wrong. Most medicines are self administered by the patient at home, and there are few numbers and reports of incidents caused by errors in this setting. But studies have shown that up to 6.5 per cent of admissions to hospital are related to harm from medicine.¹

From evidence suggesting, it is calculated that up to ten per cent of all patients within hospitals in Scotland experience medication-related harm.² Of the reported incidents which caused harm in hospitals in the UK in 2007 over 30% were caused by patient being allergic to the treatment. Omitted medicine/ingredient caused 22%, wrong route 19% and wrong medicine 17%. There is a gap between the actual number of incidents that occur and the number that is reported.¹ About 50% of all incidents causing harm are avoidable, and it is obvious that preventing this in any way possible is both significant and important.²

1.1.1 **Categorisation of medicine incidents**

The National Patient Safety Agency has defined a patient safety incident as “any unintended or unexpected incident which could have or did lead to harm for one or more patients”. A medication error is one kind of incident, where there has been an error in one of the processes listed below:¹

- Prescribing (ordering a given medicine or dose)
- Dispensing (supplying medicines to hospital wards)
- Preparation (preparing a dose of medicine for administration)
- Administration (administering the dose of medicine by the appropriate route, method and time)
- Monitoring (checking the administration and effect of a medicine)

The most frequent recorded medication incidents is administration errors.¹ An administration error is any difference between what the patients received or was suppose to receive, and what the person in charge of prescribing medicines intended in the original order³. The errors that can happen are¹:

- Dose given at the wrong time
- Wrong dose; quantity, strength, route or formulation
- Wrong frequency
- Other medicine is given instead of the prescribed medicine (similar names, packages etc.)
- Medicine given to the wrong patient
- Medicine used passed expiry date
- Dose omitted
- Incorrect administration, wrong technique (injections over too short time e.g.)
- Wrong dose preparation
- Unauthorised
- Inappropriate combinations of medicine and food, (calcium combined with tetracycline or inappropriate admixtures with parenteral therapy e.g.).

1.2 Dose omissions as a medicine incident

Of all reported medication incidents occurring in hospitals in the UK in 2007, 17.1% were omitted medicine, which involved both entirely missing a medicine from an intended medicine regimen, and missing one or more doses of a medicine.¹ A dose omission is defined as when the patient fails to receive a ordered dose of medication before the next dose is due or it is evident that the dose will not be given before that time. Wrong dose was the only one that had a higher frequency, 28.7%, while 11.5% was caused by wrong medicine¹.

1.2.1 Identification of reasons for dose omissions

Incidents of omitted doses may occur when a hospital medicines supply system fails or when hospital pharmacy opening/closing times lead to delay in medicine being

administered to the patient. Certain medicines need to be prescribed in response to the newest laboratory result to the patient. If the result is delayed or not available the prescription may not be written by the time the dose is due.¹ Other reasons for dose omissions are listed in table 1.

Table 1 Different reasons for dose omissions in general

Event	Reason
Unavailable medicine	Medicine not available in the hospital needs to be ordered.
Nil-by-mouth	The person in charge of prescribing the patients medicines have decided to take the patient off some medicines in the nil-by mouth period
Theatre	The patient are having surgery
Unable to swallow	The patient have trouble taking oral medicine, an alternative route should be used
Patient absent from ward	The patient is not at the ward at the time for medication, and needs to get it as soon as he or she returns
Refused	The patient refuses to take the medicine
Withheld	The person in charge of prescribing the patients medicines have decided that the medicine should not be given or monitoring of the patients condition, blood pressure, blood glucose levels or other lab results make the dose clinical inappropriate to give
IV-access unavailable	The patients IV access is not usable

1.2.2 Earlier studies of amount and reasons for omitted doses

A prospective study was performed at The Ayr Hospital between in 1997- 1998 ^{4,5} over the reasons for dose omissions in the orthopaedic, surgical ward, which is also one of the clinical settings in this study. The collection of omitted doses was collected both before and after electronic prescribing and administration (EPMA) was introduced to the Hospital. This system will be presented in more detail later. The findings from the study are presented in table 2.

Table 2 Frequency of reasons for omitted doses compared to the total number of prescribed doses, at the orthopaedic surgical ward in Ayr Hospital performed in 1997- 1998

Omission	Before EPMA (n= 3364)		1 month after EPMA (n= 3334)	
	n	%	n	%
Kardex unavailable eg theatre, X ray	7	0.2	-	
Nurse decision	35	1.0	32	1.0
Drug unavailable	19	0.6	19	0.6
Fasting patient	20	0.6	28	0.8
Unclear prescription	6	0.2	-	
No cause	17	0.5	1	0.03
Total	104	3.1	80	2.4

Some of the main findings from other studies from the UK are represented below. They are all performed after 2006.

In the Pharmacy Department at Kings College Hospital foundation trust in London a retrospective study was done. Number of given and omitted doses of the patients regular medicine within 24 hours was collected from 22 wards. In total 6888 doses was supposed to be given to 404 patients. Of this 473 doses was omitted, which gives a percent of 6.9%. 48.3% of the omitted doses were medicine withheld while 14.6% was caused by NIL by mouth and 9.7% from unavailable medicine (6.1% outside pharmacy opening time, and 3.6% during). In 8.9% of the cases the medicine was unable to give by prescribed route, and 7.0% were refused by the patient. Omissions were caused by 3.8% as a result of the

patient being absent from ward. In the remaining 7.7% the reason was unknown.⁶

Another study in London was performed in Queen Elizabeth Hospital NHS trust on all medical wards. The study went on for one week, including weekend. In total 714 omitted doses were recorded, of an unknown number of doses in total. Of them 37.7% of the doses were not given because the patient refused and 15.7% were caused by NIL by mouth. In 15.3% the drugs were unavailable and 11.5% were withheld. There were also a few cases where the reasons for dose omission were patient off ward, or because the drugs were non formulary drugs (both 1.3%). There were also 11.3% unknown cases because the nurse had not documented why the dose had been omitted, and 5.9% were noted as other.⁷

A third study was performed in three different hospitals in London, Highgate Mental Health Centre, St. Pancras Hospital and St. Lukes Hospital. The information of omitted doses was obtained from the patient's drug charts in a five-day period. In total 37% of all doses that were suppose to be given were omitted. About 60% of them were caused by patient not available, 24% by patient refusing, 13% by unavailable medicine and 11% by medicine not charted, (which gives a total of 108%).⁸

At the City Hospitals Sunderland NHS Foundation Trust the result from a one week- period audit on elderly wards was that 10% of the doses were omitted. There are no notifications of the reasons for the omissions.⁹

1.3 Clinical significance of dose omissions

Short time medication omissions are in most cases unlikely to cause harm to patients and not widely recognised as a risk. But of all incidents resulting in harm reported in hospitals in the UK in 2007, about 22% was caused by omitted medicines or doses. Of the cases leading to severe harm and death, omitted medicine caused 18.5% and 7.9% respectively.¹

It is an important point of view that missed doses can have no clinical significance in some

situations, while in others it may result in therapeutic failure, relapse and withdrawal.⁹

The outcome will in most cases depend on the patient's clinical condition, medical history, sex, age and the reason for why that medicine is being used. What situation the medicine is omitted in will also be of great significance, like if the patient is going through surgery or if there is a worsening in the patient's condition. A general rule is that the more critical the situation is the more critical is also a dose omission of a medicine used to treat or prevent the sickness behind it.

Table 3. The National Patient Safety Agency definition of harm to the patient

Categories of harm to the patient	Defined outcomes
No harm	Any patient safety incident that ran to completion but no harm occurred to the person(s)
Low harm	Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s)
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s)
Severe harm	Any patient safety incident that resulted in permanent harm to the person(s)
Death	Any patient safety incident that directly resulted in the death of the person(s)

1.3.1 High risk medicines

Research studies have showed that single omitted doses of medicines such as anti-convulsants, insulin and anticoagulants can have serious and even fatal consequences. Also medicines used to treat epilepsy or prevent strokes has been reported to have caused permanent harm or death when omitted¹.

There has also been reported cases of patients on long term treatment with steroid supplement who experienced to be profoundly hypotensive and hypoxic after omission of

the medicine for 24 hours.¹

Several other medicines are known to be important medicines which should not be omitted. What to do when a medicine is omitted is usually described in the medicines instructions in the package. Mostly it is recommended to take the dose as fast as possible, unless if too long time has passed. A general rule is less than half the normal dosage interval, but this depends on the agent. To double the next dose instead can for some medicines cause toxic levels, like lithium and caumadin. Sometimes the patients are advised to make contact with his or hers doctor if important medicine is omitted.

1.3.2 Scoring clinical significance of dose omissions

There is a need for classification of clinical significance of all types of drug omissions, to avoid incidents from happening which can cause harm to the patient.

The scoring of clinical outcomes from medicine incidents have in earlier, validated studies been scaled in systems from 0 to 10. 0 represented a case with no potential effect of causing harm to the patient and 10 a case that would result in death. Scoring omitted doses, especially single doses will rarely top this scoring system.^{3,10}

To achieve reliable scores scaling clinical significance at least four judges are required, and the mean score should be used as a severity factor. Earlier studies suggest that the professionals that score each case can be any experienced UK pharmacists, medical staff and nursing staff. Their mean scores would be generalizable to any other four judges selected from the same group.¹⁰

1.3.3 Earlier studies and observations of dose omissions and clinical significance.

There are not many studies performed of the clinical significance of dose omissions in the UK. Two are discussed here, and as a supplement a study made in the US is presented.

In the study performed at Ayr Hospital in 1997- 1998⁴, the method described above (scale of clinical significance from 0 to 10) was used in the study. Of 184 omitted doses there were 67.4% of the doses that scored higher than 0. None of the omitted doses scored

higher than 4.

Table 4 Scored clinical significance of omitted doses from the orthopaedic, surgical ward at Ayr Hospital

Scoring number	Frequency (n= 184)
0	60
1	77
2	37
3	8
4	2

In the study performed in Queen Elizabeth Hospital NHS 182 of 714 doses (25.5%) were categorized as high risk medication.⁷ Of them isosorbide mononitrate and benzylpenicillin were mentioned to have a reduced efficacy to the patients controlling anginal pain and infections respectively if omitted. Medicine considered to be low risk medicine in this study included mainly senna, lactulose, paracetamol and co-codamol. But an important aspect in this study was that no indication for the medications use and other information of the patient was collected.⁷

In a study performed in the US in 2002¹¹, clinical significance were scored from the medication errors observed in 36 health care facilities by a expert panel of physicians. Medical history and other clinical information were collected about each patient. In total 19% of the doses observed had some kind of error and 30% of them were dose omission. In total 288 dose omissions were judged by the experts, and 17 cases (6%) were clinical significant. This expression clinical significant was set to be “the potential to cause a patient discomfort or jeopardize the patient’s health and safety”. Some of the medicines mentioned to be scored like this were warfarin and phytonadione.

1.4 Medication in the peri-operative period

Medications used before, during and after surgery (the peri-operative period) are different in many ways from medication given on medical wards. Some drugs needs to be stopped

days or even weeks before surgery in order to reduce the risks they may impose upon the procedure. Other medicines must be continued as normal, and on top of that there are medicines which need to be given as supplementary treatment in the peri-operative period.¹² If it is not an emergency surgery, a meeting with the patient will be arranged some time before to agree on the medical regime before the admission to the hospital. Some important points of view that need to be considered are given in this section.

1.4.1 Discontinuation of medicine

Before surgery the international normalized ratio should be under 1.5, because of the risk of bleeding during procedure. Warfarin is usually discontinued three to four days before surgery to accomplish this.¹³ Aspirin can also increase bleeding and is withdrawn 7-9 days before certain types of surgery to allow sufficient replacement of normal circulating platelets. In some cases aspirin is chosen to be continued, like when the patient is suffering from unstable angina or those undergoing cardiac surgery. Other NSAIDs should also be stopped for the same reasons, and the withdraw period varies after how long-acting the NSAID is.¹⁴ Drugs that also increase the risk of venous thromboembolism (VTE) such as combined oral contraceptives should be stopped 4 weeks before major operations,¹⁵ and raloxifene should be stopped three days before surgery.¹²

The kidney perfusion gets reduced in the peri-operative period and the person in charge for prescribing medicines needs to be aware of medicines that get metabolized and eliminated through this system. Combined with tissue damage during surgery, reduced kidney function can lead to hyperkalemia. Therefore potassium-sparing diuretics are usually omitted on the morning of surgery, or a non potassium-sparing diuretic can be used.¹³

Medicines that interact with peri-operative drugs, like monoamine-oxidase need to be discontinued two weeks before surgery or an anesthetic that does not interact can be used. In worst scenario an interaction like that can lead to coma and death. It is also important to remember that discontinuing some medicines may affect the efficacy or toxicity of others.^{13,14,16}

Patients suffering from diabetes are considered to be at an increased risk of peri-operative

complications, like acute metabolic problems, infections and delayed wound healing, and mortality. It is important to maintain optimal blood glucose levels and avoid these complications. Stress, as a response to surgery, raises the blood glucose levels. Withhold of food, insulin and other diabetic medicines should be minimized and it is recommended that surgery in these patients should be held in the morning to reduce the fasting period.^{17,18}

There are also some other medicines that should be stopped prior to surgery and there are guidelines that the nurses and doctors should follow.¹²

1.4.2 Continuation of medicine

There is clear evidence for continuation for some drugs, like medicines used to control life-threatening conditions. It is also essential to optimize the treatment of patient with chronic diseases so that they are in the best condition to cope with and recover from surgery. An example is antiepileptics that are usually continued because abrupt withdrawal may precipitate rebound seizures.

Patients suffering from cardiovascular disease have an increased risk of myocardial infarction, and it is important that these patients get their medication as prescribed and that no doses are omitted.¹³ A very important medicine is the beta-blocker. When a patient normally uses these medicines the beta-adrenoceptor system is upgraded. If the beta-blocker is omitted, this system will be unmasked, and the patients will be more sensitive to the sympathetic effect of stress hormones. This will especially be a problem in the peri-operative period when these hormones are secreted in large amounts. The withdrawal effects can be seen already after 12 to 72 hours after stopping betablockade.¹³

Other medicines that should be continued throughout the peri-operative period:¹⁴

- Antiparkinson drugs
- Antipsychotics and anxiolytics
- Corticosteroids
- Drugs for asthma
- Drugs for dependence
- Immunosuppressant

- Selective serotonin re-uptake inhibitors

Continuation may require that the drug is administered by an alternative route or change to a similar product.¹⁴

1.4.3 Medicines supplements

Even if surgery increases the risk of bleeding, it also increases the risk of VTE with triggering the coagulation cascade¹⁹, which make the right treatment with anticoagulant therapy very important in the peri-operative period. The evaluation is done on an individual level, where other risk factors like age, obesity, varicose veins, thrombophilias, immobility and previous history of VTE plays an important role.^{15,20}

People using corticosteroids regularly (> or = 5mg), like patients suffering from Rheumatoid Arthritis or Chronic Obstructive Pulmonary Disease (COPD), need steroid supplement because stress connected to surgery can make the body require a higher dose of steroids. (25-100mg * 4). A too low level of steroids can cause hypo adrenal crisis, manifesting as circulatory collapse and shock.¹⁶ These medicines also needs to be restarted as soon as the patient can swallow small amounts of water again, or through an alternative route.

Medicines preventing nausea, vomiting, pain and surgical site infections (SSI) are also upgraded compared to the patient's normal regimen. Nausea and vomiting are a common problem in the peri-operative period. Opioid analgesia, anesthetics, fear and injury are some of the reasons for patients experience these reactions. It is easier to prevent it from happen, than to treat it when it has already started. Even a single dose reduces the incidence by about 30 per cent²¹, and omitted doses of these types of medicines can cause a lot of discomfort to the patient. That makes this medicine an important dose to give a patient going through surgery, even if it is rarely fatal.²¹

When it comes to treatment of pain, omitted doses in a medicine-regimen can cause inadequately controlled pain, which cause morbidity and major discomfort to the patient.²²

Surgical site infections (SSI) are a complication that is often seen because of bacterial

contamination during surgery. One of the things that are used to deal with this is antibacterial prophylaxis. If there is a high risk of post-operative infections, antibiotics should be used prophylactic. The patient should receive a single dose within two hours before surgery and another dose three hours after surgery to keep the infection rate down. For patients using longtime antibiotics, surgical prophylaxis may not be necessary, but the timing of dosing is still important to get the best effect of the antibiotics.²³

1.4.4 Pre-operative period

Patients are in risk of aspirating their stomach contents during general anesthesia. Because of this there should be a fasting period, Nil by mouth (NBM), for six hours for food before anesthetics are given. Clear water leave the stomach within two hours of ingestion, and that makes it possible to give routine medication to the patient during this time.^{14,19,24} A proton pump inhibitor or a H2- antagonist could also reduce the risks of gut problems.¹⁶

There are other reasons for a patient to be labeled NBM, like unconsciousness, to rest the gut or post-operatively as a result of the surgery itself.¹⁹

The result of not giving a dose can have different outcomes from one patient to another, and in many cases it will depend on the patient's health condition. So if a drug should be given or not in the nil by mouth period is for the doctor to decide.¹⁹

Hypotension can also occur at any time around surgery, because of blood and fluid loss and the use of cardiovascular medicines (anti hypertensives, anti-arrhythmic and drugs for angina). Extra fluid replacement may be necessary in these cases.^{14,19}

1.4.5 Postoperative period

Most medicines that have been stopped prior to surgery should be restarted at the original dose as soon as the patient is able to take oral medication. But circumstances may exist where the patient needs the medicine in a different form than before.²⁵ Reasons for this can be nausea, vomiting or delayed gastric emptying caused by the drugs they have been given. If the operation was in the gut, head or neck or if the patient needs intubation or ventilation, there could also be a need for alternative routes for medications.¹⁴

Changes to the patients' medicine regime should be planned before surgery if possible. Advices should be sought from the hospital pharmacist or medical team where appropriate.¹⁴ This is important because the dose and frequency that is prescribed by mouth may not be the same for another route.¹⁹

Some medicines should not be restarted until the risks associated with surgery has been totally removed, such as the risk of VTE and use of contraceptives.¹⁴

1.4.6 Present pre-operative fasting and drug administration guidelines at the surgical wards at Ayr Hospital

The following guidelines are the current practice at all surgical wards at the Ayr Hospital.²⁶ It applies to all patients who are being prepared for a surgical procedure unless specific written instructions have been documented by the anaesthetist. This instructions are written at the anaesthetic record for each patient, and it includes fasting procedures that can differ from the general guidelines and what medicines that should be withheld or continued.

Fasting Guidelines:

- 6 hours – Solid food, milk or drinks containing milk
- 2 hours – water

Elective morning lists:

Fasted for solids from midnight

Fasted for fluids from 7 am

Elective afternoon list:

Early breakfast prior to 7 am, then fast for solids.

Fasted for fluids from 11 am.

All routinely prescribed drugs must be given in the pre-operative period.

Exceptions

- Insulin

- oral anti-diabetic agents
- warfarin
- clopidogrel.

1.5 Medicines management and Improvements to reduce medication incidents in the UK

The primary and secondary healthcare in the UK are controlled by the health service NHS, which was created in 1948, and divided into NHS (England), NHS Wales, NHS Scotland and the Health and Social care in Northern Ireland. The four health services produce guidelines and reports which are all used in the UK.

There has been a great focus on how patients should receive better and equally high quality of care in the UK for some time now. In 2000 the NHS published “The NHS Plan: a plan for investments, a plan for reform”, which was a plan for how the governments increase in investment to the health services should be distributed.²⁷ NHS Scotland published “Our national health – a plan for action, a plan for change” around the same time. The focus was put on the health service situation and changes that needed to be made to improve the NHS itself and the nation’s health.²⁸

1.5.1 Hospital medicines management systems

Medicines management is a system of processes and behaviours that determines how medicines are used by patients and by the NHS. It should make the use of medicines cost effective, safe and effective. It encompasses the entire way medicines are selected, procured, delivered, prescribed, administered and reviewed.

There are many studies showing that hospitals do not always manage their medicines to the best effect. But with effective medicine management systems, better targeted care will be delivered, and improved compliance will be seen caused by better information to the patients.²⁹

In 2001 the Audit Commission published the report “A spoonful of sugar – Medicines

Management in NHS Hospitals.”²⁹ This report was written as a remedy to identify how good medicines are managed in hospitals. It presents suggestions for how challenges and issues can be met and overcome and how the systems can be improved to be more effective.

The fourth report from the Patient Safety Observation, Safety in doses: Medication Safety Incidents in the NHS from 2004 represents seven key actions to improve medication safety, especially in hospitals. One of them is to ensure medicines are not omitted. By identification of the scope of the problem and the reasons for the omissions, the problems can be found and action taken. It highlights the importance in looking at the whole process, from medicine storage and supply systems to administration itself. Increased reporting system, routines for documentation, good communication and an improvement in staff skills through training and information is also a step in the right direction.¹

1.5.2 Medicines storage and supply

When patients are admitted to hospital, their current drug regime needs to be manifested and new drugs prescribed, and there can be many medicines that are not available at the ward. Each ward has a medicines room with stock items, normally medicines which are commonly used, and the most important medicines a patient may need. What medicines that are chosen as stock items depend on what kind of ward it is. A medicine ward will need different medicine stocked than a surgery ward.

The hospital pharmacies normally supply medicines to the wards, and during their opening times all medicines can be ordered, as long as the pharmacy stocks them. Communication between wards and hospital pharmacies is important in ensuring the appropriate, safe and timely supply of medicines. Ordering of medicines is sometimes done by nurses and sometimes by trained technicians in charge for the top up of the medicines room.

When the pharmacy is closed in the evenings and in the weekends, an emergency room with different amounts of medicines will be available at every hospital. In some cases the staff also decides to borrow medicines from other wards. If the medicine is not available at the hospital, it will have to be ordered from other instances. A review of medicines storage and medication supply chains should be done regularly, to prevent unavailable medicines.¹

1.5.3 Administration of medicines

The nurses at the wards are both in charge of administration of regular and “if necessary” medicine, and are trusted to be able to give the right medicines to the right patients. During administration of medicines, there is as mentioned many factors that can lead to errors, and it is important that standard procedures are known by all staff and followed in daily practice, so there is no room for mistakes. The Nursing & Midwifery Council published the “National Standards for Medicine Management” in 2007, as a replacement for The Guidelines for Administration of Medicine from 2004. This is a guide to enable nurses and midwives to think through issues and be more able to judge situations in the best interests for their patients.³⁰

Abridgement from Standard 8:³⁰

- You must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible (...)
- Where medicine is not given the reason for not doing so must be recorded

The standards do not give any more detailed prescriptions of what to do in different settings where medicines are being omitted.

1.5.4 Communication and routines for documentation

Good communication between staff members is essential to minimise medication errors like omitted medicine. It is also important for ensuring that the patient receives the right care, and that the patient’s recovery and discharge is not delayed. This also requires good routines for documentation. But for every time the prescription or other information is rewritten, it’s a new chance for medicine errors to occur. Some of the weaknesses within hospitals that can lead to errors:

- incomplete or incorrect medication history on admission to hospital
- Illegible or incomplete prescriptions
- The use of abbreviations leading to misunderstandings.

- Some charts are kept at another place than the main chart. This could be medicines that needs different monitoring, or that should be given in unusual times.
- incorrect or incomplete discharge medicines
 - poor information about medicine on discharge from hospital
 - lack of monitoring or follow-up on discharge

1.5.5 Training and information – improvement in staff skills

It is obvious that new clinicians need good training and information when they first start working. But there is a need for continuing training and competency assessments for all clinicians who are involved in the prescription and administration of medicines, even if they have worked as clinicians for many years. This can help to keep the safety in medicine management up and prevent accidents.²⁵⁹

1.5.6 Pharmaceutical care

Pharmaceutical care is a very important part of Medicine management. “The right Medicine – a strategy for pharmaceutical care in Scotland”, a strategy for pharmaceutical care in Scotland, was published in 2001 as a respond to the NHS Plan published the year before. It summarises pharmaceutical care as a systematic, patient-centred approach. The pharmacist should identify, resolve and prevent medicine-related problems. The result is that the right medicine will be given in the right dose and at the right time. In the end each patient will get the desired treatment for each medical condition.³¹ The pharmacist should also make sure that understandable information is given to the patient, like advice in use of their medicine, common side effects and what the patient should do if a medicine is forgotten.²

In a pharmacist work to manage this goals, a regularly review of the medicine charts in hospitals is performed. When recording medication histories, medicine omissions can easily be identified, corrected and put more focus on. Studies by the Audit Commission and Healthcare Commission show that more hospital pharmacists are now spending time on wards doing activities such as this.¹

1.5.7 Re-designing the service

In both “The NHS Plan” and “Our National Health” which are mentioned above, there is a focus on new services to improve Hospital Medicine Management Systems. This includes topics like

- new ways of supplying medicine from the pharmacy to the wards
- patients using their own medicine brought with them on admission to hospital
- self administration of medicine

Many improvements of medicines management have been performed at Ayr Hospital included The Safer Patient Initiative that also is a wide project in the UK. The aims with this project were to reduce mortality by 15%, adverse events by 30% and harm from anticoagulation by 50%.

Targets for improvements were set to be better information to patients, new protocols and easily accessible electronic laboratory results. A greater focus was also put on the process reconciliation, used to find out what medicines the patients already use when they are admitted to hospital or transferred between wards. Supply systems of medicine from the pharmacy to the wards have also been redesigned at The Ayr Hospital, and will be described in detail below, as an important understanding for this project.³²

1.6 *Electronic prescribing and administration of medicines*

The plan from NHS Scotland from 2000 presented how a lot more money would be put into communication technology to make the information flow faster both within the hospital and between the hospital and the community.²⁸ From 2003-2006 the NHS prioritised £6.2 billions on the IT programme “Connecting for health”.³³

1.6.1 Benefits and drawbacks of electronic prescribing and administration

The scope of introducing the system was to replace the existing prescribing and administration charts with a paperless, electronic system. This was because repeated

audits demonstrated that improvements were required.⁵ The most important benefits of the system was thought to be legible prescriptions, a reduction in the number of prescribing and administration dispensing errors and information available at the point of the need. The drawbacks of the system were the price of the hardware and provision of support and training when there is a high turnover of junior medical staff.³⁴

Studies comparing electronic prescribing to the old method show a decline in medication related errors, like reduction in prescribing errors and pharmacists interventions.³⁵ They also show an improvement of legibility and completeness of prescriptions.³⁶ But there are also new types of risks with electronic prescribing. These mainly involve selection of the incorrect product, dose or frequency from a list, and inappropriate use or selection of default doses.^{35,36,37} Even if there are few quantitative data about the benefits from a UK perspective at present,³⁶ there are plans about making it a national system.³⁸

1.6.2 Electronic prescribing and administration at Ayr Hospital

Ayr hospital is the only hospital in Scotland using electronic prescribing, and it was introduced to the hospital as a pilot in 1997. The system is called Prescription Order Entry (POE), and is a part of the hospital electronic filing system. In combination with the hospitals electronic medicine administration system, it is called EPMA.

In the study described earlier from Ayr Hospital⁵ one of the main objects was to compare prescribing and administration errors before and after implementation of the EPMA system. Numbers of errors was collected from both one and 12 months after implementation, and compared with numbers from when the paper-system was still in use.

The study showed that both prescribing and administration errors got significantly better after the implementation, especially after 12 months of use. The frequency of administration errors fell from 9.0 to 5.4 ($p < 0.001$) and more medicines were administrated on time. (IV drugs and controlled drugs were not included among these errors.) At the same time the study showed a different pattern of event type, like an increase of incorrect dose given. But in total the system was concluded to be at least as safe as the existing manual system.⁵

EPMA is now in use on all wards at Ayr Hospital, and this means easy access to all information kept at the computers at any time and place within the hospital for the clinicians involved in the patient medicine team. This includes information such as medicine history, lab results, X-rays, pharmaceutical care plan and documentation of administration of each medicine dose. The reasons for omissions can be watched by accessing each medicine prescribed, and both time for prescribed dosing time and the actual time when the medicine was given can be observed. If a dose is omitted the reason have to be filled out before the next dose can be documented, and because of that there are no room for unknown omissions which could be seen in the paper based system.

1.7 *Different supply systems at Ayr Hospital*

There are three different supply systems at Ayr Hospital: The Traditional Top up, Medicine Redesign System and a new pilot that they are trying out. There are several differences between them when it comes to involvement from technicians, patients using their own medicines, storing of medicines at the wards and how new prescriptions are being handled.^{39,40} The different systems are running in different wards at the moment. Which systems that will be used in each ward are still to be decided in the nearest future.

1.7.1 The Traditional top up

This is the old system, which also could be found in many other hospitals in Scotland. The wards have a medicine room with basic drugs (on stock drugs) which is topped up by a technician normally one or two times a week. Before they go to the ward they would write out a list from HEPMA off all the drugs the patients are on, and then they would check that these things are at the ward. Things that the patient need which are not stock-drugs would be put in a separate trolley. The technician would also tidy up the medicine room and the trolley, take out overstock items and check the expiry date of the drugs.

Besides this, the staff nurses order all new drugs and items they are short of several times a day from the pharmacy. These drugs will be sent down again with a porter or with the pipe-delivery system.

Patients are also asked to bring some own medicines from home such as insulin, different hormones or other non-formula items which the pharmacy do not stock.

1.7.2 Medicine redesign system

There are two wards in the hospital that are using this system, a surgical ward and a medical ward. The system has been running for 5 and 2 years respectively.

One part of the redesign system is one-stop dispensing (OSD), which is dispensing only once for the patient during a single hospital admission. Label with full instructions and patient information leaflet are, where possible, dispensed in original pack(s).

Patients at this stations use their own medicine which they bring along from home. They also use this on discharge, or get a new supply for at least 14 days. The medicines are checked up against the patient medicine prescription chart before it can be used. The drugs conditions are also checked by a technician (or a nurse) first, and if they are in bad condition or the use-by dates has expired the patient receives new ones from the pharmacy. With this method they get an idea of the patient's compliance, and what he or she knows about their own medicines. This method is a bit time consuming because it takes time to go through the patients own drugs, but about the same time is saved when it comes to discharge because the patient's medicines are ready a lot faster. It also reduces the wastage of medicines.

The patient's drugs, an amount for at least 14 days, are kept in a bedside locker, except for drugs that they might need (PRN medicine). There is a small amount of stock items such as antibiotics, lactulose, nebulas and painkillers. This is because a lot of patients are using them, and they try to avoid opening too many packages at the same time. Medication in the lockers can only be administered to the patient on the label.

There is a technician up at the wards every day, except for the weekends. They write out lists from HEPMA over all new medicines prescribed and a list over all new patients, which they go through to make sure they have all the medicines they need available. They also check patients who have been there for 14 days, and top up their bedside lockers. Insulin, eye drops and intravenous liquids that have expiry dates less than this are checked more

often. The technician keeps a diary of things that have to be checked up on what date. They also top up the ward twice a week, as they do at traditional top up.

The nurse can also order things that might have been forgotten or things that they suddenly needs after the technicians have left the ward for the day. It will then be sent up by the pipe-system, or with a porter.

1.7.3 Pilot of a new supply system

This system is a pilot that started running on the 15th September 2008 and so far it only exists in one ward. Three times a day (8:00AM, 12:45PM and 15:00PM) the technicians write out a document of all new drugs that have been prescribed that is not a stock drug and a list of new patients on the ward since the last time. Then they put a label on the medicines with the patients name on and send them to the wards through a tube delivery system that runs within the walls or with the porter. Because it is still a pilot, there are no instructions on the medicines. The nurses then put the medicines in the patient's bedside lockers.

Once a week (Tuesdays) a technician goes to the ward and tides up the on-stock items, which are drugs the patients might need and other drugs witch normally are used on the ward. Every Wednesday the technician checks the medications in the patient's bedside lockers that have been there for more than 14 days. Insulin, eye drops and intravenous liquids are checked in the same way as in the redesign system.

Every night the nurses can print out a list of all drugs that are discontinued and all patients that are deceased transferred or discharged. They then collect the drugs from the lockers, put a label on it, document why it is taken away and send it back to the pharmacy.

All drugs have to be returned to the pharmacy and relabelled before the patient can collect them for discharge.

1.8 Process map to compare medicine supply systems

There are many processes that need to be known and followed of all staff to ensure that supply of medicines are working properly. This includes medicines ordered from the wards and delivery from pharmacy, but also procedures when the pharmacy is closed and when medicine is not available at the ward.

To identify differences between supply systems, a process map can be used. The map shows what kind of different outcomes that can occur after a row of processes and situations, and how this should be handled. Often the processes are broken up by questions about the situation, and the following procedures will be decided from the answers. The answers are normally yes or no, but there can be several solutions and possibilities for how to handle each situation that may occur.

1.9 Clinical setting

1.9.1 The surgical orthopaedic ward

The first ward included in this study is the surgical orthopaedic ward at Ayr Hospital. There are room for 36 patients in total at the ward witch are mostly occupied, and the turnover of patients varies from day to day, from 3-7 patients approximately. Normally the patients stay at the ward for 5-7 days, but in some cases they leave the same day, and in other settings they might need to stay for several months.

The patients admitted to the ward are having both minor and major operations, from small fractions to hip replacements. The procedures can be planned long time before admissions, or the patient can come from the emergency admissions to the ward. In the post operative period the patients stays in a post-up room for recovery, before they are moved to one of the other rooms.

The supply system that is used on this ward is Medicine Redesign System as described above, and technicians are supplying the ward every day during the weekdays. The ward

is also seen by a pharmacist every day during the weekdays.

Messages from nurses about what changes they think needs to be performed with a patients medicine regime, such as change of route of medicine, is given verbal to doctors and pharmacists at the ward.

1.9.2 The surgical vascular ward

The second clinical setting for this project is the surgical vascular ward at the Ayr Hospital. This is the only surgical vascular ward in Ayrshire and Arran. There are 28 beds, and approximately 90 per cent of them are occupied at any time. In general the patients can stay at the ward from one day to 10 months, and the turnover is approximately 2-3 patients. Cases of patients staying at the ward for over a year have been seen.

Even if the ward is considered a surgical ward, not all patients are admitted of this reason. There could also be medical reasons such as medicine investigation and palliative treatment. Many are admitted to receive wound management, and social imputes can, according to the nurses working at the ward, infect how long the patients stays at the ward.

The ward are supplied of medicines from the hospital pharmacy twice a week (traditional top up) and most of the time it is the nurses who order all needed medicine, not a technician as at the orthopaedic ward.

A handwritten system is used at the ward where the nurses write all messages about possible changes that needs to be done with the patients medicine regime from what they experience during administration of medicines.

2 The Project – aim and objectives

2.1 Aim

The aim of the project was to compare two medicines management systems in surgical patients in terms of; (1) the nature and the incidence of medicines dose omissions; and (2) the relative safety risk from assessment of clinical impact of the omissions.

2.2 Objectives

- Review the NHS literature on risks to patient safety of errors in medication use in the peri-operative period. Review the literature on hospital medicines management systems.
- Identification of recommendations about medications which should or should not be withheld in the peri-operative period.
- Interrogate the HEPMA system prospectively to identify recorded reasons for a dose omission. Dose omissions recorded as '*Unavailable Medicine*' will be confirmed from inspection of the medicines room.
- Design a template to summarise anonymously the clinical context for each patient that is the subject of a subset of dose omissions. [The subsets are '*Unavailable Medicine*', '*Fasting Patient*', '*Theatre*', and '*Unable to swallow*'].
- Evaluate the clinical significance of the subset of dose omissions at both individual drug and individual patient levels, using an expert group of four clinical pharmacists
- Describe in detail using a process map (flow diagram) the two medicines management systems and compare the findings.

- Develop guidelines to help inform ward staff about medicines that should not be omitted. Validate the guidelines through group interview with pharmacy and nursing staff.

3 Methods

The project was designed as a prospectively study performed to observe two surgical wards supply systems and administration of medicines. Reasons and quantification of dose omissions were identified before clinical significance of omissions causing harm to the patient were decided for a selection of the findings. The results were used to compare the two wards and target where improvements might were needed.

3.1 *Ethical approval*

Before starting up with the project an application was sent to Ayrshire and Arran Health Board Ethics Committee, which approved the study 14.01.09.

3.2 *Review of literature*

Background literature was obtained from research in the electronic library databases Medline and Embase. Both MeSH terms and free text were used to find articles on the different objects covered in the introduction. Google was a good supplement to help include articles that was not found through the sources mentioned above. The reference lists from different articles was also used to identify other articles about the same object.

Several web-sites of the health and pharmacy services in the UK and journals not on Medline (Pharmaceutical journal of Pharmacy practice) were browsed to find literature to be used in the introduction and for the researcher's background knowledge. This included both the historical and the current health situation in the UK and Scotland, medicines management systems and the changes that are in progress. Some of the most used web sites were The NHS (both England and Scotland), The Scottish Government, The Pharmaceutical Journal, The Royal Pharmaceutical Society of Great Britain and the Audit Commission.

Some literature items were also accessed at The Ayr Hospital, such as standard operative procedures, different articles about medication in the peri-operative period, and the study

about electronic prescribing performed at the hospital.

To identify use of medicines in the peri-operative period, the 'Guidelines for the management of drug therapy in the pre-operative period' made by Area Drug & Therapeutics Committee of NHS Ayrshire & Arran was used². This is the set of guidelines that the pharmacists and other medical staff use at The Ayr Hospital for what medicines should or should not be given in the time around surgery. Other sources have also been used, such as articles from the Pharmaceutical Journal, and other articles from different NHS hospitals as a supplement to those guidelines.

3.3 *Data collection of frequency and reasons for dose omissions*

3.3.1 Pilot phase

A pilot phase was performed before the actual data collection to develop and test different templates that were used in the actual data collection. The pilot phase lasted for one week and gave an idea of what numbers the investigator could expect from the different wards. An approximately time for about three weeks was set to be an ideal collecting period, but with room for change.

3.3.2 Data collection

Data were collected from all patients at the orthopaedic ward from 26th of January to 15th of February and from the vascular ward from 13th to 19th of February and from 13th to 26th of March.

The patients prescribed and administered medicines were viewed from accessing each patients medicine records at the EPMA system. Frequency and reasons for omitted doses were collected by both looking at history for each medicine prescribed and the log of medicines administered the last 24 hours. The two wards were checked for omitted doses at the EPMA system twice a day on the weekdays, about 9 in the morning and 1 in the afternoon. Omitted doses from afternoon and evening administration were recorded in

the morning the next day, while data from the weekend were collected Monday morning.

Medication that was investigated in this study included regular medication, intermittent infusions, continuous infusions and injections. As-required medication (PRN) was not investigated.

The reasons for omitted doses collected in this study were

- Unavailable Medicine
- Fasting Patient
- Theatre
- Unable to Swallow
- Absent from Ward
- Refused
- Withheld
- IV access unavailable

In some cases the patients were away from hospital and self-administered the medicine for a while, and such doses were excluded from the data collection. Other reasons that were excluded because the patient was not on the ward or because the prescription was changed.

- Administration discontinued
- Drug discontinued
- Patient discharged
- Patient deceased
- Not charted prior to discharge
- Transferred patient

3.3.3 Identification of administration issues and patterns

For the medicines recorded as unavailable an investigation was performed to confirm that the medicines actually were unavailable and if they were stock items or not.

An overview of when all medicines had been sent to the wards from the pharmacy could be seen through the EPMA system or through notes filed by the pharmacy staff (covered

both time and date).

The actual stock amounts could also be viewed in real life from the medicine room, in trolleys and in the patients bedside lockers. This was showed to be easier at the orthopaedic ward, because there was a technician at the ward each day with access to all cupboards and trolleys. The nurses were not suppose to be bothered about this, because one of the main points was to avoid to interfere the normal routines to the staff and in that way get more reliable results. Observations at the vascular ward were therefore narrowed (technician present two days a week), but delivery documentations were used at the omitted, unavailable doses that could not be observed.

To look for similarities of when medicines were recorded as unavailable, the omitted doses in this category were divided into weekdays and weekends. The omitted medicines were compared with medicines on stock to identify alternatives that the nurses could have given the patients instead of omitting the dose.

3.4 *Collection of clinical context of patients with dose omissions*

3.4.1 Inclusion of patients

Each patient in the mentioned time period that had one or more omitted doses in the four categories '*Unavailable Medicine*', '*Fasting Patient*', '*Theatre*', and '*Unable to Swallow*' was picked out. Nurses at the two stations where asked about the patients condition to find out if the patients would be fine to talk to. Patients thought to be confused, suffering from dementia or other similar problems were not included in further data collection.

Only the patients who did not get excluded in that step, were asked if they wanted to take part in the study. Written information was handed out (Appendix 1) which they got time to read trough. Then a consent form (Appendix 2) had to be signed before any further information were collected. If the patient had any difficulties with writing, but still wanted to take part, a verbal consent was taken. If the patient did not want to take part, this was respected and no clinical information was collected.

3.4.2 Collection of clinical information about the patients

A template (Appendix 3) was designed to summarise the clinical context for each patient. The template contained the patient's age, sex, presenting complaints, planned or emergency surgical procedures, medical history, current medicines and reported omitted doses. All the information was collected in an anonymous form, but coded so that there was a possibility to track the actual patient if later questions needed to be addressed. A list with the patients' names and patient number was kept separately in the hospital at all times. None of the information was collected if the patient did not give their consent.

The information was collected both from the EPMA system and from the handwritten journals. Pharmaceutical care plan and details of the medicines use and omissions was found from EPMA, which also provided surgical procedures, some presented complaints and medical history. In the handwritten journal a full medical history could be found, details around surgical procedures, presented complaints and the patients' biochemical tests.

The date for each patient's admission to hospital and how many doses that were already given before the omissions occurred were also found to be important information, and this information was also collected from the EPMA system.

3.5 *Evaluation of clinical significance of dose omissions by an expert group*

After the collection of the clinical information all patients from both wards were mixed anonymously, but still with possibility to track their identification. They were sorted after what medicine groups the omissions belonged to, with similar cases following each other. One patient after another was then introduced to a group of clinical pharmacists considered as experts. Their job was to decide the clinical significance of each omitted dose the patients had suffered from. They all got one handout each of all the patient cases, which gave them time to read through it and go back to compare cases during the meeting.

Two meetings were held with expert groups. The first one was to agree on the categorisation system chosen for clinical significance because it had not been used or validated be-

fore. Nine clinical pharmacists were present at the meeting, and the agreement was made after looking at 10 different patients. At the second meeting the expert group was narrowed to four clinical pharmacists which categorized the 34 remaining patients. The meetings lasted for approximately one hour each.

Assessment of clinical significance of dose omissions was set to be:

- 0 No threat to patient care
- 1 Minor disturbance to symptom control
- 2 Major disturbance to symptom control
- 3 Major threat to stability of patient's condition
- 4 Potentially able to precipitate a life threatening event

These categories were devised by the research group after the investigator had checked the literature and found no suitable alternatives.

3.6 Comparison of two medicine management systems using a process map

The two different medicine management systems used at the two wards investigated in this project were described and compared with use of a process map.

Information about the supply systems were collected by the researcher through direct observations by following the technicians work processes in the hospital pharmacy and on the different wards, especially the wards included in this study. Participation on administration rounds with nurses were also performed and supplementary information collected from pharmaceutical and nursing staff were also useful to get the total overview of the processes both in practice and theory.

3.7 Development and validation of guidelines

From the results collected from the expert group analyses, guidelines were developed to

identify medicines that should not be omitted. The guidelines were based on the omitted doses potentially to cause more than a minor disturbance to symptom control.

The guidelines were presented to the same expert group that was used for scoring the clinical significance at the second expert meeting. Written handouts were given to each pharmacist and verbal explanations were also given from the researcher were needed. Evaluation and approval were given to the researcher after discussions between the pharmacists.

Unfortunately the last object where the guidelines should be validated through group interview with nursing staff was not performed because of time limits.

4 Results

4.1 Quantitative description of dose omissions

A total of 9614 doses of medication were prescribed to hospital inpatients in the orthopaedic ward and 8245 doses to the patients in the vascular ward over the 3-week period (excluding medicines prescribed on an as-required basis). Of these, 972 (10.1%) and 492 (6.0%) doses were omitted in total respectively. Most of the omissions were caused by patients refusing and doses being withheld at both wards.

The breakdown of the omitted doses into omissions per day at the two wards are shown in appendix 5 and 6, and show both counts and percentages of the total amount of prescribed doses.

The following two tables show the frequency of dose omissions of different reason compared at the orthopaedic and vascular ward. The comparison is presented both from the total number of doses prescribed, and the total number of omitted doses.

The confidence intervals per proportion presented in the tables shows that there is a 95% chance that the proportion of dose omissions would be in this interval if data were collected again using the exact same methods. A visual check of overlapping between one proportion and the interval of the other proportion can give an approximately idea if there is a significant difference. If overlapping is seen, a significant difference is unlikely. The visual test does not replace proper statistic test calculating p-values.

The p-values were found using Chi-square with Yates correction when comparing omitted doses to the total number of doses, and Fischer exact test for comparison with the total number of omitted doses, because Chi-square works better with high numbers. The p-values denote if there are any significant differences between the two wards. If this value is equal or over 0.05 there is no demonstrable difference between the two wards, while a p-value under 0.05 means that there is a 95% likelihood of a real difference between the two wards based on the comparison of the two samples. The closer the p-value gets to zero, the greater are the percentages of the likelihood of difference.

Table 3. Comparison of dose omissions from total number of doses that should have been given on the Orthopaedic (n=9614) and the Vascular ward (n=8245)

	Orthopaedic ward		Vascular ward		p-value (Chi- squared)
	Count (%)	95% CI as % age	Count (%)	95% CI as % age	
Unavailable	76 (0.8)	0.6, 1.0	41 (0.5)	0.4, 0.7	0.02
Fasting patient	109 (1.1)	0.9, 1.4	27 (0.3)	0.2, 0.5	<0.0001
Theatre	62 (0.6)	0.5, 0.8	18 (0.2)	0.1, 0.4	<0.0001
Unable to swallow	12 (0.1)	0.1, 0.2	17 (0.2)	0.1, 0.3	0.25
Absent from ward	4 (0.04)	0.0, 0.1	16 (0.2)	0.1, 0.3	0.005
Refused	517 (5.4)	4.9, 5.9	167 (2.0)	1.7, 2.4	<0.0001
Withheld	188 (2.0)	1.7, 2.3	200 (2.4)	2.1, 2.8	0.04
Iv access unavailable	4 (0.04)	0.0, 0.1	7 (0.1)	0.0, 0.2	0.39
Total omissions	972 (10.1)	9.5, 10.7	492 (6.0)	5.5, 6.5	<0.0001

Table 4. Comparison of dose omissions from total number of omitted doses on the Orthopaedic (n=972) and the Vascular ward (n=492)

	Orthopaedic ward		Vascular ward		p-value (Fischer Exact Test)
	Count (%)	95% CI as % age	Count (%)	95% CI as % age	
Unavailable	76 (7.8)	6.3, 9.7	41 (8.3)	6.1, 11.2	0.76
Fasting patient	109 (11.2)	9.3, 13.4	27 (5.5)	3.7, 8.0	0.0003
Theatre	62 (6.4)	5.0, 8.2	18 (3.7)	2.3, 5.8	0.04
Unable to swallow	12 (1.2)	0.7, 2.2	17 (3.5)	2.1, 5.6	0.008
Absent from ward	4 (0.4)	0.1, 1.1	16 (3.3)	1.9, 5.3	<0.0001
Refused	517 (53.2)	50.0, 56.4	167 (34.0)	29.8, 38.3	<0.0001
Withheld	188 (19.3)	16.9, 22.0	200 (40.7)	36.3, 45.2	<0.0001
Iv access unavailable	4 (0.4)	0.1, 1.1	7 (1.4)	0.6, 3.0	0.05

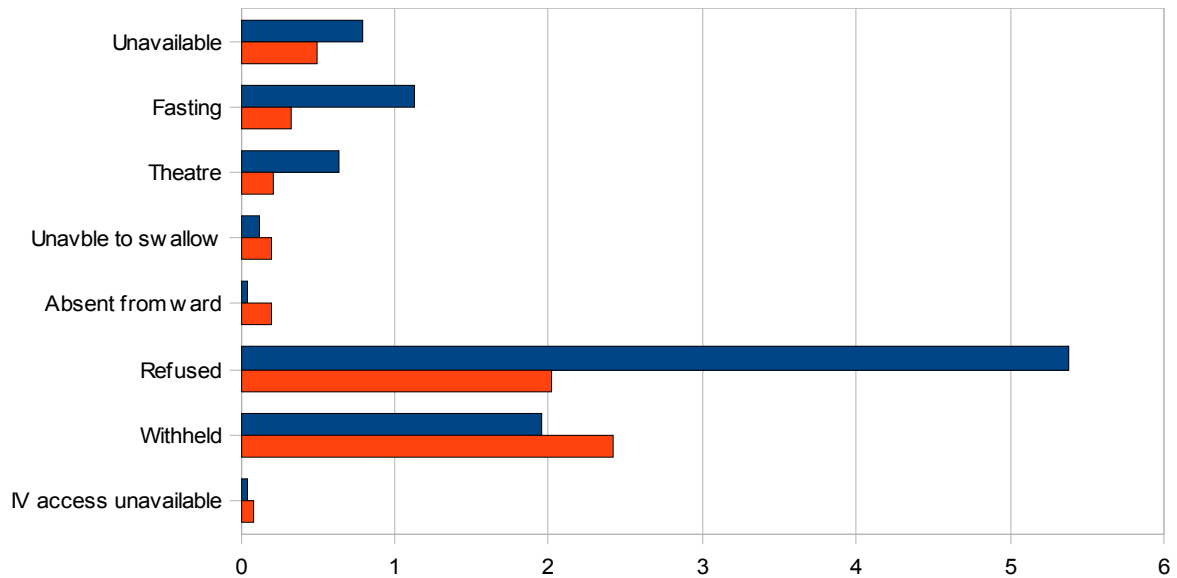


Figure 1 The frequency of different reasons for omitted doses of the total number of doses prescribed

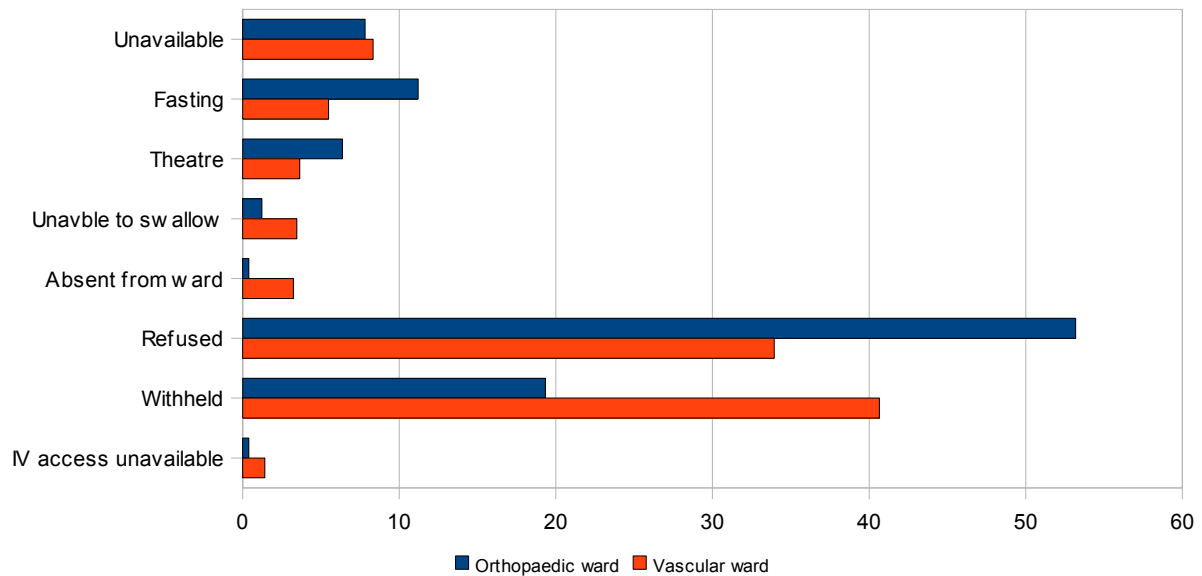


Figure 2 The frequency of different reasons for the total amount of omitted doses

The high number of refused doses were especially notable, and after the observation period it could be concluded that the laxatives lactulose and senna stood for 284 of the 517 (54.9%) omitted doses in this category at the orthopaedic ward, and 57 of 167 (34.1%) at the vascular ward ($p < 0.0001$).

4.2 Dose omissions categorized as unavailable

There was a higher frequency of doses charted as unavailable at the orthopaedic ward than at the vascular ward (0.8% and 0.5% respectively, $p = 0.02$). The data collection also showed that 38.2% (orthopaedic ward) and 46.3% (vascular ward) of the unavailable medicine were right before (7am dose) or within the pharmacy opening times, included the three hours the pharmacy is opened at Saturdays, and 61.8% and 53.7% respectively were outside the pharmacy opening times.

Inspections of the time for supply of the medicines and observations at the wards showed that 51.3% (orthopaedic ward) and 39.0% (vascular ward) were present at the ward at the time the dose was noted as unavailable. These numbers are not statistically significant different ($p = 0.34$).

Of the doses noted as unavailable at the orthopaedic ward there were 16 doses that were stock items and 14 of them were on the ward. For the vascular ward, 6 doses were stock items, and 5 of them were on the ward, ($p = 0.46$ not statistically significant different).

Of alternative medicines that were available at the wards at the point of doses omitted and recorded as unavailable there were 4 doses at the orthopaedic ward, and 1 dose at the vascular ward.

Table 7 Frequency of medicine found on the ward after recorded as unavailable.

	Orthopaedic ward		Vascular ward		p-value (Fischer's exact test)
	n	%	n	%	
Unavailable doses					
Total	76		41		
On ward	37	51.3	16	39.0	0.34
Not on ward	39	48.7	25	61.0	

Table 8 Locations of omitted doses noted as unavailable, but identified as available at the orthopaedic ward.

Frequency omitted doses	
Medicine room	3
Bench in medicine room	1
Cupboard	17
Trolley	4
Bedside locker	12
Total	37

Table 9 Frequency of stock items noted as unavailable

Unavailable doses	Orthopaedic ward		Vascular ward		p-value (Fischer's exact test)
	n	%	n	%	
Total	76		41		
Stocked	16	21.1	6	14.6	0.46
Non stocked	60	78.9	35	85.4	

Table 10 Medicines on stock that could have been given as a supplement

	Unavailable dose	Available supplement	Notes
Orthopaedic ward	Amoxicillin 500mg caps	Amoxicillin 250mg caps	Happened 2 times
	Diclofenac 75mg in 2ml inj.	Diclofenac 75mg in 3ml inj.	
	Propranolol 80mg mod.	Propranolol 40mg mod.	
Vascular ward	Senna 7.5mg in 5 ml syrup	Senna 7.5mg tablets	If the patient did not have troubles swallowing

Unavailable medicine in weekends compared to weekdays

The number of unavailable medicine in the weekends were much higher in the orthopaedic

ward than at the vascular ward, 1.2% and 0.2% respectively, compared to the total amount of prescribed doses ($p = <0.0001$) and 12.5% and 4.2% compared to the total number of omitted doses ($p = 0.01$). Data was collected from three weekends and included all doses given Saturday and Sunday.

The number of unavailable medicines during the weekdays was the same in percentages at the two wards compared to the total number of doses prescribed at each ward (0.6%). But compared to the total number of omitted doses during weekdays, the percentages of unavailable medicine was higher in the vascular ward than the orthopaedic ward, 9.7% and 6.1% respectively ($p = 0.04$).

Table 11 Frequency of omitted unavailable doses (n) of the total number of prescribed doses in weekdays and weekends, compared between the two settings

	Orthopaedic ward			Vascular ward			p-value (Chi square)
	Total prescribed doses	n (%)	(95% CI)	Total prescribed doses	n (%)	(95% CI)	
Total	9614	76		8245	41		
Weekdays	6964	44 (0.6)	0.5, 0.9	5983	36 (0.6)	0.4, 0.8	0.92
Weekends	2650	32 (1.2)	0.8, 1.7	2262	5 (0.2)	0.1, 0.6	<0.0001

Table 12 Frequency of omitted unavailable doses (n) of the total number of omissions in weekdays and weekends, compared between the two settings

	Orthopaedic ward			Vascular ward			p-value (Fischer exact test)
	Total omitted doses	n (%)	(95% CI)	Total prescribed doses	n (%)	(95% CI)	
Total	972	76		492	41		
Weekdays	717	44 (6.1)	3.4, 6.1	372	36 (9.7)	5.3, 10.1	0.04
Weekends	255	32 (12.5)	2.3, 4.7	120	5 (4.2)	0.4, 2.5	0.01

4.3 Collection of clinical context of patients with dose omissions

4.3.1 Inclusion of patients

In total 76 patients experienced omitted doses caused by one or more of the four different categories, '*Unavailable Medicine*', '*Fasting Patient*', '*Theatre*', and '*Unable to Swallow*', which was set to be the first inclusion criteria during the collection period. There were 51 at the orthopaedic ward, and 25 at the vascular. Consent was received from 44 of the patients, 32 from orthopaedic and 12 from vascular.

All together 32 patients did not give their consent. Some patients were too ill or suffering from dementia or other things that made them unable to give consent. There was also a few that after hearing about the study decided that they did not want to take part.

Unfortunately there were also some cases where the patients had left the hospital before consent had been given. Of this, 4 had received written information, but were gone when the researcher came to get consent, and 3 had left the ward while data was being collected from other patients.

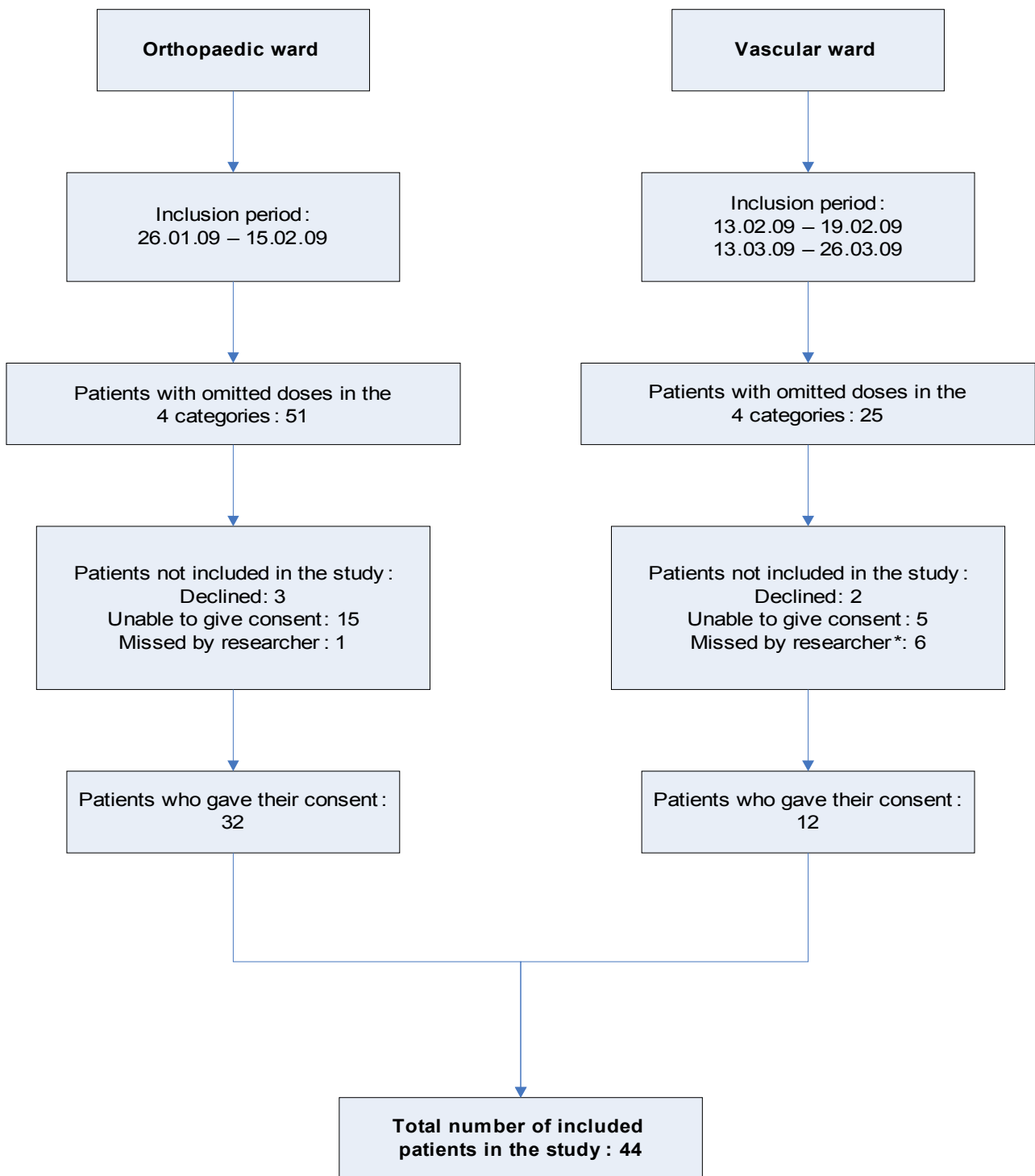


Figure 3 Inclusion of patients for collection of clinical context.

4.3.2 Description of the patients included in the study

Of the 44 patients included in the study there were several who had just one or two omitted doses during the data collection period, but there were also cases of patients who had over ten omissions. The highest number of omitted doses that one patient experienced during the collection-period happened at the vascular ward and was calculated to be 31. The average number of dose omissions for each patient was 4 at the orthopaedic ward and 5 at the vascular ward. The average age of the patients included in the study was approximately 67 years at both wards, and in both wards there were more women, 78.1% at the orthopaedic ward, and 66.7% at the vascular ward.

The data collection showed that the main cause for admissions to the two wards among the included patients were planned or emergency surgeries, 78.2 % at the orthopaedic and 50.0% at the vascular ward. There were also other reasons for admission recorded. At the vascular ward these were mostly patients with ischemic arms or legs who needed wound treatments. For patients admitted to the orthopaedic ward it was patients who had fractures and other injuries after fall, while others complained about pain in knees or hips from other reasons.

Table 13 Description of the patients included in the study (n=44)

	Orthopaedic ward	Vascular ward	Total	p-value (Fischer's exact test)
	Patient frequency of total number of patients			
Female	25 (78.1%)	8 (66.7%)	33 (75.0%)	0.46
Male	7 (21.9%)	4 (33.3%)	11 (25.0%)	
Mean age	66.5 years	67.3 years	66.7 years	
Planned surgery	19 (59.4%)	6 (50.0%)	25 (56.8%)	0.74
Emergency surgery	6 (18.8%)	0 (0.0%)	6 (13.6%)	0.17
Other reason for admission	7 (21.9%)	6 (50.0%)	13 (29.5%)	0.13
Total number of patients	32	12	44	

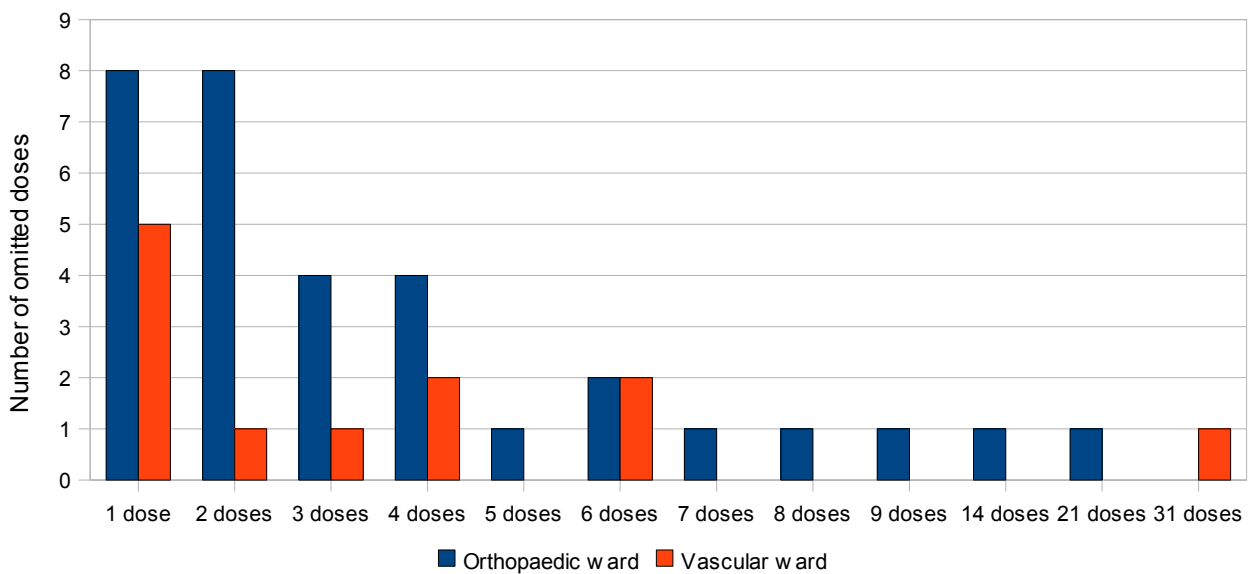


Figure 4 The frequency of omitted doses per patient who was included in the study

4.4 Scoring of clinical significance of the omitted doses by the expert group

4.4.1 The expert group's validation of the study design

Because the assessment used in this study had never been tried out before, the meaning behind the different outcomes were discussed during the expert group meetings, and cases were sometimes compared against each other to find the correct score to each case. The expert group found the gaps between 'minor disturbance to symptom control', 'major disturbance to symptom control' and 'major threat to stability of patient's condition' a bit too wide. In some cases the expert group thought the possible outcome was between to scores, and had to settle with one of the outcomes.

In most of the cases the pharmacists thought they had enough information to score the dose omission, but in some cases they had to do some assumptions. The most important lack of information was that the messages from the anaesthetists about what medicines

that should or should not be given were not collected. They decided to follow regular guidelines instead and normal procedures for withhold of medicines as they would have done it in practice. In the end all the four pharmacists had agreed with the mean scores that were set for each omission.

4.4.2 Scoring of clinical significance

In total 189 omitted doses occurring in 44 patients were presented to the expert group for decision of clinical significance. In total 41.2 per cent of the omitted doses potentiall could have caused some kind of disturbance to system control, (28% minor disturbance and 13.2% major).

In one of the cases scored as 'major disturbance to symptom control' the pharmacists were in doubt if it should have been scored as 'major threat to stability of patient's condition'. This was a medicine used for preventing thromboembolism, and will be further presented under the section about cardiovascular medicine.

There were no cases of omitted doses scores as 'potentially able to precipitate a life threatening event'.

Table 14 Comparison of the division of clinical significance of omitted doses (n=189) in the two wards.

	Orthopaedic ward	Vascular ward	Total	
Clinical significance	n (% of total number of scored omitted doses)			p-value (Fischer's exact test)
No threat to patient care	72 (56.3)	39 (63.9)	111 (58.7)	0.35
Minor disturbance to symptom control	37 (28.9)	16 (26.2)	53 (28.0)	0.73
Major disturbance to symptom control	19 (14.8)	6 (9.8)	25 (13.2)	0.49
Major threat to stability of patients condition	0 (0.0)	0 (0.0)	0 (0.0)	-
Potentially able to precipitate a life threatening event	0 (0.0)	0 (0.0)	0 (0.0)	-
Total number of omitted doses scaled for clinical significance	128	61	189	

4.4.3 Clinical significance of omitted doses in different medicine groups.

The omitted doses were divided into 15 different medicine groups after the guidelines for withheld or continuation of medicines in the peri-operative period¹². Cardiovascular medicine alone stood for 27.5 per cent of all the omitted doses scored, and there were also many doses omitted in the medicine groups “nutrition and blood”, gastrointestinal and analgesia, 14.8, 10.6 and 10.1 per cent respectively.

Table 15 Frequency of clinical significance of omissions (n=189) in different medicine groups

	No threat to patient care		Minor disturbance to symptom control		Major disturbance to symptom control		Total	
Medicine groups	Frequency (% of total amount of scored omitted doses in each scoring category)							
Gastrointestinal	11	(9.9)	7	(13.2)	2	(8.0)	20	(10.6)
Cardiovascular	12	(10.8)	30	(56.6)	10	(40.0)	52	(27.5)
Respiratory	3	(2.7)	2	(3.8)			5	(2.6)
Central nervous (CNS)	9	(8.1)					9	(4.8)
Infections			6	(11.3)	9	(36.0)	15	(7.9)
Endocrine	8	(7.2)			4	(16.0)	12	(6.3)
Obstetrics, gynaecology and urinary tract disorders			4	(7.5)			4	(2.1)
Malignant disease and immune suppression	3	(2.7)	1	(1.9)			4	(2.1)
Nutrition, blood	28	(25.2)					28	(14.8)
Musculoskeletal and joint diseases	6	(5.4)	1	(1.9)			7	(3.7)
Topical steroids	2	(1.8)	1	(1.9)			3	(1.6)
Antihistamines	4	(3.6)					4	(2.1)
Drugs used in nausea and vertigo	2	(1.8)					2	(1.1)
Analgesia	19	(17.1)					19	(10.1)
Others	4	(3.6)	1	(1.9)			5	(2.7)
Total	111	(58.7)	53	(28,0)	25	(13.2)	189	

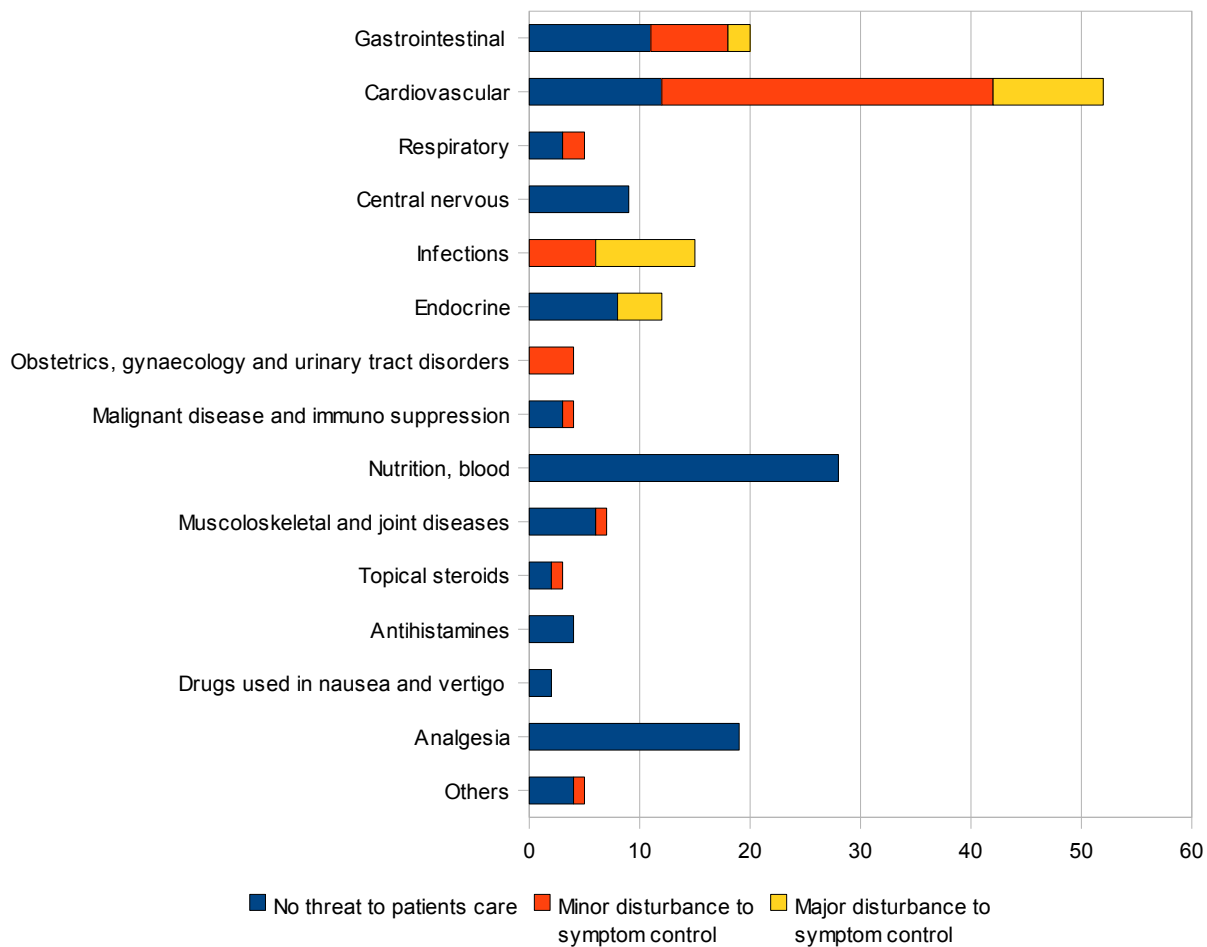


Figure 5 Clinical significance of the evaluated, omitted doses and comparison of medicine groups.

Four groups of medicines represent cases where omitted doses have caused a potential ‘major disturbance to symptom control’, which were the groups gastrointestinal, cardiovascular, endocrine and infections.

Gastrointestinal

Most of the medicines in this group were thought to not cause any harm to the patient if omitted, like lactulose and senna. But there were two cases where the patient did not receive the prescribed H2- antagonist in front of the operation, and both of them were set to be able to cause ‘major disturbance to symptom control’ by the expert group. The explanation from the expert group was that this medicine is given close up to surgery to

prevent stomach regurgitation during anaesthetic which can cause pulmonary aspiration. In both of the cases the surgery was planned.

Cardiovascular

In total 10 of 52 omitted doses in this medicine group were set to score major disturbance to symptom control. Of them there were 6 cases of omission of beta blockers in the peri-operative period, and the risk for withdrawal effect and consequence of stress hormones on the unmasked beta-adrenoceptor system¹³ were confirmed by the pharmacists who scored the clinical significance of this medicines.

The right treatment for preventing bleeding during and VTE after surgery is a complicated task that must be followed like prescribed to prevent harm to the patient. Aspirin is often stopped 7-10 days before surgery, if bleeding risk is significant¹², and omissions like this were scored as no threat to patient care. But on the other hand, if aspirin is omitted after surgery the patient loses critical treatment against VTE, and the clinical pharmacists scored the cases of this the same as they did with the beta blocker. The same was also seen in a case where the patient did not get heparin in the nil by mouth period before surgery.

The last case within the cardiovascular medicines was the only case during the expert meetings where the pharmacists were uncertain if they should score an omitted medicine as 'major disturbance to symptom control' or 'major threat to stability of patient's condition'. This was a case which also included treatment to prevent VTE. The pharmacist had decided that the patient should receive the medicine rivoroxaban straight after the procedure. This dose was omitted and not given before the next day. What was special about this situation was that the patient had pulmonary embolism among her medical history and was therefore in a greater risk of experiencing thromboembolism.

Endocrine

There were three cases where patients had not received their regular dose of prednisolone in the nil by mouth period. All three were scored as possible to cause 'major disturbance to symptom control'. The expert group concluded that patients using prednisolone regularly should not have any omitted doses of this medicine at any time in the peri-operative period, because of the great stress factors that the patient may

experience during this time.

Infections

All of the doses against infections were thought to cause some kind of disturbance to system control if omitted. Nine out of fifteen doses were scored as major, and six were categorized as minor. The choice of categorization of clinical significance depended on what the medicine was against, how serious the infection was and for how long time the patient had received the treatment before the dose was omitted.

Doses of antibiotics omitted late in the numbers of doses given to the patient were scored as minor disturbance. There were five different clinical settings for this. There were also two cases where the first dose was omitted, and one with the second dose and they were all set to be of major disturbance to system control. There was also a case where the 4th dose was categorized like this, and this was an injection given against a wound infection.

Another case of treatment of infections was a woman with MRSA, who missed both a dose of Mupirocin Nasal Ointment 2% and Stellisept med foam. Both omitted doses were set to be potential to cause major disturbance to symptom control.

There were three cases where antifungal medicine were omitted, and they were all set to cause some kind of disturbance to symptom control. These medicines were just prescribed as cures for 2-3 days with one dose a day, and if one of these were omitted the pharmacists in the expert group concluded that the meaning with the treatment was disturbed.

Medicine classified as 'No threat to patient care'

As can be seen in table.. there were most cases of omitted doses categorized as '*No threat to patient care*' at both wards, in total 56.3% and 63.9% on the orthopaedic and vascular ward respectively.

Even if the clinical history of the patients varied, there were some medicines that were set in this category every time, such as the laxatives lactulose and senna (omitted 6 and 3 times respectively). The analgesic paracetamol was omitted 17 times, and were also classified as no threat. The reason for this, according to the expert group, was that the

patients received other stronger analgesic and would not notice any differences when these doses were omitted. Cholesterol lowering medicines, antihistamines and vitamins were other medicines also were scored as no threat to patient care in several settings.

4.5 Guidelines to help inform ward staff about medicines that should not be omitted.

From the scoring of clinical significance by the expert group, there were 7 medicine groups that were concluded as medicine that should not be omitted for any reason. These were the medicines scored as potential to cause 'major disturbance to symptom control' if omitted. Some of the medicines must not be omitted at any time during the peri-operative period, while others are more important either in front of or after surgery. The exceptions are if the anaesthetist has given other instructions or if it is clinical inappropriate to give the dose.

Table 16 Guidelines for medicines that can not be omitted in the peri operative period for any reason, except if the anaesthetist have given other instructions or if clinical inappropriate.

Medicine group	Some examples of medicines	Time period
H2 antagonist	Ranitidine	Before surgery
Beta blockers	Metoprolol, propranolol, carvediol, atenolol	Before surgery and 4 days after
Antiplatelets	Aspirin, dipyridamole	After surgery
Anticoagulants	Rivoroxaban	After surgery
	Dalteparin	Peri-operative period (before and after)
Corticosteroids	Prednisolone	Peri-operative period (before and after)
Antibiotics	Mupirocin Nasal Ointment Stellisept med foam Clarithromycin Trimethoprim Doxycycline Flucloxacillin	Any time (especially first to fourth dose).
Antifungals	Clotrimazole (2-3 days treatments)	Any time

4.7 Process map comparing the two supply systems for clinical setting

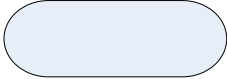

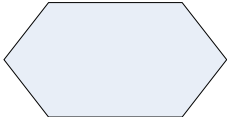

Symbol	Name	Meaning of symbol
	Terminator	Represents the first and last step of process
	Process	Represents a step in a process (activity or task)
	Question	A question with a Yes or No answer
	Connector	An arrow that connects the different boxes in the process map

Figure 6 Symbols used in the process map

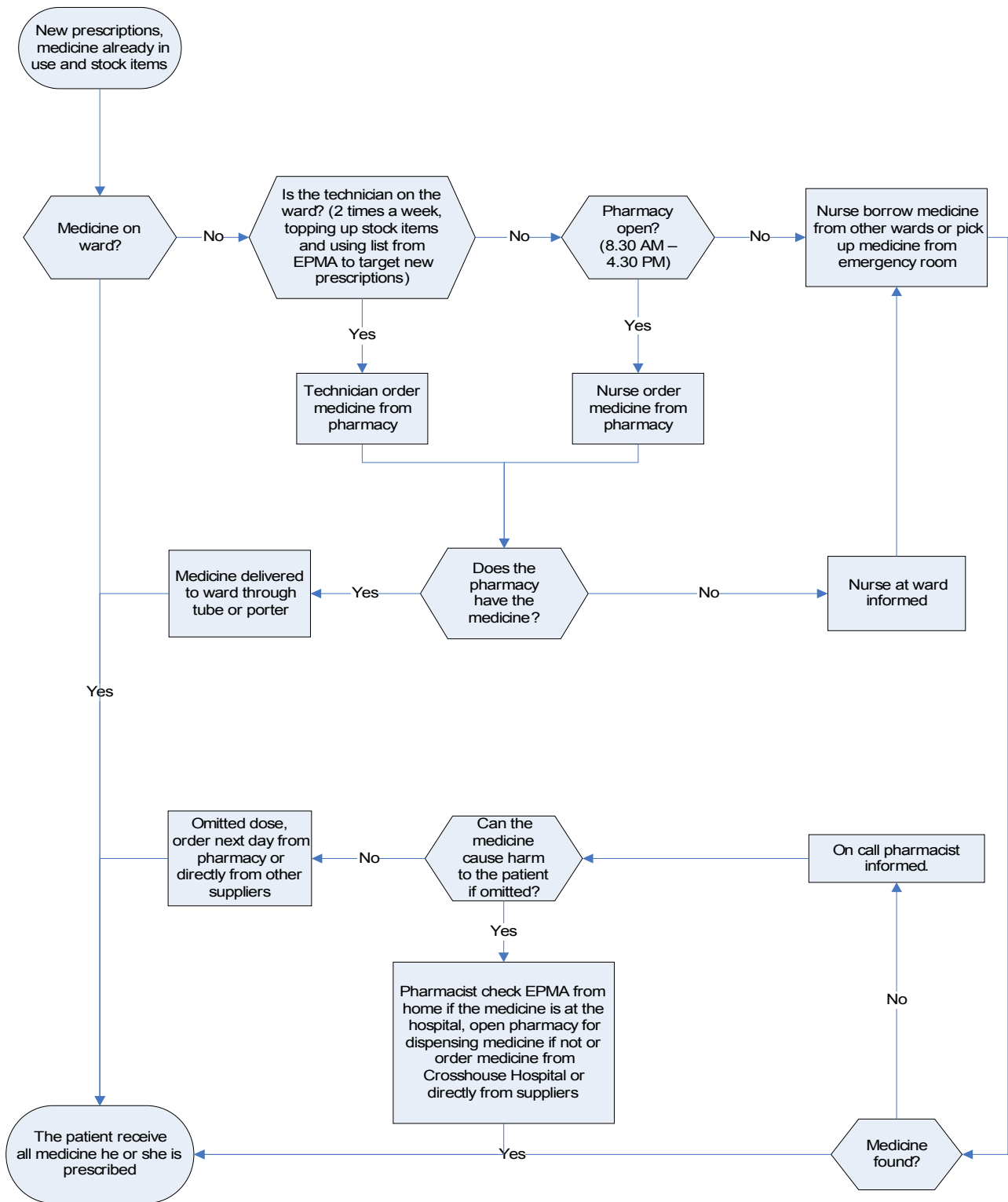


Figure 7 Process map for The Traditional Top Up supplying system

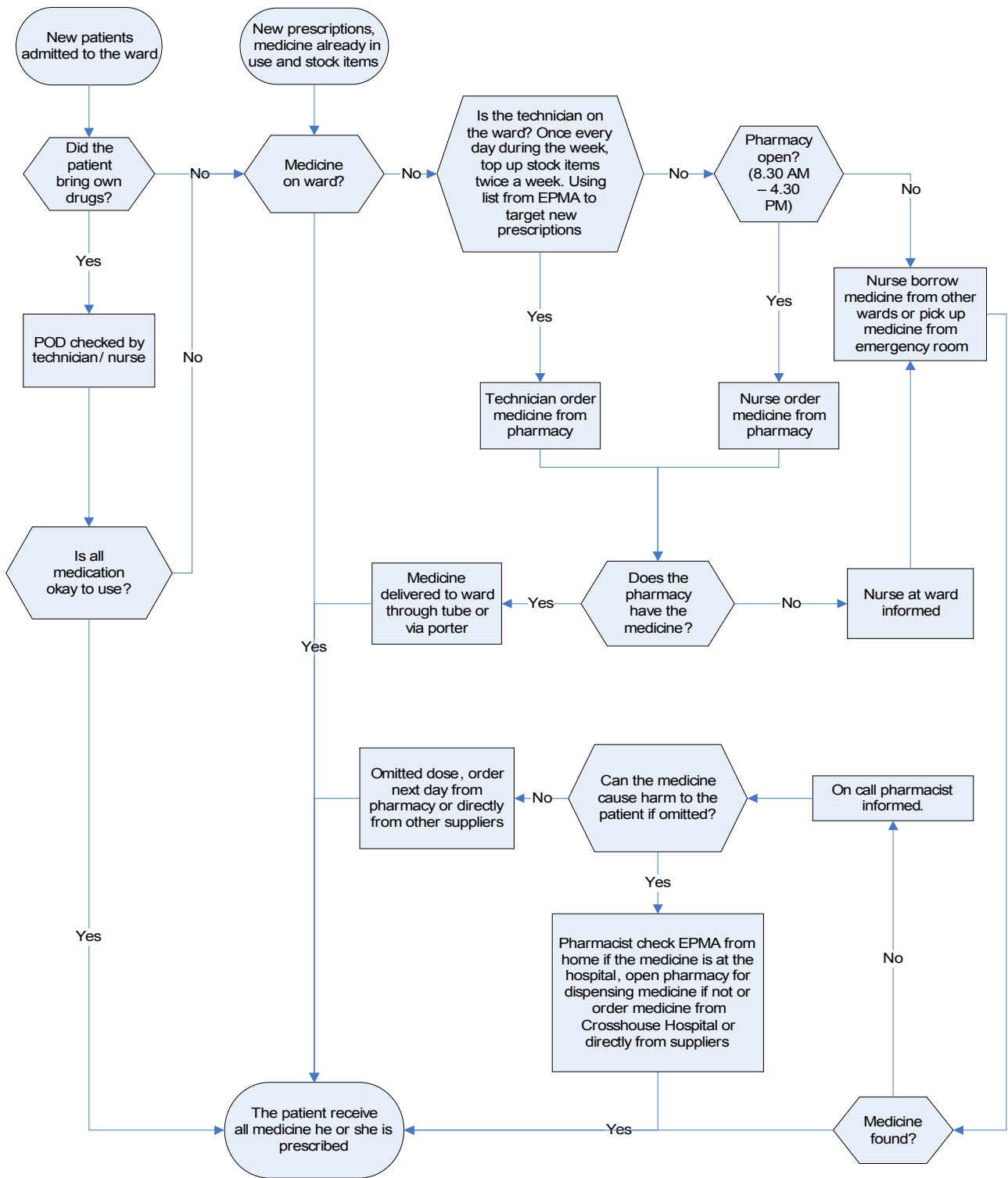


Figure 8 Process map for The Medicine Redesign supply system

5 Discussion

5.1 Data collection

5.1.1 Validation of use of EPMA to collect data

All findings from the data collection of reasons for omitted doses were found using the electronic computer system within the hospital. It was shown to be a precise and reliable method of finding information, from both present and former time. This was both because it was easily accessible from computers at both the wards and within the pharmacy, and because the history of a patient was possible to find even if the patient was discharged.

Because the nurses have to document the reason for why a dose has not been given into the system, there were no unknown results, which were very convenient for the reliability of the numbers collected.

But at the same time the EPMA system allows the nurses to wait with documenting the reason for each omission until the next dose is due. This makes it possible for documentation to be performed by another person than the original administrator. In these cases there is a possibility for wrong documentation. Even if the nurse who was in charge for the administration went back to document the reason, the actual reason could have been forgotten. A change in the electronic system at this may not manage to reduce the number of dose omissions, but it would make studies like this more reliable.

5.1.2 Validation of reasons documented for omitted doses

Because direct observation were not performed in all part of this study, it is difficult to validate the reasons collected for dose omissions. Information from the anesthetists about individual treatment in the fasting and postoperative period were not collected in this study, and limits the conclusions of the number of omitted doses in the categories 'fasting patient' and 'patient in theater'. Either the time for the patients surgeries nor the reason for the patients fasting were documented, and this lack of information makes it difficult to say if any of the omitted doses in the category 'fasting patient' could have been avoided or if they were withheld for a clinical reason.

For the reasons 'patient unable to swallow' and 'IV access unavailable' alternative route should have been used, and a pharmacist should be informed. It was possible to identify through the EPMA system that doses charted as these two reasons were not given in any other route, but because direct observation of these settings were not performed, it is not possible to say if the pharmacists knew about the situations or not.

But in some cases there were reasons to believe that the reason documented possibly could be wrong, such as one case when a patient received all medications except from one, and this dose was recorded as "patient absent from ward". There were also many omitted doses recorded as unavailable, but found on the wards medicine room, in trolleys or in the patients own bedside lockers at inspection. This questioning if the procedures that should be followed when a medicine is not found may not be performed in reality in every case.

The possible reasons for these happenings include that the nurse may write the wrong reason for dose omission as a mistake, or that the nurse looked for the medicine, but could not find it. This could be because the medicines were not looked for properly or because the medicine were not at the place where they should have been.

5.1.3 A comparison of the two clinical settings

The higher number of omissions in total at the orthopaedic ward compared to the vascular ward was caused by the reasons 'refused', 'fasting patient', 'patient in theatre' and 'unavailable medicine'.

The reasons for dose omissions recorded as 'fasting patient' and 'patient in theatre' being higher at the orthopaedic ward is probably because of the main reasons why patients are admitted to the two wards. In the vascular ward procedures are less common, and many patients are just receiving wound management and medical investigation before they are going home, while most patients in the orthopaedic ward are having surgery.

The number of refused medicine was the highest number counted of all reasons at the orthopaedic ward with 5.4 %, against the vascular ward with 2.0%. The reason for this

could be connected to the number of patients going to surgery, because vomiting and nausea often is a side effect from these procedures and could make the patients medicine intake quite difficult and unwanted. The high number of refused doses of lactulose and senna at the orthopaedic ward compared to the number at the vascular ward shows where the main difference is.

Doses charted as 'unavailable'

The orthopaedic ward had a statistical significant higher amount of unavailable doses than the vascular ward in total and in the weekends compared to the total number of prescribed medicine. The vascular ward had more unavailable doses during the weekdays. Because these last numbers is compared to frequencies of other reasons for omitted doses, the values would be less usable to draw conclusions with than the numbers that is found by comparing the total number of prescribed doses.

Both the number of patients admitted and the turnover of patients is higher in the orthopaedic ward. New patients means new medicines, which are more likely to be unavailable than medicines that the inpatients are already using. This can be one of the reasons for the number of unavailable doses is higher in the orthopaedic ward, but because the turnover is not as big in the weekends as it is during the week, there is a high possibility that the reason is more complex than that.

Just a selection of medicines is stocked at each ward, and because patients are using their own medicines at the orthopaedic ward, the medicine room do not cover as many medicines as the vascular ward. During the weekends the pharmacy is not open except from some hours on Saturday morning, and the supply of medicines is therefore narrowed in the weekends. But it is important to remember that there are a emergency room with medicines that can be used. If this happens in reality were not investigated in the study.

Another aspect is that the nurses at the orthopaedic ward with the medicine redesign system, are used to having a technician controlling the medicines during the weekdays. The nurses at the vascular ward with the traditional top up are more involved in the medicine management at the ward during the week, and it might be easier for them to control this in the weekends when the technicians are away.

Doses charted as 'absent from ward'

The reason 'absent from ward' was statistically significant different between the two wards (<0.0001), and the vascular ward scored highest at this result. The numbers were quite small at both wards, 0.04% and 0.2% of the total numbers of prescribed medicine at the orthopaedic and vascular ward respectively and a visual test shows that the 95% confidence intervals is almost covering each other. In Appendix 4 the frequency of different reasons for dose omissions per day can be seen, and it shows that 14 of the total 16 omitted doses documented as 'absent from ward' happened at the same day. The reliability of the difference between the two wards for this reason is therefore narrowed, because the result would have been completely different if this day had not been included.

Doses charted as withheld

The number of withheld is statistic significant higher at the vascular ward. The reason could be the routines they have for categorisation of omissions, but it is difficult to make any conclusions without direct observation of the administration.

5.1.4 Comparison to earlier studies

To compare the results from this study to earlier studies the setting and method should ideally be the same. Of the studies from the UK both total number and reasons for dose omissions varies. The reasons for this could be:

- different methods
 - direct observations (researcher is present at dose administration)
 - information collected from patient drug charts prospectively
 - other staff collected information witch the researcher received
- different settings (type and size – some studies from on single ward, others from several hospitals)
- time- period difference
- inclusion of reasons for dose omissions (some have excluded the numbers of clinical reasons for omissions)

The study performed at Ayr Hospital in 1997/1998^{4,5} had both the same setting and method, and showed that both total number of omissions and unavailable medicine have increased. The reason for this are beyond the scope of this study, but a interesting point of

view for the important further work on preventing dose omissions.

5.2 *Clinical significance of dose omissions*

5.2.1 The possibility of harm caused by a dose omission

The percentages of clinical significance of the omitted doses were scored between 'no threat to patient care', 'minor disturbance to symptom control' and 'major disturbance to symptom control'. No doses were scored as 'major threat to stability of patient's condition' or 'potentially able to precipitate a life threatening event'. But because of the following aspects it can not be concluded that single omitted doses are not able to cause such events.

The number of 189 doses used to find these results cover several medicine groups, but not nearly all the medicines that can be omitted. For example no medicines used to treat conditions in the CNS were scored except from analgesia. There are also a huge unknown number of situations that is possible to happen to a patient condition if errors are caused in their medicine regime. Individual differences in medical history, other medicines used, clinical setting and the combination of these are some of the reasons for the wide possibilities of outcomes. This was also confirmed by the results from the omitted doses scored by the clinical expert group, because in several cases the same medicine was scored different from case to case.

When patients were included in the study, their conditions were judged by the nurses on the ward if they would be okay to give their consent. The patients that were feeling very ill were excluded, and it can be speculated if the results could have been different if these patients had been included. The reason for this is that one of the scoring criteria for clinical significance to an omission is the patients condition, and ill patients could suffer more from an omitted dose than a patient that have his or her condition under control in some cases.

Another important point of view in the validation of the range of clinical significance scored by the expert group is the fact that the pharmacists thought some of the gaps between the scores were to wide. The results of the clinical significance of dose omissions could possibly had a different outcome if there had been a wider categorisation sys-

tem.

5.2.2 Data collected from the two different settings

There was no statistic significance between the two wards when it came to clinical significance scored by the expert group. But because there was such a small group of patients collected from the vascular ward, and that one of these patients stood for 51% of the scored omissions (31 of 61), it is difficult to say if the same result would be found if the same study was performed again. This is because the condition to this patient would be important to the outcome of the doses that were omitted. If the same omissions had happened to another patient, or a group of patient, the scoring could had differed.

5.2.3 The scores of clinical significance compared to earlier studies

None of the previous studies presented in the introduction used the same scoring system as the new one used in this study. In the study from Queen Elizabeth Hospital clinical⁷ information were not collected from the patients and in the study from US a scoring system was not used at all. None of the study settings were from a surgical ward either, and all this differences makes it difficult to compare the numbers.

From the study at Ayr Hospital in 1997/1998^{4,5} 67.4% of the omitted doses were of some kind of significance against the 41.2% showed in this study. The reason for this is probably because the scoring system that was used then had 10 different possible scores compared to 5 in this study. It would be easier to categorize a dose omission as 1 when the scale is larger.

5.2.4 Guidelines for doses that should not be omitted

It is important to inform nursing staff about the medicines that were included in the guidelines from this study, but it is only a start for the complete knowledge the persons in charge for administration of medicine should have about all medicines that should not be omitted to avoid medicine incidents from happening. This is especially because there is a probability that nurses some times make decisions themselves if a dose is okay to omit or not when it comes to unavailable medicine.

With more complete guidelines there is reason to believe that there would be less room for misjudgements. Also if the nurses were trained more about the risk a dose omission could cause, the number of omitted doses could probably be narrowed at some points, such as the number of omitted doses charted as unavailable but found on the ward.

At the same time it is important to avoid terms as low risk medicines, because even if a medicine is not scored as clinical significant if omitted in many cases, there could be situations where it could be of great importance.

5.3 Guidance for repetition of this type of study

As the project proceeded there were some points about the method that could have been changed to get more precise and reliable results. Unfortunately there were some issues that were discovered too late, as the anaesthetic records not collected for patients with omitted doses caused by the reason 'fasting'. Changes that could be done if this project is performed again are listed in table..

There could also be many other interesting aspects to discover about dose omissions which were not included in this study, such as direct observation of the use of alternative routes when needed and how procedures work out in practice when the patient is absent at the time for medication intake.

Table 17 Possible outcomes that changes in the method could have caused

Objectives	Current method	Change that could be made	Possible outcome of change
Confirmation of medicine charted as unavailable	Inspection of ward when possible during weekdays, inspection through EPMA of medicine on wards and medicine sent up, confirmation by technician	Researcher could had access to the medicine cupboards at the vascular ward for continuing investigation when technician was absent from ward	More reliable results about the actual situation of unavailable medicine at the vascular ward.
Process maps	Observation of orders from the wards and supply from the pharmacy, the rest in theory	Observation of the further process in practice, from a medicine is unavailable at both pharmacy and the wards until the medicine is received by the patient.	More results about if the theoretical process is followed in practice
Collection of the patients medicine regime before surgery	Inspection of all medication prescribed and used by the patient charted at the EPMA system	Anaesthetic Records used as a supplement	Easier for the pharmacists to make faster decisions of the score of omitted doses caused by 'fasting patient'
Collection of the time for the patients surgeries	Inspection of the patients records	Use the staff at the ward to help confirm the time	Easier for the pharmacists to make faster decisions of the score of omitted doses caused by 'fasting patient'
Scoring of clinical significance	Assessment with five scoring categories used	Inclusion of 1 or 2 more categories	A more precise scoring of clinical significance

6 Conclusion

The two wards compared in this study had both different and common outcomes when it came to frequency and reasons for dose omissions. The differences can possibly be explained by the amount of surgeries performed in each ward, the frequency of turnover of patients and the use of different medicine supply systems. Because the method used in this study did not include direct observation of the administration of medicines, the correct reasons for dose omissions can not be validated with the same confidence. The conclusions about reasons for differences between the two wards is also narrowed because of this. But the study gives a good impression of the range and proportion of doses that the patients did not receive as prescribed.

Clinical significance of dose omissions were scored by a new assessment in this study that had not been validated before. The expert group thought the gaps between the scores were a bit too wide, and the results could possibly had a different outcome if there had been a wider categorisation system. The outcomes from scoring clinical significance of omissions would possibly also vary by the selection of patients. This is because there are many important individual aspects to consider when scoring a dose omission.

The study showed that dose omissions have a quite big possibility to cause disturbance to symptom control in the peri-operative period, and some reasons for dose omissions should be possible to reduce, such as unavailable medicine. From the clinical scoring of the 189 omitted doses several guidelines were developed, which shows that these kinds of audits can contribute for possible reduction of omitted doses. Further work to create more complete guidelines is one method to get closer to this goal.

7 Appendices

Appendix 1 Patient information sheet handed out to patient included in the study.



PATIENT INFORMATION SHEET

The study of Doses of Medicines not given in Surgical and Medical Patients in the Ayr Hospital

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Sometimes doses are missed in medicines that have been prescribed. There can be a lot of reasons for this to happen. The aim of this study is to find out the reasons why this happens and to try to prevent it happening in the future.

Two final year pharmacy university students from Norway who are currently working with the pharmacists in Ayr Hospital and Strathclyde University will carry out the study. The students' names are Elisabeth Johansen and Kristin Reinaas Lysheim.

Why have I been chosen?

You have been chosen because you have been admitted to the wards that the study is taking place, which are Stations 6, 10, 12, 14, 16 during the study time period.

It is hoped we will study a total of about 200 patients during the time period.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you decide to take part in this study, your notes and the electronic prescribing system will be accessed when you are in hospital. The electronic prescribing system also contains the information about which medicines you have received and which ones you have not received. This information will be used by the students in the research.

Any information taken from your notes will be kept anonymous.

What do I have to do?

You are only required to give permission for the information in your notes to be used as part of the study.

You will not have to do anything, complete any forms or visit any clinics or hospitals during the study.

If you decide to take part in the study, you will be asked to sign a consent form. This will allow us to access your notes when you are in hospital and use the information in your notes.

After this you will not be asked to do anything else.

What are the possible benefits of taking part?

There are no direct benefits to your treatment by taking part in the study.

However, if the study produces good results it will give us information on how to prevent doses being missed in the future.

This may benefit patients in Ayrshire and Arran in the future.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed.

If you have any complaints or would like further information about the study please contact:

*Gillian A Jardine
Principal Pharmacist
Ayr Hospital
Dalmellington Road
Ayr
KA6 6DX
Telephone: 01292 614504*

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from Ayr Hospital.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential.

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for taking time to read the information sheet and for considering taking part in this study.

CONSENT FORM

The study of Doses of Medicines not given in Surgical and Medical Patients in the Ayr Hospital

Name of Researchers: Elisabeth Johansen and Kristin Reinaas Lysheim

Please initial box

- 1. I confirm that I have read and understand the information sheet dated 12/12/2008 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without any medical care or legal rights being affected.
- 3. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from Ayr Hospital pharmacy department. I give permission for these individuals to have access to my records.
- 4. I agree to take part in the above study.

Name of Patient		Date	Signature
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Name of Person taking consent (if different from researcher)	Date	Signature
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Researcher	Date	Signature
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When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes.

Appendix 3 Template used to summarise clinical context for each patient

Patient-information template

Station: 10 / 12

Patient-number: Sex: F / M Age:
Presented complains:

Emergency or planned surgery:

Medical History: Drug history:

Current drugs:

Name, Form, Route (specify if not oral)	Dose	Frequency

Omitted doses:

Date	Time	Drug	Reason recorded by nurse	Notes (actual reasons)

Appendix 4 Template used to collect numbers and medicines of each category omitted

Data collection – Dose omissions

Station:

Date:

Medicine (name, form, route)	Reasons for dose omission						With-held	Total
	Un-available medicine	Fasting patient	Patient in Theatre	Patient unable to swallow	Patient absent from ward	Refused		
Total								

Appendix 5 Frequency (percentages in brackets) of omitted doses per day (n= 972) at the orthopaedic ward

Day	Patient absent from ward	Refused	Withheld	IV Access unavailable	Unavailable medicine	Fasting patient	Patient in Theatre	Patient unable to swallow	Total number of omitted doses	Total number of doses
1	0 (0.00)	21 (3.91)	4 (0.74)	1 (0.19)	5 (0.93)	1 (0.19)	2 (0.37)	0 (0.00)	34 (6.33)	537
2	0 (0.00)	15 (3.18)	7 (1.49)	0 (0.00)	3 (0.64)	9 (1.91)	6 (1.27)	6 (1.27)	46 (9.77)	471
3	0 (0.00)	13 (2.64)	16 (3.25)	0 (0.00)	3 (0.61)	2 (0.41)	4 (0.81)	0 (0.00)	38 (7.71)	49
4	0 (0.00)	21 (4.43)	21 (4.43)	1 (0.21)	5 (1.05)	13 (2.74)	0 (0.00)	1 (0.21)	62 (13.08)	474
5	0 (0.00)	22 (4.65)	9 (1.90)	1 (0.21)	6 (1.27)	2 (0.42)	6 (1.27)	0 (0.00)	46 (9.73)	473
6	0 (0.00)	19 (4.45)	2 (0.47)	0 (0.00)	4 (0.94)	6 (1.41)	0 (0.00)	0 (0.00)	31 (7.62)	427
7	0 (0.00)	27 (5.71)	8 (1.69)	0 (0.00)	11 (2.33)	0 (0.00)	0 (0.00)	0 (0.00)	46 (9.73)	473
8	0 (0.00)	26 (7.51)	10 (2.89)	0 (0.00)	1 (0.29)	2 (0.58)	0 (0.00)	0 (0.00)	39 (11.27)	346
9	0 (0.00)	30 (5.03)	6 (1.01)	0 (0.00)	1 (0.17)	10 (1.68)	6 (1.01)	0 (0.00)	53 (8.88)	597
10	0 (0.00)	23 (4.81)	14 (2.93)	0 (0.00)	1 (0.21)	2 (0.42)	13 (2.72)	0 (0.00)	53 (11.09)	478
11	0 (0.00)	32 (6.72)	13 (2.73)	0 (0.00)	4 (0.84)	11 (2.31)	3 (0.63)	0 (0.00)	63 (13.24)	476
12	0 (0.00)	24 (5.10)	7 (1.49)	0 (0.00)	3 (0.64)	20 (4.25)	0 (0.00)	0 (0.00)	54 (11.46)	471
13	0 (0.00)	15 (3.33)	10 (2.22)	0 (0.00)	5 (1.11)	0 (0.00)	0 (0.00)	3 (0.67)	33 (7.33)	450
14	0 (0.00)	20 (4.51)	9 (2.03)	0 (0.00)	6 (1.35)	4 (0.90)	0 (0.00)	2 (0.45)	41 (9.26)	443
15	0 (0.00)	28 (6.21)	14 (3.10)	0 (0.00)	3 (0.67)	0 (0.00)	5 (1.11)	0 (0.00)	50 (11.09)	451
16	0 (0.00)	23 (5.26)	5 (1.14)	0 (0.00)	0 (0.00)	1 (0.23)	14 (3.20)	0 (0.00)	43 (9.84)	437
17	1 (0.24)	22 (5.33)	11 (2.66)	0 (0.00)	4 (0.97)	0 (0.00)	1 (0.24)	0 (0.00)	39 (9.44)	413
18	3 (0.72)	24 (5.73)	10 (2.39)	1 (0.24)	5 (1.19)	1 (0.24)	0 (0.00)	0 (0.00)	44 (10.50)	419
19	0 (0.00)	33 (7.71)	9 (2.10)	0 (0.00)	0 (0.00)	10 (2.34)	1 (0.23)	0 (0.00)	53 (12.38)	428
20	0 (0.00)	42 (9.55)	1 (0.23)	0 (0.00)	3 (0.68)	15 (3.41)	1 (0.23)	0 (0.00)	62 (14.09)	440
21	0 (0.00)	37 (8.87)	2 (0.48)	0 (0.00)	3 (0.72)	0 (0.00)	0 (0.00)	0 (0.00)	42 (10.07)	417
Total	4 (0.07)	517 (5.38)	188 (1.96)	4 (0.04)	76 (0.79)	109 (1.13)	62 (0.64)	12 (0.12)	972 (10.11)	9614

Appendix 6 Frequency (percentages in brackets) of omitted doses per day (n = 492) at the vascular ward

Day	Patient absent from ward	Refused	Withheld	IV Access unavailable	Unavailable medicine	Fasting patient	Patient in Theatre	Patient unable to swallow	Total number of omitted doses	Total number of doses
1	0 (0.00)	21 (5.57)	4 (1.06)	1 (0.27)	4 (1.06)	0 (0.00)	0 (0.00)	0 (0.00)	30 (7.96)	377
2	0 (0.00)	10 (2.82)	0 (0.00)	1 (0.28)	1 (0.28)	0 (0.00)	0 (0.00)	0 (0.00)	12 (3.39)	354
3	0 (0.00)	14 (3.93)	9 (2.53)	0 (0.00)	1 (0.28)	0 (0.00)	0 (0.00)	0 (0.00)	24 (6.74)	356
4	0 (0.00)	11 (3.08)	5 (1.40)	0 (0.00)	1 (0.28)	0 (0.00)	0 (0.00)	0 (0.00)	17 (4.76)	357
5	0 (0.00)	8 (2.35)	9 (2.64)	1 (0.29)	4 (1.17)	0 (0.00)	0 (0.00)	2 (0.59)	24 (7.04)	341
6	0 (0.00)	6 (1.65)	7 (1.89)	2 (0.54)	0 (0.00)	15 (4.04)	3 (0.81)	9 (2.43)	42 (11.32)	371
7	0 (0.00)	1 (0.30)	10 (2.96)	1 (0.30)	1 (0.30)	0 (0.00)	0 (0.00)	0 (0.00)	12 (3.55)	338
8	0 (0.00)	4 (1.12)	18 (5.04)	1 (0.28)	2 (0.56)	0 (0.00)	0 (0.00)	0 (0.00)	25 (7.00)	357
9	0 (0.00)	4 (1.10)	8 (2.21)	0 (0.00)	1 (0.26)	0 (0.00)	0 (0.00)	0 (0.00)	13 (3.59)	362
10	0 (0.00)	7 (1.95)	12 (3.34)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	19 (5.29)	359
11	0 (0.00)	14 (3.83)	3 (0.82)	0 (0.00)	3 (0.82)	0 (0.00)	0 (0.00)	0 (0.00)	20 (5.46)	366
12	0 (0.00)	10 (2.77)	5 (1.39)	0 (0.00)	12 (3.32)	0 (0.00)	0 (0.00)	0 (0.00)	27 (7.48)	361
13	0 (0.00)	10 (2.63)	8 (2.11)	0 (0.00)	2 (0.53)	0 (0.00)	4 (1.05)	0 (0.00)	24 (6.32)	380
14	0 (0.00)	3 (0.71)	12 (2.83)	0 (0.00)	2 (0.47)	0 (0.00)	0 (0.00)	0 (0.00)	17 (4.01)	424
15	2 (0.48)	3 (0.71)	6 (1.43)	0 (0.00)	3 (0.71)	5 (1.19)	4 (0.95)	0 (0.00)	23 (5.48)	420
16	14 (3.47)	7 (1.74)	8 (1.99)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	6 (1.49)	35 (8.68)	403
17	0 (0.00)	10 (2.34)	5 (1.17)	0 (0.00)	2 (0.47)	0 (0.00)	0 (0.00)	0 (0.00)	17 (3.97)	428
18	0 (0.00)	6 (1.26)	16 (3.35)	0 (0.00)	0 (0.00)	7 (1.47)	1 (0.21)	0 (0.00)	30 (6.29)	477
19	0 (0.00)	9 (2.07)	12 (2.76)	0 (0.00)	1 (0.23)	0 (0.00)	0 (0.00)	0 (0.00)	22 (5.06)	435
20	0 (0.00)	4 (0.83)	23 (4.75)	0 (0.00)	0 (0.00)	0 (0.00)	6 (1.24)	0 (0.00)	33 (6.82)	484
21	0 (0.00)	5 (1.01)	20 (4.04)	0 (0.00)	1 (0.20)	0 (0.00)	0 (0.00)	0 (0.00)	26 (5.25)	495
Total	16 (0.19)	167 (2.03)	200 (2.43)	7 (0.08)	41 (0.50)	27 (0.33)	18 (0.22)	17 (0.21)	492 (5.97)	8245

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%2520Care%2520Trust%2520\(St%2520Pancras
%2520Hospital\).doc+audit+of+dose+omission
+and+completed&cd=1&hl=no&ct=clnk&gl=no](http://209.85.229.132/search?q=cache:yjQ8ax4pUzwJ:www.londonpharmacy.nhs.uk/educationandtraining/prereg/pfizerProjectAwards2008/Dhruti%2520Bhatt%2520Camden%2520and%2520Islington%2520Mental%2520Health%2520and%2520Social%2520Care%2520Trust%2520(St%2520Pancras%2520Hospital).doc+audit+of+dose+omission+and+completed&cd=1&hl=no&ct=clnk&gl=no)
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