Preanalytical errors in hospitals
Implications for quality improvement of blood sample collection

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Umeå 2008
“You can do whatever you want”

- Olof Wallin
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ABSTRACT

Background: Most errors in the venous blood testing process are preanalytical, i.e. they occur before the sample reaches the laboratory. Unlike the laboratory analysis, the preanalytical phase involves several error-prone manual tasks not easily avoided with technological solutions. Despite the importance of the preanalytical phase for a correct test result, little is known about how blood samples are collected in hospitals.

Aim: The aim of this thesis was to survey preanalytical procedures in hospitals to identify sources of error.

Methods: The first part of this thesis was a questionnaire survey. After a pilot study (Paper I), a questionnaire addressing clinical chemistry testing was completed by venous blood sampling staff (n=314, response rate 94%) in hospital wards and hospital laboratories (Papers II–IV). The second part of this thesis was an experimental study. Haematology, coagulation, platelet function and global coagulation parameters were compared between pneumatic tube-transported samples and samples that had not been transported (Paper V).

Results: The results of the questionnaire survey indicate that the desirable procedure for the collection and handling of venous blood samples were not always followed in the wards (Papers II–III). For example, as few as 2.4% of the ward staff reported to always label the test tube immediately before sample collection. Only 22% of the ward staff reported to always use wristbands for patient identification, while 18% reported to always use online laboratory manuals, the only source of updated information. However, a substantial part of the ward staff showed considerable interest in re-education (45%) and willingness to improve routines (44%) for venous blood sampling. Compared to the ward staff, the laboratory staff reported significantly higher proportions of desirable practices regarding test request management, test tube labelling, test information search procedures, and the collection and handling of venous blood samples, but not regarding patient identification. Of the ward staff, only 5.5% had ever filed an error report regarding venous blood sampling, compared to 28% of the laboratory staff (Paper IV). In the experimental study (Paper V), no significant preanalytical effect of pneumatic tube transport was found for most haematology, coagulation and platelet function parameters. However, time-to-clot formation was significantly shorter (16%) in the pneumatic tube-transported samples, indicating an in vitro activation of global coagulation.

Conclusions. The questionnaire study of the rated experiences of venous blood sampling ward staff is the first of its kind to survey manual tasks in the preanalytical phase. The results suggest a clinically important risk of preanalytical errors in the surveyed wards. Computerised test request management will eliminate some, but not all, of the identified risks. The better performance reported by the laboratory staff may reflect successful quality improvement initiatives in the laboratories. The current error reporting system needs to be functionally implemented. The experimental study indicates that pneumatic tube transport does not introduce preanalytical errors for regular tests, but manual transport is recommended for analysis with thromboelastographic technique. This thesis underscores the importance of quality improvement in the preanalytical phase of venous blood testing in hospitals.
# LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ASA</td>
<td>Acetylsalicylic acid</td>
</tr>
<tr>
<td>CADP</td>
<td>Collagen membrane coated with ADP</td>
</tr>
<tr>
<td>CEPI</td>
<td>Collagen membrane coated with epinephrine</td>
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<tr>
<td>COES</td>
<td>Computerised order entry system</td>
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<tr>
<td>CT</td>
<td>Closure time</td>
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<tr>
<td>CV</td>
<td>Coefficient of variation</td>
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<td>DP</td>
<td>Desirable practice</td>
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<td>ER</td>
<td>Error reporting</td>
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<td>PFA</td>
<td>Platelet function analyser</td>
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<td>PPM</td>
<td>Parts per million</td>
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<tr>
<td>PTST</td>
<td>Pneumatic tube system transport</td>
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<tr>
<td>R</td>
<td>Time to clot formation</td>
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<tr>
<td>TEG</td>
<td>Thromboelastograph</td>
</tr>
<tr>
<td>TTP</td>
<td>Total testing process</td>
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<td>VBS</td>
<td>Venous blood sampling</td>
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ORIGINAL ARTICLES


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PROLOGUE

I have always been interested in risks: in assessing, analysing and taking appropriate preventative actions. As a climber and mountain guide, and particularly as a physician, this is part of my daily work. As a climber I use basic routines and regular training to prevent risks from turning into accidents. When an accident occurs, it is often investigated and published for everyone to learn from. As a physician, I have learned that this is not always the case in health care.

A few years ago, during my undergraduate medical studies, I attended a lecture entitled “Preanalytical variations and blood testing” held by Professor Kjell Grankvist, my supervisor to be. The lecture was one of my first encounters with the field of medical errors and it awakened a curiosity for patient safety. Later, working weekends and late nights as an enrolled nurse, it became apparent to me that many aspects of the health care system in general, and the collection and handling of blood samples in particular, could be improved. Consequently, I then became interested in why the useful principles for reducing risks, taken for granted in climbing, are not always utilised in health care.

As a physician, I have come to understand that there is little time to reflect and act on medical errors in daily work. Even worse, the safety culture too often involves a good deal of hiding and blaming – and not learning from errors. As a junior physician, one is not always invited to suggest improvements, which for me makes it even more of a challenge to try...

My research project addresses a seemingly obscure but fundamentally important topic; the collection and handling of blood samples. Perhaps not unexpected, obtaining funding has been a challenge. This thesis is therefore the result of a good deal of unpaid, yet very rewarding, work. The intellectual support and positive feedback have continually motivated me. I have learned a lot. Enjoy!
BACKGROUND

Introduction

“First, do no harm”

– Hippocrates some 2000 years ago

In 1999, the Institute of Medicine published the report “To err is human: Building a safer health system”. The report suggested that up to 98 000 patients die each year in the United States, as a result of preventable medical errors [1]. The report has been debated [2] and the high number of deaths questioned [3, 4], but the bottom line remains: patients do get injured and occasionally die every year because of mistakes by physicians and nurses. The report gained tremendous interest in the media and from the public [5] and resulted in an increase in research projects related to patient safety [6]. However, the transition of knowledge about preventable errors into improved patient safety seems to be less obvious [6]. In fact, it took 6 years until national action was taken in the United States [7]. It seems important to plan research projects to which health care staff can relate to in their daily work. Then the results can inspire the staff to quality improvement in routine health care.

Medical errors

Medical errors cause suffering and anxiety for the patient and a large number of deaths annually, along with excess economic burden [1, 8]. Medical errors are increasing, despite efforts to improve patient safety [8]. This raises an obvious question: What is a medical error? It certainly involves health care, but several definitions exist [9]. One commonly used is: “The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”, as defined by the Institute of Medicine [1]. However, a clear and widely accepted definition is still lacking [10]. This might at a first glance not seem very important. However, without a clear definition, it is impossible to compare error rates, or to evaluate the effects of interventions. Further, the more inclusive the definition is, the higher the error rates will become. It is beyond the scope of this thesis to produce a definition of a medical error, but the aspect is important to keep in mind.

Another related concept worth mentioning is risk, defined by Oxford English Dictionary as “subject to hazard” [11]. As for errors, there are many definitions of risk. Most of them involve elements of some kind of possibility of an event (unknown or probable), associated with a negative outcome [12]. In epidemiology, risk usually mean risk factor, i.e. a component that confers an increased probability of disease. Risk is linked to patient safety, as the risk of error. The prediction and prevention of risks are used to reduce medical error, for example in laboratories [13].
The way one perceives errors and risks is important; it aims the investigation for causes, and thus possibilities for prevention, of errors. If searching for human error or lack of routines, one will probably find both, if you look closely enough. There are often combinations of several factors that give rise to an error [14, 15]. Thus, a “fix-all” solution is seldom sufficient to prevent an accident from happening again.

The current way of viewing error is as system errors, meaning that most errors are a product of failed organisational structures, rather than individual mistakes [1]. An 85-15 rule has even been suggested, meaning that 85% of all errors or problems are caused by systems or processes and only 15% by an individual person [16]. This is a very favourable way of looking at errors for the individual, since this view is less likely to produce blaming and feelings of guilt, and pave the way for constructive changes in practice.

**The total testing process**

The previously mentioned report from the Institute of Medicine recognised diagnostic errors as an important part of the medical errors [1]. The total testing process (TTP) is the total process from the ordering of a test to the interpretation of a test result. The TTP starts and ends with the patient, and can be subdivided into three distinctive phases: the preanalytical step (before the analysis), the analytical step (the actual analysis) and the postanalytical step (after the analysis), as described in Figure 1.

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**Figure 1** The total testing process starts and ends with the patient.
Errors can occur in every step of the TTP. Of all errors in the TTP, approximately one fourth have consequences for the patient [17-19]. These consequences include a delayed test result or renewed sample collection, but also life threatening [20] and tragic consequences, such as unnecessary chemotherapy and coma [21]. In a case report, one patient had 15 consultations, 77 laboratory tests and a computer tomography, as a result of one erroneous test result [22].

Studies today suggest that 0.01 to 0.5% of all test results are erroneous [19, 23], although none of the studies are from Sweden. The actual error rate is probably higher [24], since estimating errors in the TTP is a difficult task [25, 26]. Many errors are also detected by quality control systems in the laboratories and corrected before they produce an erroneous test result [27, 28]. Both detected and undetected errors may cause unnecessary and costly investigations and consequences for the patient. Further, these errors might not be detected next time. The under-detection of errors in the TTP is illustrated in Figure 2. The error rates are greatly dependent on the method for error detection that has been used [24, 26]. The better the method, the more errors it will find. Previously used methods include registration of errors in the laboratory [29-32], registration of errors by the responsible physician [17] or by a multidisciplinary team [18, 19], direct observation [33] and classifying error reports [33, 34].

![Figure 2](image-url)  
**Figure 2** Errors in the total testing process can be identified before or after the test result. Identified errors cause unnecessary work, may be repeated and are thus costly. Errors that are not identified can cause consequences for the patient. An unknown, but probably larger, number of errors are not detected at all, as indicated by the right-hand triangle. These errors also affect patient safety and care.

As for medical errors, a widely accepted definition of errors in the TTP is still lacking, and contributes to the uncertainty of the true error frequency [23]. It has been suggested that 75% of all errors produce test results within the reference intervals [35]. It is of utmost importance that all test results are judged against the patient’s clinical picture, with the limitations of a laboratory test in mind, since erroneous test results otherwise can lead to serious consequences [20-22, 36].
The error rates in the TTP are much higher than what is tolerated in industrial quality standards [37, 38]. Examples of laboratory quality indicators in the United States include the 5200 parts per million (PPM) rate of sample label errors, 6500 PPM rate for missing wristbands and 244 000 PPM error rate in the timing for therapeutic drug monitoring [37]. This could be compared to the airline industry, in which the best airline has a 400 PPM rate of lost bags [39], or world-class performance in industry, which is considered to be 3.4 PPM [37]. Although industrial products and humans cannot easily be compared, some quality improvement strategies, originally developed to improve industrial manufacturing, can be useful in health care [40]. Since each error has the potential to adversely affect the care of the patient, a constant reduction of errors is necessary for a safe TTP.

The relative frequency of errors in the TTP may seem rather low, but many samples are collected each year, and a large number of analyses are conducted on these samples. Although relatively small, the Clinical Chemistry Laboratory at Umeå University Hospital conducts approximately 4 million analyses annually, and the numbers are increasing. Laboratory tests are stated to generally have a major impact on medical decisions [41] and increase the certainty of the diagnosis [42]. Thus, reduction of errors is important for everyone involved in the TTP, since the total number of errors with consequences for patient care, and the accompanying excess expense, become very high.

**Venous blood samples**

The topic of this thesis is venous blood samples, the most common biological sample type in hospitals. These samples are usually collected by puncture of the antecubital vein by a needle, connected to an evacuated test tube, referred to as venous blood sampling (VBS) in this thesis. A minority of the venous blood samples are collected from a peripheral or central venous catheter. Other kinds of biological samples include arterial blood for blood gas analysis, and capillary blood, most often used for measurement of plasma glucose, haemoglobin or C-reactive protein. Samples are also collected for anatomical pathology (surgical and cytological). Many of the discussed problems in the TTP are similar for all biological sample types collected in hospitals.

Venous blood samples are mainly used for clinical chemistry analysis (haematology, coagulation and general clinical chemistry), but can also be used, e.g. for microbiological diagnostics and pretransfusion testing. General clinical chemistry analyses can also be carried out on other biological sample types, such as urine and cerebrospinal fluid. Laboratory testing can be performed outside the laboratory, usually referred to as point-of-care testing. Common examples include plasma glucose, haemoglobin count and C-reactive protein. In contrast to laboratory testing, analytical error is common in point-of-care testing [43]. One important reason is that this testing is not always covered by quality control systems used in the laboratory. Another is that staff not primarily working with laboratory testing often carry out these analyses. Preanalytical errors are a problem, including patient identification [43]. Post-analytical errors are also an issue, since many point-of-care instruments are not connected to the laboratory data system [43]. Initiatives are in place to improve quality of point-of-care testing in Sweden [44] and elsewhere [45].
Preanalytical errors

When summarising previous studies, it is evident that the majority of all errors in the TTP are of preanalytical origin, i.e. they occur before the sample arrives in the laboratory [17-19, 23, 25, 26, 28, 34]. Previous reports account for 46–68% as shown in Figure 3, although no previous report is published from Sweden. Of all blood specimens sent to the laboratory for analysis, 0.1–10% are erroneous for preanalytical reasons [18, 19, 29-32, 46]. As previously mentioned, the total error rate in the TTP varies widely between studies. However, the distribution of error, with the majority originating in the preanalytical phase, is fairly constant and is independent of the study design, country, definition of error, or method used for data collection [23, 26]. Although several of the above mentioned results are based on data collected some years ago, and originating from various settings, altogether they provide consistent evidence that the majority of all errors in the TTP originate in the preanalytical phase. Therefore, reduction of preanalytical errors is an important issue for everyone involved in the TTP.

Errors within the total testing process

![Diagram showing the distribution of errors within the total testing process.](image)

Figure 3 Distribution of errors within the total testing process. Included are examples of errors in each step. Modified from Karla [23].

Preanalytical errors are largely attributable to human mistakes [23, 29] and the majority of these errors are preventable [19, 34]. This is understandable, since the preanalytical phase involves much more human handling, compared to the analytical and postanalytical phases. The total uncertainty in the test result due to preanalytical reasons can be calculated [47]. For example, differences in preanalytical procedures can explain up to 41% of the variation of prevalence of hypercholesterolemia [48]. Errors prior to ordering of the test (pre-preanalytical) are difficult to measure, since a major part takes place in the brain of the physician. Efforts to measure these errors indicate that this part of the TTP process can cause a large number of errors [49], including over-utilisation of laboratory tests [50].
Other important sources of preanalytical error not related to human mistakes include medications, which can cause errors through analytical (in vitro) or biological (in vivo) effects [51], and biological variation, which is the major source of variation for certain analyses [52]. The biological variation consists of two parts. The intra-individual part is the normal variation of the analysed substance in each individual during the day. The inter-individual part is the normal variation of the analysed substance between individuals. Other patient-related physical variables, such as stress, diet and exercise, can also have effects on the test result [53]. Important areas of the preanalytical phase, after the test has been ordered, will be given a further presentation below.

**Patient identification and test tube labelling**

Improving the accuracy of patient identification is the highest priority for patient safety [54]. Patient identification at VBS is an important source of error in blood transfusions, due to non-compliance with guidelines [24]. Mistakes in the patient identification procedure before VBS can be responsible for up to 25% of all preanalytical errors [29]. Further, in up to 75% of all blood transfusions, the valid identification procedure is not followed [55]. Mistakes in the identification and labelling procedure in blood testing can result in serious adverse events [19, 20, 27], including the death of the patient [56]. Critical patient identification errors in the TTP occur in approximately 1 out of 1200 test requests, or in median in 1 out of 2600 billable tests [27, 46]. In fact, 1 out of 18 identification errors in laboratory testing result in an adverse event, which would imply at least 160 000 adverse events annually in the United States, as the result of patient identification errors in the TTP [27]. Mistakes in patient identification often originate in manual tasks not easily avoided with technological solutions. Patient identification and labelling of test tubes are not only a task limited to the TTP; they have importance in all areas of health care.

One way of improving the identification procedure is to use identification wristbands, usually made of plastic, containing the patient’s name and identification number, and sometimes also a barcode. Previous studies have noted error rates of 0.3–11% for identification wristbands [33, 57-59]. These errors include missing or incomplete wristbands, but also the wrong wristband on the patient. Therefore, those studies stress the importance of proper routines for patient identification in hospitals.

Labelling of test tubes, an equally important preanalytical step and a focal point for improvement of care [60], should always be performed immediately before sample collection [61]. Mislabelling of test tubes for blood transfusion pre-testing, a highly regulated task, is reported to occur in median in 1 out of 165–200 test tubes [62, 63]. Mislabelling is responsible for 50% of all identification errors in the TTP [27]. By labelling the test tube after sample collection, there is an increased risk of the collection of blood from the wrong patient, reported to occur in median in 1 out of 1300–2000 test tubes in blood transfusion pre-testing [63, 64]. In fact, test tubes with minor labelling errors are 40 times more likely to contain the wrong patient’s blood, as compared to correctly labelled test tubes [65]. Correct patient identification and test tube labelling before VBS are therefore of utmost importance for patient safety in the TTP.
Sample collection

Errors arising during sample collection and specimen handling are the most common type of preanalytical errors [29]. This handling can be the major uncertainty component for some analyses [52]. Even with a standardised procedure, VBS by different phlebotomists can have a higher variation than the laboratory precision [66]. Experimental studies show that differences in the performance of specific preanalytical tasks can have clinical important effects on the test result. One example is the positioning of the patient before and during VBS [67-70]. Insufficient patient rest before VBS allows escape of fluid into the interstitial space [68, 71]. Thus, components that cannot pass the vessel wall, mainly proteins, will increase in concentration. In the same way, freely passing constituents, such as electrolytes, will achieve a lower concentration.

Prolonged venous stasis during VBS can also have clinically significant effects on the test result [48, 72-74], with a similar physiological background as for insufficient patient rest. For example, prolonged venous stasis can cause a 7% variation in the prevalence in hypercholesterolemia [48]. If a sample for analysis of cholesterol is collected without stasis before the introduction of a medication, and with prolonged stasis at the follow up testing, the cholesterol value might be falsely high, and an unnecessary medication could be introduced. Further, prolonged stasis, and also hand clenching, can lead to local hypoxia and thus acidosis, which can affect for example potassium measurements [51].

Other examples of clinically important sample collection procedures include vertical test tube storage after sample collection, desirable for a proper coagulation of serum samples. Inversion of citrated, heparinised and EDTA-containing test tubes is recommended to adequately mix blood with the anticoagulant [61, 75, 76]. Inadequate inversion of test tubes can cause clotting of the blood, reported to constitute an important part of preanalytical errors in VBS [30, 32, 46, 77]. The sequence of the test tubes during sampling is important to avoid contamination by anticoagulants. Both time before centrifugation [78] and storage temperature [79] can produce preanalytical errors. VBS from peripheral venous catheters is known to be prone to haemolysis [80]. The amount of this haemolysis is dependent on the size of the test tube that is used [81]. Despite the known importance of these and other steps in the collection of samples, almost nothing is known about the routine performance of these tasks in the clinical setting.

Test requests

One important source of preanalytical error is incorrect or incomplete information on the test request or on the test tube label [28, 64]. In fact, erroneous requests and labels may account for more than two thirds of all rejected samples in the laboratory [64]. Several other studies confirm that test requests can be a clinically important source of errors [19, 29, 46, 77, 82-85]. Paper-based test requests are themselves a risk; they can be incompletely filled in, placed in the wrong collection box, or simply be lost. Computerised order entry systems (COES) replace the paper-based test request by allowing entry of ordering information directly into a computer. Such a system is often combined with an electronic delivery of the test result, ultimately fully connected to the patient’s electronic medical
record. Assuming high security information technology systems, a COES will eliminate many sources of error, mainly those connected with paper-based information, such as entry error and lost requests or results.

*Transport of blood samples*

Transport of samples to the laboratory can give rise to clinically important errors [34] if transport conditions are not optimised [86]. Prolonged transport time contribute to a prolonged turnaround time, and thus delayed patient care. In hospitals, test tubes are often transported by pneumatic tube system transport (PTST), since this reduces laboratory turnaround time [87-89] and labour. A PTST consists of a system of tubes, linking stations on wards and laboratories together, as described in Figure 4. If not transported by PTST, the samples are often manually transported to the laboratory. If the analysis is centralised to another hospital, the sample may have to be transported, e.g. by car, to the laboratory, which can have effects on test results [52].

![Figure 4 A summary of the main features of a pneumatic tube transport system, commonly used in hospitals for transporting test tubes to the laboratory. The test tubes are placed in the inner tube before transport. The inner tube is propelled by pressurised air, and computers at the transfer station then direct delivery to the correct end station.](image)

The forces applied on a blood sample transported by PTST include accelerations and decelerations, as well as vibrations. The latter can cause damage to red blood cells [90]. Transport of blood samples by PTST can cause elevations in lactate dehydrogenase concentrations [91-94] and haemolysis [95, 96], as an effect of damaged red blood cells. PTST has also been reported to cause changes in blood gas measurements [97-100]. Haematology, coagulation, and chemistry parameters, such as red and white blood cell counts, prothrombin time, and potassium and sodium measurements, have been reported to be mainly unaffected by PTST [89, 91-93, 101-103].
Most of these studies were performed a number of years ago. There have been improvements in analytic techniques during this time period. Newer analyses, such as platelet volume and reticulocyte parameters, have not been investigated. Further, a recent study reported an effect of PTST on platelet function [104]. Since an effect of PTST could give consequences for a large number of patients, it is important to analyse the preanalytical influence on test results, using modern instruments in clinical use today.

**Analytical and postanalytical errors**

Even if the preanalytical phase is responsible for the majority of the errors in the TTP, the analytical and postanalytical phases also contribute to errors with consequences for patient care [17-19, 22, 23, 25, 26, 28, 34, 36, 38, 49]. Of all errors in the TTP, 7–13% have been reported to occur in the analytical, and 19–47% in the postanalytical phases, as shown in Figure 3. Errors in the analytical phase can be either systematic errors (bias), or random errors (imprecision) [51]. The analytical imprecision is dependent on the biological variation, since a small biological variation will demand a low analytical imprecision [105].

A common source of analytical errors is interferences, for example in immunoassays [22, 36]. Quality control programs, such as proficiency testing [106] and technical evolution, have reduced analytical errors over the years [107]. The error-prone internal manual handling of test tubes can be fully automated in the near future [108]. Further quality improvement efforts will therefore be most effective if applied on the pre- and postanalytical phases of the TTP.

The postanalytical step mainly concerns the delivering of a test result. A COES eliminates error-prone steps in the transmission of information [109] and can therefore improve the postanalytical step. If connected to the patient record, a COES eliminates the error-prone delivery of the paper-based test result. The postanalytical step includes the post-postanalytical step, which involves properly interpreting and taking appropriate action to a test result. The post-postanalytical step can also give rise to important errors [49]. The COES can include a decision support for interpretation of the test results, in order to reduce these errors.

**Sources of preanalytical information**

Today, information about a correct preanalytical procedure is generally provided to VBS staff through online laboratory manuals on the Internet and/or on the intranet. The method of analysis used by the laboratories can vary and change over time, and each method can require a different procedure for sample collection. Thus, it is important with an updated laboratory manual for a correct preanalytical procedure. Information about the practical general performance of VBS is provided in an instruction manual for health care staff (known in Sweden as Handboken) [110]. This manual is issued by the Swedish Association of Local Authorities and Regions to provide guidelines for general procedures in health care. An example of a proper procedure for VBS is given in Table 1.
Table 1
A summary of a proper procedure for the collection and handling of venous blood samples (Modified from Papers I–III).

<table>
<thead>
<tr>
<th>Preanalytical step</th>
<th>Proper procedure for the collection and handling of venous blood samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall instruction</td>
<td>The instructions for prevention of mix-ups, issued by the National Board of Health and Welfare in Sweden (named SOSFS) [111] should always be followed.</td>
</tr>
<tr>
<td>Information search</td>
<td>Information regarding the handling and collection of venous blood samples is obtained from online manuals issued by the local laboratory.</td>
</tr>
<tr>
<td>Test request management</td>
<td>The information on the paper-based test request is compared with the ordering information. The patient’s name and Swedish identification number are written by hand or stamped on the request. During patient identification, the patient's name and Swedish identification number are compared with the corresponding information on the test request. Priority (acute or normal) is noted on the request. A check is made that the orderer of the test is marked via barcode or otherwise written by hand on the request.</td>
</tr>
<tr>
<td>Time of sampling</td>
<td>The time of sampling is noted on the test request during the sampling procedure.</td>
</tr>
<tr>
<td>Patient rest</td>
<td>Sitting or supine for more than 15 minutes prior to sampling.</td>
</tr>
<tr>
<td>Patient identification</td>
<td>Should be performed before sample collection by asking the patient to state name and Swedish identification number (which can be compared to a social security number), and by checking ID-card with photo or ID-wristband. This information is compared to the corresponding information on the test request. Patient identification should be performed even if the patient is known. The test request is signed to confirm that patient identification is accomplished.</td>
</tr>
<tr>
<td>Test tube labelling</td>
<td>If analysis-specific labels do not exist, then the requested analysis is written by hand on the correct label on the back of the test request. Priority (acute or normal) is noted on the label. The label is transferred to the test tube after patient identification and before sampling.</td>
</tr>
<tr>
<td>Stasis</td>
<td>If stasis is necessary, it is used for the shortest time possible and should be removed before the first venous blood sample is collected.</td>
</tr>
<tr>
<td>Handling of test tubes</td>
<td>Each tube is filled until the vacuum effect is lost. Tubes with additives are inverted. If tubes with different substances are used, they are filled in a predetermined order. Test tubes are stored in a vertical position, and are then handled according to local instructions.</td>
</tr>
<tr>
<td>Bar-code numbers</td>
<td>The barcode number on the test request and test tube are compared to ensure that they match.</td>
</tr>
</tbody>
</table>

Reference intervals and decision limits, used to interpret test results, are based on samples collected by a standardised procedure. This standardised procedure is stated in the laboratory manual and is usually based on generally accepted terms [75, 76] and the method of analysis used by the laboratory. It is a requirement that all samples are collected using the same procedure used for the reference intervals and decision limits [112]. Test results from samples collected with different preanalytical procedures cannot easily be compared. The use of incorrect (or non-compliance with valid) instructions for sample collection in the laboratory manual increases the risk of postanalytical errors with consequences for patient care.
The online manual is much easier to update than the previously used paper-based manuals. Indeed, the paper-based laboratory manuals can suffer from incomplete revision [113, 114]. Other sources of information include calling the laboratory for advice, which may have impact on laboratory workflow [115], or asking a colleague, which involves a risk of distributing incorrect information. The online manuals themselves have been evaluated [114-116], but little is known about whether VBS is performed according to the instructions stated in the online manual, and if the online manuals are the primary means by which staff obtain VBS information.

**Error reporting**

For decades, error reporting (ER) have been used to improve safety in high-risk areas such as the aviation, nuclear and oil industries [117]. In recent years, health care providers have introduced ER as a way of handling medical errors [118-120]. In the past, mostly local ER systems have been used. Now, some of those local systems have been extended into nation-wide ER systems which are in the planning stages, or have already been introduced [10]. It is important that an ER system is sanction-free, confidential, allows learning, is simple and is supported by the staff [117]. In Table 2, possible advantages and disadvantages of ER are summarised.

The information in an ER system can be used to identify contributing factors to the adverse event. This is important, since more than 50% of all reported errors can be preventable [121]. Different methods for structural analysis are used to identify the contributing factors. Examples include the root-cause analysis, organisation accident causal model and significant event auditing [122]. After the analysis, recommendations that may prevent the repetition of the mistake can be given. It is important that “What you look for is what you find” [123], i.e. the model of analysis will find the contributing factors it is designed for. This implies an important continuation: “What you find is what you fix” [123]. It is important to be aware of the limitations of the model used for structural analysis of reported errors.

Since ER is likely to underreport adverse events [33, 121, 124, 125], all ER systems must be evaluated carefully, so that they are likely to catch preventable system errors. Most previous research presents ER rates per patient or bed day and no previous report has evaluated ER among VBS staff. It is therefore important to survey if VBS staff report errors. In that way, the ability of the current ER system to catch preventable errors in the preanalytical phase could be evaluated.
Table 2
A summary of possible advantages and disadvantages of error reporting systems in health care.

<table>
<thead>
<tr>
<th>Advantage</th>
<th>Disadvantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serves as a starting point for quality improvement</td>
<td>We already know where the main problems are, data available</td>
</tr>
<tr>
<td>Used successfully in other industries (mainly machines)</td>
<td>Better with overall improvement than preventing a specific event</td>
</tr>
<tr>
<td>Could be a tool for involvement and empowerment</td>
<td>Takes time and resources from acting on known errors</td>
</tr>
<tr>
<td>Provides an insight in trends of appearing types of errors</td>
<td>Disempowerment if feedback is not provided, or action not taken</td>
</tr>
<tr>
<td>Gives an overview of appearing errors</td>
<td>Error reporting underreports errors – can be misleading</td>
</tr>
<tr>
<td>Great possibility for learning</td>
<td>Can be better to look at successes than at failures</td>
</tr>
<tr>
<td>Create awareness of errors at the local level</td>
<td>Many accidents unique – will never happen again</td>
</tr>
<tr>
<td>Can serve as a trigger tool</td>
<td>Not all staff categories involved in reporting errors</td>
</tr>
<tr>
<td>Can provide arguments for change</td>
<td>Reports can delay action</td>
</tr>
<tr>
<td>Can discover system vulnerabilities</td>
<td>Can create misleading statistics – risk of incorrect use</td>
</tr>
<tr>
<td>Global system provides for global learning</td>
<td>Often little action taken, a lot of time to administrate</td>
</tr>
</tbody>
</table>

Quality improvement

Clinical laboratories have a long history of working with quality improvement to reduce error, dating back to the early 1950s [126]. This has lowered analytical error rates [38]. In other areas of health care, quality improvement initiatives have been much more recent. The activities in a laboratory are often precisely defined and thus fairly easy to control – in some aspects more comparable to industrial production, than routine health care. Thus, quality improvement strategies, originally developed for industrial production, have been easier to implement in laboratories than in other areas of health care.

Accreditation is assessment of competence by an external organisation [51, 127]. The accreditation guarantees that an organisation has the right competence for a certain task, and that should reduce errors. Most hospital laboratories are accredited [128]. This implies that the laboratory staff perform their work, including the preanalytical procedure, according to strict routines, aimed at reducing errors. One common standard for accreditation of laboratories is the ISO/IEC 17025 [127]. The ISO/IEC 15189 is a newer standard, further developed for medical laboratories. No specific standard exists for hospital wards and very few hospital wards in Sweden are accredited according to the general ISO 9000-system. Certification is an assessment of competence on the individual level. One example is a competence certificate for VBS staff, which is mandatory in some laboratories. This certificate must be renewed regularly. It guarantees that each staff member has the minimum required updated competence for a high quality VBS procedure.
Interventions for improvement of the TTP outside the laboratory have successfully been implemented in routine health care. Examples in the pre-analytical phase include diagnostic algorithms, panel testing (testing of a predefined set of tests) and reflex testing (additional tests automatically performed as a result of the first test) [49, 129]. Examples in the post-analytical phase include interpretive comments from the laboratory physician [49, 129, 130] and automatic critical value reporting by the laboratory [131].

Error reporting can collect reliable information of medical errors [118, 119]. Such information can be used to correctly aim patient safety interventions. Replacement of paper-based requests with a COES can improve quality in some areas of health care [19, 132, 133] and can reduce transcription errors [109]. A COES also has unique possibilities of not only providing information about sample collection, but also to include decision support for the ordering of the test, as well as for the interpreting of the test result.

The quality improvement initiatives for VBS performed in the laboratory have lowered preanalytical error rates. VBS performed by laboratory staff is associated with lower error rates than VBS performed by other staff categories [77, 134-136]. Preanalytical error rates are also higher for inpatient samples (collected by ward staff) than for outpatient samples (collected by laboratory staff in the laboratory) [26, 29, 31, 137]. The preanalytical phase outside the laboratory should therefore be prioritised, in order to most effectively reduce errors in the TTP, and thereby increase patient safety.

**International context for sample collection**

Many different categories of staff perform VBS internationally. The staff categories include registered nurses, physicians, enrolled nurses (also called licensed-to practice, assistant or practical nurses), biomedical technicians, and specifically trained phlebotomists (common in the United States, for example) [52, 138]. Sometimes specific VBS staff are employed by the laboratory to regularly perform phlebotomy rounds in the wards. In other locations, the staff employed in each ward performs the VBS.

In hospital wards in Sweden, VBS is most often performed by the enrolled nurses (or in the psychiatric wards, the equivalent psychiatric orderlies), employed in each ward. These staff categories perform basic patient care, as well as other tasks, such as echocardiography and blood pressure checks. Their education includes three-years of upper secondary school in a technical or vocational program. Specific VBS staff are normally not employed for inpatient VBS in hospitals in Sweden. Registered nurses most often perform VBS only on special occasions and physicians normally do not carry out VBS.

The biomedical technicians staffed in the laboratory mainly perform VBS in hospital laboratories in Sweden. They have a three-year university education and conduct biochemical analyses, manage analytical equipment and perform VBS at the laboratory inpatient and outpatient phlebotomy room. Enrolled nurses also work specifically with VBS in some laboratories.
RATIONALE

The total testing process is a source of clinically important errors, and in several aspects, the errors are of far higher numbers than what is accepted in industrial standards. Furthermore, reported error rates, which reflect only detected errors, probably only represent the tip of the iceberg. This raises the question of how the total testing process could be improved, and where the greatest potential for improvement is located.

The majority of the errors in the total testing process originate in the preanalytical phase. This phase includes several error-prone manual tasks, not easily avoided with technological solutions. The analytical phase contributes with very little error and will in the near future be fully automated. The pre-pre and post-postanalytical phases, at the level of the physician, still remain a critical issue, but interventions have been successfully tested, and some are in routine clinical use. Thus, in the future, the total testing process will be even more dependent on the quality of the preanalytical phase.

Despite the known importance of the preanalytical phase, research has mainly focused on measuring total error rates, rather than investigating potential sources of error. This is the case for venous blood samples for clinical chemistry testing, the most common biological sample type in hospitals. The routine performance of venous blood sampling practices, a highly manual task, is largely unexplored. In fact, only one study that has investigated venous blood sampling practices was published previous to this thesis. That study surveyed laboratory staff, and reported unsatisfactory knowledge about important steps in venous blood sampling [139].

Therefore, it is important to survey venous blood sampling practices in hospitals, to identify suitable targets for interventions, aimed at improving quality of the total testing process. This thesis will focus on potential preanalytical sources of error in venous blood sample collection for general clinical chemistry testing.
AIMS

The general aim of the present thesis was to survey the preanalytical procedure in hospitals to identify potential sources of error.

The questionnaire study

Specific aims:

To survey venous blood sampling practices (patient identification, test tube labelling, test request management, patient rest, stasis removal, the handling of test tubes after collection and information search procedures) reported by venous blood sampling staff in hospital wards (Papers I–III)

To identify factors associated with desirable reported venous blood sampling practices in hospital wards, such as education or routines, type of ward and frequency of sampling (Papers II–III)

To survey interest in re-education and in developing routines among venous blood sampling staff in hospital wards (Thesis)

To compare reported venous blood sampling practices between hospital ward and laboratory staff (Papers II–III)

To survey error-reporting practices among venous blood sampling staff in hospital wards in comparison to hospital laboratory staff (Paper IV)

The experimental study

Specific aim:

To investigate the preanalytical effect of pneumatic tube transport on venous blood sample analyses (haematology, coagulation, platelet function and global coagulation) (Paper V)
METHODS

In this thesis, one cross-sectional survey and one experimental study were carried out to address the aims. To further illustrate the findings of the cross-sectional survey, staff responsible for quality control issues in the hospital laboratories and transfusion medicine departments of the surveyed hospitals were asked for data on preanalytical errors. These data were not part of a study, but were routinely collected information. Note that the different laboratories used different definitions and indicators of preanalytical errors. Not all laboratories provided data on all detected errors or on the total number of test requests. Therefore, these data most certainly represent a major underestimation of the actual error rates and provides an insight into the magnitude of the problem of preanalytical errors in clinical practice.

The questionnaire study

Design and setting

For the first part of the thesis, a cross-sectional descriptive design was used (Papers I–IV). A pilot study was performed in a highly specialised surgery ward with 25 beds, situated at a university hospital. The ward was selected by contacting the head of the ward, known for interest in research. After the pilot study (Paper I), the main survey (Papers II–IV) was performed in two district hospitals situated in two different counties. Hospital A had 230 beds and 13 wards, while Hospital B had 152 beds and 12 wards. The two hospitals were selected since they were of comparable size and judged to be representative of the average hospital in Sweden. The main survey also included two hospital clinical chemistry laboratories, one situated in a district hospital and the other in a university hospital. The wards and laboratories in the main survey are hereafter collectively referred to as units. All units used identical vacuum test tubes for VBS for clinical chemistry testing. All units also used comparable paper-based test requests. The requests had prefabricated test tube labels on the back, all containing a unique identification (barcode) number. The laboratories also used a COES for a minor portion of their VBS. According to the heads of the units, two of the 25 wards, and both laboratories, had documented routines for VBS. Only the laboratories had introduced certification and accreditation for their VBS staff.

The standard VBS procedure for the surveyed units are summarised in Figure 5. The respondents in the wards were responsible for the VBS from inpatients, while the respondents in the laboratories had both in- and outpatients. Hospital A and both laboratories used the same laboratory manual. Hospital B belonged to another county, and used a laboratory manual issued by another laboratory. However, the VBS instructions in the two laboratory manuals were equivalent. Despite the differences between the ward and laboratory staff, VBS should always be performed according to VBS instructions in the laboratory manual. All participants had equivalent instructions for VBS. Therefore, the conditions for VBS could be considered comparable between the laboratories and the wards, and also between Hospital A and B.
Figure 5 A summary of the standard venous blood sampling procedure in the pilot study ward, in all wards in two district hospitals and in two hospital laboratories (Modified from Papers I–III).

Participants
In the pilot study (Paper I), all enrolled nurses working in the selected ward during the study period (March 2005) were included. In the main survey (Papers II–IV), all staff on duty and responsible for the majority of VBS in the selected hospitals and laboratories during the study period (November 2006 – January 2007) were included. Of the 335 individuals eligible for inclusion, 295 were enrolled nurses and psychiatric orderlies from the wards, and 40 were biomedical technicians and enrolled nurses from the clinical chemistry laboratories. The basic characteristics of all participants in the questionnaire survey are shown in Table 3.
In the pilot study, the response rate was 94%, 90% were women and the total internal missing rate (mean frequency of items left blank) was 10%. In the wards in the main survey, the response rate was 93%, 96% were women and the total internal missing rate was 5.6%. In the laboratories, 98% were women, the response rate was 100% and the total internal missing rate was 1.9%. The most notable differences between the wards and the laboratories in the main survey were the proportion of respondents working full time, performing VBS at least weekly, having received re-education in VBS, and having documented routines, accreditation and certification in VBS. The participants in the wards consisted of enrolled nurses and psychiatric orderlies, while the participants in the laboratories were almost all biomedical technicians. The differences in basic characteristics between respondents in Hospital A and B were the proportions of respondents working full time (39% vs. 75%, \( p<0.001 \)), performing VBS at least weekly (89% vs. 73%, \( p<0.001 \)), having received re-education in VBS (3.5% vs. 11%, \( p=0.013 \)), mean age (49 years vs. 52 years, \( p=0.027 \)) and mean time since basic education (16 years vs. 19 years, \( p=0.021 \)).

**Development procedure for the questionnaire**

For Papers I–IV, data were collected by means of a questionnaire. The questionnaire was based on the proper procedure for VBS, included in the laboratory manual and summarised in Table 1. These instructions are in line with international recommendations [75]. The questionnaire addressed the collection and handling of venous blood samples in vacuum test tubes (EDTA, citrate, Li-heparin or without anticoagulant) for clinical chemistry laboratory tests. The questionnaires in the pilot and main surveys are published online [140].
The questionnaire for the pilot study (Paper I) was developed in cooperation with a clinical chemist, VBS instructors at the local clinical chemistry laboratory and nursing researchers with experience in questionnaire development. A random selection of persons with experience of different aspects of VBS tested and commented a preliminary version of the questionnaire.

The final version of the pilot study questionnaire included 63 items. The items were related to practical VBS, the handling of samples and frequency of error reporting in VBS. The response alternatives were yes/no, or a scale of five alternatives ranging from always to never. The questionnaire also included three open-ended questions allowing for respondents to suggest improvements of VBS. The open-ended questions, and three others, where excluded from this thesis, since the results were of interest mainly for the pilot study ward. The general structure of the included items are summarised in Paper I, Tables 2–6.

For the main survey (Papers II–IV), the questionnaire was further developed, taking into consideration comments from the participants in the pilot study. The major changes included an adjustment of the previous five-point scale to a four-point scale (the alternative ‘sometimes’ was removed). Some items were added and some removed. The language was adjusted to make sure that misunderstandings were minimised and a new layout was produced.

Content validity was achieved by extensive discussions with professionals on different aspects on VBS and questionnaires. These professionals included registered nurses, enrolled nurses, biomedical technicians, physicians, heads of wards, senior consultants in clinical chemistry, VBS instructors, a quality control officer from a hospital clinical chemistry laboratory and researchers with considerable experience in questionnaire design. An extensive review of the literature was also performed. In order to obtain face validity, the questionnaire was reviewed and discussed on two different occasions by a group of enrolled nurses with considerable experience of practical VBS, who had worked in several different departments. Their role was to further identify and clarify any item that could possibly be misinterpreted.

During the development process of the questionnaire, extensive efforts were made so that each item was clearly worded, easy to understand, and could not be misinterpreted. The layout of the questionnaire was designed to be easy to read. The number of pages was limited, to ensure that the questionnaire could be completed in a reasonable period of time. The final version of the questionnaire included 56 items. The general structure of the included items is summarised in Paper II, Table 3, in Paper III, Table 2 and in Paper IV, Table 2.

The participants were considered as re-educated in VBS if their latest education in VBS was at least one year later than their original VBS education. Responses to the item regarding frequency of VBS were grouped into the categories ‘at least weekly’ or ‘more
seldom’. The wards were categorised into type of ward: surgical (including orthopaedic), medical, psychiatric, intensive care (including post-operative), women’s health/paediatrics and emergency. As described in Paper II, Table 3, in Paper III, Table 2 and Figure 2 and in Paper IV, Table 2, the responses to all items regarding VBS practices were dichotomised into either desirable practice (DP), representing a correct practice according to the laboratory manual, or undesirable practice, representing an incorrect practice according to the laboratory manual. The responses to the item regarding patient rest were categorised into ‘more than 15 minutes’, representing DP, and ‘15 minutes or less’, representing undesirable practice. The number of completed error reports were categorised into ‘no report’ or ‘at least one report’.

In order to obtain general scores, four grouped variables were constructed: one for stasis removal practices, one for test tube storage and two for test tube labelling (‘labelling by oneself’ and ‘labelling by someone else’). Each response was given a value ranging from one to four, with increasing values representing more DP. For each new grouped variable, an average score was calculated for each respondent. Finally, the score was dichotomised at the third quartile into DP and undesirable practice. Prior to the construction of the grouped variable, missing values were manually replaced when possible. Otherwise the case was deleted from the scale. Due to high internal missing rates (64–70%), three ‘by other means’ response choices were excluded from this thesis. One item regarding identification and one item regarding stasis removal were also excluded, since the construction of these items was found to be misleading. The open-ended question, allowing for suggestions for improvement of VBS, and one item regarding time of sampling, was not evaluated in this thesis. All responses from the psychiatric wards and the laboratories were excluded for the item regarding identification by wristband, since these units did not use wristbands for all patients.

Procedure for data collection

In the pilot study (Paper I), permission was obtained from the head of the ward along with a list of eligible subjects. The questionnaires were then distributed at three regular staff meetings. Information on how to complete the questionnaire and on the purpose of the study was provided. The head of the ward assisted in the distribution and collection of the questionnaires in sealed envelopes.

In the main survey (Papers II–IV), permission to perform the survey was obtained from the head of each unit. The head of each unit provided a list of eligible participants, including information on sex, job title and working hours. The head of each unit was also asked for the existence of documented unit-specific routines for VBS practices. They informed the participants about the study according to provided instructions and distributed the questionnaire in an envelope marked with the participant’s name. The envelope also contained an introduction, a description of the study and an unmarked envelope.

Participation was voluntary and participants could withdraw from the study at anytime without declaring a reason. All participants were assured confidentiality, i.e. that results
would only be presented at group level. All questionnaires were coded in order to allow reminders to be sent to non-responders. Only the investigators had access to the code key, and all questionnaires were decoded prior to entry into the data file. The head of each unit collected the unmarked sealed envelopes containing the completed questionnaires. After two weeks, a reminder was distributed. After four weeks, a similar reminder and new questionnaires were sent to those subjects who still had not returned the completed questionnaire (n=14).

Statistical analysis

Background information on the participants and data from the completed questionnaires were coded and transferred manually by the researchers (OW, JS) to an Excel data sheet (Microsoft Corp., Redmond, WA) and then transferred to SPSS 13.0 for Macintosh and SPSS 14.0 for Windows (SPSS Inc., Chicago, IL) for all statistical analyses. All questionnaires were manually rechecked against the final data file by the researchers (OW, JS). Basic descriptive statistics were used, and in the main survey (Papers II–IV), categorical variables were also compared with Chi-Squared or Fischer’s exact test, and continuous variables with Students t-test. In all statistical analyses, the significance level was set at $p<0.05$. All statistical tests and $p$-values were two-sided, and $p$-values were not corrected for multiple testing.

Ethical considerations

The pilot study was a questionnaire survey of hospital personnel, not patients. According to the Regional Ethical Review Board, ethical approval was not needed, and was therefore not obtained for the pilot study. However, the study conformed to the principles outlined in the Declaration of Helsinki. The study protocol for the main survey was reviewed by the Regional Ethical Review Board in Umeå (D-No 06-104M). The returning of the questionnaire was accepted as informed consent. One ethical issue specific to this thesis is possible feelings of guilt or anxiety among participants, if the results should indicate inadequate VBS practices. The participants may also feel that they are bad performers if the results indicate an unfavourable VBS practice. The participants may have felt obligated to respond, since the head of the unit distributed the questionnaires. However, these risks were minimised by presenting results only on the group level and by collecting the questionnaires in sealed unmarked envelopes. The questionnaires were also coded, as described above, since it was judged to contribute to a higher response frequency, important for the results to be usable. A low response frequency would be a greater ethical problem than the coded questionnaires.

The possible benefits for participation in the survey included an increased awareness about the importance of VBS in modern health care. This could contribute to an increased satisfaction with work. More knowledge about VBS practices could assist in the development of new routines, which could make daily work easier. Increased awareness of the importance of the preanalytical phase could make it easier to provide funding for educational initiatives, which would contribute to increased satisfaction with daily work or improved working climate in the workplace.
The experimental study

Subjects and sample collection

An experimental design was used in the second part of the thesis to investigate the effect of PTST on test results (Paper V). The study subjects consisted of 15 male and 13 female healthy volunteers (mean age 39 years). Before participating, all subjects received an information letter which described the study and potential risks. VBS was performed in accordance with international recommendations [75], before and after a one-week treatment with 75 mg acetylsalicylic acid (ASA) per day. After discarding the first test tube, two 4.5 mL plastic Vacutainer® test tubes with 3.8% citrate, and two 4.5 mL plastic Vacutainer® test tubes containing EDTA, were collected (Becton Dickinson, Franklin Lakes, NJ).

Sample transport and analysis

One test tube containing citrate and one containing EDTA were transported by PTST from the laboratory to a transfer station and back (mean transit time 155 s, approximately 500 m). The paired test tubes (one citrate and one EDTA) remained in the laboratory. The PTST used in this study has a tube diameter of 100 mm and operates with a constant speed of 5–6 m/s. The Department of Biomedical Engineering and Informatics, Umeå University Hospital, performed measurements on the surveyed PTST, as shown in Figure 6.

![Graph showing forces applied on a test tube](image)

**Figure 6** Forces applied on a test tube transported by the surveyed pneumatic tube transport system. According to calculations and practical measurements, the highest forces applied to a sample during transport were approximately 150 g at sudden decelerations at transfer and at end stations. Courtesy of the Department of Biomedical Engineering and Informatics, Umeå University Hospital.
All analyses were carried out according to the manufacturer’s instructions. The citrated samples were centrifuged at 1860 g for 15 min, and analysed for antithrombin, fibrinogen and activated partial thromboplastin time (all Siemens Medical Solutions Diagnostics, Deerfield, IL), prothrombin time according to Owren and D-dimer (both MediRox, Nyköping, Sweden) on a Sysmex CA 7000 (Sysmex Corp., Kobe, Japan). The citrated samples were also analysed for platelet function on a PFA-100® (Siemens Medical Solutions Diagnostics, Deerfield, IL) and for global coagulation with a thromboelastograph (TEG 5000®, Haemoscope Corp., IL). The EDTA samples were analysed for haematology parameters on a Sysmex XE-2100 (Sysmex Corp., Kobe, Japan).

**Statistical analysis**

The test results and background information on the subjects were entered manually onto an Excel data sheet (Microsoft Corp., Redmond, WA) and then transferred into SPSS 13.0 for Macintosh (SPSS Inc., Chicago, IL) for all statistical analyses. All test results were manually rechecked against the final data file. In case of reported medication prior to sample collection, or an instrument error during the analysis, the subject or test result was excluded. Descriptive statistics were the median and quartiles. The paired difference between non-PTST and PTST samples was evaluated with Wilcoxon’s signed rank sum test. The correlation between the PTST transit time and CT and R were tested using linear regression. The significance level was set to $p<0.05$.

**Ethical considerations**

The study protocol was reviewed by the Regional Ethical Review Board in Umeå (D-No 07-013M). One ethical issue specific to the study included the possibility of achieving a pathological test result. However, senior consultants in clinical chemistry were involved in the project, and thus, could react to a pathological finding. All subjects gave informed consent to participation. Trained phlebotomists performed all VBS in order to minimise any discomfort for the subjects. To assure confidentiality, all involved staff had professional secrecy. All samples were coded and destroyed after the analyses. Only the researchers had access to the code key. The benefit of participation for the subjects was mainly a safer preanalytical procedure in the future. The risks were judged as minimal.
CONSIDERATIONS

The questionnaire study

Study design
For the first part of this thesis, a cross-sectional design was used. In a cross-sectional study, data are collected in a population during a short period of time [141]. Since the outcome and the exposure are measured simultaneously, causality cannot be established. The cross-sectional design was judged as suitable to answer the aims of this thesis. The design has the advantage of being relatively fast and inexpensive [141]. That made it possible to perform a relatively large survey of all VBS staff from two different hospitals located in two different counties. Furthermore, the aims consisted of several variables to be measured at the same time, where the cross-sectional design is appropriate [142]. A longitudinal design or an intervention study would not have been a suitable alternative to answer the aims of this thesis.

Data collection
The aim was to evaluate VBS practices on the group level during a short period of time. A self-administered questionnaire is suitable for large sample sizes and for measuring practices [142]. Therefore, a questionnaire was judged to be the best choice for collection of data. A questionnaire also provides an opportunity for education and feedback for the participants. A crucial aspect is that a questionnaire provides an indirect measurement of the surveyed topic, i.e. reported practices, not actual practices.

A self-reported questionnaire has two major limitations of importance for a measure of VBS practices. The first is that such a measure is affected by the intra-individual variation in responses [141]. For example, the mood of the subject can affect how he or she answers a specific question. The second is the inter-individual variation in responses. That is, different subjects can interpret the questions or the response alternatives differently [141]. To compensate for the above mentioned limitations [141], the importance of the study was presented for the participants and clearly written instructions explained how to complete the questionnaire. During the development process of the questionnaire, extensive efforts were made so that each item could not be misinterpreted. The relative large sample size in this thesis can also compensate for variation in responses. Another common limitation of a self-reported questionnaire is low response frequency, which can lead to the concern that the results are not representative [141]. Since the response frequency was very high, this was not a problem in this thesis.

Bias is probably not a major problem in the questionnaire survey. Any bias in responses would be expected to tend toward “good behaviour” [142]. Since several potentially serious inadequacies were observed, the responses seem likely to underestimate areas in need of improvement. Recall bias is probably not an issue, since the vast majority reported
to perform VBS daily or weekly. Selection bias is not an issue, since a total survey in two hospitals and two laboratories was performed.

A structured observational survey, by which data are collected in a structured manner by observers (often the researchers themselves) could provide reliable information. That type of study is complicated and costly [142]. An observation also entails an particularly high risk of good behaviour bias, meaning that the subjects respond or act in a more favourable manner when they are being observed [142]. A change of behaviour would be expected for observed VBS practices. Therefore, an observational data collection method was not used in this thesis. A measure of the error rates in the studied laboratories would have been useful, but some data were already available, and several such studies had already been published, as previously mentioned.

Comparisons between the wards and the laboratories may have been affected by the more extensive basic education for the biomedical technicians. However, the laboratory staff had received their basic education many years ago, and awareness about the magnitude of the preanalytical problem has only been raised in recent years. VBS is a repetitive and not very complicated task, which should be performed identically at all times. The prevalence and types of preanalytical errors seem to be fairly constant when comparing studies from different countries [17-19, 23, 25, 26, 28-32, 34]. Since the level of basic education for VBS staff varies all over the world, it is likely that basic education is not a major determinant of VBS quality, in line with a previous study [139].

**Internal validity**

The internal validity addresses how well the questionnaire measures what it is supposed to measure. Direct observation was judged to be too prone to “looking good” bias to be useful for assessing validity. To the best of the author’s knowledge, no other instrument or standard existed to measure practical VBS. Therefore, criterion validity (comparing the results with a standard) was not measured for the questionnaire. Accreditation of the laboratories [51, 127] and the results of previous studies [29, 31, 46, 77, 134-137], demonstrate that laboratory staff can be regarded as a local golden standard for VBS and specimen handling. This suggests some degree of validity, since the results indicated a ‘better’ performance by laboratory staff, compared to ward staff.

The extensive development process for the questionnaire included a continuous discussion with various professionals on questionnaires and VBS, as well as a focus group including staff with considerable experience of practical VBS in varied settings. A pilot study was performed, after which the questionnaire was further refined. The face and content validity (the appropriateness as judged by non-experts and experts, respectively) is thus likely to be reasonable. The layout of the questionnaire was designed to be easy to read and the number of pages was limited, to ensure that the questionnaire could be completed in a reasonable period of time. Relevant literature in questionnaire design was consulted [142, 143]. The subjects were informed about the importance of answering all questions truthfully. Altogether, this suggests reasonable internal validity for the questionnaire survey.
Reliability

The measure of reliability that is most applicable to the questionnaire study in this thesis is the test-retest reliability (stability). The test-retest reliability is the reproducibility of the results on the same subject, usually obtained by performing the survey a second time, after a time interval. Stability indices are most appropriate for enduring attributes such as personality or height [142] and therefore less suitable for measures of VBS practices, which can easily be changed. A change of practice as a direct result of the first administration is likely [142]. A test-retest can be affected by memory interference and by changes in knowledge and behaviour over time, independent of the stability of the measure [142]. The results were used to draw conclusions on the group level with a large sample size. In this case, the stability is of less importance [144]. Altogether, for these reasons, the project group decided not to calculate stability. The test-retest reliability could be of importance in a follow up survey. The results from the main survey are largely in line with the results from the pilot study. This indicates that the findings could be reproducible.

External validity

The external validity concerns the generalisability of the results. This is an important issue in science, in which studies are performed on samples in order to obtain results applicable to the whole population. A major strength of the questionnaire study in this thesis is the sample. All staff responsible for the majority of VBS in all wards in two hospitals in two different counties, and in two hospital laboratories, were included. Thus, the majority of hospital-related VBS situations and settings in two different counties, i.e. organisational structures, were covered.

VBS is a very specific task that should always be performed in a consistent manner, according to laboratory instructions, generally based on recommendations from international organisations [75]. No clear pattern could be seen when comparing VBS practices between the two hospitals or types of wards, in line with previous reports [18, 19, 30, 32]. This suggests that VBS is performed similarly in inpatient settings. When comparing the results from several studies, the reported prevalence and types of preanalytical errors seem to be fairly consistent for inpatient VBS [17-19, 23, 25, 26, 28-32, 34], despite the variation in staff categories performing VBS internationally. Since the enrolled nurses are generally the personnel with the most VBS experience in hospital wards in Sweden, they are most comparable to other inpatient VBS staff categories internationally.

The most important limit of this thesis is that it compares the results of the questionnaire, related to a specific local situation, with data from international literature, where data may have been obtained in different organisational situations. However, the preanalytical error rates obtained from the local laboratories indicate that inadequate VBS practices give rise to preanalytical errors of clinical importance, consistent with international studies. The results of the main study (Papers II–IV) were largely in line with those of the previous pilot study (Paper I), but confirmation of the findings in other settings, of course, would be valuable.
Statistical analysis

With a $p$-value set at 0.05, there is a 5% risk that a significant result will be due to chance only. Given the large number of statistical analyses performed in the present studies, some of the significant findings might be the result of multiple testing, since the $p$-values were not corrected in this thesis. However, the results are in line with previous studies and the clinical experience of the project group. Despite the relatively large sample size, a greater number of participants would have provided more statistical power for subgroup analyses. Analysis for missing values was not performed, since the response frequency was high and the internal missing rate low.

In analysing some of the items, general scores (or indices) were used. General scores are suitable when the items are equally important and measured on the same scale [144], as was the case for the scores in this thesis. The scores were dichotomised based on the distribution and clinical relevance of the responses. This gives a risk of misclassification when a response is near the point for dichotomisation. The scores were only used for comparing groups, and not for descriptive statistics. The dichotomised scores for different groups were consistent with the descriptive statistics for the included items. Thus, misclassification was not a major problem in this thesis.

The experimental study

The major strengths of the experimental study are the use of modern instruments in clinical use and the careful planning to avoid any bias or confounders. The range of haematology and coagulation parameters included was higher than in previous reports. Global coagulation provides a new approach to study the effects of PTST on blood samples. One limitation was that patients were not included. In patients with platelet disorders, for example secretion defects, exhaustion of platelets might possibly be more pronounced after PTST. However, there are several problems when including patients. The most important is to define the patient group, since the effect of PTST can be different for different patient groups. Another is to recruit a sufficient number of patients, since most haematological disorders have low prevalence. Since fresh samples are used for analysis of platelet function and global coagulation, bio-banks cannot be used.

Since treatment with ASA was included, we tested one aspect of impaired platelet function, mimicking some pathological platelet disorders. A greater number of subjects would have provided more statistical power for sub-group analyses. An important question is if the results can be generalised to other PTST. This is somewhat difficult to assess, since the factor of highest importance for preanalytical disturbances of PTST is not known. Possible factors are the impact forces and vibrations applied to a blood sample transported by PTST. Therefore, an instrument measuring the forces applied on the surveyed PTST could be valuable for generalisation of the results.
RESULTS AND DISCUSSION

“What concerns everyone can only be resolved by everyone”

– Freidrich Durrenmatt

Patient identification and test tube labelling

The results for patient identification in VBS are presented in Paper III, Table 2. Of the respondents in the wards, 91% reported the DP of always asking the patient to state his/her name and Swedish identification number prior to VBS. This should always be done, as described in Table 4. Only 57% of the participants in the wards reported the DP of never using the patient’s health care card for patient identification. The health care card, issued to all residents of Sweden, contains name, Swedish identification number and address, but no photograph, and should never be used for patient identification. Of the ward staff, 83% reported the DP of checking patient identity, even if already knowing the patient. Patients with similar names can get mixed up, with serious consequences [14]. The identification procedure should thus always be performed, even if the patient is known to the VBS staff.

Table 4

<table>
<thead>
<tr>
<th>Task</th>
<th>Instruction from the National Board of Health and Welfare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Sample collection and handling must always be performed in such a way that mix up of patients and test tubes are avoided</td>
</tr>
<tr>
<td>Routines</td>
<td>The valid instructions in SOSFS 1989:1 and SOSFS 2006:18 (updated version 2007:21) should be used when designing standardised procedures. All units involved in VBS must have documented routines assuring a proper identification procedure</td>
</tr>
<tr>
<td>Patient identification</td>
<td>All patients in hospitals in Sweden must have an identification wristband. Patient identification should be performed by asking the patient for name and Swedish identification number (comparable to a social security number). This information should be compared with the corresponding information on the identification wristband or identification documentation</td>
</tr>
<tr>
<td>Test tube labelling</td>
<td>The test tube must be labelled and the test request marked before sample collection</td>
</tr>
</tbody>
</table>

*According to a legal expert at the National Board of Health and Welfare (personal communication, 2007), these rules apply to all blood sampling, not just blood samples for pretransfusion testing

Only 22% of the respondents in the wards reported the DP of always checking the identification wristband as a part of the identification procedure. Use of wristbands can result in an improved identification process [55] and should be done, as described in Table 4. Further, refusal by the VBS staff to perform VBS without a proper wristband can decrease wristband error rates [57]. This can have a clinical importance, since wristbands can be associated with surprisingly high error frequencies [33, 57-59].
Although undesirable, some of the shortcomings in the patient identification procedure may have explanations, as presented in Paper III, Table 5. Not performing patient identification because of already knowing the patient was more often reported in the psychiatric wards, which may be due to the longer durations of stay among patients. Always asking the patient for name and Swedish identification number was more seldom reported in the intensive care, psychiatric and women’s health/paediatric wards. In these wards, patients more often have an impaired ability to communicate. However, in the surgical and medical wards, very few respondents reported to always use wristbands for identification purposes. This is undesirable, since patients with impaired consciousness at times are taken care of in these wards.

The results for test tube labelling are presented in Paper II, Table 3. Only 2.4% of the respondents in the wards reported the DP of always labelling the test tube at the patient’s side, immediately prior to sampling. This is a serious finding, since test tubes should always be labelled before sampling [61], as described in Table 4. Of the ward staff, 78% noted the DP of not labelling the test tube at a later occasion, after having left the patient. Similarly, 78% reported the DP of not allowing somebody else to label the test tube after sampling. This suggests that one fifth of the VBS staff sometimes label test tubes at a later occasion, and that one fifth sometimes allow somebody else to label the test tube after sampling. Earlier studies regarding VBS for pretransfusion testing (a highly regulated task) report labelling errors in 1 out of 165–200 samples [62, 63]. In fact, identity mismatches for as many as 4 out of 20 test tubes collected from one unit have been reported [86]. Of all samples sent by mail from primary health care, 4% were labelled with the wrong patient identity in one study [86]. Altogether, our results indicate a substantial risk of mislabelling of test tubes in the surveyed wards, in line with previous reports.

Do the above-mentioned risks in patient identification and test tube labelling result in preanalytical errors? The results from the local laboratories (Table 5) clearly indicate that this is the case. For example, the year after the survey, 9 critical patient identification errors were detected in pretransfusion testing in the university hospital. Of these, two were verified as wrong blood in the test tube (the blood groups in the blood group screening and antibody testing did not match), roughly representing an error rate of 71 PPM. This is an underestimation, since a patient identification or test tube labelling error causing wrong blood in the test tube will pass unnoticed, if the blood groups are matching. Considering the underlying distribution of AB0 blood groups in Sweden, the 71 PPM error rate has to be multiplied with 1.6 [63]. This will give an error rate of 114 PPM for wrong blood in the test tube in pretransfusion testing the university hospital. In one of the surveyed district hospitals, a preanalytical error rate of almost 18 000 PPM was registered for pretransfusion testing two years prior to the present survey. VBS staff will probably be more cautious when performing VBS for pretransfusion testing, since the potential life threatening consequences of a mistake are more obvious, compared to regular VBS. This testing is also more explicit regulated, even if patient identification should be equally performed for all VBS (Table 4). Thus, the error rates in clinical chemistry testing are most certainly a far higher number.
The results in this thesis indicates that the instructions for patient identification and test tube labelling issued by the National Board for Health and Welfare are not always followed (Table 4). One reason for the reported deviations could be that one of these instructions was published during the study period. Another is that instructions for patient identification differ slightly between the laboratory manuals [145, 146], the previously described instruction manual for health care staff (in Sweden known as Handboken) [110], and the mandatory instructions issued by the National Board for Health and Welfare (Table 4). Altogether, patient identification and test tube labelling in VBS require urgent attention, and represent the most important target for further development of current VBS routines.

### Table 5
Examples of preanalytical errors (errors per year) from hospital laboratories in the two surveyed counties. The error rate is standardised to parts per million (PPM) when possible.

<table>
<thead>
<tr>
<th>Errors</th>
<th>Requests</th>
<th>PPM</th>
<th>Year</th>
<th>Type of preanalytical error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion Medicine, University Hospitala</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>28 000</td>
<td>321</td>
<td>2007</td>
<td>Critical patient identification or test request error</td>
</tr>
<tr>
<td>2</td>
<td>28 000</td>
<td>71</td>
<td>2007</td>
<td>Wrong blood in the test tube</td>
</tr>
<tr>
<td>177</td>
<td>29 126</td>
<td>6077</td>
<td>2004</td>
<td>Total number of registered errors</td>
</tr>
<tr>
<td>71</td>
<td>29 126</td>
<td>2438</td>
<td>2004</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>Transfusion Medicine, Hospital Ab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>113</td>
<td>6345</td>
<td>17809</td>
<td>2004</td>
<td>Total number of registered errors</td>
</tr>
<tr>
<td>17</td>
<td>6345</td>
<td>2679</td>
<td>2004</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>Transfusion Medicine Total, Swedena</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7939</td>
<td>1 050 680</td>
<td>7556</td>
<td>2004</td>
<td>Total number of registered errors</td>
</tr>
<tr>
<td>3072</td>
<td>1 050 680</td>
<td>2924</td>
<td>2004</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>60</td>
<td>1 050 680</td>
<td>57</td>
<td>2004</td>
<td>Patient mix-up or wrong identity</td>
</tr>
<tr>
<td>Clinical Chemistry, University Hospitalb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>526</td>
<td>-</td>
<td>-</td>
<td>2004</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>384</td>
<td>-</td>
<td>-</td>
<td>2006</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>281</td>
<td>-</td>
<td>-</td>
<td>2007</td>
<td>Patient identification error or problem</td>
</tr>
<tr>
<td>Hospital laboratory, Hospital Ab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>140</td>
<td>-</td>
<td>-</td>
<td>2004</td>
<td>Inpatient requests with erroneous identification</td>
</tr>
<tr>
<td>150</td>
<td>-</td>
<td>-</td>
<td>2005</td>
<td>Inpatient requests with erroneous identification</td>
</tr>
<tr>
<td>141</td>
<td>-</td>
<td>-</td>
<td>2006</td>
<td>Inpatient requests with erroneous identification</td>
</tr>
<tr>
<td>157</td>
<td>-</td>
<td>-</td>
<td>2007</td>
<td>Inpatient requests with erroneous identification</td>
</tr>
<tr>
<td>Hospital laboratory, Hospital Bb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>540</td>
<td>-</td>
<td>-</td>
<td>2006</td>
<td>Error with possible effects for patient safetyc</td>
</tr>
</tbody>
</table>

aData for all preanalytical errors are only available for 2004. Data for critical patient identification errors are available for all years, but only errors for 2007 are shown.

bTotal number of test requests not available.

cExtrapolated data. Approximately 45 error reports regarding preanalytical errors were registered during October 2006.

### Test request management

The results regarding test request management are presented in Paper II, Table 3. In the wards, 90% of the subjects reported the DP of always comparing the patient’s name and Swedish identification number with the corresponding information on the test request. This should always be done to ensure correct identification of the patient. Of the ward staff, 75% reported the DP of always signing the test request. Not signing the test request can
complicate error tracking. Only 66% reported the DP of checking the test request if someone else had completed it. This suggests that one third of the ward staff do not always perform this check, which most definitely entails a risk of an erroneous test request. The results are in line with earlier findings which indicate that test requests can be a source of clinically important preanalytical errors [19, 28, 29, 46, 77, 82-85] and can cause more than two thirds of all rejected samples in the laboratory [64].

During the conduction of the present studies, a COES has been implemented in the ward investigated in the pilot study. The central features include printing of the patient’s name and Swedish identification number, the time and date of sampling and a short sampling instruction on each test tube label. This will most certainly demand an improvement of the labelling procedure in the surveyed wards. The implementation also includes standardised routines for ordering of tests and handling of test tube labels. This COES would probably eliminate most of the investigated error-prone test request practices, but will not cover several of the important manual VBS practices surveyed in this thesis.

The implementation of the COES has been performed stepwise. Test request error rates show a prominent decrease, as the implementation continues (Figure 7). Even if the data cannot be considered reliable, the total number of received requests has increased. It is likely that the COES has contributed to the decreased error rates. A few identification errors are still registered, indicating that the COES alone is not enough for a reliable preanalytical procedure. The implementation of a COES should still be considered as top priority, to reduce errors associated with paper-based test requests.

**Figure 7** Frequency of registered test requests with identification errors in one hospital laboratory. A computerised order entry system (COES) has gradually been implemented since the beginning of 2005. The total number of errors is subdivided into paper-based and computerised requests for 2005–2007.
Information search procedures

With respect to information search procedures in VBS (Paper II, Table 3), only 29% of the ward staff reported the DP of not using paper-based manuals located in the ward, when unsure about a VBS procedure. These manuals were last issued approximately in 1999, in both Hospital A and B. Thus, the information in these manuals was possibly out of date. Of the ward staff, 20% stated the DP of not asking a colleague when unsure about a VBS procedure. If the colleague had used the paper-based manual, or other unreliable sources of information, there would be an obvious risk of distributing incorrect information about VBS in the wards.

This thesis is the first to evaluate the use of an online laboratory manual among VBS staff. Online laboratory manuals should be considered the preferred source of information for VBS procedures, since they can be updated easily. However, only 18% of the ward staff noted the DP of always using the online manual, the only source of updated VBS information in the surveyed units. The previously mentioned general instruction manual for health care staff (known as Handboken in Sweden) [110] could have been used, although no respondent noted this in the “By other means” item. Further, not all online manuals are user friendly [115]. The high rates of reported use by the laboratory staff in the questionnaire survey (Paper 2, Table 5) suggest that these were not the main reasons for the low reported use by ward staff.

The online manual has only been available for 2 years in Hospital A, which could be one reason for the low use. This is supported by the fact that the use of the online manual was significantly more often reported in Hospital B, where the online manual have been used for 6–7 years (Table 6). It is of utmost importance that VBS instructions are updated and easily accessible since preanalytical information from laboratories changes over time [114, 115, 147]. Therefore, increased use and development of electronic instructions, combined with a COES as mentioned above, could increase patient safety in the surveyed wards.

Table 6
Significant differences in desirable venous blood sampling practices and basic properties between respondents in all wards of two district hospitals.

<table>
<thead>
<tr>
<th>Process</th>
<th>Hospital A</th>
<th>%</th>
<th>n</th>
<th>Hospital B</th>
<th>%</th>
<th>n</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the patient by checking the</td>
<td>16</td>
<td>28</td>
<td>34</td>
<td>32</td>
<td></td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>wristband</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not identify by checking the</td>
<td>62</td>
<td>108</td>
<td>47</td>
<td>44</td>
<td></td>
<td></td>
<td>0.020*</td>
</tr>
<tr>
<td>patient’s health care card</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do not have someone else label the</td>
<td>83</td>
<td>147</td>
<td>66</td>
<td>61</td>
<td></td>
<td></td>
<td>0.002*</td>
</tr>
<tr>
<td>test tube</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always sign the test request</td>
<td>89</td>
<td>157</td>
<td>49</td>
<td>45</td>
<td></td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Never have someone else note the</td>
<td>20</td>
<td>35</td>
<td>34</td>
<td>32</td>
<td></td>
<td></td>
<td>0.009*</td>
</tr>
<tr>
<td>time of sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never search for information</td>
<td>23</td>
<td>39</td>
<td>39</td>
<td>35</td>
<td></td>
<td></td>
<td>0.009*</td>
</tr>
<tr>
<td>using the paper-based manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always search for information using</td>
<td>8</td>
<td>14</td>
<td>36</td>
<td>33</td>
<td></td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>the online manual</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stasis removal before sampling</td>
<td>12</td>
<td>20</td>
<td>27</td>
<td>22</td>
<td></td>
<td></td>
<td>0.003*</td>
</tr>
<tr>
<td>Invert the test tube immediately</td>
<td>51</td>
<td>91</td>
<td>72</td>
<td>68</td>
<td></td>
<td></td>
<td>0.001*</td>
</tr>
<tr>
<td>after sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertical test tube storage</td>
<td>37</td>
<td>63</td>
<td>21</td>
<td>19</td>
<td></td>
<td></td>
<td>0.006*</td>
</tr>
<tr>
<td>Report errors even if worried about</td>
<td>91</td>
<td>110</td>
<td>79</td>
<td>52</td>
<td></td>
<td></td>
<td>0.020*</td>
</tr>
<tr>
<td>consequences</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p-values measured with *Chi-2 test or *Fischer’s exact test
Patient rest, stasis removal and test tube handling

The results for patient rest, stasis removal and test tube handling after VBS are presented in Paper III, Table 2. Almost all (87%) of the respondents in the wards reported the undesirable practice of removing venous stasis after VBS. Prolonged venous stasis should be avoided, since this may have clinically important effects [48, 72-74]. Only 18% of the respondents in the wards reported the DP of allowing the patient to rest for more than 15 minutes before VBS. This is required [75, 76], since the positioning of the patient before and during VBS can have clinically important effects [67-70]. However, this is probably an issue of greater importance in outpatient VBS, since many inpatients are in a horizontal position most of the time.

Only 58% of the respondents in the wards reported the DP of inverting the test tubes with additives after sampling. Test tube inversion is recommended [61, 75, 76], to avoid clotting of the blood. Blood clotting causes an important part of the errors in VBS [30, 32, 46, 77]. Only one participant (0.4%) reported the DP of using an automatic test tube inverter, probably due to the lack of such devices in the surveyed wards. However, some studies report that inadequate inversion of test tubes does not have preanalytical effects on coagulation and haematological testing, at least not in healthy volunteers [148-151]. As few as 31% of the participants in the wards noted the DP of not storing test tubes horizontally (for example lying on a bench top), while only 47% reported the DP of using a test tube stand for test tube storage. Vertical storage of test tubes is recommended for proper coagulation of serum samples.

The results suggest that use of venous stasis, patient rest before VBS and the handling of test tubes after VBS were not performed in accordance with VBS instructions and international recommendations [61, 75, 76, 145, 146]. This can have clinical consequences [30, 48, 52, 66-70, 72-74]. The results regarding stasis and test tube inversion confirm previous findings from a questionnaire study of laboratory personnel [139], although the preanalytical effect of inadequate test tube inversion needs further investigation.

The numerous deviations from VBS instructions identified in this thesis are probably unknown to the clinicians when interpreting test results. This increases the risk of postanalytical errors, since reference intervals and decision limits require a standardised procedure for sample collection [75, 76, 112], stated in the laboratory manual. Thus, manual tasks with known risks of preanalytical error should be considered when attempting to improve quality in the preanalytical phase, for example when implementing a COES.

Education and routines in the wards

Surprisingly, reported practices in the wards were somewhat better for respondents with less education in VBS, although the pattern was not clear (Paper II, Table 4, and Paper III, Table 6). A previous study among laboratory VBS staff reported that education was not associated with better knowledge about VBS procedures [139]. The vast majority of the respondents had been working for a long time (mean 12 years) and their basic education had
been completed many years previously (mean 17 years) (Table 3). This is probably one explanation for the surprisingly low association between education and desirable VBS practices.

Only 58% of the ward staff totally agreed that they had enough knowledge for VBS (Table 7), while 45% (n=121) demonstrated interest in more education in VBS. Only 6.2% reported having received re-education in VBS (Table 3). It is obvious that this staff category had recognised the need for continuous education, which apparently was not the case for top management. No significant differences in VBS practices were found between the two wards in which the heads of the wards reported having documented unit-specific routines for VBS, compared to the 23 wards without such routines (data not shown). The results lead to the speculation that some factor, other than VBS re-education or routines, is important for the reported deviations in VBS practices. As much as 44% (n=118) of the respondents in the wards would consider increased responsibility for VBS routines. This enthusiasm and sense of responsibility is important, since motivation, as well as the recognition of a need for change, are crucial to the implementation of changes [152]. It is encouraging that the ward VBS staff are willing to participate in developing their daily work, despite the traditional lack of quality improvement.

<table>
<thead>
<tr>
<th>Table 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of agreement in statements concerning venous blood sampling (VBS) in all wards of two district hospitals.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To what extent do you agree with the following statements?</th>
<th>% Do not agree at all</th>
<th>n</th>
<th>% Agree to some extent</th>
<th>n</th>
<th>% Totally agree</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have enough knowledge for my daily work with VBS and specimen handling</td>
<td>2.2</td>
<td>6</td>
<td>40</td>
<td>110</td>
<td>58</td>
<td>158</td>
</tr>
<tr>
<td>Proper collection and handling of VBS is considered a priority in my ward</td>
<td>12</td>
<td>32</td>
<td>43</td>
<td>116</td>
<td>45</td>
<td>122</td>
</tr>
</tbody>
</table>

**Hospital, type of ward and frequency of VBS**

Statistically significant differences in response frequencies were found between the two hospitals for eleven items (Table 6). However, neither hospital was clearly better than the other with respect to overall adherence to the desirable procedure for VBS, except for information search procedures, as previously discussed. When comparing responses among the types of wards, the responses differed significantly for several items (Paper II, Supplementary Table, and Paper III, Table 5). As for the hospitals, no clear pattern was evident. Conflicting results are reported on the prevalence of preanalytical problems from different types of wards [18, 19, 30, 32]. When comparing responses between respondents performing VBS more often (VBS at least weekly or working full time) and more seldom, no clear pattern could be found (Paper II, Table 4, and Paper III, Table 6).
Differences between the wards and the laboratories

Differences in basic characteristics between the wards and the laboratories are shown in Table 3. For all statistically significant differences in responses to VBS practices, the laboratories reported better practices than the wards (Paper II, Table 5 and Paper III, Table 4) in line with previous studies [26, 29, 31, 77, 134-137]. Some possibilities for preanalytical errors differ between inpatient and outpatient VBS. Examples include the risk of blood sample dilution by intravenous infusions in inpatients. However, no such differences were addressed in this thesis. As previously discussed, differences in basic education are not likely to explain the differences in reported VBS practises. No clear differences in reported practices could be seen with respect to education, routines, hospital, type of ward and frequency of VBS among the ward staff. The VBS instructions in the laboratory manuals were equivalent in all units. It seems likely that the quality improvement initiatives in the surveyed laboratories (Table 8) may explain the reported better VBS practices among the laboratory staff. However, no significant differences in responses were found with respect to patient identification, indicating that there is also room for improvement of the preanalytical phase in the laboratories.

Table 8
| Accreditation | In accordance with the ISO/IEC 17025 [127] standard, which regulates sample collection performed by laboratory personnel |
| Certificate    | All phlebotomists have to regularly undertake a test on venous blood sampling procedures to achieve a competence certificate for venous blood sampling. This certificate is a requirement for work with venous blood sampling |
| Setting        | A waiting room destined for patients, with signs stating reasons for patient rest of more than 15 minutes before phlebotomy. Specific phlebotomy rooms with a patient chair designed for phlebotomy and all necessary equipment, including a test tube stand and an automatic test tube inverter |

Aspects on VBS staff in Sweden

Potential explanations for undesirable VBS practices, such as insufficient education or lack of routines, could not be identified. The ward staff performed VBS often and are therefore likely to be skilled in this task. They expressed a desire for re-education and to participate in developing routines for VBS. This suggests that they are willing to improve their knowledge to ensure patient safety. Thus, it seems likely that the reported undesirable VBS practices in the wards are not related to the individual VBS staff. This is in line with the conclusions of the previously discussed Institute of Medicine report [1]. The deviations are more likely related to other aspects and factors, of which the organisation may have a major importance.

Organisational emphasis on quality is very important. Lack of such emphasis is negatively associated both with the likelihood of errors and with suboptimal patient care [153]. Organisational and leadership practices, such as defining quality and safety as top priorities,
are positively associated with measurable differences in quality and safety [154]. No clear
differences between types of wards or the two hospitals could be found, in line with
previous findings [18, 19, 30, 32]. The two hospitals were situated in two different
counties, with different top management. Thus, it is probably not the organisation in the
single ward, hospital or county that has a major influence. It is more likely unreflected
routines or traditions in the health care system itself that have importance for the reported
deviations.

Strömberg concluded that men more often occupy high status positions in health care,
which is also observed in other industries [155]. Almost 96% of the participants were
women and only 6.2% had received VBS re-education (Table 3). The enrolled nurse is a
low-income, mainly female occupation, with little tradition of quality improvement
initiated from top management. The apparent low priority is remarkable since the enrolled
nurses perform several tasks with major impact on patient care. VBS is one such task that
tradition has been performed by enrolled nurses. It is not surprising that only 45% of
the ward staff totally agree that VBS is considered a priority in the ward (Table 7). Tasks
involving dirt and contact with body fluids, such as blood, are traditionally viewed as low-
status [155, 156]. This leads to the speculation that the apparent view of VBS as a low-
status task, mainly performed by women, could be a contributing factor to the apparent low
priority of quality improvement initiatives.

**Error reporting practices**

As shown in Paper IV, Table 2, only 5.5% of the ward staff reported to have ever
completed an error report regarding VBS. Given the magnitude of the preanalytical error
rates [17-19, 23, 25, 26, 28-32, 34, 46] and the results in this thesis, this could only be
interpreted as a massive underreporting, in line with earlier findings [33, 121, 124, 125].
Almost one third (28%) of the laboratory staff reported to have completed at least one error
report regarding VBS, a significantly higher proportion than the ward staff ($p<0.001$). This
further emphasises the underreporting among the ward staff, since laboratory VBS staff have
the lowest preanalytical error rates [26, 29, 31, 77, 134-137] and also reported better VBS
practices in this thesis. The possibility of punishment can be a major reason for not
reporting errors [157]. It is encouraging that the vast majority of the surveyed staff reported
not to be worried about possible consequences of reporting errors.

Health care staff are more likely to report witnessed errors with an immediate outcome, such
as patient fall accidents, than more distant types of errors [124]. Thus, one reason for the
low ER rates could be due to the fact that the respondents will probably not notice the
result of an error in VBS, i.e. an erroneous test result. Other reasons for the low ER rates in
the questionnaire survey could have been lack of feedback [124], the lack of a definition of
medical errors [158], or a lack of consensus of what should be reported to an ER system
[10]. Feedback and clear definitions of what should be reported and what does not have to
be reported must be supplied to the users. Altogether, the results suggest that the surveyed
ER system is likely to underreport adverse events in VBS, in line with previous research.
Pneumatic tube transport

Samples transported by PTST were compared with non-transported samples. No clinically significant differences could be seen for most haematology and coagulation parameters (Paper V, Table 1), in line with a recent report [101]. In some cases statistically significant differences were seen. However, these differences were small and clinically unimportant. Treatment with low-dose ASA did not have any clinically important effects on the results (Paper V, Table 2). The number of analyses was high, including modern parameters never reported before, such as reticulocyte parameters, platelet volume, platelet distribution width, immature platelet fraction, antithrombin and D-dimer. No report has investigated the effect of treatment with ASA before.

In contrast to a previous study of platelet function with PFA-100® [104], no significant influence of PTST could be found on CT, also in subjects treated with ASA (Paper V, Table 3). However, when comparing non-PTST and PTST samples, the distribution of CT change was large. For example, in the non-ASA group, 61% of the cases had a CEPI CT change over ±10% (Paper V, Figure 3). This distribution should be compared to the obtained and earlier reported CVs, ranging from 4 to 13% [159].

Interestingly, the variability seemed to originate from a minor portion of subjects who increased or decreased considerably in CT, when comparing non-PTST and PTST samples. This finding is in line with a recent publication, reporting a considerable variability in CT in patients treated with ASA [160]. Therefore, the detected variability in CT in the experimental study probably was not an effect of PTST, but rather a reflection of some other unknown factor.

This thesis is the first to report the preanalytical effect of PTST on global coagulation. With the thromboelastograph (Paper V, Table 4), a significant decrease of the time-to-clot formation (R) could be seen (16%, p=0.037), when comparing non-PTST and PTST samples, also in the ASA group (22%, p=0.043). The results indicate that PTST causes an in vitro activation of global coagulation by an unclear mechanism. One possible explanation could be the activation of coagulation factors, although that might have been reflected by other coagulation analyses.

Another explanation could be activation of platelets. One study reported that platelets become more procoagulant with prolonged storage time, as demonstrated by (1), a shortening of R-time measured with a thromboelastograph and (2), changes in the kinetics of thrombin generation [161]. PTST did not have any clinically significant influence on the other parameters in the thromboelastograph in the experimental study, also after treatment with ASA. This further supports the results in the experimental study that PTST did not influence platelet function analysis with PFA-100®.
One implication of the results for the thromboelastograph would concern samples collected from patients with prolonged R-time. Such samples transported by PTST could possibly be assessed as falsely normal in a thromboelastographic analysis. This would give a risk of bleeding complications caused by under-treatment with plasma or coagulation factors. Transport by PTST is easily avoided when the thromboelastograph is used as a bedside analysis, which is common in cardiac surgery [162].

Recent reports indicate that other patient categories may benefit from this analysis, e.g. sepsis [163], trauma [164] and pregnancy [165]. In Umeå University Hospital, the thromboelastograph is situated in the cardiac surgery department, approximately 500 m from intensive care and obstetrics. If the preanalytical effect of PTST were not known to clinicians, the blood samples would probably be sent to the thromboelastograph via PTST, since most of the other blood samples are transported in this way.

An obvious continuation of the experimental study would be to repeat the study including patients, preferably with haematologic or bleeding disorders. Defining patient groups and gathering enough subjects could be difficult, as previously discussed. A comparison between samples transported manually and by PTST would also be interesting. To evaluate the possible activation of coagulation factors, markers of activation such as thrombin-antithrombin complex, fibrinopeptides and other factors could be considered. To evaluate platelet activation, platelet aggregometry, flow cytometry and thrombin generation models could be used. It is also necessary to investigate the preanalytical effect of PTST on other analyses that have not yet been evaluated. Finally, it would be of value to further investigate the discrepancy between duplicates for samples analysed with PFA-100®.
IMPLICATIONS FOR QUALITY IMPROVEMENT

The reported undesirable venous blood sampling practices in this thesis imply a risk for preanalytical errors in the surveyed wards. This can have consequences for patient safety. The better practices reported by the laboratory staff are likely to be the result of quality improvement initiatives in the laboratories. The competence certificate for VBS staff, used by the surveyed laboratories, would be a suitable alternative for quality improvement of the preanalytical phase in the surveyed wards. This would result in a defined level of competence among all VBS staff. Standardisation, training and collaboration between laboratories and wards can all reduce preanalytical errors [48, 62, 166]. Perception of control and training are key factors in adherence to VBS instructions [167]. A working team, consisting of a few interested VBS staff in each ward, could therefore introduce the certificate, in collaboration with laboratory VBS staff.

All health care personnel are, according to Swedish law, responsible for performing their daily work in a correct manner. The head of each unit is responsible for maintaining proper education and routines for their staff. Organisational emphasis on quality plays a key role in quality and safety outcomes [153, 154]. Thus, the responsibility for a high quality preanalytical procedure affects all levels. A combination of a top-down and a bottom-up approach in improvement initiatives is valuable to harness insights and motivations among health care staff [168]. For the success of a quality improvement initiative, active support from top management is probably a key factor. The competence certificate would facilitate the bottom-up perspective, and would also highlight the importance of the preanalytical procedure and the staff who perform it.

Use of quality indicators, such as turnaround time, patient identification, test request errors, specimen acceptability and blood product wasting, are suggested as an important part of quality improvement of the total testing process [82, 166, 169]. Data on quality indicators should routinely be collected in the laboratory to measure the effectiveness of improvement initiatives. With this data, it will probably be easier to achieve the necessary funding and active support from top management. Estimating errors in the total testing process is a difficult task [25]. Therefore, when drawing conclusions from quality indicators, it is important to consider that the true error frequencies can be underestimated.

A proposal for how the surveyed venous blood sampling procedures might be prioritised in quality improvement strategies is presented in Table 9. Patient identification is probably the most important task in all medical procedures. Therefore, efforts to ensure compliance with standardised identification routines should be prioritised. Continuous monitoring [57-59], feedback from laboratories [62], new technology such as barcodes and radiofrequency identification [60] and improved design of wristbands [170] can all reduce patient identification errors. These measures could be considered to improve the undesirable patient identification practices identified in this thesis.
Table 9
The surveyed venous blood sampling practises, prioritised by the author after clinical importance. Examples of possible consequences and degree of seriousness are included.

<table>
<thead>
<tr>
<th>Preanalytical error</th>
<th>Possible consequence</th>
<th>Degree of seriousness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient identification</td>
<td>Sample collected from the wrong patient</td>
<td>Mild to Life threatening</td>
</tr>
<tr>
<td>2. Test tube labelling</td>
<td>Wrong patient's blood in the test tube</td>
<td>Mild to Life threatening</td>
</tr>
<tr>
<td>3. Test request management</td>
<td>Incomplete or erroneous test request</td>
<td>Mild to Severe</td>
</tr>
<tr>
<td>4. Error reporting</td>
<td>The repetition of preventable mistakes</td>
<td>Mild to Severe</td>
</tr>
<tr>
<td>5. Information search procedures</td>
<td>Venous blood sampling performed incorrectly</td>
<td>Mild to Moderate</td>
</tr>
<tr>
<td>6. Stasis removal</td>
<td>Increased or decreased concentration of analysed substances</td>
<td>Mild to Moderate</td>
</tr>
<tr>
<td>7. Patient rest</td>
<td>Increased or decreased concentration of analysed substances</td>
<td>Mild to Moderate</td>
</tr>
<tr>
<td>8. Pneumatic tube transport</td>
<td>Erroneous test results</td>
<td>None to Severe</td>
</tr>
<tr>
<td>9. Test tube inversion</td>
<td>No mixing of blood with additive</td>
<td>None to Moderate</td>
</tr>
<tr>
<td>10. Vertical test tube storage</td>
<td>Incorrect coagulation of serum samples</td>
<td>None to Mild</td>
</tr>
</tbody>
</table>

Replacement of paper-based test requests with a COES can improve quality in some areas of health care [19, 109, 132, 133]. However, the design and implementation of computerised information systems can also have adverse effects [20, 133, 171, 172], including increased mortality [173] and increased number of frequently occurring risks [174]. Still, the implementation of COES is an emergent issue, since it eliminates many of the error-prone test request practices discovered in this thesis. Proper design and continuous monitoring of error rates is likely to be crucial for the success of such a system.

Standardisation of preanalytical procedures can improve quality in the total testing process [48, 69, 175-177]. Since only two out of the 25 wards had documented VBS routines, the introduction of such routines, for VBS procedures not included in the laboratory manual, would probably be of value. This is most important for the manual tasks that are not easily covered by technological solutions such as a COES. All sources of preanalytical information should also be harmonised to avoid contradictory information.

Accreditation is used by the surveyed laboratories and seems like a logical way to reduce errors. However, the effect of lowering error rates has not been clearly established, which may be due to the lack of studies. Some degree of variance in the performance of a task can be desirable, since this can compensate for complex environments and variations in conditions [178]. It is also in the human nature to adapt to working conditions that save time [178]. Furthermore, quality improvement in health care is an evolutionary process involving continuous adaptation to organisational factors [179]. Thus, quality assurance and strict routines would probably be suitable, but not the only solution, for a successful quality improvement for venous blood sampling.
Error reporting can be of value to collect reliable information on errors in health care [118, 119] and to decrease errors in the total testing process [46]. Constructive changes in practice can be achieved by discussing and taking responsibility for mistakes [180]. Thus, error reporting can play an important role when new routines for improved patient safety are developed. Interventions can improve error reporting [181, 182]. Since the results in this thesis indicate low use of the current error reporting system, an intervention aimed at increasing the reporting of errors would probably be of value.

Pneumatic tube transport is a safe means of transporting samples for haematology and coagulation analysis. However, for analysis with thromboelastographic techniques, manual transport should be used. Otherwise, the patient’s global coagulation may be overestimated, resulting in a risk of bleeding complications.

The apparent lack of quality improvement initiatives in the preanalytical phase in the wards could be related to the low priority of sample collection, a task mainly performed by enrolled nurses. By tradition, this is a low-status, mainly female profession. The considerable interest among the surveyed staff to participate in developing preanalytical practices should be considered a valuable resource. Top management must define quality as a priority for the organisation and must recognise the importance of the preanalytical phase in sample analysis, e.g. by supplying sufficient resources for quality improvement initiatives.

The major implication of this thesis is an increased recognition of the importance of quality improvement throughout the total testing process. All hospitals are recommended to review their preanalytical procedures, particularly manual tasks not easily replaced by technology. In summary, based on the results of this thesis and current research, the following suggestions can be made for quality improvement of the total testing process:

- A competence certificate for all ward staff performing sample collection
- Education of venous blood sampling instructors in each ward
- Cooperation with laboratory staff
- Focus on patient identification and test tube labelling
- Registration of key indicators of preanalytical error
- Introduction of a computerised order entry system
- Documented general routines for venous blood sampling in each ward
- Efforts to increase the use of the current error reporting system
- Defining quality as a top goal for the organisation
FUTURE RESEARCH

Evidence-based practice can be viewed as the combination of the best available research evidence, the clinical experience of the staff, sufficient resources (for example financial or staff training) and the expectations and needs of the patient [183]. As previously discussed, the surveyed staff members are likely to be clinically skilled, but sufficient resources for development of the preanalytical procedure are apparently not supplied. The needs and expectations of the patient are probably a safe and accurate preanalytical procedure. Quality improvement initiatives in the preanalytical phase are largely unexplored, particularly with respect to venous blood sampling practices. Therefore, scientific evidence for the recommendations in the previous chapter must be established in future studies.

An intervention study aimed at improving quality of venous blood sampling practices and reporting of errors is the most important continuation of this thesis. Data could be collected before and after the implementation of a competence certificate, standardised routines and a computerised order entry system. That would provide the necessary evidence to improve quality in an evidence-based manner. Suitable outcome measures could be:

- Financial savings
- Improved patient or staff satisfaction
- Patient outcomes, such as reduced mortality or morbidity
- Improved venous blood sampling and error reporting practices
- Reduction in key indicators of preanalytical error, such as turn-around times, specimen acceptability, haemolysis, renewed sampling or identification errors

The questionnaire developed in this thesis could be a valuable tool to measure improved venous blood sampling and error reporting practices. Prior to use, the questionnaire could be further validated, e.g. by comparing questionnaire responses with reliable data on detected preanalytical errors. The stability of the questionnaire could be assessed before it is used to evaluate an intervention.

Practical experiments that demonstrate the preanalytical effect of different procedures for test tube handling (storage, inversion, sequence during sample collection) and the preanalytical effect of venous blood sampling from peripheral catheters (mainly haemolysis) could be valuable to develop the laboratory manual. The correctness of identification wristbands, haemolysis rates and the time available for each patient in different departments could also be studied. The effect of prolonged turn-around time on patient care could also be evaluated.

The general importance of blood test results for medical decisions at admittance or discharge of patients would also be interesting to study. Since venous blood sampling practices are largely unexplored, a qualitative study could be valuable to provide a deeper understanding that cannot be obtained by a quantitative study. In summary, further studies of the preanalytical phase are clearly needed, both nationally and internationally.
CONCLUSIONS

This thesis is the first to survey venous blood sampling practices in hospital wards, and the first to compare these practices with those in hospital laboratories.

In the surveyed hospital wards, the desirable procedure for venous blood sampling were not always followed for patient identification, test tube labelling, test request management, patient rest, stasis removal, the handling of test tubes after collection and information search procedures.

Venous blood sampling re-education, documented unit-specific routines, type of ward and frequency of sampling were not clearly associated with desirable venous blood sampling practices.

The surveyed venous blood sampling staff in the wards demonstrated a considerable interest in re-education and increased responsibility for routines.

The laboratory staff reported significantly better venous blood sampling practices than the ward staff in line with previous studies.

Error reporting in venous blood sampling was almost nonexistent in the wards, but more common in the laboratories.

Pneumatic tube transport does not introduce preanalytical errors when transporting samples analysed for haematology, coagulation and platelet function parameters, with the exception of global coagulation, where an in vitro activation could be seen.
EPILOGUE

What have I learnt during the course of this project? Firstly, I have become more convinced that the health care system has potential for quality improvement. The health care staff wants to provide the best possible care for the patient, but this is at times challenging under the current organisational structure. Secondly, I hope that everyone in a position to implement change will be encouraged to harness the potential of the staff, more than what typically has been the case. The approach has to be both top-down and bottom-up. The positive response to this project has inspired me to continue in the field of patient safety and quality improvement in the organisational level of health care. Finally, there are no shortcuts to quality. The work is continuous. And fun!
POPULÄRVETENSKAPLIG SAMMANFATTNING

Ett blodprov utgörs av en kedja av händelser som börjar med att en analys beställs och slutar med att ett analyssvar tolkas. Forskning visar att de flesta felen i denna process uppstår innan provet har anlänt till laboratoriet. Dessa felfel uppkommer ofta vid den manuella hanteringen som inte går att ersätta med tekniska lösningar.

Vanliga fel är misstag vid patientidentifiering, provrörsföring och remissionering, samt fel vid provtagning och provhantering. Trots relativt stor kunskap om att dessa fel påverkar patientsäkerheten har inga studier gjorts som undersöker hur den praktiska provtagningen och provhanteringen utförs på vårdavdelningar.

Kliniska laboratorier har under lång tid arbetat med att förbättra säkerheten vid analys och provtagning på laboratoriet. Samtidigt är det mer ovanligt med försök att förbättra säkerheten vid provtagning utanför laboratoriet, exempelvis på vårdavdelningar. Studier visar att provtagning på laboratorier ger upphov till färre fel jämfört med provtagning på vårdavdelningar. Dessa fynd tyder på att förbättringsarbetet på laboratorierna varit framgångsrikt.

I denna avhandling har en stor enkätundersökning utförts på alla vårdavdelningar vid två sjukhus och på två kliniska sjukhuslaboratorier. Undersökningen är den första i sitt slag. Enkätten innehåller frågor om praktisk provtagning och provhantering av venös blodprover, som är den vanligaste typen av blodprov på sjukhus.


En väldigt liten del av personalen hade fått vidareutbildning i provtagning. En stor andel ville ha vidareutbildning och ville också ta ett ökat ansvar för att förbättra provtagningen. Provtagningspersonalen, som nästintill uteslutande var kvinnor, ansåg också att provtagning inte var en prioriterad uppgift på avdelningarna.


Ett kompetensbevis för all provtagningspersonal kan vara ett sätt att förbättra kvaliteten vid blodprovstagning på de undersökta avdelningarna. Kompetensbeviset bör kombineras med datoriserad remisshantering, mätning av antalet fel på laboratoriet och en ökad rapportering av fel och missstag. Eftersom informationen om en korrekt provtagningsprocedure skiljer sig något åt mellan olika informationskällor bör dessa anpassas där det är möjligt.

Det är viktigt att ledningen för sjukvården gör det tydligt att god kvalitet alltid ska prioriteras i det dagliga arbetet och att blodprovstagnings en betydelsefull uppgift, exempelvis genom att tillföra tillräckliga resurser för ett förbättringsarbete. Sammantaget rekommenderas alla sjukhus att undersöka den egna provtagningen och provhanteringen, framför allt avseende manuella moment som inte enkelt kan ersättas med tekniska lösningar.
ACKNOWLEDGEMENTS

Jag vill passa på och tacka alla som direkt och indirekt bidragit till denna avhandling:

All provtagande personal som delat med sig av sin tid och sitt dagliga arbete. Ni har givit ett ovärderligt bidrag.

Alla avdelningschefer och övriga på sjukhus och laboratorier som hjälpt till.

Forskningspersonerna i rörpoststudien, för ert bidrag till studien.

Christine Brulin, för att du utan att tveka accepterade uppdraget som min huvudhandledare. Jag har lärt mig mycket av ditt pedagogiska sätt och din syn på forskning och sjukvård. Du har en enastående energi och har alltid tid, fast du kanske inte har det egentligen.


Bethany van Guelpen, för teaching me the noble art of scientific writing, including the heart-rending task of deleting “the darlings” in a manuscript. You have truly improved the presentation, structure and conclusions in my papers (feeling a bit shaky writing this without your support).

Johan Hultdin, för grymma men bra kommentarer. Och för inspiration till att dyka ner i ett forskningsproblem. Det är bara att gräva där man står!

Johan Söderberg, för allt slut med datainsamlingen, alla presentationer och allt manuakrivande. Och alla sista-minuten granskningar, det är inte ditt fel om det blir några errata! Och för fem långa år på läkarprogrammet. Man kan alltid lita på dig, i alla fall om du har snusdosan i fickan…

Andreas Jonsson, för snabba och smarta kommentarer på studieupplägg och manus. Ditt skarpa sinne är inspirerade. Nu behöver jag renoveringstips istället…


Johan Thor, för inspiration till framtida kvalitetsarbete och för medförfattarskap. Det finns mycket värdefull information och insikt i din avhandling.

Inger Rautio, för noggranna kontroller av viktiga data. Tack för all hjälp!

Camilla Selénius, Ulla Boström och Lars-Gunnar Gunnarsson, för noggrann exparthjälp med rörpoststudien.

Birgitta Berglund, Terry Persson och Åsa Lundsten för ovärderlig hjälp. Utan er skulle det inte bli så mycket forskat på institutionen.
Birgitta Nilsson, Susanna Hermansson och Ann-Britt Lindström för att ni har ställt uppmärksamheten på granskningar.

Undersköterskorna vid Bemanningsbyrån på NUS, för att ni fikostigt delade med er av erfarenhet.

Urban Edström, Markus Lindkvist, Ronnie Lundström och de andra vid MTI för givande samarbete och en snygg figur till kappan.


Medicinska fakulteten vid Umeå universitet och Socialstyrelsen för ekonomiska bidrag.

Pia Hedberg, Lenita Lindgren, Rose-Marie Isaksson, Carin Franzen, Susann Backteman, Kristina Lemås och Susanne Rundgren för värdefulla kommentarer vid rundabordsmötet.

Henrik Wretling och Pawel Grabowski för att ni ställde upp under några viktiga veckor.

Daniel Furudahl, någon gång blir det Kjerag. Vi börjar med Nissedal till sommaren.

Ulrik Carlsson, det kanske dröjer tills det blir någon Camaro, men jag kommer gärna förbi och svarar lite till dess…

Johan Gille, nu ska jag komma i kapp på kilklättringen. Men bouldring är inte så dumt…

Kerstin och Göran Norin, mina kära svärföräldrar. Jag känner mig alltid välkommen hos er!


Och sist men viktigast, min kära Cissi, som jag får dela mitt liv med. Tack för allt! Nu börjar sommaren!
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