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# Exploring the extent of post-analytical errors, with a focus on transcription errors – an intervention within the VIPVIZA study

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## Abstract

**Objectives:** We examined the magnitude of transcription errors in lipid variables in the VIPVIZA study and assessed whether education among the research personnel reduced the error frequency at follow-up. We also examined how the errors affected the SCORE2 risk prediction algorithm for cardiovascular disease, which includes lipid parameters, as this could lead to an incorrect treatment decision.

**Methods:** The VIPVIZA study includes assessment of lipid parameters, where results for total cholesterol, triglycerides, HDL cholesterol, and calculated LDL cholesterol are transcribed into the research database by research nurses. Transcription errors were identified by recalculating LDL cholesterol, and a difference >0.15 indicated a transcription error in any of the four lipid parameters. To assess the presence of risk category misclassification, we compared the individual's SCORE2 risk category based on incorrect lipid levels to the SCORE2 categories based on the correct lipid levels.

**Results:** The transcription error frequency was 0.55 % in the 2019 VIPVIZA research database and halved after the educational intervention to 0.25 % in 2023. Of the 39 individuals who had a transcription error in total or HDL

cholesterol (with the possibility of affecting the SCORE2 risk category based on non-HDL cholesterol), six individuals (15 %) received an incorrect risk category due to the error.

**Conclusions:** Transcription errors persist despite digitalisation improvements. It is essential to minimise transcriptions in fields outside the laboratory environment, as we observed that critical decisions also rely on accurate information such as the SCORE2-risk algorithm, which is dependent on lab results but not necessarily reported by the laboratory.

**Keywords:** clerical error; laboratory quality assurance; lipid parameters; post-analytical error; SCORE2; transcription error

## Introduction

Quality in laboratory medicine has previously been defined as “an unfinished journey”, and it is still a vital quest to continue the journey, as laboratory information is of increasing value for physicians for making appropriate clinical decisions [1]. High-quality laboratory information is also essential for patient safety, as it has been shown that 19 % of laboratory errors lead to further inappropriate investigation, and 6.4 % of laboratory errors were associated with improper care [2].

Laboratory errors were previously synonymous with the test's analytical performance. However, at present, the concept of laboratory errors has, hand in hand with technological developments and increased awareness, developed into a different meaning. It is now evident that the total testing process (TTP) should be considered to enhance the quality of laboratory information [3]. The TTP can be divided into three phases: pre-analytical, analytical, and post-analytical. It is estimated that the error frequency in the pre-analytical phase ranges from 46 to 68.2 %, 7–13.3 % in the analytical phase, and 18.5–47 % in the post-analytical phase [4, 5]. Thus, the pre- and post-analytical phases are more error-prone [6].

The pre-analytical phase and its errors correspond to all steps, from preparing the patient to collecting and

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transporting the sample to and within the laboratory. This has previously been described in detail [7]. Analytical errors originate from within the laboratory. Over the last decades, extensive work with quality assurance and within the laboratory has already been done. Therefore, there has been an impressive reduction in analytical errors [8]. This has been thanks to the widespread use of internal and external controls and the formation of laboratory networks such as the Cholesterol Reference Method Laboratory Network (CRMLN) to develop standardisation protocols to ensure the accuracy of the analytical methods [9]. Additionally, the implementation of laboratory accreditation has further improved the development of the quality assurance journey [10]. Post-analytical errors include, for example, incorrect transcriptions, reporting and interpretation of lab results. The literature is sparse in general for the extra-analytical phases, but for the post-analytical phase, the literature is exceptionally scarce since it is difficult to establish their frequency [11]. However, the post-analytical phase is increasingly recognised as an essential step in maximising the quality of laboratory information [12].

The extent of errors in the post-analytical phase varies since the reported error frequencies depend on the method used to detect them. Even though there have been improvements in recent years, e.g. by requirements for post-analytical processes according to the ISO15189 standard [13], there are not yet any widely accepted standardised methods to detect the errors in the extra-analytical phases available, leading to different methods for estimating error frequency in different studies [14–17]. This further contributes to the uncertainty of the true error frequency, especially for minor errors [18].

Whilst transcription errors have been reduced due to digitalisation in laboratory medicine, they have not been eliminated, and there are no automated methods to detect them. Additionally, many transcriptions are still performed in other areas of clinical practice, e.g. when using different risk prediction algorithms. SCORE2 is a risk prediction algorithm for cardiovascular disease (CVD) prevention. It is based on traditional CVD risk factors such as age, smoking status, systolic blood pressure, and non-HDL cholesterol [19]. Depending on the level of risk factors, the patient will be assigned to a risk category (low-moderate, high or very high). In clinical practice, the physician often transcribes the lab results and risk factors on a website to calculate the risk category and recommend a suitable preventive intervention to the patient.

Hence, we aimed to investigate the post-analytical error frequency in the VIPVIZA trial, focusing on transcription errors in lipid parameters at two different time points. We also aimed to examine how the errors affected the SCORE2

risk prediction algorithm for cardiovascular disease, which includes non-HDL cholesterol, as this could lead to an incorrect treatment decision. Additionally, we wanted to determine whether education among the research personnel between the time points decreased the extent of errors.

## Materials and methods

### Study population

To assess transcription errors, we used data from the VIPVIZA study (VIzualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program), ClinicalTrials.gov NCT01849575. The VIPVIZA study involves transcribing laboratory results into the research database and has previously been described in detail with available study protocols [20]. In summary, the study aims to improve cardiovascular disease prevention, including longitudinal risk factor screening, such as measuring plasma lipid levels assessed as total cholesterol (TC), HDL cholesterol (HDL-C), LDL cholesterol (LDL-C), and triglycerides (TG) at several time points.

The lipid parameters were analysed using standard clinical practice methods at the Department of Laboratory Medicine, Clinical Chemistry, University Hospital Umeå, accredited to ISO 15189:2012 and Swedac accreditation no. 1397. TC, HDL-C and TG were analysed with enzymatic colourimetric methods. LDL-C was calculated according to the Friedewald formula [21]. The research nurses then transcribed the results into the VIPVIZA database. This was studied within the VIPVIZA study at the 3rd and 6th year follow-up.

The study was approved by the Swedish Ethical Review Authority, DNR 2011-445-31 M (2019-04691). The study adhered to the ethical guidelines of the Declaration of Helsinki, which included obtaining informed written consent from the participants before inclusion.

### Identification of transcription errors and affected covariates

To identify the transcription errors, LDL-C levels were recalculated according to the same Friedewalds formula as the laboratory ( $LDL-C = TC - HDL-C - (0.45 \times TG)$ ), and the difference between our newly calculated LDL-C and the reported LDL-C in the research database was evaluated. A difference  $>0.15$  was used as a cut-off value and indicated the presence of a transcription error in any of the four lipid parameters.

The cut-off value of 0.15 was chosen as differences  $<0.15$  were caused by the number of decimals used, as the laboratory system uses two decimals for calculations, but reports test results for these analytes with one decimal. Consequently, differences between 0 and 0.15 corresponded to differences caused by rounded numbers. To establish that no transcription errors were missed with this cut-off level, all LDL-C differences between 0.12 and 0.15 were also assessed, and the cut-off value of 0.12 identified no further presence of errors.

To identify which of the four lipid parameters were erroneously transcribed, all lipid parameters for the individual with an identified cut-off value  $>0.15$  were validated in the laboratory database, and the transcription errors were corrected. This made it possible to find transcription errors in all four lipid parameters (TC, HDL-C, LDL-C, and TG), including minor errors that are otherwise impossible to identify by using methods based on searching for improbable results.

To assess how the transcription errors in lipid parameters affected the individual's SCORE2 risk category, the number of individuals assigned the wrong risk category, i.e. risk category misclassification, was identified. Category misclassification was determined by evaluating individuals with a transcription error in total or HDL cholesterol, as non-HDL cholesterol (=total – HDL cholesterol) is included in SCORE2. The individuals with identified transcription errors were first risk assessed according to the SCORE2 algorithm using the incorrect lipid parameters (present in the research database from the start), and later risk assessed with the correct lipid variables. Thereafter, the two risk categories for the same individual were compared, establishing how many of the individuals would have been misclassified if the transcription errors in lipid parameters had not been discovered.

## Intervention among the research personnel

The lipid variables were corrected for the first time after completing the VIPVIZA baseline survey in 2016 as part of the quality assurance of the variables in the research database. The quality work was continued after the third-year follow-up of the VIPVIZA study (2019) and after the 6th year follow-up (2023). The results from the quality assurance in 2019 were also announced to the VIPVIZA personnel during multiple conferences as part of the quality work, i.e., an educational intervention was conducted. The assessment of the quality of the lipid variables in the database was then repeated in 2023 at the sixth-year follow-up in VIPVIZA.

## Results

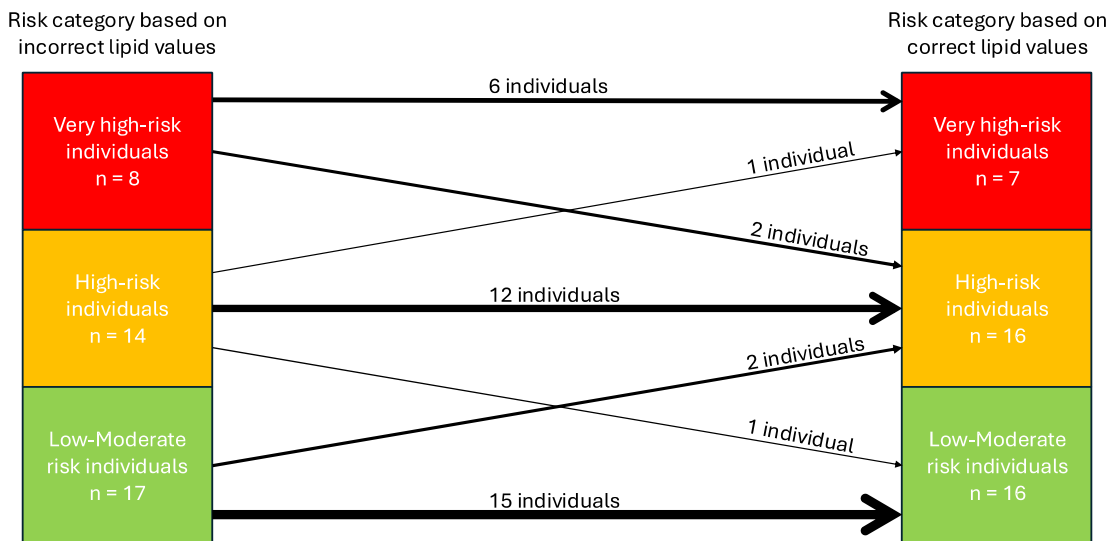
The number of transcription errors identified in VIPVIZA 2019 and VIPVIZA 2023 study can be seen in Table 1. As four lipid parameters were assessed (TC, LDL-C, HDL-C, and TG) for every individual, there were 12,460 transcriptions in VIPVIZA 2019 and 10,576 in VIPVIZA 2023. Some individuals had more than one error in the lipid parameters. Consequently, in VIPVIZA 2019, there were 69 transcription errors, affecting 56 individuals. This error frequency corresponds to 1.80 %, and when converted into parts per million (ppm) to 18,000. In 2023, the corresponding number of transcription errors was 26, and the number of individuals with errors was 25, corresponding to 0.95 % (9,500 ppm). The frequency of errors approximately halved from 0.55 % (5,500 ppm) in 2019 to 0.25 % (2,500 ppm) in 2023.

The number of individuals that were misclassified according to the SCORE2 risk prediction algorithm are visualised in Figure 1 for VIPVIZA 2019. As non-HDL cholesterol is the sole lipid parameter included in SCORE2, individuals with transcription errors in total and/or HDL cholesterol were the only ones affected, corresponding to 39 individuals. In total, we identified six individuals that would have been risk misclassified, i.e. 15 % of the transcription errors resulted in risk misclassification. Of these six individuals, three were assigned a lower risk category after correction, and three were assigned a higher risk category. The distribution of individuals in different risk categories can be further seen in Figure 1. In the 2023 VIPVIZA survey, none of the individuals had a transcription error in total or HDL cholesterol. Consequently, no risk misclassifications were identified at this time point.

**Table 1:** The extent of transcription errors in lipid parameters in the VIPVIZA study at two different time points, with an educational intervention in between.

	VIPVIZA 2019	VIPVIZA 2023
Total individuals, n	3,115	2,644
Individuals with an error in any of the lipid parameters, n	56	25
Frequency of individuals with transcription errors, %, ppm <sup>a</sup>	1.80 (18,000)	0.95 (9,500)
Total transcriptions, n	12,460	10,576
Total transcription errors, n	69	26
Frequency of transcription errors, % (ppm) <sup>a</sup>	0.55 (5,500)	0.25 (2,500)

<sup>a</sup>Parts per million.



**Figure 1:** The extent of transcription errors leading to risk reclassification based on the SCORE2 category in VIPVIZA 2019.

## Discussion

We found that the frequency of transcription errors was 0.55 % (5,500 when converted to ppm) in the 2019 VIPVIZA research database, with 1.80 % (18,000 ppm) of individuals having one or more errors. The extent of these errors halved after the educational intervention, resulting in a transcription error frequency of 0.25 % (2,500 ppm) and 0.95 % (9,500 ppm) of individuals in 2023. Thus, it was observed that this type of intervention was effective in a controlled environment, such as among research personnel. We also discovered that the transcription errors led to SCORE2 risk misclassification in 15 % of cases, potentially resulting in patients receiving an incorrect risk assessment or physicians making incorrect treatment decisions.

This study is an example of a simple, applicable method for data quality assurance in research databases, which is an essential aspect of publishing high-quality research with generalisability. To our knowledge, this error identification method of lipid parameters has not been previously published. A strength is that the method is easily reproduced and identifies post-analytical errors of a smaller magnitude. Errors of smaller magnitude have been a challenge to identify in the research field, but also a well-known problem in the extra-analytical phase within the laboratory community, concluding that the actual error frequency is under-detected [4, 18, 22]. For instance, a previous study found that the true incidence of errors was at least four times the actual events detected [18].

The true error frequency is highly dependent on the method for error detection, and currently, no uniform

method for managing errors exists for the post-analytical phase. For example, the error frequency previously reported was based on the clinicians being asked to pay extra attention to suspected laboratory errors and discuss them with a laboratory physician daily [2, 15]. Other described methods are that the laboratory personnel double-check the results [16] or identify an edit in the computerised system [17]. Additionally, many previous studies reporting post-analytical error frequencies are old since laboratories report digitalised results and are currently not dependent on transcription. This makes it a challenge to find studies with updated frequencies of the true error frequency that represents the current situation, where most transcription occur outside the laboratory environment, e.g. in point-of-care-systems. The reported error frequency in the post-analytical phase has been estimated to be 18.5–47 % and thus varies greatly depending on the method [4]. Of the studies that have explicitly reported transcription errors, the error frequency is estimated to be 11.7 % in one study [16] and 1.1 % in a study from a transfusion laboratory [17]. However, many studies on post-analytical errors have not assessed transcription errors explicitly and, therefore, not reported the extent. Similar studies in fields other than the laboratory community have, however, assessed transcription errors, such as when administering pharmaceuticals. The reported transcription error frequency in a study assessing medical errors in cancer patients was estimated to be 11.54 % [23] and 2.21–8.11 % in an intensive care unit with transcriptions of blood glucose levels [24]. Thus, the errors are considerably more common in clinical practice compared to our study, estimated to be 0.25–0.55 %.

In our case, the extent of errors was assessed as part of a pragmatic trial, and it is not unreasonable to hypothesise that the error frequency is higher in clinical practice because of the high number of staff involved, the need to cut expenses, and work under stress, compared to the research environment. However, our reported error frequency is quite similar in magnitude to the one reported in a transfusion laboratory, which also reported a reduction of errors after educational intervention among the personnel, consistent with our results [17]. This may indicate that the laboratory community's extensive quality journey has increased the awareness of potential sources of errors and, therefore, reduced their error frequencies compared to other medical fields. Still, many transcriptions are conducted in clinical practice daily, such as entering laboratory results into risk motors or results from point-of-care systems.

Despite our relatively small error frequency, we still estimated that 15 % of the individuals with an error in total and/or HDL cholesterol would have been risk misclassified according to SCORE2. If the same magnitude of transcription errors are assumed to be present in clinical practice, this would lead to several patients receiving incorrect pharmacological treatment and risk assessments. Moreover, transcribing all laboratory variables and other risk factors into a risk motor is common, further yielding a potential for more transcription errors than indicated by this study. In addition, we also noticed that in the VIPVIZA 2019, there were eight transcription errors in LDL-C, and three of these participants would have missed out on receiving lipid-lowering therapy according to CVD prevention guidelines because the transcription error presented a falsely low LDL-C value. Thus, the post-analytical quality of laboratory results is an essential aspect of patient safety.

Regarding the SCORE2 risk misclassification, there are some crucial aspects to consider associated with the known limitations of the risk algorithm [25]. Because the risk algorithm assesses the absolute risk for a cardiovascular event in the next 10 years, younger individuals with a high burden of risk factors will still be assessed as low risk, as long as the risk factor burden is not extreme, i.e. an underestimation of the actual CVD risk is common in young individuals. In this study, this means that participants could have a significant transcription error in lipid variables (>1 mmol/L). However, despite this, the participant is still not classified into a higher or lower risk category if the other risk factors are normal, and the individual is young. Nevertheless, the transcription error could have been clinically relevant in other aspects.

There are some limitations to this study. For example, there is still a possibility that our method for error identification does not identify particularly small errors < 0.1 mmol/L;

consequently, there is a chance that the true error frequency is, in fact, higher than reported in this study. However, these minor errors correspond to a magnitude similar to the analytical uncertainty and would not affect the clinical assessment. There is also the possibility that minor errors are present in other variables in our research database, as these (e.g. blood pressure) are also transcribed by the research nurses, but we had no standardised method to detect them. Consequently, we did not account for the fact that other risk factors included in the SCORE2 algorithm (blood pressure or smoking status) probably have transcription errors, leading to an underestimation of the risk misclassification frequency reported in this study. Additionally, as this study only assessed the error frequency within the research database, it was not possible to assess whether the errors led to actual clinical events, i.e. if the participants received incorrect treatment or not, as previously presented in other studies investigating the consequences of laboratory errors [1].

Nevertheless, this study sheds light on the importance of evaluating the quality of laboratory information in research databases and adds further updated information regarding the true frequency of transcription errors. Additionally, we illustrate the potentially harmful effects of entering incorrect lipid values into a risk motor such as SCORE2. The reported error frequency might be modest, but we still highlight the detrimental effects of transcription errors that might lead to incorrect risk assessments and treatment decisions in individual cases, especially as we hypothesise that the error frequency is higher in clinical practice. We therefore emphasise the further need for digitalisation to assure patient safety.

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**Research ethics:** The study was approved by the Swedish Ethical Review Authority, DNR 2011-445-31 M (2019-04691). The study adhered to the ethical guidelines of the Declaration of Helsinki.

**Informed consent:** Informed consent was obtained from all individuals included in this study.

**Author contributions:** M.M. and J.H. contributed to the conceptualisation of the work. U.N. contributed through the acquisition of data from VIPVIZA. M.M., U.N. and J.H. validated the data in the research database. M.M. and J.H. were the main contributors to drafting the manuscript. M.M., K.E., K.S., A.S., U.N., and J.H. contributed to the study design,

critically reviewed the manuscript, interpreted the data, and provided important intellectual content. All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

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**Data availability:** The data that support the findings of this study are available on reasonable request from the corresponding author, [M.M.]. The data are not publicly available due to ethical restrictions.

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