International Journal of Medical Science and Clinical Inventions 4(6): 3034-3036, 2017
DOI:10.18535/ijmsci/v4i6.14 **ICV 2015: 52.82**
e-ISSN:2348-991X, p-ISSN: 2454-9576

Research Article

The impact of preanalytical variable like delay in sample transportation and post analytical variable like deep freezer temperature on combined Measurement Uncertainty.

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Abstract:
Measurement uncertainties in patient's clinical chemistry parameters include variation in both preanalytical and analytical phases, as well as intra-individual biological variations are also observed. All laboratories have to develop tools to identify the sources of uncertainties in all phases in laboratory testing and thereby reduce uncertainty. Focusing on combined uncertainty and reducing them can improve quality of laboratory testing. In our laboratory we took one factor (i.e., Sample transportation time) in preanalytical phase & one factor (i.e., Retained sample storage temperature) in post analytical phase to begin with for measuring uncertainties in these phases. We also tried to study the impact of these uncertainties on few analytes measurements. Parameters like calcium and AST were found to be highly sensitive to the delays in sample transportation indication error in reporting of these parameters on transportation delay. Parameters like chloride and urea were found to be highly sensitive to the retesting indication no retesting or delayed testing of such parameters should not be entertained.

INTRODUCTION

The phases in the clinical laboratories testing involve pre analytical, analytical and post analytical phases. Measurement uncertainties in patient's clinical chemistry parameters include variation in both preanalytical and analytical phases, as well as intra-individual biological variations are also observed. Preanalytical variables including sample collection, sample handling, sample transport, and its storage influence patient results before it is measured. Previous studies indicate use of standardized procedures minimize preanalytical variations thereby it decreases the numbers of errors in this phase. Routinely improvement of quality assurance in clinical chemistry laboratories focus on uncertainties in analytical processes, but due consideration is not given to the uncertainties in whole process from phlebotomy to reporting of results. All laboratories have to develop tools to identify the sources of uncertainties in all phases in laboratory testing and thereby reduce uncertainty. Focusing on combined uncertainty and reducing them can improve quality of laboratory testing. Previous studies suggest combined uncertainty is a function of magnitude and probability distribution of all the uncertainty sources. Combined uncertainty sources can be assessed and the data collected can be used for reduction of total uncertainty thus improving quality of laboratory testing.(Marit Rynning et,al).

The goal in laboratory testing is always focused to minimize all the errors in the laboratory to deliver accurate and precise values to the clinician to help them efficiently diagnose and treat the patients.

In our laboratory we took one factor (i.e., Sample transportation time) in preanalytical phase & one factor (i.e., Retained sample storage temperature) in post analytical phase to begin with for measuring uncertainties in these phases. We also tried to study the impact of these uncertainties on few analytes measurement.

Objectives of the study were to determine the uncertainty in the pre analytical variable like sample transportation time & its impact on the measurement of certain routinely tested analytes and to determine the uncertainty in the post analytical variable like retained sample storage temperature & its impact on the measurement of certain routinely tested analytes (For retesting & add on test requests).

Materials & Methods

I. Method of collection of data & Statistical analysis:

Uncertainty of Sample Transportation time:

According to our documented procedure the samples has to be transported from the sample collection centre every 10 minutes & the overall (Turn-Around-Time) TAT is also fixed after considering this transportation time. But in practice it is very difficult to follow this procedure due to various reasons like insufficient staff etc & also the time set is too short to be practical. Hence we decided to look for the Uncertainty of Sample Transportation time

for both outpatient samples & Inpatients samples & the impact of the same on the few chosen biochemical tests.

- The study on Uncertainty of Sample Transportation time has been conducted in the month of May 2017.
- Twenty randomly selected samples of outpatients & twenty randomly selected samples of inpatients were assessed for the sample transportation time every day for twenty days.
- The Mean sample transportation time for both OP & IP patient samples was calculated for each day.
- Twenty days data were analyzed to calculate the Mean, Standard deviation & % CV of the sample transportation time for both OP & IP patient samples.
- The Uncertainty were calculated using the formula MU = % CV x 1.96

Then the impact of this uncertainty on the estimation of few chosen analytes was evaluated.

Impact Analysis of the Sample transportation delay on the few chosen biochemical tests:

To carry out this study we collected two set of samples from each twenty patients. The first set of samples were immediately transported & processed for estimating Creatinine, AST, Potassium, Calcium, Glucose (after following the routine protocol for clotting & centrifugation) . Then the second set of samples was processed after one and half hour (45 min Transportation delay + 45 min for clotting & centrifugation – as the routine protocol in the laboratory is to keep the sample for clotting & centrifugation for 10 mins.) Processing of samples were done using Vidas autoanalyzer and Vitros 250/ vitros 5.1 auto analyzer**.** Paired T-test was used for statistical analysis of this data.

2. Uncertainty of Retained sample storage temperature: twenty days data of deep freezer temperature record, in which samples are stored for 48 hrs as per the sample retention policy of the lab was analyzed.

Impact analysis of the uncertainty in the temperature recorded for the retained sample storage refrigerator on the measurement of few routinely retested & add on test analytes.

Twenty random samples which are stored for 48 hours in that refrigerator were retested to look for any significant difference in the values of few chosen tests. Paired T-test will be used for statistical analysis.

Result:

1. Uncertainty of Sample Transportation time for Inpatient samples:

Mean	42.965 min
SD	12.39 min
%CV	28.84%
MU	56.52%

2. Uncertainty of Sample Transportation time for outpatient samples:

Mean	22.91 min
SD	4.20 min
%CV	18.32%
MU	35.91%

Uncertainty was too high for both inpatient & outpatient samples & the mean transportation time for both the groups were 42.9 minutes (IP samples) & 22.9 (OP samples). Hence we decided to study the impact of this uncertainty on the estimation of few chosen analytes.

Impact Analysis of the Sample transportation delay on the few chosen biochemical tests:

To carry out this study we collected two sets of samples from each twenty patients after taking their consent. The first set of samples were immediately transported & processed (after following the routine protocol for clotting & centrifugation. Then the second set of samples were processed after one and half hour (45 min Transportation delay + 45 min for clotting & centrifugation – as the routine protocol in the laboratory is to keep the sample for half an hour for clotting & centrifugation for 10 mins.)

Paired T-test was used for statistical analysis.

Result:

Sl. No	Parameters	p value
1	Creatinine	0.748
2	AST	0.012*
3	Potassium	0.794
4	Calcium	0*
5	Glucose	0.61

p value < 0.05 is considered as significant

* represents parameters which show significance

There was a significant difference in the values estimated for calcium & AST between the first & second set of samples. Other analytes were not significantly affected.

Hence the decision was taken to increase the sample transportation time to maximum of 45 minutes & at the same time the technical staffs were advised to take care of the samples with test request for the analytes like calcium, AST etc whose values may be influenced by the long term contact with the RBCs to be transported as early as possible & immediately processed for initial processing based on sample collection time.

II : MU – Post analytical Phase

3. **Uncertainty of Retained sample storage temperature:**

This was calculated using the twenty days data of deep freezer temperature record, in which samples are stored for 48 hrs as per the sample retention policy of the lab.

Mean	-15.61 ^{o} C
SD	2.37 ^{o} C
%CV	15.16%
MU	29.71%

4. **Impact analysis of the uncertainty in the temperature recorded for the retained sample storage refrigerator.**

Twenty random samples which were stored for 48 hours in that refrigerator were retested to look for any significant difference in the values of few chosen tests. Paired T-test was used for statistical analysis.

Result:

Sl No.	Parameters	p value
1	TSH	0.15
2	Chloride	0*
3	Glucose	0.707
4	Urea	0.028*

p value < 0.05 is considered as significant

* represents parameters which show significance

Chloride & Urea (Urea - mainly for one extremely different value – which squid the data) showed significant difference in the values.

Discussion:

The parameters for determining combined measurement uncertainty for both pre and post analytical phases were selected based on uncertainty observed during routine clinical chemistry testing. Parameters like calcium and AST were found to be highly sensitive to the delays in sample transportation indication error in reporting of these parameters. Parameters like chloride and urea were found to be highly sensitive to the retesting indication no retesting or delayed testing of such parameters should not be entertained. Hence the policy for sample retention has to be revised based on further detailed study considering even other analytes.

This study highlights the importance of the preanalytical and post analytical phase (combined) measurement uncertainties and suggests that each laboratory should have tools to measure their sources of uncertainty and determine the steps to reduce them hereby improving the overall quality of the laboratory testing.

References:

1. Marit Rynning, Tore Wentzel-Larsen, and Bjørn J. Bolann1, A Model for an Uncertainty Budget for preanalytical Variables in Clinical Chemistry Analyses. *Clinical Chemistry* 53:7 1343–1348 (2007)