SKUP evaluation protocol for troponin

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CONCLUSIONS

It is an extensive work for SKUP to prepare for evaluations of components not evaluated by us earlier, but the time and effort put into this work is of high priority to perform evaluations of great value both for the manufacturer as well as for the intended users in primary health care. For information about SKUP please visit www.skup.org

INTRODUCTION

SKUP, Scandinavian evaluation of laboratory equipment for primary health care, has performed independent evaluations of laboratory equipment for the last 25 years. Many different measuring systems, measuring a wide variety of components, have been evaluated so far. Now SKUP has received requests to perform evaluations of point of care (POC) systems that measure cardiac troponin (cTn), which is a new field for us.

AIM

To design an evaluation of POC systems intended for measurement of cTn

- ✓ performed under optimal conditions by biomedical laboratory scientists (BLSs)
- ✓ performed under real-life conditions by health care personnel in an emergency department (ED)
- ✓ design applicable for cTnI and cTnT, conventional and high-sensitive (hs) assays

METHODS

- ✓ literature research to understand troponin release under myocardial infarction (MI), to learn about the analysis method, and to understand how results are interpreted and diagnosis is set
- ✓ extensive discussions concerning study design and quality goals within SKUP, with a manufacturer, and with professionals

RESULTS

A protocol for evaluation of POC hs cTnI measuring systems has been written (figure 1). Under optimal conditions, 100 leftover samples from routine analysis will be selected and analysed on the evaluated system by BLSs at a clinical laboratory. Under real-life conditions, health care personnel will sample consenting patients coming into an ED with suspected MI. The samples will be analysed on the evaluated system by the same personnel, and on the routine method at a clinical laboratory. The aim is to get results above cut off for 50 patients, but maximum 400 will be included. The results from the evaluated method will be compared to the results from the routine method and the agreement between methods will be presented (table 1).

Table 1. *EXAMPLE, fake numbers.* Agreement between methods; comparison of paired results from the evaluated measuring system and its cut off to the corresponding patient result on the comparison method.

Evaluated measuring system	Comparison method results above cut off	Comparison method results below cut off
results above cut off	90	15
results below cut off	10	285
	Agreement 90 %	**Agreement** 95 %

In addition, the samples will be analysed in duplicate to calculate the imprecision (CV) of the evaluated system (table 2). For a hs cTn assay the CV at the 99th percentile is recommended to be ≤10 %. Finally, the evaluating personnel under real-life conditions will be asked to evaluate the user-friendliness.

Table 2. *EXAMPLE, fake numbers.* Imprecision (CV) of the evaluated measuring system for cTnI measured in capillary/venous whole blood samples. Results achieved by intended users.

Level*	n**	Excluded results (statistical outliers)	Mean cTnI value, ng/L	CV (90 % CI), %
1	15	2	20	9,0 (7,5 – 10,5)
2	25	1	100	8,0 (7,0 – 9,0)
3	15	0	500	7,0 (6,5 – 7,5)

*Level below, or close to, limit of quantification is not included.
**Number of results (n) are counted before exclusion of statistical outliers. Mean and CV are calculated after exclusion.

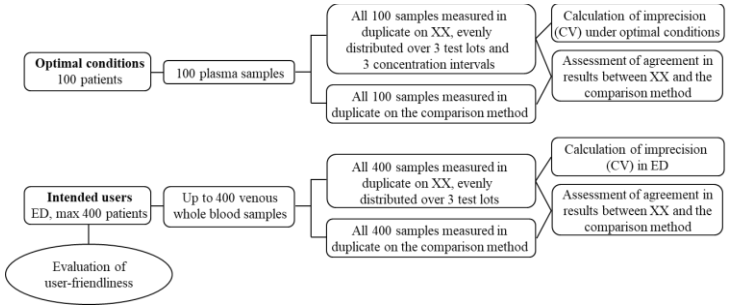

Figure 1. Illustration of the SKUP evaluation design, XX = evaluated measuring system.