Exchange of Two Laboratory Systems with Homologous Function: a Usability Study

Laboratory systems have to be replaced regularly. The aim of this study is to determine changes in usability upon exchange of a core laboratory system, focusing on user satisfaction and its impact on usability. EN ISO 9241-210:2010 describes usability as comprised of effectiveness, efficiency and user satisfaction. These three components can be described by the collected data and quantifiable conclusions can be made.

Introduction

When making decisions about equipment acquisition, technical parameters frequently predominate, while the aspect of user satisfaction is underestimated. One of the focal points in this thesis was to develop a means of evaluating user satisfaction, which could improve decision making in acquisition of new laboratory equipment, thus, making usability in such decisions quantifiable. Any exchange of an analyzer is associated with changes in all three components of usability mentioned above. This adaptation process in user satisfaction is difficult to simulate and test, especially during the engineering process of any device.

The purpose of this thesis is to quantitatively describe potential effects of exchanging an analyzer on user satisfaction, leaving all other parameters unchanged (i.e. staff, data processing, transport processes).

Materials and Methods

All observations were performed during routine testing at Zürich Blood Donation Center, consecutively, with cobas 201 and cobas 6800, during two three-month periods. Both analyzers test for HIV, Hepatitis B and Hepatitis C Virus in a PCR multiplex assay. The only analytical difference is that cobas 6800 is using a dual target approach in the HIV assay. The parameters for effectiveness (= invalid results per number of tested samples) and efficiency (= time expended to produce a valid result) were retrieved from existing quality control documents. To measure user satisfaction, the author developed a dedicated visual analog scale (VAS) of 100 mm length that was completed by the laboratory technicians.

Results

Effectiveness: During the two three-month periods reviewed, 18473 samples (on cobas s201) / 19225 samples (on cobas 6800) were analyzed, respectively, of which 3.37% (3.1%; 3.6%) on cobas s201 / 2.66% (2.4%; 2.9%) on cobas 6800 yielded invalid test results.

Efficiency: median efficiency in minutes per sample was 2.9 (IQR 13.4) on cobas s201, and 2.6 (IQR 1.9) on cobas 6800.

User Satisfaction: the VAS was recorded at two time points: START and RESULT; the level of satisfaction with the technician's own performance (TP) and also with the machine's performance (MP) was recorded (results presented as: cobas 201/cobas 6800).

The mean satisfaction with TP at START was: 98/99, and 97/98 with MP. The mean satisfaction with TP at RESULT was: 98.4/99.8, MP: 96.818/96.819.

In terms of usability, the two analyzers differed significantly in all 3 main parameters (p < 0.001).

In all VAS evaluations the new analyzer was rated significantly better. However, given the small difference of the means, the relevance to practical experience in this setting is questionable.

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Discussion

The importance of usability in device engineering is pointed out by directive 98/79/EC which stresses the concept that improved usability leads to minimized risks. This directive demands that usability questions be considered when developing a new medical device or in-vitro diagnostic application. The human-centered approach towards measuring the impact on usability due to the exchange of an analyzer is one of the novelties in this paper. Therefore this study aims to provide a method to optimize this process and make it quantifiable (i.e. using the VAS).

An important benefit of using a VAS as measuring tool is the short time needed to complete and the self-explanatory character.

The adaptation process in user satisfaction is difficult to simulate and test, especially during the engineering process. As in that phase IEC 62366 is used, some inconsistencies with the ISO 9241 standard used in this work arise, particularly due to differences in definitions of usability between the two standards.

Keywords

Usability, Effectiveness, Efficiency, User satisfaction, MPX-Test (HIV, HCV and HBV); cobas s201, cobas 6800, dual-target-PCR, Routine-Testing, Blood donation; IEC 62366:2015; EN ISO 9241-210: 2010; exchange; laboratory system