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Screening for transfusion transmissible infections using rapid diagnostic tests in Africa: a potential hazard to blood safety?

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Abstract

Rapid diagnostic tests (RDTs) are routinely used in African blood centres. We analysed data from two cross-sectional studies representing 95 blood centres in 29 African countries. Standardized panels of sera containing varying concentrations of anti-human immunodeficiency virus (HIV) antibodies (Ab), hepatitis B virus antigen (HBsAg) and antihepatitis C virus (HCV) Ab were screened using routine operational testing procedures at the centres. Sensitivity of detection using RDTs was high for HIV Ab-positive samples, but low for intermediately HBsAg (51·5%) and HCV Ab (40·6%)-positive samples. These findings suggest that current RDT use in Africa could pose a hazard to blood safety.

Keywords

Africa; blood transfusion; hepatitis B; hepatitis C; HIV; rapid diagnostic test

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Disclaimers

CP, SL, JJL and XJ contributed to the design of the study. All authors contributed to the acquisition, analysis or interpretation of data. CP drafted the manuscript. SL, ELM, EMB, ZK, MT, JJL and XJ revised the manuscript critically for important intellectual content.

Conflict of interests

The authors declare no conflict of interests.

Introduction

Blood transfusions are frequently performed in Africa, yet quality assurance remains a challenge [1]. Due to economic and logistical constraints, rapid diagnostic tests (RDTs) are routinely used in many African blood centres to screen for transfusion transmissible infections (TTI). However, their accuracy in this setting is largely unknown. The Anglophone and Francophone African Groups for Research in Blood Transfusion aim to establish an external quality assessment system for blood transfusion centres in Africa. Specifically, this consortium seeks to evaluate the current use of RDTs with a focus on diagnostic accuracy in TTI screening under operational conditions. The groups recently conducted two cross-sectional studies of testing proficiency in 12 Anglophone and 17 Francophone African countries that, respectively, included 44 and 51 blood centres [2, 3]. Here, we report on a pooled analysis of those studies that represent a total of 95 blood centres in 29 African countries.

Materials and methods

The studies were conducted under the auspices of the Blood Systems Research Institute, San Francisco, USA, and the Institut National de la Transfusion Sanguine (INTS), Paris, France, using the same study protocol and procedures. INTS prepared standardized panels of 25 diluted sera containing varying concentrations of anti-human immunodeficiency virus (HIV) antibodies (Ab), hepatitis B virus (HBV) antigen (HBsAg) and antihepatitis C virus (HCV) Ab as well as negative controls. Blinded panels were sent to national study co-ordinators in each country who recruited transfusion centres for participation in the study. Centres were asked to screen samples using their routine operational tests including RDTs, enzyme immunoassays (EIAs) or antigen/antibody combination EIAs. For this study, we evaluated strong and intermediately positive samples (n = 286) and negative controls (n = 925) that were screened with RDTs. Weakly positive samples were excluded from the analysis. Samples were classified as strong (+++/>100 ng/ml), intermediately positive (++/10 ng/ml) and weakly positive (+/≤1 ng/ml) according to the biological profile obtained with confirmatory assays for HIV and HCV and the HBsAg titre for HBV. Descriptive statistics were used to report the number of centres (laboratories) that performed RDTs, and the sensitivity and specificity of RDTs by infectious agent.

Results

Overall, RDTs were used in 34 (66·7%) laboratories in Francophone countries, but only 3 (6·8%) laboratories in Anglophone countries. The sensitivity of RDTs used by the laboratories in the Francophone and Anglophone countries is presented in Fig. 1. Sensitivity was high for the detection of strong (98·1%) and intermediately (94·4%) HIV Ab-positive samples and of strong HBsAg (93·8%) and HCV Ab (90·6%)-positive samples. However, sensitivity was low for the detection of intermediately HBsAg (51·5%) and HCV Ab (40·6%)-positive samples. Specificity of RDTs used by laboratories in the detection of HIV Ab, HBsAg and HCV Ab was 99·5% [standard error (SE) ± 0·3], 99·6% (SE ± 0·4) and 97·3% (SE ± 1·0), respectively.

Discussion

The World Health Organization recommends that all blood donations should be screened for HBV, HCV and HIV using highly sensitive EIAs; however, it has been estimated that each year millions of viral infections are still being contracted worldwide via blood transfusion due to ineffective TTI screening [4, 5]. A recent literature review of studies that evaluated RDTs for TTI screening in Africa observed variable test performance with suboptimal sensitivities in some available RDTs [6]. The present study reports on RDT use in two aligned studies for the foundation of an external quality assurance system in the screening for TTI. The use of diluted blood samples enabled assembly of standardized sample panels. The latter were needed to survey the high number of blood centres (95 transfusion centres representing 29 African countries). While the use of diluted samples is a potential limitation, the alternative use of undiluted blood samples is not logistically feasible. However, weakly positive samples were excluded from the analysis; instead, only strong and intermediately positive samples were evaluated. Their biological profiles reflect viral concentrations observed in real-world samples. Nevertheless, an influence of dilution on essay performance cannot be ruled out. A markedly higher proportion of blood centres in Francophone than in Anglophone countries used RDTs. This may be ascribed to differences in the level of infrastructure, capacity and financial resources of participating blood centres in Anglophone vs. Franco-phone countries. Evaluation of the diagnostic accuracy of RDTs revealed an alarmingly high proportion of false-negative test results associated with more challenging, weakly reactive HBsAg and HCV Ab-positive samples. These findings suggest that current RDT use for TTI screening in Africa is deficient and could pose a hazard to blood safety on the continent. We would like to note, however, that RDTs may be significantly better than no testing, particularly for HIV. The observed deficiency may not be ascribed to the assays themselves, but rather to the way they are used, calling for systematic evaluation to understand the reasons that underlie suboptimal performance. In the light of logistical and financial constraints, RDTs arguably are the only available option for TTI screening in many resource-poor African blood transfusion centres. Therefore, effective quality assurance systems are required to improve the diagnostic accuracy of TTI screening using RDTs in such settings.

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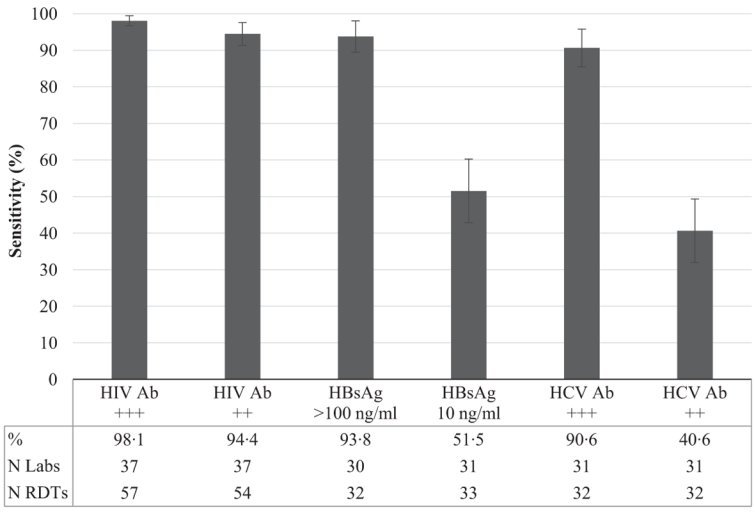

	HIV Ab +++	HIV Ab ++	HBsAg >100 ng/ml	HBsAg 10 ng/ml	HCV Ab +++	HCV Ab ++
%	98·1	94·4	93·8	51·5	90·6	40·6
N Labs	37	37	30	31	31	31
N RDTs	57	54	32	33	32	32

Fig. 1.

Sensitivity (%) of rapid diagnostic tests performed in laboratories in Francophone and Anglophone countries across Africa, by viral marker. +++/>100 ng/ml: strong; ++/10 ng/ml: intermediately positive; Ab: antibodies; HBsAg: hepatitis B surface antigen; HCV: hepatitis C virus; HIV: human immunodeficiency virus; Labs: laboratories; RDTs: rapid diagnostic tests. Error bars show standard errors.