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# Findings of Phlebotomy Practices in Kenya in 2010: Need for Action

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#### Abstract

**Background**—Phlebotomy, a commonly performed medical procedure in healthcare, is essential for disease diagnosis and patient management. However, poorly performed phlebotomy can compromise patient safety, healthcare worker (HCW) safety, and specimen quality. We carried out a study between June and July 2010 to assess knowledge, quality and safety of phlebotomy before implementation of a public-private partnership between Becton, Dickinson and Company and the US President's Emergency Plan for AIDS Relief.

**Methods**—This was a cross-sectional observational study in 8 healthcare facilities within 4 regions of Kenya. HCWs were observed conducting venous and capillary blood collections, and pre- and posttests were offered during HCW training.

**Results**—Of 283 blood samples obtained, 194 were venous draws conducted by 72 HCWs and 89 were capillary draws performed by 33 HCWs. Based on 12 preset quality-associated criteria, none of the 194 observed phlebotomies met the standard. In total, 91 HCWs were trained in phlebotomy. The mean knowledge increase between pre- and posttraining test was 41%, ranging from 39% to 45% (95% confidence interval, 29.3%–53.5%; P < .001).

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Supplementary Data

Supplementary materials are available at http://jid.oxfordjournals.org. Consisting of data provided by the author to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the author, so questions or comments should be addressed to the author.

**Disclaimer.** The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention (CDC) or the government of Kenya.

**Potential conflicts of interest.** R. G. is employed by BD as Vice President, Global Health. All other authors report no potential conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

#### Keywords

phlebotomy; public-private partnerships; preanalytical errors; blood specimen quality

Phlebotomy is one of the most commonly performed medical procedures in healthcare practice, being essential for disease diagnosis and patient management [1]. When done properly, it contributes to reliable laboratory results, leading to appropriate clinical decisions. Poorly performed phlebotomy, however, can compromise patient safety, healthcare worker (HCW) safety, and specimen quality. Patients may suffer injuries at the site of blood drawing [2] or acquire infections through nonsterile or contaminated blood drawing devices or improperly cleaned blood drawing site. Capillary blood collections have been associated with hepatitis B virus (HBV) outbreaks [3]. Needle-stick injuries can spread blood-borne pathogens, including HBV, hepatitis C virus, human immunodeficiency virus (HIV), and viral hemorrhagic fevers [4]. High rates of needle-stick injury have been reported in Africa; most of these are related to injections for treatment [5, 6]. Although concerns about the quality and safety of phlebotomy have been raised, there are few documented studies in Africa on this practice [7]. A case-control study involving HCWs who acquired HIV through occupational exposure in Europe and the United States showed that bloodfilled needles as used in phlebotomy pose a higher risk of transmission than non-bloodfilled needles [8]. In addition, higher risk was associated with injury involving a device that was visibly contaminated with the source patient's blood and procedures involving a needle placed in the source patient's vein or artery.

About two-thirds of errors that affect laboratory test results occur in the preanalytical phase, the period before assay performance [9,10]. Phlebotomy-related errors account for >60% of errors in this phase [11]. Poor-quality samples owing to hemolysis, clotting, or inadequate volume lead to incorrect results and may lead to delayed or incorrect treatment. Repeat sampling and testing adds additional healthcare costs and increases the turnaround time for reporting results, a key performance measure for laboratories [12]. Improved quality safety-engineered equipment for blood collection is now available [13, 14], but there is often reluctance to accept and use such equipment owing to inadequate staff training [15]. The risk of needle-stick injury is increased when HCWs are incompetent in the use of phlebotomy devices. In Kenya, the rapid scale-up of HIV testing, care, and treatment and expansion of other health services has led to a significant increase in blood collection for diagnosis and monitoring [16]. Because of Kenya's high prevalence of HIV (5.6%) [17], HBV (11.4%) [18], and other blood-borne pathogens, the potential for exposure to such pathogens is increased.

The Kenya Ministry of Health (MOH) identified phlebotomy safety as one of the highpriority interventions for support from the US President's Emergency Plan for AIDS Relief (PEPFAR). Becton, Dickinson and Company (BD), the US Centers for Disease Control and Prevention (CDC), and PEPFAR entered into a public-private partnership (PPP) to support

the improvement of safety and quality of phlebotomy practices. Before this partnership, limited information was available on the phlebotomy practices in Kenya, elsewhere in Africa, or other resource-limited settings. Although our study was done in 2010, to date no phlebotomy-related data from the region have been published, to our knowledge.

This study evaluated the knowledge and practices for phlebotomy before the intervention phase of this PPP. Through this partnership, we were able to assess the knowledge of phlebotomists and the quality and safety of phlebotomy. This enabled us to design a contextspecific program with interventions that addressed specific gaps identified in phlebotomy practice. The aim was to improve specimen quality for better patient management and improved HCW and patient safety.

#### METHODS

#### **Study Design**

This was a cross-sectional observational study in 8 healthcare facilities within 4 regions in Kenya. Three provincial hospitals with 323–588-bed capacity, 3 district hospitals with 196–216-bed capacity, and 2 health centers with 20- and 65-bed capacities were selected. These facilities were selected to cover different healthcare setups, different amount and types of blood collections, adult and pediatric settings, and different levels and types of health institutions in Kenya. Four staff members from the MOH were trained by BD experts on how to perform direct observation and how to complete data collection tools. The BD experts were global health fellows who had laboratory and phlebotomy experience and a clinical background. Each of the 4 MOH staff members was to conduct observations in 2 facilities. There were 2 observation/data collection tools, one for venous and the other for capillary blood collection. The tools were used to capture the actual technique of the Procedure, the types of devices used, and any peculiarities noted. Each tool had a section indicating the department in which the blood was collected, the date, and the cadre of the HCW. The tools had check boxes to check off the observations as the procedure was carried out. A new tool was used for every procedure observed.

#### **Study Participants and Recruitment**

In Kenya, blood collection is carried out by a wide range of cadres, including laboratory technicians, clinicians, nursing staff, and medical interns, depending on the departments where they are stationed. HCWs who drew blood in different departments within these facilities were selected by convenience sampling; those found drawing blood at the time of the assessment were sampled. Each HCW was observed collecting blood from multiple patients.

#### Measures and Data Management

A standard phlebotomy procedure was defined as one in which all steps were performed as described in the World Health Organization (WHO) guidelines on blood drawing [19]. Steps that ensure patient safety, such as patient identification, hand hygiene, gloves use, site cleaning, and tourniquet application were noted, as were steps intended to increase HCW safety, including blood transfer technique, needle recapping, availability of sharps container

within an arm's length, and disposal of device into a sharps container. Observations related to specimen quality, such as mixing technique, volume of the sample, and bubbling or frothing of specimens were also noted. Similar observations related to patient and HCW safety were made for capillary blood drawing.

After the observations, a total of 4 trainings were held for the HCW who drew blood. At each training, a pre- and posttraining test consisting of 44 questions was administered to gauge the trainee's knowledge at the beginning and end of the course (Supplementary Appendix 1).

#### **Data Analysis**

Data from the observations as well as pre- and posttraining tests were entered in an Excel spreadsheet. Analysis was conducted using SAS software (version 9.3) and consisted of descriptive statistics presented as sums and percentages.

#### **Ethical Statement**

This study was approved by the CDC's institutional review board. Verbal consents were obtained from all HCWs and patients included in the observations. The observation team signed a confidentiality agreement form and did not take pictures of the procedures or other records.

#### RESULTS

Of 283 blood sampling events observed in 8 facilities, 194 were venous phlebotomy procedures and 89 were capillary blood collections. The 72 staff performing venous blood collection included 37 (51%) laboratory staff, 22 (30%) interns (clinical or medical officers), 7 (10%) clinical/medical officers, 5 (7%) nurses, and 1 (1%) unspecified cadre. Of the 33 staff performing capillary blood collections, 27 (82%) were laboratory staff and 6 (18%) were nursing staff.

#### **Phlebotomy Procedures**

The steps observed included 10 related to patient safety, 4 related to sample integrity, and 5 related to HCW safety (Figures 1–3). None of the 194 observed phlebotomies adhered to all the steps of a standard procedure. Only confirmation of the patient's identity (52%) and application of pressure to the site after removing the needle (80%) were performed in more than half of the observed phlebotomies. With regard to patient safety, HCWs did not perform hand hygiene before 190 (98%), did not use a new pair of gloves in 122 (63%), did not use a new moistened swab to clean the phlebotomy site in 171 (88%), and touched the puncture site after the area was cleaned in 37 (19%) of the procedures. In addition, blood collection tubes were labeled before the procedure in 137 (71%) of the phlebotomy procedures.

With regard to sample quality, the tourniquet application time exceeded the recommended 60 seconds in 117 (60%) of the phlebotomy procedures, and HCWs did not properly mix the samples in 174 procedures (90%). The volume of the sample was inadequate in 168 (87%) procedures, and 25 samples (13%) were observed to have bubbling or frothing.

With regard to HCW safety, 180 (93%) of the sharps used for blood drawing were disposed into the sharps container, of which 124 (69%) were within arm's reach. The rest of the devices were disposed into other waste containers that are not meant for sharps disposal. Syringes and needles were used in 82 (42%) of the procedures; of these, 12 (15%) were performed with reuse prevention syringes that are inappropriate for phlebotomy (data not shown). Forty-five (23%) of the transfers of blood from syringe into collection tubes was done by injecting blood into a tube while holding it with the other hand; 35% of the needles were recapped after the procedure, and 21 (55%) of those were recapped using a 2-hand technique.

#### **Capillary Collection Procedures**

A total of 89 capillary procedures were observed in 53 adults and 36 children (Figures 4 and 5). Overall, 59 (66%) of capillary procedures were performed for blood slides for malaria test, 18 (20%) for blood glucose tests, 9 (10%) for rapid HIV tests, and the rest for hemoglobin or other tests. The finger was the site used for all capillary procedures, for both adults and children. None of the procedures was preceded by hand hygiene. The site was cleansed using a new moistened swab in 5 (6%) of procedures, and only 2 (2%) of the prick sites were allowed to air dry before the skin puncture. Capillary blood was sampled using a lancet and a hypodermic needle in 71% and 29% of procedures, respectively.

As with phlebotomy, there was higher adherence to practices intended to maintain HCW safety. Capillary blood drawing devices were disposed into a sharps containers in 83 (93%) of the collections, and 73 (88%), of the containers were within arm's reach of the HCW.

#### **Pre- and Posttraining Tests**

The HCWs were selected for training based on their experience in blood collection, interest and availability to train others, and good communication and mentoring skills. Eighteen master trainers, including 12 laboratory technologists, 4 physicians, and 2 nurses, were trained by BD experts and showed an improvement of 74% between pre- and posttraining tests, from 53% to 92%, respectively (P = .009) (Table 1). Facility staff that frequently collected blood was selected for training. The master trainers trained 73 trainees in 4 classes, and these trainees showed a mean improvement in knowledge of 91%. The improvement for all classes was statistically significant: class A had a mean increase of 40% (95% confidence interval [CI], 9.4%–70.6%; P = .20); class B, 45% (16.8%–73.2%; P = .006); class C, 43% (917.5%–68.5%; P = .003), and class D, 40% (14.8%–65.2%; P = .005). The overall mean increase for all 91 HCWs trained was 41%, ranging from 39% to 45% (95% CI, 29.3%– 53.5%; P < .001).

#### DISCUSSION

None of the blood collection procedures in this study adhered to all the steps of a standard phlebotomy procedure as described by WHO [19]. This could affect both patient and HCW safety as well as sample quality. This finding is not unique; Gabriel et al [11] documented a deviation rate of 60% in phlebotomy procedures.

The majority of deviations were on practices that could compromise patient safety, including hand hygiene, gloves use, site cleaning, patient identification, and sample labeling. Although the WHO guidelines on blood collection recommend hand hygiene before and after every procedure, either with hand washing or with hand sanitizer, and use of a new pair of gloves for every patient [20], compliance was only 2% for hand hygiene and 22% to 36% for gloves use. Hand hygiene is one of the basic elements of universal precautions but has been shown to have poor compliance among HCWs [19, 21]. This increases the risk of disease transmission from patients to HCWs or between patients. The findings in this study agree with those of Sacar et al [22] showing poor compliance with hand hygiene and glove and tourniquet use. We also observed that about 9 of 10 blood collections were not performed using newly prepared or prepacked swabs, as recommended by WHO. Presoaked cotton swabs may become contaminated with environmental bacteria, posing risk of infection to the patient [19]. Only half of patients had their identity checked; inadequate patient identification is a common preventable medical error [23]. Only a third of specimens were labeled after the blood collection in the direct view of the patients, as recommended [24]. A mislabeled specimen can have devastating consequences for diagnosis and treatment.

Several errors that could have compromised specimen quality were noted. The maximum recommended tourniquet time was exceeded in 6 of 10 draws. Prolonged tourniquet time (>60 seconds) is associated with falsely elevated results for glucose and potassium [25, 26]. Recommended blood mixing techniques were not followed in 90% of the phlebotomy procedures, creating opportunities for hemolysis or clot formation [25, 27]. We found that 87% of the blood samples were of inadequate volume, which may result in hemolysis, formation of microclots, prolonged coagulation times, or changes in cell morphology [27]. Among the 40% of phlebotomies conducted using syringe and needle, procedures that increase risk of HCW injury (eg, as 2-handed sample transfer from syringe to tube and needle recapping) were observed in 23% and 35% of the procedures, respectively. Phlebotomies were carried out using safety-engineered closed systems in about half of all procedures. These systems have associated safety features for HCW protection [14, 15, 28]. When properly used, they ensure the correct sample volume and minimal risk of hemolysis.

Two-thirds of the capillary procedures were performed using standard lancets, and a third were performed using hypodermic needles, which pose a safety risk for both patient and HCW. With standard lancets and hypodermic needles, puncture depth cannot be controlled. This increases the risk for nerve damage, cellulitis, and, in infants, osteomyelitis of the calcaneus [29, 30]. In addition, HCWs can sustain percutaneous injuries during handling and disposal of hypodermic needles and standard lancets. A worrying finding was that all the capillary procedures were performed as finger sticks, irrespective of patient age. This approach can be particularly risky for infants, as described above.

The low performance in the pretraining test (<50%) was consistent with the poor practices in blood collection observed. However, there was uniform and marked improvement in knowledge after the training across all the sites. This indicates that the training made an impact and the practices were likely to improve.

Our study had some limitations. First, the sampling was performed at facilities that were selected to participate in the BD-PEPFAR partnership project and may not be nationally representative. Second, the observations were based on the HCW who was found at the time of assessment in a facility and may not have represented the practices of the other HCWs. Third, because they are being observed, HCWs could have tried to improve their blood collection practices. Finally, some of the smaller facilities had very few blood collections observed. Despite these limitations, we believe that this study provides important baseline data that may be applicable to many other facilities in Kenya and the region.

The findings of this study indicated major gaps in safety and quality of blood collection and called for urgent action to improve these procedures. This was especially critical when universal access to HIV-related laboratory testing was becoming a reality through laboratory networking. Timely and quality results would depend on a high-quality blood specimen from a high-quality phlebotomy procedure. This was especially important for blood collection for early infant diagnosis programs for HIV-exposed infants, because timely results are a prerequisite to treatment initiation, and delays have led to early deaths [31].

Driven by this consideration, the CDC, MOH, and BD implemented the safe phlebotomy PPP to address the gaps. Specific activities of the PPP included training of HCWs; supply of safety-engineered devices and other related supplies for safe phlebotomy procedures; and development of policies, guidelines, and standard operating procedures. In addition, the PPP supported surveillance of needle-stick injuries and mucous membrane splashes as well as access to and uptake of postexposure prophylaxis for HIV. Through cascade training starting with BD experts, the partnership sought to strengthen local capacity and build a sustainable quality assurance system. To build national capacity, CDC and BD established a Center of Excellence at Kenya Medical Training College to ensure that there is ongoing preservice training in phlebotomy.

The baseline study findings not only guided planning for the PPP but also triggered training institutions and clinical services to improve blood collection curricula and practices, respectively. Safe phlebotomy is critical to improving the quality of samples for better patient management and reduced HIV transmission in healthcare settings in Kenya, as envisioned in the Kenya AIDS Strategic Framework and the Kenya National AIDS Strategic Plan [32, 33].

#### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

#### Acknowledgments

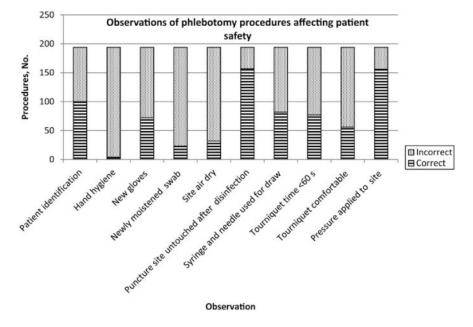
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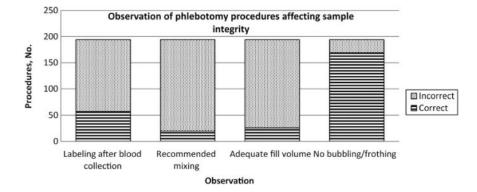
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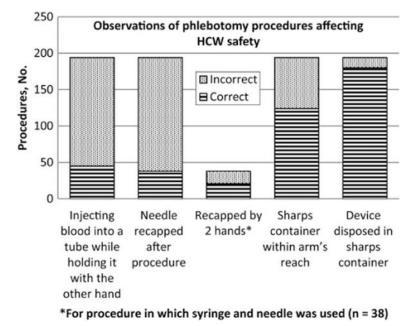






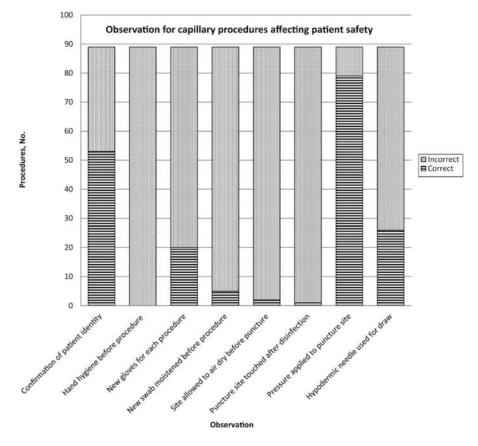
#### Figure 2.

Observation of phlebotomy procedures affecting sample integrity in 8 facilities in Kenya, 2010.



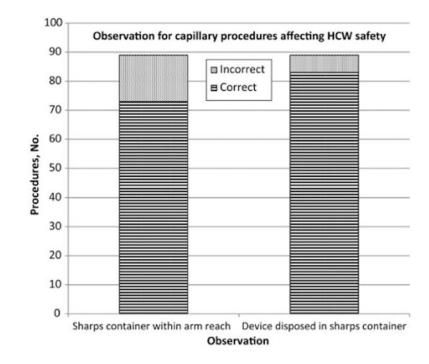
### Figure 3.

Observation of phlebotomy procedures affecting healthcare worker (HCW) safety in 8 facilities in Kenya, 2010.





Observation of capillary procedures affecting patient safety in 8 facilities in Kenya, 2010.



#### Figure 5.

Observation of capillary procedures affecting healthcare worker (HCW) safety in 8 facilities in Kenya, 2010.

## Table 1

Trainee Performance in Pre- and Posttraining Tests in the Master Class and Initial 4 Classes Conducted in June–July 2010

Class	Trainees, No.	Pretest, %	Posttest, %	Trainees, No. Pretest, % Posttest, % Difference, Mean (95% CI), % P Value	P Value
Master	18	53	92	39 (12.8–65.2)	600.
A	16	42	82	40 (9.4–70.6)	.02
В	17	43	88	45 (16.8–73.2)	900.
С	20	47	06	43 (17.5–68.5)	.003
D	20	51	91	40 (14.8–65.2)	.005
Total	91	47	88	41 (29.3–53.5)	<.001

Abbreviation: CI, confidence interval.