Open Access Library Journal
2023, Volume 10, e9966
ISSN Online: 2333-9721
ISSN Print: 2333-9705

Quality and Safety in the Phlebotomy Units of Medical Structures in Lubumbashi

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How to cite this paper: Ilunga, E.K., Kambote, A.K., Masanka, P.K. and Mposhy, E.P.M. (2023) Quality and Safety in the Phlebotomy Units of Medical Structures in Lubumbashi. *Open Access Library Journal*, **10**: e9966.
https://doi.org/10.4236/oalib.1109966

Received: March 4, 2023
Accepted: April 21, 2023
Published: April 24, 2023

Abstract

A correct pre-analytical phase procedure is essential to obtain an adequate sample, unfortunately this phase is littered with many errors and risks. It is within this framework that we carried out a survey in the laboratories of the city of Lubumbashi, Likasi and Kolwezi in the Democratic Republic of Congo and this by a questionnaire imposed on the heads of the laboratories. 3588 responses were validated and analyzed. Our results showed that the first line of the health level is more represented by Health Centers (CS), followed by Polyclinics, Reference Health Centers (CRS) and Hospitals Reference Generals (RGH). We have observed variations in the implementation of the reference standards on good sampling practice both in terms of general organization and in terms of risk management, for the staff and for the patient. What requires training, the establishment of a quality management system in phlebotomy units.

Subject Areas

Diagnostics

Keywords

Phlebotomy, Quality, Security

1. Introduction

Clinical laboratories play an important role in improving patient care, generating knowledge that can facilitate patient safety, improve patient outcomes, shorten patient journeys, and lead to more cost-effective healthcare [1]. Indeed,

patient care and public health depend on the reliability and quality of clinical laboratory tests, as laboratory tests represent the most frequently ordered diagnostic procedures in all patient encounters [2].

Venous blood sampling (phlebotomy) is the most common invasive procedure performed in patient care. Guidelines on the correct practice of phlebotomy are available, including the H3-A6 guideline issued by the Clinical Laboratory Standards Institute (CLSI) [3]. In Africa, most countries or even laboratory practitioners are unaware of the existence of these quality procedures related to the collection of venous blood samples and therefore an assessment of the quality and safety of phlebotomy units is essential and constitutes thus the purpose of this article.

Because the identification of reliable quality indicators (QI) is a crucial step to allow users to quantify the quality of laboratory services, the current lack of attention to extra-laboratory factors contrasts sharply with the body of evidence indicating the myriad of errors that continue to occur in the pre- and post-analytical phases [4]. This is why we conducted this study to identify the various problems in our phlebotomy units, in order to set up an improvement plan with effective corrective action.

2. Method

Thus, through surveys and visits to laboratories in the cities of Likasi, Lubumbashi and Kolwezi, we were able to collect 3588 responses that we recorded using Google form and analyzed using Microsoft Excel 365 for the representation forms form of Pie charts, histograms and tables and with Epi Info 7.3 in order to calculate the relative risk and the Confidence intervals on the wearing of PPE.

3. Results and Discussion

From Figure 1, we observe that Health Centers are the most represented structures (73.6%) in the cities of our study, followed by polyclinics (19.78%), Reference Health Centers (3.85%) and General Hospitals of Reference (2.73%). The observation thus made shows an increased number of first-line structures, an

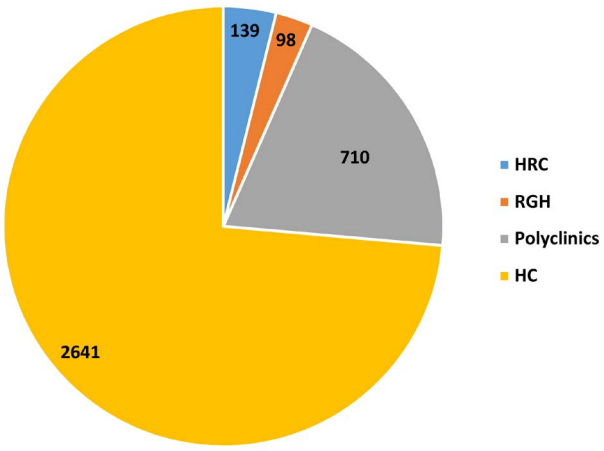

Figure 1. Distribution of structures according to health level.

observation also made by Chenge *et al.* in their article entitled: The health map of the city of Lubumbashi, Democratic Republic of Congo Part I: problem of health coverage in urban areas Congolese ; his results reveal an exponential evolution in the number of first-line structures [5] and likewise Samuel Bosongo *et al.* affirms that in Kisangani in the Democratic Republic of Congo, the services of doctors on the first line is a de facto situation, unplanned and unsupported, which is largely due to the need for professional integration of doctors [6]. This phenomenon does not correspond to the current health policy because front-line service is devolved to nurse practitioners [7].

The verification of the implementation of quality parameters in phlebotomy units according to the health level shows that a glaring absence of sampling procedure in around 80% and this regardless of the health level and in contrast, the presence of Job Aids of samples appears from 61% to 84% depending on whether one passes from Health Center, RGH, HRC and polyclinics. And about the training of phlebotomists, it was effective in turns of 43% in the HC, 60.1% in the polyclinics, 61.1% in the CSR, and 70.4% in the HGR (**Figure 2**).

It should be noted here that the training of phlebotomists is of great necessity to master the pre-analytical part in the laboratory, a very crucial phase regarding the quality of the results, as the concept "Garbage in Garbage out" says: The quality of the output is determined by the quality of the input. Indeed, it is that Gabriel Lima-Oliveira *et al.* found that training phlebotomists for 20 days eliminated non-compliance procedures [8] and compliance with the exact procedure of blood collection by venipuncture from the according to CLSI/NCCLS H03-A6 improves the quality of the process [3]. Because indeed, a correct organization or management of the personnel and the procedures relating to blood sampling by venipuncture are of fundamental importance, because the various stages of realization of the blood sampling represent in themselves sources of variability in the laboratory [9].

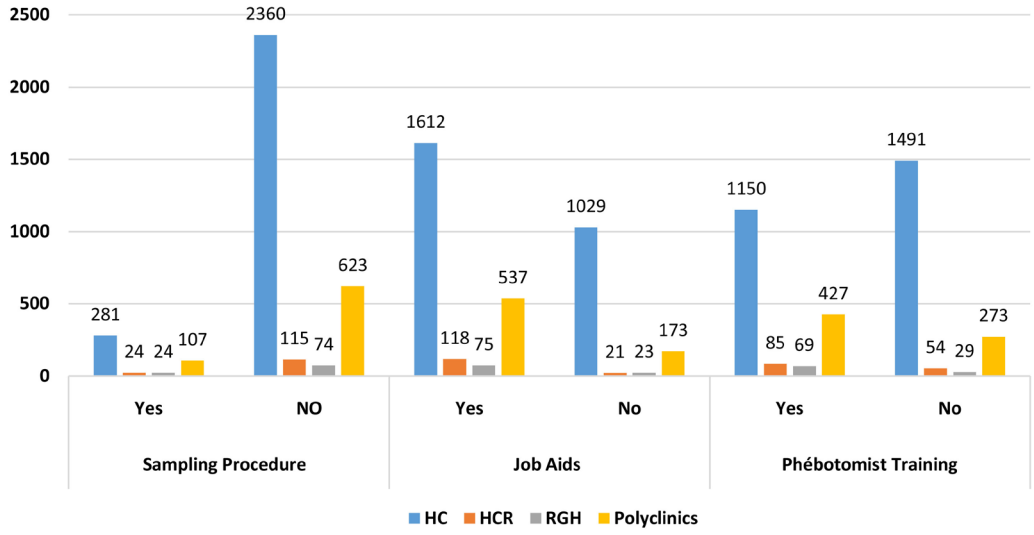

Figure 2. Quality parameters in phlebotomy units.

It should be noted that there is a mismatch between v the presence of Direct Debit Procedures on the one hand and that of JobAid on the other; in the phlebotomy units, the present job aids are part of the documents provided after training, in most cases, in the care and diagnosis of HIV/AIDS.

About the Organization of safety in the phlebotomy units, we observe from Figure 3 a use at each level of appropriate single-use materials and good storage of workstations in the CS and CSR and less in polyclinics and HGR and this in the almost very high absence of safety pictograms, which we have noticed in around 15% of structures at all levels combined.

We also note the presence of bins with unsoiled objects respectively at 71%, 82%, 91% and 87% depending on whether one is in the phlebotomy units of the CS, CSR, HGR and Polyclinics; which is the opposite of the presence of soiled Object bins which are becoming rarer. The situation deteriorates further when it comes to sharp object bins, which are only used at 14.5% in CS, 28.7% in CSR, 34.6% in HGR and 18.59% in polyclinics.

The evidence of cleaning of surfaces by the presence of the sheets, is not very present in the CS and sufficiently present in the CSR, HGR and Polyclinics. We also observe, the use at 52% and 60% in the CSR and HGR, while in the CS and polyclinics the use is successively at 36.9% and 32.1%.

The safety of healthcare workers and patients is the main concern during phlebotomy procedures; this is why it is essential to have guidelines guiding staff towards best practices [10] [11]. Thus, all staff members must be trained in phlebotomy to prevent unnecessary risks of exposure to blood and to reduce adverse events affecting patients and this training must at least cover the essential points [12] [13] [14] whose purposes of this training are patient safety, adequacy of laboratory specimens, and the safety of health care workers and the community.

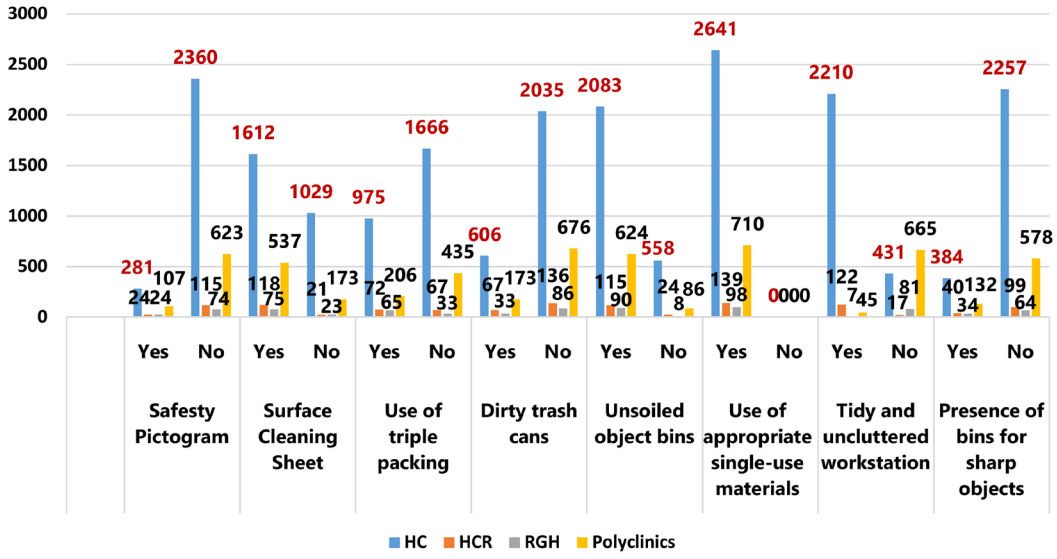

Figure 3. Safety organization in phlebotomy units.

And in this specific case, it is the anatomy of the phlebotomy sites that the health worker is allowed to access; infection prevention and control; patient protection; health worker protection; types of equipment available for blood collection and acquisition and use of such equipment; adverse events and their management; occupational exposures and their management; waste management, including disposal of waste and sharps/sharps and spill or breakage procedures. Laboratory practices, including sample types, forms, labeling and transport; as well as the standards of practice that define the points followed in this investigation [15].

The concern for quality monitoring, observed by the notification of complaints, non-conformities as well as the recording of rejection of samples is better monitored in the polyclinics, then in the HGR, the CSR and finally in CS. Indeed, WHO guidelines for blood collection: best practice in phlebotomy require that a monitoring and evaluation system be in place to monitor the management of phlebotomy services and the management of adverse events, as well as to save improvements. This system must monitor the indicators, those identified in **Figure 4** [15].

Figure 5 shows that the safety of the phlebotomist is ensured in satisfactory ways for the wearing of gloves, followed by that of the wearing of medical boots and finally the wearing of PPE; on the other hand, the wearing of glasses and the presence of first aid kits are not ensured in a satisfactory manner and in compliance with the recommendations of the WHO which gives the following details:

Regarding personal protection that health workers should wear tight-fitting sterile gloves when taking blood samples; they must also practice hand hygiene before and after each act on a patient and before putting on and after taking off their gloves [16].

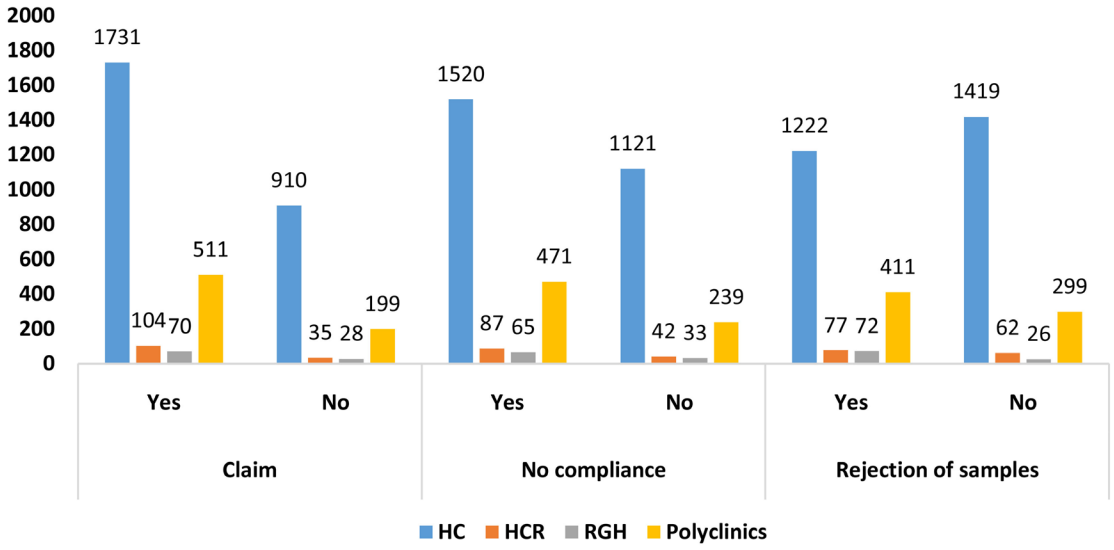

Figure 4. Monitoring the quality of work and customer satisfaction.

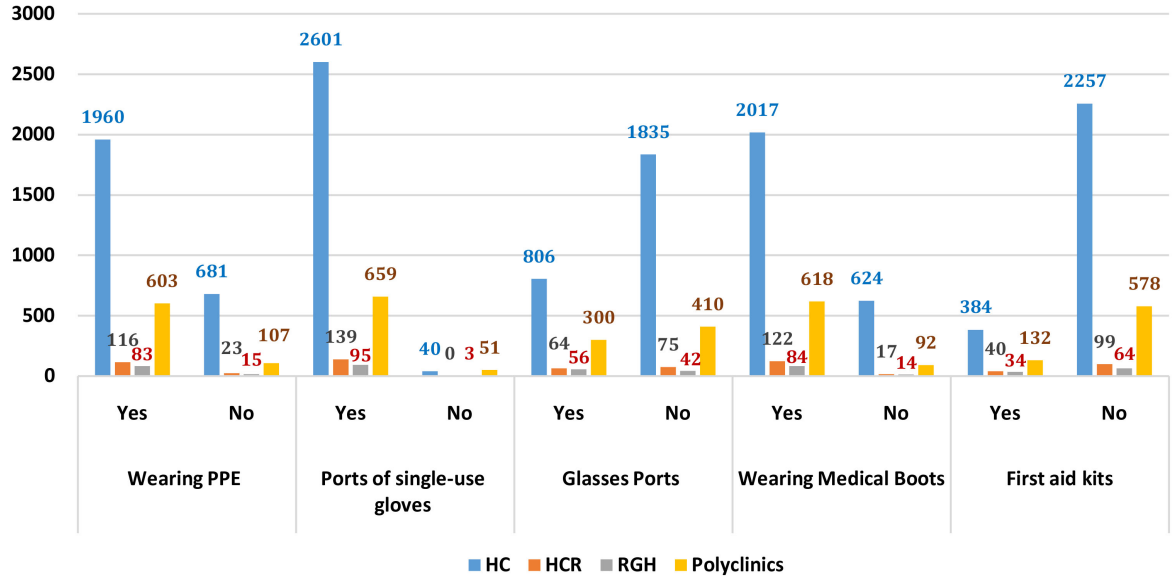

Figure 5. Safety of the phlebotomist.

Regarding the safe disposal of sharp objects [17], the collection device: a needle and syringe, a needle and an evacuated tube holder or a butterfly needle – must be disposed of immediately after use without being disassembled. It should be placed in a closed, leak-proof, puncture-resistant sharps/sharps container that is installed so that it is clearly visible and within easy reach of the health-care worker [18].

Wearing gloves can reduce the acquisition of microorganisms on the hands. But it does not completely prevent hand contamination. Also, improper use of gloves may increase the risk of cross-transmission through contaminated gloved hands [19].

Table 1 shows the follow-up of the respect of the wearing of Epis, it appears from this table that there is a statistically significant association between the wearing of Epis and the various components including: gloves, glasses, and medical boots. This association, with an RR > 1, testifies to an increase in the frequency of the event, which is also a beneficial effect provided by wearing Epis in combination with gloves, glasses, and medical boots. This is because the more parts of the body covered in PPE, the better the protection it provides. However, this is also associated with increased difficulty in donning and doffing PPE, and PPE is less comfortable. Coveralls are the most difficult PPE to remove, but they can provide the most protection [20]. In this regard, one of the objectives of wearing Epis is to cover a larger part of the body which leads to better protection. However, as is usually associated with increased difficulty putting on and taking off PPE. This is so following CDC guidelines for removal of apron or gown, or any instructions for removing PPE should be required [21].

Figure 6 points out at each health level, each laboratory uses syringes and vacuum tubes for blood sampling, and they sometimes use vacuum needles (68.89% in the HC, 83.5% in the polyclinics, 86.3% in the HCR and 96.9% in the

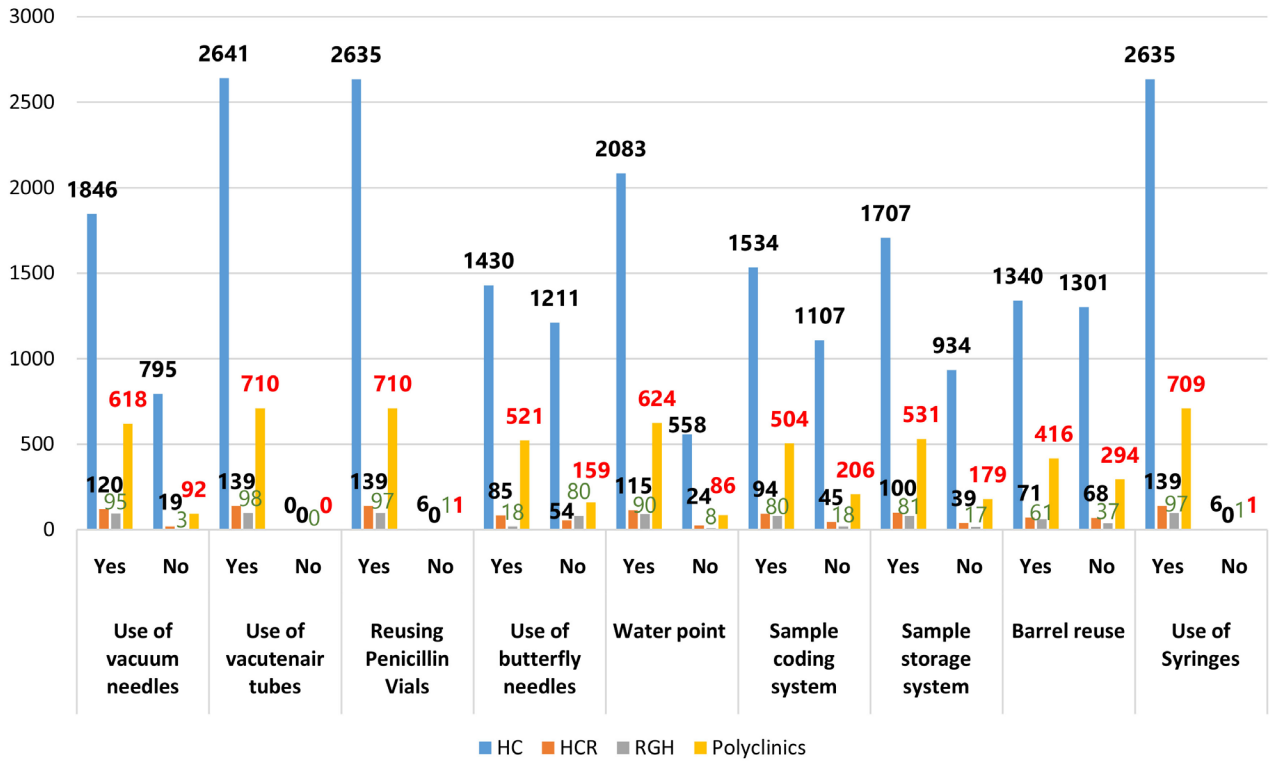

Figure 6. Organization of the collection unit in the laboratory.

Table 1. Monitoring of wearing safety of EPIS.

	PPE	No	Yes	p-Value	RR
Gloves	Non	28	798	0.00	4.92 [2.76 - 8.77]
	Oui	19	2743		
Glasses Ports	Non	686	140	0.00	1.36 [1.31 - 1.42]
	Oui	1676	1086		
Wearing Medical Boots	Non	301	525	0.00	2.25 [1.99 - 2.55]
	Oui	446	2316		

RGH). With reuse of the cylinder around 50% of the structures for the sanitary level sets.

We note the reuse in many laboratories of penicillin vials for the collection of urine and stool. The presence of water points for hand washing is more present in RGH and HCR (91%) followed by polyclinics (87.8% at and HC (78.8%). The sample coding system is only present at 81.6% in the HGR, 70.9% in the clinics 67% in the CSR and 58% in the HC The storage system was present respectively at 82.65% for the RGH, 74% for the Polyclinics, 71% for HCR and 64.63% for HC It is true that the use of vacuum extraction tube systems as closed systems for blood collection reduces the risk of direct exposure to blood and facilitates the collection of multiple samples from a single venipuncture. And these systems are widely available in most countries with sufficient resources [22].

Also, the choice of blood collection tube has a significant effect on the detected metabolites and their overall abundance [23].

Regarding the sample coding and storage system, JL Dhondt believes that the pre-analytical phase must require all attention to ensure the quality of the prescribed analyzes and the identification of the tubes is a key step, especially that, in the continuation of the assumption of the biological file [24]. Paul N Valenstein and Ronald L Sirota believe that misidentification involves misidentification of a patient or specimen. Either has the potential to harm patients. These errors can occur at any part of the test cycle; however, most occur in the pre-analytical phase [25]. Hence the need to properly organize the system for storing and coding the samples to minimize their occurrence, and that special attention should be given during the pre-analytical phase. Because for the clinical laboratory, the errors of the pre-analytical phase of the tests vary up to 75% of the total laboratory errors; 26% of them can have adverse effects on patient care, and contribute to unnecessary investigations or inappropriate treatments, increased lengths of hospitalization, as well as dissatisfaction with health services [26].

While reusing tourniquets may compromise patient safety [27], so will reusing the barrel, as it has been shown that tourniquets used for peripheral venous vascular access such as blood samples are regularly contaminated by clinical routine [28]. The facts mentioned above also apply to the reuse of drug vials for the collection of stool or urine samples.

4. Conclusion

Laboratory testing, an extraordinarily complex process usually subdivided into three traditional analytical phases (pre-analytical, analytical, and post-analytical). Many errors come from the pre-analytical phase, being due to individual or system design flaws. To reduce errors, the pre-analytical phase must therefore be preferred. In addition to the purchase of equipment, the development of procedures and training, the establishment of a quality management system in the laboratory can be a tool to reduce errors in sample collection and the handling of pre-samples.

Conflicts of Interest

The authors declare no conflicts of interest.

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