BD Global Public Policy Position

Improving Phlebotomy and Blood Collection Practices

ISSUE: **Poor phlebotomy and blood collection practices adversely affect patient outcomes, place healthcare workers at risk, and waste public health resources.**

POSITION: **BD supports regulatory and public policy frameworks that promote safe and high-quality specimen collection practices. The following key elements should be included in a comprehensive approach to advance proper specimen collection.**

1. **Professional councils dedicated to phlebotomy should be developed. Alternatively, phlebotomy should be designated as an area of responsibility for existing professional councils.**

   Professional councils play a critical role in healthcare systems by developing training curriculum and certification standards through expert, collaborative and transparent processes. These councils also provide continuing education and professional development throughout a healthcare worker's career. Currently, there are few professional councils that are either dedicated to phlebotomy or have phlebotomy as an area of responsibility. This gap is an impediment to ensuring high quality and safe blood collection practices.

   Training curriculum and certification standards should be established by professional councils with a responsibility for phlebotomy. In the absence of a dedicated phlebotomy council, government policy should promote inclusion of phlebotomy within the mandate of existing medical technology councils.

2. **Phlebotomy should be recognized as a distinct and critical discipline in healthcare delivery, accompanied by training requirements with proficiency standards, certification, and oversight.**

   Training criteria and proficiency standards are essential to ensure that healthcare personnel `engaged in phlebotomy, whether as their primary function or among their duties, have an acceptable minimal level of training and demonstrated competency. Countries should establish national policies that require mandatory training and proficiency assessment through certification for healthcare personnel who draw blood specimens from patients. As healthcare systems develop, licensing of personnel engaged in phlebotomy should also be a national goal.

   Phlebotomy should be recognized in occupational standards as a distinct discipline within allied health sciences. Academic curricula and employment pathways (including job descriptions) should align with these occupational standards to reinforce the practice of phlebotomy as a distinct discipline.

3. **Governments should develop and implement enforceable national or regional guidelines on specimen collection.**

   - Guidelines are a critical tool in ensuring that best practices are disseminated.
   - They should be developed in a consultative process that engages all key stakeholders.
   - Governments should actively promote guideline development, implementation, and enforcement to ensure the safety of patients and healthcare workers, as well as the fiscally responsible utilization of resources.

4. **Quality systems should be developed and maintained to ensure the training of personnel and adherence to best practices in specimen sampling, based on established guidelines.**

   Quality systems are critical to ensure that training and adherence to best practice, based on established guidelines, are sustained and integrated into laboratory operations. Regulatory and accrediting bodies should require the institutions that they regulate to develop and maintain such systems.

5. **Recording and reporting of key adverse events is important and should include both the incidence of preanalytical errors that result in specimen rejection or compromised care and the incidence of needle stick injuries during blood collection.**

   Accurate measurement of errors is essential to improving outcomes and ensuring the safety, quality, and efficiency of specimen collection and testing. Mandatory recording and reporting is the most reliable mechanism to ensure accurate measurement of incidents. In the absence of mandatory reporting, well-designed pilot programs in reporting management that are benchmarked and demonstrate enhanced outcomes should be required and funded.

6. **Medical technologies for strengthening phlebotomy practice specifically, improving overall quality and efficiency of specimen collection and testing, and improving healthcare worker safety, should be evaluated for implementation.**

   - Technology plays an important role in reducing errors in sample collection and preparation, and in reducing risks to healthcare worker safety. Such technologies should be evaluated for implementation.
   - Given their essential role in specimen collection, healthcare workers should be included in the evaluation process.

Background

Phlebotomy Plays a Critical Role in Healthcare Delivery and Patient Care

Phlebotomy, which is the science of drawing blood, is among the most common procedures in healthcare and a core component of diagnosis and laboratory analysis. Estimates indicate that nearly 70% of medical decisions

are based on laboratory results which often rely on phlebotomy to produce a blood sample ready for laboratory analysis[1].

Despite the critical role of phlebotomy, there is often a lack of adequate priority and resources to ensure that healthcare workers who engage in phlebotomy are properly trained on best practice, are aware of and adhere to guidelines, and understand the consequences to patients and their own safety from improper sample collection practices. In many settings, there are few or no training opportunities for healthcare workers who draw blood. Additionally, in many countries there is a lack of strong national guidelines; or guidelines may exist, but there is an insufficient level of awareness, training, and enforcement. In emerging economies where healthcare systems are growing at a rapid pace, it is particularly important to develop policies and programs to support best practice in sample collection.

Poor Blood Collection Practices Introduce Serious Errors into Diagnosis and Laboratory Analysis

Studies indicate that more than 50% of diagnostic errors are attributed to the poor collection and preparation of samples, steps that occur before any laboratory test is undertaken (i.e., in the pre-analytical phase).[2,3,4,5] These errors are often the result of poor phlebotomy practices and they place patients at risk of receiving inaccurate diagnoses, which can lead to inadequate, incorrect, or unnecessary treatment. An estimated 26% of these "pre-analytical" errors have a significant effect on patient outcomes.[6]

Common pre-analytical errors introduced by poor phlebotomy practices

Hemolysis	Hemolysis is the breakage of the red blood cells' membranes, causing the release of the hemoglobin and other internal components into the surrounding fluid. It can be due to pathological conditions in a patient, but is often due to improper specimen collection, processing, or transport.
Contamination	A sample can be contaminated due to improper site preparation, improper handling of equipment – including washed vials and tubes, and errors in sample preparation.
Insufficient sample volume	Improper techniques in drawing blood can result in an insufficient volume being collected to support analysis.
Inaccurate labeling	Errors in labeling can result in improper test and /or patient identification.
Spillage	Spillage can occur during manual transfer of blood to vials or during specimen transportation in loosely sealed containers.
Fibrin clots	The formation of fibrin clots in blood collection containers can interfere with tests and can cause analyzer malfunction over time. Causes include errors in the preparation of additives, mixing or transfer time.

Errors Introduced by Poor Phlebotomy Practices Can Harm Patients and Waste Public Health Resources

Compromised samples must be recollected to ensure accuracy of laboratory results and optimal patient care. Consequently, specimen recollection often leads to delayed treatment, which can be particularly harmful for patients in intensive care or emergency rooms. If compromised specimens are not recollected, errors can be made in testing of these samples which can lead to incorrect clinical decisions, thus putting patients at risk for inadequate, incorrect, or unnecessary procedures. For outpatients, repeated tests require another visit to the clinic, with added inconvenience and costs for travel and potential out-of-pocket expenses.

At the health system level, blood collection errors impose real costs. Studies indicate that blood culture contamination can result in unnecessary antibiotic administration, additional laboratory costs and increased hospital lengths of stay.[1] Such errors waste scarce healthcare resources due to repeat of laboratory tests, unnecessary tests and procedures, and complications that result from inadequate and delayed treatments.[7,8] This can also adversely affect the public's confidence in healthcare systems.

Poor Phlebotomy Practices Present Risks to Healthcare Worker Safety

Poor and unsafe phlebotomy practices also place healthcare workers at risk due to exposure to blood-borne pathogens from needlestick injuries[2]. Such exposures increase risk of transmitting serious infectious diseases such as hepatitis B, hepatitis C, HIV, malaria, and dengue[9,10]. When inappropriate phlebotomy practices result in needlestick injuries, healthcare workers can face severe stress as they await test results to determine if they have been infected[11], and they may require post-exposure prophylaxis that can be expensive and have debilitating side-effects, resulting in absenteeism and additional costs[12].

Common Examples of Poor Phlebotomy Practices

WHO has highlighted several common examples of poor phlebotomy practices that can both compromise the validity of the test result and also pose significant risks to the safety of healthcare workers[13]. These include:

- Pressing the syringe plunger to force the blood into a tube which should be avoided because it creates a level of pressure that can damage red blood cells in the sample
- Using a needle to manually transfer blood into a tube which can cause accidental needlestick injuries to healthcare workers and damage the sample
- Underfilling or overfilling the sample tube resulting in improper ratio of blood to coagulant which can compromise the sample
- Re-using tubes that were not properly cleaned and disinfected which can cause infection
- Unsafe collection and disposal of syringes and needles which can result in accidental needlestick injury

These are but a few of the most commonly cited poor phlebotomy practices that can introduce significant risks to patients and healthcare workers.

Large Variations Exist in Phlebotomy Practices and Training

Phlebotomy practices vary greatly among healthcare personnel, between countries and between institutions and individuals within the same country. These differences include variation in blood-sampling technique, training, use of safety devices, disposal methods, and reuse of devices.[14,15,16] In many countries, there is either no formal training, or a very low level of formal training for those who practice phlebotomy, which puts both patients and healthcare workers at heightened risk of errors and injuries.

Improving Phlebotomy: Guidelines, Training, Performance-Based Certification, and Quality Systems

Achieving best practice in phlebotomy is critical to enhancing patient outcomes, improving health system efficiency and protecting healthcare worker safety – all of which are important to the sustainable management of high quality healthcare systems worldwide. To accomplish this, several key elements should be in place:

[1] Studies have shown lengths of stay increasing by several days due to these errors.

[2] Phlebotomy involves the use of large, hollow needles that have been in a blood vessel. These needles can carry a large volume of blood that, in the event of an accidental puncture, may expose healthcare workers to blood-borne exposures.

- Guidelines and formal training to help standardize practice, reduce health risks to patients and staff, and reduce waste in health systems. WHO recommends structured proficiency training and supervision for all staff who engage in phlebotomy, including groups that historically have not had formal training[17]. This training should be documented and include an understanding of best practice, awareness of the risks from blood exposure and the consequences of poor practices.
- Quality systems that include monitoring, evaluation and incidence reporting should also be established at the healthcare institution level. The design of quality systems can vary according to the resources and size of an institution, but basic elements should exist, including measurement of staff training and proficiency, adherence to guidelines and incident reporting.

Conclusion

Improving the practice of phlebotomy is important for improving patient outcomes, reducing healthcare costs by reducing waste, and minimizing risks to the safety of healthcare workers. Importantly, government policies to advance these goals are essential for sustainable progress. Public policy frameworks that mandate proficiency training, certification, reporting, and quality systems while also establishing professional councils to inform and guide best practice will create the foundation for progress.

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BD Initiatives to Strengthen Phlebotomy Practice

Through BD's Global Health initiative, the Company has launched a variety of Safer Blood Collection training programs, working with partners such as PEPFAR, the US CDC and local government Ministries of Health to train healthcare workers in blood-drawing, specimen handling and safety measures. Some highlights include:

- **Labs for Life Partnership with PEPFAR in Kenya, Zambia and Tanzania**. Building on a long-standing relationship with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), BD launched Labs for Life in 2012, a $20 million, five-year public-private partnership aimed at strengthening laboratories in sub-Saharan Africa as well as India.

  Over the past several years, safe blood collection has become increasingly important in sub-Saharan nations and other developing countries with high incidences of HIV/AIDS. Given the incidence of disease and the substantial increase of blood collection draws for HIV screening and monitoring tests—several million draws of blood per year—it is imperative that healthcare workers follow best practices in blood collection both to avoid compromising patient outcomes and to protect themselves and their patients from blood borne infections, such as HIV.

  Since 2010, the program has reached over 2,000 health workers in over 30 health facilities throughout sub-Saharan Africa. Results to-date show greatly improved blood-drawing knowledge and skills, reductions in improper practices and higher levels of healthcare worker confidence.

- **Center of Excellence in Phlebotomy in Mumbai, India**. In partnership with Grant Medical College and Sir JJ Group of hospitals, the initiative provides a two-day certification course that includes intensive training on fundamental principles of safe blood collection, specimen handling and reporting. The hospital will also house a simulation laboratory that will offer the opportunity to learn and practice in a realistic yet risk-free environment.