



Commentary on International Policies and Practices Health Sciences and the Development of Transfusion Medicine- An International Perspective

Cees Th. Smit Sibinga*

IQM Consulting and University of Groningen, The Netherlands

***Corresponding author:** Cees Th. Smit Sibinga, MD, PhD, FCRCP Edin, FRCPath, IQM Consulting and University of Groningen, The Netherlands, Tel: +31594502670; Email: chsmitsibinga@gmail.com

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Abbreviations: NBTS: National Blood Transfusion Services; TTI: Transfusion Transmissible Infections; ME: Monitoring and Evaluation; UHC: Universal Health Coverage; CME: Continuous Medical Education; CPD: Continuous Professional Development; VNRD: Voluntary Non-Remunerated Donor.

Introduction

The global blood supply is heavily skewed to developed countries, where around 16% of the global population lives. Over 40% of all blood collections occur in Very High or High Human Development Index (VH/H-HDI) countries [1]. Blood donation rates in many Low and Medium Human Development Index (L/M-HDI) countries with around 84% of the global population, represent <1% of the national population [2]. Yet demand for blood in L/M-HDI countries is high largely due to maternal hemorrhage; other causes of anemia, e.g., malaria in under 5-years old children; HIV/AIDS; trauma and traffic accidents, armed conflict, civil war and insurgence [2,3]. This is particularly true in countries where National Blood Transfusion Services (NBTS) face a range of barriers and challenges to collect, maintain and deliver a safe and adequate blood supply [4,5] such as:

a) Weak, outdated, unenforced policies and/or regulations ranging from national-level Blood Policies to standardized work instructions used at the facility-level. No process descriptions. Low political awareness about the role of blood collections, blood laboratory and clinical transfusion services within the broader healthcare system where blood transfusion is often overlooked or under-funded as a component of comprehensive primary healthcare services and not an integrated part

of the health care and academic structure.

- b) Management capacity with poorly described communication channels, delegation of authority/responsibility, and chains of command.
- c) Human resources with major problems due to lacking or imprecise (e.g., “nurse” vs. “blood collection nurse” or “phlebotomist”) job descriptions; gaps in pre- and in-service education and training opportunities; no continuous education programs (CME, CPD); poorly defined or unavailable career structures within the NBTS. Additionally an absence of applied research and development.
- d) Quality management where quality assurance, standards and programs are not in place or not enforced, documented Quality System Management is rudimentary and quality culture is non-existing.
- e) Blood donor culture and population epidemiology shows a low community awareness about voluntary blood donation, blood transfusion and the risks associated with both; lack of outreach and education programs to mobilize and retain an adequate pool of willing blood donors with low behavioural risk profiles (e.g., voluntary, non-remunerated, regular donors) and high community prevalence of transfusion transmissible infections (TTI), e.g., HIV, HBV, HCV, syphilis.
- f) Infrastructure with inconsistent and/or inefficient procurement and supply logistics, especially cold-chain, reagents; lack of quality-assured and standardized laboratory screening for TTI markers; inadequate cross-matching laboratories, and weak/non-existent infection control and waste management systems.

- g) Inappropriate use of blood due to low prescribing thresholds (inexperience, patient demand, tradition, lack of alternatives); wastage and/or unnecessary pressure on supplies due to irrational prescribing practices, and absence of proper traceability.
- h) Hemovigilance non-existing due to incomplete documentation, traceability, and monitoring and evaluation (M&E) systems.
- i) Little interest and funding for applied research, look-back or benchmark studies due to inappropriate data management and a non-developed science-oriented culture.
- j) Ethics show inconsistent use of informed consent for donors and transfusion recipients, regular coercion, poor privacy protection and counseling.
- k) Financing illustrates few functional cost-recovery models (e.g., South Africa), with NBTS budget often embedded in laboratory or clinical services, or outsourced to an NGO (e.g., Red Cross/Red Crescent) and inadequate funding due to demands elsewhere in the healthcare system (e.g., national HIV/AIDS response, vaccination programs) and lack of awareness about continued need.
- l) Sustainability at risk due to dominance of international donors (e.g., PEPFAR, EU, WB, ADB) with time-limited contributions; difficult transition planning in a rapid scale-up environment; few domestic financing options beyond government subsidies.
- m) Considerable knowledge gap with absence of an evidence-base (no applied scientific research) and limited quality education [6].

Approach

In many developing countries blood is often collected, processed and transfused in a policy environment lacking adequate regulatory controls or standards. Blood programs are often fragmented and dependent on independent factors and often limited to specific hospitals, e.g., the availability (or not) of trained staff, funds for procurement, a population of willing blood donors and competent prescribers of blood for transfusion. Research was initiated to study the gaps inherent in these systems and exploring methodologies developed over the last two decades to address knowledge and structural barriers to safe, health system integrated and efficient blood transfusion systems, based on evidence through health sciences oriented research. These projects were done by under- and postgraduate students and fellows as well as PhD fellows, guided by IQM Consulting and other institutions, often in a bilateral between a western University and a University in the country of origin.

Observations

Global blood safety programs have developed a substantial body of (result oriented) methods to address challenges, including:

- a) Assessment techniques and methodologies derived from field-based observations and studies;
- b) Focused Health Sciences research projects (International twinning);
- c) A growing evidence-base in the scientific and “gray” literature on best practices and other strategies to address the technical and policy gaps;
- d) Principles, ethics and technical guidelines for blood donation and clinical transfusion;
- e) Strategies to link blood safety programs and goals to broader development objectives, such as the Millennium Development and Sustainable Development Goals [7,8], Universal Health Coverage (UHC) program [9] and the WHO Model Lists of Essential Medicines, in vitro Diagnostic, and Medical Devices [10-12], WHO EMRO Strategic framework for blood safety and availability 2016-2025 [13], WHO Action framework to advance universal access to safe, effective and quality-assured blood products 2020-2023 [5], WHO Global Patient Safety Action Plan 2021-2030 [14].
- f) Health Sciences oriented research and development projects at Master and PhD level, to build up the evidence base needed to improve and sustain achieved results.

More importantly, international blood safety research projects initiated by various institutions over the last 30 years have identified several key common gaps in blood transfusion systems in countries with poor economics. These gaps include:

1. Weak, outdated or unenforced legal and regulatory frameworks;
2. Low political awareness;
3. A lack of organizational infrastructure, including management capacity, communication channels, and unclear chains of command and job descriptions;
4. Incomplete pre- and in-service education and training opportunities;
5. Lacking or underutilized quality assurance standards and programs;
6. Low community awareness about blood donation, blood transfusion and the risks associated with both;
7. An inadequate pool of willing voluntary blood donors with low behavioural risk profiles for HIV and other blood transmissible infections;

8. Inconsistent and/or inefficient procurement (collection, processing and testing, storage and distribution) and supply logistics, especially cold-chain;
9. Weak hygiene and waste management systems (domestic and bio-hazardous);
10. Low clinical awareness about appropriate and evidence based use of blood and alternatives;
11. Incomplete documentation, traceability and monitoring and evaluation systems, and a low level of applied research (Health Sciences oriented);
12. Inconsistent use of informed consent for donors and transfusion recipients;
13. Inadequate or absent contingency planning (humanitarian, nature, pandemic);
14. Uncertain financing or sustainability planning (corruption).

The role which International donors (e.g., PEPFAR, EU, JICA, WB, ADB) play(ed) in strengthening NBTS in developing countries has been considerable, but has not been coordinated nor comprehensive. For instance the US PEPFAR program has invested since 2004 over \$250 million in blood safety programs worldwide, but investment in infrastructure including governance, stewardship and leadership, research and development has not or inadequately been done [15].

Investments in WHO Aide-Mémoires recommendations [16] have produced impressive though short-term results such as increased collections from VNRD (mostly first time only); decreased prevalence of HIV, HBV, HCV in donated units; development of policies and documentation systems, and application of more structured training programs [2]. However, sustainability remains a major challenge as a result of absence of ownership, incompetent stewardship and leadership, inadequate funding, absence of monitoring and evaluation (mid and long term follow-up) and no or incidental benchmarking for improvement through applied Health Sciences oriented research.

Conclusion

Global blood safety and healthcare development programs have created a substantial body of methods to address the gaps observed and contributed to the development of Transfusion Medicine, strengthening and integrating existing blood supply and consumption systems in national healthcare structures.

Resources include:

- a) Assessment techniques and methodologies derived from field-based observations;
- b) Focused Health Sciences oriented research projects;

- c) A growing evidence-base in the scientific and “gray” literature on best practices and other strategies to address the technical and policy gaps;
- d) Principles and ethical guidelines for blood donation and transfusion;
- e) The WHA and WHO EB resolutions and Recommendations (since 1975);
- f) Strategies to link blood safety goals to broader development objectives such as, the Millennium Development Goals (MDG, 2000-2015)[7], the Sustainable Development Goals (SDG, 2016-2030)[8], the UN Universal Human Rights Declaration (1948) [17], the UHC program [9], the WHO Model Lists of Essential Medicines, in vitro Diagnostics and Medical Devices [10-12], and the WHO Action Plans and Strategic frameworks [5,13,14].

Countries beginning the process to strengthen their blood service (procurement and clinical use) may benefit from this growing knowledge base initiated through Health Sciences oriented research on how to develop evidence-based transfusion medicine ‘vein-to-vein’, integrating in the healthcare structure and eliminating avoidable harm to patients.

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