The Influence and Impact of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) on blood transfusion services in Africa
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Summary, Discussion and Future Perspectives
9.1 Summary

The previous chapters reported on progress Namibia has made over the last decade in improving the safety and adequacy of its blood supply (research questions 1, 4, and 5, text box 1 below). These chapters have also sought to present Namibia’s technical accomplishments (research question 2, text box 1) in the context of changes in Namibia’s economy and the epidemiology of disease burdens (e.g., HIV and malaria). The influence of external donor funding from PEPFAR, currently the world’s largest global health initiative, is also described (research question 3, text box 1), with particular attention given to the new – and potentially unforeseen – risks to sustainability associated with the rapid introduction and subsequent withdrawal of substantial external funding. Lastly, gaps and on-going technical and sustainability challenges globally (research question 6, text box 1) are addressed through an analysis of the recent history of external donor support for blood safety projects. This analysis, which is discussed below, looks at how technical interventions to improve safety may also impact broader health systems issues such as quality or adequacy, and assesses some of the challenging unfinished business (e.g., defining ‘country ownership’) external donors and recipient countries must confront as funding is scaled back or reallocated to other health problems.

Text box 1: Main research questions addressed by this thesis

- How have investments in the blood transfusion service improved access to blood in Namibia?
- What impact have investments in new technologies had on the safety and availability of platelets in Namibia?
- To what extent did PEPFAR subsidize the cost and price of blood in Namibia – and if a subsidizing effect occurred, what challenges may it present for Namibia as PEPFAR funds are reduced?
- Who consumes Namibia’s blood supply – and what diagnoses drive current use?
- Is transfusion surveillance (also known as hemovigilance) possible in Africa? What are the barriers to reporting and the collection and use of data about adverse transfusion events? What lessons can be learned from Namibia’s national hemovigilance system?
- What are the most common gaps in the global knowledge base about blood safety? How do these gaps negatively impact the safety and availability of blood in low-resource settings? What can be done to bridge them?

In Chapter 2, the history of blood transfusion was summarized alongside a catalogue of current strengths, weaknesses, opportunities and threats facing the global blood supply. Special emphasis was placed on identifying gaps in developing and resource-limited countries that have precluded more rapid advances in the safety and adequacy of national blood supplies, and have inhibited progress toward the system strengthening objectives recommended by WHO’s Aide-Mémoire. [1] This chapter sought to make clear distinctions between challenges
due to healthcare worker capacity, which in many countries are less of a threat due to external technical assistance and staff who have benefitted from higher education and training in Europe or the United States, and threats linked to weaknesses in non-technical aspects of health care systems, including leadership, human resource management and supervision; routine administration and financial management; procurement systems; logistics; and the absence of reliable electricity and water supplies. That blood services struggle to recruit and retain blood donors, and to meet routine and emergency blood demand is largely, this chapter argues, a function of administrative deficiencies and political will. While the PEPFAR experience has demonstrated that rapid progress can be made when these issues are addressed, [2, 3] this author (as a technical advisor within the PEPFAR blood safety initiative since 2006) is mindful of the possibility that the injection of more than $500 million may have cast a temporary shadow over these problems without actually addressing them in a sustainable manner. In conclusion, this chapter argues that a deeper crisis exists in African healthcare systems: Namely that African governments continue to face substantial challenges mobilizing adequate funding for 100% of core healthcare services in the face of large, expensive, HIV/AIDS, tuberculosis and malaria budget requirements, and plateauing or declining external donor support.

Chapters 3, 4, and 5, as well as Chapters 7 and 8 described and investigated the incredible technical progress that a geographically large, socially and economically diverse African country was able to make with a combination of external donor support, a functional domestic cost-recovery system, and a coherent national strategy. In each of these chapters, limitations are discussed around the data and how they may (or may not) be generalizable to the rest of Africa. Specific attention is paid to data quality, and the chronic challenge African blood services have collecting data and managing national databases. While Namibia clearly benefitted from a functional computerized information system, it, too, remains subject to the imperfect logistics of transferring paper blood request forms to the capital, and the risk of human error during the transcription process. Still, whether specific data on blood utilization or cost-recovery are applicable to neighboring countries or not, the data presented in these chapters send two clear messages to resource-limited blood services in Africa. First and foremost, it is possible to compile and analyze national data on the distribution and utilization of blood in an African country. Second, having a computerized information system is essential to complete these analyses. These are simple messages, but reflecting on nearly a decade of experience as a program officer within PEPFAR, the process of developing these chapters has made the author realize that simple interventions may actually be the most important ones.

9.2 Discussion

This dissertation has focused extensively on improvements to the safety of Namibia’s blood
### Assumption
1) Developing or strengthening healthcare services, whether a blood service, malaria prevention intervention or an antiretroviral drug program, requires governments and external donors to understand program costs, appreciate how current and future demand will influence costs, and develop policies and plans to ensure consistent (and sufficient) funding.

Since 2004, Namibia has invested heavily in its cost-recovery system, including the development of a mathematical pricing model and the creation of a National Blood Programme under which stakeholders discuss annual production costs and unit pricing. The studies presented in the preceding chapters have also contributed to a better understanding of current and, potentially, future demand for blood.

In 2009/2010, a breakdown in communications between PEPFAR, NAMBTS and the MOHSS resulted in a short-fall in the MOHSS budget to cover invoices from NAMBTS. Stakeholders were able to identify and address this gap thanks to routine contacts via the National Blood Programme structure, however, this mini-crisis highlighted the long administrative process to request additional government funding for healthcare.

2) In the context of sub-Saharan Africa, financial and human capacity resources for health are generally scarce.

Since 2004 and 2009, a strategy that allowed the service to use domestic resources to fund the construction of a new blood center. Recent graduates from the Polytechnic of Namibia's medical laboratory degree program have been hired to work in the NAMBTS serology, ID-NAT and component production laboratories.

Namibia suffers from a chronic shortage of trained healthcare workers [6], and remains highly dependent on expatriate expertise for high-level technical jobs. World-wide, human resource costs generally increase over time due to increasingly sophisticated job requirements, inflation, and competition for scarce labor resources – all phenomena Namibia will face in the future.

3) Financing for healthcare in sub-Saharan Africa is usually achieved through a combination of domestic and external funding sources – with external donors often creating subsidies that recipient countries are unable to fully absorb.

PEPFAR's subsidizing effect allowed NAMBTS to leverage domestic resources for large capital infrastructure projects, and permitted an expansion of blood use in lower income regions.

Namibia's government has demonstrated a high level of commitment to absorb HIV/AIDS costs previously assumed by PEPFAR or the Global Fund, [2] but as the country approaches the 15% Abuja declaration target, healthcare system planners must be mindful of the potential that demands for other social services, e.g., education, may increase competition for scarce domestic resources.

4) Functional cost-recovery systems are rare in African blood services, but are a potentially powerful solution to financing challenges faced by blood services in low-resource settings.

Namibia's cost-recovery system allows NAMBTS to access resources from three diverse sources: The public sector, private insurance schemes and patients' out-of-pocket expenditures.

Unit prices charged must be renegotiated with the Ministry of Health and private insurance companies on an annual basis, and revenue is 100% dependent on consumers' willingness and ability to pay.

5) Technology can (and probably must) play a role in achieving Africa's blood collection goals – but the costs associated with introducing and sustaining the use of such technologies should be carefully considered to avoid creating a sustainability gap.

Apheresis equipment was essential to converting Namibia's platelet supply from pooled to single-donor units; ID-NAT platforms have provided an extra level of security in a country with historically high HIV prevalence and incidence.

The use, maintenance and replacement of advanced technologies raises the sustainability bar for cost-recovery and the recruitment and retention of trained staff.

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**Table 1a: Mapping research assumptions (1-5) against Namibia’s progress and challenges for the future**

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<td>2)</td>
<td>NAMBTS used PEPFAR funds to subsidize core technical staff salaries between 2004 and 2009, a strategy that allowed the service to use domestic resources to fund the construction of a new blood center. Recent graduates from the Polytechnic of Namibia's medical laboratory degree program have been hired to work in the NAMBTS serology, ID-NAT and component production laboratories.</td>
<td>Namibia suffers from a chronic shortage of trained healthcare workers [6], and remains highly dependent on expatriate expertise for high-level technical jobs. World-wide, human resource costs generally increase over time due to increasingly sophisticated job requirements, inflation, and competition for scarce labor resources – all phenomena Namibia will face in the future.</td>
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<td>6) Changing patterns of disease will influence how much blood is needed by African countries, and how available blood stocks will be used.</td>
<td>During the study period NAMBTS did not report substantial gaps in its ability to meet current demand for blood and components, even during a period in which new cancer treatment facilities and surgical services were launched in Namibia. Blood stock targets were generally sufficient to cover up to nine days of demand per facility, but would dip to fewer than nine days during holiday periods when donations would decrease.</td>
<td>Data are not currently available about unmet demand for blood units, a gap that prevents a true understanding of supply and demand in Namibia. Information about patient outcomes following transfusion are also lacking, making assessments of the appropriate use of blood difficult. Future blood stock target setting and other planning should include operational research to investigate these two important questions.</td>
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<td>7) Blood and blood components are unevenly distributed globally and within individual countries (e.g., urban areas tend to benefit more from scarce blood stocks than rural areas).</td>
<td>Namibia successfully increased the number of rural facilities providing transfusion services and the number of units consumed overall by rural facilities. However, disparities remained between urban hospitals, which consumed the majority of blood issued between 2008-2011, and rural facilities.</td>
<td>As Namibia’s healthcare system continues to mature and add specialty services, it is likely that those services will remain concentrated in the capital and other urban centers. The expansion of private sector healthcare services, which consume blood from the same NAMBTS stocks, may also create unintentional competition between patients seeking (and paying for) care in the private sector, and those receiving government subsidized care in the public sector.</td>
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<td>8) Effective data systems are an essential prerequisite to document progress and gaps.</td>
<td>The NAMBTS blood donor database and laboratory information system was developed in Namibia based on a lot release algorithm designed by NAMBTS staff. To date it has safely processed more than 100,000 donations without a reported cross-matching error. The NAMBTS invoicing and financial management data system is also unique in Africa and essential to support the cost-recovery system.</td>
<td>Validation of blood service computer systems is an important element in a national blood service quality management system. While the NAMBTS system has proved its effectiveness through daily use over the course of the last decade, it has not been formally validated by an external evaluator. The NAMBTS data system is also dependent on consistent transcription of variables from paper-based blood request forms, an activity that requires additional staff.</td>
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<td>9) Investments made in the name of preventing the spread of a single pathogen or disease (HIV/AIDS) can have positive ripple effects across a country’s broader healthcare system – but single disease programs may also divert funds from other pressing healthcare issues (e.g., maternal mortality).</td>
<td>Improvements in the availability of blood in Namibian regions neglected prior to independence were linked to funding provided by PEPFAR in support of the national HIV prevention strategy. Similar improvements in the number of clinicians exposed to training for quality management, internal auditing, and appropriate clinical use of blood were also made possible by HIV prevention funds.</td>
<td>In Africa causal pathways have not been confirmed between investments in blood safety and improved patient outcomes or other measures of healthcare system efficiency or effectiveness. This is largely due to a paucity of studies on patient outcomes. Future research in Namibia and elsewhere should look at methods to establish these causal associations.</td>
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<td>10) The concept of “sustainability” is dependent not only on a stable source of funds, but on adequate human capacity, political will, data to drive evidence-based decision-making, and leadership.</td>
<td>The progress demonstrated by Namibia’s National Blood Programme (catalogue of materials produced since 2005 follows below) demonstrates a high level of political will and capacity to support the blood service. The NAMBTS data systems also provide strong and easily accessible data for decision-making and planning.</td>
<td>Revision of guidelines and policies, as well as training for new health care workers (within the blood service and in the broader healthcare system) are resource dependent, but can be accomplished with adequate leadership. Much has been done in other areas of global health to understand “sustainability.” NAMBTS and the global blood safety community should build relationships and invest in studies to ensure blood and blood services are included in these broader global analyses.</td>
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**Table 1b: Mapping research assumptions (6-10) against Namibia’s progress and challenges for the future**
supply during the period of intensive PEPFAR support – positive changes that have been observed and reported in other large PEPFAR-supported countries, including Cote d’Ivoire [4] and Kenya. [5] The chapters summarized above have also sought to illustrate how Namibia addressed the 10 assumptions made around this dissertation’s key research questions (text box 1, above). The following tables (Tables 1a, 1b) map those 10 assumptions against specific progress documented in Namibia, and against remaining challenges the blood transfusion service and the Ministry of Health may face as both organizations plan for the future and make choices about expanding services, training staff, and upgrading equipment.

As PEPFAR enters its second decade and realigns its prevention strategy to address the main drivers of national epidemics (e.g., key populations, heterosexual transmission, mother-to-child transmission), blood services in countries (like Namibia) that have benefitted from PEPFAR funding since 2004 will face the challenge of sustaining current levels of safety, adequacy and quality with reduced external funding. Indeed, since 2010, as PEPFAR has reduced blood safety funding across Africa, evidence is emerging that national blood stocks remain at risk due to deficiencies in domestic budgets. As recently as January 2015, a Kenyan newspaper quoted the head of the Kenyan National Blood Transfusion Service (which has received $59.4 million from PEPFAR since 2004) as saying blood shortages were linked to “a delayed procurement process,” which forced regional blood centers to send specimens to Nairobi for HIV and other infectious disease testing. [8] Similar shortages were reported in Botswana ($14.7 million in PEPFAR support since 2004) in 2013, where a shortage of test kits lasted “several weeks,” forcing the government to “halt blood transfusion at government health facilities,” according to local news reports. [9] In 2014, the blood service in Cote d’Ivoire published a review of shortages in the national blood supply which concluded that, [emphasis added] “[t]he inability of the NBTS of Ivory Coast to meet national requirements for labile blood products is not due to the fact that the potential donors and infrastructure do not exist but rather to the lack of material for blood collection and motivation of blood donors, in other words logistical difficulties.” [10] Personal communications received by this author from PEPFAR partners suggest that other routine blood service operations, such as blood donor mobilization and the operation of automated testing platforms, are also increasingly at risk due to budgetary short-falls for basic resources, such as fuel for mobile blood drives, and reagents (names withheld by author at the request of sources).

To help countries address funding gaps for core activities such as lab reagent procurements, as well as technical assistance to support human capacity development, some kind of international donor support will likely need to be mobilized to fill in behind the receding PEPFAR program. However, as noted by global health leaders like Paul Farmer [11] and other evaluations of countries’ lack of progress toward the MDGs, [12] recipient countries must also re-evaluate current domestic spending plans in order to emphasize health.

Namibia’s government has set a positive example within the African region,
ly meeting reductions in external donor support for HIV/AIDS, malaria and tuberculosis with substantial increases in domestic funding for healthcare. [7] But, as noted in the introduction, limited progress has been made by most African governments (including Namibia) to meet the full commitments for health made in the 2001 Abuja Declaration. Signatories pledged to “ensure that the needed resources [for healthcare] are made available from all sources,” and committed “to set a target of allocat[ing] at least 15% of our annual budget to the improvement of the health sector.” Of note, the declaration also called on industrialized donor countries to ramp up commitments to provide 0.7% of Gross National Income (GNI) to International Development Assistance (IDA). Over the next 10 years, WHO reported that 26 African countries had “increased the proportion of total government expenditures allocated to health,” but only one, Tanzania, had achieved the “at least 15%” target. [13] Nine African Union countries had “reduced their relative contributions of government expenditures to health.” [13] International donors helped make up much of the deficit, but the 2011 WHO report noted that while overall IDA for health increased during the last decade, “the benefits are not spread evenly, with a few countries receiving relatively large contributions, and some virtually nothing.” [13]

This unevenness in the distribution of IDA is also apparent in the choices external donors have made to prioritize the prevention or control of certain diseases, often at the expense of other healthcare needs. [14] Historically significant initiatives like PEPFAR certainly contributed to this lopsided acceleration in IDA. But as has been discussed throughout this thesis, even though massive financial investments like those made by PEPFAR have been necessary to help countries pull back from the edge of an HIV/AIDS disaster, they have not been sufficient to address Africa’s many other structural and systemic healthcare needs. [15-17] Indeed, while the proportion of IDA dedicated to HIV/AIDS has consumed a greater proportion of available funding, average IDA contributions from donor countries hit hard by the 2008 global financial crisis, actually retreated from 0.4% of GNI in 2001 to an average of 0.31% of GNI by 2009, according to WHO. [13] In addition to criticism about insufficient IDA contributions to global health, others have criticized the way in which still substantial sums of HIV/AIDS-specific IDA have been distributed and used (or misused). In 2010, Lu et al. published a scathing review of IDA (which they referred to as Direct Assistance for Health, or DAH) provided directly to governments. The systematic review of IDA provided by industrialized countries to developing countries between 1995-2006 described an “overall ...negative and significant effect on domestic government spending on health such that for every US$1 of DAH to government, government health expenditures from domestic resources were reduced by $0.43 (p=0) to $1.14 (p=0).” [18] The study also found that IDA/DAH provided directly to non-governmental organizations (NGOs) had a “positive and significant effect on domestic health spending,” but in both cases called for strengthened systems to monitor health impact. [18]

The correlation between adequate financing and progress toward health-related objec-
tives such as the Millennium Development Goals (MDG) – or blood safety – cannot be overstated. The WHO’s 10-year evaluation of the Abuja Declaration grimly concludes with a projection that “only three countries are on track with respect to the health MDGs whereas 27 countries have no or insufficient progress.”[13] This gloomy prognosis has also been picked up by researchers in the blood transfusion field. In 2008, Bates et al. conducted a systematic review of maternal hemorrhage reports from sub-Saharan Africa. [19] The authors found quantitative evidence that more than a quarter (26% (16–72%)) of maternal hemorrhage deaths were linked to blood shortages. “Reasons included non-affordability of blood, lack of blood donors, unwillingness of relatives to donate and inadequate supplies and transport.” The authors concluded that “better financing mechanisms and more efficient management systems” were among the leading potential interventions to reverse this trend.

For African countries struggling with major structural challenges including (but not limited to) the migration of trained healthcare workers to developed countries, [20-22] crumbling or inadequate infrastructure, [23, 24] and weak procurement and supply chain systems, [25-27] as well as competing challenges from world-leading burdens of infectious disease and maternal and child mortality, [28-30] the often diffuse and incomplete attention paid to national blood transfusion services is somewhat understandable. In 2014, South Africa’s Minister of Finance, Nhlanhla Nene, summarized the challenges faced by developing countries worldwide: “Governments everywhere face difficult choices because the gap between what is required and what can be afforded is very wide. And so we have to be steadfast in our resolve to do more, together, with less.”[21]

The sustainability challenges described above not only threaten the safety of blood supplies in Africa, but cast a dark shadow over the pressing issue of adequacy. As noted in the introduction, most blood collections occur in wealthy, industrialized countries which account for a minority of the global population – while collections in the countries where 85% of the global population live are insufficient. [31] Addressing this imbalance is a multi-faceted challenge, especially in countries with relatively high population growth rates, substantial incidence of malaria and maternal hemorrhage, huge proportions of young people (many of whom will live longer and experience higher rates of chronic diseases), and increasingly sophisticated healthcare systems capable of providing more complex services (e.g., Caesarean sections, cancer therapies).

Figure 1 clearly illustrates this challenge: Between 2003 and 2010, nine PEPFAR-supported countries saw aggregated blood collections increase 86%, from 396,498 units in 2003 to

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737,054 units in 2010. However, during the same period, adequacy – as represented by the mean number of units collected per 1,000 population – remained relatively flat, ranging from 3.9 to 5.7 units per 1,000 population. Only two countries, Namibia and Botswana, were able to achieve the 10 per 1,000 minimum adequacy target recommended by WHO. Because of robust population growth rates, the rest of the continent struggled to meet half of the estimated need for blood.

As PEPFAR and other international development groups consider effective ways to support blood services in Africa in the future, significant attention should be paid to understanding the difference between countries’ estimated ‘need’ for blood, and the level of demand national health care systems can actually support. While the WHO target of 10 whole blood units collected per 1,000 population has been a useful guide for countries as services begin to scale-up collection, screening and distribution services, very little is known about health-care systems’ absorptive capacity for blood and blood components. As noted above, Namibia’s data system did not allow for an analysis of cases in which blood was needed but not available. Anecdotally, Namibian transfusion facilities did not report substantial instances of unmet demand, but shortages of short shelf-life products like platelets must have occurred.

A similar national blood utilization study recently completed by CDC in Tanzania (data have not yet been published) found a surprisingly small gap between supply and demand in public and private transfusion facilities. Based on preliminary analysis of data from 42 transfusion facilities, blood units were not available to match approximately 14% of adult requests. If that estimate is a true reflection of supply and demand nationally, Tanzania would need to collect approximately 29,300 additional whole blood units per year. Increasing collections by that amount would bump Tanzania’s current per 1,000 population ratio up from 3.5 units per 1,000 population (at 171,300 whole blood units per year in 2014) to 4.0 units per 1,000 population, a figure still far below the recommended target of 10 units per 1,000 population. But is that how Tanzania should define adequacy? It could be, at least for the present, based on current absorptive capacity. But at the same time it likely masks unmet need due to other barriers to patients’ ability to access healthcare facilities where transfusion services are offered. In either case, understanding actual consumption patterns, access-to-care barriers, and post-transfusion patient outcomes will be essential for both external donors and recipient countries as they plan future interventions in Tanzania and elsewhere. Indeed, ironically, the sustainability of future blood collection targets and operational plans may in part depend on countries not collecting blood that goes to waste.

South Africa, a major recipient of PEPFAR support, is excluded from this example since its annual blood collections are so large as to skew and distort the progress made by other countries in the sub-Saharan African region. Tanzania and Nigeria are also excluded from this figure since they did not report blood collection data to PEPFAR in 2003 or 2004.
**Figure 1: Minimum, mean, and maximum number of units collected per 1,000 population, nine PEPFAR-supported countries in sub-Saharan Africa, 2003-2010**

* Mean, Maximum, and Minimum refer to number of whole blood units collected per year per 1,000 population.

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**9.3 Future Perspectives**

**9.3.1 Namibia**

The Blood Transfusion Service of Namibia operates one of the most sophisticated blood services in sub-Saharan Africa. By 2012, the final year evaluated for the purposes of this dissertation, Namibia’s unique domestic financing system – cost-recovery with financial inputs from the Namibian government, a robust private insurance sector, and out-of-pocket payments by individual patients – was effectively self-sustaining. However, the country faced the prospect of substantial unit price increases for red blood cells as PEPFAR withdrew and NAMBTS invested heavily in laboratory infrastructure to return infectious disease screening to Windhoek (all screening had been performed by the South Africa National Blood Service during the study period covered by this dissertation). In 2013, Namibia joined South Africa as the second country in the region to operate a national laboratory that screens every unit of blood in the
national supply for HIV and viral hepatitis markers by individual donation nucleic acid testing (ID-NAT). The advantages of ID-NAT as a means of reducing residual risk due to the HIV window period in high prevalence settings has long been established in South Africa, [32] and reaffirmed in the study of safety among Namibian platelet donors in Chapter 5.

In addition to the use of technology to reduce the chance of HIV window-period infected units entering the national blood supply, much of Namibia’s progress over the last decade has been linked to work to strengthen the policy and regulatory environment. These investments also reflect Namibia’s collaboration with PEPFAR on issues related to the political ownership and stewardship “dimension” described in PEPFAR’s transition strategy. The revision of Namibia’s National Blood Policy in 2007 reaffirmed the Ministry of Health’s commitment to a coordinated approach to blood collection, screening and distribution, with NAMBTS activities overseen by a National Blood Programme (NBPr) – a body charged with “ensuring” support for policy implementation, infrastructure development and resource mobilisation at national and international level.” Within the NBPr, a Core Working Group made up of representatives from NAMBTS, the Ministry of Health and Social Services (MOHSS), the Namibia Institute of Pathology (NIP), and external partners (WHO, CDC), was established to finalize the National Blood Policy and shepherd the development of additional regulatory and professional guidance documents. Between 2006 and 2010, this Working Group successfully completed and published revised Guidelines for the Appropriate Clinical Use of Blood and Blood Products in Namibia (2006), a Strategic Plan for the National Blood Policy Implementation, 2007/8-2009/10 (2008), National Blood Programme Guideline Documents (2010), and a revised Standards for the Practice of Blood Transfusion in Namibia (2010).

On-going investments in human capacity development and quality improvement can also be


24 The NBPr Guideline Documents for Namibia included documents covering the following technical areas:

1) Guidelines on the level of blood transfusion services to be delivered to the hospitals (a document covering the kind and level of services NAMBTS would provide to hospitals as the sole provider of blood in Namibia).

2) Guidelines for the Management of Health Care Risk Waste (a document advising NAMBTS and transfusion facilities on the management of potentially infectious waste accrued from the collection, processing, storage and use of blood and blood products).

3) Quality Management System (an outline of the scope and structure of a blood service quality management system).

4) A Code of Ethics and Professional Conduct for the National Blood Programme (a Namibian code of ethics adapted from ISBT, European Commission and WHO standards).

5) Monitoring and Evaluation Plan for the National Blood Programme (a document providing case definitions, programmatic rationale, and indicators with which national blood services should be monitored and evaluated).
linked to the publication of the standards and guidelines listed above. Specifically, NAMBTS produced and implemented a national training program to support the implementation of the 2010 blood transfusion standards document. Between 2005-2009, NAMBTS and WHO (a PEPFAR-supported technical assistance provider) trained 177 doctors, 359 nurses and 58 laboratory and support staff nationally using a locally developed course called GACUB, or Guidelines for the Appropriate Clinical Use of Blood and Blood Products. The GACUB approach was refined starting in 2010, when NAMBTS medical officers launched the Better and Safer Transfusions course, also known as BeST, a training approach adapted from a similar quality improvement course developed in Australia. Between 2010 and 2012, more than 850 doctors, nurses and other healthcare workers (e.g., laboratory and pharmacists) were trained.25

The availability and use of blood study published in Chapter 3 suggests a strong temporal association between the launch of these training programs and improvements in clinical use in Namibia. For example, during the study period, the mean number of units used per transfusion increased from less than two red cell units per patient nationally in 2003, to 2.6 units per patient in 2011. While it was impossible to describe a causal link between the introduction of a comprehensive training program and this change, the temporal association cannot be ignored – and should be tracked by surveillance and future evaluations. The strength of Namibia’s training program was further confirmed in 2012, when a revised BeST course added modules on hemovigilance and the identification of adverse transfusion reactions. These modules were developed in direct response to the 2010 studies published in Chapters 7 and 8 which found substantial under-recognition and under-reporting of adverse transfusion events. Additional research is needed to better understand why under-recognition persisted despite the high number of clinicians trained via GACUB and BeST since 2005. Initial suspicion pointed to the relatively high level of turnover among physicians (many doctors working in Namibia are expatriates), however, the lack of funding for regular and refresher training should also be investigated as a possible reason for the low capacity to identify adverse transfusion events documented in Chapter 8.

The development of the Monitoring and Evaluation plan in 2010 laid the groundwork for Namibia’s successful application for AABB accreditation, and played a role in the development of the AfSBT standards, which were piloted in Namibia in 2011/2012. [33] While the indicators described in the 2010 document reflect core surveillance elements collected by the WHO Global Database on Blood Safety and others, including PEPFAR, the Namibian document also had the foresight to include indicators to track the development of Standard Operating Procedures (Namibia Monitoring & Evaluation Plan, 2010, Table 3, Procedures, pg. 30). The BeST project also introduced Namibian transfusion facilities to the practice of internal and

external auditing. These audits, started in 2010, engaged healthcare workers for the first time in a feedback process to evaluate their own practices and participate in activities to remediate any deficiencies. The audits lead to the development of the next generation of national documents, including a Maximum Surgical Blood Ordering Schedule, specialized procedures for nurses engaged in blood transfusions, uniform formats for information entered on requisition forms (including transfusion indications). The audits also stimulated discussions within the Ministry of Health about the use of standardized forms and patient identification tools (e.g., wristbands), as well as techniques and equipment to improve the blood cold chain after units are dispatched from a blood bank to a hospital ward. These projects to raise awareness also led to the creation of permanent hospital-based transfusion committees charged with overseeing transfusion safety and reporting to the NAMBTS medical officers who managed the national hemovigilance system – all concrete steps on the sometimes difficult-to-quantify pathway towards local 'ownership.'

Beyond the engagement of in-service clinical staff to adopt and support quality management interventions, NAMBTS has also taken important steps to support longer-term national efforts to reduce the country’s dependency on foreign healthcare workers and build national capacity to train laboratory and other medical professionals. In 2012/13, graduates from the Polytechnic of Namibia’s medical technology degree program (also supported by PEPFAR) joined NAMBTS as the first cohort of young Namibians trained in laboratory science in a Namibian university.

These improvements show that NAMBTS remains committed to sustaining and building on the progress achieved since 2004 (and may serve as a model for other countries seeking accreditation to emulate), but they will come at a price. With the re-opening of the infectious disease screening laboratory in Windhoek, NAMBTS estimates production costs have increased by as much as 30% (personal communication, NAMBTS finance department) – costs that will eventually have to be passed on to consumers (the largest of which is the Ministry of Health) via the cost-recovery system. The transition away from the contract-based testing arrangement NAMBTS previously had with SANBS will merit further study, especially if, as seems the case, this change resulted in higher, not lower operating costs for NAMBTS. Direct PEPFAR support to NAMBTS is scheduled to be phased out by the end of fiscal year 2015 – a transition that has been at least five years in the making, but which, as noted in Chapter 6, may contribute to unit price increases.

Looking to the future, the past may also be useful prologue for NAMBTS and Ministry of Health planners in Namibia – and for leaders at Namibian research institutions where students and faculty will carry much of the burden associated with filling a research gap identified by Bruce Noden in 2012. [34] Noden’s paper reflects the relative paucity of biomedical literature from and about Namibia (and by Namibian authors). In a review of 450 publications that met biomedical and Namibian search criteria between 1995 and 2009, just over a quarter (28.6%) had a Namibian author and nearly half were conducted by researchers who were not
based in Namibia. If Namibia is to tackle emerging threats to the blood supply, such as Hepatitis E, or prepare for new demands for blood products, such as radiation-associated cancers, new research capacity will be needed to update findings from the pre-independence era, and expand the current national knowledge base.

9.3.2 The future of blood safety within PEPFAR

Globally, the identification and removal of HIV-infected units from circulation must remain a priority for all countries, as called for in numerous World Health Assembly resolutions. However, in countries that have benefitted from PEPFAR’s substantial investments, the proportion of overall HIV incidence attributable to blood transfusion is very likely smaller today than it has been in a generation. Recent estimates based on UNAIDS modeling suggest that the proportion of HIV incidence attributable to blood transfusions in countries as diverse as Morocco, Kenya, Thailand and Burkina Faso may range between 0.6% and 1%. [35-37] A number of questions have been raised about the accuracy of estimates produced by these models, [38] but even with the models’ limitations, it is likely that in countries that have adopted WHO guidelines on donor recruitment and laboratory screening blood transfusion’s contribution to incidence is no longer as high as the 5-10% of incidence estimates historically cited by transfusion studies. However this may not hold true in countries where HIV rapid test kits remain the norm for blood screening.

The likelihood that transfusion contributes less to national HIV epidemics is good news, and is due to a combination of factors, including better laboratory screening, and, potentially more importantly, better donor selection. But it presents a difficult programmatic challenge as PEPFAR realigns its strategy. To wit: If unsafe blood is no longer a driver of national epidemics, how can it be justified within a strategy that seeks to achieve epidemic control among populations that contribute the greatest proportion of new cases each year? The answer to this question deserves a dissertation of its own, but can be summarized with a simple comparison with male circumcision, another PEPFAR-supported bio-medical intervention to reduce the rate of new HIV infections. Like male circumcision, blood safety programs are heavily dependent on trained health care workers, specialized equipment and facilities, complex logistics, a supply chain that must be continually refreshed, and monitoring and evaluation. However, unlike circumcision, which in most cases results in few complications and is a per-

26 The current UNAIDS Modes of Transmission model likely underestimates the contribution of unsafe blood transfusions due to a number of incorrect assumptions built into the model, most notably the assumption that each transfusion event be treated as a single exposure to a single ‘partner.’ This assumption overlooks the reality that most transfusion recipients receive more than one unit of blood per transfusion event, and that each unit was likely donated by a different donor (i.e., each event should be equated with exposure to multiple ‘partners’). The UNAIDS model is available from the following link: http://www.unaids.org/en/dataanalysis/datatools/incidencebymodesoftransmission.
manent, one-off procedure, donated blood is not only biologically perishable, but in constant high demand. This requires the same cycles of donor mobilization, collection, screening, storage, and distribution processes to repeat themselves on a daily, weekly, monthly and yearly basis – *forever*. In short, ensuring the safety of a national blood supply requires a permanent, consistent, and, as described in Chapter 6, ever-increasing, budget to succeed. And, as noted above, future international development efforts to support “blood safety” around the world should be expanded to address issues of adequacy and appropriate use of blood, as well as the reduction of transfusion-transmitted infections.

The realignment of PEPFAR’s global prevention strategy around emerging evidence that early and consistent antiretroviral therapy – also known as ‘treatment-as-prevention’ – can substantially reduce sexual transmission in sero-discordant couples, [39, 40] is certainly one of the keys to breaking the back of the 40 year-old global HIV/AIDS pandemic. However, as a recent HIV outbreak in Cambodia illustrates, [41] medical transmission remains a potentially explosive mode of transmission. In the 2015 Cambodian outbreak, 212 cases of HIV in a low-risk population were linked to unsafe injections and infusions – a substantial number for a country that has reported declining incidence and estimated there would be only approximately 899 incident infections among high-risk groups (e.g., commercial sex workers, persons who inject drugs, and their partners) in 2015. [42]

Apply this model to countries where procurement or other issues reduce the scope or quality of laboratory screening for donated blood, and the number of incident infections attributable to medical transmission could also potentially increase. Indeed, this may already be happening in parts of Africa. As described by Bloch et al. in a review of HIV screening in 44 blood bank laboratories in 12 African countries, test kit performance (especially rapid test kits) and laboratory proficiency issues were linked to “variable and deficient” sensitivity in approximately 40% of the 44 laboratories surveyed. [43] This is an alarming finding, in part because a number of those laboratories had received substantial support from PEPFAR, but also because it suggests that funds for external quality assurance and/or routine proficiency testing are not part of domestic budgets as projects are transferred from external donor support to national “ownership” – and, therefore, must be added to the list of items countries must fund in the future.

As PEPFAR enters its second decade, the blood safety initiative is pursuing a number of strategies to remain relevant within the HIV/AIDS context. It is also seeking to mobilize other donors and resources from non-HIV/AIDS budgets, e.g., maternal and child health, to address the safety, sustainability, and adequacy challenges described above.

To respond to the reduced funding environment, a new framework has been developed to focus PEPFAR’s blood safety projects on so-called “Core” activities, i.e., those activities that directly contribute to epidemic control goals, or to specific sub-objectives such as quality assurance. One of these sub-objectives is accreditation, the attainment of which requires blood services to demonstrate use of quality management systems and compliance with accepted
standards of practice. The PEPFAR-supported African Society for Laboratory Medicine (ASLM) has developed a structured diagnostic laboratory improvement program called Strengthening Laboratory Management Toward Accreditation, or SLMTA. While some PEPFAR-supported blood bank laboratories have enrolled in SLMTA, the PEPFAR blood safety project recognizes that SLMTA (and other diagnostic laboratory standards, such as ISO 15189) does not cover all blood bank activities, such as donor mobilization, collections, component production, storage and distribution. To bridge the gap between SLMTA/ISO standards and the needs of a modern blood service, PEPFAR’s new blood safety technical assistance framework has prioritized working with the African Society for Blood Transfusion (AfSBT) to promote the AfSBT’s blood bank-specific Step-Wise Accreditation System. [33] The new technical assistance framework includes three primary objectives (Figure 3), all of which contribute to the ultimate outcome – accreditation. The three outputs are:

1) **Development of Accreditation Roadmaps.** These roadmaps will guide work plans to focus activities on specific gaps requiring remediation in order to qualify for blood service accreditation. These gaps will be identified through a self-assessment process.

2) **External Quality Assurance (EQA).** Participation in laboratory EQA is an accreditation requirement. PEPFAR will increasingly redirect bi-lateral funds to support countries to identify and enroll in EQA.

3) **Blood service information systems.** While information systems are not required for accreditation, the use of electronic data management tools are essential to routine quality management, and longer-term monitoring and evaluation and assessments, the results of which can be used for quality improvement. Implementing cost-effective, robust and sustainable information systems is a priority. Technical assistance will focus on helping countries consider, select and implement appropriate systems.

It remains unclear how the transition framework proposed above will work. In late January 2015, the level of PEPFAR funding available to support technical assistance activities had dipped below a sustainable level, leaving many of the technical assistance partners facing imminent staff lay-offs and project closure. Similar challenges were reported by field offices, where delayed and reduced blood safety budgets were impacting NBTS partners’ ability to fund operations. Without a substantial infusion of funds from external donors including PEPFAR, the vision described above may remain a drawing board idea. Similarly, reform appeals raised by others, [44] especially proposals for innovative solutions to chronic challenges such as donor mobilization, will be unlikely to move forward in an environment of constrained resources. Research will also be crippled, including PEPFAR-supported WHO projects to create workable models for estimating national blood need, or studies to quantify blood use by HIV-infected patients enrolled on antiretroviral therapy.

Resource mobilization efforts continue internally and externally, but the first quarter of 2015
has laid bare in harsh and concrete terms the sustainability risks alluded to throughout this dissertation and in the chapters. The author hopes this essay may serve as a modest call to arms for donors and others interested in supporting the sustainable development of blood transfusion services in Africa. Inherent in this appeal is, of course, a call for greater appreciation of the contributions blood services make to broader development and sustainability goals (e.g., MDGs and the proposed ‘post-2015’ UN Sustainable Development Goals27). After 10 years in which PEPFAR support successfully allowed countries in sub-Saharan Africa to make measurable progress toward safer and more available blood supplies, much remains to be done. While PEPFAR’s measurable success on programmatic indicators linked to operational investments (e.g., spending on new vehicles or additional blood collection bags led to increases in net national blood collections), progress toward sustainable growth in less tangible indicators, such as leadership or human capacity development, have proved more difficult to document. Namibia’s successful implementation of a National Blood Programme, with its associated quality systems and hospital-based transfusion committees, and the hiring of re-

27 Seventeen objectives are included in the proposed UN Sustainability Goals developed during the 201TK Global Forum on Sustainable Development. The full list is available in the UN proposal document: https://sustainabledevelopment.un.org/content/documents/1579SDGs%20Proposal.pdf

Figure 3: Blood Safety technical assistance cascade: Objectives, outputs and outcomes


1) All national blood transfusion services (NBTS) achieve Step 1 accreditation through the Africa Society for Blood Transfusion Step-wise Accreditation system for >50% of blood centers in the NBTS network.
2) All NBTS use an electronic data system to manage blood donor and donation registries at all blood centers in the NBTS network.
3) All NBTS laboratories are enrolled in a routine laboratory EQA program or participate in the ASLM rapid test kit quality improvement program

ASLM: African Society for Laboratory Medicine
ently graduated laboratory technologists from a newly opened Namibian training program, are examples of what can be accomplished when a country invests in people and systems. However, these examples are rare. As of early 2015, only two (Namibia and South Africa) of the 20-plus countries supported by PEPFAR have achieved accreditation, although more than six have begun the pre-accreditation assessment process with AfSBT.

An analysis of the handful of health systems indicators collected by the WHO Global Database on Blood Safety (GDBS) reveals some of the systems-level gaps. For example, in 16 of 28 PEPFAR-supported countries that reported data to GDBS in 2012, only two reported having hospital transfusion committees in 100% of the hospitals performing blood transfusions. (Table 2) Two other countries, one in the AFRO region and one in the EURO region were above 50%, reporting 84.4% and 70.9%, respectively. The size of a country’s population – and therefore its health care system – certainly seems to influence success on this indicator, with larger countries generally reporting smaller proportions of participating hospitals. Most countries also reported less progress on indicators requiring external technical assistance, logistics for site visits, or data collection or communications systems (clinical audits and hemovigilance), suggesting the importance – yet apparent lack – of dedicated funding for these activities that may be considered ‘non-essential.’

Another potentially useful GDBS measure of blood services’ progress toward country ownership is the indicator measuring the proportion of funding received from external and domestic sources, including direct funding from Ministries of Health, private sector grants, and revenue generated through cost-recovery (e.g., insurance company payments, out-of-pocket expenditures by patients, etc.). Of 19 PEPFAR-supported countries worldwide for which complete data were available,28 15 reported receiving some external funding for a proportion of their annual budgets (range 1.7% - 92.8%). Of these 15, 10 reported external donor contributions accounting for more than 50% of their annual operational budgets (range: 57.2% - 92.8%). (Table 3) Encouragingly, eight countries reported generating between 5.4% and 100% of their operational budgets from fees and/or cost recovery, and only three reported being 100% depended on national government budgets for the entirety of their operational budgets.

As Namibia has demonstrated, successfully putting together all of the pieces described above – leadership, consistent domestic funding, a deepening pool of well-trained staff, effective use of technology, and the embrace of quality management systems across every department – is possible in a middle-income country, even one facing substantial development challeng-

28 The author recognizes these data may be subject to significant reporting bias, including under-reporting of total budgets and misclassification of the type of funding. These data are nevertheless the only source of information available on financing for blood services in resource-limited countries, and as such offer a unique window into an area of inquiry that admittedly requires additional study.
<table>
<thead>
<tr>
<th>Country</th>
<th>Number of hospitals in the country</th>
<th>Hospitals performing blood transfusion that have, or participate in a hospital transfusion committee</th>
<th>Hospitals performing blood transfusion that have, or participate in clinical audits</th>
<th>Hospitals performing blood transfusion that have, or participate in a system for reporting adverse transfusion incidents and reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Namibia</td>
<td>46</td>
<td>46 100.0%</td>
<td>46 100.0%</td>
<td>46 100.0%</td>
</tr>
<tr>
<td>AFRO [A]</td>
<td>33</td>
<td>28 84.8%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>AFRO [B]</td>
<td>100</td>
<td>15 15.0%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>AFRO [C]</td>
<td>248</td>
<td>6 2.4%</td>
<td>- n/a</td>
<td>6 2.4%</td>
</tr>
<tr>
<td>AFRO [D]</td>
<td>480</td>
<td>76 15.8%</td>
<td>- n/a</td>
<td>76 15.8%</td>
</tr>
<tr>
<td>AFRO [E]</td>
<td>75</td>
<td>8 10.7%</td>
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<td>75 100.0%</td>
</tr>
<tr>
<td>AFRO [F]</td>
<td>737</td>
<td>178 24.2%</td>
<td>10 1.4%</td>
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<tr>
<td>AFRO [G]</td>
<td>7</td>
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<td>0 0.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>AFRO [H]</td>
<td>19</td>
<td>19 100.0%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>AFRO [I]</td>
<td>261</td>
<td>60 23.0%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>AFRO [J]</td>
<td>217</td>
<td>2 0.9%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>AFRO [K]</td>
<td>150</td>
<td>11 7.3%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>EURO [A]</td>
<td>108</td>
<td>0 0.0%</td>
<td>0 0.0%</td>
<td>0 0.0%</td>
</tr>
<tr>
<td>EURO [B]</td>
<td>103</td>
<td>73 70.9%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>WPRO [A]</td>
<td>43</td>
<td>5 11.6%</td>
<td>- n/a</td>
<td>- n/a</td>
</tr>
<tr>
<td>WPRO [B]</td>
<td>33</td>
<td>1 3.0%</td>
<td>1 3.0%</td>
<td>1 3.0%</td>
</tr>
</tbody>
</table>

Notes:
- Countries with 0% responses reported a zero in the number column. Countries that did not provide a figure, including zero, were assigned a (-) and assumed not to have reported on the indicator.
- Country names withheld at request of WHO, which had not formally published these data as of March 3, 2015.
- Letters assigned to countries in Table 2 do not correspond to letters assigned to countries in Table 3.
<table>
<thead>
<tr>
<th>Country</th>
<th>Total estimated funding (US$) for operating the blood centres covered in this report (incl. staffing and operations)</th>
<th>Proportion of total funding from the national government</th>
<th>Proportion of funding from fees and cost-recovery</th>
<th>Proportion of funding from external donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Country A]</td>
<td>$80,000</td>
<td>37.5%</td>
<td>0.0%</td>
<td>62.5%</td>
</tr>
<tr>
<td>[Country B]</td>
<td>$700,000</td>
<td>100.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>[Country C]</td>
<td>$937,447</td>
<td>2.5%</td>
<td>95.8%</td>
<td>17.0%</td>
</tr>
<tr>
<td>[Country D]</td>
<td>$1,043,000</td>
<td>42.8%</td>
<td>0.0%</td>
<td>57.2%</td>
</tr>
<tr>
<td>[Country E]</td>
<td>$1,528,608</td>
<td>34.6%</td>
<td>0.0%</td>
<td>65.4%</td>
</tr>
<tr>
<td>[Country F]</td>
<td>$1,600,000</td>
<td>68.8%</td>
<td>0.0%</td>
<td>31.3%</td>
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<tr>
<td>[Country G]</td>
<td>$2,062,553</td>
<td>30.9%</td>
<td>5.4%</td>
<td>63.7%</td>
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<tr>
<td>[Country H]</td>
<td>$2,141,910</td>
<td>100.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>[Country I]</td>
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<td>23.3%</td>
<td>15.6%</td>
<td>61.1%</td>
</tr>
<tr>
<td>[Country J]</td>
<td>$3,200,000</td>
<td>15.6%</td>
<td>0.0%</td>
<td>84.4%</td>
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<tr>
<td>[Country K]</td>
<td>$3,220,478</td>
<td>0.0%</td>
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<td>15.9%</td>
</tr>
<tr>
<td>[Country L]</td>
<td>$4,150,000</td>
<td>24.1%</td>
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</tr>
<tr>
<td>[Country M]</td>
<td>$5,863,461</td>
<td>5.7%</td>
<td>7.1%</td>
<td>87.2%</td>
</tr>
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<td>[Country N]</td>
<td>$5,706,023</td>
<td>7.2%</td>
<td>0.0%</td>
<td>92.8%</td>
</tr>
<tr>
<td>[Country O]</td>
<td>$6,324,600</td>
<td>32.8%</td>
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<td>67.2%</td>
</tr>
<tr>
<td>[Country P]</td>
<td>$6,510,124</td>
<td>48.7%</td>
<td>8.1%</td>
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<td>[Country Q]</td>
<td>$8,195,381</td>
<td>6.2%</td>
<td>67.8%</td>
<td>26.1%</td>
</tr>
<tr>
<td>[Country R]</td>
<td>$25,000,000</td>
<td>0.0%</td>
<td>100.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>[Country S]</td>
<td>$59,577,500</td>
<td>100.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Notes**

- Country budget totals are estimates and may not reflect actual costs or expenditures.
- Country names withheld at request of WHO, which had not formally published these data as of March 3, 2015.
- As noted in Table 2, alphabetical codes used for country identification in Table 3 do not correspond with similar codes used in Table 2.
- Dark grey shading in external donor column highlights countries reporting >50% dependence on external funding. Light grey shading in fees and cost-recovery column highlights countries reporting any revenue from cost-recovery or fees.
es. Global data paint a less rosy picture of progress on structural issues, but some progress is nonetheless evident in the GDBS tables presented above. Lessons learned in Namibia may be useful for countries and external donors seeking to invest in blood safety or sustainable blood system strengthening activities, especially those reflecting the critical importance of strong human capacity, routinely collected and easily accessible data for decision-making, and a solid grasp of financial data. It is the author’s hope that continued progress in this critical area of health systems development will occur in an environment marked by greater emphasis on equity [45] and a continued evolution of donors’ and recipient countries’ understanding of the meaning and implications of the term “sustainability.” [11]

9.4 References

10. Diane MK, Dembele B, Konate S. Blood collection to cover national needs in sub-Saharan


