CHAPTER 1

Introduction
1.1 Introduction

Blood is vital to human survival. As a core element of mammalian circulatory and respiratory systems, blood components are responsible for transporting oxygen, nutrients, immune system proteins, and waste to and away from cells throughout the body. Humanity has a long and complex history with blood, from early physicians’ and mystics’ guesswork about its purpose and powers, [1] to the first successful transfusions in the 19th century, [1-3] and a flowering of clinicians’ and scientists’ understanding of the risks associated with the practice. [4, 5] In the modern era (since 1950), the benefits of an adequate blood supply have been well-documented across numerous medical disciplines, ranging from the importance of blood components on the battlefield and other trauma settings, [6-8] to positive impacts in peri-partum and neo-natal cases, [9] to advanced therapies for cancers and other malignancies. Transfusion safety issues – for donors and recipients – have also been thoroughly documented, especially since the start of the global HIV/AIDS pandemic in the 1980s. [10] Yet despite its biological importance, the administrative, logistical, and medical systems to collect, screen, process and distribute blood are frequently lacking in low-resource countries. The introduction of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) in 2003/04, and concurrent HIV/AIDS-specific investments by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the World Bank (WB), Asian Development Bank (ADB), and others introduced dramatic and historically unprecedented changes in the amount of funding available for blood safety programs, especially in sub-Saharan African countries with high burdens of HIV/AIDS. But while much has been done to strengthen blood transfusion services in developing countries, the impact of externally funded blood safety projects has not been well documented.

Similarly, the singular focus on HIV prevention for programs like PEPFAR raises interesting questions about the potential for opportunity costs to exist in other areas, such as hepatitis prevention, that may have contributed more to population health in recipient countries.

1.2 Literature review

A rich global literature exists regarding challenges attaining and sustaining adequate stocks of blood. This literature ranges from Richard Titmuss’s 1970 sociological appeal for altruism in blood donation, The Gift Relationship, to papers describing new technologies and other strategies to manage seasonal blood shortages, [11, 12] to cutting edge work by molecular biologists searching for ways to reduce or eliminate the need for blood donations by producing oxygen-carrying erythrocytes from stem cells. [13] However, while clinicians, epidemiologists, public health specialists, and economists have analyzed a range of core questions about the adequacy, safety, and availability of national blood supplies, the bulk of this research has
emerged from, and been designed to assist, hospitals, clinicians and policy makers in developed countries – countries where blood stocks are generally sufficient, safe and stable. The richness of the global literature on blood transfusion masks important differences between wealthy industrialized countries and nations in less-developed regions where national blood transfusion services have historically been fixated on fundamental issues of adequacy, access, and safety. Concerning the available blood safety literature for Africa, a recent PubMed search (October 21, 2014) using the term “Transfusion”, and combinations of the key words “Transfusion and Safety,” and “Transfusion and Africa,” revealed a substantial imbalance between generalist papers about blood transfusion and specialist papers focused on transfusion safety or transfusion issues in Africa. Between 1980 and 2014, a total of 104,997 generalist papers were published, while specialist papers with safety or African sub-themes accounted for only 7,017 and 2,050 papers, respectively, during the same 34 year period. (Figure 1)

**Figure 1: Annual frequency of journal articles published about general transfusion themes, about specific transfusion safety themes, and about transfusion issues in Africa (1980-2014).**

Figure 1 also reflects an apparent influence exerted by the HIV/AIDS epidemic on research into transfusion safety since the mid-to-late 1980s, a phenomenon that has also driven calls for international development programs to support blood transfusion services in Africa. [14]

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1 Results presented here reflect results returned when key words were applied to all fields. However, similar searches by MeSH term, by title, or by title and abstract returned similar distributions by year.
A deeper historical review of transfusion publications from Africa shows how the emergence of transfusion-associated HIV in the 1980s led to a dramatic shift in the focus of blood transfusion research in Africa. For example, in 1970, when only six “Transfusion and Africa” papers are reflected in the PubMed index, researchers covered a diversity of topics, from malaria, [15] ectopic pregnancy [16] and haemophilia, [17] to cytomegaly [18] and the use of transfusion among casualties from Nigeria’s civil war. [19] By 1988, the same PubMed search terms returned 53 articles, of which 30 (57%) were about HIV screening techniques, [20-22] HIV transmission via transfusion, [23-27] or other transfusion-associated infection issues, including the cost-effectiveness of screening donated blood for other blood-borne pathogens, including hepatitis (versus the costs of morbidity and mortality per transfusion-associated infections). [28] Maternal health issues continued to be represented (6/53, 11%), but remained under-represented if considered in the context of the burden of morbidity and mortality related to maternal hemorrhage compared to transfusion-associated HIV.

1.2.1 Blood, blood transfusion, and blood safety in Namibia

Papers about blood transfusion services – or the safety or adequacy of blood in Namibia – do not feature prominently in the scientific literature from Namibia prior to 2008, when data from Namibia were included in a global summary of progress during the first five years of the PEPFAR initiative. [29] Separate Google and PubMed searches – as well as a review of the online archive of the South African Medical Journal – for the terms “South West Africa and blood transfusion” and “Namibia and blood transfusion” revealed seven articles published between 1967 and 1999 about topics specifically relevant to a blood transfusion service, or related to clinical presentations that may require transfusion.

Table 1 lists these seven papers, which cover topics ranging from an innovative method of cross-matching in low-resource settings [30], to an evaluation of genetic differences between racial groups and the non-need for labeling blood units by race [31], to brief descriptions of the prevalence and treatments for onyali, a rare but not-uncommon form of thrombocytopenia in northern Namibia [32-34], to an evaluation of a rare blood antigen found in two African sisters [35], to a first look at viral (including HIV) seroprevalence among Namibian blood donors [36], and a subsequent assessment of Hepatitis C prevalence among Namibian blood donors [37].

A review of additional literature on other diseases and healthcare services in Namibia found a number of references to papers containing information of potential use to the blood transfusion service or to clinicians caring for patients with cancers.

2 The author recognizes this is likely a vast under-estimate of the actual number of journal articles published in and about Africa in 1970 – but never indexed on an electronic database like PubMed. However, despite the small “n” involved in this example, as a representation of the relative proportion of articles in this subject area during this time period, this list retains its usefulness for illustrative purposes.

Table 1: English and German-language scientific papers directly related to blood or the use of blood in South West Africa or Namibia prior to 2008

<table>
<thead>
<tr>
<th>Publication Year</th>
<th>Authors</th>
<th>Journal</th>
<th>Title</th>
</tr>
</thead>
</table>

For example, Table 2 includes references to a series of papers about an apparent outbreak of Hepatitis E in the 1980s – an outbreak that could not be confirmed until more sophisticated testing systems became available. Although no follow-up work has been done on Hepatitis E prevalence in Namibia, these historical articles are of particular interest given emerging concern about Hepatitis E among blood services worldwide. [38-40]

Table 2: Articles related to an outbreak of Hepatitis E in Namibia

<table>
<thead>
<tr>
<th>Publication Year</th>
<th>Authors</th>
<th>Journal</th>
<th>Title</th>
</tr>
</thead>
</table>
Similarly, Table 3 includes references to papers published in the 1980s and 1990s that contain information about other viral markers of interest to a transfusion service, notably Hepatitis B, HTLV and an early report on HIV.

Table 3: Articles related to other viral pathogens of interest to a blood transfusion service

<table>
<thead>
<tr>
<th>Publication Year</th>
<th>Authors</th>
<th>Journal</th>
<th>Title</th>
</tr>
</thead>
</table>

A 1999 study of pediatric blastomas in Namibia [34] is of particular historical interest given the findings of higher-than-expected blood use for pediatric oncology during the period covered by this thesis. Prevalence of other cancers in the Namibian population are also a feature of the Namibian literature, largely due to concerns by mining companies about occupational exposure to radiation and the impact such exposure has on employees. [44-46]

Since 2008, Namibian blood donors have served as the study population for a number of zoonotic disease studies, including a survey of *Coxiella burnetii*, Spotted Fever and Typhus Group Rickettsiae, and *Bartonella henselae*, [47] and an evaluation of flavivirus risk, [48] both published by Noden et al. in 2014, and for a genetics survey in 2013 [49]. Blood safety data from Namibia also featured in the 2011 update of the CDC MMWR report on progress within the PEPFAR blood safety initiative. [50] A more detailed profile of viral marker prevalence among NAMBTS donors was published in 2014. [51]

1.2.2 Beyond the published literature

In addition to a thorough review of available information in the scientific literature, this thesis is based on analysis of programmatic data from large international development projects, including PEPFAR, the GFATM, and other OECD member states. An internal NAMBTS report on blood use in Namibian hospitals was also consulted and used as a counterpoint for the four year blood use survey described in Chapter 4. [52] Data for the multi-country analyses were...
drawn from several sources, including non-public sources available to the author through his work at the Centers for Disease Control and Prevention, and public sources including internet-based datasets maintained on public Web sites by PEPFAR, GFATM, and the OECD. Other data were obtained through personal communications and local observations (in Namibia and other PEPFAR-funded countries), or through program reports available on-line.

1.3 Background

1.3.1 A brief history of development support for blood transfusion services in low-resource settings

In developed countries, systems to collect, screen and deliver a safe and adequate supply of blood are considered sine qua non components of modern medical services. In less developed and resource-limited countries, blood transfusion services also play crucial supportive roles within healthcare systems. The International Federation of the Red Cross and Red Crescent (IFRC) is blunt in its assessment of blood transfusion services’ role in national healthcare systems: “The safety and integrity of a nation’s blood supply is fundamental to the security of its health system.” The IFRC and others, including the World Health Organization (WHO), have also advocated for blood as an “essential medicine” and as a core element in countries’ strategies to attain the UN Millennium Development goals (MDG) related to reducing child mortality (Goal 4), improving maternal health (Goal 5), and combatting HIV/AIDS, malaria and other diseases (Goal 6). However, unlike industrialized countries, blood services in developing countries have historically struggled to secure adequate funding for routine operations, despite high level commitments on funding for healthcare, such as the Abuja Declaration.

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4 Non-public resources include confidential budget and work plan submissions by CDC-funded cooperative agreement partners, as well as CDC technical reviews of those submissions.

5 http://www.pepfar.gov

6 http://www.theglobalfund.org/en/

7 http://www.oecd.org/statistics/


9 In 2013, WHO revised its Essential Medicines List (EML) to include whole blood and blood components. This decision was taken after considerable debate over whether to expand the EML recommendations to include whole blood and blood components (e.g., red blood cells, fresh frozen plasma, platelets) or retain the List’s traditional focus on plasma-derived medicinal products (e.g., Factor VIII). Both sides of the debate are captured in detail at: http://www.who.int/selection_medicines/committees/expert/19/en/.
Since 2000, IDA-supported blood safety projects, including PEPFAR, have helped bridge funding gaps for national blood services in selected countries, but the impact of these external investments has not been widely investigated.

An objective review of the impact of global blood safety initiatives should be conducted in three parts. First, since “blood safety” projects have generally been funded by HIV/AIDS initiatives which call for progress on relatively discrete and easily quantifiable safety questions such as the number of blood units screened for HIV and the prevalence of HIV in donated blood, primary analyses should describe changes within these indicators. Secondary analyses, including those seeking to establish a causal relationship between the availability of blood and broad MDG indicators such as maternal or child survival, have proved elusive. Third, regardless of the type of data available (e.g., laboratory data on the prevalence of viral markers in donated blood or clinical data from hospitals), most current analyses also strive to link technical indicators to operational and management targets recommended by the WHO Aide-Mémoire on strengthening national blood services. [59, 60]

As will be described in subsequent chapters about Namibia’s experience, limited data from transfusing hospitals hampers researchers’ ability to draw conclusions about the true impact of the availability or lack of blood on clinical practice and patient outcomes. But when analyzed separately, a picture of substantial progress emerges about the relative safety (i.e., reduction of infectious disease risk) of African blood supplies compared to previous decades. [29, 50, 61]

1.3.2 Blood Safety and Blood Transfusion Services in Namibia

Blood transfusions have been performed in southern Africa since the 1920s, when South African hospitals began practicing techniques learned on European battlefields during World War I. [62] The first blood transfusion services were established in South Africa in the mid-1930s. [63] Blood collection and transfusion services were first offered in South West Africa (a South African protectorate following the end of German colonial occupation during WWI until Namibia’s independence in 1990), in the 1950s when Dr. Werner Kiwi launched a small service under the auspices of the South West Africa Red Cross Society. The South African Institute for Medical Research (SAIMR) took over laboratory screening services from the Red Cross in the mid-1960s, [62, 63] and supported Red Cross blood collections efforts. Blood collection nonetheless represented a small portion of the Society’s main activities, which were focused on humanitarian activities such as hunger relief. [64] The first formal national blood transfusion service was established in the late 1980s, and was converted, after independence, into the Blood Transfusion Service of Namibia, or NAMBTS, a private, non-profit organization authorized by the government of Namibia to be the country’s sole provider of safe blood. [65]

All laboratory screening and blood component production has historically been performed in Windhoek, first in a small facility on the campus of Windhoek Central Hospital, and,
since 2007, at a modern headquarters in downtown Windhoek. All blood is collected from voluntary, non-remunerated blood donors (more than 50% are repeat donors), the majority of whom live in and around Windhoek. NAMBTS experimented with a permanent collections base at Oshakati hospital in the 1990s, but scaled back collections in the northern part of the country due to cost and logistics challenges. During the period documented by this thesis, mobile collection teams visited the north on a monthly basis; other mobile teams dispatched from Windhoek and from Swakopmund, a city on the Atlantic coast, visited sites elsewhere in the country.

While this thesis does not presume to present a comprehensive history of healthcare or blood transfusion services in Namibia, given the success reported in subsequent chapters related to improvements in the distribution of blood to previously underserved areas, it is instructive to note briefly that prior to independence, healthcare services were unequally distributed in South West Africa based on race, a phenomenon that no doubt also impacted access to blood transfusion services. While Apartheid policies were technically abandoned by the white minority government in the late 1970s – and repudiated completely after independence – disparities linked to ‘neo-apartheid’ policies from 1977 until independence, and chronic socio-economic inequalities since 1990, continue to negatively impact equitable access to healthcare.

This thesis describes progress achieved by one country in Africa: Namibia. However, the author is mindful of the fact that Namibia, due to its strong economy, advanced transportation, electricity and water infrastructure, and its relatively small population, is not an ideal model from which to make generalizable statements about the challenges faced by blood transfusion services elsewhere in Africa. Observations made throughout this document, therefore, should be considered within the domestic situation as it existed in Namibia during the study period and not as a general reflection of blood safety in Africa. That said, the author hopes that data presented here may be helpful to other countries as they face situations and opportunities similar to those confronted by Namibia during the first 10 years of the 21st century.

1.3.3 PEPFAR’s global blood safety initiative

President George W. Bush launched the President’s Emergency Plan for AIDS Relief, or, PEPFAR, in his annual State of the Union address on January 28, 2003. “Seldom has history offered a greater opportunity to do so much for so many,” he said. “We have confronted, and will continue to confront, HIV/AIDS in our own country. And to meet a severe and urgent crisis abroad, tonight I propose the Emergency Plan for AIDS Relief, a work of mercy beyond all cur-

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10 Between 2007-2012 infectious disease screening was outsourced to the South African National Blood Service (SANBS) through an innovative contract mechanism. Specimens were flown to Johannesburg daily for testing; results were returned within 24 hours via e-mail.
rent international efforts to help the people of Africa.” While blood safety was not specifically mentioned in the speech or in the global targets to treat two million people and provide care to seven million, averting infections via blood transfusion was included in the authorizing legislation as part of PEPFAR’s objective to prevent 10 million new HIV infections within the initiative’s first five years. With an initial appropriation of $15 billion over five years, PEPFAR rapidly evolved into a global health juggernaut that accounted for 75% of all US official development assistance for health between by 2014, rising from 44% of all US global health assistance in 2001. (Figure 2) [71]

**Figure 2: Evolution of U.S. Government funding for global HIV/AIDS, malaria, maternal & child health, and other global health activities, 2001-2014**

1.3.4 Blood Safety and PEPFAR’s Legal Framework, 2003-2014

In the original 2003 legislation authorizing the first five years of PEPFAR (Public Law 108-25, or, the “United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003”), blood safety was buried in the brief description of HIV prevention activities to be supported by PEPFAR (emphasis added):

11 The pie charts in Figure 2 are derived from U.S. Government data compiled by the Kaiser Family Foundation. A complete table is available at: http://kaiserfamilyfoundation.files.wordpress.com/2013/05/ghi-budget-fs-historical-funding-table-fy14-request-5-21-13.pdf.
“(d) ACTIVITIES SUPPORTED.—Assistance provided under subsection (c) shall, to the maximum extent practicable, be used to carry out the following activities:

“(i) PREVENTION.—Prevention of HIV/AIDS through activities including—

“(A) programs and efforts that are designed or intended to impart knowledge with the exclusive purpose of helping individuals avoid behaviors that place them at risk of HIV infection, including integration of such programs into health programs and the inclusion in counseling programs of information on methods of avoiding infection of HIV, including delaying sexual debut, abstinence, fidelity and monogamy, reduction of casual sexual partnering, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of condoms;

“(B) assistance to establish and implement culturally appropriate HIV/AIDS education and prevention programs that focus on helping individuals avoid infection of HIV/AIDS, implemented through nongovernmental organizations, including faith-based and community-based organizations, particularly those organizations that utilize both professionals and volunteers with appropriate skills, experience, and community presence;

“(C) assistance for the purpose of encouraging men to be responsible in their sexual behavior, child rearing, and to respect women;

“(D) assistance for the purpose of providing voluntary testing and counseling (including the incorporation of confidentiality protections with respect to such testing and counseling);

“(E) assistance for the purpose of preventing mother-to-child transmission of the HIV infection, including medications to prevent such transmission and access to infant formula and other alternatives for infant feeding;

“(F) assistance to ensure a safe blood supply and sterile medical equipment;”

The 2003 law authorized the State Department’s Office of the Global AIDS Coordinator, or OGAC, to spend up to $15 billion over the initial five years. Subsequent reauthorizations would

Table 4: Year-on-year PEPFAR budgets, with proportional break-out for Blood Safety

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Care</th>
<th>Governance &amp; Systems</th>
<th>Management &amp; Operations</th>
<th>Prevention</th>
<th>Treatment</th>
<th>Total</th>
<th>% Blood Safety</th>
<th>% Prevention sub-total</th>
<th>% PEPFAR total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>119,000,000</td>
<td>107,000,000</td>
<td>62,100,000</td>
<td>268,500,000</td>
<td>210,400,000</td>
<td>787,900,000</td>
<td>27,600,000</td>
<td>10.9%</td>
<td>3.5%</td>
</tr>
<tr>
<td>2005</td>
<td>186,100,000</td>
<td>166,500,000</td>
<td>73,300,000</td>
<td>303,300,000</td>
<td>315,800,000</td>
<td>1,205,000,000</td>
<td>53,400,000</td>
<td>13.9%</td>
<td>4.4%</td>
</tr>
<tr>
<td>2006</td>
<td>290,600,000</td>
<td>213,600,000</td>
<td>93,400,000</td>
<td>495,200,000</td>
<td>550,400,000</td>
<td>1,703,200,000</td>
<td>31,900,000</td>
<td>6.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>2007</td>
<td>556,700,000</td>
<td>381,400,000</td>
<td>132,500,000</td>
<td>749,800,000</td>
<td>1,026,200,000</td>
<td>2,850,800,000</td>
<td>48,200,000</td>
<td>6.4%</td>
<td>1.7%</td>
</tr>
<tr>
<td>2008</td>
<td>772,600,000</td>
<td>535,200,000</td>
<td>195,800,000</td>
<td>1,018,400,000</td>
<td>1,379,600,000</td>
<td>3,002,600,000</td>
<td>55,100,000</td>
<td>5.5%</td>
<td>1.4%</td>
</tr>
<tr>
<td>2009</td>
<td>884,600,000</td>
<td>604,500,000</td>
<td>277,000,000</td>
<td>940,800,000</td>
<td>1,245,700,000</td>
<td>3,087,100,000</td>
<td>55,400,000</td>
<td>5.6%</td>
<td>1.4%</td>
</tr>
<tr>
<td>2010</td>
<td>895,100,000</td>
<td>638,800,000</td>
<td>349,300,000</td>
<td>1,129,000,000</td>
<td>1,336,100,000</td>
<td>4,104,700,000</td>
<td>52,500,000</td>
<td>4.6%</td>
<td>1.3%</td>
</tr>
<tr>
<td>2011</td>
<td>884,300,000</td>
<td>795,400,000</td>
<td>354,600,000</td>
<td>1,151,100,000</td>
<td>1,102,000,000</td>
<td>4,208,700,000</td>
<td>50,700,000</td>
<td>4.4%</td>
<td>1.2%</td>
</tr>
<tr>
<td>2012</td>
<td>880,500,000</td>
<td>705,800,000</td>
<td>218,300,000</td>
<td>1,012,900,000</td>
<td>961,000,000</td>
<td>3,577,500,000</td>
<td>42,400,000</td>
<td>4.2%</td>
<td>1.2%</td>
</tr>
<tr>
<td>2013</td>
<td>719,600,000</td>
<td>670,200,000</td>
<td>205,600,000</td>
<td>1,025,200,000</td>
<td>1,051,300,000</td>
<td>3,075,700,000</td>
<td>38,000,000</td>
<td>2.7%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

Total 5,950,800,000 $4,758,400,000 $1,211,700,000 $8,184,000,000 $9,138,600,000 $29,944,100,000 $4,555,300,000 5.6% 1.5%

raise this ceiling to $48 billion. Over the first 10 years of the PEPFAR initiative more than $29 billion was budgeted for HIV/AIDS prevention, care and treatment programs world-wide. Of this, approximately $455 million was directed to blood safety programs. (Table 4) On an annual basis, blood safety budgets ranged from a high of 4.4% of the total allocation (2005) to 1% in 2013. As a proportion of funding devoted to HIV prevention, blood safety accounted for an average of 5.6% during the 10 year period (range: 13.9% in 2005; 3.7% in 2013).

The 2003 law has been revised and reauthorized twice by the U.S. Congress, in 2008 and 2013. With each authorization, the title has been updated to reflect changes in the PEPFAR initiative’s strategic direction. In 2008, PEPFAR was re-authorized under the title, “Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008,” named after the reauthorization bill’s two main sponsors (Congressional representatives from California and Illinois, respectively). Blood safety was again included in a modified and shortened list of priority interventions to be funded through PEPFAR’s prevention strategy. These modifications, listed below, included the addition of medical male circumcision, and in the line describing blood safety, the replacement of the term “ensure” with the term “maintenance”:

“(14) support other important means of preventing or reducing the transmission of HIV, including—
“(A) medical male circumcision;
“(B) the maintenance of a safe blood supply;
“(C) promoting universal precautions in formal and informal health care settings;
“(D) educating the public to recognize and to avoid risks to contract HIV through blood exposures during formal and informal health care and cosmetic services;
“(E) investigating suspected nosocomial infections to identify and stop further nosocomial transmission; and
“(F) other mechanisms to reduce the transmission of HIV;”

This small nuance in the wording of the 2008 reauthorization signaled a major shift in PEPFAR’s support for National Blood Transfusion Services worldwide. Where PEPFAR’s annual blood safety budgets had ranged from $27.6 million to $56.1 million per year for programs in only 14 priority countries under the first five-year cycle, fiscal year 2008 represented a peak in funding while simultaneously opening the door to a massive expansion in the number of countries supported by PEPFAR’s annual blood safety budget. Between 2009 and 2014, the number of countries receiving PEPFAR support for blood safety nearly doubled, from 14 to 27, while annual budgets were reduced by more than 46% (to approximately $30 million in FY2014). (Figure 3) As a result of these changes, PEPFAR was no longer able to fund many of

the operational activities, including staff salaries or the procurement of consumable supplies, which helped drive Namibia’s successes.

Note: Each dot signifies a country that received PEPFAR support for blood safety during the fiscal year (FY). The location of the each dot on the vertical axis represents the size of the annual budget for each country. HMBL is the PEPFAR coding designation for Blood Safety programs.

By 2013, the year President Barak Obama signed the third PEPFAR reauthorization into law, the language of the legislation had evolved again, this time in a way that clearly reflected the Congress’s growing unease about the costs associated with such a massive global health undertaking. The title of the third reauthorization law (PL 113-56) does not even include the term “HIV/AIDS.” Rather, it bluntly describes a need for the initiative to devote itself to controlling costs and staying focused on specific epidemic-control objectives. The “PEPFAR Stewardship and Oversight Act of 2013” does not mention blood safety as a specific intervention, although it remains part of the initiative’s prevention strategy due to its inclusion in the source legislation from 2003 and 2008. For the first time, however, prevention activities are presented not as a list of priority interventions, but, rather, as elements to be evaluated:
“(H) A description of partner country and United States-funded HIV/AIDS prevention programs and policies, including
“(i) an assessment by country of progress towards targets set forth in subparagraph (B), with a detailed description of the metrics used to assess—
“(I) programs to prevent mother to child transmission of HIV/AIDS, including coverage rates;
“(II) programs to provide or promote voluntary medical male circumcision, including coverage rates;
“(III) programs for behavior-change; and
“(IV) other programmatic activities to prevent the transmission of HIV;
(ii) antiretroviral treatment as prevention; and
(iii) a description of any new preventative interventions or methodologies.”

Changes in PEPFAR’s overall legal framework have similarly been reflected in technical priorities and funding decisions made by PEPFAR-funded country teams through the annual Country Operational Plan process. The narrowing of PEPFAR’s approach to blood safety from direct bi-lateral support for operations to a technical assistance strategy focused on quality assurance and accreditation will be discussed in detail in the conclusion.

1.4 Other Donor Support for Blood Safety

1.4.1 The Global Fund to Fight AIDS, Tuberculosis and Malaria
After PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) has been the next largest and most consistent source of external funding for blood safety in developing countries. However, unlike PEPFAR, the GFATM functions under a “demand-driven” model in which low and middle-income countries propose activities rather than respond to a menu of goal-linked activities proposed by a donor. [72] Under this approach, countries are not obliged to fund blood safety (as they were under the first two PEPFAR cycles) with GFATM grants; rather, grant applications are structured based on existing national strategic plans for HIV/AIDS. Between 2002 and 2009, GFATM provided nearly $92 million to blood safety projects in 56 countries and two broad regional groupings (Western Pacific and West Africa) through the Prevention portfolio of HIV/AIDS grants (personal communication, GFATM, November 1, 2012). Of note, the largest proportion of these funds (20%) was awarded to China.

1.4.2 Other Industrialized Donors: OECD Data
In addition to HIV/AIDS-specific investments made by PEPFAR and the Global Fund, blood safety programs worldwide have also benefitted from other sources of financial support. The Organization for Economic Cooperation and Development (OECD) tracks IDA reported by its

Full text available at: https://www.congress.gov/113/plaws/publ56/PLAW-113publ56.pdf
member states. Data reported to OECD do not include major U.S. initiatives including PEPFAR, but is a useful source of information about how blood safety is funded through non-HIV/AIDS-specific programs. Between 2005 and 2010, six OECD member states reported nearly $26 million in funding for projects including the terms “blood safety,” “blood bank,” or “blood transfusion” in their descriptions in 12 African countries (and one U.S. Government regional initiative for sub-Saharan Africa). Multi-lateral organizations, including EU Institutions, the World Bank, and UNDP channeled a further $186 million in OECD member states’ contributions to similar projects in 10 African countries between 2003 and 2010.15

Table 5 shows the diversity of program areas in which “blood safety” projects are mentioned in the OECD members states’ filings to the organization’s database on international development funding. A slight majority of projects (56.6%) and an even wider majority of funding (75.3%) for projects that mention “blood safety” elements fall within the population and reproductive health category, suggesting an appreciation of the link between blood transfusion services and maternal and child health. At the same time, however, coordination with PEPFAR and other HIV/AIDS “blood safety” projects has been weak, limiting the potential impact of cross-cutting strategies focused on education, child survival or maternal health.

Table 5: Distribution of “blood safety” references in OECD projects by technical area

<table>
<thead>
<tr>
<th>OECD Project Designation</th>
<th>Projects</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>I.1.a. Education, Level Unspecified</td>
<td>2</td>
<td>0.9%</td>
</tr>
<tr>
<td>I.5.b. Conflict, Peace &amp; Security</td>
<td>2</td>
<td>0.9%</td>
</tr>
<tr>
<td>IV.2. Other Multisector</td>
<td>2</td>
<td>0.9%</td>
</tr>
<tr>
<td>VII. Action Relating to Debt</td>
<td>6</td>
<td>2.7%</td>
</tr>
<tr>
<td>I.2.b. Basic Health</td>
<td>13</td>
<td>5.9%</td>
</tr>
<tr>
<td>I.6. Other Social Infrastructure &amp; Services</td>
<td>14</td>
<td>6.4%</td>
</tr>
<tr>
<td>I.2.a. Health, General</td>
<td>28</td>
<td>12.8%</td>
</tr>
<tr>
<td>I.5.a. Government &amp; Civil Society-general</td>
<td>28</td>
<td>12.8%</td>
</tr>
<tr>
<td>I.3. Population Pol./Progr. &amp; Reproductive Health</td>
<td>124</td>
<td>56.6%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>219</td>
<td>100%</td>
</tr>
</tbody>
</table>

The significant sums allocated to support transfusion services via programs devoted to improving maternal and child health or other health or development-related initiatives is en-

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15 OECD public records are not an exhaustive source of information about member states’ IDA spending in any given year. PEPFAR is a perfect example of the kind of large bi-lateral program that is not reported to the OECD system. Still, these figures provide useful context about additional funding for blood transfusion services through projects other than those dedicated to the support of national HIV/AIDS responses.
couraging, but also a daunting reminder of the challenges donors and recipient countries face ensuring that funding for specific objectives is well coordinated.

While PEPFAR’s growth has been hailed for dramatically increasing the number of people tested for HIV and enrolled on antiretroviral therapy for HIV/AIDS in high burden countries, especially in Africa, [73-75] this praise has been accompanied by voices of concern about the “crowding out” effect PEPFAR has had on other global health priorities, such as maternal mortality, hepatitis, neglected tropical diseases, and emerging chronic diseases and conditions, such as hypertension and diabetes. [76-78] In this debate, blood safety programs face an unusual and not entirely unwelcome challenge. On one hand, global blood safety programs have benefitted from substantial support via the vast funds appropriated for PEPFAR. But on the other hand, PEPFAR’s dominant role over the last decade has created certain dependencies within partner countries (discussed in detail in Chapter 6), and may have dis-incentivized other donors from funding blood safety programs in countries where PEPFAR is active.

As recipient countries and donors look to the future, untangling financial dependencies and building the capacity of national stakeholders to manage, operate, and, eventually, self-finance, large HIV/AIDS programs has emerged as a priority. Blood transfusion services may look to the recent transition of PEPFAR care and treatment programs for hints about steps blood services should take to build national capacity and “ownership.”

Since 2008, PEPFAR has required countries to transition the management of HIV care and treatment programs from international implementing partners to local partners. The care and treatment transition has generally been viewed as successful, although serious challenges remain as heavily-affected countries and the international community ponder how to achieve (and fund) global targets for antiretroviral therapy (ART) coverage worldwide. [79] The success of PEPFAR’s move from international implementing partners to local partners was due, in part, to a massive technical assistance and monitoring and evaluation project undertaken by PEPFAR, which emphasized the development or strengthening of core administrative, management and leadership capacity. [80, 81] Many of these capacity-building elements are also recommended for blood transfusion services and have been supported over the years by PEPFAR through its technical assistance providers; but PEPFAR has not invested in blood service capacity building at the same level as it has in care and treatment program systems.

Evaluations of PEPFAR’s efforts to transition certain components of its programs and address the sustainability questions that surround these transitions have identified a curious duality in the relationship between donor investments and the progress a recipient country is able to make with those investments. Quantifying this duality is a challenge, as described by Kuehn et al. in an evaluation of the PEPFAR care and treatment transition in Zambia and Botswana, where pre-existing strengths within the Zambian healthcare system may have contributed to a smoother transition to local “ownership” than in Botswana. [80] Palen et al. touched on this phenomenon in 2012 when they wrote [emphasis added], “Ev-
idence demonstrates that scale-up of HIV services has produced stronger health systems and, conversely, *that stronger health systems were critical to the success of the HIV scale-up.*” [82] In other words, while technical assistance and other investments are important, if not crucial to, strengthening capacity in low-resource settings, sustaining that capacity if and as external support wanes may depend on a combination of underlying national capacity (i.e., “strengths” that may have pre-dated the external investments) and, as noted by Sharma et al., “continued investment in leadership, staff retention, and quality improvement.” [83] Writing about the sustainability of a community-based ART program in Mozambique, Rasschaert et al. described challenges that echo the concerns above, and should resonate with blood transfusion service planners: “To maintain good quality ... the overall health system will need strengthening, ensuring adequately trained health staff, uninterrupted drug supply and logistical means to perform supervision activities.” [84]

Whether the ‘continued investment’ noted above comes from within the country or from an external source – and how any money is used within a health system once it is allocated – are questions that lie at the heart of current debate within the global health community. [85] Within PEPFAR, country ownership is understood as a framework based on four “dimensions”:

- Political ownership and stewardship
- Institutional and community ownership
- Capabilities
- Mutual accountability, including finance

The following chapters (1-8) trace the progress that one country, Namibia, has made toward attaining many of the “country ownership” goals described in Table 6 for its national blood transfusion service – and describe the remaining sustainability challenges the country faces as it continues to grow economically and demographically.

Beyond Namibia, it is the author’s sincere hope that the work presented in this dissertation will contribute to on-going discussions and debate about the advantages and risks associated with continued large-scale external donor support to expand countries’ blood transfusion services – and the need to develop smarter strategies that mix short-term development aid with longer-term technical assistance to build sustainable local capacity.

1.5 Objectives

This thesis seeks to fill some of the gaps described above through an in-depth exploration of the changes that accompanied nearly a decade of PEPFAR support for blood safety and blood systems strengthening activities in Namibia, one of the 14 countries with high HIV burdens originally funded by PEPFAR starting in 2004. The following chapters catalogue six specific
### Factors for Strong Country Ownership

<table>
<thead>
<tr>
<th>Ownership Dimensions</th>
<th>General Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Political ownership and stewardship</strong></td>
<td>• Host Government has a clear aspiration for what should be accomplished in each stage of program development, implementation and monitoring, generated with input from their own cities and rural areas, civil society, NGOs, and private sector, as well as their own citizens&lt;br&gt;• National plans are aligned to national priorities to achieve planned targets and results, with full costing estimates and plans incorporated&lt;br&gt;• Host country (public and private sectors) is the architect that fully implements and provides oversight of national plan to achieve results and applies and scales-up evidence-based best practices; this includes specific activities conducted by stakeholders in each stage from design to delivery of programs</td>
</tr>
<tr>
<td><strong>Institutional and community ownership</strong></td>
<td>• Host country institutions (inclusive of government, NGOs, civil society, and the private sector) constitute the primary vehicles through which health programs are delivered and take responsibility for each program&lt;br&gt;• Host country institutions adopt and implement transparent, evidence-based policies/regulations for priority areas that align with national plans&lt;br&gt;• Host country institutions manage funds</td>
</tr>
<tr>
<td><strong>Capabilities</strong></td>
<td>• Host country has effective workforce, organizations and systems at all levels able to perform activities and carry out responsibilities that achieve priority health outcomes&lt;br&gt;• National coordinating bodies and local institutions have the ability to gather and analyze epidemiological and program data to plan and measure program progress and results&lt;br&gt;• Host country institutions have the capabilities required to perform or oversee activities for programs&lt;br&gt;• Host country institutions have the ability to dynamically modify programs based on evidence and feedback from monitoring processes</td>
</tr>
</tbody>
</table>

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accomplishments by the Blood Transfusion Service of Namibia (NAMBTS) as it worked to expand access to blood transfusion services and improve the safety and quality of blood components and transfusion practices in Namibia. Emphasis is placed on quantifying these improvements through a deep analysis of a rich (and unique for sub-Saharan Africa) electronic database maintained by NAMBTS. This database is one of the few existing electronic data sources in Africa that capture information about every donor, donation, laboratory process, distribution step, blood bank process, and transfusion recipient on a national scale. The main blood service information system, which was upgraded with PEPFAR support in 2007, is complemented by an equally rich financial database maintained to support the NAMBTS cost-recovery system, another rarity in the region. Through the evaluation of progress in Namibia, the subsequent chapters also attempt to document the sustainability challenges created by the infusion, and subsequent withdrawal, of external donor support, and suggest ways other countries may learn from Namibia’s experience.

1.6 Research Questions

The availability of a multi-year national dataset that captured information about every unit of blood collected and distributed made Namibia an ideal location to investigate a number of questions about the general strength of a blood service and demand for transfusion services in an upper middle income African country. Because the period under review also coincided with the early, peak and waning years of PEPFAR’s blood safety investments in Namibia, this period offered a unique opportunity to attempt to describe PEPFAR’s contributions to improving the safety and availability of Namibia’s blood supply, and assess some of the sustainability benefits and challenges PEPFAR may leave in its wake (in Namibia and elsewhere).
Because Namibia’s experience did not occur in a vacuum – indeed, it occurred during a period of historic investments in healthcare systems across Africa – this thesis also seeks to understand the broader development challenges faced by blood transfusion services in low-resource countries, and to document the sometimes uncoordinated nature of international development assistance (IDA) provided by external donors in the name of improving the safety of or access to blood worldwide.

Specific questions asked by this thesis include:

- 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?

Lastly, as noted above, although a comprehensive history of Namibia’s healthcare system is beyond the scope of this thesis, the progress documented within Namibia’s blood transfusion service must also be seen as a reflection of the historic progress Namibia has made in addressing structural and legal inequalities linked to apartheid-era policies prior to Namibia’s independence in 1990.

1.7 Thesis Outline (Chapters 2-8)

This dissertation is structured in three parts. First, Chapter 2 seeks to systematically describe existing gaps faced by blood transfusion services in developing countries. Second, Chapters 3-8 describe and evaluate the impact of PEPFAR’s investments in Namibia’s blood transfusion service. Third, Chapter 9 discusses the sustainability challenges observed in Namibia and elsewhere, and presents a roadmap for the future, with specific recommendations for PEPFAR and other large multi-lateral donors, e.g., The Global Fund.

The rapid expansion of blood collections and distribution systems in Namibia between
2004 and 2011 – and the temporal association with PEPFAR investments during the same time frame – are discussed in Chapter 3. During this period, rural areas of Namibia (including areas of high population density that had historically been neglected by Apartheid-era regimes), witnessed substantial growth in the numbers of facilities offering transfusions. Similarly, Chapter 4 profiles blood use in Namibia over a four year period – a first for sub-Saharan Africa – and discusses how changes in Namibia’s healthcare system and underlying epidemiology of chronic and infectious disease are influencing the diagnoses driving blood demand. Chapter 5 continues the evaluation of Namibia’s transition from a whole blood-based transfusion system to a system dominated by the production and use of blood components. In this chapter the transition from whole blood-derived pooled platelets to single-donor apheresis platelet production is described and analyzed. This transition was made possible, in part, by PEPFAR funding for the purchase of apheresis equipment and supplies.

The economics of blood transfusion in Namibia are discussed in detail in Chapter 6, which describes and evaluates the subsidizing influence PEPFAR’s annual grants had on production costs and unit prices for red cell concentrate units sold to the public sector between 2004 and 2011.

Chapters 7 and 8 describe and evaluate the performance of one of the initiatives – a national hemovigilance system – that may be put at risk in the future if NAMBTS is not able to sustain its current level of operations. Chapter 7 reports the findings from a first-ever evaluation of a national hemovigilance system in sub-Saharan Africa. The hypothesis for this evaluation was that reporting through relatively new surveillance systems generally underestimates the size of the problem being studied.

Chapter 8 investigates some of the potential reasons for under-reporting via the hemovigilance program. For this chapter, more than 300 healthcare workers at 46 hospitals throughout Namibia were surveyed.

Lastly, Chapter 9 summarizes the findings reported above, and proposes a new framework for donor funded blood safety programs going forward. This framework is based on an on-going project to realign PEPFAR’s blood safety programs within the broader initiative’s focus on controlling national HIV/AIDS epidemics and improving the quality and sustainability of core clinical and laboratory services related to HIV/AIDS responses.

1.8 Hypotheses

This thesis explores the premise that challenges of unsafe and inadequate blood supplies in sub-Saharan Africa can be addressed through timely and adequate investments in the core technical, procurement and leadership elements recommended by WHO to strengthen national blood transfusion services [59]. To describe how this basic premise has been achieved in Namibia – and to explore how the introduction of external aid to achieve these ends may
also create sustainability challenges for recipient countries – ten broad assumptions were made.

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 and human resources.

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

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.

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.

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 sustainability gaps.

6. Changing patterns of disease will influence how much blood is needed by African countries, and how available blood stocks will be used.

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).

8. Effective data systems are an essential prerequisite to document progress and gaps.

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).

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.

To address the research questions and investigate the assumptions listed above, we studied data from Namibia, a large but sparsely populated country in southern Africa. As noted above, Namibia was a unique study site due to the ability to review multi-year electronic databases containing variables about blood donors, component production, transfusion recipients, and costs. While the strength of Namibia’s overall economy and its blood service’s relatively long history set the country apart from many of its neighbors in sub-Saharan Africa, Namibia also faces significant challenges with income inequality, maternal mortality, education, and child
nutrition – challenges that are comparable to less developed neighbors in the Africa region. This dichotomy makes Namibia a unique laboratory in which to observe the impact of IDA on a health care system that is simultaneously capable of delivering complex services including cancer therapy and cardiac surgery, while grappling with chronic shortages of healthcare workers, healthcare facilities, and equipment.

1.9 References

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