Case Study on Point-of-Care Electronic Data Systems for ART Clinics in Malawi: Baobab Health Trust

MIT Sloan School of Management
Global Entrepreneurship Lab: Global Health Delivery, Africa
Project Deliverable

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Executive Summary

As global awareness of the HIV/AIDS epidemic has increased, so has funding to combat the problem in the developing world. Assistance has poured in from sources such as the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR). Such funding has enabled Malawi to dramatically scale up its antiretroviral therapy (ART) program; yet, progress has not come without challenges. The country's monitoring and oversight policies have proven difficult to scale, as have efforts to ensure consistent, quality care.

The following study was conducted by four students from the Massachusetts Institute of Technology's Sloan School of Management. It analyzes the application of point-of-care healthcare technology in the developing world by comparing it with both manual (non-electronic) data systems and back-entry electronic data systems (EDS). Using the Baobab Health Anti-Retroviral Therapy System (BART) is as an example, the report examines the key issues that point-of-care systems address, and the applicable costs and benefits. It concludes that point-of-care systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry and manual systems cannot.

The study highlights a number of issues that can be addressed by a point-of-care EDS:

- Patient Management – Clinics face a burgeoning volume of paperwork associated with managing thousands of patient records, which are often missing or incomplete.
- Quality of Care – Nurses make several complex calculations and decisions during each roughly four-minute ART visit. These include staging, adherence, dosage, and body mass index determination.
- Data Collection – The Malawi MOH conducts quarterly supervision visits to each ART clinic in the country. Data is collected manually, subjecting it to errors and inaccuracies.
- Logistics and Planning – The MOH purchases $15 million worth of ARVs each year. There is a high human cost to understocking of drugs, and also measurable costs associated with overstocking, including transportation costs of redistributing drugs and disposal costs.

Acknowledging the problems identified above, in 2005, the MOH initiated a pilot program for EDS in Malawi. Two firms participated: Baobab Health and Luke International Norway (LIN). Eight sites are currently using the Baobab system, including 2 pilot sites. Baobab and LIN are working with MOH to expand EDS use to sixty four sites over the next five years.

Baobab and LIN are in the process of determining the full cost of implementing EDS. This will depend on the size of the clinics selected, as larger clinics will benefit from economies of scale, lowering the total cost per patient. The MIT team believes that the costs incurred by clinics should also be considered, since they contribute to Malawi's total healthcare burden. For example, clinics would greatly benefit from an on-site resource that is equipped to perform basic maintenance and troubleshooting (resetting the devices, ensuring all cables are connected, etc.). While training such individuals would increase Baobab's costs, it would also reduce the sites' future support burden. Such a policy could reduce retraining costs associated with clinical employee turnover.

Point-of-care electronic data systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry systems and paper processes cannot. Benefits can be realized in data collection, logistics and planning, and clinical care. While benefits are achievable using a back-entry EDS, most are only made possible through the point-of-care approach. The MIT Sloan team identified the following benefits of implementing point-of-care EDS:

Data Collection

- Quarterly Supervision Visits – shift focus of supervision visits from data collection to improving quality of care.
- Clinic Preparation for Quarterly Supervision Visits – increase the number of patient visits by eliminating time spent compiling data for visit. Estimated additional patient visits to be 179,760 patients per year across all 214 clinics.
- Data Entry Center – eliminate the need for data entry center necessary for back-entry EDS.
- Accuracy of Data Collected at Supervision Visits – improve accuracy of data by reducing possibility of human error.
- Point-of-Care versus Back-Entry EDS Data Accuracy – improve data accuracy, completeness and timeliness by entering at the point-of-care.

Logistics and Planning

- Inventory Management Savings – allow for more effective forecasts and cost-efficient purchasing of drugs.

Quality of Care

- Patient Registration – faster registration, easy patient record look-up.
- Patient Vitals – accurate, quick calculation of body mass index.
- Patient Staging – automatic staging allows for task shifting to less educated healthcare workers.
- Laboratory Samples – improve sample management by reducing transcriptions and linking lab results to patient digital profile.
- Clinical Process – standardize patient care and increase clinical decision support to allow for task shifting to less educated healthcare workers. Track effectiveness of treatment through easy access to patient records.
- Pill Count and Adherence Calculation – perform a more exact adherence calculation. Spend less time on calculating adherence and more time focusing on the patient.
- Pharmacy Management – reduce error rate through automatic dosage and access to records by pharmacists. Aggregate data helps prevent stock-outs and overstocks.
- Scheduling and Appointment Management – optimize patient scheduling to smooth demand for services and ensure more consistent utilization of employees.
- Missed Appointment Tracking – track no-shows to help prevent emergence of resistance to first-line drug regimen.
- Vertical Integration of Patient Management – potential to integrate patient records across the entire healthcare sector into other programs such as tuberculosis treatment, prevention of mother-to-child transmission, and HIV testing and counseling.
- Staffing Management - plan staffing levels in advance by tracking patient volume. Monitor clinic staff by using software as performance management tool.

There are several factors that are needed to ensure a successful nationwide point-of-care EDS deployment.

- Hardware Suited to Situation – use hardware built to last in hot, dusty environment with limited or inconsistent power supply.
- User-Oriented Software Development Process – involve the user in the development phase to create a user-friendly interface. Develop software using local talent.
- Systematic Training – conduct systematic training program for clinic staff and support, to include provision of training documentation.

- Dedicated Support and Maintenance Team – provide substantial ongoing support and maintenance to current customers for a fee.
- Data Security and Back-Up – ensure adequate onsite and offsite back-up of patient data.

Point-of-care electronic data systems promise many benefits for health care in Malawi. At the same time, there are several noteworthy cautions and caveats.

- Support – preventative maintenance and timely support are critical. Failure to provide adequate and timely support can create the perception that the technology does not work, which can have ramifications in future deployment plans.
- Transition – transitioning from paper to EDS will be gradual, given the learning curve and prudent risk control policies. For processes where both EDS and paper are used, however, duplication of efforts will at least temporarily slow care provision.
- Theft – loss of a Baobab terminal would not compromise patient data, although provisions are made for a security closet. Server theft, however, could lead to significant data loss and/or compromise.
- Scalability – centralized system would enable remote, real-time data analysis, maintenance, upgrades, and backups. It is possible that significant changes in architecture and/or software platform would be required to construct such a system.
- Integration – Malawi is deploying two major point-of-care systems (LIN and Baobab). Appropriate data standards will need to be developed and implemented if these systems are to be linked.

As the volume of patients on ART increases, the Malawi MOH asserts it has no choice but to adopt an EDS to manage the volume. By providing additional clinical decision support, a point-of-care EDS is more than a data collection, monitoring and evaluation tool. As such, point-of-care electronic data systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry systems and paper processes cannot. Malawi still has a long way to go in improving healthcare delivery to all members of society. The care it has taken in managing the expansion of its ART program gives us hope that this next step in digitalizing its operations will provide further benefit to those under MOH care.

Table of Contents

Table of Figures

Introduction

As global awareness of the HIV/AIDS epidemic has increased, so has funding to combat the problem in the developing world. Assistance poured in from sources such as the Global Fund and the President's Emergency Plan for AIDS Relief (PEPFAR). Such funding has enabled Malawi to dramatically scale up its antiretroviral therapy (ART) program; yet, progress has not come without challenges. The country's monitoring and oversight policies have proven difficult to scale, as have efforts to ensure consistent, quality care.

The following study was conducted by four students from the Massachusetts Institute of Technology's Sloan School of Management. It analyzes the application of point-of-care (POC) healthcare technology in the developing world by comparing the point-of-care concept with both manual (non-EDS systems) and back-entry EDS. Point-of-care electronic data systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry systems and paper processes cannot. This report examines the key issues point-of-care EDS addresses, and the costs and benefits of the technology using Baobab Health anti-retroviral therapy system (BART) as an example. It begins with an overview of Malawi's healthcare situation and proceeds to analyze the costs and benefits, deployment success factors, and other considerations associated with deployment point-of-care technologies.

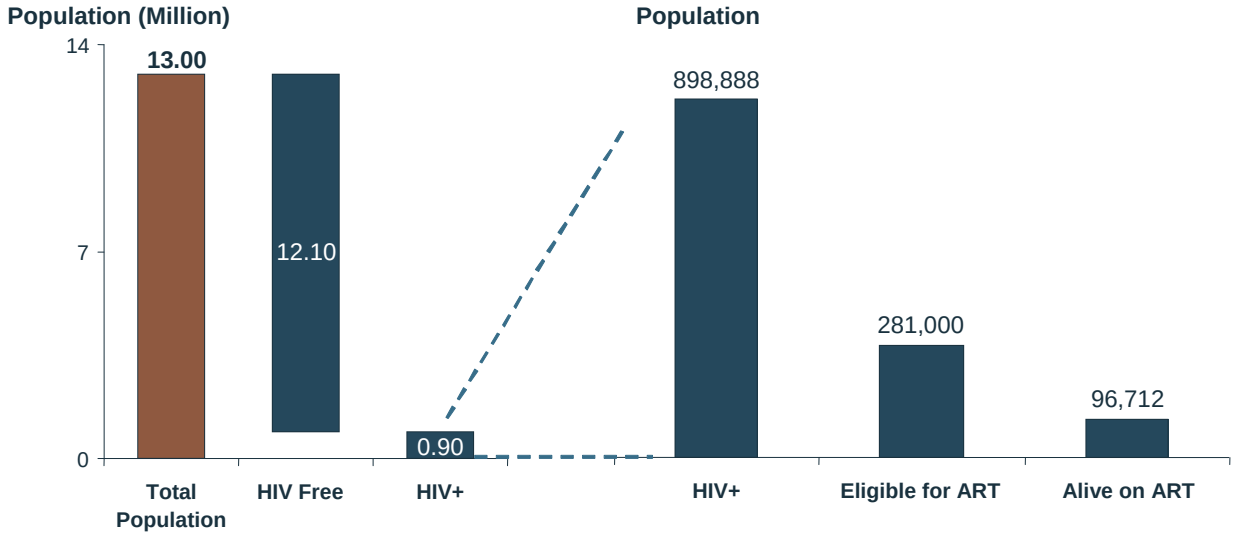
Part One: Background Information

Population Statistics

The National Statistical Office of Malawi estimates the country's total population at 13 million.[1] In 2005, this population had one of the highest HIV/AIDS rates in the world, with 12% of those aged 15 to 49 infected.[2] Life expectancy has fallen to just 39 years as a result of the epidemic, from a projected 54 years in its absence. In addition, the cumulative number of orphans produced by HIV/AIDS in Malawi has reached almost 700,000—a figure which increases by over 60,000 per year. [3]

The Ministry of Health's (MOH) response has been a rapid scale-up of anti-retroviral treatment (ART) throughout the nation. Between 2004 and 2008 the number of ART patients grew from under 4,000 to 180,000.[4] By September 2008, 135,264 of these patients remained alive and continuing treatment. Based on historic data, the team projects 150,976 will be alive and on treatment by the end of 2008.

Figure 1: HIV prevalence breakdown in Malawi (2007)[5]



Healthcare Sector

Government plays a significant role in Malawi's healthcare sector, as most patients are treated at public hospitals and clinics. According to a 2005 report by the African Development Fund, the MOH

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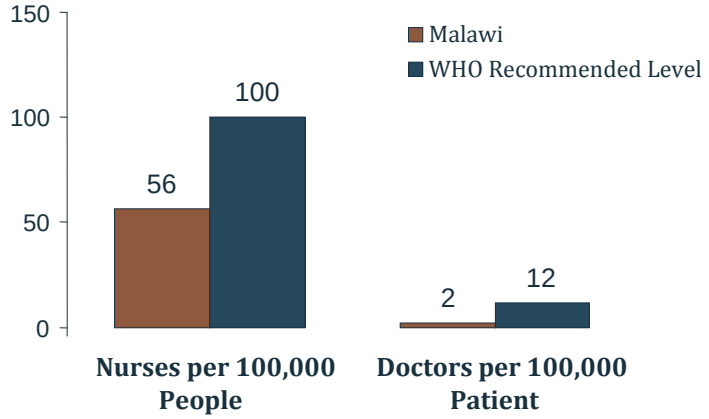
[1] National Satistical Office of Malawi Website. http://www.nso.malawi.net. Accessed January 12, 2009.
[2] Ministry of Health, Malawi. "HIV and Syphilis Sero – Survey and National HIV Prevalence and and AIDS Estimates Report, 2007. Page 5.
[3] Ministry of Health, Malawi. "Treatment of Aids: Guidelines for the use of Antretroviral therapy in Malawi." Second Edition. April 2006. Page 12.
[4] Ministry of Health, Malawi. "Antiretroviral Treatment in Malawi: Results up to 30th September, 2008."
[5] Data for "Eligible for ART" is based on 2007 Actual Patients Started ART and interview with MOH official who estimated that 50% of the people eligible for ART have received treatment.
Ministry of Health, Malawi. "HIV and Syphilis Sero – Survey and National HIV Prevalence and and AIDS Estimates Report, 2007. Page 5.

funds 60% of patient visits, with the Christian Health Association of Malawi (CHAM) supporting the next largest portion at 37%. There are 15,700 healthcare workers in total, including 219 doctors concentrated primarily in urban areas. 84% of Malawians live within 8 km of at least one public or private clinic.[6]

The MOH divides Malawi into 27 districts and has zonal offices that service five to six districts apiece. CHAM has 160 rural health units, which are primarily sponsored by independent religious and volunteer organizations. MOH services are free, whereas CHAM charges a small fee.[7]

Figure 2: Health worker resources in Malawi



In June 2004, the MOH launched a six-year human resources emergency plan. It provided funding for higher salaries and the expansion of recruitment and training programs.[8] This led Malawi to count 56 nurses and two doctors per 100,000 residents by 2007. Still, the country remains a long way from the World Health Organization's recommendation of 100 nurses and twenty doctors per 100,000 residents. A 2006 MOH survey suggested that the vacancy rate for nurse positions was as high as 60%.[9]

Ministry of Health ART Program

According to the MOH, the overall goal of its ART program "is to reduce morbidity and mortality of HIV/AIDS in adults and children." To achieve this, it pursues the following tactical objectives[10]:

1. To provide long-term ARV therapy to eligible patients.
2. To monitor and report treatment outcomes on a quarterly basis.
3. To attain individual drug adherence rates of 95% for patients on ARV therapy.
4. To increase life span so that over 50% of patients on ARV therapy are alive and ambulatory after three years of ARV therapy.

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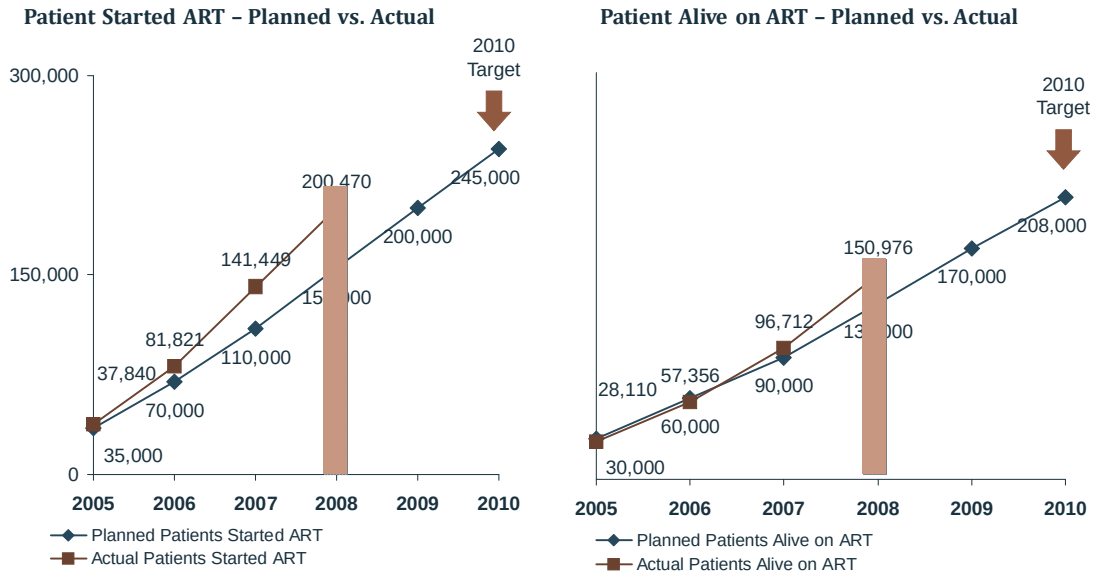
[6] African Development Fund. "Appraisal Report: Support to the Health Sector Program, Republic of Malawi." September 2005.
[7] African Development Fund. "Appraisal Report: Support to the Health Sector Program, Republic of Malawi." September 2005.
[8] Medecins Sans Frontier. "Malawi's Emergency Human Resources Plan: A Ray of Hope?" May 24, 2007.
[9] Mponda, Felix. "Malawi Health Service Ailing from Brain Drain." *Mail & Guardian Online.* October 7, 2007. (http://www.mg.co.za/article/2007-10-07-malawi-health-service-ailing-from-brain-drain)
[10] Ministry of Health, Malawi. "Treatment of AIDS: A Five-Year Plan for the Provision of Antiretroviral Therapy and Good Management of HIV-Related Diseases to HIV-Infected Patients in Malawi 2006-2010." December 2005.

5. To ensure that over 50% of patients on ARV therapy are engaged in their previous employment or any other productive activity within 6 months of starting ARV therapy.

Figure 3: ART program expansion (2005-2008) [11]



Funding Sources

In 2009, Malawi is expected to receive more than USD $790 million for HIV programs from international donors.[12] The MOH's HIV unit receives most of its funding from the Global Fund. Of particular interest to organizations producing point-of-care EDS technology is that the Global Fund recommends spending seven to ten percent of its contributions on monitoring and evaluation (M&E) programs. In total, the Global Fund has approved nearly USD $385 million in HIV/AIDS funding for Malawi. Since inception, this translates to a minimum of USD $27million for M&E programs.[13] MOH officials disclosed that a significant increase to current M&E spending would be necessary to meet this target.

Of U.S. government aid in Malawi, 60% is allocated to HIV/AIDS programming.[14] The U.S. President's Emergency Fund for AIDS Relief (PEPFAR) provided USD $24 million in fiscal year 2008.[15] Among the participating agencies, the U.S. Centers for Disease Control (CDC) is responsible

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[11] 2008 full year data was projected based on the 2008 quarter 3 reported patients started on ART (179,505) and actual patients alive on ART (135,264).
Ministry of Health, Malawi. "Antiretroviral Treatment in Malawi: Results up to 30th September, 2008."
[12] Robertson, Jamie. "HIV/AIDS Funding in Malawi: Major Contributors to HIV Programming Budget." http://aids-hiv-in-africa.suite101.com/article.cfm/hivaids_funding_in_malawi.
[13] Global Fund to fight AIDS, Tuberculosis and Malaria website. http://www.theglobalfund.org/programs/portfolio/?CountryId=MLW&Component=HIV/AIDS&lang=en. Accessed February 19, 2009.
[14] Robertson, Jamie. "HIV/AIDS Funding in Malawi: Major Contributors to HIV Programming Budget." http://aids-hiv-in-africa.suite101.com/article.cfm/hivaids_funding_in_malawi.
[15] Global Health Facts website. http://www.globalhealthfacts.org/topic.jsp?i=54. Accessed February 27, 2009.

for providing technical support in the implementation of electronic data systems. As of January, 2009, Baobab Health received the majority of its funding from the CDC.

In 2004, to harmonize an array of funding sources, Malawi adopted a Sector Wide Approach (SWAp) plan for its healthcare sector. The plan specifies a list of broadly relevant success indicators from which donors can choose. Many international donor organizations have contributed to the plan, including Department for International Development (DfID), USAID, Norwegian Agency for Development Cooperation, the African Development Bank, and various United Nations agencies. DfID now supplies 90% of its funding directly to the SWAp, rather than to individual programs. The six year workplan for the SWAp was priced at USD $763M.[16]

[16] NORAD Collected Reviews. "Malawi Health Swap Mid-Term Review: Summary Report." January 2008.

Part Two: Key Issues Addressable by Electronic Data Systems

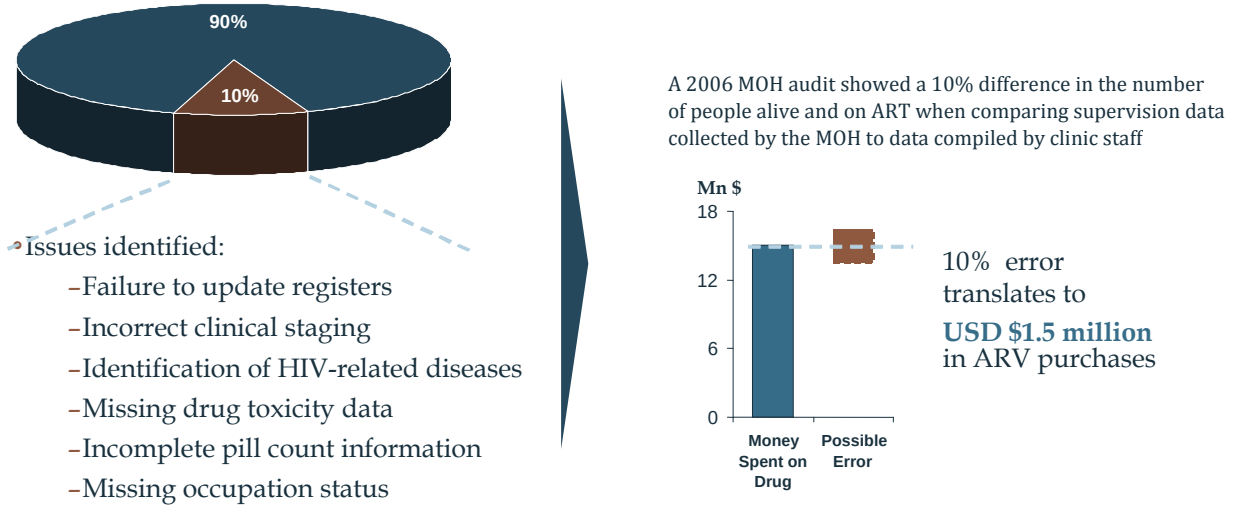
The MIT Sloan team identified a number of issues in healthcare delivery in Malawi that can be addressed by an EDS. These issues are organized into data collection, logistics and planning and clinical care. The data collection issues surround the difficulty of maintaining accurate data. In logistics and planning, the MIT Sloan team identified issues with inventory management. In clinical care the issues focus around the volume of paper records, education levels of staff and patient volume as well the complex decisions made by nurses and clinical officers.

Data Collection

Each quarter, MOH officials travel to every ART clinic in the country to collect patient data for monitoring and evaluation purposes. Where the data is manually recorded, collection can be very tedious and prone to inaccuracies, particularly at high burden clinics. Officials must verify and aggregate thousands of paper records. The MOH stated that this process has proven so difficult to scale, that continued growth of the ART program will require an EDS regardless of cost.

The quarterly supervision data indicate that the current patient default rate (lost to follow-up) is 10%. Official records of patients stopping treatment, however, sum to less than 1%. Anecdotal evidence suggests that 50% of defaulters are dead,[17] and the rest must either stop treatment or switch clinics. The transfer rate is 12%, but it is difficult to verify where the patients have actually transferred without an EDS.

Figure 4: Issues in the completeness and accuracy of the manual data collection



Numerous interviews called into question the accuracy and completeness of the manually collected data. The MOH reported in 2007 that data "deficiencies include the lack of [updated] registers; incorrect clinical staging and identification of HIV related diseases; absent drug toxicity reporting; lack of pill count information (e.g. only 31% of second quarter 2005 patients), and missing occupation status."[18] MOH sources point to a 2006 audit[19] that revealed a 10% error in the number

[17] Ministry of Health Interview, January 6, 2009.

[18] Lowrance, David et al. "Assessment of a National Monitoring and Evaluation System for Rapid Expansion of Antiretroviral Treatment in Malawi." *Tropical Medicine and International Health.* Volume 12, No. 3. March 2007. Page 379.

of people determined to be alive and on ART. Timeliness is another issue. MOH officials report frequent delays in receiving and compiling data. Such issues make it difficult to develop country-level plans and to secure timely funding from donors.

The manual data collection process may even be responsible for some inaccuracies. When MOH officials spend significant periods of time onsite, it creates incentives for workers to change their behavior. There are reports of nurses copying or fabricating data to satisfy MOH officials' requests. Interference can also be politically motivated, as aggregate statistics are often cited by elected officials. Paper systems facilitate such ill-motivated interference. Data inaccuracy may cause donors to perform their own parallel data collection processes, which draws on funds that could be applied to improving health outcomes.

Logistics and Planning

The MOH purchases $15M of ARVs each year for nationwide distribution, with purchases made semi-annually. MOH established a distribution system for ARVs that bypasses central medical stores in order to ensure adequate supply at the clinics. Approximately three months of stock are held at any given time. The MOH has limited means, however, to forecast future ARV demand. This is especially true given the large variation in lead time along with delays in approval for procurement funding. Twice a year, MOH uses the quarterly supervision data to make a rough forecast of demand for ARVs and then submits it to UNICEF which procures the ARVs. The lack of timely data from the clinics can delay the funding process.

There are costs associated with understocking or overstocking ARVs. Overstocking can lead to drug spoilage and significant waste in the system. The true cost of overstocking, however, is greater than this. Disposing of expired drugs is a bureaucratic process, and involves oversight by numerous agencies including police, poison control, and state assembly. Representatives from each agency are paid a per diem allowance for participation in the disposal. One pharmacist roughly estimated the cost of these agencies' allowance to be 10,000MK (approx. $67) per disposal.

Understocking, on the other hand, has high human costs. The MOH sought to avoid stock-outs by placing a monthly ceiling on the number of new patients started on ART. This makes the clinics more manageable but also limits ARV availability to those needing treatment. There have been no nation-wide stock-outs of ARVs to date, but the team heard several accounts of localized stock-outs. The MOH addresses this issue by transferring drugs between clinics on an ad hoc basis. This redistribution, and the applicable cost, could be reduced with better data and forecasting methods.

In one instance, the team observed a clinic returning drugs that had been redistributed, because they were found to be unneeded after all. This was done to avoid the disposal costs discussed previously. Clearly, it is not optimal for unneeded drugs to be shipped several times between clinics before ultimately being disposed. The expansion of ART and growing need for second and third-line treatments will likely further complicate forecasting and exacerbate this problem. Better data can lead to more cost-efficient purchasing and distribution of ARVs nationwide.

[19] The MIT Sloan Team was unable to locate 2006 audit document.

Clinical Care

Patient Management

One area of focus for the MIT Sloan team was on the delivery of ART at clinics and the challenges of patient care. The team's observations suggest that the average manual registration takes five to fifteen minutes. In cases where the patient forgets his health passport, clinical staff must sort through thousands of entries in the registration book to locate the applicable records. Patient master cards are also occasionally misplaced, resulting in the loss of patient treatment history. This makes it difficult for nurses to identify adherence concerns or problems of drug resistance. Meanwhile, patients often wait several hours prior to registering or being seen by a nurse.

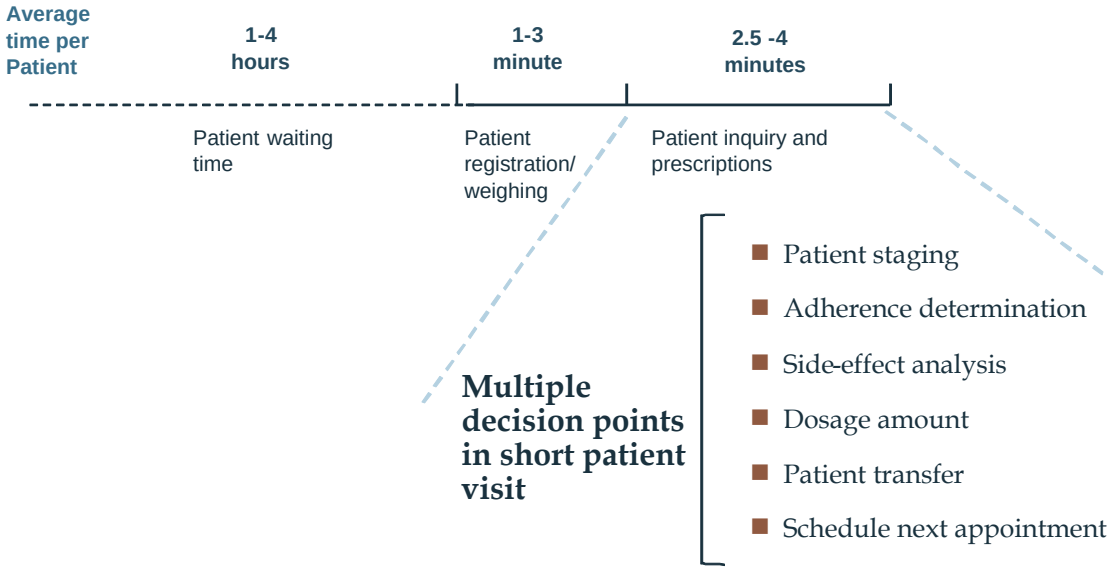
Most users of the Baobab system have no prior experience with computers. Registration clerks typically have a secondary education, while nurses undergo three years of training. This relatively low level of education makes it challenging to design protocols that can be widely implemented.

Many clinics mentioned that they have difficulty managing fluctuating patient volumes. At paper-based clinics, nurses generally schedule appointments by counting forward a set number of weeks. This complicates the adherence calculation in that the patient visits are often on a twenty-eight day cycle, while the regimen lasts thirty days. One clinic pointed out that the discrepancy leads patients to accumulate extra pills over time.

Quality of Care

An average ART nurse visit is very short, particularly when compared to the number of hours a patient spends waiting at the clinic. One clinic manager estimated that a visit typically lasts four minutes. In this time, the nurse makes several complex determinations including patient stage, dosage, body mass index (BMI), drug resistance and drug adherence.

Figure 5: Breakdown of patient visit



Since CD4 counts are often unavailable, the WHO defined four stages of disease progression based on symptoms. Only stage III and IV patients should receive ART. Clinic managers informed the team, however, that nurses often over-stage patients simply because "they look sick." This results in excessive drug disbursement, which creates side-effects and toxicity risks for patients who do not need ARVs. Meanwhile, if a nurse were to understage, patients would be denied the treatment they need in order to counter the progression of the disease. It is also important to have accurate stage data at the national level so that resources can be allocated effectively.

Accurate adherence calculations are equally important. At paper-based clinics, nurses determine adherence by counting the number of pills that patients have remaining. If a patient has less than eight pills left, he is deemed adherent; otherwise, he is deemed non-adherent and referred to counseling. This system fails to take into account the time that has elapsed between visits and the number of pills the patient had left at the previous visit. As a result, some patients are deemed adherent simply because they missed an appointment and consumed more pills before coming to the clinic. Unfortunately, the complete calculation is challenging for nurses to complete, especially under a time constraint. Some patients therefore miss out on counseling that they need, or receive counseling despite complete adherence. This wastes clinics' resources and can contribute to some patients to developing drug resistance which can require administering more expensive second-line drugs. A study by Drs. Oyugi and Bangsberg in Uganda showed patients had a roughly 50% chance of developing resistance with disruptions lasting more than forty-eight hours.[20] It also showed that adherence is an important predictor of survival with full viral suppression.

For pediatric patients, ARV dosage depends on weight. Nurses use dosage charts to determine the appropriate regimen, which can be time consuming. They also do this for BMI determination, which all patients require. A larger than 10% loss in BMI indicates HIV wasting syndrome and that the patient should be referred to nutrition counseling. Under the current system, there is significant opportunity for this to go awry.

[20] Oyugi, J.H. and Bangsberg, D.R. "Treatment Disruptions Predict Resistance in HIV-Positive Individuals Purchasing Fixed-Dose Combination Anti-Retroviral Therapy in Kampala, Uganda." *AIDS*. May 11, 2007.

Part Three: EDS Implementation in Malawi

There are two leading point-of-care electronic data systems currently available in Malawi that are specifically designed for use in ART clinics.

Baobab Health Trust

Baobab Health Trust was founded by Gerald Douglas to "provide eHealth solutions to the Ministry of Health [to help] solve the healthcare crisis in Malawi." At the core of Baobab's approach is a clinical touchscreen appliance that provides assistance to nurses and clerks as they treat patients. The appliance guides healthcare workers through treatment protocol and simultaneously collects data that is needed by the Ministry of Health (MOH).

To date, over 800,000 patients have registered on Baobab's systems and 18,000 receive Baobab-facilitated HIV/AIDS treatment. This success is at least partially due to the touchscreen appliance's unique design, which is custom-tailored to the developing world. Its software interface is geared toward users with no prior computing experience, and its hardware is durable and compensates for unreliable power.

Luke International Norway

In 1997, Norsk Lukas Misjon, with the English name "Luke International Norway" (LIN), was established as an NGO in Norway to assist Pingtung Christian Hospital (PTCH) in developing and strengthening its identity as a Christian hospital. In 2008, LIN initiated registration to be an international NGO in Malawi. One of its major working areas is on the ART EDS project.

The LIN System uses a similar point-of-care approach as Baobab. The system uses off-the-shelf hardware components with software running on a Windows-based system. LIN is committed to maintaining the current 5 ART sites listed below with its EDS and will support the proposed expansion plan with additional sites in the north and providing training and maintenance for its sites.

Pilot Program

Acknowledging the problems identified above, in 2007, the MOH initiated a pilot program for point-of-care EDS in Malawi with both Baobab Health and LIN. Baobab installed its systems at Dedza and Salima, while LIN worked with Nkhata Bay and Mzuzu. The MOH selected these four sites because they were medium-burden district hospitals with around 3,500 patients ever started on treatment and they receive minimal non-MOH support.

Currently, Baobab and LIN have installed software at the following clinics:

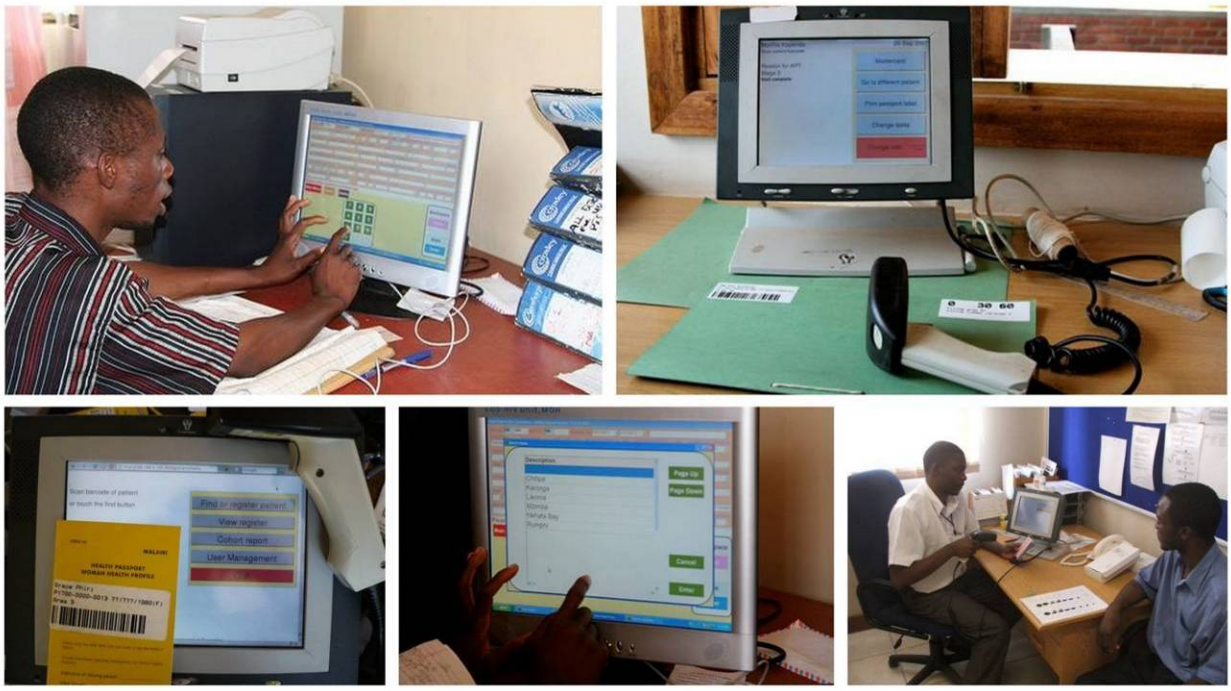
<u>Baobab</u>:

- MACRO Clinics – 4 sites running legacy software for HIV testing and counseling (HTC)
- Lighthouse/Martin Preuss – Baobab ART (BART) plus additional modules for pharmacy, counseling, and specimen labeling
- Kamuzu Central Hospital – patient registration, X-ray, and pharmacy modules
- Queen Elizabeth Central Hospital – BART
- Partners in Hope – BART
- Ministry of Health – 2 sites running outpatient diagnosis and registration system in Lilongwe District (rural health centers)

- Bwaila Hospital – Patient registration module with server at Martin Preuss and HTC
- Partners in Health, Neno – BART

LIN:
- Mzuzu Central Hospital – LIN System
- NkhataBay District Hospital – LIN System
- Rumphi District Hospital – LIN System
- St John's Missionary Hospital – LIN System
- Karonga Hospital – LIN System

Figure 6: Point-of-care electronic data systems used in Malawi[21]



(Note: top-left, bottom-middle: LIN System; top-right, bottom-left, bottom right: Baobab System)

Some additional clinics have also adopted miscellaneous EDS packages. For instance, the Medecins Sans Frontier (MSF) organization has employed a back-entry EDS at several clinics. Dignitas, based in Zomba, also uses an MS Access-based EDS.

Baobab Expansion Plan

Baobab recently submitted a preliminary proposal to the MOH outlining the expansion of ART systems to sixty-eight additional HIV/AIDS ARV clinics over the next five years. The target clinics are both private and government clinics that remain paper-based and have the highest number of patients on treatment. Management and user acceptance of an EDS, proximity to an EDS support center and funding of the system will be considered as well. Under the proposal, Baobab would deploy in the Central and Southern regions while LIN would be deployed in the North.

[21] Strategies for Building National-Scale Longitudinal Electronic Patient Monitoring Systems for HIV Treatment and Care in PEPFAR Countries. Conference Materials. Lusaka, Zambia. October 2-5, 2007.

The goal is to complete four installations in year one, and sixteen installations a year in years two through five. The organization will also concentrate on scaling its service and maintenance operations. Each site would receive on average three touch screens, a server, label printer, barcode scanner, battery back-up system, and some spare items. Five days of training will be supplied to each clinic, followed by a week of onsite support and back-entry of historical data.

Baobab would continue to support the central region from its Lilongwe headquarters, as well as establish a regional center near Blantyre, where most of the heavy burden clinics are located. This office would supply basic IT support to supplement the dial-in help desk.

Expansion Plan Cost

Baobab has historically focused on producing and supporting its technology, and costs have not been as exhaustively researched. The organization is currently working diligently, however, to refine its estimates and produce well-supported figures. Baobab will certainly begin charging for supplies and services that had previously been provided for free (e.g., label and ink refills), which will help stabilize its cost structure. Cost estimates should include the full costs associated with replacing hardware once it reaches the end of its three to five year useful life. Unique arrangements with clinics having poor or no electricity (solar or wind powered units) will also need to be included in the estimates. The cost per patient needs to include the fact that clinics that serve more patients, particularly those that serve over 2,000 patients, will enjoy considerable economies of scale.

The MIT Sloan team believes that the costs incurred by clinics should also be considered, since they contribute to Malawi's total healthcare burden. For example, clinics would greatly benefit from an on-site resource that is equipped to perform basic maintenance and troubleshooting (resetting the devices, ensuring all cables are connected, etc.). While training such individuals would increase Baobab's training costs, it would also reduce sites' future support burden. It could reduce retraining costs associated with clinical employee turnover.

Part Four: Benefit Analysis

Point-of-care electronic data systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry systems and paper processes cannot. This section examines the possible achievable benefits in data collection, logistics and planning, and clinical care. Some of the benefits described in the data collection section are achievable using a back-entry EDS. However, most benefits, particularly in clinical care, are only possible using a point-of-care EDS.

Data Collection

Given Malawi's relatively low cost of labor, the financial benefits of a point-of-care EDS system are small compared to what they might be in the developed world. The primary cost savings are derived from simplifying the Ministry of Health's quarterly supervision visits. A point-of-care EDS also eliminates all costs associated with back entry at a data entry center. While the financial benefits of implementing a point-of-care EDS are relatively small, the team has identified other benefits that are difficult to quantify yet are substantial.

In an interview with U.S. Government officials responsible for the distribution of PEPFAR funds, one official asserted that the biggest challenge at the district level is data collection. This is due to the cumbersome nature of the paper systems currently in use. Paper-based clinics have difficulty ensuring patient records are current, accurate and complete. The Ministry of Health goes to great lengths to gather data from these systems. Similarly, a back-entry EDS can have difficulties with data accuracy and completeness. Numerous organizations rely on the accuracy of the resultant report to make important HIV/AIDS policy and funding decisions.

Quarterly Supervision Visits

Ministry of Health and NGO officials visit each of Malawi's 214 ART clinics every quarter. A total of sixteen officials, in teams of two to three, spend two to three weeks traveling between clinics. The Ministry budgets USD $13,000 per quarter ($65,000 annually) for food, accommodation, car and driver, and per diem expenses associated with this process. Assuming the MOH sends fourteen officials who earn an estimated MWK 80,000[22] (USD $533) per month, and assuming the visits take two weeks to complete, the total salary expense is USD $3,733 per quarter, or $15,000 per year. This figure does not include the cost of any NGO-sponsored officials who participate in the visits. The complete annual cost of the supervision visits is estimated at USD $80,000.

The Ministry of Health has indicated that it will not discontinue its quarterly supervision visits following an EDS implementation. The visits are valuable because they give the Ministry a better feel for the situation at the clinics. They also allow the MOH to conduct physical drug inventory stock counts and review the clinics' infrastructure. Currently, however, the MOH review teams spend about 80% of each visit gathering and validating data from the clinics' paper records. This time could be alternatively used to provide counseling to the clinic staff, and perhaps even see patients which would help to increase the quality of care and boost employee morale.

Clinic Preparation for Quarterly Supervision Visits

Preparing for the quarterly supervision visits imposes a heavy burden on clinics that employ manual systems. One such clinic indicated that four employees spend approximately twenty hours over three to four days preparing the Ministry's report. The employees sort through thousands of

[22] Salary estimate provided by an NGO-sponsored employee at the Ministry of Health.

patient records to make sure they accurately reflect the status on the accompanying patient master cards. The master cards sometimes require updating as well. When the register and master card records match, the clinic builds the Ministry's report document, which involves counting the number of patients that meet each report criterion.

An MOH official indicated that clinic employees can earn anywhere from MWK 18,000 (USD $120) per month to MWK 125,000 (USD $833) per month. If one assumes an average monthly salary of $476, the employee cost per hour is $2.98. The total cost of labor associated with preparing for an MOH visit, then, is approximately $238 per quarter, or $952 per year. The cost for all 214 clinics is approximately $203,000 per year.

The time spent preparing for quarterly visits can also be expressed in terms of the number of patients that might have been treated during that time. Given Malawi's resource constraints, clinics can hardly afford to sacrifice a nurse's time for the cause of generating reports. A medium burden clinic sees an average of seventy patients per day; in that time, 210 patients could have been treated. This translates into an average of 840 forgone visits per clinic per year, or 179,760 visits across the 214 clinics.

An EDS can simplify the quarterly review process for both the clinics and the Ministry of Health. Baobab's system generates the MOH report at the push of a button. Point-of-care systems are particularly useful for this purpose, because the data is accessible onsite, whenever it is needed by the MOH. The data is also not subject to the inaccuracies introduced by manual data transformation.

Data Entry Center

Point-of-care systems have another financial benefit over back-entry systems. Because nurses record data as it is generated, no data entry center is required. This can result in a significant cost savings. While MSF was unable to provide an estimate of the costs for operating a data entry center the team did learn that MSF's data entry center employs two international managers, eight Malawian full-time data entry clerks and one full-time file clerk. None of these are necessary with a point-of-care EDS.

Accuracy of Data Collected at Quarterly Supervision Visits

A 2007 article assessing the expansion of ARV treatment in Malawi asserted that "the quality of the recorded data is variable, but generally high and improving steadily with the sites' experience."[23] The previously mentioned 2006 audit, however, showed that the clinics' reported number of patients alive and on treatment was off by 10%. The MOH's quarterly site visits are intended, in part, to keep such inaccuracies to a minimum. While accompanying the MOH on its quarterly visits, however, the team observed that the supervision process still allows for a wide range of errors.

The first step is to review the patient registers and ensure they match the patient master cards. The register indicates whether a person is alive, dead, defaulted, transferred out to another clinic, or stopped treatment. A person is recorded as having defaulted when more than three months have passed since the person's last visit. During the matching process, a MOH official has to look at each master card and manually calculate the time since the last visit. When thousands of records need to

[23]Lowrance, David et al. "Assessment of a National Monitoring and Evaluation System for Rapid Expansion of Antiretroviral Treatment in Malawi." *Tropical Medicine and International Health.* Volume 12, No. 3. March 2007. Page 379.

be reviewed, a MOH official must be able to quickly identify defaulters just by glancing at the master card. We observed that each MOH official had a different level of thoroughness in reviewing the master cards. We also observed how fatigue can influence how thorough officials are in the review process. It is difficult remain thorough and accurate after 2-3 hours of tediously reviewing master cards. This process leaves room for error, and as a result, the number of defaulters is likely understated.

After spending hours reviewing each patient record and master card, MOH officials begin compiling the report. They sort through the register books and manually count the patients alive and on ART, patients who have died, patients who have defaulted, patients who have stopped treatment, and patients who have transferred out. They then tally the numbers for ambulatory, employed, pregnant, children, on TB treatment, and male versus female. Each count is done individually by reading through the entire register once per tally. Clearly, there is extraordinary opportunity for fatigue and error, particularly at larger clinics.

The accuracy of the MOH report is critical. The Ministry of Health and National AIDS Commission (NAC) for Malawi both utilize it in determining policy and allocating resources. Donors also rely on it to inform their funding decisions. The data must therefore be reliable, accurate, granular, complete and timely. The manual quarterly review process allows for human error to be introduced in the data, which can negatively impact its accuracy. A point-of-care EDS automatically generates the MOH reports without human involvement, which eliminates the risk of human error compromising the data.

Point-of-Care Versus Back-Entry EDS Data Accuracy

While a back-entry EDS can facilitate data collection, the data will potentially be less reliable than if recorded by a point-of-care system. MSF, which has operated in Malawi since 2001 and has 30,000 patient records, uses a back-entry system. At MSF's clinic, a clinical care worker completes a carbon paper form at the time of each patient visit. One copy of the form is then given to the patient and another is sent to MSF's data-entry center. The data-entry center inputs the data from the form into their Fuchsia database, which is linked to MSF's headquarters in Paris. Similar systems are employed at other MSF sites in 60 countries. When patients return for follow-up visits, they are asked to bring copies of all forms they have received. If the patient loses the forms, the data can be recovered, but only with significant delay.

In 2007, MSF Malawi reviewed the quality of its data and found it to be inadequate. Issues were discovered in three main areas: database entry, lab data transcription, and on the carbon forms themselves. MSF's data-entry center employs seven individuals to enter 10,000 to 13,000 records per month, or one hundred records per employee per day. The repetitive nature of the work often caused the employees to enter CD4 counts, ages, heights, and dates into the system incorrectly. In 2007, MSF discovered 1,500 patient records with no age or sex. Lab data transcription errors are produced because labs generally use their own forms and then copy the data onto MSF's form later. MSF found that this extra step produced a nontrivial decrease in data quality. Finally, clinical staff do not always complete the forms correctly, completely, or legibly. If there are errors on a form, the data-entry center has no way to find out what was meant. What ultimately goes into the database can be guesswork at best.

MSF has made efforts to increase the quality of its data since 2007. It has hired two expatriates to work on the issue and implemented new quality control procedures. Transcription errors, however, will always be possible when data-entry is separated from the care provision process.

When data is entered by clinicians at the point-of-care, it is more likely to be accurate, complete, and timely. If invalid data is detected as it is recorded, the clinician can be asked to make corrections. The Baobab system, for instance, displays a warning if suspicious data is entered (e.g. a weight increase of 100 lbs. in one month). Of course, data quality is still dependent on the clinician and whether the warnings of the point-of-care system are heeded. The MIT Sloan team believes, however, that point-of-care systems are likely to produce a significant net increase in data quality.

Logistics and Planning

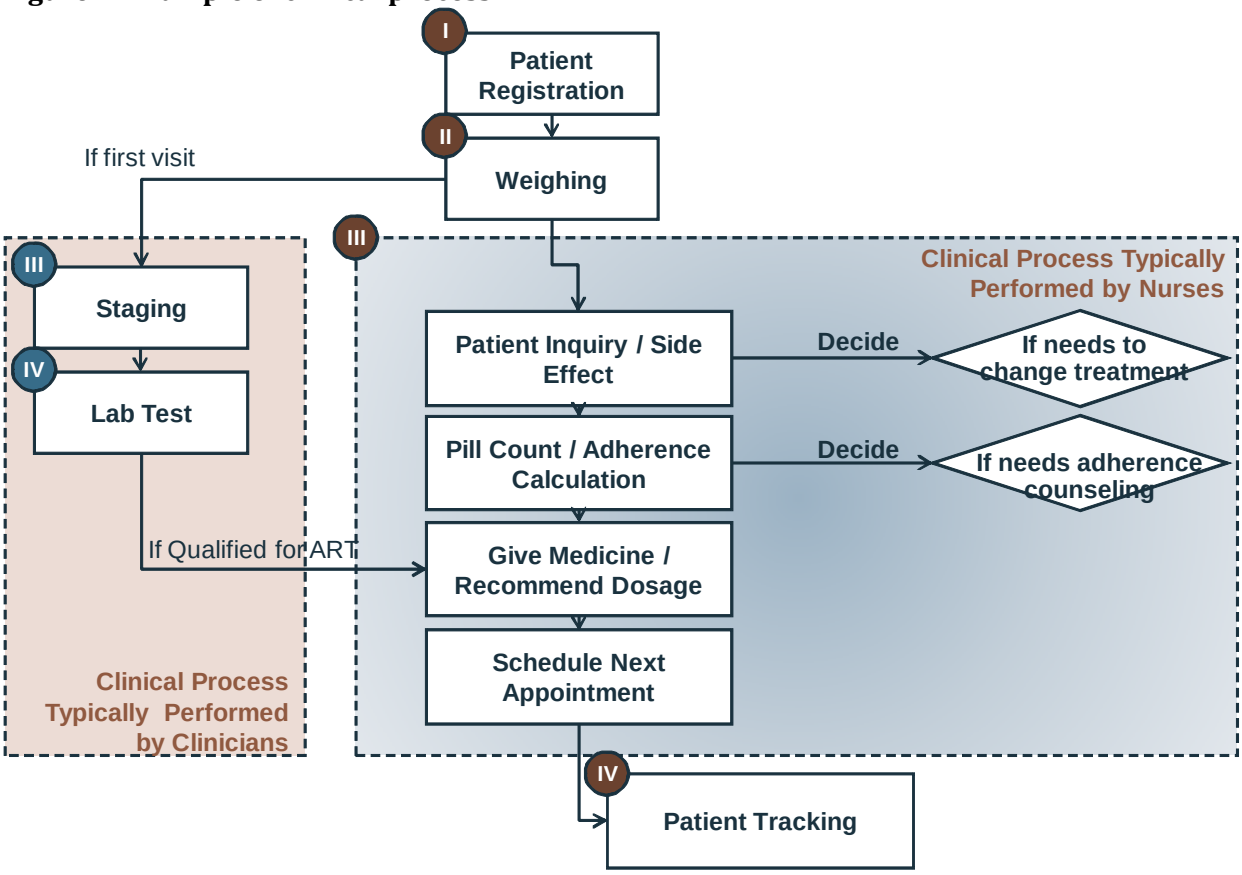
The 2006 audit revealed that, had the MOH not verified the data it received from clinics, its count of patients alive and on ARV would have been off by 10%. This implies a USD $1.5 million deviation in drug procurement for the year. The total understocking or overstocking costs associated with this error—drug spoilage and disposal, patients not receiving drugs, etc.—is likely to be significantly greater.

In a rapidly expanding healthcare sector, increasing data quality can have a significant impact on procurement and distribution costs. Current MOH forecasts are based on data that is over one month old. Deploying an EDS that captures real-time or close to real-time statistics will result in more effective forecasts and also provide the granularity needed to improve inventory management at the clinic level. This will help avoid instances where drugs need to be redistributed between clinics at a cost.

Clinical Care

Only an EDS used at the point-of-care can improve the quality of care patients receive. The system can provide workers with access to historical patient data and assist in decision-making. The following remaining sections of the benefit analysis analyze specific aspects of clinical care that are improved by a point-of-care EDS.

Figure 7: Example of clinical process[24]



Patient Registration

The patient registration process depends on whether the encounter is a first visit or a follow-up. For first visits, the registration clerk must record detailed patient information, including a demographic profile, guardian profile, and contact details. For follow-up visits, the clerk records the date and then locates the patient master card in one of numerous binders.

Baobab's patient registration module guides the clerk to capture all relevant patient information at the first visit and automatically creates a profile in the system. For follow-up visits, it retrieves the patient's information when the clerk scans a barcode on the patient's health passport.

According to clinic employees, the time to register a new patient using the Baobab system is around 2-5 minutes. This is much faster than on a manual system, which takes an estimated five to fifteen minutes. The difference is due to the fact that health workers no longer need to write in the

[24] Based on clinical visits. Note that the actual process might vary at different clinics.

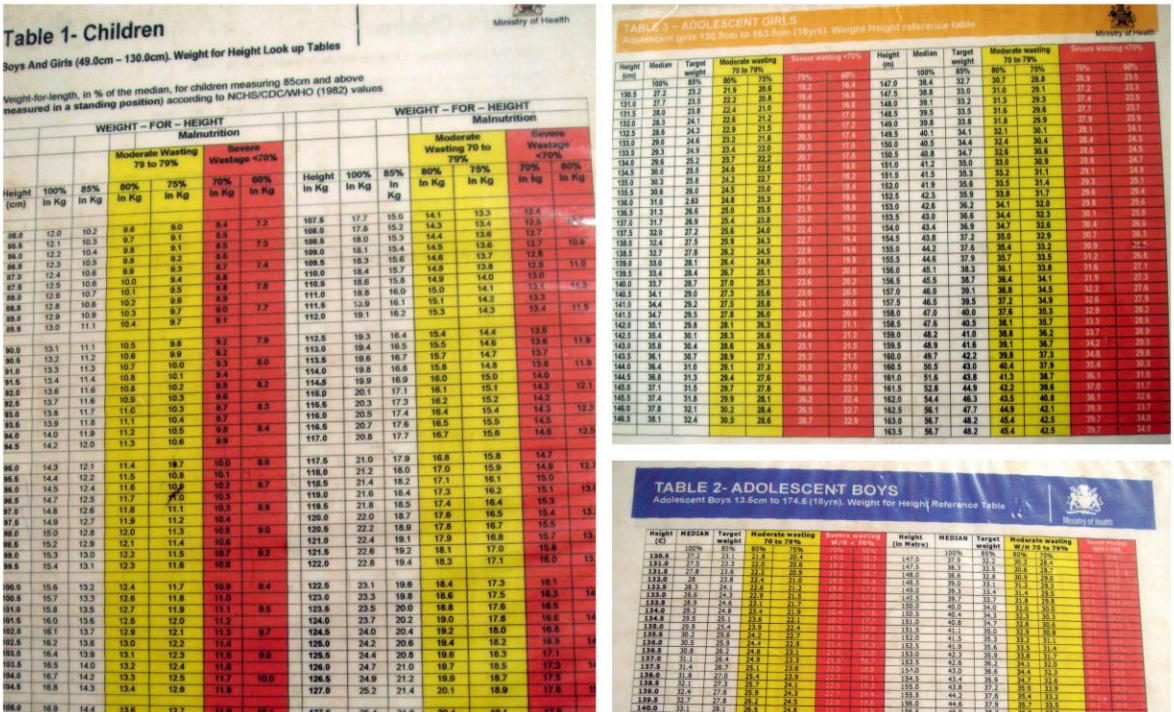
registration book or sort through the thousands of paper records to find the patient master card. Clinic employees indicate that patients seem to greatly appreciate the faster registration process. [25]

In some cases, a patient may lose the health passport or forget to bring it to the clinic. Under the manual system, the registration clerk is forced to search the registers for the passport number, and then use this to locate the master card. The Baobab system, in contrast, allows the clerk to find the patient by name (or a host of other identifiers), and eliminates the manual process.

Patient Vitals

Following registration, a nurse records the patient's height and weight. Using this data, she finds the patient's BMI on a chart and compares it to past measurements. Drastic changes can indicate wasting syndrome.

Figure 8: BMI chart for clinics without point-of-care EDS



With an EDS at the point-of-care, most of the calculation can be done automatically. This saves time and effort and ensures an accurate calculation. As the typical clinic treats 60 to 150 patients per day, health workers greatly appreciate this feature.

The team also observed that, at clinics using manual systems, nurses sometimes simply forget to review a patient's weight history. With the Baobab system, this is not a concern, since the nurse is

[25] Based on clinical visit.

guided through this step and the system provides a chart of the patient's weight history automatically on the screen. This allows the worker to easily monitor weight loss and refer the patient to nutrition counseling earlier and more correctly.

Patient Staging

Where CD4 counts are unavailable, the WHO specifies a staging process to determine whether a patient qualifies for ART. The staging process involves answering a series of questions regarding the symptoms that are present. The presence of certain symptoms (stages III or IV) indicates that ART will be beneficial.

Unfortunately, staging is sometimes misunderstood by nurses and carried out incorrectly. Patients are sometimes overstaged because the nurses feel they look sick. These patients may be given drugs even though the side-effects may outweigh the benefits. Point-of-care EDS improves the accuracy of the staging decision. This ensures that the patient receives appropriate treatment as well as facilitates national planning based on aggregate data.

The patient staging process is a prime example of task-shifting. Given the shortage of physicians in the developing world, "task-shifting" has become an important coping mechanism. Tasks that are normally handled by a doctor might be shifted to a nurse or assistant instead. Having an EDS at the point-of-care helps less skilled workers to make complex decisions without the aid of a doctor. Key functions can be performed by those with less education if the EDS can automate any complex calculations and decisions. This improves the clinic's overall resource-efficiency and healthcare outcomes per dollar spent.

Laboratory Samples

If possible, patient CD4 counts are taken on the first visit and every six months thereafter. Tracking and managing laboratory samples can be difficult for the clinics, however, because results are transcribed numerous times before being communicated to the patient. This sometimes leads to sample mishandling, transcription errors, and mix-ups.

Point-of-care systems can improve sample management by linking lab results to a patient's digital profile. The team observed such a system at the Lighthouse clinic, one of Baobab's flagship test sites. The clinic uses the Baobab system to print a barcode label that is pasted to the laboratory sample. This allows the clinic to scan the label at any time and track the sample's origin and progress.

Clinical Process

Health workers are expected to follow protocols in determining the best treatment for a given patient. Protocols ensure that patient care meets or exceeds a minimum standard. A study in the United States on catheter-related bloodstream infections showed a significant and sustained reduction in infection rates (up to 66%) following the implementation of basic protocol.[26] One challenge of delivering healthcare in resource-poor settings is ensuring quality care for the patient. Overworked staff frequently cut corners. This not only hampers data collection, but also decreases the quality of care that patients receive.

[26] Pronovost, Peter, MD et al. "An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU." *The New England Journal of Medicine.* Vol. 355. December 28, 2006. Pages 2725-2732.

Point-of-care systems like Baobab's are designed with an understanding of the treatment workflow in countries like Malawi. The benefits of the point-of-care approach, therefore, extend beyond data collection and into quality assurance. Baobab's systems guide nurses through each step of a patient visit, making it difficult to cut corners. Anecdotally, the team's observations at several clinics revealed that nurses in EDS-enabled facilities seemed far more organized and confident in the sequence of their tasks.[27]

There are, additionally, considerable benefits to having a patient's complete history readily to the clinician. He can more easily track the effectiveness of past treatments and identify failures and toxicity issues early.

Pill Count and Adherence Calculation

Pill counting is one of the most important steps in a typical clinical visit. Nurses determine patients' adherence to the treatment regimen, and whether counseling is necessary, by counting unused pills. If a patient has fewer than eight pills remaining, he is deemed adherent; otherwise, he is deemed non-adherent and referred to counseling. This system is flawed, however, because it does not take into account the number of pills a patient had at the previous visit or how much time has elapsed since then. Electronic systems perform a more complex calculation that gives a more accurate adherence rate.

Figure 9: Nurses doing pill count without point-of-care EDS

An ancillary benefit is that as nurses are freed from calculating adherence numbers, they can do more for the patient in terms of care. This is increasingly true as the adherence issue becomes more complex with the proliferation of first-line alternative and second-line drug regimens where

[27] Based on clinic visit.

dosages and regimens are more variable. To the best of the team's knowledge, adherence to second-line treatments is frequently not even calculated.

Pharmacy Management

The quantity of drugs dispensed depends on a patient's regimen and next scheduled appointment date. For adults, it also depends on whether the appointment is a first visit or a follow-up visit. Pediatric dosages depend on weight and nurses locate the correct prescription on a dosage-weight chart. The nurse then records the amount dispensed and writes dosage instructions on the patient's health passport and medicine bottle.

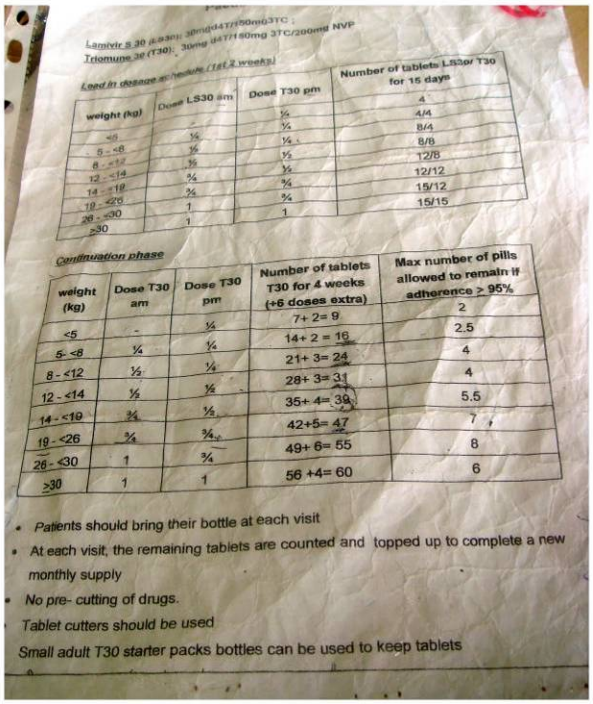
In most clinics, medicines are brought from a central pharmacy daily or weekly, and dispersed directly to patients in the nurses' room. Excess drugs are frequently stocked with a portion to be returned when the medications expire.

Point-of-care EDS makes this process easier for nurses in several ways. The system recommends the correct regimen and dosage based on the patient's condition. The system prints out instruction stickers for the health passport and medicine bottle. After dispensing the medicine, the nurse only needs to scan the printed barcode to retrieve the relevant records from the system.

Since the system automatically computes the correct drug amounts according to a patient's health records, the error rate is sharply reduced. This is particularly true for children, who require continually changing dosages as their weight increases. Errors are also reduced on the part of the patient, since the system printout is generally easier to read than the nurse's rushed, handwritten instructions.[28]

[28] Baobab is currently developing a pharmacy module to help track stock levels which could offer additional benefits in supporting pharmacy management.

Figure 10: Dosage calculation chart used in clinics without point-of-care EDS



Lamivir S 30 (LS30): 30mg/d4T/150mg 3TC ;
Triomune 30 (T30): 30mg d4T/150mg 3TC/200mg NVP

Lead in dosage schedule (1st 2 weeks)

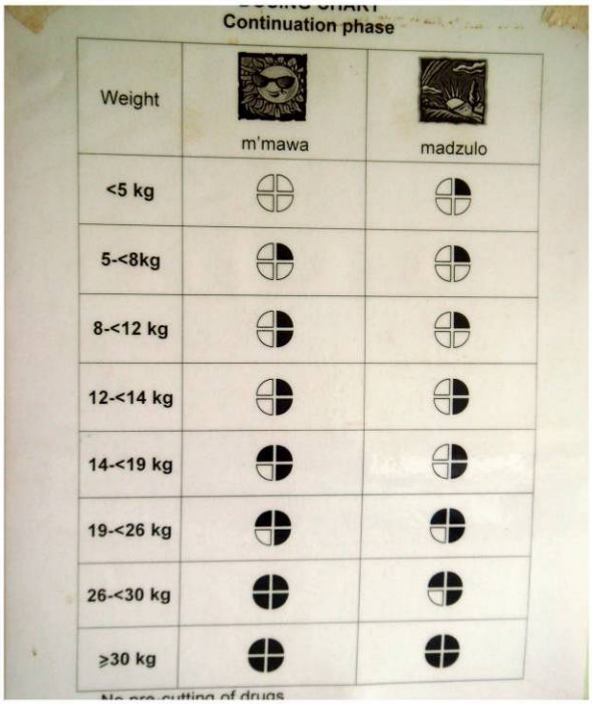
weight (kg)	Dose LS30 am	Dose T30 pm	Number of tablets LS30/ T30 for 15 days
<5	-	½	4
5 - <8	½	½	4/4
8 - <12	½	¼	8/4
12 - <14	½	½	8/8
14 - <19	½	½	12/8
19 - <26	¾	½	12/12
26 - <30	¾	¾	15/12
≥30	1	¾	15/15
	1	1	

Continuation phase

weight (kg)	Dose T30 am	Dose T30 pm	Number of tablets T30 for 4 weeks (+6 doses extra)	Max number of pills allowed to remain if adherence > 95%
<5	-	½	7+ 2= 9	2
5 - <8	¼	¼	14+ 2 = 16	2.5
8 - <12	½	¼	21+ 3= 24	4
12 - <14	½	½	28+ 3= 31	4
14 - <19	¾	½	35+ 4= 39	5.5
19 - <26	¾	¾	42+5= 47	7
26 - <30	1	¾	49+ 6= 55	8
≥30	1	1	56 +4= 60	6

- Patients should bring their bottle at each visit
- At each visit, the remaining tablets are counted and topped up to complete a new monthly supply
- No pre- cutting of drugs.
- Tablet cutters should be used

Small adult T30 starter packs bottles can be used to keep tablets



Continuation phase

Weight	m'mawa	madzulo
<5 kg		
5-<8kg		
8-<12 kg		
12-<14 kg		
14-<19 kg		
19-<26 kg		
26-<30 kg		
≥30 kg		

No pre-cutting of drugs

Additionally, an EDS is able to quickly aggregate patient prescriptions and report usage patterns for an entire clinic. This helps to avoid stock outs at the clinic level or within the nurse room, which could delay the treatment of patients.

Scheduling and Appointment Management

A patient's next appointment date depends on how long he has been on treatment and how well he adheres to regimen. Normally, the appointment date is set one or two months forward; occasionally it is three months.

One benefit of point-of-care EDS is that they can optimize patient scheduling. As illustrated in Figure 12 below, patient visits per day varies widely. With an EDS, patient volume can be shifted away from heavy days, so that the staff has a consistent schedule. This helps the clinic to make better use of its employees and increase total patient capacity.

Staffing Management

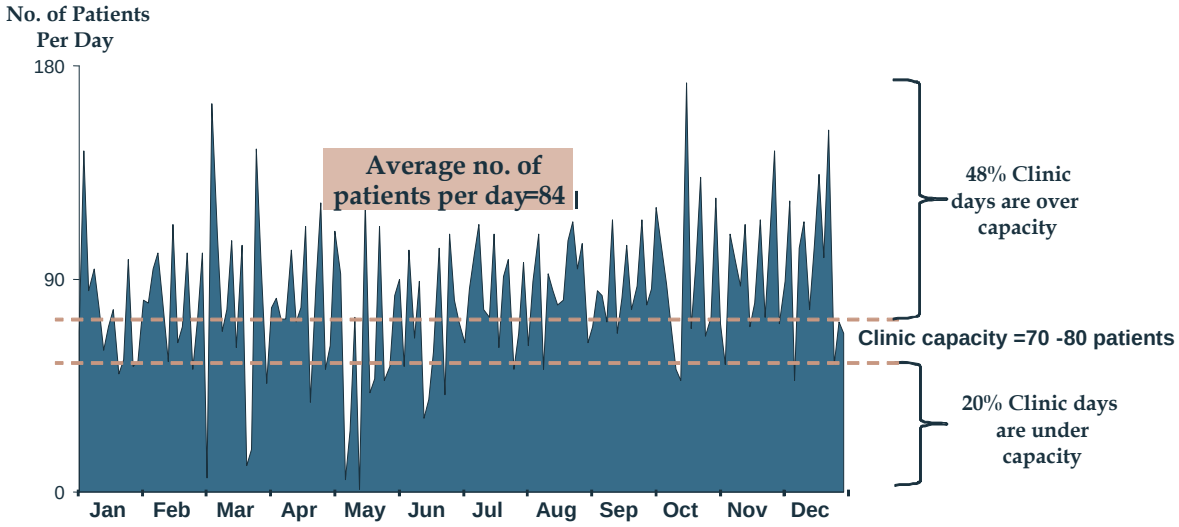
Several clinics cited difficulties anticipating patient volume for the coming day or week,[29] which complicates staffing decisions. If too many workers are hired, the clinic will incur excess costs or have to furlough employees. If too few workers are hired, patients may not receive adequate care. Along these lines, the Lighthouse Clinic found that Baobab's scheduling function can be used to monitor monthly patient increases and project future hiring needs.

A point-of-care EDS can potentially be used as a performance management tool to monitor nurses, clinical officers, and clerks. The patients treated by each nurse are recorded, as are the applicable

[29] Based on clinic visit.

diagnoses. Incentive systems could be built around performance metrics monitored by the system. Metrics that will encourage increased quality-of-care must be chosen. Simply rewarding nurses for the number of patients they treat per day would incentivize them to cut more corners.

Figure 11: Patient registrations at Salima District Hospital (2008)[30]



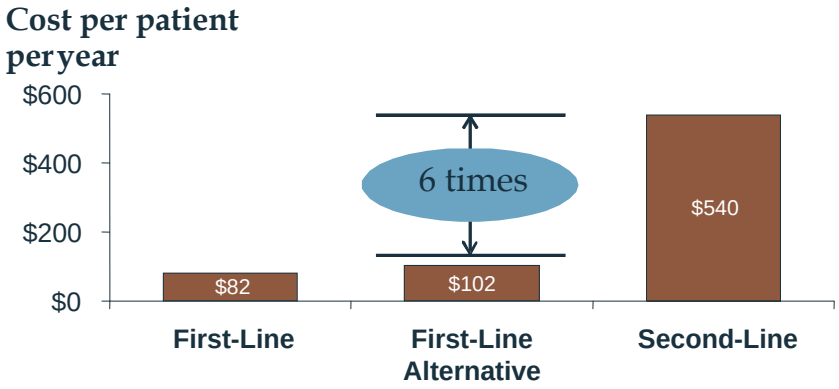
Missed Appointment Tracking

An EDS can also report which patients are missing appointments and how frequently the problem occurs. These patients might benefit from counseling. Most paper-based clinics, however, have no simple method to track missed appointments.

The Lighthouse Clinic developed its own system to track missed appointments. It is able to follow up with the no-shows and ensure that they do not run out of drugs and begin to develop resistance. Drug resistance presents a considerable risk to the effectiveness of first-line treatment and total program cost. Reports show that second-line treatment costs anywhere from two to nine times as much as first-line treatment.[31] The WHO estimates that, were it not for drug price reductions, "as much as 90% of the funds for providing ARV treatment [would] be spent on second-line drugs."[32] It also requires more medical expertise to manage a patient on second-line treatment, which strains clinics' scarce medical staff. Lastly, there is the risk that as drug-resistant strains of HIV proliferate, new drug creation will not keep up.

[30] Based on data recorded using Baobab EDS at Salima Clinic.
[31] United Nations Integrated Regional Network. "WHO Narrows Down Second-Line ARV Options." February 7, 2008.
[32] United Nations Integrated Regional Network. "WHO Narrows Down Second-Line ARV Options." February 7, 2008.

Figure 12: Cost difference between ART Regimens



Vertical Integration of Patient Information

HIV/AIDS patients likely receive treatment under other vertically related programs such as tuberculosis treatment, prevention of mother-to-child transmission, and HIV testing and counseling. Unfortunately, it can be difficult to link a patient's records across programs.

The true value of EDS may lie in its potential to integrate patient records across the entire healthcare sector. Future systems could be designed to track and facilitate patients' entire involvement with HIV-related programs from testing through treatment. This would not only improve continuity of care, but also make it easier to identify defaulters.

Part Five: Deployment Success Factors

The MIT team believes that several factors are important to the successful deployment of a point-of-care EDS. The following sections discuss these factors and how Baobab and/or LIN were able to implement them.

Hardware Suited to the Situation

Dust is prevalent in Malawi during the dry season. Most clinics, meanwhile, are not modern buildings with ideal computing conditions. They tend to be busy, have open air spaces and are often unclean. Most Malawian organizations expect their desktop computers to last about one year under such conditions. Poor infrastructure is the norm in most regions, and there is often no stable source of electricity. Outages can occur almost daily and typically last between ten minutes and five hours. The systems, moreover, are often used by people who lack the manual dexterity required to operate a traditional computer.

As a consequence, it is important for any hardware to be user-friendly and robust. Systems that are designed specifically for poor infrastructure and inexperienced users have an improved chance of success.

Touch-screen terminals

Touchscreens make an EDS intuitive to users without prior computing experience. The alternative mouse and keyboard can be cumbersome for someone who has not used a traditional computer. Forgoing these devices removes unnecessary training for nurses and clinicians and limits the opportunities for mechanical failure caused by dust and debris. When paired with user-friendly software featuring large buttons, touchscreens are a superior choice for users in the developing world.

Single Usage for Clinical Operations

Unlike a conventional desktop, the Baobab clinical workstation is designed to run only a single application. The software is configured in such a way as to prevent users from accessing the operating system and installing other applications.[33] This helps to prevent against viruses and other detractors from user productivity.

Durable and Robust Hardware

Baobab's systems employ components that are able to tolerate harsh environments. The workstations are cooled with heat sinks rather than fans, which prevents excess dust from accumulating. Instead of a traditional hard disk, Baobab uses a solid-state flash memory device with no failure-prone, moving parts.

Efficient Power Solutions

The system uses power-over-ethernet, and requires very little power to operate: just 13 Watts per workstation, which is less than a light bulb. The backup power system consists of four, 12-volt deep-cycle batteries which can be purchased off-the-shelf. This enables the systems to run reliably for over 24 hours when power is lost. When the system is used in areas without a power grid, alternative energy sources can be used (e.g., solar or wind).

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[33] Douglas, Gerald P. "Contrasting the Applicability of General-Purpose Desktop Computers vs. Special-Purpose Clinical Workstations in the Malawi Healthcare Setting."

User-friendly Software Development

Both developers and users must be considered when planning for sustainable software development. Nurses, receptionists, and clinicians are the key users of the system, and it is essential to tailor the software to their unique needs. If an organization is to be sustainable, it is also important to incorporate the local talent pool into development efforts.

Baobab and LIN each developed local teams and fully considered the applicable user base in their development processes.

- **Building a user-friendly interface**: Baobab's software has a simple "wizard-like" user interface that features step-by-step registration and clinical care assistance. It presents a series of simple screens, where each screen collects a single piece of data. The system also creates tokens and labels that save the user from redundant writing. Users can quickly become proficient in the system with only minimal training.

- **Building a local technology talent pool**: Baobab is committed to developing local software development expertise. Of its twenty-five staff members, twenty-four are local, full-time employees. The software and hardware management team also consists of local Malawians. Baobab builds local expertise by hiring expert mentors, embracing software engineering best practices, and using exclusively open source software.[34]

Systematic Training

Electronic systems are not always immediately accepted by users, especially in locations where computer systems are not prevalent. The MIT Sloan Team, in visiting several Baobab clinics, observed that switching to an EDS can be a gradual process. It takes time for users to build comfort, and clinical staff often require a substantial amount of training. Education levels can be low, as the typical registration clerk has a secondary school education. Training is important, however, to ensure that health workers follow applicable protocol. Understanding diagnoses and the applicable steps supports correct use of the EDS.

In interviewing key Baobab and LIN staff, the MIT Sloan team observed that both organizations made concerted efforts to ensure sufficient training. Each organization, moreover, mentioned that it is important to properly budget and account for training costs. Some sites, however, continue to operate without ongoing training.

- **Systematic Training Program:** Baobab typically runs a five-day training program on-site for new installations. The program was designed to be highly interactive and to quickly familiarize users with the software's interface and key functions. The session is followed by several weeks of on-the-job training.

- **Official Training Manual:** Baobab is developing an official manual which will guide the training of new clinical staff and help users to troubleshoot basic problems. The manual opens with pictures of each system component, and an explanation of the key buttons on a terminal. It then provides step-by-step instructions on how to start and operate the system.

[34] McKay, Michael V. and Douglas, Gerald P. "Touchscreen Clinical Workstations at the Point of Care: Guiding Protocols and Managing Data In Malawi."

It includes a check-list of common problems that a user might encounter and likely causes and solutions.

Dedicated Support and Maintenance Team

Support and maintenance are extremely important in ensuring a sustainable deployment. When the MIT Sloan team visited Macro—a Baobab site that had difficulty securing maintenance funding—it observed many difficulties using the EDS. It is critical that sites budget enough funding for continuous operation of the EDS they implement.

As the number of clinics with EDS increases, suppliers' ability to provide support will be extremely important to the success of any national plan. In reviewing Baobab's recent rollout plan, the team noticed significant emphasis on support and maintenance service functions.[35] In particular, the plan outlines the following initiatives:

- Establishment of a Baobab field support-office
- Deployment of a mobile support team
- Active help-desk implementation
- Monthly supervision visits to every site in support of reporting

Ownership by Users

During the deployment, it is also crucial to make sure the user takes ownership of the system. If they treat the system as owned by Baobab or LIN, they will feel that they are obliged to fill-in the data for MOH and not see the value of using the data in their own work. The user will then be inclined towards taking short-cuts in using the system.

Users need to realize how the system can help them ease their work and improve the clinical care process. By taking ownership of the system, they are more likely to follow the protocol and best utilize the system.

This issue will be particularly problematic if the focus of the system expands from providing clinical decision support to include more metrics needed for M&E of programs. Even though inclusion of all the metrics is important for supporting MOH program decisions, it makes the system less valuable to the user and the user, in turn, will be less likely to take ownership of the system.

A number of steps are essential to create the sense of ownership by users. Baobab and LIN have both taken initiatives to make that happen. This issue must also be included in the MOH agenda to further foster the sense of ownership by health workers.

- **Involving the user in development**: LIN involves users in developing its software. They invite users to join in software tests and then incorporate their feedback. This ensures that the software is tailored to users' needs and improves buy-in once users assume ownership over system development.[36] Baobab's office is located on-site at Kamuzu Central Hospital, close to the Lighthouse Clinic. This enables the organization's staff to interact with and consult users.

[35] "Proposal for Implementation plan for the roll out of the Electronic Data System for the Antiretroviral Treatment Programme." (Draft)
[36] Interview with LIN.

- **Training**: During training, it is very important to let the nurses know the convenience the system would bring them and how the tool can improve their work, in order for them to treat the system as an indispensable part of their job. Also, they need to learn to seek answers for the simple fix-up according to the manual guide and explore the system themselves to make full use of it.

- **Internal EDS Coordinator**: The Lighthouse Clinic, which runs the Baobab system, has an onsite expert in charge of the system. As a result, the operation of the system has been running more efficiently. A suggested strategy is to appoint a key coordinator in each clinic to ensure that the clinics and users take ownership of the program

Data Security and Backup

During visits to multiple EDS clinics, the team saw that no facility employed an exclusively electronic process. Most clinics simultaneously recorded data on paper and in the EDS. Policy-making officials, meanwhile, expressed concern over electronic data loss. Without assurance that electronic data are secure and always available, some benefits of point-of-care EDS cannot be fully realized. These include faster patient registration, cost savings against manual reporting, and enabling nurses to spend time with patients rather than writing.

Both Baobab and LIN complete regular manual and automatic data backups. LIN automatically backs up terminal data on a daily basis. It also schedules on-site visits to complete manual backups. Such provisions are important to any plan for widespread EDS deployment.

Part Six: Challenges and Other Considerations

Point-of-care electronic data systems promise many benefits for healthcare in Malawi. At the same time, there are several noteworthy cautions and caveats. The team regards the following as the most pressing at this time.

Support

Point-of-care electronic data systems have particularly high reliability requirements, since the devices are incorporated directly into care provision. Service disruptions have an immediate impact on clinics' workflow. As such, preventative maintenance and timely support are especially important. In combination with ongoing training and ordinary site support, these considerations can add significantly to the total cost of deployment.

In addition, many users cannot tell the difference between major and minor technical problems. They simply observe that the system is not working. As a result, failure to provide timely support and preventative maintenance can cause a perception that the technology is flawed. This perception can quickly spread among key stakeholders of the system.

Transition

All EDS sites that the team observed maintain some level of paper records. The transition from paper to EDS will necessarily be gradual, given the applicable learning curve and prudent risk control policies. For processes where both EDS and paper are used, however, duplication of efforts will at least temporarily slow care provision.

Baobab made some effort to reduce duplicated efforts. For instance, the organization recommended that their system's label printer be used to record data onto patient master cards and registers. Labels containing all data from each patient visit are affixed to these documents. This recommendation was recently approved by the MOH.

Theft

The point-of-care approach places terminals in highly-visible, easily-accessible locations. This puts them at increased risk for theft. While theft has not been an issue for Baobab historically, such an issue is not beyond imagination. Baobab endeavored to reduce its exposure by supplying clinics with secure server cabinets. Baobab is also investigating further means to secure its systems including crippling them against non-medical use and bolting terminals to secure tables.

It is worth noting that the loss of a terminal would not compromise patient data. Server theft, however, could lead to significant data loss and/or compromise. This is particularly true for rural sites, for which offsite backups are generated infrequently.

System Interconnectivity

One view of the ideal point-of-care system is that it would electronically connect all participating clinics. This would enable remote, real-time data analysis, maintenance, upgrades, and backups. It would also enable patients to transfer seamlessly from one clinic to another, as their records would be universally accessible. In stark contrast, there is presently no way to know if a transferring patient ever enrolls elsewhere. A truly interconnected system would solve this problem.

It is possible that the construction of such a system would require significant changes in current software architecture and/or platform. The prevailing selections appear to favor rapid development over the performance that is needed for centralized computing.

Integration

Malawi has simultaneously deployed two major point-of-care systems: LIN in the north and Baobab in the central and southern regions. The selection of multiple standards provides clinics with flexibility in choosing an EDS, but also introduces the challenge of interoperability. Appropriate data standards will need to be developed and implemented if these systems are to be linked. This will likely increase the total cost of EDS development in Malawi.

Conclusion

As the volume of patients on ART increases, the Malawi MOH asserts it has no choice but to adopt an EDS to manage the volume. Point-of-care electronic data systems promise to improve the delivery of anti-retroviral therapy in Malawi in many ways that back-entry systems and paper processes cannot. The data collection benefits include more accurate, granular and complete data. Better data can be used for more cost-efficient purchasing and distribution of drugs. It can also relieve the burden of quarterly supervision visits, freeing up MOH to focus on improving healthcare delivery at clinics rather than compiling numbers.

A point-of-care EDS, however, is more than a data collection, monitoring and evaluation tool. It provides additional clinical decision support and clinic management functions. Clinic staff are expected to make a number of complex treatment decisions and calculations in a short period of time. With a national shortage of nurses and doctors as well as relatively low levels of education among healthcare workers, these decision support functions can help standardize patient care and allow for task-shifting to workers with less education. In particular, patient adherence to the drug regimen is essential to reducing the rate at which drug resistance develops within the population. This in turn reduces costs in the long-run and improves health outcomes for individual patients.

In conclusion, there is a significant amount of benefit that can be gained. However, a number of factors and constraints must be addressed to ensure a successful implementation. These include develop software and hardware with local staff that is suited to the environment, involve the users in the development process, provide sufficient training and ongoing support/maintenance, and ensure adequate data security. The transition from a paper system will take many years, and issues of theft, scalability of the system and integration of multiple systems will be ongoing. Malawi still has a long way to go in improving healthcare delivery to all members of society. The care it has taken in managing the expansion of its ART program gives us hope that this next step in digitalizing its operations will provide further benefit to those under MOH care.

Appendix A: SQL Queries for Primary Data Analysis

A1. This query extracts a list of tablet counts and drug dispensations, paired by patient and date. The result set was then ported into MS Excel for a comparison of pre- and post-Baobab adherence calculations.

```
SELECT              pwtrb.id, pwtrb.patient_id, pwtrb.drug_id, pwtrb.visit_date, pp.time_period, pp.drug_id, pwtrb.total_remaining,
                    sum(pp.dose_amount), sum(pp.quantity), count(1)
FROM                patient_whole_tablets_remaining_and_brought pwtrb
RIGHT OUTER JOIN    patient_prescriptions pp
ON                  (pwtrb.patient_id = pp.patient_id
                    AND pwtrb.visit_date = date(pp.prescription_datetime))
GROUP BY            pwtrb.id, pwtrb.patient_id, pwtrb.drug_id, pwtrb.visit_date, pp.time_period, pp.drug_id, pwtrb.total_remaining
ORDER BY            pwtrb.patient_id ASC, pwtrb.visit_date DESC, pwtrb.drug_id ASC
```

A2. This query was not used in our analysis and is incomplete. It was intended to extract the outcomes of patient stagings for back-entered versus non-back-entered data. Timestamps of 23:23:59, 00:00:00, and 00:00:01 are widely used as flags for imported or back-entered data in the Baobab system, which is why the query tests for these conditions. In order to complete the query, the WHERE clause should be updated to include the full range of stage 1-4 condition concepts. A UDF or CASE statement should also be employed that outputs a value of 1-4 and passes it into the MAX aggregation function.

```
SELECT     temp1.maxIndicator, temp1.oneToMidnight, temp1.atMidnight, temp1.onePastMidnight,                    count(1)
FROM       (
       SELECT    o1.encounter_id as encounterID,
              TIME(o1.obs_datetime)='23:59:59' as oneToMidnight,
              TIME(o1.obs_datetime)='00:00:00' as atMidnight,
              TIME(o1.obs_datetime)='00:00:01' as onePastMidnight,
              MAX(o1.concept_id) as maxIndicator
       FROM      obs o1
       WHERE     (o1.concept_id >= 390 AND o1.concept_id <= 393)
              AND o1.voided = 0
              AND o1.value_coded = 3
       GROUP BY  encounterID, oneToMidnight, atMidnight, onePastMidnight
       ) temp1
GROUP BY    temp1.maxIndicator, temp1.oneToMidnight, temp1.atMidnight, temp1.onePastMidnight
ORDER BY    temp1.oneToMidnight, temp1.atMidnight, temp1.onePastMidnight, temp1.maxIndicator
```

A3. This query was not directly used, but helped to give the team an understanding of the variation in daily patient volume. It extracts the unique HIV/AIDS patient count in the encounters table, broken out by date.

```
SELECT          dt, count(1)
FROM            (
                SELECT    date(encounter.encounter_datetime) as dt, encounter.patient_id, count(1)
                FROM      encounter
                WHERE     encounter_type IN(1,2,5,6)
                GROUP BY  dt, encounter.patient_id
                ) t1
GROUP BY        dt
```

Appendix B: Acronyms

ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral drug
BART	Baobab Anti-Retroviral Therapy system
BMI	Body Mass Index
CDC	Center for Disease Control
CHAM	Christian Health Association of Malawi
DfID	Department for International Development (United Kingdom)
EDS	Electronic Data System
HTC	HIV Testing and Counseling
LIN	Luke International Norway
M&E	Monitoring and Evaluation
MOH	Ministry of Health (Malawi)
MSF	Medecins Sans Frontiere
NAC	National AIDS Commission
PEPFAR	President's Emergency Plan for AIDS Relief
POC	Point-of-Care
SWAp	Sector-Wide Approach

Acknowledgements

We would like to thank everyone who supported us in our research efforts and taught us everything we know about Malawi. First and foremost, we would like to thank Gerry Douglas, Sabine Joukes, Andrew Azman, Oliver Gadabu, Soyapi Mumba, Alex Gondwe and everyone in Baobab Health Trust, without whom the project would not have been possible. We acknowledge Mike McKay, Bill Rodriguez, Jeff Rafter, Evan Waters, Gari Clifford, Molly McNairy, Jon Payne, Rebecca Weintraub and Jonathan Jackson for providing background information and material for the project.

In addition, we would like to thank the representatives from the following organizations who took the time to speak to us in Malawi:

Malawi Ministry of Health staff, particularly the HIV/AIDS Department
United States Agency for International Development
United States Centers for Disease Control and Prevention
United Kingdom Department for International Development
United States Department of State
PEPFAR
National AIDS Commission
Lighthouse Clinic
Salima ART Clinic
Dedza ART Clinic
Dowa Clinic and Supervision Team
Luke International Norway
Partners in Health
Partners in Hope

Most importantly, the MIT Sloan team gives a hearty “zikomo” to Nancy who kept these four mzungus healthy and well-fed.

Lastly, we thank the Sloan School of Management for funding our trip and Professor Anjali Sastry for guiding our project.