Performance assessment of point-of-dispensing practices of donated oncology medicines: The Max Foundation

Sabra Zaraa

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Andreas Stergachis

David Grembowski

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Abstract

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Sabra Zaraa

Chair of the Supervisory Committee:

Andreas Stergachis

Department of Pharmacy & Global Health

Background Cancer is one of the leading causes of morbidity and mortality worldwide, yet financial barriers limit access to life-saving oncology drugs in low- and middle-income countries (LMICs). For the past 15 years, the Glivec® International Patient Assistance Program (GIPAP), established by Novartis and implemented in partnership with The Max Foundation, has been improving patient access to quality assured oncology drugs in LMICs. However, there have been no performance assessments to-date of medicine-related services at point-of-dispensing sites. The primary goal of this study was to evaluate the quality of performance at 48 point-of-dispensing sites located in 41 LMICs. By doing so, the evaluation establishes a baseline of the procedures' weaknesses and the strengths for continuous quality improvement.

Methods A cross-sectional embedded mixed-method study was conducted. We performed a secondary data analysis of pre-recorded data collected from January 2017 until December 2017, using a checklist and a site report template. The analysis consisted of analysis and interpretation of descriptive statistics and a directed approach to content analysis to assess the quality of ten quality categories, including storage conditions, diagnostics, and adverse event reporting. The quality of data

collected was also assessed in terms of completeness and content validity. The results were used to develop a set of recommendations for future performance assessments of point-of-dispensing sites.

Results Fourteen point-of-dispensing sites were classified as top performers, while 24 were classified as average performers and seven sites were called to implement most improvements. Data were 100% complete for four out of 10 selected quality categories; the other categories had 2-38% missing values. Content validity was "good" in eight quality categories, "average" in two categories and "poor" in one category.

Conclusion The quality of the performance in point-of-dispensing sites as well as the quality of the performance of the assessment tool can be improved. Completeness and content validity of data collected was not achieved at a number of sites. Seven recommendations are proposed to address weaknesses of measurement procedures and data collection to ensure better performance and performance assessment at point-of-dispensing sites in the future.

Keywords Quality improvement, Performance assessment, Medical donations, Low- and middle-income countries, Imatinib, Patient assistance programs.

List of abbreviations

AE: Adverse event.
CIS: Commonwealth of Independent States.
CML: Chronic myeloid leukemia.
DALY: Disability-adjusted life year.
EU GDP: European good manufacturing and distribution practices.
FEFO: First expired, first out.
FIFO: First in, first out.
GIPAP: Glivec® International Patient Assistance Program.
GIST: Gastrointestinal stromal tumors.
LMIC: Low- and middle-income countries.
MAS: Max Access Solutions.
NGO: Non-governmental organization.
PATS: Patient Access Tracking System.
PCR: Polymerase chain reaction.
PQMD: Partnership for Quality Medical Donations.
RH: Region head.
SOP: Standard operating procedures.
TPG: Tanner Pharma Group.
WHO: World Health Organization.

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I. BACKGROUND AND SIGNIFICANCE

To fulfill its vision, "Dignity and hope in the face of cancer," The Max Foundation directs life-saving medicine donations to underserved populations suffering from cancer in countries where such medical products are generally inaccessible locally. In the past decade, The Max Foundation has collaborated with 2,791 physicians in 117 countries globally to deliver over four million monthly doses of oncology medicines to 96,047 patients. [1] Figure 1 shows the worldwide locations of the treatment access programs, patient support programs, Max Global Network partners, and the regional offices and representations.

Figure 1 Map of The Max Foundation's global reach [1]

Cancer is one of the leading causes of morbidity and mortality worldwide. In 2016, there were 17.2 million incident cancer cases, 8.9 million deaths, and 213.2 million disability-adjusted life years (DALYs) due to cancer globally. [2] Reducing the burden of cancer in low- and middle-income countries (LMICs) is challenging for several reasons, including the scarcity of diagnostic and

treatment capacity as well as the lack of adequate access to oncology medicines and their expensive prices.[2] The Glivec® International Patient Assistance Program (GIPAP) was established by Novartis and implemented in partnership with The Max Foundation, a Seattle-based, non-profit, international non-governmental organization (NGO). GIPAP ensures that patients with specific cancers have access to treatment, e.g., chronic myeloid leukemia (CML), metastatic malignant gastrointestinal stromal tumors (GIST). For the past 15 years, physicians and institutions have partnered with The Max Foundation to provide Glivec® to patients through GIPAP. GIPAP was the first of its kind program to enable patients primarily from LMICs to access essential oncology therapies at no cost to patients. [3,4]

In continued collaboration with the drug manufacturer, GIPAP has transitioned from an industry-owned program, i.e., Novartis, to a program owned and led by The Max Foundation. The new program, Max Access Solutions (MAS), involves a network of institutions and physicians, drug manufacturers, international distributors of medicines (e.g., Tanner Pharma Group) and local patient support organizations that help provide medicines to markets of need, while strengthening the local healthcare system.[1] Tanner Pharma Group is a global pharmaceutical services company that specializes in patient access to medicines with more than 15 years of experience in supply chain and regulatory compliance and serves as The Max Foundation's third party logistics provider.[5]

The process for medical donations is complex and undesirable consequences can arise from inappropriate handling and management of donations, including issues related to medicines due to expire soon.[6,7] In the case of GIPAP, the problem is multi-faceted. Relevant issues include the potential for stock outs due to changes in the regulatory environment of the countries where The Max Foundation operates as well as the potential for poor inventory management.[1] These consequences may incur costs to both donors and recipients, and may have a negative impact on sustainable access to medicines. [6] The World Health Organization (WHO) and, separately, the

Partnership for Quality Medical Donations (PQMD) developed guidelines for medicine donations.[7,8] It is important to help ensure that procedures for distributing and dispensing donated pharmaceuticals are conducted according to these guidelines to avoid waste, stockpiling unused drugs or problems of disposal at the receiving end. As such, and as part of a quality improvement initiative, visits to point-of-dispensing sites were conducted in order to assess medicine-related services associated with the dispensing of The Max Foundation donated medicines. Point-of-dispensing sites are hospitals, physician offices, or pharmacies where donated products are received once they clear customs and then dispensed to the end user[1]. Performance assessment serves as a baseline that enables The Max Foundation to continuously improve processes to make them more efficient, effective, and safe.[9] Performance assessment is also a tool for monitoring that generates findings to guide program improvements. Identifying, understanding and analyzing problems helps generate evidence-based solutions.[9] Quality improvement is especially important in these settings since effective medicine handling and dispensing, as well as communication between The Max Foundation and physicians are crucial to help ensure high quality oncology care delivery to patients.

II. Conceptual framework

The Max Foundation's primary goal is to increase global access to treatment, care, and support for people living with cancer. The logic model of the performance assessment of point-of-dispensing medicine-related services is shown in Figure 2. The logic model specifies that training The Max Foundation staff to perform the site visits, complete the performance assessment, and analyze the data collected during site visits enhances relationship building between The Max Foundation and its network of participating physicians and institutions.

Another component of the model is the use of information systems and technology. Site visits are a mechanism to stress to the participating physicians the importance of using the Patient Access Tracking System (PATS®). PATS® is a proprietary, in-house, web-based, customer relationship management tool that supports and coordinates The Max Foundation's activities in GIPAP. PATS® serves as a mechanism for physicians and The Max Foundation's staff to communicate with each other and track the patient's treatment lifecycle. The patient's lifecycle includes an eligibility review, approval to the program, and ongoing treatment status, such as changes in dose and/or case closure. Such information helps local coordinators follow up with patients and aids in demand planning. PATS® also enables physicians and The Max Foundation's staff to report adverse events (AEs) in compliance of regulatory guidelines regarding patient safety.[10]

By improving communication and involving the healthcare providers in each site visit, The Max Foundation clarifies the goals of the partnership and establishes how both parties can work together to strengthen the donation system. The logic model also stipulates that the knowledge gained from the performance assessment helps the team review, revise, and validate the toolkit resulting in a better assessment of performance that leads to continuity of treatment as prescribed by the partner physician. The longer term outcomes of these site visits potentially include: improvements in dispensing practices, such as introduction of a dispensing log; improvements in supply chain logistics, such as efficiencies in length of time from product shipment, customs clearance, and delivery to the treating institution; and improvements in clinical effectiveness, appropriateness of care, efficiency and safety, by communicating with physicians the availability of clinical resources and/or other oncology products available through The Max Foundation.

Figure 2. Logic model of performance assessment of point-of-dispensing practices of donated oncology medicines

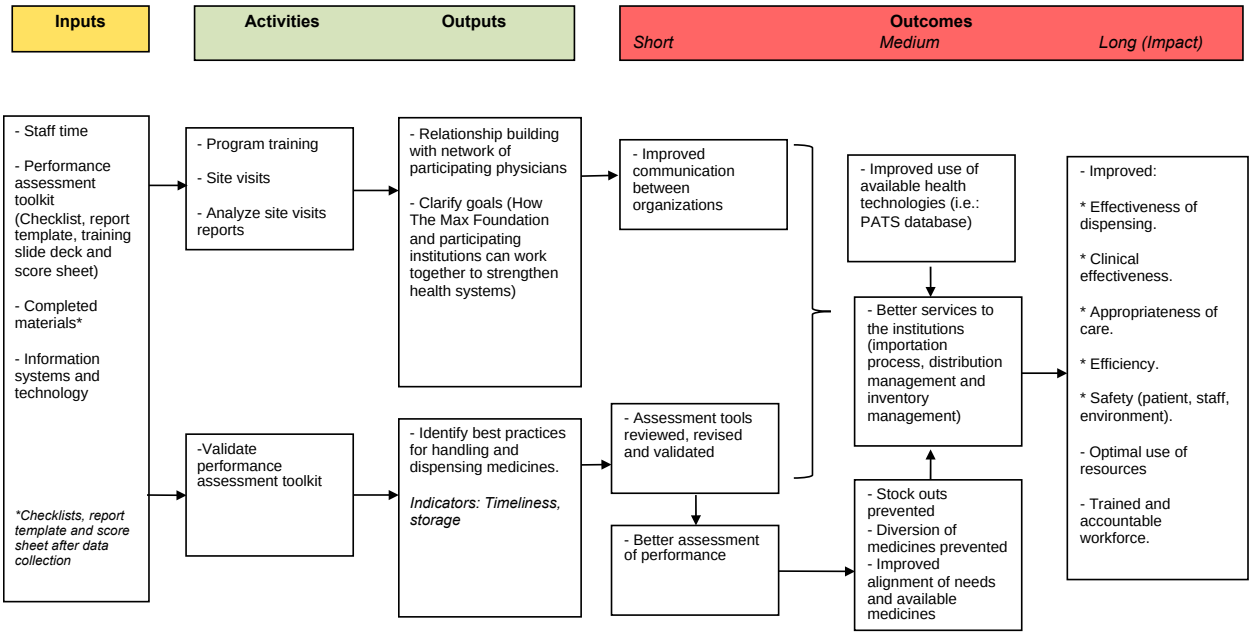
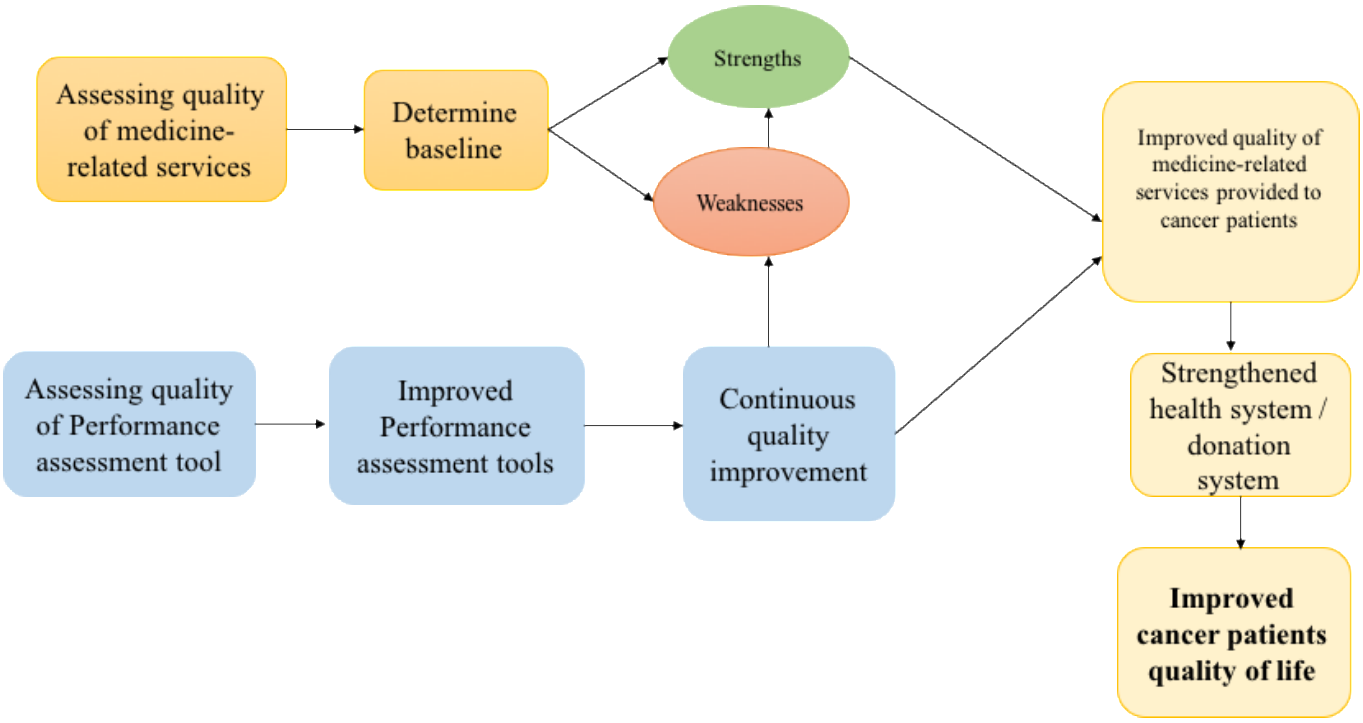


Figure 3 illustrates The Max Foundation's quality improvement strategy. This model depicts that the use the information gathered from point-of-dispensing sites serves as baseline assessments. The information collected forms a foundation of knowledge of the practices at the sites and defines the strengths and weaknesses of the system. Coupled with an improved performance assessment tool for continuous quality improvement, the strategy can lead to improved quality of medicine-related services for cancer patients, strengthened health system and donation system, and in due course, an improved quality of life for cancer patients.

Figure 3 Illustration of The Max Foundation's quality improvement strategy



III. GOAL AND SPECIFIC AIMS

The primary goal of this study is to evaluate the performance of medicine-related services at 48 point-of-dispensing sites assessed in 41 LMICs. By doing so, the evaluation establishes a baseline of the point-of-dispensing sites' procedures' weaknesses and the strengths, for continuous quality improvement. The specific aims of this study are as follows:

1. To assess the quality of medicine-related services provided at point-of-dispensing sites.
2. To evaluate The Max Foundation performance assessment toolkit for assessing medicine-related services at point-of-dispensing sites with the aim of providing specific recommendations for its improvement.

IV. METHODS:

Specific Aim One: To assess the quality of medicine-related services provided at point-of-dispensing sites.

Study design:

To assess the quality of medicine-related services at point-of-dispensing sites, we used a cross-sectional, embedded mixed-method design that involved two stages of analysis and a combination of quantitative and qualitative methods. First, using the data collected by means of a semi-structured interview guide (Appendix A), we performed a quantitative assessment of the quality of services presented in Table 1. This step was followed by a qualitative analysis with the goal of explaining quantitative findings. Second, we integrated the findings from the quantitative and qualitative analyses to provide multi-faceted insights into addressing this specific aim. The combination of the two methods combined complement each other by providing insights that each method individually could not provide.

Table 1 Quality categories of interest and their description

Quality category	Description
Access to internet	Ability of participants and institutions to connect to the internet using computers and other devices.
Adverse events (AE) management	Process in place to report any unfavourable and unintended sign, symptom, or disease temporarily associated with the use of a medical product, whether or not considered related to the medicinal product
Diagnostics	Access to molecular testing, specifically polymerase chain reaction (PCR), for diagnostic and monitoring purposes.
Drug recall	Process in place to remove a defective or potentially harmful product from the market.
Expired and returned medicines	Process in place to handle expired and returned medicines.
Inspection	Process of physical inspection of shipment to ensure the quantity and quality matches the invoice upon receipt.
Patient access tracking system (PATS®)	PATS® is a platform used by healthcare professionals around the world who are accessing cancer treatment through The Max Foundation on behalf of their patients.[1]
Stock management	Process in place that allows to accurately manage, track and report on drug inventory for planning and procurement purposes.
Storage (description and security) *	Products are maintained in a clean and secure location intended to protect against product loss.
Capacity building	Process of developing and strengthening human and institutional resources.

Study population:

The study was conducted from January 2017 until December 2017 at 48 point-of-dispensing sites located in 41 countries in the regions where The Max Foundation operates, namely Africa, Asia Pacific, Central Europe, Latin America, and South Asia. At the time of data collection, these 48 sites

**Quality categories descriptions were subjective statements from the participants noted during interviews and confirmed by objective observations during site visits by interviewers.*

were treating a total of 7,315 people living with chronic myeloid leukemia (CML) or metastatic malignant gastrointestinal stromal tumors (GIST). The study sample was the dispensing sites' staff who were available to meet with The Max Foundation staff conducting the site assessments. Study samples' backgrounds varied from one site to another; there was a total of 92 physicians, 34 pharmacists, 12 pharmacy technicians, 31 managers, 17 hospital directors, six patients, five nurses, two NGO representatives, four laboratory workers, and two social workers.

Their distribution per region is shown in Table 2, with a total count of 205 participants. In most countries, only one site was visited. In this case, the institution was referred to by the name of the country where it was located. When more than one site was visited in one country, we noted the country and the specific name of the institution.

Table 2 Geographical distribution of study participants classified by credentials

Region	Study participants									
	Physicians	Pharmacists	Pharmacy technicians	Hospital directors	Patients	Managers	Nurses	NGO Representatives	Laboratory Workers	Social Workers
Africa	47	11	10	15	4	9	2	1	0	0
Asia Pacific	15	5	0	0	0	7	0	0	3	0
Central Europe	15	5	0	0	0	2	0	0	0	0
Latin America	26	12	2	2	2	13	1	1	1	2
South Asia	4	1	0	0	0	0	2	0	0	0
Total	92	34	12	17	6	31	5	2	4	2

Data sources, sampling strategy and recruitment

We conducted a secondary data analysis of pre-recorded data from site visit records. Data sources consisted of the site visit reports as recorded and submitted by The Max Foundation team members performing the site visits, using a checklist and template developed by The Max Foundation and Tanner Pharma Group (TPG), i.e., The Max Foundation's third party logistics provider. For this assessment, The Max Foundation staff conducted purposive sampling. Point-of-care dispensing

sites were selected based on the schedules of The Max Foundation's team members, countries believed to be safe for travel, and various programmatic and geographic factors. For example, in the Africa region, it was difficult for the Region Head from The Max Foundation to visit all institutions in all countries, because there was only one Region Head and more than 30 institutions in over 30 countries.

If a team member made the decision to visit a site, s/he would make every effort to visit all sites located in that country. That said, the majority of countries had only one, central cancer center or resource hospital where the institution or physicians partnered with The Max Foundation under GIPAP. When not all sites in a region could be visited, it was the region head of The Max Foundation who decided how to prioritize his/her or his/her staff's time. If a site had a history of stock shortages while another site had only a handful of active patients, the region head would prioritize the site with a history of at least one stock shortage over a site with a small patient population. Similarly, if a site was visited at least once in the past by a Max Foundation team member, a different site that was never visited by a Max Foundation team member would be prioritized.

Data collection strategy & study instruments

To assess the performance of medicine-related services at point-of-dispensing sites, information was gathered by The Max Foundation staff using a checklist (Appendix A) and a site visit report template (Appendix B) served as interview guides.[5] The checklist's main objective was to assess whether or not each point-of-dispensing site had adequate facilities to safely store medicines and had processes in place for appropriate handling of medicines. The checklist comprised six main categories:

1. External building
2. Internal building
3. Quality control

4. Adverse events reporting
5. Regulatory
6. Licensing

Within each category, interviewers were trained and instructed to collect applicable supportive material, e.g., pictures, observations and ask relevant questions about good distribution practice standards and document those responses. For the "external building" category, interviewers were instructed to photograph the building and include the address, if possible. For the "internal building" category, storage description and security were the focus of the questions asked. The "quality control" category encompassed investigating the persons responsible for releasing medicines from customs, persons responsible for inspecting medicines upon receipt and the process of inspection, persons responsible for the quality control of stored medicines and how issues and/or improvements were documented. It also included questions about whether the point-of-dispensing staff received formal training and whether there were written procedures for staff on storing and handling medicines and how the inventory was managed in each institution. The three last questions in the quality control category covered whether the institution accepted returned medicines from patients and if there was a process for disposing of returned or expired medicines and for drug recalls.
The "adverse events reporting" category collected information about processes for managing patients' complaints and/or adverse events. The two last categories were about the institution's audit frequency and the institution's license to trade or to accept and dispense prescription medicines.
The site visit report template (Appendix B) contained additional information about the site visit such as the name of The Max Foundation staff who conducted the site visit, the participants and their credentials, the total number of active patients and approved physicians, and available diagnostics and monitoring tests.

The Max Foundation's staff who conducted the site visits were the regional head, the program officer, or a local coordinator also referred to as MaxStation (MS). On occasion, MS would attend the clinic to meet with patients and physicians. Each region head worked with his/her team to establish an agenda. Agendas for the meetings with study participants were developed based on the RH's institutional knowledge and experience with the site. All RHs had been employed by Max between 10 and 15 years. Upon appointing a team member to collect data, a training was provided over GoToTraining™, The Max Foundation's preferred training platform. The 1.5-hour training was delivered by a PowerPoint™ presentation. A recording of the training was made available to any team member unable to attend due to scheduling conflicts and/or time zone. The training consisted of instructions on how to prepare for a site visit, how to communicate with the physicians, which materials interviewers needed in advance, which materials they had on hand and which data to collect at the sites. The training also focused on relationship building, specifically which messages to convey, details about the new MAS program, and what differentiated it from the previous GIPAP program. Because The Max Foundation did not wish to give the impression that the site visit consisted in an audit, site visits were largely conducted based on team members' memory of the checklist and site visit report. The interviewers only had a pen and paper in hand and interviews were conducted in an organic fashion and intended to feel more like a conversation, with open-ended questions. In a few Commonwealth of Independent States (CIS) countries, the interviewers had the assistance of a translator. However, the presence of a translator was not noted in the reports.

Analysis

Quantitative evaluation

Descriptive statistics expressed as counts and percentages were computed for quality categories that were represented by dichotomous variables (i.e. Yes/No questions, such as "Is there a person

responsible for inspection upon the receipt of medicines?"). After compiling these variables into a Microsoft Excel sheet, with Yes= 1 and No= 0, data were imported into the statistical package R to calculate descriptive statistics.[11]

Qualitative evaluation

The checklists and the summary reports for each site were uploaded into ATLAS.ti.[12] A directed approach to content analysis was conducted. This method provided predictions about the selected quality categories of interest and/or predictions about the relationships among variables which determined the initial coding scheme and relationships between codes.[13] Our methodology for use of the directed content analysis consisted of a single coder beginning the coding process immediately with predetermined codes, i.e., quality categories in Table 1. The data collected were already catalogued in the reports and checklists and a set of coding criteria was explicitly articulated to assure intra-coder reliability. The data that could not be coded were analyzed to assess whether they represented a new category or subcategories of a quality category. Depending on the breadth and importance of different quality categories to address our first specific aim, we identified subcategories with subsequent analysis.

Coding consisted in linking selected segments of data to relevant codes or labels (i.e. quality categories). Upon completing the coding phase on ATLAS.ti, each code grouped all the quotations across checklists and reports pertinent to each quality category. This method enabled us to make cross-site comparisons for each quality category. Within certain categories, we relied on values coding to capture and label subjective perspectives. Values coding was the application of codes onto interview transcripts and field notes and observations to represent the participant's perspectives. [14]

In order to assess an overall point-of-dispensing ranking, we assessed a score from 1-3 per quality category for each point-of-dispensing site with 1 as the lowest performance and 3 the best performance. Subsequently, we calculated an overall percentage to evaluate each site.

<u>Specific Aim 2:</u> To evaluate the performance of The Max Foundation toolkit used for assessing the quality of medicine-related services provided by point-of-dispensing sites.

We evaluated the site visit assessment tool in terms of data quality dimensions. First, we identified which quality categories needed to be assessed for data quality. Second, we selected two data quality dimensions to use among the six quality dimensions defined by Data Management Association (DAMA), namely completeness and content validity.[15] Completeness consisted of asking the question: "Are all data sets and data items recorded?" It was the proportion of collected data against the potential of "100% complete," and was measured by the absence of blank values or the presence of non-blank values. For completeness, we calculated the proportions of non-blank values for each quality category data.

Content validity was defined by the degree to which data measured what they were supposed to measure. We assessed the quality of the data for content validity by rating the quality of recorded information as bad, average or good. When the data measured 0-33% of the content needed to describe a quality category, data quality was classified as bad. When data measured 33-66% of the content, data quality was classified as average, and when data measured more than 66% of the content, quality was classified as good.

We applied the assessment criteria to the quality categories, and we reviewed the results to determine if the data quality was acceptable or not. Finally, we recommended actions intended to improve data collection related processes, relying on what other organizations and healthcare institutions used for their quality assessment of medicine-related services, and what tools were used in the past studies in order to inform the recommendations for improving the existing site assessment tool.

V. Results

Specific Aim 1: To assess the quality of medicine-related services provided at point-of-dispensing sites.

Quantitative analysis:

Table 3 presents the number of positive responses, the number of respondents and the percentage of sites that met each quality criterion. The response rate for these yes/no questions varied between 89% and 100%. Having access to diagnostics in the institutions was the quality category with the lowest percentage of affirmative responses (31%), and storage cleanliness and security had the highest percentage of affirmative responses (100%).

Table 3. Descriptive statistics of yes/no questions for each quality category

Questions with Yes/No responses	Numerator, i.e., Number of positive responses	Denominator, i.e., Number of respondents	Sites that met quality criterion (%)
Is there access to diagnostics in the institution?	15	48	31
Is there a process for drug recalls?	20	43	46
Is there access to training and written procedures?	25	42	60
Is there a process for adverse event management?	30	47	64
Does the institution accept returned medicines?	31	45	69
Is there a process for returned and expired medicines?	34	45	75
Is there access to internet?	37	47	79
Is there someone responsible for quality control?	43	47	91
Is PATS used in this institution?	45	48	94
Is there someone responsible for inspection?	45	46	98
Is storage clean and organized?	48	48	100
Is storage secure?	48	48	100

Qualitative analysis

The following results include a description of each of the ten following quality category and sample comments from the participants: storage, inspection, stock management, capacity building, processes for returned and expired medicines, processes for drug recalls and for adverse event management, diagnostics, access to internet and access to PATS®.

Quality categories

1- Drug storage

a- Location and description

All of the storage locations for medicines within institutions (n=48) were observed to be clean and free of contaminants, dust and debris, food or personal effects. The location where medicines were stored varied from one institution to another. While some of the points-of-dispensing kept all the medicines in one place, others kept them in different spaces. Sites such as Cameroon, Zimbabwe, Niger and Haiti, maintained a bulk of Glivec® at the central pharmacy warehouse, and only a small amount in a locked cabinet in the warehouse manager's or the physician's office. Table 4 lists the different locations where medicines were stored within different point-of-dispensing sites. When stored in the physician's office, the medicines were either on top of a cabinet, in cartons, or inside of a refrigerator. The Pharmacy category encompassed central hospital pharmacies, pharmacy units in either the Hematology or Oncology department (or both). In the pharmacy itself, Glivec® was stored on shelving or closed boxes stacked on pallets, in glass cabinets or in closets. At some point-of-dispensing sites, the medicines were stored in an office space near the physician's office. The staff from these locations agreed that donated Glivec® must be kept separate from other medicines to ensure it was only used for GIPAP patients.

Table 4 Different locations of Glivec® storage by country

Physician's office	Pharmacy	Office space	Warehouse
Benin	Belarus Cambodia	Jamaica university	El Salvador
Burkina Faso	Cameroon	hospital	
Ghana (Accra)	Cote d'Ivoire	Mali	
Jamaica national public	Ghana (Kumasi)	Nicaragua	
health	Guatemala Roosevelt		
Niger	Guatemala San Juan		
Paraguay	Jamaica Cornwall		
Togo	Nepal		
	Niger		
	Morocco		
	Papua New Guinea		
	Zimbabwe		

Some of these locations were diligent about keeping the temperature cool while others were not. Relying on values coding, three categories emerged as shown in Table 5:

- Sites with no temperature control. In these sites, medicines were kept in "very hot" temperatures.
- Sites where medicines were stored in a location that received cool air.
- Sites where the temperature was controlled 24/7.

Different methods were reportedly used to keep the room temperature under control. In Cambodia, the room temperature was observed to be maintained at 23°C, 24 hours a day, 7 days a week. There were two air-conditioners in the room: one was on during the day and the other was on at night. In Jamaica Public Health, the physician kept the medicines at her office where temperature was controlled with air conditioning on working days and a general ventilation system on weekends. In Fiji, medicines were stored in a fire, waterproof cabinet, in a room with thick walls, without windows, which kept the temperature stable and protected the medicines from the moisture from outside. There was also one air-conditioner machine to keep the room temperature at 23°C for 24/7. All the staff who entered the room were required to wear shoe covers to keep the dust away. The

room was well organized, clean and tidy. The room was only used to store cancer medicines, cancer medicine record files and folders. The Solomon Island point-of-dispensing site also had an air-conditioner to control the room temperature. They reported that:

"When air-conditioning broke down, we used roof fans to make airflow to keep the room temperature under control."

In Honduras, the pharmacy had air-conditioning and a thermometer to check the temperature every day, keeping record of it on a form. In case of an energy interruption, the institution had a backup generator. The Surinam and Nigeria point-of-dispensing sites made sure even the means of transporting the medicines from customs to the hospital were appropriate and adhered to the chain cold requirements.

However, in Niger, the site visit assessor reported:

"I observed that many of the donation drugs ~from China were kept on the floor, outside of the pharmacy in a very hot temperature. The Pharmacist explained that they do not have enough storage space to meet the storage need of donations the institution is receiving."

Table 5 Distribution of institutions with different temperature control categories by country or site

No temperature control	**Temperature somewhat controlled**	**Temperature controlled**
Niger	Guatemala – Roosevelt	Belarus Cambodia Fiji Honduras Jamaica Cornwall Jamaica National Public Health Kazakhstan Nepal B P Koirala Memorial Cancer Hospital (BPKMCH) Nigeria Paraguay Solomon island Surinam Tanzania Timor Leste

b- Security

All of the storage locations within institutions (n=48) were locked under key. Participants' answers confirmed by interviewers' observations showed that locked under key or "secure" had different meanings across institutions. By relying on values coding, three categories emerged:

- Mediocre: Medicines were stored on an open shelf, in a room that was unlocked or only locked after hours.
- Good: Medicines were stored in a locked cupboard in an unlocked room and vice versa (Medicines were stored in an unlocked cupboard in a room that was always locked).
- Excellent: Medicines were secured by at least two locks to which access was only granted to the person responsible for dispensing, or medicines were kept in the physician/dispenser's office, and only physicians/dispenser have the keys.

Table 6 below shows where each point-of-dispensing site is classified according to their security level category.

Table 6 Distribution of institutions according to their security level categories

Mediocre	Good	Excellent
Cambodia	Bahamas	Azerbaijan
Haiti	Bhutan	Belarus
Nepal - BKPM	Jamaica national public health	Benin
Nepal - Patan	Mali	Cote d'Ivoire
	Nigeria	Fiji
	Papua New Guinea	Ghana (Accra)
	Rwanda military hospital	Guatemala – Roosevelt
	Rwanda Partners in Health	Guatemala – San Juan
	Surinam	Honduras
		Kazakhstan
		Kyrgyzstan
		Mongolia
		Morocco
		Niger
		Paraguay
		Solomon island
		Timor Leste
		Togo
		Uganda cancer institute
		Uganda Joint Clinical Research Center (JRC)
		El Salvador
		Jamaica Cornwall
		Jamaica university hospital
		Nicaragua
		St Lucia
		Cameroon

Within the "Excellent" category, point-of-dispensing sites in three countries surpassed the rest of the countries in terms of security. These were Jamaica Cornwall, where access was only granted through three locked doors, Guatemala Roosevelt, where there was a closed surveillance circuit with camera in place in addition to the two locked doors, and El Salvador where a police officer was in charge of opening an outside lock in the morning. In Haiti, an example of "Mediocre" security practices, Glivec® was stored on open shelves in three different places within the hospital, where

the door was locked only after working hours. The key was kept by one employee, who was in charge of all the keys, and who needed to be reached in order to access certain areas of the hospital, including the general depot where Glivec® was kept.

2- Inspection

Ninety-eight percent (n=45/46) of the point-of-dispensing sites had at least one person responsible for inspecting the medicines upon shipment arrival. Relying on values codes, three categories emerged:

- A complete inspection included a visual inspection, and total count of shipment received, expiration date and batch number, making sure the shipment documents of the inventory matched the items delivered (number of units, expiration dates and batch numbers).
- A semi-complete inspection included all of the above without inspecting the batch number.
- A visual inspection consisted of screening for external signs of damage such as dampness and tampering.

Point-of-dispensing sites were categorized according to their level of inspection (complete, semi-complete or a visual inspection) and findings are displayed in Table 7. Two of the participants within the "complete inspection" category reported doing a first count upon receipt at the customs before sign off and final handoff of products and a second round upon arrival to the hospital (i.e. Cote d'Ivoire and Mali). In some institutions, the shipment was inspected by a committee of at least one physician and one pharmacist to check that the number of units received on the invoice correlated with the stock received (i.e. Kyrgyzstan, Kazakhstan, Mongolia).

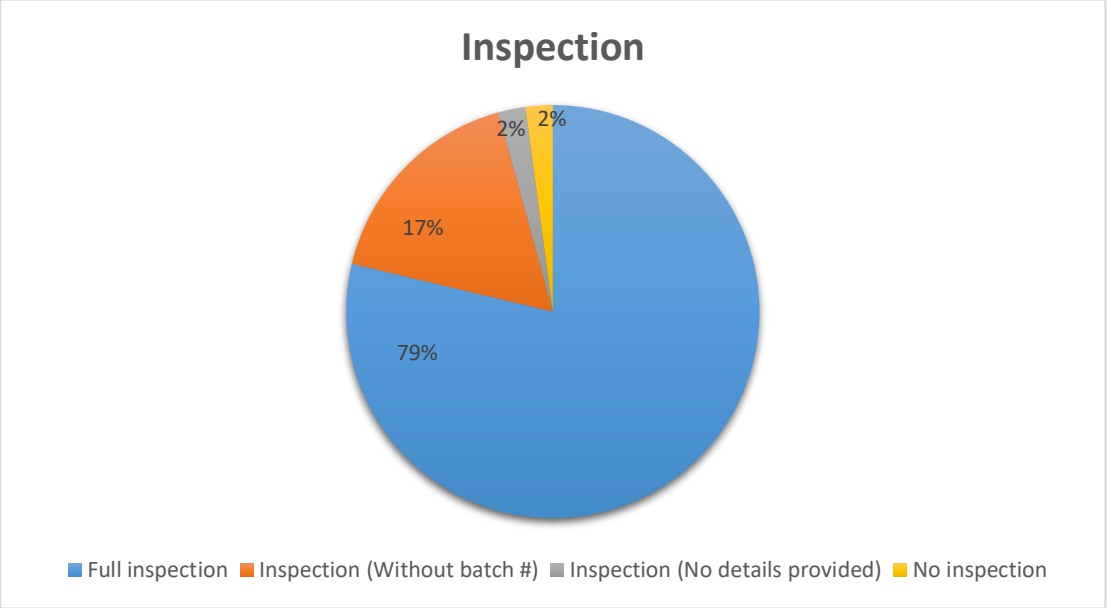
As for the institution with no one responsible for inspection (i.e. Morocco), the head pharmacist reported that he did not inspect Glivec® donations on receipt because Novarits did this prior to delivering the medication to the hospital.

Table 7 Distribution of point-of-dispensing sites according to their level of inspection

Complete inspection (n=36)	Semi complete inspection (n=8)	No details (n=1)	No inspection (n=1)
Bahamas	Cameroon	Azerbaijan	Morocco
Belarus	Rwanda military hospital		
Benin	Rwanda partners in health		
Bhutan	Uganda cancer institute		
Burkina Faso	Uganda JRC		
Cambodia	Zimbabwe		
Cote d'Ivoire	Papua New Guinea		
El Salvador	Timor Leste		
Fiji			
Ghana Accra			
Ghana Kumasi			
Guatemala Roosevelt			
Guatemala San Juan			
Haiti			
Honduras			
Jamaica Cornwall			
Jamaica national public health			
Jamaica university hospital			
Kazakhstan			
Kyrgyzstan			
Kenya			
Mali			
Mongolia			
Nepal BPKMCH			
Nepal Patan			
Nicaragua			
Niger			
Nigeria			
Paraguay			
Saint Lucia			
Senegal			
Solomon island			
Surinam			
Tajikistan			
Tanzania			
Togo			

Figure 4 below displays a visual illustration of the proportions of point-of-dispensing sites with different levels of inspection.

Figure 4 Proportions of point-of-dispensing sites with different levels of inspection



3- Stock management

Supply of Glivec® at the point-of-dispensing sites was either managed following FIFO (first in first out) procedure or FEFO (first expired first out) procedures. Fifty-six % (n=23/41) institutions followed the FIFO procedure. Table 8 shows the distribution of point-of-dispensing sites using each method of stock management. We noted that the three point-of-dispensing sites in Jamaica (i.e., Jamaica National Public health, Cornwall and University hospital) did not use FIFO nor FEFO although they were aware of these managing stock rules. Those sites received the Glivec® boxes for each patient in a separate envelope, so they just checked that the medication was not expiring before being taken by patients. In Honduras, participants used the method FIFO. However, when the hospital received more than one batch at the same time, they used FEFO to make sure medicines did not expire. Ninety-four percent (n=32/34) of the sites kept dispensing logs. Eight of the 32 institutions kept dispensing logs using an electronic platform (either a software or an Excel

spreadsheet) to manage their inventories. Only Niger and Senegal did not keeping a dispensing log. In Niger, the physician put the quantity dispensed on the patient's respective medical record, which made doing quarterly inventories more challenging. In Ethiopia, the stock manager was rigorous about notifying the physician about the amounts remaining in stock and reminding him about resupply in order to avoid stock outs.

Table 8 Distribution of point-of-dispensing site according to their stock management procedure

First in first out (n=23)	First expire first out (n=18)
Belarus	Bahamas
Benin	Cote d'Ivoire
Bhutan	El Salvador
Burkina Faso	Guatemala – Roosevelt
Cambodia	Guatemala – San Juan
Cameroon	Mali
Fiji	Morocco
Haiti	Nicaragua
Honduras	Niger
Ghana (Kumasi)	Nigeria
Kazakhstan	Paraguay
Kyrgyzstan	Rwanda Military hospital
Kenya	Rwanda - Partners in Health
Mongolia	Saint Lucia
Nepal BPKMCH	Uganda cancer institute
Nepal - Patan	Uganda JRC
Papua New Guinea	Timor Leste
Senegal	Zimbabwe
Solomon Island	
Surinam	
Tajikistan	
Tanzania	
Togo	

4- Capacity building

Approximately 60% (n=25/42) of the institutions reported that their employees who were responsible for handling the donated medicines received prior training on storing, handling and

dispensing medicines. However, training levels varied from one point-of-dispensing to another. Relying on values coding, three groups arose when it came to categorizing training levels: mediocre, good and excellent. The training level was classified as mediocre if the staff did not receive any training or received an informal training prior to occupying the position to handle, store and dispense medicines. The training level was classified as good if the new staff underwent trainings. The training level was classified as excellent if the new staff underwent an initial training followed by regular trainings and/or trainings whenever new processes or procedures were introduced and put in place. In Table 9, institutions were classified into one of the three mutually exclusive categories. In the point-of-dispensing sites where training level was categorized as "Mediocre," 78% (n=13/17) of the sites reported that their staff did not receive any sort of training in the past. The remaining received an informal training. In Cambodia, there were no formal training programs for staff designed to handle the donated products, but they had trainings in general for people responsible for drug dispensing in the hospital. However, according to the participants in that site, the training was not documented in a written form. In Fiji, participants reported that:

"There is only the person-to-person training. There are no scheduled or annual training. We need a proper training".

As for sites where the training level was classified within the "Good" category, most of them reported being trained when they were hired (i.e. El Salvador, Tanzania). Some of the staff working within the department were trained pharmacists or pharmacy assistants and were expected to have a certain level of training on the handling of medicines with no further formal follow-up training provided by the site (i.e. Zimbabwe, Haiti, Kyrgyzstan, Bahamas).

Table 9 Institutions classified according to their training level category

Training level for capacity building		
Mediocre (n=17)	**Good (n=13)**	**Excellent (n=12)**
Benin	Bahamas	Belarus
Bhutan	Cameroon	Ethiopia
Burkina Faso	El Salvador	Ghana (Kumasi)
Cambodia	Guatemala (San Juan)	Kazakhstan
Cote d'Ivoire	Haiti	Kenya
Fiji	Honduras	Nicaragua
Ghana Accra	Kyrgyzstan	Rwanda (Military Hospital)
Guatemala Roosevelt	Mongolia	Senegal
Mali	Nigeria	Tajikistan
Morocco	Rwanda (Partners in Health)	Solomon Island
Nepal BPKMCH	Surinam	Uganda (Cancer institute)
Nepal Patan	Tanzania	Uganda Joint Clinical Research
Niger	Zimbabwe	Center (JRC)
Papua New Guinea		
Saint Lucia		
Timor Leste		
Togo		

For the remaining institutions, they mentioned receiving follow-up trainings, but they were "*few and far between*". (i.e., Nigeria, Mongolia, Guatemala, Cameroon and Honduras):

"70% of physicians in Mongolia travel outside of Mongolia to obtain specialty training as the education system is weak in the country. Access to physician training resources and opportunities is desperately needed."

Sites where training level was categorized as "Excellent" reported being stricter about training their staff. All of these sites trained their staff when they hired them. In Nicaragua, Belarus, Kazakhstan and Tajikistan, this training was provided through the Ministry of Health and Drug Regulatory authorities. In Kenya, new staff undertook a mandatory 30-day orientation program. They thought that it was important and they reported that it helped them "*familiarize themselves with the operations of*

the department, including SOPs." Staff in sites such as Ethiopia conveyed that they were receiving a monthly training while other sites reported that training occurred when new processes or procedures were implemented, or as need arose, e.g., Ghana Kumasi, Senegal, Rwanda military hospital, Uganda Cancer institute and Uganda JRC. In Solomon island, participants stated:

"On Tuesday of every week, there is Pharmacist Staff Continuing Education meeting in pharmacy department. The topics are chosen by presenters and from time-to-time, there will be topic of storing and handling medicines."

5- <u>Returned and expired medicines:</u>

When asked whether there was a process for addressing returned medicines from patients and expired medicines or not, 75% of the point-of-dispensing sites (n=34/45) responded positively. Three different categories emerged: institutions either had an internal process, used an external process, or returned the medicines to Novartis. An internal process was defined as sending the expired or returned medicines to a different department within the hospital, e.g., the hygiene service unit, pharmacy department, a waste disposal unit, or the hospital's incinerator. An external process was defined as an external structure in charge of the destruction process. These structures either depended on the Ministry of Health, where an official incineration process was followed and legally documented, or the structures were third-party entities such as the national institute of health, the national department of pharmacy, or a private waste management service. Table 10 displays the distribution of sites according to their returned and expired medicine management process.

Table 10. Description of returned and expired medicine management processes

Internal process	External process	Novartis
Belarus	Benin	Guatemala San Juan
Bhutan	Cameroon	Honduras
Burkina Faso	Guatemala - Roosevelt	Jamaica Cornwall
Cote d'Ivoire	Mali	Jamaica NPH
Ethiopia	Nicaragua	Mongolia
Fiji	Senegal	Peru
Jamaica university hospital	Timor Leste	
Kenya	Uganda cancer institute	
Morocco	Uganda JRC	
Nepal BPKMCH		
Nepal Patan		
Nigeria		
Paraguay		
Rwanda military hospital		
Rwanda Partners in Health		
Solomon Island		
Surinam		
Tanzania		
Togo		
Zimbabwe		

In Guatemala Roosevelt, returned and expired medicines were sent for destruction to a third-party private waste management site called Ecotermo. For these services outside of the hospital, the institutions paid for each destruction of medicines. Another example of an external process took place in sites such as Timor Leste, the participant said:

"The clinic collects the returned or expired drugs and other medical supplies and equipment for disposal in a container van. They bring it to a dumpsite and burry them under the ground. We do it at least once or twice a year."

In Fiji, point-of-dispensing staff explained that:

"There is the record book name "Expiry Items Register" to record the details of expired medicine. Then the medicine will be placed in the "Clinical Waste Bin" which would be automatically locked once it is closed and then sealed with a tape show "Cytotoxic Waste". Then the hospital cleaner for contained waste will pick up for sending to destroy in the other proper department. The whole bin will also be destroyed."

Sites such as Nigeria, even though they had an incinerator in the hospital, reported:

"Using the FEFO method, we never experienced expired medicines with Glivec®."

As for handling processes for returned medicines, 31% of the institutions (n=14/45) did not accept returned medicines from their patients. When they did accept them, these institutions relied on the same processes as expired medicines to manage them except for six sites. If medicines were in a good condition and not expired, physicians in Bhutan, Cambodia, Ghana (Kumasi), Haiti, Kazakhstan and Kyrgyzstan reused the medicines by redistributing them to other patients. The physician in Ghana - Kumasi explained:

"The returned drugs that has not expired are giving to new patients in critical conditions waiting to be registered in to GIPAP".

6- <u>Drug recalls:</u>

Fourty-six percent of the point-of-dispensing sites (n=20/43) indicated that there was a process in place for drug recalls. Some sites had an internal process, which consisted within a platform where they had access to patient's updated information, phone numbers and addresses along with the batch number of the medicine dispensed to them. The remaining sites indicated that they relied on

an external process that reported to the ministry of health or the national department of pharmacy and complied to local regulations of drug recalls. Table 11 shows the distribution of sites according to whether they relied on an internal process or an external process.

Table 11 Distribution of point-of-dispensing sites according to their drug recall management procedure

Recall	External process
Cote d'Ivoire	Rwanda Military hospital
El Salvador	Rwanda PIH
Fiji	Senegal
Guatemala Roosevelt	Uganda cancer institute
Honduras	Uganda JRC
Jamaica Cornwall	Zimbabwe
Jamaica NPH	
Jamaica university hospital	
Kenya	
Nicaragua	
Nigeria	
Paraguay Solomon Island	
Tanzania	
Togo	

While some of the sites relied on a manually recorded database, Kenya had a medicines' recall management policy. Physicians and dispensers reportedly used the software CARE 2000®, a dispensing system that was able to display the name and contact of the patient who received the drug that was recalled. In Togo, the physician also had patient contact information to call and request recalled medications to be returned to the hospital. He shared that he also used this recall system to ensure patient's safety:

"Once, I noticed that the medication dispensed had expired; so I called back the patients to bring back the drugs and I was able to replace the supply with a new batch."

In Fiji, patients were reported to be readily accessible. If not by phone, then there was a process where zone nurses do house-to-house visits to patients' homes.

In the remaining 54% (n=23/43) of sites, a drug recall situation had not yet occurred and participants were unsure whether or not there was a process in place. In Papua New Guinea, participants reported:

"Incomplete addresses and lack of other means of communication are a big challenge to us in monitoring and following up our patients."

7- <u>Adverse event management:</u>

When physicians were asked how they handled adverse events, four patterns emerged: reporting to local regulatory authorities, reporting using the Max Foundation's online system, reporting in accordance with the hospital's direction, or referring to a specialist to symptomatically treat the adverse event. Table 12 displays how adverse events are managed at point-of-dispensing sites. Fifty-one percent (n=16/31) used The Max Foundation's online system protocol PATS® to report adverse events and 12% (n=4/31) did not report to local safety authorities nor to The Max Foundation.

Table 12 Distribution of point-of-dispensing sites according to their adverse event management approach

Reporting to local regulatory authorities (n=11)	Reporting through PATS®† (n=16)	Internal reporting (n=3)	Refer to specialist (n=1)
Bhutan	Benin	Bahamas	Burkina Faso
Cote d'Ivoire	Cameroon	Cambodia	
Guatemala Roosevelt	El Salvador	Ghana	
Kenya	Fiji		
Nigeria	Haiti		
Rwanda PIH	Jamaica Cornwall		
Rwanda military hospital	Jamaica National public health		
Saint Lucia	Jamaica University hospital		
Surinam	Mali		
Tanzania	Morocco		
Uganda	Nicaragua		
	Niger		
	Paraguay		
	Senegal		
	Solomon Island		
	Togo		

8- <u>Diagnostics:</u>

Only 31% of the point-of-dispensing sites (n=15/48) had access to an equipment and kits to perform PCR testing to detect, and sometimes to quantify, breakpoint cluster region-Abelson gene (BCR-ABL) in bone marrow cells of patients with CML in their institutions. The remaining 69% (n=33/48) of the sites were divided in three different categories: access to an equipment but no kits, access to PCR diagnostics locally, and access to PCR diagnostics internationally.

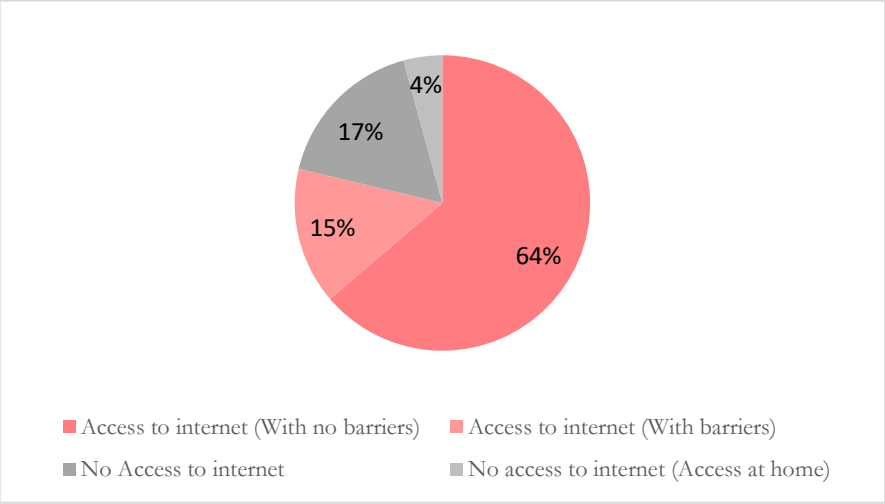
† Reporting through PATS® is the GIPAP /The Max Foundation's online system protocol

Nine out of the 33 institutions that did not have access to PCR testing did have access to a machine that was primarily used for tuberculosis and/or HIV testing, but none of them had a budget allocated to buy kits for GIPAP patients. Six out of the 33 institutions that did not have access to PCR testing referred their patients to a local nearby institution that offered PCR testing. The remaining 28 out of 33 institutions only had access to PCR testing internationally. Patients either had to ship their samples for testing or had to travel to be tested. Apart from institutions in Bhutan, Solomon Island, Haiti and Nepal Patan, patients had to pay out of pocket for the test, and prices varied from $150-$700 USD.

9- <u>Access to internet:</u>

Seventy-nine percent (n= 29/37) of the institutions had access to the internet, but according to their experience, having access did not necessarily mean the internet was reliable. In seven out of 37 of the institutions where there was access to internet, participants expressed barriers to using the internet. Figure 6 shows the proportions of sites with access to internet (with or without barriers) and proportions of sites without access to internet (with access at home).

Figure 4 Proportions of sites with access to internet (with or without barriers) and sites with no access to internet



In fact, in Benin for instance, a participant reported that:

"There is good internet access available at the hospital, but our team members do not all have access to a laptop or a computer at the hospital."

In Bhutan, Morocco, Niger, Rwanda, and Togo, as well, it was reported that the connection was too slow. Below, statements from participants from Morocco followed by Niger.

"There is internet access, but the connection is weak, and there are frequent outages."

"The hospital has a shared internet network which is usually very slow"

In the latter case, the physician used his mobile phone as a hotspot to connect to his laptop to navigate on PATS® when he was at the hospital. In Tajikistan, the interviewer reported:

"*Internet connectivity is a significant challenge, because of two reasons. First, the lack of quality IT equipment and second, the lack of technical knowledge and understanding of how to troubleshoot IT issues. For example, rolling blackouts kick the physicians off of the internet, and when the power comes back on they do not have the technical IT understanding of how to reboot the system."*

In the remaining 30 out of 37 institutions where access to internet was available, all the participants reported that connection was very consistent and reliable, so connectivity was not a barrier to using PATS®. Twenty-one percent (n= 10/47) of the institutions did not have access to the internet. However, in two out of these 10 sites, physicians reported that they paid for the internet expenses themselves to connect from home (i.e. Ethiopia, Burkina Faso).

10- <u>Patient Access Tracking System®:</u>

Ninety-four percent of the institutions (n=45/48) reported having access to PATS®. Senegal, Zimbabwe and Guatemala San Juan were the only three institutions without access to PATS®. In 19 sites, The Max Foundation's staff examined whether the number of patients in the PATS® database matched the medical records and 58% of the cases (n=11/19) had no match. When asked "why isn't the PATS® database accurate?," two main reasons were reported: physicians had no access to PATS® during consultation, and physicians had to update PATS® after work hours. In Cote d'Ivoire, one respondent reported that:

> *"Although the hospital does have access to internet, the structure is set in such a way that the physician cannot be logged into PATS® while consulting. All notes related to patient during consultation are hand written on the patient's paper files. Physicians input data in PATS® outside of consultation and working hours."*

In Ethiopia, Ghana (Accra), Morocco, Nigeria and Togo, physicians confirmed that it was time consuming and difficult to keep PATS® updated:

> *"It is very hard and time taking for us to access PATS® and register patients and make re-approval. Each of us takes patient list at home and do all during our family time and also bed time"*
>
> - Participant from Ethiopia

In Togo and Zimbabwe, participants reported that the process was very slow mostly because of the internet connectivity. The participant from Togo described:

"There are times that PATS® spins for too long before moving to the next page or just freezes and previous work is lost. This process is very frustrating and slows the enrolment of new patients."

Finally, the site visit was an opportunity for The Max Foundation to provide a training on how to use PATS® in seven sites where participants were not familiar with the platform and where they reported that familiarity was a barrier for using PATS®, i.e. Benin, Burkina Faso, Papua New Guinea, Solomon Island, Kazakhstan, Haiti and Nepal BPKMCH.

Point-of-dispensing ranking

While each point-of-dispensing site had a high performance value in at least one of the quality categories, none had a high performance value across all of the quality categories. This performance assessment allowed us to identify how well point-of-dispensing sites performed in each of the ten criteria, and provide guidance on which sites may serve as exemplary models for other sites where improvements may be warranted.

Percentages varied between 0.61% for the lowest performance, i.e., Benin, Nepal BKPMCH and Niger, and 0.972% for the highest performance, i.e., Paraguay. Three sites were not included in the classification as data was missing in more than three quality categories, i.e., Rwanda Military hospital, Azerbaijan and Peru.

Table 13 shows the classification of 45 out of 48 point-of-dispensing sites in terms of performance. In each column, countries with a better performance appear first.

Table 13 Classification of point-of-dispensing sites according to their overall performance on quality of dispensing measures

Top performance	Average performance	Most improvements may be needed
Paraguay	Rwanda PIH	Ethiopia
Honduras	Ghana Accra	Morocco
Nigeria	Togo	Papua New Guinea
El Salvador	Uganda cancer	Haiti
Solomon Island	Uganda JRC	Nepal BKPMCH
Tanzania	Guatemala San Juan	Niger
Fiji	Mali	Benin
Guatemala Roosevelt	Cote d'Ivoire	
Jamaica Cornwall	Bhutan	
Jamaica Public Health	Cambodia	
Jamaica University Hospital	Ghana Kumasi	
Nicaragua	Kazakhstan	
Kenya	Kyrgyzstan	
Belarus	St Lucia	
	Surinam	
	Timor	
	Bahamas	
	Mongolia	
	Nepal Patan	
	Senegal	
	Cameroon	
	Zimbabwe	
	Burkina Faso	
	Tajikistan	

Aim 2: To evaluate the performance of The Max Foundation toolkit used for assessing the quality of medicine-related services provided by point-of-dispensing sites

For Aim 2, we evaluated the toolkit in terms of completeness of data and content validity of data collected. Table 13 below displays each question of the checklist accompanied by the completeness percentage of the relevant data collected and its content validity. Only four quality categories, i.e.,

storage cleanliness and security, diagnostics and PATS, had 100% complete data; the other categories had between two and 38% missing values. Content validity was "good" in eight quality categories, "average" in two categories and "poor" in one category (Table 14).

Table 14 Evaluation of data completeness and content validity

Question asked	**Completeness (%)**	**Content validity**
Is storage clean and organized?	100	Average
Is storage secure?	100	Good
Is there someone responsible for inspection?	96	Average
Is there access to training and written procedures?	87	Good
Is there a process for returned and expired medicines?	94	Good
Does the institution accept returned medicines?	94	Good
Is there a process for drug recalls?	89	Good
Is there a process for adverse event management?	64	Good
Is there access to diagnostics in the institution?	100	Good
Is there access to internet?	98	Good
Is PATS used in this institution?	100	Poor

VI. Discussion

Aim 1: To assess the quality of medicine-related services provided at point-of-dispensing sites

In this study, we evaluated the quality of selected aspects of medicine-related services delivered by The Max Foundation's affiliated point-of-dispensing sites. Within each quality categories, some sites were recognized for their high performance while other sites were identified for improvements to be made. The results of this study can be used as a starting point to indicate the strengths of some sites and areas for improvement at others with whom The Max Foundation can share best practices to be implemented. For each quality category, we discuss herein how improvements might be made.

1. Storage:

The data showed that storage locations for donated medicines differed across dispensing sites. While most medicines were stored in pharmacies, some of the point-of-dispensing sites kept donated medicines in the physician's office, in a warehouse or in an office space. Additionally, some of the point-of-dispensing sites were not rigorous about drug security or temperature control. According to WHO guidelines, drugs need to be stored in a specially designed secure area or space of a building in order to avoid contamination or deterioration, avoid damaging the labels, prevent infestation of pests and vermin and maintain the integrity of packaging and hence guaranteeing quality and potency of drugs during shelf life.[7]

The storage environment should most importantly possess an adequate temperature because exposure of medicines to high temperatures in storage or in transit could reduce their efficacy. Glivec®'s safety information specifies that the storage should be at 25°C with excursions allowed to 15°C to 30°C (59°F to 86°F) to avoid damaging or degrading the product, that is why it is crucial that point-of-dispensing sites keep temperature logs in the storage rooms.[16]

The storage environment should have sufficient lighting, clean conditions, humidity control, and adequate shelving to ensure integrity of the donated drugs. WHO guidelines also suggest that shelves should be strong, robust and made of steel or treated wood.[17] Fiji's storage illustrated a best practice for storage conditions. As for storage security, it is important to make sure medicines are stored in a secure place in order to reduce pilferage or losses.[7] Sites classified within the mediocre security category should move the Glivec® stock to a more secure area that has at least one lock at all times, only accessible to the physician or the person responsible of dispensing.

2. Inspection

Different levels of drug inspection upon receipt were reported in point-of-dispensing sites: a complete inspection, a semi-complete inspection and a visual inspection. Each pharmaceutical shipment was physically inspected at every site, i.e., order completeness verified and, packages and labels examined. However, 21% (n=10/46) of the sites did not carry out a complete inspection, i.e., did not inspect nor record the batch number. According to the FDA, a batch (or lot) is "a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits." A batch number (or a lot number) is "a unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined." Within the institutions, a system must be in place by which the distribution of each batch of active pharmaceutical ingredients (API) can be readily identified to permit its recall, if warranted.[18]

3. Stock management

First in first out (FIFO) methods were the most common stock management procedure across point-of dispensing sites with 23 sites out of 41 sites using this approach. According to WHO

guidelines, the FIFO rule should always be applied to guarantee that drugs that were received first would be used first, except where the new stock has shorter expiration dates than the old stock. If a product has a shorter expiration date, then the principle of first expired first out (FEFO) should be applied. It is recommended that drugs with shorter expiration dates be first placed in front of the shelves. Those with longer expiration dates should be placed behind those with shorter dates.[17]

Honduras can serve as an example, because the site used the FIFO method on a regular basis, except when more than one batch was delivered at the same time. In that case, they used the FEFO method and the issue of expiration of Glivec® was never experienced. The Max Foundation should emphasize the importance of these guidelines in sites such as Morocco where the pharmacy does not have established procedures for stock management and staff training. It is also important to emphasize the importance of keeping a dispensing log that would make submitting a quarterly inventory of the medicines to The Max Foundation easier. Quarterly inventories are an efficient way to maintain a minimum count of products in the institution, that are neither damaged nor expired. At sites such as the one in Ethiopia, the stock manager defined the threshold below which the physician was notified to resupply. This practice should be shared with all the sites.

4. Capacity building

Fourty percent (n=17/42) of the institutions reported that their employees responsible of handling the donated medicines did not receive any prior training on storing, handling and dispensing medicines. Training and other approaches to capacity building are very important especially in this context of donated drugs. Health professionals such as pharmacists and prescribers as well as other dispensers need specialized training and information to ensure the delivery of high-quality medicines but also to assure the appropriate use of medicines to achieve desired treatment outcomes, and protect patients from inappropriate use of medicines and preventable side effects.[19] Pharmaceutical

systems in LMICs are challenged by limited access to pharmaceutical training and a lack of up-to-date training curricula. Electronic information sharing and media could be a solution to ensure widespread access to learning and knowledge exchange.[20] The WHO has a dedicated information portal on essential medicines and health products with more than 5000 pharmaceutical management related documents that could be used. [17,21] Additionally, no information was obtained on whether the dispensers provided patients with important and relevant information on how to safely use Glivec®, which has very specific precautions that patients need to be aware of, e.g., dosing and administration precautions, risk of fluid retention and edema, drug interactions.[16] This issue should be addressed in future site visits.

5. Returned and expired medicines

Twenty-five percent (n=11/45) of the point-of-dispensing sites did not have a process in place for safe disposal of returned and/or expired medicines. Unused medicines pose a risk to public health through poisoning and suicide when allowed to accumulate at home and to the environment if disposed poorly.[22,23] Therefore, minimizing the quantity of unused medicines generated and ensuring the safe disposal of unavoidable unused medicines is an important public health concern. It is important to have a good drug management system by maintaining a well-functioning stock inventory control system, by practicing FEFO and FIFO for drugs stocked, and by negotiating with suppliers for the possible return of drugs that are about to expire. Among the 75% (n=34/45) of sites that had a process in place for safe disposal of returned and expired medicines, some sites had to use the services of third-party private waste management companies which was costly. Due to constraints in funding for disposal of waste pharmaceuticals, cost-effective management and methods are needed to minimize the amount of waste.

Sixty-nine percent of point-of-dispensing sites accepted returned medicines from their patients. In six out of the 45 sites, physicians reported that when medicines were in a good condition, they redistributed the them to other patients. According to the US FDA compliance policy guide Sec. 460.300 return unused prescription drugs should not be returned to pharmacy stock. [24]

6. Drug recalls

While 46% of the sites reported having an effective drug recall management system implemented, 54% of the point-of-dispensing sites did not, mainly because a drug recall situation had not yet happened. A drug recall is an instance to return a batch or an entire production of a drug product to the maker, typically due to the detection of safety issues or drug product defect. [25] Further distribution or use of the product should stop immediately and when appropriate, the recipients should in turn notify the next party in the chain of distribution of the recall; in this case, point-of-dispensing sites should notify GIPAP patients to return the products to protect them from a defective or potentially harmful product. The process of recall involves a planned specific course of action, and the need for public warning. That is why it is important to keep a complete record of patients, their addresses and phone numbers to facilitate monitoring and follow-up of patients. The example of Kenya, using the software CARE 2000®, can be shared with other sites and recommended to enable point-of-dispensing sites to track the names of the patients and their batch numbers, in case drugs must be recalled. [25]

7. Adverse event management

In instance when patient adverse events (AE) occurring, 12% of the point-of-dispensing sites indicated that they referred patients to specialists without reporting adverse events to local safety authorities or to The Max Foundation. According to the US FDA, an adverse drug experience is defined as any AE associated with the use of a drug in humans, whether or not considered drug

related.[26] Treatment with Glivec® is usually well tolerated. However, the majority of the patients experienced drug-related AE to imatinib at some point of their treatment course as the treatment continues for the entire lifespan.[27] The majority of AEs are reported to be mild to moderate and are often reversible by supportive care or temporary cessation of treatment. However, sometimes it is necessary to switch to an alternative treatment.[28] Identifying and managing AEs is key to ensuring long-term patient adherence and benefit from therapy. An optimal management requires intimate knowledge of response criteria and of timing as well as of potential toxicities and their basis, best approaches to avoid them, strategies to manage them when identified and how they may affect response to therapy and patient outcome. [29,30] When a serious risk may be associated with exposure to a medical product, reporting this AE either to the product sponsor or directly to FDA becomes essential from the perspective of systematic data collection and promoting public health. That is why all approved physicians should comply to the GIPAP agreement between The Max Foundation and the approved institutions that specifies that the qualified physician should report adverse events as required by their national legislation and to The Max Foundation. The agreement also states that The Max Foundation will report to Novartis all AEs reported by GIPAP patients. The Max Foundation reports all AEs to Novartis and Novartis directs all follow-up questions to the GIPAP physicians and submits AE reports to appropriate health authorities as required.[10]

8. **Diagnostics**

In 33 out of 48 point-of-dispensing sites, there was no access to PCR diagnostics for CML diagnosis and monitoring, even though in six of these sites there was access to a GeneXpert® machine, but kits were not accessible. GeneXpert® machines cost $10,000-$70,000 USD, and each cartridge used for a test costs around $50 USD.[31] Twenty-eight out of these 33 sites only had access to PCR testing in other countries, which was generally costly varying between $150 USD and $700 USD and paid for by patients out of pocket. Chronic myeloid leukemia (CML) is defined by a consistent

cytogenetic abnormality known as the Philadelphia (Ph) chromosome. Most patients with CML, who are treated with imatinib achieve cytogenetic disease remission, where the Ph chromosome-positive cells become undetectable by cytogenetic evaluation.[32] Continuous monitoring of disease levels in individual patients is required to determine the effectiveness of targeted therapies so that appropriate and timely decisions can be made timely concerning treatment strategy. Achieving reductions in residual disease within specified timeframes has prognostic significance in terms of the durability of treatment responses as well as progression-free survival.[33] Because of the presence of the leukemia-specific *BCR-ABL* gene, CML disease status can be monitored using quantitative reverse transcriptase PCR techniques (RQ-PCR), the standard for molecular monitoring of CML patients. [34] That is why The Max Foundation should prioritize increasing access to CML diagnostics for the point-of-dispensing sites through partnerships, such as the one that was established with Fred Hutchinson Cancer Research Institute to provide low-cost tests to diagnose CML for patients in participating countries. [35]

9. Access to internet

Twenty-one percent of the point-of-dispensing sites reported challenges in accessing the internet. The internet remains the most rapid and efficient way for healthcare providers to not only communicate with The Max Foundation, e.g., confirmation of receipt, issues with inventory managements, and to update patient's records on PATS, but also to access electronically-mediated trainings and resources for storage, handling and dispensing of medicines. Inadequate infrastructure is a challenge when implementing a patient management system or an e-learning training in resource-constrained countries. [36,37]

The major barriers to using the internet cited in the literature include limitations in bandwidth, which may cause slow speed and low quality of videos or visual outputs, difficulties reading or

watching content from a computer screen, slow speed of downloading from the internet, inadequate computer facilities, limited access to computers, and frequent electrical power failures. [37-40] However, the challenge of bandwidth availability is being addressed in the most resource-challenged areas, and bandwidth is expected to increase by 2,400% in East Africa with a reduction of costs by almost 50% upon the completion of undersea cables currently under construction.[41] In the meantime, several studies describe e-learning programs in rural areas and propose using blended learning with limited technological demands (mobile or low-bandwidth) to be more adaptable and to address unreliable access to internet. [42-44] This approach could be considered by The Max Foundation with the creation of a mobile application for PATS® that requires less technological demand and expertise.

10. Patient Access Tracking System®:

Keeping PATS® records updated was reported to be challenging for most physicians. The main barriers were lack of access to the internet or slow internet connectivity, absence of computers, lack of training, and constrains associated with the consultation setting. Not having access to computers during the consultations made registering patients and updating their PATS® records a time-consuming task. The barriers to using PATS® reported in LMICs mostly arise from the lack of adequate infrastructure or training. There is a need to further train personnel on how to log in on PATS® and easily complete the required task, and the difficulties encountered can be shared with The Max Foundation or other point-of-dispensing sites to achieve interoperability. [45] Mobile e-learning applications can also be developed and used during consultations to provide support for physicians in rural areas where resources are scarcest.[46]

The widespread adoption of mobile phones can partially ameliorate this issue. The penetration rates of mobile phones are increasing year after year in developing countries, providing opportunities to implement systems that require less resources in new ways. [47,48] For these reasons, mobile health (part of a broader field known as telemedicine) is proving to be useful to offset the lack of an

adequate infrastructure.[49] PATS® has much potential for computer-based or mobile-based tools to significantly enhance the quality of medical care and increase the efficiency of medical practice. These tools may include reminder systems that identify patients who are due for medication refills, check-up appointments, alerting systems that detect contraindications among prescribed medications. Numerous other "decision-support" tools can be developed and may soon facilitate the practice of clinical medicine. [50]

<u>Specific Aim 2:</u> To evaluate the performance of The Max Foundation toolkit used for assessing the quality of medicine-related services provided by point-of-dispensing sites.

In the light of the results of Aim 1 and Aim 2, a list of corrective actions was established. Table 15 displays the suggestions of questions to integrate in the evaluation assessment tool to guarantee data quality in terms of completeness and content validity in future site visits. Not having the checklist and site visit report template in hand while conducting the interviews was suspected to be the reason why data were not complete for some of the quality categories as shown in Table 13. Therefore, we recommend that staff have the checklist in-hand while conducting future site visits to ensure the absence of blank values.

In the checklist, there were two questions regarding storage (Table 13). There were no blank values for the two first questions and the data were estimated to be 100% complete, i.e., "Is storage clean and organized?" "Is storage secure?" Content validity was average for the question "Is storage clean and organized?" because this question did not entirely measure whether the medicines were stored in good conditions, i.e., original packages, adequate shelving, sufficient lighting, humidity control, per the WHO storage guidelines.[7] Content validity was defined "Good" for the question "Is storage secure?" because the data collected did measure the storage security, and interviewers reported detailed observations on how access to medicines was granted in each site. In 33% of the sites,

interviewers additionally collected data about temperature control even though the question was not on the checklist. Because temperature control is important for drug stability, The Max Foundation should integrate a question about temperature in the checklist within the storage conditions' quality category. For inspection, content validity was "average" because data collected did not include suitability of the delivery vehicle or temperature contamination.

Content validity for the PATS® quality category was "poor" because data collection was not consistent. Different questions were asked at each point-of-dispensing site, which made it challenging to identify patterns and to make cross-site comparisons. When examining the data collected, five subcategories were identified as questions to be added to the checklist: access, responsibility, familiarity, training, reliability (whether it matched the patients records or not). Table 15 presents the suggestions of revisions to integrate in the toolkit to ensure content validity.

Table 15 Suggestions of additional questions to integrate in the evaluation toolkit

Question asked in the toolkit	**Questions to ask in the revised tool kit**
Is storage clean and organized?	Is the storage clean? Are medicines stored in their original package? Does the room have sufficient lighting? Is the humidity controlled? Is the shelving adequate?
Is storage secure?	Is the storage always locked? Who has access to the medicines?
∅	Is the temperature controlled in the storage? How do you make sure the temperature is always below 25°C?
Is there someone responsible for inspection? If medicines are inspected upon receipt, are any of the following included in inspection?	Who is responsible for inspection? How are medicines inspected upon receipt? List of probes, if not mentioned, i.e., review of the supplier & delivery address, suitability of delivery vehicle, product name, batch number, expiry date, quantity received, damages, dampness, temperature, contamination or evidence of tampering.
Is there access to training and written procedures?	What kind of trainings does the staff receive (storage, handling, dispensing, stock management)? How often?
Are there written procedures for staff on managing stock control?	How do you manage your stock? Is there a recording method for batch number, expiry date, & product name? How easy or difficult would it be to complete quarterly inventory reports?
Is there access to internet?	Are there barriers to access internet? If yes, please list barriers
Is PATS used in this institution?	Who has access to PATS®? Who updates the records? Is everyone familiar with PATS®? Did you receive a prior training on how to use PATS®/ Do you need a training? Do the PATS® files match the patient's medical records?
Is there a process for drug recalls?	Transition question to drug recalls: How updated are patients' records? Have you had drug recalls in the past? If yes, how did you deal with them? If no, are you prepared to deal with them and how?
Is there a process for returned and expired medicines?	What is the process for returned and expired medicines?
Is there a process for adverse event management?	What is the process for AE management? Do you report them in PATS®? If not, why?
Is there access to diagnostics in the institution?	Do you have access to a PCR machine + kits? If not, how do you diagnose, monitor and follow up your patients?

VII. Recommendations

Using validated instruments is the best guarantee for dependable and meaningful findings.[51] Studies support the evidence about strong relationships between improving performance assessment tools and quality improvement to achieve improved effectiveness of dispensing, clinical effectiveness, appropriateness of care, efficiency, safety, optimal use of resources and trained an accountable workforce. [52,53]

Standardization of the instrument

In future point-of-dispensing site visits, we recommend confirmatory studies be implemented, with focused aims and a well-bounded sample of persons and sites and a well-standardized structured instrument design. Unclear performance expectations can lead to an overload of data that affects the efficiency and power of the analysis. Because evaluation is the purpose of The Max Foundation, the instrumentation should be more closely keyed to the selected variables of interest. Therefore, standardization of the performance assessment instrument is recommended to ensure completeness and content validity of data. Standardization of instrument allows a multiple-case study where findings can be displayed side by side and compared in the course of analysis. When an interviewer is observing, asking questions and recording, he/she does modify the observation, interview, and recording from one field visit to the next to make them look similar or different. Thus, The Max Foundation needs a standardized protocol and instrument to reduce missing data and avoid biases.[54]

Rating scales and magnitude

A classic evaluation checklist uses simple dichotomous items, e.g., yes/no, done/not done. Because dichotomous items are frequently insufficient for the assessment of complex tasks, this format could be extended to include rating scales, magnitudes or more categories, e.g., done/done incorrectly/not done, degree of pressure physicians felt to adopt an innovation, e.g., PATS®, their satisfaction with the assistance they received, "roughness" or "smoothness" of the implementation. [55-57]

Continuous quality improvement

Point-of-dispensing sites can be observed more than once. A single interview or observation sometimes is not enough. One learns how to ask a question in the site's terms and learns new perspectives that emerge during the first visit. Instrumentation can be modified steadily and accordingly to explore new leads, address a revised research question, or interview a new point-of-dispensing.

Involving participating dispensing sites' staff

In order to improve the performance assessment, evaluative interviews in the form of focus groups with the staff from dispensing sites should be conducted. Focus groups could explore and discuss monitoring and evaluation, services that should be improved and the current implementation strategy. The close follow-up of the process in every institution visited will allow The Max Foundation to see clearly all barriers and facilitators influencing the course of the evaluation. Based on the barriers and facilitators identified in the implementation strategies, an implementation plan can be developed that can be used as a guide for participating institutions in the future. MAS approved physicians and their teams can also be invited to work voluntarily with the selected quality categories to monitor their practice, the intention being that voluntary rather than obligatory will mean that caregivers will apply the quality information in a more considered manner. Participating physicians can be recommended to evaluate quality categories twice a year in order to see what aspects of medicine-related services are going well and which ones need improvement.

Better communication of expectations

Checklists can serve not only as evaluation tools but also as a common and easy means of communicating a set of expectations regarding effective performance and guidelines.[55] When performance expectations are unclear, it is difficult for participating dispensing sites to assess their own competence. A tighter connection between process improvement strategies and education and

training activities will accelerate improvements in quality and safety. [55] The Max Foundation could use the results of this report to communicate guidelines and expectations to the participating institutions.

Implementing a procedure for the receipt of donated drugs

For storage and inspection, we recommend implementing a procedure for the receipt of donated drugs that consists of three steps: receiving, inspecting and accepting. Receiving is the act of taking possession of the medicines in order to stage them for inspection, place them into inventory, in order to dispense them to the patient. Inspecting is the act of examining products that have been delivered to determine conformance to the invoice. Acceptance is acknowledging that the shipment is conform to the invoice. This procedure would require including a checklist with every shipment to be completed by the approved physician. Once completed, the checklist should be uploaded to PATS® or emailed to The Max Foundation. Table 16 is a proposed checklist to include with shipments. It is a modified version of the tool for visual inspection of medicines that was produced by the International Council of Nurses in partnership with the United Sates Pharmacopoeia (USP) and modified by the Military and Emergency Pharmacists Section of Federation International Pharmaceutical (FIP) (Appendix C), adapted to the needs of The Max Foundation.[58] It holds the dispensing site's receiver accountable to perform a complete inspection before storing the donated medicines and facilitates submitting the checklist to The Max Foundation in a timely manner.

Use the full potential of PATS®

PATS® can be an excellent resource to point-of-dispensing sites and physicians. The main reported barriers to using PATS®, i.e., slow internet connectivity, absence of computers and the consultation settings, can be overcome if a mobile-based application was developed, patients' PATS® records can be updated in a timely manner, during consultations and slow internet connectivity will no longer have an impact on the use of a PATS® mobile-based application. PATS® can also be a means for

point-of-dispensing sites to communicate with each other. First, a forum could be created where physicians can ask each other questions or share concerns. Second, a frequently asked questions (FAQs) section could be added by The Max Foundation to avoid addressing the same problem multiple times. Third, a "highlight" section can be added, where point-of-dispensing sites with high performance in storing, handling and dispensing medicines can be featured on a regular basis, e.g., quarterly. This will not only be having access to an example of best practices, but could also motivate point-of-dispensing sites to achieve higher performance so they can be featured.

Table 16 Suggested checklist to be implemented documenting receipt and inspection of donated medicines

	Yes	No	Comments
The quantity received matches the invoice.			
No damage or breakage.			
PACKAGING			
Container and Closure			
1.1.1- Does the container and closure protect the product from the outside environment; e.g. is the container properly sealed?			
1.1.2- Do they assure that the product will meet the proper specifications throughout its shelf life?			
1.2 Label The information written on the label is very important. All information must be legible and indelible			
1.2.1 Is all information on the label legible and indelible?			
1.2.2 The batch (or lot) number Medicines with the same batch/lot number are expected to be equivalent.			
1.3.1 Does the numbering system on the package correspond to that of the producing company?			
1.2.10 **The date of manufacture and the expiry date:** An expired product should not be dispensed under any circumstances			
Are the manufacture and expiry dates clearly indicated on the label?			
1.2.11 Storage information:			
Is the product properly stored? - Temperature below 25 C. - In a secure area.			

VIII. Limitations

Because The Max Foundation is not an academic institution, nor were site visits conducted with the rigor of research surveys, team members' responses to the checklist and summary report likely varied based on a number of factors, including language barriers, limited time spent during the visit, limited time involved with the organization, differences in levels of training completed by team members and their memorization of the checklist and site report template. We also recognize the disadvantages of convenience sampling and the vulnerability of this study to selection bias. The results were not representative of all of the point-of-dispensing services provided by The Max Foundation partner institutions. Social desirability bias was another limitation of the study, which may be overcome by confirming participants' statements with on-site observations. The directed approach also presented challenges to the naturalistic paradigm. Using this approach may result in researchers approaching the data with an informed but, nonetheless, with a bias. Hence, researchers might be more likely to find evidence that is supportive rather than non-supportive of a theory. [59] Because there was a single coder, intra-coding reliability was assured with a set of explicit definition for codes but may be subject to researcher's bias.

IX. Conclusion

While many point-of-dispensing sites acted as examples of quality practices, this study found that the quality of the performance in some point-of-dispensing sites as well as the quality of the performance of the assessment tool can be improved. Completeness and content validity of data collected were not achieved using the assessment tools at a number of sites. With some adjustments to the quality categories and measurement procedures, The Max Foundation's performance evaluation instrument can be standardized and used across all point-of-dispensing sites. A set of seven recommendations are identified to strengthen the assessment process. Validation of the assessment tool is recommended in order to achieve continuous improvement of medicine handling

conditions and standards for medicine-related patient safety system.

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APPENDIX A Checklist developed by TGP and The Max Foundation used as an interview guide

Tanner Pharma GROUP

The Max Foundation

Institution Site Visit Report

Institution Name:	Date of Site Visit:	Max Representative:
Institution Address:	Institution Representative(s):	Licence Details & Issuing Authority:

OBJECTIVE
Confirm that the Institution:
1. **Has adequate facilities to safely store medicines**
2. **Has processes in place for appropriate handling of medicines**

Report Written by (printed name & position) at Max:

Signature & Date:

Report Reviewed & Accepted by (printed name & position) at the Institution (optional):

#	Item	Good Distribution Practice Standard	Check, if yes	Observations & Evidence Reviewed
1	**External Building**	Capture a photo of the building. Include the address, if possible		
2	**Internal Building**	**Please mark your observations:**		
2.1		Medicines are stored in a separate & secure area, specifically, access to the medicines must be granted by an individual with a key.		
2.2		The storage area for medicines is clean & organised, e.g., there is no loose packaging or accumulated dust debris.		
2.3		The storage area for medicines is free of contaminants, e.g., food, drink, or other personal medications		
3	**Quality Control**	**Please ask the following questions:**		
3.1		Is there a person responsible for releasing medicines from customs? • Kindly provide name(s) & title(s).		
3.2		Is there a person responsible for inspecting medicines upon receipt? • Kindly provide name(s) & title(s), if different from above. • Does this individual have access to a computer with internet?		
3.3		If medicines are inspected upon receipt, are any of the following included in inspection? • For example: review of the supplier & delivery address, suitability of delivery vehicle, product name, batch number, expiry date, quantity received, damages, dampness, temperature, contamination or evidence of tampering.		
3.4		Is there a person with overall responsibility for the quality control of stored medicines? • What is the scope of his/her responsibilities? • How are issues &/or improvements documented?		
3.5		Is there a formal training program for staff on storing & handling medicines? • How often does staff undergo training?		
3.6		Are there written procedures for staff on storing & handling medicines? • How often are they updated?		
3.7		Are there written procedures for staff on managing stock control? • For example: first in, first out (FIFO) • Is there a recording method for batch number, expiry date, & product name? • How easy or difficult would it be to complete quarterly inventory reports?		
3.8		Does the Institution accept returned medicines from patients?		
3.9		Is there a process for disposing of returned or expired medicines?		
3.10		Is there a process for drug recalls? If so, how are patients notified?		
4	**AE Reporting**	Is there a process for managing patient complaints or adverse events relating to medicines?		
5	**Regulatory**	Is the Institution audited? If so, by whom and how frequently?		
6	**Licensing**	Is it possible to view & obtain a copy of the Institution's license &/or any other key regulatory documentation granting permission to treat patients & dispense medicines? Correlate with ship-to address, if possible		

APPENDIX B Summary report for internal use at The Max Foundation

The Max Foundation | Dignity and hope in the face of cancer

SUMMARY REPORT OF [Country] SITE VISIT
[Date]
Report submitted by [Name] to [Name]

Date of Site Visit	
Institution Name	
Site Visit Conducted By	
Participants	

Institution Ship-To Address	
Institution Validation	☐ Institution Validated on [Date] ☐ Institution Not Yet Validated Progress:
Date Institution Approved in GIPAP	
Date First Patient Approved in GIPAP	
Total Number of Active Patients	
Number of Approved Physicians	
Available Diagnostics & Monitoring Tests	

Areas Visited Within the Institution	
Number of Patient Files Reviewed	
Other Meetings	

Stock management

Responsible Person:

Action	Process	Comment
Importation process		
Inventory management		
Dispensation		
Review of inventory		

Patient case management
Responsible Physician(s):

200 NE Pacific St, Ste 103 | Seattle, WA 98105 USA
Phone: 425.778.8660 | Toll-free: 888.462.9368 | Fax: 425.778.8 .org

Action	Process	Comment
Clinic logistics		
Use & Accessibility of PATS		
Review of patient records		

Recommendations and/or requests

General comments

Follow up action items

Item	Responsible	Deadline