

Advocacy in Low & Middle-Income Countries

**A study on overcoming barriers to
accessing diagnostics in CML**

The Max Foundation Report, March 2014

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Table of Contents

Acknowledgements.....	i
Executive Summary.....	1
Background on CML & Disease Monitoring.....	2
Introduction	3
Methodology.....	4
Survey Highlights.....	5
Focus Group Results.....	9
<i>Reasons for Becoming a Patient Advocate</i>	9
<i>Skills or Qualities Needed as a Patient Advocate</i>	11
<i>Barriers to Accessing PCR Testing</i>	12
<i>Barriers Patient Advocates Can Target to Improve Access to PCR Testing</i>	15
<i>Partnering to Improve Access to PCR Testing</i>	17
Discussion.....	20
Conclusions	23
Recommendations	24
Appendix	a
<i>Venn Diagrams on Focus Group Results</i>	b
<i>Focus Group: Consent Form</i>	e
<i>Survey Questions</i>	f

Executive Summary

In partnership with patient organizations worldwide, The Max Foundation launched the “What is MY PCR?” campaign to help raise awareness of the critical need for disease monitoring among CML patients. In addition to raising global awareness, the campaign aimed to increase patients’ understanding of treatment milestones and to increase patients’ involvement in treatment.

As momentum gathered following the campaign’s first year, The Max Foundation set out to learn more about the level of access CML patients have to PCR testing in targeted low- and middle-income countries and the challenges encountered by patients. Patient advocates from 29 countries were asked to complete an online survey as well as participate in one of three regional focus groups. A total of 35 patient advocates participated in this research from Latin America, Africa, and Asia-Pacific.

Common themes and shared experiences emerged despite the cultural and geographic differences. Advocates talked about the lack of information, among patients and physicians alike, regarding the importance of PCR testing. Among those patients and physicians keenly aware of the importance of PCR testing, the cost of testing itself posed a significant barrier to their ability to monitor the disease. Partnerships and strategies were discussed as ways to overcome barriers to PCR testing. In general, participants exchanged ideas about how to advocate for increased access to PCR.

These findings will be shared with campaign partners, sponsors, and patient organizations so that together we can build a foundation for ongoing advocacy efforts. CML patients have the right to reliable diagnostics. This research provides insight into the state of CML diagnostics in emerging regions. As we aim to broaden access to PCR testing through advocacy, we continue to find ways of collaborating across regions and of growing partnerships to achieve this goal.

Background on CML & Disease Monitoring

Chronic Myeloid Leukemia (CML) is a disease in which the bone marrow makes too many white blood cells.¹ CML is characterized by the presence of the Philadelphia Chromosome, a reciprocal translocation between chromosomes 9 and 22. This translocation forms the hybrid gene, BCR-ABL, which activates a tyrosine kinase enzyme in the bone marrow.² This process causes mutated cells to proliferate and crowd out normal white blood cells, red blood cells, and platelets. Patients may be unaware of this change until they exhibit symptoms or until they go in for a routine blood test showing an abnormal increase in white blood cells.

Targeted therapy consisting of tyrosine kinase inhibitors (TKIs) halts the proliferation of mutated cells and has helped transform treatment, and subsequently, improved survival outcomes for patients with CML. To date there are five approved TKIs. Second- and third-line TKIs offer effective therapeutic options for patients who are unable to achieve sufficient response to first-line treatment.

Reliable, regular, and sensitive monitoring of the disease is important to evaluate the effectiveness of treatment. Monitoring BCR-ABL transcripts by polymerase chain reaction (PCR) has enabled more precise assessment of patients' response to treatment for CML. The European Leukemia Network (ELN) and the National Comprehensive Cancer Network (NCCN) are leading global entities that set forth guidelines for monitoring CML treatment.

While Quantitative PCR testing is one of the key tools to monitor CML patients' responses to treatment, few patients are systematically monitored as per the ELN or NCCN schedule. In some countries, PCR testing is available but not always offered to patients. Patients might not be aware of the importance and need for such monitoring, and many of them do not know their PCR levels. In addition, many hospitals in low- and middle-income countries simply do not have the capability to perform PCR testing.

¹ General Information About Chronic Myelogenous Leukemia:

<http://www.cancer.gov/cancertopics/pdq/treatment/CML/Patient/page1>

² What is MY PCR? Campaign's "Frequently Asked Questions on PCR": <http://www.whatismypcr.org/>

Introduction

There is a significant need to increase awareness in the CML patient community of the importance of monitoring residual disease levels and understanding PCR test results. Only then can patients be educated partners and fully participate in decisions regarding their treatment.

With this in mind, The Max Foundation led an international initiative in 2012 to improve awareness of the need to monitor the treatment of CML by PCR testing. To date, the “What is MY PCR?” campaign has united 39 patient organizations from 35 countries for which access to PCR by their members is considered an unmet need. During 2012 and 2013 the “What is MY PCR?” Campaign distributed more than 40,000 educational materials for patients in 21 languages.³

In 2013 The Max Foundation sought to strengthen the impact of the campaign by conducting a Participatory Action Research (PAR) project to engage patient advocates in low- and middle- income countries (LMICs). We embarked on this research to better understand the challenges faced by advocates, as well as to identify key components of an advocacy agenda for those wishing to improve access to diagnostics and monitoring for people living with CML. Moreover, we hoped to learn and develop a plan to increase the impact of the “What is MY PCR?” campaign.

The Max Foundation collected data and information through a mixed method approach. In order to assess patient access to PCR in LMICs, a survey was delivered to patient advocates in targeted countries. The survey was designed to collect demographic information as well as information about PCR testing in participants’ countries.

The focus group was designed to collect more detailed information as well as a range of views and opinions regarding access and barriers to PCR. The focus group and survey results described in this report are part of the PAR conducted with patient advocates in three regions – Africa, Asia-Pacific, and Latin America.

The goals of these focus groups were to:

- Understand patient advocates’ perspectives regarding advocacy
- Understand patient advocates’ perspectives regarding increased access to PCR

It is important to ensure the validity of survey responses through a process of triangulation, or cross-verification of data, from alternate sources. For this reason, as a follow up to the research findings described in this document, The Max Foundation will conduct structured interviews with key partners from targeted LMICs.

³ What is MY PCR? Campaign: <http://www.whatismypcr.org/>

Methodology

The Max Foundation conducted a total of three focus groups in Africa, Asia-Pacific, and Latin America. The first of these focus groups was conducted in April 2013 in Beijing, China adjacent to the Rising Sun conference. In coordination with the conference steering committee, the focus group was scheduled as an independent event to be held on-site.

Because of the number of advocates attending the Rising Sun conference, The Max Foundation extended the invitation to everyone attending and asked participants to RSVP one month prior to the start of the conference. In response to this invitation, 11 individuals replied. One individual responded after the deadline and was not invited to participate. Ten individuals responded prior to the deadline and were asked to complete an online survey. The survey was in English and was made available online through Survey Monkey. Individuals were allowed approximately one week to complete the survey. All 10 individuals who responded to the survey participated in the focus group. The focus group was conducted in English.

In August 2013 CML advocates from the Latin America region met at the LA LMC working group in San Jose, Costa Rica. The focus group was held on-site and was incorporated into the working group meeting as a workshop session. Fifteen (15) individuals were asked to complete an online survey in advance of the focus group. The survey was in Spanish and was made available online through Survey Monkey. Individuals were allowed approximately one week to complete the survey. The focus group was conducted in Spanish.

In November 2013 CML advocates from the Africa region met at the CML Life Africa conference in Durban, South Africa. The focus group was held on-site and was incorporated into the conference as a workshop session. Ten (10) individuals were asked to complete an online survey in advance of the focus group. The survey was in English and was made available online through Survey Monkey. Individuals were allowed approximately one week to complete the survey. The focus group was conducted in English with French interpretation, as needed.

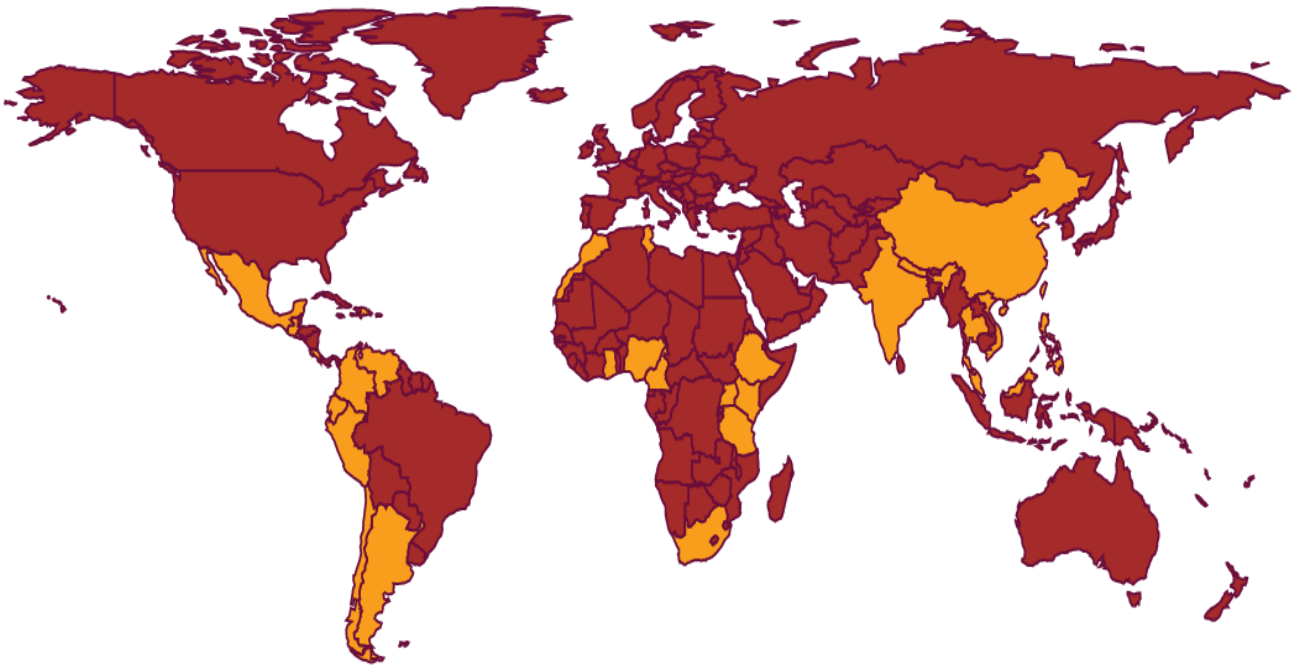
Each of these focus group contained one moderator and two observers. A moderator's guide was developed to help structure the conversation. Two observers were trained in verbal and non-verbal data capture.

Survey Highlights

The survey collected both demographic information as well as information on the availability of PCR in the participant's country. A total of 35 participants hailed from 29 different countries:

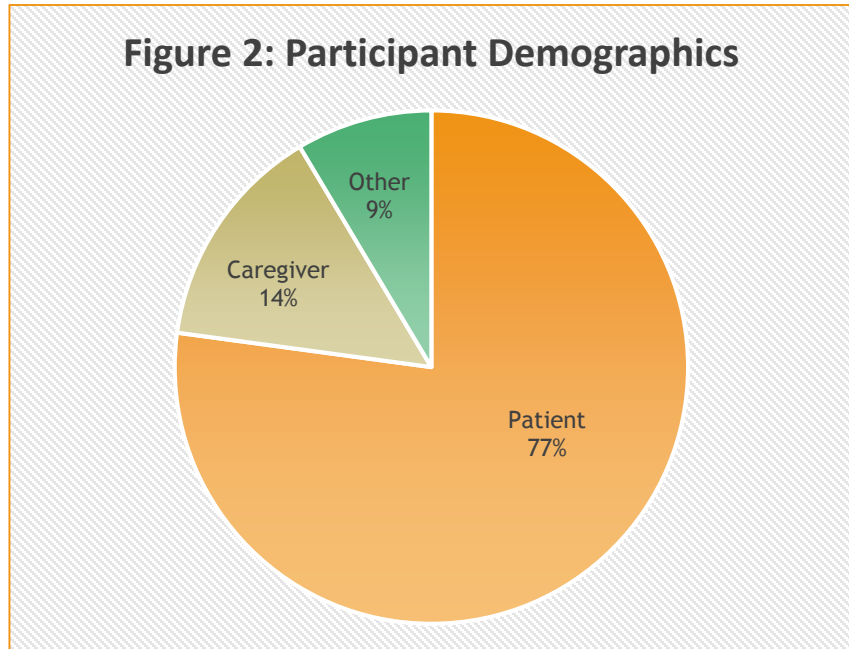
Latin America Region (n=15)		Africa Region (n=10)		Asia-Pacific Region (n=10)	
Argentina	Ecuador (2)	Cameroon	Nigeria	China	Philippines
Chile (2)	El Salvador	Ethiopia	South Africa	India (2)	Taiwan (2)
Colombia (2)	Guatemala	Ghana	Tanzania	Malaysia	Thailand
Costa Rica	Mexico (2)	Kenya	Tunisia	Nepal	Viet Nam
Dominican Republic	Peru	Morocco	Uganda		
	Venezuela				

Figure 1: Participant Countries



Among the demographic information collected, it was notable that the majority of participants (77%) identified as patients while 14% identified as caregivers and 9% as “other”. This “other” group of participants self-identified as patient advocates &/or representatives of cancer organizations.

Of particular note, while the demographics were mixed in Asia-Pacific and Latin America, participants in the Africa focus group were made up entirely of patients.



Among all participants 57% were male and 43% were female. The Latin America group was comprised mostly of female participants (64%), and the Asia-Pacific and Africa groups were comprised of mostly male participants (70%). Additional demographic information revealed that the majority held a college degree or higher.

Figure 3: Participant Demographics

Gender:

Male 57%
 Female 43%

Education:

< College 14%
 College Degree 52%
 Advanced Degree 34%

Age (median):

40 years old

Year of Diagnosis (median):

2002

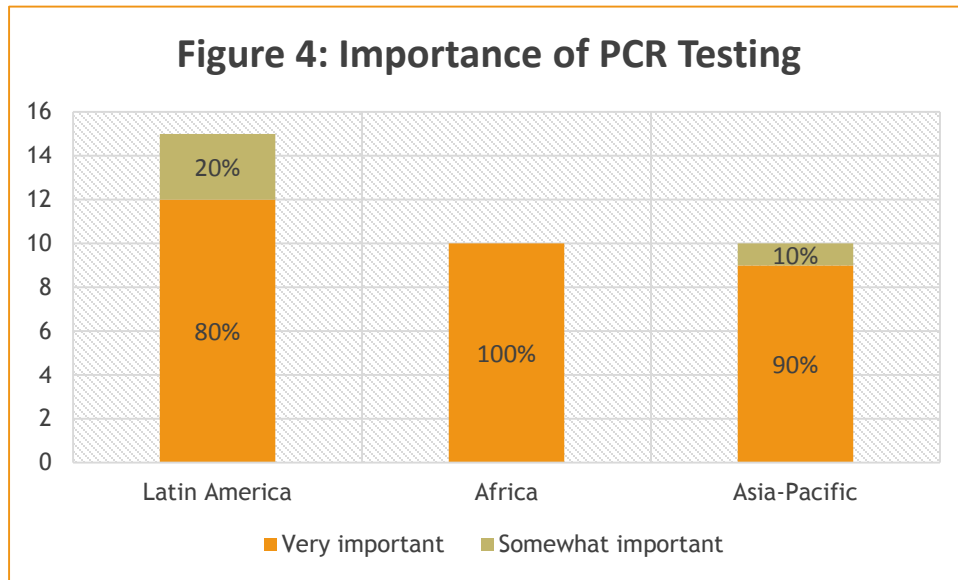
Average Number of Years as Advocate:

6 years

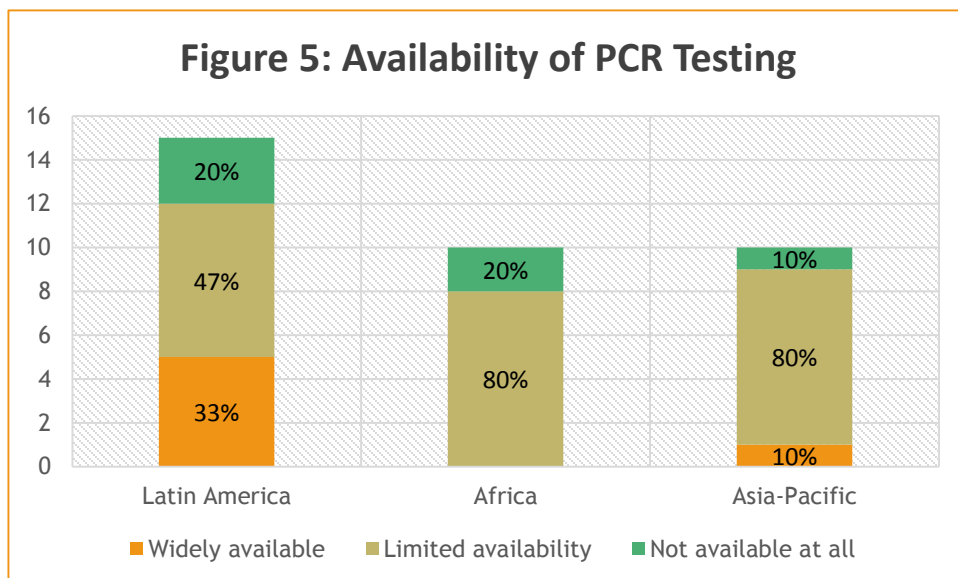
Participants were a relatively young group of CML survivors with median age of 40 years and median diagnosis occurring in 2002. Participants tended to have lived with CML longer in the Latin America group (12 years median), followed by the Asia-Pacific (10 years median) and Africa groups (7 years median).

Participants have been advocates for an average of 6 years, with the Asia-Pacific and Latin America groups having spent an average of 7 years as advocates, and the Africa group having spent an average of 4 years as advocates. Most participants reported having become advocates within three to five years of diagnosis.

Participants were also asked to rank the importance of PCR testing in an effort to better understand how important this issue is to them. The majority of participants (89%) believed PCR testing to be very important.

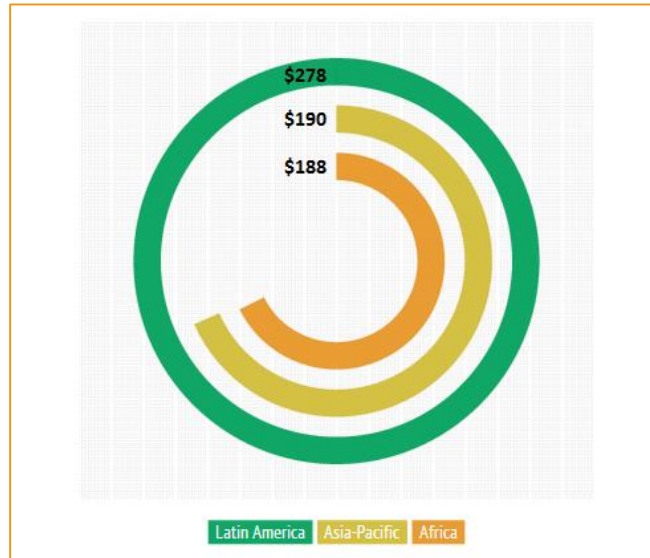


When asked about the availability of PCR testing in their countries, the majority of participants indicated that PCR testing had limited availability (66%). This question did produce some variances within countries for those who had more than one representative participating. In these cases, participants indicated that their country had either widely available or limited availability in PCR testing, which may be attributed to each individual's unique experience with access.



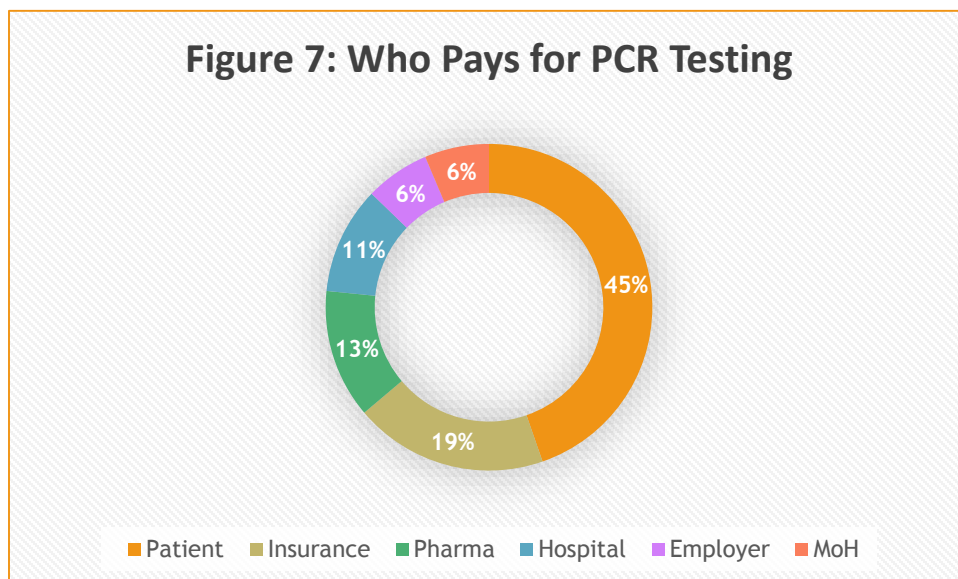
Participants were also asked to self-report on the cost of PCR testing in their country. The average cost of PCR testing was similar between Africa (n=6) and Asia-Pacific countries (n=7) where it was reported to be \$188 and \$190 respectively. This varied from Latin American countries (n=8) where the average cost per test was reported to be \$278. These figures were based on out-of-pocket cost to the patient.

Figure 6: Cost of PCR Testing (USD)



When asked who pays for the test, participants reported slight differences across regions. The majority reported that patients are often asked to pay (45%). This is followed by insurance, pharma, hospitals, and Ministries of Health.

Figure 7: Who Pays for PCR Testing



Focus Group Results

Each focus group centered on the following questions:

1. Why did you become a patient advocate?
2. What skills or qualities did you feel were needed as an advocate?
3. What are the barriers to accessing Quantitative PCR testing in your country?
4. Which barriers do you think you can target to improve access to Quantitative PCR testing in your country?
5. Who would you need to include, or partner with, to improve access to Quantitative PCR testing in your country?

Our findings are summarized below and includes region-specific reporting as well. Diagrams of these results may be found in the Appendix.

Reasons for Becoming a Patient Advocate

Across all groups, there were some advocates who were appointed as advocates by someone else, such as a physician or another leader. However, most advocates who were drawn to patient advocacy did so from a personal desire to give back. Through their shared experiences, patient advocates felt they had something to offer to others like them, whether it was specialized knowledge or a personal touch. Some participants also talked about having known someone with cancer, whether a parent or a friend, that inspired them to give back.

While many similarities existed across groups regarding the reasons for becoming advocates, these reasons were often steeped in culturally complex and nuanced layers. In general, participants in the Latin America group became patient advocates in order to help others access treatment, while participants in the Africa group became patient advocates in order to increase access to information and help raise awareness, and participants in the Asia-Pacific group became patient advocates in order to address the psychosocial needs of people living with CML.

Latin America

Participants became advocates for a variety of reasons. All of the participants were drawn to advocacy to **address deficiencies in the healthcare system** (n=15). “I fought to get access to treatment” was one particularly poignant comment that spoke to the experience of many in the group. Another said that her doctor told her “Now you are going to have to fight, and you’ll have to put on the gloves.” It was because of their personal experience with lack of treatment or limited access to treatment that participants later came to view themselves as advocates or patient leaders.

“Now you are going to have to fight, and you’ll have to put on the gloves.”

Many participants reflected on a **human connection** in their decision to become patient advocates (n=7). This human connection was described in social, emotional, and spiritual terms. One participant talked about having an emotional and spiritual motivation to ask what she can do to help, while another said he felt it was “predestined” after he met and connected with others at a patient group meeting. Still another participant talked emotionally about the patient group’s founder passing away, and he felt compelled to continue the work based on what he learned from the founder.

Most participants approached the question by telling their personal story about their journey with CML. They talked about how the process unfolded on a personal level, and some referenced the **psychosocial component** of a diagnosis as what moved them to become patient advocates (n=2). While several participants struggled to gain access to the prescribed medication in their local healthcare system, at least one talked about how lack of access was worse than the diagnosis itself.

In addition, a few participants were **nominated** to positions of leadership by someone they knew, particularly physicians (n=3). Others felt that they had specialized **knowledge**, such as scientific or legal knowledge, to offer or else recognized a knowledge gap among patients that needed to be filled (n=3).

Related to this need for knowledge, there was one participant diagnosed with CML in the late 1990s, prior to the advent of TKIs. At that time, there was not a lot of information available about CML and not many treatment options. **Clinical trials** motivated this patient advocate (n=1) to learn more about a novel therapy and to advocate for access.

Africa

The group spoke at length about their reasons for becoming patient advocates and shared personal stories. Most participants pinpointed specific needs and shortcomings for patients as reasons for becoming patient advocates.

Almost everyone identified the **psychosocial impact** (n=8) of a diagnosis as the primary reason for becoming an advocate. They spoke of finding value and satisfaction in counselling, empowering, providing support, and offering hope to other patients. One participant also shared the isolation he experienced following a diagnosis saying it was a “lonely space having to live with the disease on my own; not sharing with people as they did not know how to respond.”

Most of the group also mentioned **information** (n=7), or the lack thereof, as a key motivator for them to become advocates. They described wanting to spread knowledge and awareness among patients, or having the experience of being a patient with unanswered questions, or feeling kept in the dark by physicians.

Other participants wanted **to give back** (n=5), wanted to help **improve access to treatment** (n=5), or were **nominated** by a physician (n=2).

Asia-Pacific

When asked why participants became an advocate, the majority indicated that they did so out of a desire **to give back** (n=7). Two participants indicated that someone had extended a personal **invitation** to join the patient group’s leadership team (n=2).

Participants spoke passionately about their reasons for giving back, which varied widely. Many were due to personal experiences along the participants' CML journey. One person mentioned having received a "personal touch" from someone at the time of diagnosis. Another person talked about how going through the same diagnosis allows people to understand others' experiences. This shared experience makes it easier to understand and support one another. One participant had the unique perspective of being both patient and physician and discussed how this impacted his ability to empower others as well.

Skills or Qualities Needed as a Patient Advocate

Participants provided a wide range of skills and qualities needed as patient advocates. Taken together, it is notable that the skills and qualities are the same one might attribute to any good leader.

Figure 8: Skills & Qualities Word Cloud



Credit: Wordle™

Latin America

Many qualities were highlighted by the group as essential for a patient advocate, while only a few specific skills were referenced. This highlighted the group's tendency toward emphasizing passion and action as central tenets of their approach. There was consensus among the group that **knowledge** (n=15) as well as **solidarity** (n=15), specifically support from other patients &/or the patient community, were critical qualities.

Empathy (n=3) was noted as an important quality along with emotional support, honesty, and also people skills. **Commitment** (n=3) was also mentioned alongside tenacity or constancy. The **ability to**

communicate was noted as an important skill, particularly the ability to speak directly, clearly, and concisely (n=2).

Finally, two participants felt that **experience** was an important quality in a patient advocate (n=2). An example was a patient advocate's comment "to live it" when talking about her experience as both a survivor and a leader.

Africa

The important qualities and skills named by the group represented two general types – 'soft' skills (n=5) and 'hard' skills (n=3). Soft skills referred to more intangible qualities, such as personality traits or people skills. These included communication and social skills, passion, dedication, leadership, integrity, patience, and a giving spirit. Hard skills referred to more concrete technical skills. These included planning and organizational skills, computer literacy, budgeting, and utilizing social media.

The group provided such a far-ranging list of qualities and skills that in general it was difficult to categorize them into more specific themes. However, one consensus that emerged within the group was that **communication** and **social skills** (n=10) are essential to being a patient advocate. Every member of the group agreed with that statement. A theme that was not as strong but still noticeable was **dedication** (n=3). Those participants spoke of the importance of "dedication," "tenacity," and "commitment."

Asia-Pacific

Participants in the Asia-Pacific group cited specific skills as useful for patient advocates more often than qualities or personality traits. When participants were asked to tell us what skills or qualities are needed to be an advocate, three referenced their **professional skills** as being helpful (n=3). Two leaders work in health care, while one works in business. Still another person said **planning skills**, which could also be the result of professional or educational training (n=1). One person felt that a good advocate has **empathy** for others (n=1).

Barriers to Accessing PCR Testing

Participants recognized that disease monitoring and PCR testing specifically are important tools to help patients achieve positive treatment outcomes. Across all regions, the main barriers identified by participants to accessing PCR testing were cost and lack of knowledge or information. As highlighted in the survey, most participants' countries have limited access to PCR testing.

In addition, participants identified misinformation, limited knowledge, &/or lack of awareness regarding the importance of PCR testing by both patients and physicians as key barriers. It was stated that not all physicians treating CML patients are CML experts. This can impact the physician's awareness of new therapies, advances in diagnostics and monitoring, or updated international guidelines.

In some instances, the physician was seen as contributing to patients' lack of knowledge by not discussing the importance of disease monitoring with patients. This was particularly acknowledged by leaders from Asia-Pacific, where participants referenced a cultural hesitation of patients to ask questions

of their physician. In Africa, participants suggested that some physicians may try to spare patients who they know cannot afford the test by not making patients aware of the test at all. Participants also agreed that physicians generally have limited time to spend with patients as well; thus limiting patients' ability to learn from their doctors.

Other barriers shared by patients in the Africa and Asia-Pacific regions included transportation &/or geographic accessibility of laboratories performing PCR testing. In addition, patients encountered barriers to testing due to the lack of availability generally or for CML specifically. For instance, advocates in the Africa region talked about the availability of PCR testing for HIV/AIDS patients but that labs lack the training and reagents needed to perform PCR for CML patients.

Latin America

The participants all agreed that the main obstacle to PCR testing in their country is **cost** (n=15). They were split into two categories – those living in countries where PCR testing is paid for by a third party and those living in countries where PCR testing is paid for by patients. In the latter, the out-of-pocket cost to the patient is quite high. One participant noted that even patients covered under the national health scheme end up paying for the tests themselves due to bureaucratic delays in the public system.

A second barrier to PCR testing was **misinformation**, both on the part of the doctors and the patients (n=8). For instance, one participant said that “doctors don’t consider it relevant” while another said “it doesn’t go further than the doctor”. This comment in turn references the challenge patient’s face in learning about their disease and disease monitoring.

Latin American advocates also described **administrative hurdles** (n=3) that prohibit or delay access to PCR testing. Some of these hurdles were perceived to have been set up intentionally, either by the hospital, the pharmacy or the government, in order to limit access for financial or logistical reasons. Interestingly, only one participant stated that there are no obstacles in her country (n=1). In her country, everyone is tested every 3 months in a centralized laboratory.

Africa

Physician and patient **knowledge** were viewed by the group as significant barriers to PCR testing (n=13). For several participants, physician knowledge was seen as a barrier but for different reasons. One participant said that “the physician does not know about PCR . . . only the hematologist knows,” while another said “physicians are not prescribing [PCR] for patients.” Others said that physicians know about PCR but undervalue its importance to patients.

“If I cannot stop treatment, why should I do my PCR?”

Patient knowledge was seen as a barrier due to a lack of understanding or a lack of interest from patients. One participant said that patients ask, “If I cannot stop treatment, why should I do my PCR?” This highlights the complexity of the science behind monitoring, and the lack of information and understanding that patient advocates must contend with in their efforts to raise awareness about PCR.

Cost (n=4) was another recurring theme in the discussion, though again, it consisted of a few different threads. Three participants stated cost as a barrier in terms of its out-of-pocket expense, while another stated that insurance does not cover PCR in their country, making it cost-prohibitive for patients. Cost was referenced indirectly in other comments as well. For example, one participant said, “If the doctor knows that you have money, they might refer [for PCR testing].” In this person’s experience, cost and affordability dictates the physician’s response. Others in the group disagreed with this approach, saying that it is the physician’s responsibility to prescribe what the patient needs so that the patient knows what is missing. Ultimately, then, this would appear to be a physician knowledge issue, but the issue of cost is nonetheless a component of the decision-making process for some physicians.

Other barriers included **availability** of testing in country (n=2), availability of **testing for CML** specifically (n=2), **culture** (n=1), **transportation** (n=1), and **corruption** (n=1). Participants talked about the availability of PCR, but differentiated between its availability in their country and the availability of PCR testing specifically for CML. Two participants said it is not available in their country, and two others said that the technology is available, but laboratories are not equipped to test for BCR-ABL.

The cultural barrier was described as a tendency to trust in foreign labs instead of local labs, and corruption and availability of transportation were mentioned as two other barriers that prevented some patients from receiving PCR testing.

Asia-Pacific

When asked what the main barriers were to accessing PCR, Asia-Pacific advocates reached consensus around cultural norms in the **patient-physician relationship** (n=6). In many Asian cultures, patients hesitate to question their physician, and/or are expected to trust their physician completely. This factor discourages open dialogue regarding patients’ health status and contributes to decreased requests for second opinions.

Some participants talked about a **lack of awareness** for PCR testing among physicians and among patients (n=2). Physicians who are familiar with international guidelines for PCR testing are typically located in large cities or at large hospitals. Sometimes it is difficult for patients in rural areas to reach these physicians, so **geographic location** can be a barrier to disease monitoring (n=2). Even if patients can reach a large, urban hospital, two participants acknowledged that PCR testing is simply **not available** (n=2). One participant stated that samples from his country must be shipped to a neighboring country for testing.

Again, the **cost** of the test itself was perceived as a significant barrier for many patients in the Asia-Pacific region (n=4). The cost is different in different countries and sometimes even among different laboratories within a country. Navigating these cost differences can be perplexing for the patient, and in some cases, advocates indicated that patients question whether physicians receive profit from referring to certain laboratories.

Interestingly, participants from this region also mentioned **fear** as a barrier to disease monitoring and PCR testing (n=2). One participant acknowledged that there is a psychological deterrent to testing as the results could mean that the patient is not responding to treatment. Fear of the unknown can critically impact a patient’s willingness to get tested. For some, this could also mean awareness of a death sentence if there are no other options for second-line treatment.

Barriers Patient Advocates Can Target to Improve Access to PCR Testing

When asked what barriers they would target in order to improve access to PCR testing, in all the focus groups most participants felt that their groups could address lack of information among patients and physicians. In addition, participants in the Latin America and Africa regions felt that there was an opportunity to increase training availability for health professionals, such as physicians or lab technicians, on up-to-date techniques in PCR testing for CML patients. It was not clear whether training of health professionals was something that advocates felt they could address themselves or would work with partners to help facilitate. In those countries where PCR is available but limited, this training would also help raise the profile of cancer patients.



Credit: exdez

Finally, the groups all acknowledged that the cost barrier needed to be addressed, and in the Latin America region, some advocates talked about their experience negotiating costs down with local labs.

Latin America

Participants identified the following barriers to PCR testing:

- Patient Awareness (n=15)
- Physician Education (n=3)
- Cost (n=3)

There was consensus among Latin American advocates that lack of **patient awareness** about the importance of PCR (n=15) was an important barrier they needed to address first. Second, the group felt it was also important to **educate physicians** about the importance of monitoring (n=3). The group felt that shortcomings in both patient and physician understanding would necessitate a two-pronged approach to solving it.

Though **cost** was described as the most significant barrier (n=3), this was one that participants believed they had the capacity to address. Patient advocates discussed agreements they were able to negotiate with laboratories, allowing them to consolidate the testing on a particular date and organize a large number of patients to be tested at the same time. Consequently, this arrangement lowered the cost of testing for each patient. This appeared to be a model others felt they could replicate in their own countries.

Africa

Participants felt that in order to make PCR testing more available, they would need to address the following issues:

- Physician & Patient Information (n=4)
- Availability (n=3)
- Training of Technicians (n=2)
- Cost (n=2)

Participants discussed the importance of helping patients and physicians understand the need for PCR testing, despite the cost. While cost itself was an issue, at least one person believed cost to be something that is open to negotiation while another noted that support systems should be in place to provide relief.

In addition to educating patients and physicians, the group identified two additional barriers they felt they could address in their own countries, specifically the availability of the instrument &/or reagents and the training of technicians in carrying out PCR testing. One participant said, “The process of getting the machine was difficult as people did not understand the need. Now it is there, and now we have to train the technicians.”

Asia-Pacific

Patient advocates felt that in order to make PCR testing more available, they would need to address the following barriers⁴:

- Availability
- Cultural norms in the patient-physician relationship
- Geographic Location
- Physician & Patient Education
- Cost

The discussion centered on the need for information sharing among physicians and patient advocates. One advocate (n=1) felt that PCR testing is a very complex topic and is not for the patients to try to understand. Cost was also a key barrier, and at least one advocate talked about a real need to lower costs.

⁴ Due to limitations in data capture, we were unable to record ‘n’ and to subsequently rank these issues.

Partnering to Improve Access to PCR Testing

As discussed in the previous section, all of the groups referenced the cost of PCR testing and the possibility of partnering with laboratories as a way to negotiate down these costs. This was a theme shared amongst all the groups.

In addition, the Africa and Asia-Pacific groups talked about partnering with a subset of physicians, specifically “up and coming” key opinion leaders who were not set in the “old” ways of doing things but were open to new and emerging technologies and therapies. Participants expect that these physicians will be more open to the patient experience and to bringing patients along as active participants in the treatment process.

The Africa and Asia-Pacific groups described partnerships with industry and with other patients and patient leaders as key in any effort to improve access to PCR testing within their own countries. The Latin America and Africa groups talked about working with health authorities or public hospital administrators as a means of facilitating social change at the country level.

Latin America

This question produced broad consensus in several areas, both in the specific partners to associate with and in the action recommended by participants. The question ultimately led to a discussion about specific tactics advocates can use to overcome barriers to PCR access, highlighting the activist philosophy of the Latin America focus group.

Members of the group viewed cooperation with **doctors** (n=15) as essential for increased access to PCR. Some members of the group emphasized the importance of advocates’ attending hematology conferences, such as the annual American Society of Hematology (ASH) conference, where they can build relationships with physicians and where physician and advocates alike have access to updates in CML management.

There was also consensus in the group about the importance of engaging **health authorities** (n=15) in ways both educational and adversarial. A last group of potential partners included **laboratories** (n=3) as a targeted partner to bring down the cost of PCR testing.

At this point, the discussion shifted to patients’ access to second line treatment. It is interesting to note that access to second line treatment was viewed as a critical next step following access to PCR testing. Participants discussed the importance of partnering with other groups in order to advocate for health care as a right. Other NGOs were also seen as integral parts of the process, especially NGOs working on behalf of patients with other diseases. The group saw opportunities to pool resources and to advocate more effectively alongside those organizations.

Other potential partners in a campaign to bring second-line treatment included human rights groups and the media. Human rights groups were viewed as partners in applying pressure to health authorities through the legal system, and the media was mentioned as a way of supporting this type of action.

Participants discussed at length about how they would engage those partners to achieve their goals. Much discussion was devoted to the merits of applying pressure to the government to demand access to

life-saving therapies. This legal action and pressure, in the views of some, required advocates to have knowledge of constitutional law in order to know what they are legally entitled to do. Some participants had also seen success in the past by recruiting human rights groups to assist them in their individual fight for treatment.

Africa

Participants agreed that in any campaign or initiative, it is important to identify strategic partners. Advocates would need to connect with a diverse group of partners including **government officials**, such as policy makers or public hospital administrators (n=4), **other patient leaders and advocates** (n=3), and members of the **media** (n=3).

There was considerable discussion devoted to members of government as partners. Policy makers are in a unique position to help change legislation including adopting international protocols and/or prioritizing non-communicable diseases (NCDs) nationally. One participant noted that “we have a right to treatment.”

Members of the group also identified their colleagues in the room as people they could partner with to share information and effect change. One participant noted that a “united voice is a stronger voice.” Patient leaders and advocates can work together to keep members of government accountable to the people.

In addition, participants identified strategic partners in private medical facilities, such as **private laboratories** (n=1), **industry partners** (n=1), **young physicians** (n=1), and **religious leaders** (n=1). Interestingly, young physicians were identified as key partners because they are still in training and influencing them can affect long-term change.

Asia-Pacific

The focus group participants agreed that advocates would need to connect with **physicians** (n=10), **patients** (n=5), **industry partners** (n=2), and **labs** (n=2). Participants also agreed that potential partners varied from country to country.

There was considerable discussion devoted to physicians as partners. There was consensus in the room that physicians are a key partner in any campaign or initiative targeting PCR testing. Participants’ conversation focused specifically on how important it is for physicians to see value in PCR testing. In order for patients to access PCR, they need to be referred by their treating physician.

“Emerging senior doctors are the key... If they endorse PCR, other doctors will follow.”

The group also identified three distinct groups of physicians. The first group is made up of the most senior physicians who have been practicing for many years. These physicians are sometimes less keen to adopt new guidelines in the fast evolving field of CML treatment. A second group is represented by young physicians who are new to medicine and may not be as experienced in managing rare cancers like CML. The group identified a third group of physicians as “up-and-coming.” These are key

opinion leaders who have had enough experience managing CML, are likely to attend international conferences, and are better able to accept advocates as their partners. In fact the group noted that the relationship with these physicians is mutually beneficial, as this group of physicians sees their partnership with patient organizations as a benefit as well.

Most of the group felt that it would be helpful to work with this group of physicians in targeted advocacy efforts. These up-and-coming key opinion leaders can be sought as champions of patient advocacy group efforts.

Some participants felt that industry partners could put pressure on physicians to follow international guidelines regarding disease monitoring, while perhaps laboratories could help as well. At least one participant felt these were sensitive issues and not much time was devoted to this discussion.

Finally, there was discussion that patients need to be included in building education and awareness. Current information about PCR testing is too technical and difficult for patients to understand. In some countries the patient group can provide education that physicians do not have the time to provide. Patients can also help shift medical culture by learning how to talk to their doctors.

Discussion

The demographic characteristics of the participants in this PAR provide an important point of discussion. Participants are leaders of patient organizations who represented their organization in at least one regional meeting in 2013. Most of them are founders or otherwise hold leadership positions in their organizations. The majority of participants are college educated or have advanced degrees.

The median age of participants at the time of this project was 40 years old, and the majority of them had been living with CML between 7 and 12 years. On average, most participants reported to have become patient advocates within three to five years of diagnosis. All of them had been able to access treatment for their disease, whether by overcoming great difficulties or receiving help through an access program. At the time of this research, participants were in anecdotally good health.

These characteristics underscore the importance of access to treatment and subsequent positive clinical outcomes in order to create a vibrant advocate community. Advocates tend to be young, energetic, educated, have their disease under control, possess a strong value system, and hold high professional skills.

Issues of cost and affordability also merit further discussion. As highlighted in these findings, the cost of PCR testing is viewed by advocates as a hardship for patients across all regions. According to survey results, the cost varies from a reported average of \$188 USD in the Africa region, to \$190 USD in the Asia-Pacific region, and \$278 USD in the Latin America region. To understand the financial burden this represents to CML patients, the following three countries may be examined more closely – Guatemala, South Africa and Viet Nam.

In Guatemala, \$278 USD is equivalent to approximately 68% of the average monthly income; in South Africa, \$188 USD is equivalent to approximately 20% of the average monthly income; and in Viet Nam, \$190 USD is equivalent to approximately 63% of the average monthly income.⁵ These comparisons show the heavy financial burden that PCR testing places on patients given the frequency of testing recommended in ELN and NCCN guidelines. Although all groups recognized the barrier represented by cost, participants viewed price negotiation as an area they could target to address the affordability of PCR testing.

Each of the focus groups highlights a unique social and political context in which advocates operate. It is important to understand this context in order to advance access to PCR testing as well as identify strategies that are specific to the needs of patients within each region.

In the Latin America region, patient advocates have a unique relationship with the government that is both adversarial and cooperative. While laws exist to protect patients, patients often must resort to legal action in order to have these rights recognized. This process is often a long and hard fought one, and requires resources and expertise.

⁵ These calculations are based on Gross National Income per capita at Purchasing Power Parity. They adjust for exchange rates and cost of living but do not account for employment rates or household size. World Bank, Gross National Income Per Capita PPP: <http://databank.worldbank.org/data/download/GNIPC.pdf>

Once patient leaders have paved the way, other patients are able to have their rights recognized. This has created in advocates a strong sense of self-reliance as well as an expectation that cancer patients can rely on the judicial system to legitimize their needs.

In the Africa region, the patient experience can be seen as a great mosaic. The needs of patients vary based on the level of access patients have to health services in each country as well as the political and economic stability of each country. Overall, there is a reported, pressing need for information and education both for physicians and patients. Infrastructure within African countries is generally poor and generally confined to urban areas. The population must deal with limitations in electrical power grids, internet, roads, transportation, etc. This lack of basic infrastructure greatly limits access to information. Advocates can play a key role providing education for their constituents and other community members.

In this region, governments and constitutions may not always be stable. It is difficult for the average person to operate within this unstable environment, and there is an inherent mistrust due to past disappointment and corruption. Like in other regions, it can also be dangerous for individuals to engage in politics or challenge the status quo, so advocates must tread sensitively and delicately. As such, patient leaders must be savvy in their communications with stakeholders.

The private insurance system is not well established in many countries in Africa, and cancer care is usually centralized. While some civil servants may have basic coverage through the government, this coverage does not include innovative treatments. A great portion of the population must pay out of pocket in order to meet basic needs.

Finally, cultural beliefs and illiteracy can play a part as well. Some patients believe they may have been 'bewitched' following a cancer diagnosis. In such cases, patients seek treatment from traditional healers rather than from specialists. It is important for advocates to work towards eradicating myths and stigma associated with the diagnosis.

In the Asia-Pacific region, it is the patient-physician relationship that is perceived as a key factor. As it might be the case in other cultures, physicians are kept in very high esteem within the society; they are to be trusted explicitly and never questioned. There is a common respect for authority, and patients hesitate to ask questions. They do not want to "offend" their physician by requesting a test that the physician did not him or herself recommend. There is concern that this may be misinterpreted as mistrust of the physician or else the patient knowing more than the physician. Likewise, patients hesitate to seek second opinions, or else do so "quietly," should this harm the relationship they have with their primary physician.

There is a tendency to refrain from engaging with government on policy making as well. This is especially true in countries with strong, centralized governments where strict laws prohibit certain liberties. In those countries, advocates must resort to carefully finding ways to operate within this controlled environment. Often developing a good working relationship with the physicians is key to their success.

It is particularly notable that one of the barriers to PCR testing reported, or implied, in all regions is fear. Without an engaging physician to help answer their questions, patients may be unable to put their PCR results in context or understand what the results will mean to their lives. Still other patients will fear what recourse they would have should they not be responding to treatment. The issue of access to second- or third-line treatment becomes relevant to the discussion among participants in LMICs.

In summary, this discussion among patient advocates confirms the benefit of the work the advocacy community has done to improve the lives of people living with CML. While the results may not be generalizable to all people living with CML, the range of experience and opinions among participants represents a significant group of CML survivors in LMICs. As well, it provides a rich basis to develop future strategies. Continuing and expanding the focus on education and information both at the patient and physician levels is key. As well, a concerted effort to understand the perspective of physicians must follow.

Patient advocates provide countless benefits to their communities at great personal expense, and their work and personal effort should be commended and supported. Providing them with the tools they need can result in exponential improvements in their communities. It is for them and with them that we continue to generate the needed change in order to improve the lives of all people living with CML.

Conclusions

1. Advocates shared similar experiences of becoming leaders and patient advocates for CML. Participants, who were themselves patients, had successfully accessed treatment. Most became patient advocates through a desire to give back and an awareness of their own skills and potential to change the system. Among the latter, participants were motivated to fight for a world in which people living with CML have access to treatment, education, and diagnostics.
2. Although advocates agree that PCR testing is important, most also agree that patients lack knowledge or information about PCR testing. Patients are often unaware of treatment milestones and the need for disease monitoring. Education and patient friendly information is important to help improve understanding among patients in order to improve long-term treatment compliance.
3. Cost is another key barrier that, according to advocates, prevents patients from accessing PCR testing. PCR testing is expensive, and when done according to ELN or NCCN guidelines, may represent a considerable financial hardship for many patients in LMICs.
4. In achieving greater access to PCR testing, advocates agree that this work cannot be done alone or in isolation. Important partners in these efforts include physicians, laboratories and national health authorities. While participants suggested they would negotiate with laboratories directly to help drive down cost, in some instances pressure on policy makers may be a more sustainable method for increasing the availability and decreasing the cost of PCR testing.
5. Advocates agree that a critical partner in achieving greater access to PCR testing are treating physicians, especially “up and coming” key opinion leaders. These physicians are not only open to new and emerging technologies, but they will one day set national policy or standards of care in their own countries. It will be important for patient advocates to identify those physicians and seek their partnership and guidance as they set to develop a strategy for advocacy around PCR testing.

Recommendations

Patient Education

The “What is MY PCR?” Campaign has been one way that CML organizations have sought to educate patients on the importance of PCR testing. The Frequently Asked Questions (FAQ) booklet provides information about the PCR test, PCR levels, and so on. The language of this booklet may be difficult for some patients to follow.

We recommend a low literacy focused, introductory publication on CML that also helps put PCR testing in context. Simpler language and graphics may engage more patients and assist less literate patients in assimilating the information.

Learning Opportunities for Patient Advocates

CML patient advocates benefit greatly from networking opportunities. Within each focus group, participants were able to learn from each other about the challenges and opportunities for promoting PCR testing. Although the focus groups followed a specific format, there was a natural progression for participants to brainstorm and problem-solve. In addition, some participants appeared better able to formulate their strategies for increased access to PCR testing as the focus group progressed.

We recommend to organize regional working groups in order to further develop a plan of action to improve access to PCR.

Ongoing Collaboration with Key Opinion Leaders

It is clear that physicians are key stakeholders in any initiative for access to PCR testing. The next step is to better understand what drives physicians in the three regions – Latin America, Africa, and Asia-Pacific. Moreover, engaging KOLs in this process may shed light on opportunities for collaboration between advocacy organizations and physicians in local efforts made by CML patient organizations to improve access to PCR testing.

We will reach out to KOLs in these three regions for structured, one-on-one interviews in order to gain further insight into these issues. These findings will build on our understanding of the challenges and opportunities for increased access to PCR testing in LMICs.

Appendix

- 1... *Venn Diagrams of Focus Group Results*
- 2... *Focus Group: Consent form*
- 3... *Survey Questions*

Venn Diagrams on Focus Group Results

Diagram 1 – Reasons for Becoming a Patient Advocate

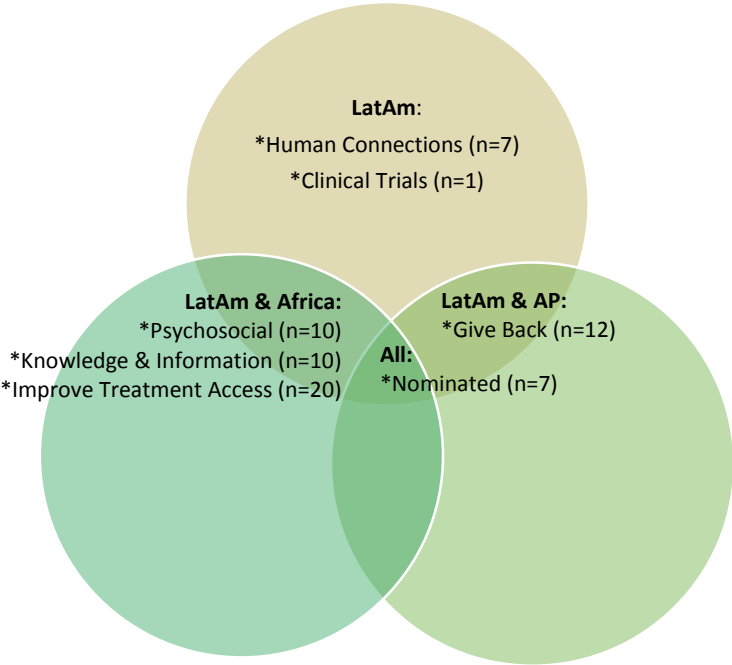


Diagram 2 – Skills or Qualities Needed as a Patient Advocate

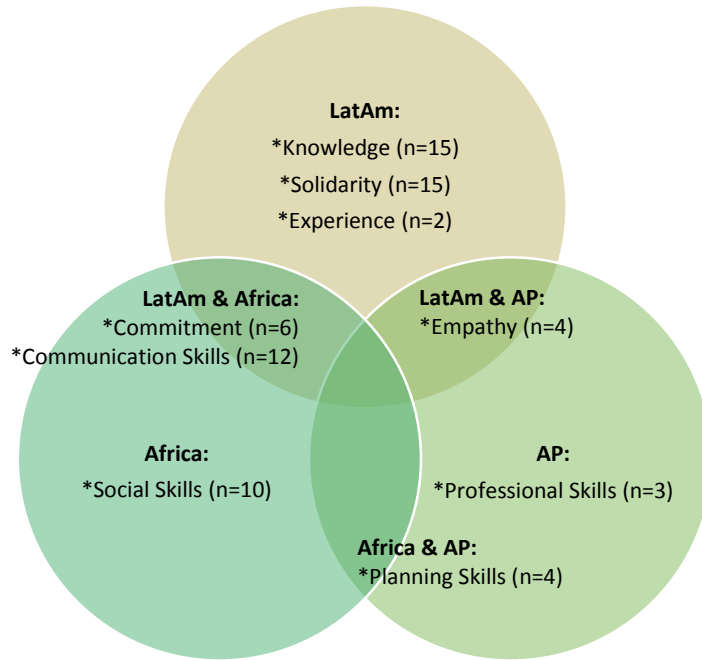


Diagram 3 – Barriers to Accessing PCR Testing

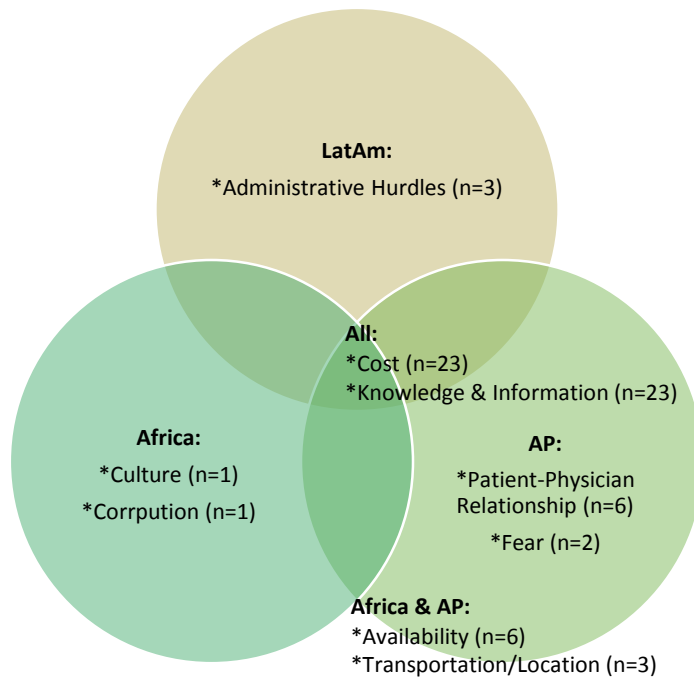


Diagram 4 – Barriers Patient Advocates Can Target to Improve Access to PCR Testing⁶

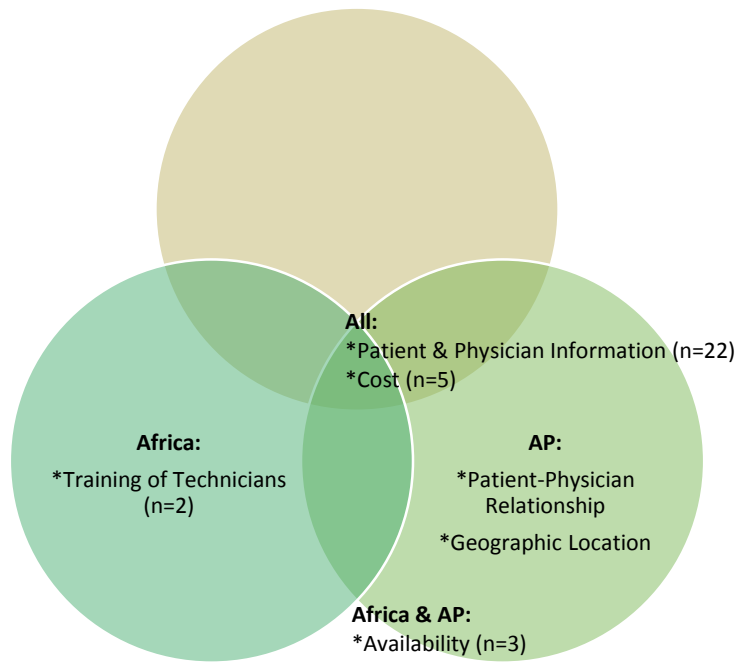
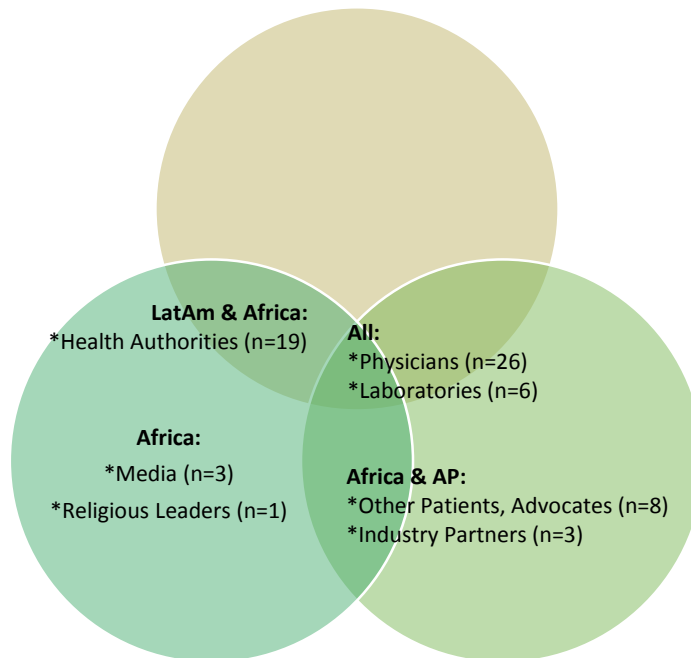


Diagram 5 - Partnering to Improve Access to PCR Testing



⁶ Due to limitations in data capture in the Asia-Pacific group, we were unable to record 'n' and to subsequently rank these issues.

Focus Group: Consent Form

Purpose

The Max Foundation (MAX) is conducting a series of focus groups to inform our understanding of advocates' ability to affect change. MAX is conducting focus groups with the goals of:

- Understand patient advocates' perspectives regarding advocacy
- Understand patient advocates' perspectives regarding access to PCR
- Form the basis for an advocacy & empowerment curriculum for patient advocates

A minimum of three focus groups will be held with patient advocates in 2013. Participants will be asked questions about their experiences, perspectives, and feedback concerning patient advocacy within their countries.

Participation

You are being asked to participate in a focus group that will last 1.5 hours. The information collected will be kept confidential. In order to ensure the confidentiality of all participants, focus group members may not share any conversations or information revealed during the focus group with anyone outside of the focus group.

Each focus group will have a facilitator and two observers. The role of the observers will be to transcribe the discussion. The discussion will also be recorded for the purpose of accuracy. Written reports will not include any information that could identify participants.

Your participation is voluntary. You are not obligated to answer any questions that make you uncomfortable. You may decline to participate at any time during the focus group.

Project Sponsor

The Max Foundation is sponsor of this project.

Questions

If you have any questions related to this research, you may contact Ann Kim Novakowski at +1-425-778-8660 or info@themaxfoundation.org.

Agreement to Participate in the Focus Group:

- _____ I have read or someone has read this document to me.
- _____ I understand what the focus group is about and how and why it is being done.
- _____ The moderator has answered all of my questions.
- _____ I understand that I do not have to take part in this focus group.
- _____ I voluntarily consent to participate in this focus group.
- _____ I will receive a copy of this signed informed consent form for my records.

Name of Participant

Signature of Participant

Date

Ann Kim Novakowski
Name of Investigator

Signature of Investigator

Date

Survey Questions

Kindly provide some basic information about yourself.

Patient Advocate

1. Name*
2. Country of Residence*
3. Are you the Patient or Caregiver?
 - a. Patient
 - b. Caregiver
 - c. Other (please specify)
4. If you are the patient or caregiver, what is the year of the patient's diagnosis?
 - a. 1960-1964
 - b. 1965-1969
 - c. 1970-1974
 - d. 1975-1979
 - e. 1980-1984
 - f. 1985-1989
 - g. 1990-1994
 - h. 1995-1999
 - i. 2000-2004
 - j. 2005-2009
 - k. 2010-2013
5. For how many years have you been a patient advocate?*

 - a. 1
 - b. 2
 - c. 3
 - d. 4
 - e. 5
 - f. 6
 - g. 7
 - h. 8
 - i. 9
 - j. 10
 - k. 11
 - l. 12
 - m. 13
 - n. 14
 - o. 15

Kindly answer the following demographic questions.

Demographics

6. What is your gender?
 - a. Male
 - b. Female
7. What is your age?
 - a. 16-25
 - b. 26-35
 - c. 36-45
 - d. 46-55
 - e. 56-65
 - f. 66+
8. What is your religious affiliation?
 - a. Buddhist
 - b. Catholic
 - c. Christian
 - d. Hindu
 - e. Jewish
 - f. Muslim
 - g. None
 - h. Other(please specify)
9. What is your highest level of education?
 - a. Primary School
 - b. High School
 - c. College or University
 - d. Advanced/ Graduate School
10. What is your field of employment?
 - a. Academic
 - b. Agriculture
 - c. Business
 - d. Health Care
 - e. Government
 - f. Homemaker
 - g. Non-profit
 - h. Retired
 - i. Self-employed
 - j. Service Industry (such as hotel & restaurant)
 - k. Student
 - l. Unemployed
 - m. Other(please specify)

Kindly help us better understand access to PCR in your country.

CML Monitoring

11. Which of the following tests are available in your country? Check all that apply.*
- a. Complete blood count (CBC)
 - b. Bone marrow biopsy
 - c. Fluorescence in-situ hybridization (FISH)
 - d. Qualitative polymerase chain reaction (PCR)
 - e. Quantitative polymerase chain reaction (RQ-PCR)
 - f. I am not certain, or I don't know.

The following questions are regarding quantitative PCR, or RQ-PCR, specifically.

12. In your opinion, how important is RQ-PCR in the monitoring of CML?*
- a. Very important
 - b. Somewhat important
 - c. Neutral
 - d. Not very important
 - e. Not important at all
13. To your knowledge, how often should a patient be monitored through RQ-PCR?*
- a. Once a week
 - b. Once a month
 - c. Every three months
 - d. Every six months
 - e. I am not certain, or I don't know.
 - f. Other (please specify)
14. How widely available is RQ-PCR in your country?*
- a. It is widely available.
 - b. It has limited availability.
 - c. It is not available at all.
 - d. I am not certain, or I don't know.

If respondent answers a) to question 14

15. You state that PCR is widely available in your country. To your knowledge, do all patients access RQ-PCR in your country?*
- a. Yes
 - b. No

If respondent answers b) to question 14 or 15

16. What are the steps that a patient takes to access RQ-PCR?*
17. What are the barriers to accessing RQ-PCR in your country? Check all that apply.*
 - a. Availability (such as, available in certain clinics only)
 - b. Geographic accessibility (such as, distance or location)
 - c. Affordability (such as, high cost)
 - d. Acceptability (such as, the value or importance placed on RQ-PCR by physicians)
 - e. Please explain.
18. To your knowledge, what is the cost of RQ-PCR in your country (specify currency)?*
19. Who pays for RQ-PCR testing in your country? Check all that apply.*
 - f. Employer
 - g. Hospital
 - h. Insurance
 - i. Ministry of Health
 - j. Patient
 - k. Pharma
 - l. I am not certain, or I don't know.
 - m. Other (please specify)

Thank you for your time and attention in responding to these survey questions.

Advocacy in Low & Middle-Income Countries
A study on overcoming barriers to accessing diagnostics in CML
The Max Foundation Report
March 2014

For Reprints or Questions about this Report, contact The Max Foundation at info@themaxfoundation.org.