Increasing Access to Care for Chronic Myeloid Leukemia Patients: Assessment of a Scaling-up Program

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Abstract: **Background**. The Glivec International Patient Assistance Program (GIPAP) is designed to provide access to the cancer therapy Imatinib (Glivec®), which is indicated for the treatment of chronic myelogenous leukemia (CML) and gastrointestinal stromal tumors (GIST). **Objectives**. To identify factors those influence the quality of care and structural improvements. **Design**. Physicians (n=50), hospital administrators (n=10) and Ministry of Health officials (n=7) in 39 developing countries participated in qualitative interviews. The interviews focused on the impact of GIPAP on service delivery, patient tracking systems and cancer registries, health financing, and workforce. **Results**. Service delivery, patient management, access to care, diagnostic capacity, and health workers' skills improved at participants' institutions following implementation of GIPAP. **Conclusions**. Positive institutional changes that improve care of CML/GIST patients arose from GIPAP. Some of these changes may strengthen institutions' capacity to treat other diseases as well. The GIPAP model could be deployed to improve access to care for patients with other chronic diseases.

Key words: Cancer program, developing countries, access to care, chronic myeloid leukemia.

Chronic myeloid leukemia (CML) is a hematologic malignancy with an incidence of 0.6–2.0 people per 100,000 annually[1,2]. As a consequence of population growth, aging, and reduced mortality from infectious diseases, the incidence of cancer is rising in developing countries[3,4]. The percentage of newly reported cancers occurring in these countries has more than tripled over the past 40 years, and it is anticipated that 70%

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of all cancers will be diagnosed by 2030[3]; only about 5% of the global resources spent on cancer are deployed in developing countries and, as a result, cancer is a substantial cause of premature death in these parts of the world[3]. The cost of newer, targeted cancer therapies and limited health care infrastructure create barriers to cancer care[3,4]. The programs and policies evaluating new approaches may be instructive in developing novel strategies for improving access and outcomes in developing countries.[3–6]

Imatinib (Glivec) is a small molecule inhibitor of the bcr-abl tyrosine kinase created by the Philadelphia chromosome abnormality (Ph+) in chronic myeloid leukemia (CML). Imatinib is indicated for the treatment of several forms of Ph+ CML, CD117-positive gastrointestinal stromal tumors (GIST), and other cancers in which CD117 or PDGF receptor are known to play a role.[7] Although the availability of Imatinib has changed the treatment paradigm for Ph+ CML and GIST in most developed countries, its cost of $2,500 to $3,500 USD per month has limited its adoption in developing countries. To address this health disparity, the manufacturer of Glivec (Novartis, Basel, Switzerland) implemented the Glivec International Patient Assistance Program (GIPAP) in 2002. This program, which was implemented in collaboration with several non-governmental organizations (NGOs), is designed to provide access to Glivec for CML and GIST patients in developing countries. A key feature of GIPAP is that it considers the local threshold on a country-by-country basis to reflect national needs, resources, and patients' economic capacity to contribute to the cost of Imatinib therapy. The criteria and processes for participation in GIPAP have been described previously.[1,8,9]. Briefly, GIPAP provides Glivec at no cost to patients and institutions in developing countries that cannot afford to buy it. The program has been implemented in 80 developing countries, including 49 low-income countries, enabling 44,496 patients, 4,300 of which are in developing countries, to receive Glivec.

In the current GIPAP institutional assessment we evaluated the perspectives of physicians, hospital administrators, and Ministry of Health (MoH) personnel in developing countries with respect to how participation in GIPAP has driven change in participating institutions' capacity to care for patients with Ph+ CML and CD117 GIST.

The goal of this study was to identify factors that influence the quality of care as well as systematic improvements that enhance institutions' ability to diagnose and treat CML, GIST, and other cancers.

Methods

The GIPAP institutional assessment was conducted in two phases in 2011. In phase 1, qualitative interviews were conducted with 15 physicians in different countries (Table 1). Using a step-down approach, each eligible physician was asked to refer one hospital administrator from his or her institution for inclusion in the qualitative interviews, and each hospital administrator was then asked to refer one MoH official. Based on these referrals, qualitative interviews were conducted with 10 hospital administrators and seven MoH Officials (including administrative personnel and public health practitioners working at the MoH level) (Table 1). These interviews focused on the impact that GIPAP was perceived to have had on service delivery, patient tracking systems and cancer registries, health financing, and health workforce. Respondents were also asked

Table 1.

GEOGRAPHIC DISTRIBUTION OF PERSONNEL PARTICIPATING IN THE GIPAP ASSESSMENT

	Phase 1: Qualitative Interviews			Phase 2: Quantitative Survey
Country	Physicians	Hospital Administrators	Ministry of Health Officials	Physicians
Albania				X
Armenia				X
Azerbaijan				X
Benin				X
Bhutan				X
Burkina Faso				X
Byelorussia				X
Cambodia				X
Cameroon				X
Congo	X			X
Ethiopia	X			X
Fiji				X
Gabon				X
Georgia	X	X	X	X
Ghana	X		X	X
Haiti				X
Kenya				X
Kyrgyzstan	X	X	X	X
Madagascar				X
Malawi	X		X	X
Mali	X	X		X
Mauritius	X	X		X
Moldova				X
Mongolia	X	X	X	X
Nepal	X	X		X
Nigeria				X
Papua New Guinea				X
RDC				X
Rwanda	X	X		X
Saint Lucia	X		X	X
Senegal				X
Seychelles				X
Sudan				X
Suriname				X
Tanzania				X
Togo	X	X	X	X
Uganda				X
Uzbekistan	X	X	X	X
Zambia	X	X		X

for input on lessons learned with respect to implementing GIPAP in their countries or institutions.

The results of these interviews were used to design a survey tool that was implemented in phase 2 of the study. In this survey, physicians were asked to quantitatively assess changes in their institutions' capacity following participation in GIPAP. These responses were assessed on a 5-point Likert scale that ranged from 1 = very poor to 5 = very good. The survey tool also gathered data on distinctive changes in institutions' operational processes as a result of participation in GIPAP. The survey tool was administered electronically to a sample of 79 physicians participating in GIPAP (including the 15 who had participated in the phase 1 qualitative interviews) in 39 developing countries (Table 1). Results of this quantitative survey were presented in percentages and in mean values. Differences in proportions were compared for significance using the Chi Square test, with the significance level set at $p<.05$. When the assumptions of the Chi Square test were not fulfilled, the Fisher exact test was used.

The results of the qualitative interviews with hospital administrators and MoH personnel were analyzed separately in order to gain additional insight into the perceived impact of GIPAP on participating institutions and countries.

Results

Baseline characteristics of institutional assessment. Of the 79 physicians to whom the survey tool was sent, 50 responded, corresponding to a total response rate of 63.3%. Responses were received from physicians in Africa (64%), Europe (18%), America (7%), Asia (7%), and Oceania (4%). The majority of respondents practiced at public hospitals (85%), including 12 in teaching hospitals and one military hospital. Private hospitals (9%) and hospitals run by NGOs (6%) were also represented in the responses. Several physician specialties were included in the survey: hematology (28%), oncology (20%), internal medicine (12%), hematology/oncology (4%), emergency medicine (4%), pathology (2%), and family practice (2%). The mean age and mean duration in the practice of medicine among respondents were 49.5 years (Standard Deviation (SD)=9.9 years) and 24.0 years (SD=10.1 years), respectively.

Impact of GIPAP participation on capacity to deliver care. Survey results for physicians' perspectives on service delivery, diagnostic capacity, patient management, access to cancer care, and health management information systems prior to and after implementation of GIPAP are summarized in Figure 1. Physicians indicated that service delivery improved following implementation of GIPAP. While 32.6% agreed that service delivery was good or very good prior to GIPAP, 82.7% agreed with this following implementation of the program. Patient management also improved, with 6.5% and 75.6% of physicians rating it good or very good prior to and after implementation, respectively ($p=.001$). Access to care was rated as good or very good by 18.2% and 81.8% prior to and after GIPAP implementation, respectively ($p=.005$).

Physicians' opinions on diagnostic capacity, health financing, health workforce, and access to care at their institutions since implementation of GIPAP are summarized in Table 2. A majority of respondents agreed or strongly agreed that there have been changes in diagnostic capacity, health workers' skills, and patient access to cancer care

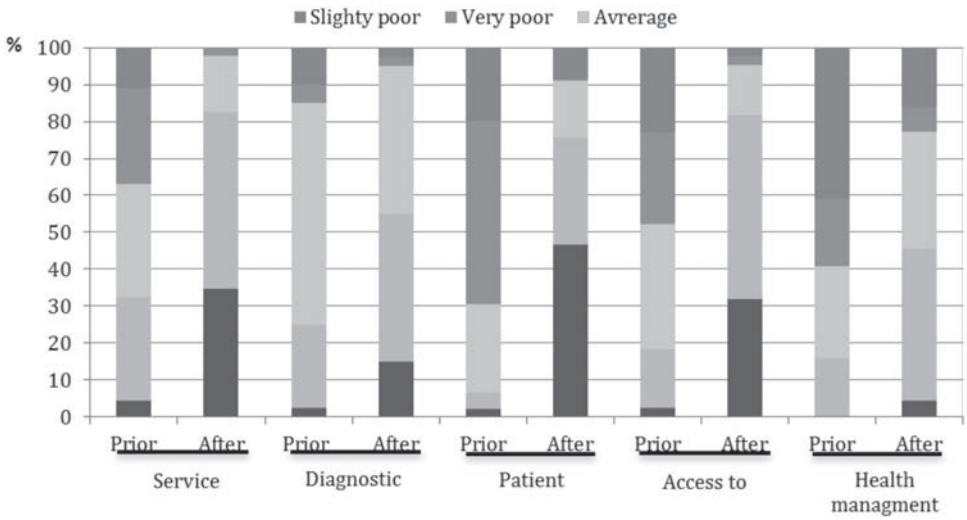

Figure 1. Quantitative assessment of physician perspectives on service delivery, diagnostic capacity, patient management, access to care, and health management information systems at their institutions prior to and after implementation of GIPAP (results are expressed in percentages).

at their institutions since the program was implemented. Specific improvements in health workers' skills were reported in the areas of bone marrow biopsy, bone marrow aspiration, and blood chemistry, hematology, and immunology. Less than half of respondents reported GIPAP-related changes in health financing. A significant increase in the number of CML patients seen at participating institutions was also reported after implementation of GIPAP. The mean difference in the number of patients seen annually prior to and after GIPAP was 41. Improvements in the utilization of CML/GIST guidelines, patient tracking systems, and institutional operations were also reported. Improvements in guideline usage include: increases in the use of national and international patient management guidelines, advanced laboratory testing, and use of Imatinib for first-line therapy; increased rate at which patients are seen by health care professionals; and modification of follow-up schedules. Nine of the responding physicians (18.0%) indicated that they did not use any treatment guidelines. Sixty-one percent of physicians indicated that implementation of GIPAP had a positive influence on the management of patients with other cancers and chronic diseases. These positive effects appear to result from GIPAP providing a framework in which to develop treatment regimens for other diseases. Additionally, participation in GIPAP appears to increase strategic thinking about cancer care overall and improve the quality of health care professionals recruited to deliver care at participating institutions.

Physicians associated implementation of GIPAP with several aspects of increased access to patient care, including: improvement in health and duration of treatment outcomes, new equipment, improvement in treatment, increased patient awareness of GIST and CML treatments, and an increase in the number of patients and donors

Table 2.

QUANTITATIVE ASSESSMENT OF PHYSICIAN PERSPECTIVES ON DIAGNOSTIC CAPACITY, HEALTH FINANCING, HEALTH WORKFORCE, AND ACCESS TO CARE SINCE GIPAP IMPLEMENTATION (RESULTS ARE EXPRESSED IN PERCENTAGES)

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Diagnostic capacity					
Adequate technology and resources available in the institution	9.1	45.4	9.1	25.0	11.4
Equipment for diagnosis have changed since GIPAP	10.0	40.0	22.0	24.0	4.0
Health financing					
GIPAP has influenced types of patient assistance programs	12.2	22.4	36.8	20.4	8.2
There have been changes in donor funding for cancer in institution	6.5	10.9	39.1	32.6	10.9
Health workforce					
Changes in skills of health workers observed since GIPAP implementation	8.3	52.0	31.3	6.3	2.1
Access to care					
GIPAP has increased access to care in the institution	31.1	51.2	13.3	0	4.4

participating in GIPAP after observing the success of the program. Sixty-five percent of physicians indicated that their institutions had undertaken initiatives to increase access to cancer treatment after implementing GIPAP, including: the introduction of educational seminars and conferences for doctors and patients, initiation of hospital-based cancer programs, and the development of government grants to support cancer therapy. Although patient access to cancer care improved following implementation of GIPAP (Figure 1, Table 2), physicians report that managing GIST and CML patients effectively continues to be a challenge. Other challenges identified by responding physicians include: access to a local hospital, illiteracy, poverty, cost of drugs, financing restrictions, lack of provider knowledge, regular follow-up, having hematologic care delivered only at hematology centers, limited availability of onco-hematologists in rural areas, human resource shortages, training issues, and laboratory performance.

Implementation of GIPAP did not appear to address issues around access to second-

line therapies for Imatinib-resistant disease or the availability of cytogenetics or testing for Ph+ chromosome or BCR-ABL status. Physicians indicated that increasing access to these elements of care would further improve the treatment of CML and GIST patients. Additional physician recommendations for improving care for these patients include: involvement of surgeons, improved technology and training, building and training networks of community and health workers, building laboratories locally, development of government health insurance programs, working with volunteers and NGOs that have expertise in oncology, improving education and knowledge of the medical community, and providing hematologic care beyond formal hematology centers (i.e. development of hematology departments in hospitals).

The survey tool also gathered data on distinctive changes in institutions' operational processes as a result of participation in GIPAP. A total of 48 respondents provided input on this question, of which 38 (79%) reported changes, including improved medical care and prolonged lives, improved duration and quality of treatment, positive changes concerning diagnosis, treatment, and follow-up, improved training, and improvements in the reputation and quality of the institution. The other 10 respondents (21%) reported no change, primarily because GIPAP involves a relatively small number of patients and staff, and affects a small section of the institutions' services and facilities. Nine of the respondents to the question of operational change reported positive changes (19%), such as improvement in diagnosis, treatment, and care; improved duration of treatment outcomes, enhanced credibility and quality of the institution, and modernized treatment procedures. The strengths and weaknesses of GIPAP as reported qualitatively by responding physicians are summarized in Table 3.

The results of an analysis of the qualitative interviews conducted with hospital administrators and MoH officials in phase 1 of the study were consistent with the results of the physician survey. MoH officials reported positive changes in: cancer policies, national cancer guidelines, demand for cancer care, national and local budgets for cancer care, and the supply of cancer care specialists. Among hospital administrators, the greatest amount of perceived change was reported for the number and skill level of cancer department personnel (10/10) and for distinctive changes in operations (6/10). Three of the ten hospital administrators perceived that GIPAP had a positive influence on patient tracking systems at their institutions, and three also perceived that GIPAP had an impact on their cancer registries. Perceived changes in hospital funds and changes in government or donor funding for CML, GIST, and other cancers and diseases were each reported by two hospital administrators.

Among the seven MoH officials interviewed, the greatest areas of perceived change following implementation of GIPAP were: changes in the national guidelines (5/7), change in demand for cancer care services (5/7), and change in the supply of health care workers specializing in cancer care (4/7). Only two respondents perceived a distinctive change in the way the MoH operates as a result of GIPAP implementation. Limited change was perceived with respect to resource allocation for cancer services, particularly for CML and GIST services (1/7) and the influence of GIPAP on health policy (1/7).

The strengths and weaknesses of GIPAP as reported by responding hospital administrators and MoH personnel are included in Table 3.

Table 3.

QUALITATIVE STRENGTHS AND WEAKNESSES OF GIPAP AS REPORTED BY PHYSICIANS, HOSPITAL ADMINISTRATORS, AND MINISTRY OF HEALTH OFFICIALS

Strengths	Weaknesses
Physicians	
Improved access for patients unable to afford treatment	Difficulty in access different types of second-line therapy
Improved quality of life and duration of treatment outcomes	Lack of diagnostic confirmation by PCR
Improved supply of Glivec and response time for new requests	Testing constraints prevent the program from being used by 100% of patients who would be eligible
Good tracking system	Difficult to convince government and health authorities of program's benefits
Rapid patient registration (approval received the same day)	Lack of diagnostic support
Regular provision of Glivec	Lacks sustainability
Efficient computerized program	Program files are not computerized
Competent and hardworking staff	Poor diagnostics (especially c-kit and BCR-ABL) for patients who are located far from the treatment center and cannot come every month for testing and supplies
Provides training opportunity for physicians	Patient follow up is not adequate
	Does not provide ability to train staff
	No dedicated personnel for recording patient data and writing reports
Hospital Administrators	
Regular supply of free drugs	Expensive diagnostics
Easy and free access to guaranteed treatment	Coverage of a very limited number of patients
Improved quality of treatment	Not enough knowledge of the program
Improved quality of follow up	No available literature on use of Glivec in the treatment of GIST/CML
Improved patient quality of life	
Regular monitoring of the program and patients	
Ministry of Health Officials	
Free medicine	Expensive diagnostics
Increased access to drugs	Lack of prevention and educational programs
Improved quality and length of patients' lives	No specific training for pharmacists
Improved professional level of doctors	Lack of GIPAP visibility in rural areas
Improvement in the level of investigation and treatment	Lack of supportive literature about treatment

Discussion

The results of this study demonstrate that participation in GIPAP seems to have significantly improved patient management and access to cancer care and the health information system. Importantly, respondents perceived that these benefits were achieved without diverting resources from other programs. Some of these improvements may provide benefit to patients beyond GIPAP by strengthening infrastructure and enabling new approaches to delivering health services[8,9].

Results of the qualitative interviews with hospital administrators suggest that participation in GIPAP can lead to a change in the capacity of oncology department health care personnel, with respect to personnel number as well as skill. Ministry of Health officials noted in qualitative interviews that GIPAP implementation had helped to increase cancer visibility as a national health priority, increased patient demand for cancer care, and led to changes in national guidelines and resource allocation for cancer services, especially for GIST and CML Interestingly, the perceptions of patient follow-up and patient access to care are quite different between physicians and administrators. These two groups have different interactions with patients and with the health system as a whole, and it is likely that each group's unique perspective and professional responsibilities account for the different perceptions reported here. Increases in the supply of health workers specializing in cancer care and human resource capacity for cancer services were also noted as benefits associated with participation in GIPAP[1,9].

Both administrators and MoH officials listed a lack of literature on CML/GIST treatment as a weakness of the program despite the availability of a very large body of published data on the use of Imatinib and other therapies in these indications. These results suggest that these audiences could benefit from inclusion of relevant publications in the GIPAP materials. Increased understanding of the positive impact that Imatinib has on the outcome of patients with CML or GIST could provide a more meaningful context in which hospital administrators and government officials make decisions about GIPAP participation. Similarly, enhanced understanding of the role that Imatinib can play in treating CML and GIST could strengthen additional efforts to optimize care for these patients[9].

Not all changes reported by administrators were positive, including recognition that GIPAP provides Imatinib for free but does not cover other costs associated with treatment, which have to be incurred by the patients' health care facilities. With respect to non-drug costs associated with implementation of GIPAP, both hospital administrators and MoH officials listed the expense of the diagnostics associated with CML and GIST testing as a weakness of the program. Similarly, physicians cited the lack of personnel dedicated to recording GIPAP patient data and preparing program reports as a weakness. Without such support staff, physicians must complete these activities themselves, which imposes a time cost. Despite concerns about additional costs associated with GIPAP, 93% of respondents indicated that implementation of GIPAP at their institutions did not divert resources from other programs. It is likely that the low incidences of CML and GIST and the small number of such patients participating in GIPAP at any single institution may limit the effects of program-associated costs. Furthermore, economic models that estimate a more affordable drug cost based on societal values

are currently being developed and tested, and may further improve patient access to cancer treatments[10–12].

GIPAP is designed as a full product donation program. Several issues have been raised with regard to such programs, including: lack of sustainability; additional non-drug costs of care that recipient countries or institutions must bear; slowing the pace of structural changes that are essential for overall improvement of national health care systems; creating a disincentive for local research and development of new drugs; and lack of alignment between recipients priorities and resources that donors provide. Imatinib has increased the survival and response rates of patients in developing countries, with minimal side effects. Zeba et al reported that hematologic, cytogenetic, and molecular responses to Imatinib observed in patients in developing countries were similar to the responses reported in patients from Western countries[13–16]. These changes are also likely to provide value to participating institutions beyond the scope of GIPAP as other treatments for CML become available. Sustainability of such programs will be essential as treatment options increase.

Although improvements were noted in key areas, this study also shows that GIPAP did not have a significant impact on the use of health management information systems, equipment utilization, proportion of funds devoted to cancer care, and the use of guidelines for treating CML or GIST. As a result, GIPAP does not have the scale or critical mass to drive broad changes in overall health management. However, these factors may be important in improving patient care and access.

Additionally, a sustainable approach to ensuring that all CML and GIST patients receive appropriate treatment must go beyond simple drug donation. A variety of models have been established with respect to the participation of pharmaceutical companies, national governments, and NGOs.[17,18]. A number of these models have been deployed beyond HIV and are now being applied to cancer and other diseases.[5,9] The GIPAP model has evolved over time and novel approaches have been developed to improve sustainability and access to Imatinib for patients with CML or GIST in the developing world. Understanding the costs and benefits that GIPAP imparts to patients, health policy, and health services remains important to further refining the program so that it can provide sustained access to Imatinib to those patients who may benefit from the drug. The challenges experienced in the management of CML in developing countries are often due to economic factors and require comprehensive approaches by and input from key stakeholders, including clinicians, pathologists, health economics, medical insurers and policy makers. All of these stakeholders must work together to achieve the common goal of finding sustainable solutions that address the health challenges of CML patients[22].

A primary limitation of this study is that it evaluated the perceived impact of GIPAP over a 10-year period, which makes it difficult to discern if the reported changes are due to implementation of the program or to the evolution of treatment approaches over time. However, in the period studied there have been few changes with respect to funding for health care and relevant health care policies, suggesting that the observed effects are due to GIPAP rather than to other forces. Although GIPAP is focused on providing Imatinib to patients with CML and GIST, the model used to achieve that goal could be readily adapted to incorporate additional contributions to provide treatment

to patients with other types of cancers. Additionally, given the fact that imatinib may be used to treat CML over long periods of time, the model could also be adapted to the treatment of other cancers and chronic conditions.

Expanding access to treatment to include all eligible CML and GIST patients will require input from multiple stakeholders, such as governments, NGOs, the scientific community, insurance companies, Novartis, Axios International, the Max Foundation, and others, to explore new alternatives than can include additional contributions to secure better coverage and patient outcomes[23]. Expansion of affordable health insurance programs within these countries and additional government programs that help to defray the cost of care should increase the number of patients who can contribute to the cost of their treatment.

Disclosure

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Notes

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