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# Modernising diagnosis and treatment of Chronic Myeloid Leukaemia for improved patient outcomes in a resource-limited setting: Experiences from Ghana's premier teaching hospital

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## Abstract

**Introduction:** Until 2013, diagnosis of Chronic Myeloid Leukaemia (CML) at Korle-Bu Teaching Hospital (KBTH) in Ghana was based on white blood cell morphology ascertained from peripheral blood and bone marrow aspirate. Access to cytogenetic studies or molecular testing locally was limited, making testing prohibitively expensive and out of reach of majority of patients. Additionally, the only treatment options available were the antimetabolites, hydroxyurea and busulfan, which produced suboptimal disease response and haematological remission. These treatment options are considered outmoded currently, especially after the introduction of tyrosine kinase inhibitors, which have improved patient survival considerably. This paper details the processes and outcomes of a transformative reform of CML management in Ghana's foremost teaching hospital.

**Methods:** We collected data on the processes implemented for the commencement of the Glivec International Patient Assistance Programme (GIPAP) for CML management in KBTH. Data on program partnership, infrastructure development, health worker training, supply of medications and other logistics, as well as implementation and treatment outcomes, were collected.

**Results:** From 2007, the Haematology Department of the KBTH progressively commenced a series of initiatives to advance the diagnosis and treatment of CML. This included leveraging patient-assisted programmes to build strategic and functional partnerships, sourcing of funding for infrastructure improvement and formation of a patient support group. The GIPAP has given patients at the KBTH CML Centre access to tyrosine kinase inhibitors since 2007 and also the ability to do molecular testing in-house since 2013. Uptake of molecular testing has increased, just as monitoring of molecular status during treatment, with almost all patients on treatment achieving haematological remission within a relatively short time of two months.

**Conclusions:** Availability of in-house molecular testing and treatment with tyrosine kinase inhibitors, apart from being relatively cheaper than traditional management modalities have resulted in improved uptake of CML management and patient outcomes.

**Keywords:** Chronic Myeloid Leukaemia, molecular, diagnosis, treatment, tyrosine kinase inhibitor

## Citation

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## Introduction

Chronic Myeloid leukaemia (CML) is a myeloproliferative neoplasm which arises from a haematopoietic stem cell and is characterised by the Philadelphia chromosome [1]. The Philadelphia chromosome, which results from a translocation between chromosomes 9 and 22, houses the Breakpoint Cluster Region – Abelson Murine Leukaemia (BCR-ABL) fusion gene. This abnormal gene gives rise to a BCR-ABL oncoprotein, which has enhanced tyrosine kinase activity and leads to abnormal proliferation of myeloid cells[1,2].

The advent of molecular testing via polymerase chain reactions and treatment using oral targeted therapy against the constitutively activated tyrosine kinase has revolutionised the management of CML [3,4]. However, these advancements in the management of CML have taken variable time in reaching resource-limited settings [4,5]. In instances where these are utilised, they are sourced from advanced countries, with attendant implications on cost and timeliness of the needed interventions [6].

Prior to 2013 at the Korle-Bu Teaching Hospital, Ghana's foremost tertiary and referral hospital, diagnosis of CML was based on findings from physical examination and white cell morphology ascertained from peripheral blood film and bone marrow aspirates [6]. A diagnosis of CML was made if a patient had a combination of the following: increased white blood cell count (leucocytosis) with or without increased basophil (basophilia) or Increased eosinophil (eosinophilia), anaemia, and a low, normal or increased platelet level on complete blood count; whole spectrum of early myeloid precursors on blood film comments; hypercellularity and expansion of the myeloid cell line in a bone marrow aspirate. Cytogenetic and molecular tests, which are more sensitive and reliable alternatives, were seldom used. In instances where they were used, they were mostly sourced from advanced countries because of limited in-country capacity to conduct these tests. This resulted in high costs and long turnaround times that negatively impacted the uptake and usability of these tests as well as the overall management of patients. In addition, treatment of CML in Ghana was limited to the anti-metabolites hydroxyurea and busulphan [6], which are considered outmoded and have been ineffective in achieving rapid response and subsequent remission. Even after a year of therapy with hydroxyurea, disease control was limited and enlarged spleens persisted.

In this paper, we describe the transformative processes the CML Centre at the Haematology Department of the Korle-Bu Teaching Hospital in Ghana underwent to offer patients with CML enhanced diagnoses and treatment options for better outcomes. We focused on the processes and short-term outcomes for the first few years of programme implementation.

## Methods

Data were collected on the program design and implementation, including the processes completed for the GIPAP-assisted interventions. Clinical data were purely secondary data extracted from archived patient records. These data include outcomes such as BCR-ABL test results, which were conducted using the international scale. A comprehensive description of the implementation arrangements, including partnership formation, infrastructure development, health worker training, support group formation and treatment outcomes, is detailed.

### Program description

The program is a partner-supported facility-based capacity-building suite of interventions. It included collaboration with external partners for seed funding and supply of medications, followed by infrastructure development and human resource capacity building for the diagnosis, treatment and monitoring of CML for improved outcomes.

### Program setting

The Glivec International Patient Assistance Programme (GIPAP) was implemented at the Korle-Bu Teaching Hospital CML Centre. Korle- Bu Teaching Hospital is the oldest and the largest tertiary hospital in Ghana, established in 1923 [7]. The facility serves as the ultimate referral hospital for advanced medical conditions, particularly from the southern part of Ghana and beyond[8,9]. Patients access care at the hospital from the different regions of Ghana and even from neighbouring countries within the sub-region, such as Liberia, Cote d' Ivoire, Sierra Leone and Togo [8]. As part of the different services provided at the facility, there is a well-structured Haematology Department, which has managed patients with CML since its establishment. However, in 2007, the CML centre and clinic were established within the Department of Haematology to provide a focus for CML diagnosis and management. The Haematology Department of the hospital attends to 15 to 20 patients with CML every year.

### Collaborations for advancement in treatment, diagnosis and monitoring CML patients

The CML centre leveraged existing patient-assisted programs to form collaborations. These programs required reorganisation of the Haematology Department, which gave birth to the CML Centre, as well as improvement in infrastructure and reliability of supply of medications for patient care. In order to improve diagnostic and treatment capacity, the CML centre identified the Glivec International Patient Assistance Programme (GIPAP), now Max Access Solutions, for partnership. The GIPAP is a global cancer access program designed by Novartis and implemented with the Max Foundation, which used the "direct-to-patient" model that enabled individual patients to

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get the drugs directly from their treating physicians [4]. The GIPAP at the Korle-Bu Teaching Hospital progressively evolved from treatment of molecular and cytogenetically confirmed CML with free tyrosine kinase inhibitors to the development of an in-house capacity for performing molecular tests. Patients were eligible for free tyrosine kinase treatment if they had molecular or cytogenetically confirmed CML. In October 2007, the first seven eligible patients were enrolled into the GIPAP at the centre. In this program, patients who had a molecular or cytogenetic diagnosis of CML had access to free tyrosine kinase inhibitor, imatinib. Molecular and cytogenetic tests were, at the time, performed outside Ghana, in South Africa. Patients eligible for enrolment into the GIPAP were those with Philadelphia chromosome-positive CML who were not insured, not reimbursed, or could not pay for the treatment privately and were in countries that have minimal reimbursement capabilities and where regulatory approval or at least an import license for imatinib for CML had been obtained.

The partnership with GIPAP led to opportunities for the centre to join an international preceptorship program aimed at building diagnostic capacity in Ghana. In 2011, the CML Centre joined the International Chronic Myeloid Leukaemia Foundation (iCMLf) preceptorship program and partnered with other global CML centres and physicians to explore ways to optimise CML patient diagnostic and management capabilities. The partnership enabled the centre to apply for and obtain an iCMLf grant for improving access to diagnosis and testing. Through the joint effort from the partnership, as well as Cepheid and Max Foundation, the Centre secured rapid, accessible, lower-cost, and highly accurate molecular testing for BCR-ABL1 through the GeneXpert. The GeneXpert platform detects p210 BCR-ABL, which is the phenotypic expression of the Philadelphia chromosome, mostly associated with CML. It uses the peripheral blood of patients with CML on tyrosine kinase inhibitors. This makes it therefore, possible to determine molecular status (remission, or relapse) in these patients with its attendant implications for subsequent management. The infrastructure capacity was complemented by a corresponding development of workforce capacity. In order to build onsite human resource capacity for conducting these tests, a web-based online training in molecular testing for CML was conducted for the in-country multidisciplinary team of two haematologists and three biomedical scientists.

The GeneXpert System is typically used for monitoring of BCR-ABL1 during treatment for CML; however, to address the gap in CML diagnosis, certain haematological parameter thresholds were used to enable the platform run diagnostic samples. These were a total white blood cell count (WBC) of less than 100 x 109/L, and the platelet count was less than 600 x 109 /L. Haematological parameters exceeding any of these thresholds registered an error with the GeneXpert. Thus, new patients were given hydroxyurea till their WBC and platelet counts fell within this range before molecular testing was done.

## Formation of a patient support group

A patient support group was formed to augment the effort of the CML Centre. Advocates for CML Ghana (CMLAG), the first patient support group in haematology in Ghana, was inaugurated in April 2012 to provide support and information to patients with CML and their caregivers. Membership includes persons living with CML and their families, medical doctors, nurses and other health professionals involved in the management of persons living with CML.

The support group provided a perfect opportunity for the establishment of patient care relationships and the exchange of experiences and words of encouragement among the members. Having this group has also afforded the medical and non-medical teams the opportunity to keep patients updated with information on the disease, address challenges faced by the patients and respond to the psychosocial needs of patients living with CML. The patient support group networked with other CML patient support groups from other countries. The leadership of the support group in Ghana had interactions with leaders of CML patient support groups from other countries to discuss cases and make decisions concerning CML patients. These collaborations enhanced the sharing of ideas and best practices with other patients with CML and CML support groups in other countries.

## Ensuring sustainability of the CML Centre

The CML Centre has operated the GIPAP without a break since 2008. This has been achieved as a result of steps taken by the team from the onset of the program to ensure the program was self-sustaining. Seed money was obtained from the proceeds accrued from the tests done with 50 donated kits from the Max Foundation at the onset. This enabled the Centre subsequently purchase more cartridges at a discounted rate through Max Foundation. The cost of tests done was thus cheaper and more affordable. Additionally, the team strategised and leveraged the robust accounting and governance structures to ensure prudent management of the funds realised. This was done by ensuring payments are made through the institutional accounting systems, and funds are accessed through laid-down procedures. This approach was put in place to ensure accountability and guarantee enough reserves to buffer unanticipated costs, and allow for the continuous and timely supply of kits purchased for patient care.

## Data protection and patient privacy

All data were obtained from patients' clinical records, which were securely kept in the records room under lock

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and key with access to only persons involved in providing clinical care to patients. The extracted data was kept by the corresponding author with access only to the programme team. The clinical data will be kept at the hospital according to the hospital's data retention policy.

### Quality assurance

To ensure data quality, the data was abstracted by trained medical professionals. The lead author of this paper routinely reviewed the extracted data to identify any errors. With regards to ascertainment of the outcomes, laboratory testing, including molecular outcomes were validated through standard internal control measures such as ensuring the samples were collected in the appropriate containers and tested in time using standard operating procedures. Clinical outcomes were assessed by the trained medical team of the centre. The outcome assessors were not blinded but were trained as part of the programme implementation. The training of the clinicians and staff of the centre ensured that they all used the same case definition for ascertaining clinical outcomes. The outcome assessment was done as part of their routine clinical management of patients and not as part of a study. Results were reconciled by comparing the laboratory findings with the clinical records.

### Ethical consideration

This manuscript describes a program design and implementation, and resultant patient outcomes. It did not go through any formal Ethics Review Board approval. All data used were aggregate data with no personal identifiers. All the patients who were treated gave informed consent and were managed according to the hospital protocols. For enrolment into the GIPAP programme, all patients signed an informed consent form.

## Results

A total of 58 patients were included, out of which 35(60.3%) were males. The male-female sex ratio of the patient population included in this study was 1.5:1. The majority, 56 (96.5%) of the patients enrolled, were diagnosed in the chronic phase. The median white blood cell count at presentation was 216 x 109/L (range: 27-793).

### Improvement in clinical management and patient outcomes

Testing increased from eight per year to 20 within six months of having on-site molecular testing (150% increase). Between 2007 and 2012, in the absence of onsite molecular testing, 10 (27.0%) out of 37 CML patients enrolled in the GIPAP program had repeat PCR testing after their initial diagnostic testing. However, within eight months of onsite molecular testing, which commenced in 2013, 30 (52%) of 58 patients (including those enrolled from 2007 to 2012) on GIPAP were able to repeat their PCR after initiation of treatment.

Currently at Korle-Bu Teaching Hospital, more than 100 PCR tests for CML are done annually. On-site BCR-ABL1 testing in CML has thus become a viable tool for patients and providers, as it is four times cheaper than testing from outside the country. The average turnaround time for diagnosing CML has been reduced from two weeks to an average of two hours. As a result of simply diagnosing more patients accurately and facilitating access to tyrosine kinase inhibitor therapy, the revolution of tyrosine kinase inhibitors has been experienced first-hand by the Korle-Bu Teaching Hospital CML Centre. Forty-eight (40%) patients have been able to repeat testing at least once after diagnosis; out of which half did at least 2 tests per year (range 2-4). Hitherto, only 10 patients carried out repeat tests in order to monitor their response to treatment over a period of 5 years (2007-2012) [6].

With the onsite molecular testing and tyrosine kinase inhibitor therapy, haematological remission is typically achieved within two months of initiation of treatment. Haematological remission was reported to have occurred based on the European LeukemiaNet (ELN) criteria of total numbers of white blood cells less than 10 x 109/L and platelets less than 450 x 109/L are normal or on the absence of palpable organomegaly [10]. Between 2007 and 2009, for example, all 35 patients (nine on imatinib) achieved haematological remission, and massively enlarged spleens were no longer palpable. These observed successes in CML treatment outcomes, generally limited in the past, have subsequently been achieved.

Twenty-three (47.9%) of 48 patients who repeated their tests at least once between 2013 and 2017 have achieved at least a major molecular response defined as no more than 0.1 per cent (1 out of 1,000 cells) having the BCR-ABL1 cancer gene [10]. The centre moved from using haematological remission to using major molecular response as a measure of treatment effectiveness and risk of disease progression.

The impact on patients' lives and their families beyond disease response is evident; those who had to stop work due to ill health are able to, at a minimum, engage in trading to improve their financial status and quality of life for their families. Access to a second-line tyrosine kinase inhibitor option has afforded patients who are not responding to more options and continued hope. In our view, nearly half of the patient population achieving MMR in a low-middle income country (LMIC), where patients often present late and face logistical barriers to care, is a remarkable finding worth considering as a strength of the programme implementation. On the other hand, when compared to high-income countries (HICs), where major molecular response rates of above 70 percent[11–13], it shows a clear gap that requires improvement strategies. However, these high rates in HICs were observed in

clinical trials where conditions were near ideal, with excellent follow-up and uninterrupted provision of drugs and other logistics. The patients included in these clinical trial studies were also more likely to be motivated to participate in a structured trial than in the real-world situation in our programme.

Comparing to other countries in sub-Sahara Africa, however, the major molecular response of 47.9% exceeds those observed in Nigeria (39.4%) [14], and Ethiopia where molecular status was unknown for a majority of patients because of inability to afford molecular monitoring The reasons for this also included suboptimal adherence and its resultant treatment interruption which were driven by financial barriers to care [15]. In the programme at the Korle-Bu Teaching hospital, only grade 1 and 2 side effects, including muscle pain, hypopigmentation of skin, nausea and fatigue. No patient discontinued treatment because of these side effects, which were promptly managed. This suggests that the components of our programme are key in mitigating traditional real-world barriers in LMICs. In terms of sustainability, the staff who have been trained have retained their skills and are training others. The in-house testing, which is still ongoing, has also lowered testing costs, while patient support groups that continue to exist serve as safety nets to ensure adherence and mitigate stigma associated with the disease.

### Challenges that remain: The future

The GIPAP programme is still running and providing accessible care to patients. At present, the test kits for testing are being procured through Max Foundation at a heavily subsidised price, which makes management of cases affordable. Patients who do not respond to first-line TKIs are also now benefiting from second and third-generation TKIs.

In spite of the successes, there remain some challenges impeding the successful management of CML. Unfortunately, patients still present late with signs and symptoms such as massively enlarged spleen, markedly increased white blood cell count and morbid complications such as hearing loss and priapism. There is thus a need to increase awareness of the disease in Ghana for earlier diagnosis, improved treatment and quality of life. Rehabilitation of patients who have developed complications of the disease will further enhance their current quality of life. While molecular testing is comparatively more affordable now, it is still beyond the reach of some patients. We look forward to a time when the cost of molecular testing will not be a barrier for any patient living with CML. On-site mutational testing is also needed as a next step so that the judicious and appropriate use of alternate tyrosine kinase inhibitors can be offered to those not responding to imatinib. The centre has therefore initiated discussions on potential partnerships as initial steps to enhancing access to mutational testing in the country.

### Lessons learnt

Establishing a focused program for CML patients and collaboration with the GIPAP programme has ensured improved access to diagnosis and a more efficient treatment option. Early diagnosis of patients in the chronic phase resulted in early initiation of optimised treatment and better clinical outcomes. Having 'in-house' molecular testing at Kore-Bu Teaching Hospital has had a great impact on our diagnostic and monitoring capabilities.

The collaboration between clinicians, laboratory personnel and program managers has ensured a good continuum of care for patients. Robust monitoring, evaluation and learning plans with well-defined indicators are useful for measuring the success or otherwise of such programs.

### Limitations

While reporting the successful implementation and the associated outcomes, it is important to acknowledge limitations that must be taken into consideration in the interpretation of the results. Firstly, we acknowledge that the positive outcomes reported cannot be solely attributed to the program, as we did not analyse data from a comparison group. Additionally, general improvements in treatment and access to TKI, concurrent health system improvements outside this program and biases in the selection of patients to include could contribute to the changes observed in the outcomes. Secondly, it was not possible to isolate the intervention effects. We, however, considered the TKI access (in the GIPAP) as an enabler (fundamental prerequisite) for the clinical outcomes and considered the main drivers of the clinical outcomes to be the in-house molecular testing, staff training and formation of patient support groups. The in-house testing made it possible for quick feedback for timely clinical decision making on dosage adjustment and adherence counselling if need be. This was not possible prior to the programme commencement. Finally, since the results are from a single institution with its context-specific experiences, replicability in similar settings will require careful consideration of requirements for a successful implementation.

## Conclusions

The transformation of services from a traditional to more advanced but affordable diagnostic and treatment options was associated with improved treatment outcomes of CML in Ghana's foremost teaching hospital. Leveraging opportunities for collaboration and maximising available resources for a diagnostic and therapeutic revolution has been achieved to enhance the management of CML in a resource-limited centre. The transition from outdated diagnosis and treatment modalities of CML to more advanced diagnostic methods, such as molecular testing domiciled in-house, has made treatment initiation for CML patients in Ghana faster and molecular monitoring of

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treatment easier. Cost of testing and turnaround time for receiving test results have reduced considerably. In setting up such a system and basic infrastructure that would work in similar or comparable settings, it is important to ensure that continued access and sustainability are built into the program design from the outset.

**What is already known about this topic**

- CML management depends on molecular diagnosis and targeted therapy with TKIs.
- Resource-limited settings face diagnostic and therapeutic inequities due to cost and infrastructural barriers.
- Few African centers have reported sustainable, locally implemented CML programs integrating molecular diagnostics and TKIs.

**What This Study Adds**

- Demonstrates a sustainable model for in-country molecular testing and TKI access in Ghana.
- Reports significant improvement in diagnostic turnaround, affordability, and patient outcomes.
- Highlights the importance of partnerships and patient support networks in sustaining cancer care in LMICs

## Conflict of Interest

The authors declare that they have no conflict of interest with the funders of the Program. The lead author is a physician on the programme.

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## Authors' contributions

AABK and MM conceived this study and analysed the program-related data. AABK drafted the initial manuscript which was revised and approved by MM..

## Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

## Disclosure

Initial findings of this research were presented at American Society of Hematology Conference

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