REALITY CHECK FROM A CLINICIAN PERSPECTIVE:
HOW PATIENTS ARE MONITORED IN LMI

DR. DR. QIAN JIANG FOR DR. AMMA ANIMA BENNEH-AKWASI KUMA
Consultant, Department of Haematology, Korle-Bu Teaching Hospital, Accra, Ghana
Lecturer, College of Health Sciences, University of Ghana, Accra, Ghana
• Ghana is an English-speaking country in West Africa with a population of approximately 30 million.

• Health care is delivered at the primary, secondary and tertiary levels.

• Patients with haematological malignancies (cancers) have to pay out of pocket for their care as it is not covered by insurance.
• Our centre; Department of Haematology is situated at the Korle-Bu Teaching Hospital which is the largest tertiary hospital in the country.

• Referrals are received from all over the country as well as other West African countries such as Sierra Leone, Liberia, Togo and the Ivory Coast.
• A Chronic Myeloid Leukaemia (CML) clinic is run every Thursday at our centre.

• Referred cases are seen and patients already on treatment are reviewed with their full blood count and PCR results.

• This dedicated clinic day affords us the opportunity to concentrate solely on patients living with CML and makes monitoring easier.

• For new patients it makes them realize they are not alone and gives them encouragement and hope.
Diagnostic and Monitoring Process

• Diagnosis of CML at the Department of Haematology is by morphology and molecular testing.

• “In house” molecular testing using the GeneXpert system became possible six years ago and has really revolutionized diagnosis and monitoring of patients at our centre.

• New patients are given requests for a Full Blood Count (FBC) and a peripheral film comment after history taking and examination.
• Once the peripheral film is suggestive of CML, diagnosis is confirmed by molecular testing.

• Cytogenetic testing is not available “in house” and it is very costly to have it done abroad.

• Though the GeneXpert system was designed for monitoring we have managed to use it to confirm our diagnosis as the presence of a BCR-ABL transcript is an indication that t(9,22) has occurred.

• Hydroxyurea is given to reduce the white cell count before using the Genexpert to confirm the diagnosis.
With the diagnosis confirmed an application is sent to Max Access Solutions, successful patients are then enrolled in the programme giving them access to Glivec.

The importance of monitoring is discussed from day 1.

The ELN guidelines is our standard but in reality very few patients can afford to do their PCR every three months.

Most patients depend on relatives to be able to attend the clinic and pay for their tests as they have stopped working as a result of the illness. Affordability becomes a major stumbling block.
• Nonetheless we strongly advise that PCR is done after the first 3 months of therapy, 6 months and 1 year during the first year of therapy.

• Subsequently we recommend that it is done at least twice a year depending on the response to therapy. However there are some who adhere to the 3 monthly testing although they are in the minority.

• Counselling on the need for constant monitoring is done during reviews not only by clinicians but also nurses and during patient group meetings to avoid complacency.
THE EFFECT OF LIMITED RESOURCES ON TIMELY DIAGNOSIS AND APPROPRIATE TREATMENT

• Lack or inadequate number of equipment for PCR testing for a given country can affect timely diagnosis, monitoring and ultimately appropriate treatment.

• Affordability also plays a significant role as in most LMI countries the cost is paid out of pocket.
THE ROLE OF ADVOCATES TO HELP IMPROVE ACCESS, QUALITY OF DIAGNOSTICS AND MONITORING

• Advocates need to educate and engage policy makers and private sector to address issues that hinder improved access, diagnostics and monitoring.

• Hopefully once awareness is created and the stumbling blocks enumerated and explained fully the situation can be improved.

• Advocates need educate and be each others keeper so that monitoring is adhered to leading to better treatment outcomes.
CHALLENGES THAT AFFECT MONITORING

• Lack of awareness of CML in the general populace

• Diagnostic capabilities

• Affordability

• Complacency on the part of patients
• Most patients delay in seeking medical attention when they first notice the symptoms and signs. Various reasons except the right one are attributed to the features.

• For example a mass in the abdomen doesn’t ring alarm bells because it is painless. Its only when it becomes large enough to cause early satiety that sends the individual to hospital.

• Education of the general populace and also health personnel is important as early detection leads to better outcomes and the need for additional testing which may be expensive and not readily available can be avoided. E.g. mutational analysis
• Accessibility and affordability of PCR in most LMI countries also affects monitoring. Patients may have to travel long distances in order to get the PCR done. Transportation cost then becomes a significant part of the total cost of testing.

• Patients sometimes put monitoring at the bottom of their priority list especially for those who tolerate the tyrosine kinase inhibitors well.

• They feel very well, get back to their normal activities and have normal full blood counts thus they forget that the earliest detection of inadequate response to therapy is by PCR.
CONCLUSION

• The importance of monitoring cannot be overemphasized.

• The challenges highlighted I believe prevail in most if not all LMI countries.

• Education of the general populace including policy makers and patients and enhancement of diagnostic capabilities are essential to improve monitoring especially in LMI countries.
THE TEAM
Monitoring CML in China

Qian Jiang, M.D.

Peking University People's Hospital, Beijing, China
Survey in China

• Physicians and New Sunshine Charity Foundation designed a cross-sectional study using anonymous questionnaires.

• From May to October, 2014 questionnaires were distributed to adults with CML receiving TKIs in China via the Internet and in printed copies at patient advocacy groups, PAP pharmacies and out-patient clinics at Peking University Peoples Hospital.

• The questionnaire focused on demographics, CML-related variables before starting TKI, specifics of TKI therapy, response, tolerance, monitoring, annual out-of-pocket expense and major impediment to receiving a TKI.

• 1038 questionnaires were collected 91% of which were evaluable.

• Median age of respondents was 41 years (range, 18–88 years).

TKIs Received in China

- **Glivec®**: 69%
- **Sprycel®**: 4%
- **Tasgina®**: 9%
- **Chinese generic imatinib**: 6%
- **Chinese generic dasatinib**: <1%
- **Foreign generic dasatinib**: <1%
- **Foreign generic imatinib**: 12%
- **Other**: <1%

From May to October, 2014

819 respondents in chronic phase outside clinical trials were evaluable

• 819 respondents in the chronic phase outside clinical trials were evaluable

• 731 (89%) respondents had ≥1 BCR-ABL level test by Q-PCR

Molecular Monitoring Patterns by TKIs Used in China

<table>
<thead>
<tr>
<th>Drug</th>
<th>Never</th>
<th>Irregular</th>
<th>Every 3 mo</th>
<th>Every 6 mo</th>
<th>Every 12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glivec® (n=565)</td>
<td>29%</td>
<td>14%</td>
<td>38%</td>
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<td>9%</td>
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<tr>
<td>Chinese generic imatinib (n=52)</td>
<td>3%</td>
<td>14%</td>
<td>21%</td>
<td>33%</td>
<td>14%</td>
</tr>
<tr>
<td>Foreign generic imatinib (n=99)</td>
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<td>14%</td>
<td>28%</td>
<td>48%</td>
<td>14%</td>
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<tr>
<td>Tasigna® (n=71)</td>
<td>7%</td>
<td>16%</td>
<td>45%</td>
<td>25%</td>
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</tr>
<tr>
<td>Sprycel® (n=29)</td>
<td>7%</td>
<td>14%</td>
<td>45%</td>
<td>25%</td>
<td>7%</td>
</tr>
</tbody>
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\[ p = 0.002 \]

Older age, starting TKI therapy >1 year from diagnosis, and use of generics were associated with a lower frequency of monitoring.
### Issues

- Many patients not monitored according to guidelines
- Older age, financial burden and physician non-adherence to guideline recommendations are associated with less monitoring

### Solutions

- Physician and patient education
- Financial coverage
Thanks to My CML Patients and Their Families
Thank You for Your Attention!

jiangqian@medmail.com.cn