WHO Technical Consultation on malaria case management in the private sector of high burden countries

1-3 May 2019, Salle D, World Health Organization, Geneva, Switzerland
Interventions to improve quality of care in drug shops

Source: HANSHEP*. Engaging the private drug retail sector to make faster progress towards pro-poor Universal Health Coverage in low and middle-income countries. Unpublished report.

* Harnessing non-state actors for better health for the poor
[https://www.hanshep.org/]
Treatment seeking of febrile children in SSA

- Preliminary analysis of 22 national-level surveys completed in sub-Saharan African countries between 2014 and 2017 showing first-place of treatment seeking of febrile children.
- In 5 countries, i.e. Nigeria, Chad, Uganda, DRC and Ghana over 50% of the children affected by febrile illness seek first treatment in the private sector. Proportions seeking treatment in the informal versus the formal private sector vary among countries.
Treatment seeking of febrile children in SSA

• With the exception of Kenya, the proportion of febrile children who took antimalarials was systematically higher than those who received a diagnostic test, suggesting that antimalarial treatment continues to be prescribed on the basis of fever without laboratory confirmation in the private sector.

• Based on ACTwatch surveys, the majority of malaria blood tests sold or distributed in private-for-profit medical health facilities were microscopy tests while in pharmacies and drug stores, RDTs were mainly used.

Percentage of febrile children under 5 who received a diagnostic test and who took antimalarials among those seeking care in the private sector, in selected countries, 2014-2017

Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Objectives of the Technical Consultation

1. To review the data supporting the rationale for an international effort to engage private-sector players in malaria case management, and the evidence base that this can be done safely and effectively.

2. To review the laws, regulations and policies influencing the use of medicines and point-of-care diagnostic tests in malaria case management in a set of high-burden countries in Africa.

3. Based on this review, to identify the main bottlenecks and outline steps, including research priorities, to reduce barriers to enable improved quality of care for malaria across the entire health sector.

4. To draw upon documented lessons learned from major global, regional and country initiatives to improve malaria case management in the private sector, including the Global Fund Co-Payment Mechanism, the UNITAID project Creating a private-sector market for quality-assured RDTs, the Accredited Drug Dispensing Outlets (ADDO) project in Tanzania, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) framework for engaging the private sector in malaria case management.

5. To review results of recent private-sector outlet surveys, and the main determinants of supply chain and distribution mechanisms for malaria medicines and diagnostics in the private sector, taking into consideration the experience of pharmaceutical and diagnostic companies in priming the market in high-burden malaria endemic countries.

6. To identify key lessons learned and best practices from other public health programs – including family planning, tuberculosis and HIV – with a long history of private-sector stakeholder engagement.
• GMP PDT in collaboration with SEE unit established a multiagency team to support the preparations of the technical consultation, involving Drs L. Barat (USAID PMI), A. Cameron (UNITAID), G. Jagoe (MMV), S. Filler (GFATM), C. Goodman (LSTM&H), R. Orford (PMI Impact Malaria), A. Pratt (BMGF), J. Tibenderana (Malaria Consortium) and T. Visser (CHAI), providing advice on key resources, analytic work and pre-reads.

• The technical consultation involved 70 participants representing NMCP and NRA of the 7 countries, public health experts involved in regulatory reviews, outlet surveys and research on malaria case management and other public health programs in the private sector, including private sector representatives (suppliers of prequalified ACTs and RDTs, and first-line buyers (FLB) involved in Global Fund Co-Payment Mechanism (CPM)).

• CHAI, MC and PSI completed “policy profiles” of the 7 countries on policies & regulations affecting antimalarial medicines, antibiotics, and in-vitro diagnostics. These, their comparative analysis and selected publications were shared as meeting pre-reads, together with results of first-line buyers procuring ACTs via the CPM in Ghana, Kenya, Nigeria, Tanzania and Uganda.

• Using methodology adapted from PSI’s “Keystone Design Framework”, participants in 7 country teams discussed main market constraints along the supply chain, how to reduce barriers and promote best practice to improve access to quality of care for malaria in the private sector.
Conclusions

Common Vision

• All patients, whatever their social status and wherever they live, have the right to access quality malaria case management.
• As a majority of patients access care for febrile illness first through private sector, this sector must be able to deliver quality malaria case management.
• The private health sector needs to be considered as an integral part of the national health systems.
Objective 1 – current evidence base

- Limited evidence on different ways to improve case management in the private medicine retail sector (PMRs), consisting of pharmacies, authorized and informal drug shops, and medicine sellers/hawkers.
- To move research and pilot projects to scale, regulatory restrictions on who can test, treat, and sell health products need to be removed/harmonised so that tasks can shift to where patients are accessing care.

Availability & Affordability:
- Lowering purchase cost (through co-payments) of quality-assured antimalarials and diagnostic services or providing quality assured commodities free of charge to providers and patients, together with associated BCC programs, can increase availability and affordability. However, in the absence of pre-treatment diagnostic testing, increased availability and affordability of ACTs leads to a high level of inappropriate treatment of non-malarial fevers.
• The AMFm and Global Fund CPM have been successful in both increasing the market share and reducing the price of QAACTs.
Objective 1 – current evidence base

Quality of Care:
• There is limited knowledge on the best way to introduce mRDT testing into PMRs. There is evidence that PMR staff can successfully perform the test and adhere to the results, often better than formal healthcare workers. However, as in the public sector, this needs adequate training and regular follow-up.
• Appropriate protocols for the management of non-malarial fevers are also required, adapted to private sector in limited resource settings

Consumer Knowledge:
• BCC is crucial to change consumer behaviour and expectations when seeking care in the PMRs.
• Existing demand for testing services does not exist everywhere and testing is perceived as a commodity that has to be paid for.

Surveillance:
• There is little experience on developing appropriate surveillance for the private sector, with appropriate tools, incentives, and systems.
Objective 2 – regulation and enforcement

- All countries have regulations in place for ACTs and IVDs, but in some legislation and regulatory policies for IVDs are still evolving.
- Countries still lack the capacity to fully enforce the regulations especially for post-marketing surveillance and enforcement of controls. This means that practice, especially around diagnostic testing and the prescribing of antibiotics, is often inconsistent with laws and regulations.
- Countries differ in risk classification of ACTs and antibiotics

<table>
<thead>
<tr>
<th>Country</th>
<th>ACTs</th>
<th>Antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRC</td>
<td>OTC</td>
<td>POM</td>
</tr>
<tr>
<td>Ghana</td>
<td>OTC</td>
<td>POM</td>
</tr>
<tr>
<td>Kenya</td>
<td>POM</td>
<td>POM</td>
</tr>
<tr>
<td>Nigeria</td>
<td>OTC</td>
<td>POM</td>
</tr>
<tr>
<td>Tanzania</td>
<td>AL = OTC, all other = POM</td>
<td>POM</td>
</tr>
<tr>
<td>Uganda</td>
<td>AL = OTC, all other = POM</td>
<td>Amoxycillin =OTC, all other =POM</td>
</tr>
</tbody>
</table>

OTC = Over the counter; POM = prescription-only medicine

- Differences in risk classifications between ACTs and antibiotics are a barrier for appropriate care of non-malarial febrile illnesses, including pneumonia, in case of negative malaria test.
Objective 2 – regulation and enforcement

- Countries have restrictions on what types of facilities are allowed to perform mRDTs

<table>
<thead>
<tr>
<th>Country</th>
<th>Premises where mRDTs can be performed</th>
<th>Professionals permitted to perform mRDTs</th>
<th>Professionals permitted to sell mRDTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chad</td>
<td>Health centres, Clinics Private laboratories</td>
<td>All health care workers (including CHWs)</td>
<td>Accredited pharmacists</td>
</tr>
<tr>
<td>DRC</td>
<td>Hospitals, Clinics Registered pharmacies with accredited pharmacists</td>
<td>Accredited pharmacists CHWs</td>
<td>Accredited pharmacists</td>
</tr>
<tr>
<td>Ghana</td>
<td>Hospitals, Clinics, Pharmacies Accredited drug stores</td>
<td>All health care workers in the formal sector</td>
<td>All health care workers in the formal sector</td>
</tr>
<tr>
<td>Kenya</td>
<td>Community level Level 1–3 health facilities</td>
<td>Laboratory technicians CHWs</td>
<td>Hospitals</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Pharmacies, Clinics, Dispensaries, Hospitals Accredited drug stores</td>
<td>All formal health care workers</td>
<td>Staff in PPMVs, pharmacies, Clinics, Dispensaries, Hospitals</td>
</tr>
<tr>
<td>United Republic of Tanzania</td>
<td>Formal health facilities Clinics Private laboratories</td>
<td>Health laboratory practitioners People with specialized training (incl. licensed registered drug shops staff and CHWs)</td>
<td>People registered with Tanzania Food and Drugs Authority, including ADDOs</td>
</tr>
<tr>
<td>Uganda</td>
<td>Hospitals, Clinics, Pharmacies Accredited drug stores Private diagnostic facilities</td>
<td>Health laboratory practitioners People with specialized training</td>
<td>Pharmacists Pharmacy technicians Nurses</td>
</tr>
</tbody>
</table>

- All countries require registration for IVD products.
- None of these 7 countries regulate prices of RDTs
- Taxes on imported RDTs – minimal in Tanzania and Uganda
Objective 6 – lessons from other public health programs

Conclusions: emerging common themes

Key Themes

• **Promotion:** Governments, NMCPs, and other key stakeholders need to generate demand for better quality of care in the private health sector in the population. The general public needs to be better educated for behaviour change on the need for malaria testing and compliance with results.

• **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector can be enhanced through:
  • Accreditation systems for drug shops.
  • Training in malaria and non-malarial fever case management and professional development schemes for private health care providers.
  • Increasing availability and affordability of quality diagnostics and medicines.
• **Policy & Regulation:** country policies and regulations should be reviewed and revised so as to support the implementation of appropriate case management.
  - Clarity and consistency of policy and regulation on where and who can carry out the malaria rapid diagnostic testing and where and who can prescribe and/or sell antimalarials.
  - Alignment of policy makers and regulators on technical specifications requirements for health products (diagnostics and medicines).
  - Policies and regulation that support the extension of quality malaria testing to ensure rational use of malaria medicines.
  - Develop guidance and promote behaviour change to ensure that health care providers and patients know what should happen in the event of a negative malaria test result.
  - Robust supervision and enforcement of the regulations supported by training and follow-up programmes.
Key Themes (cont’d)

• **Market Information:** address lack of detailed information on the private sector market dynamics, especially outside the large urban areas, and disseminate results among all stakeholders. Each country needs an *in-depth market review*.

• **Surveillance:** develop simple systems that allow the private sector to be fully integrated into national surveillance systems.

• **Pricing and Incentives:**
  
  • Ensure that the *pricing of quality-assured products supports the crowding out of poor quality or inappropriate products*.
  
  • Ensure that the cost to the caregiver/patient of the package of testing and treatment is affordable and promotes appropriate case management.
  
  • Ensure that *tax and tariff systems are aligned* so that diagnostics are not disadvantaged against pharmaceutical products.

• **Co-ordination:** Different stakeholders are not always aligned on delivery of quality case management and how to involve the private sector in this. It will be necessary to bring all groups together to work out ways to overcome this constraint.
ACT deliveries by sector: 2005 - 2018

Pre-qualified ACT in private sector: - 43% - 81%

Source: WHO data for WMR2019 from 10 manufacturers eligible for procurement by WHO/UNICEF
Conclusions – further support & guidance

Key requests to WHO

- **Advocacy:** for the importance of the private sector to ensure quality case management is available to all, as an **essential component to achieve UHC.**

- **Support and guidance:** to governments (including sharing best practice) on how best to engage the private sector:
  - To facilitate cross-sectoral coordination through country based forums.
  - To make investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.

- **Quality case management:**
  - Guidance on how to assess the quality of care in the private sector, not just quality of health products.
  - Continued promotion of appropriate **use of malaria diagnostics** to deliver quality of care of febrile illnesses in malaria endemic countries.
  - Recommendations on the correct **protocols to manage patients with negative mRDT** that recognises the actual pressures on-the-ground.
Key request to WHO (cont’d)

- **Affordability**: based on a range of business models/pricing strategies, make recommendations on how proper case management can be made affordable to patients while ensuring a proper return to private health care providers.

- **Innovation**: develop innovative systems and incentives to promote reporting from the private sector and integration into the national surveillance systems.

- **Local manufacture**: Support transfer of technologies in malaria endemic countries to increase the amount of local production of ACTs and mRDTs that meet quality requirements needed for procurement with international funds.

Ideally these should be brought together into a Roadmap (similar to the TB Roadmap) for integration of the private sector into national strategies to improve malaria case management. This should provide direction to Ministries of Health and other national agencies on how best to engage with the private sector, especially PMRs, to deliver proper diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.
Proposed next steps

- Support main streaming of private sector initiatives, through WHO internal working group, led by Health Governance and Financing Department.

- Core elements: effective governance of the private sector, maintaining the strategic direction for the health system aligned to UHC values, collecting and using intelligence to correct undesirable trends and distortions, articulating the case for health in national development, exerting influence through regulation and partnerships and establishing transparent and effective accountability mechanisms.

- GMP review of evidence and development of best practice manual for NMCP managers
Many thanks for your kind attention