



THE EARTH INSTITUTE
COLUMBIA UNIVERSITY

WHO

The Community Laboratory Initiative CLI

Discussion overview and recommendations

CDC Chamblee Campus, Atlanta - USA
17 & 18 November 2009

The Community Laboratory Initiative

The Vision

Good laboratory and screening procedures should be available to all people... irrespective of where they live.

The Mission

Decentralize laboratory services to community level and institutionalize this approach in national health systems and national health policies.

Meeting Objectives

- Identification of the most appropriate Community Laboratory infrastructure, software, hardware etc. as the minimum standard;
- Development of a basic, standard package of diagnostics and training that should be accessible at the village health centre level and by community health workers;
- Discussion of how the CLI can create a case for decentralization of laboratory systems and services.

This meeting brought together the World Health Organization (**WHO**), the Foundation for Innovative New Diagnostics (**FIND**), the Centers for Disease Control and Prevention (**CDC**), the President's Emergency Programme for AIDS Relief (**PEPFAR**) and the Millennium Villages Project (**MVP**) based at the Earth Institute (**EI**) at Columbia University to reflect, refine, and make plans for the Community Laboratory Initiative (CLI).

Background

In many resource-limited countries, the majority of people (up to 60% or more) live in rural or difficult to access areas, and are out of the reach of existing, formal structures of the national healthcare systems, particularly for diagnostic services. National laboratory structures are normally present at referral, regional, district, and sub-district levels, but capacity at community level is largely absent. This top-down structure fails to reach the very people who stand to benefit most from it. There is therefore a recognized gap between the availability of diagnostic services and the majority of the people who would stand to gain most from them.

The CLI has been established to develop and validate a model of an “integrated package” of diagnostics aimed at the key health MDGs - the reduction of infant and maternal mortality in remote rural communities, the challenges posed by malaria, HIV/AIDS, TB, diarrhoeal diseases, respiratory infections, nutrition deficiencies, neglected tropical diseases and other locally relevant public health threats.

Rather than a patient-centred approach in top-down mode, the CLI aims to institutionalize a bottom-up people-centred approach which will eliminate the current gap in access to diagnostics and create coherence across the whole platform of diagnostic technologies – from sophisticated national reference laboratories to rapid diagnostic tests carried out by primary healthcare workers in their communities.

Steps to a community laboratory approach



- Determine the basic diagnostic services to be provided at community/household level
- Determine minimum infrastructure requirements
- Determine the diseases to be considered
- Determine minimum diagnostic tools needed
- Address human resources issues
- Develop framework for ensuring diagnostic services quality and results reporting
- Discuss supply chain issues and requirements
- Determine indicators for monitoring and evaluation
- Identify pilot sites and partners

Agenda

Tuesday, November 17

Presentations – background concept:

- *Millennium Villages Project -- Dr. Joanna Rubinstein, Earth Institute*
- *Laboratory strengthening – Dr. John Nkengasong, CDC/ILB*
- *POC diagnostic approaches – Dr. Akos Somoskovi, FIND*
- *Parasitological Confirmation of Malaria Diagnosis – Dr. Sergio Spinaci, WHO*
- *Ensuring diagnostic quality at the community level – Dr. David Bell, FIND*

Presentations – reality in the field:

- *Philippines: Community health services network – Marvi Ribaya Rebuena (Trudeau), Philippines Shell Foundation*
- *Kenya: Role of community participation – Dr. Joseph Ndungù, FIND*
- *Role of community health extension workers in Ethiopia – Dr. Hailay Teklehaimanot, The Earth Institute*
- *(Presentation) – Earl Long, CDC South Africa*
- *Earth Institute Country Experience: Use of RDT – Dr. Yanis Ben Amor, The Earth Institute / Dr. Evan Lee, FIND*
- *Training and instruction material development for malaria RDT– Dr. David Bell, FIND*
- *Use of HIV diagnostics at the community level – Dr Miriam Sabin, WHO*
- *Community Laboratories and TB – Kim McCarthy, CDC/DTBE*

Definitions: getting on the same page - I (short plenaries followed by discussion)

- *Define concept of a village*
Moderator: Dr. Yanis Ben Amor, The Earth Institute
- *Determine minimum standards of an integrated community health care center*
Moderator: Dr. Sergio Spinaci, WHO
- *Wrap up*
Dr. Giorgio Roscigno, FIND / Dr. John Nkengasong, CDC/ILB

Wednesday, November 18

Definitions – getting on the same page II

1. *Determine the basic diagnostic services to be provided by a community health care center and a dispensary*

Moderator: Dr. Sergio Spinaci, WHO

2. *Determining the minimum diagnostic tools/ equipment and their maintenance, waste management*

Moderator: Dr. Giorgio Roscigno, FIND

3. *Determining the minimum responsibilities, training/ re-training requirements, support and format for a community health care worker*

Moderator: Dr. John Nkengasong, CDC

4. *Determine the minimum requirements for adequate communication and monitoring*

Moderator: Dr. Yanis Ben Amor, The Earth Institute

Community Laboratory Initiative: Who are we?

- *Criteria for participation, roles and responsibilities, planning for next steps*
- *Decide on pilot countries Ethiopia, Kenya, Uganda, Philippines, Rwanda, Senegal*
- *Identify potential partners, including donors, **funding and financing** mechanisms*
- *Define role and involvement of Ministries of Health and links to national lab policies and strategic plan*
- *Planned activities for 2010*

Moderators: Dr. Joanna Rubinstein, The Earth Institute / Dr. John Nkengasong, CDC / Dr. Giorgio Roscigno, FIND / Dr. Sergio Spinaci, WHO

The Presentations

This overview of the discussions held in Atlanta and the preliminary recommendations arising does not include the formal presentations mentioned in the above agenda. These will be included in the Annex at the end of this document and may also be consulted on www.finddiagnostics.org.

However, the insights gained from the experience of the various community level examples presented on the first day of the meeting were an essential ingredient for the discussion covered here and participants made frequent reference to them.

The discussions – Getting on the same page

Participants provided a wide range of experience and examples which all contributed to narrowing down the minimum requirements for the Community Level Laboratory, with a clear focus on diagnostic services.

Rather than structuring this report strictly along the lines of the agenda, this overview limits itself to the key points of the discussion and the initial recommendations. These are arranged according to four chapter headings and a concluding session. Selected consensus statements from the moderators are also included.

1. The concept of a Community Level Laboratory (CLL)
2. The minimum standards for the CLL
3. The basic diagnostic services and tools at CLL level
4. The minimum requirements for adequate communication and monitoring
5. Concluding session

1. The concept of a Community Level Laboratory

The discussion

In the initial discussion about what constitutes a village, participants offered definitions based on their own experience or national situation. Is a village a community? And is a community always a village? Not necessarily so it appears. What are the criteria? Population size, geographical location or political structure? Is a community not just a grouping that exists by virtue of some common bonds between the people who live there? It can also be a very concentrated community and equally well spread out over a certain area in which people have easy access to each other.

It was agreed that communities where a Community Level Laboratory (CLL) should be stationed would be those at the lowest level of the existing formal healthcare system. This level would vary from country to country. Communities in urban settings should also be included. The suggestion which then gained general approval was to talk of the level at which Primary Health Care (PHC) operates – a well established and WHO approved concept.

It was then suggested that a more precise way of defining what the community is can be provided by talking in terms of output. What should this community health station be able to do? What tests should it to perform? The definition should rather be about what is to be achieved than to describe an existing situation.

Maybe, it was suggested, each district level should make a plan and list the outcomes that are expected or needed from the lowest level. The result would be a map of community centres which correspond to local conditions.

Clearly a new stratification should not be introduced, except in those situations where it may be necessary to introduce a lower (PHC) level in the system. It must also be recognized that some countries are well ahead in terms of PHC services. So the definition does not seek to prescribe what the levels should be, but rather to determine the criteria for whatever the lowest level is in accordance with the healthcare system in the country.

Although there was agreement on the PHC approach it was finally felt to be rather loose for purposes of definition. Maybe it was suggested, select a group of pilot countries and see how the general principles would be applied in their case. From that experience, a more precise concept can evolve.

Preliminary recommendation

At this stage, the concept of the CLL is defined in the following manner:

- ✓ The CLL constitutes a first stage (in a sequence of ever more sophisticated diagnostic services) able to provide basic diagnosis and management of selected infectious diseases and conditions with public health importance, such as malaria, HIV, syphilis, TB, HAT, reproductive health, anaemia, high blood pressure, diabetes)
- ✓ The services of the CLL must be easily and freely available to all members of the community without distinction as to means, origin, religion etc.
- ✓ The CLL should be established and maintained in partnership by the community and the government.
- ✓ The community may identify the healthcare worker to be trained according to appropriate government standards.
- ✓ The government may opt to integrate the facility into the existing healthcare system.

2. The minimum standards for the CLL

The discussion

There was general agreement that the governments (specifically Ministries of Health) have responsibility for establishing standards for laboratories, even at the community level, although it was agreed that a community might have specific requirements. So, as for the previous session on the definition of the community/village, it is proposed that outcomes determine the criteria because in some countries standards will be clear, whereas in others this is not always the case.

Although several participants provide examples from valuable personal experience, the CLL in the way it is being conceived does not yet exist – there are no reference standards which describe what a community lab should look like today. In some cases this would be limited to simple RDTs and in other settings it could include sample collection and simple microscopy. The purpose of this discussion is to come up with suggestions for governments so that they can issue standards or guidelines for community lab initiatives.

Standards or guidelines would cover the following:

- Infrastructure
- Equipment
- Human resources (people and training)
- Supervision and monitoring
- Reporting

So the issue is: what is the best practise that can be offered to governments as basic standards for a minimum level lab? These standards should be linked to the vision.

The discussion revolves around the functions to be performed at this lowest level lab. There are two levels:

- a) The basic lowest level (or quasi-lab) which does not go beyond performing RDTs and some screening.
- b) Still a basic level but with the ability to collect sputum samples for transport to a centre where microscopy is available.

Each function has its own requirements in terms of infrastructure. There needs to be a toilet if urine samples are to be collected. There needs to be a separation for men/women etc.

It is recommended that community labs should be established within the existing governmental healthcare system and that the public-private partnership model has its place within this and is in coherence with it in a variety of ways.

The CLL could possibly be built onto an existing dispensary, provided with more equipment and maybe an additional space for certain tests. A simple supervisory mechanism would be required similar to what is in place for dispensaries in Kenya. The community should be able to specify any special needs and then put together the facility in a modular form – the terms “ikea or lego” were used to describe this process.

In the case of a memorandum of understanding (MOU) between a government and a community or a similar structure which is probably a partnership, the community needs to have a clear identity for legal reasons. There should be parity between the parties and a clear definition of attributions and responsibilities as the contract must be recognized and enforceable in law. The aim is to institutionalize the CLL, so the final decision on organizational set-up will rest with the government.

So there is a three part process:

- a) the government sets down the rules about what can be done – standards.
- b) the government provides the funding for infrastructure and training
- c) there is room for additional private financing according to local requirements and possibilities.

Several suggestions are made about how to deal with waste, whether this is expired drugs, used RDTs or sharps. There are groups which deal with injection safety (MMIS project, others) so they should also be brought into the waste management discussion in the future. The issue is how to dispose of millions of RDTs at community level...separation of sharps etc...rural and urban conditions will vary...waste sharps to be kept in a secure place (maybe with expired drugs) until they are collected.

Some suggestions:

- RDTs, drugs and sharps should be kept in a locked place which could be as simple as a metal box
- Patient records should be stored in a safe place
- RDT waste to be returned with the sharps
- Dispose of waste on the spot (bury) – this is not recommended

There are existing guidelines (on a disease by disease basis) which should be followed. The basic requirements for storage and waste management are an item for future discussion.

In general

For Africa at least, the solution needs to be very practical and to take account of human resource skills, training capacity, financial capacity and the RDTs that are available. It is the availability of novel RDTs that can be performed at grass roots level and with a minimum of training that makes this approach possible at all. The technology is driving the structure. Nowadays RDTs enable the process to start from the bottom upwards to meet the microscope, creating an uninterrupted flow of diagnostic technology.

Key points

- The standards for a lab should be established by the government, even though a community might have specific requirements.
- Community labs should be established within the existing governmental healthcare system within which the public-private partnership model will find its place.
- The community should be able to specify any special needs and then put together the facility in a modular form.

Preliminary recommendation

The CLL should have the following as minimum physical standards:

- ✓ Clean running water
- ✓ A toilet
- ✓ A waiting area
- ✓ TB sputum collection area
- ✓ At least 2 rooms with the capacity and safety measures for:
 - Providing confidential counselling
 - Proper storage for results, diagnostic commodities and drugs
 - Routine rapid diagnostic testing
 - Specimen storage
 - Waste management procedures

A quote from the Moderator:

Whilst we are using the word “lab” it is important to remember that our concept goes further than just technology – it a peripheral health hub with the potential to diagnose a number of ailments, with permanent staff trained in the use of the relevant technology. The government would oversee the activity of this unit, could provide funding and also work in a public-private partnership mode.

In terms of the facility itself, we see it as being able to generate its own solar power, to have clean water, provision for the storage of materials and the safe handling of samples. Storage for medicines for malaria, TB and HIV should also be provided (for example sufficient quantity for the first few months of treatment after diagnosis).

3. The basic diagnostic services and tools at CLL level

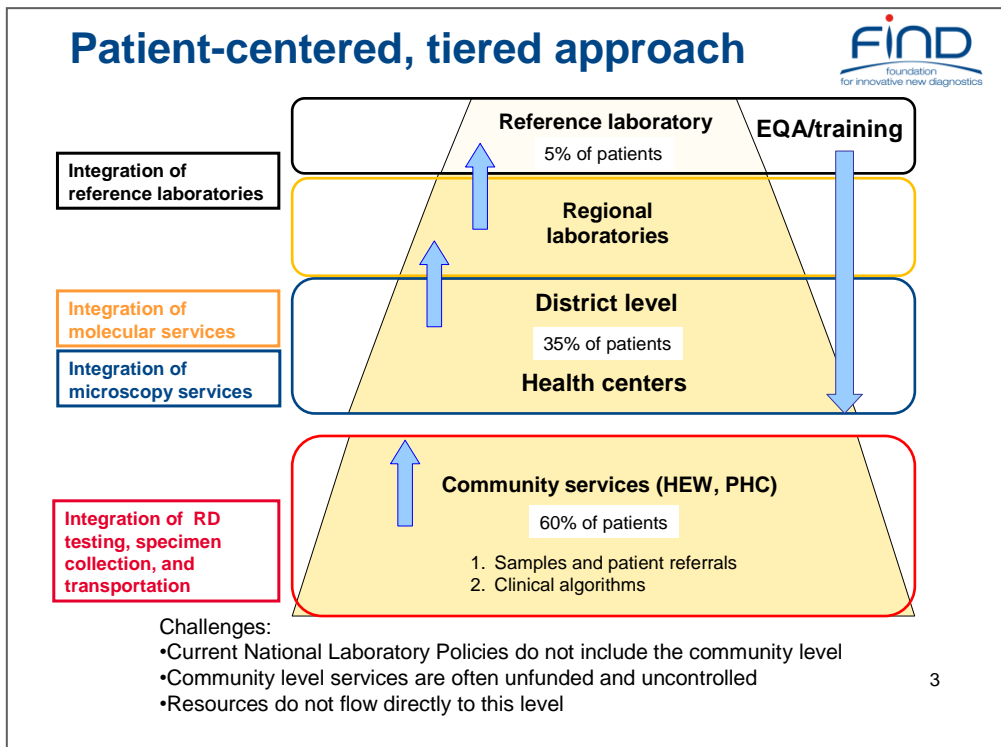
A) Services

The discussion

The vision is to have the three diseases (malaria, TB and HIV) to carry the lab platform and then use it to build on other tasks related to chronic diseases, maternal and child health and so on.

The ensuing discussion and several exchanges of experience at national levels (Uganda, Ethiopia, Kenya, India and The Philippines – in line with the background and experience of several of the participants) raised the following points:

- The absence of a physician at this level limits what can be expected even from a well trained healthcare worker.
- Human resource capacity needs to be continuously strengthened – even simple RDTs require a certain level of quality assurance.
- The novelty of the approach lies in the new technology now available which allows diagnostics and screening to be decentralized down to the lowest possible level. That is the strategy behind FIND's diagnostic platform approach which goes beyond a disease approach and is now ready for scale up in the context of the CLL – a people centred approach. (see diagram on page...)
- The CLI cannot be imposed from outside. It must be a government lead (institutionalized) approach which ensures that there are strong links between the community level, the district and beyond. “Coherent” and “integrated” are two key words in this respect.
- The experience of the Millennium Villages is given as an example of how, with the right kind of interventions, the MDGs can be achieved. With a basic standard of one health worker for every 5000 people, diagnostics have become essential to understanding the impact of the interventions.
- Diagnostics have the potential to act as the “glue” which links the various levels of the healthcare infrastructure in a country together. In the case of malaria, effective diagnostics have meant better treatment, lower costs and certainly better health outcomes.



The model being proposed needs testing. It is not a matter of establishing another health centre; it is the strengthening of existing capacity at community level which is essential. The model will need to be given strong advocacy support so that it is taken seriously from the outset. It would be a sad waste if the CLI remained on the periphery of the health system as just one more initiative destined to wither on the tree of unsuccessful good ideas.

The discussion covered a number of other questions that will require resolutions, namely:

- Who is going to make the decision as to which tests should be provided?
This means a link with physicians higher up the chain.
- Which of these tests would lead to a positive patient outcome?
- What is the next step based on the result of the test?
- The result of the test must be linked to a...what next?

Key points

- The CLI is the first entry point for diagnosis and then treatment at a higher level.
- The CLI cannot be imposed from outside. It must be a government lead (institutionalized) approach which ensures that there are strong links between the community level, the district and beyond.
- Participants agree on the following three criteria:

1. A quality service with no second best allowed.
2. Appropriate training in primary healthcare for one person or more and additional services (unspecified)
3. A fixed structure with minimum requirements for the safety of equipment and medicines, running water, toilet, waste management etc.

Preliminary recommendation

The conditions for which basic RDTs, specimen collection and counselling should be provided.

- ✓ Malaria
- ✓ HIV
- ✓ TB sputum collection
- ✓ Dried Blood Spot collection for HIV testing (EID)
- ✓ HAT
- ✓ Syphilis
- ✓ Pregnancy and antenatal care
- ✓ High blood pressure
- ✓ Diabetes

A quote from the Moderator:

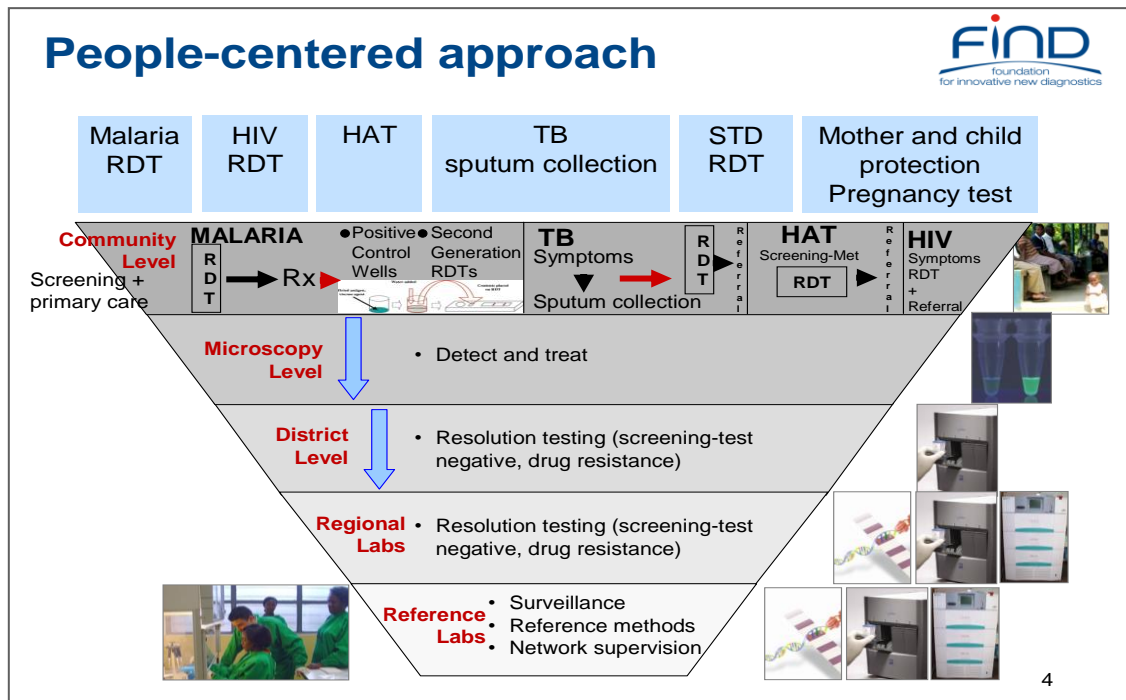
The end user of our initiative is the Ministry of health to whom we should be recommending this decentralization and institutionalization of diagnostics.

We will ultimately offer our evidence to governments to help them to institutionalize (or integrate) our approach into their overall healthcare system, otherwise it will never work.

What we are doing when we move from a patient to a people or community centred approach is to turn the pyramid upside down – see below - and this is a fairly revolutionary way of looking at things...

The Community Health Station and lab must be part of the system; it is not separate, but an additional dimension to what we believe should be available at community level.

We have agreed that RDTs and lateral flow technology are the most appropriate for this level of the system. They are also the tests which stand the best chance of being implemented given the circumstances (absence of doctors, level of training of primary healthcare workers, logistics etc).



B) Tools

The discussion

Considerable attention was devoted to discussing the pros and cons of microscopy. Participants were divided between those for whom this was a technology clearly beyond the means and the ability of the community level and those for whom microscopy today is working well at this same level.

However, the distinguishing feature of microscopy is that it is a platform technology applicable to several diseases and as such presents advantages. But it requires interpretative training (in contrast to the simpler yes/no of the RDT) which in most countries is not available at this level. So caution should be shown with microscopy unless it becomes fully part of the system and EQA is maintained. Country situations vary to such an extent that the choice is one for the government to take according to the priorities of its epidemiological environment. Maybe in the future it will be possible to recommend simpler robotic microscopy that would help to overcome some of the current QA and training issues.

Conclusion

Even though there are situations in which microscopy is performed efficiently and according to EQA at community level, there is consensus that the potential use of microscopy as a diagnostic platform may be beyond the reach of this level at this point.

A quote from the Moderator:

We have a full consensus on the value and appropriateness of RDTs at community level. On microscopy we have concluded that its use would depend on epidemiology and the country.

Training has to become part of the country EQA system from top to bottom.

Reporting will have to follow current lines, but with the option to introduce new technologies.

The overall recommendation is not to reinvent the wheel, but to reinforce the system through the lab strengthening activities being proposed.

4. The minimum requirements for adequate communication and monitoring

The discussion

Diagnostics must be considered in the context of the various national health systems. There are differences in local realities between continents and countries, so whatever is established (e.g. for diagnostics communications & monitoring) should be in coherence with the way the public health system manages records. The proposal is not to build a parallel system but to ensure there is interoperability. There must be real time information, not dead paper – there must be a contribution to strengthening the national health system.

Mobile networks and SMS transmission

The ubiquity of mobile networks makes a strong case for using them to strengthen the health system and its management.

There is general agreement on the advantages to be gained from using the SMS to diminish the time delay between test, diagnosis and appropriate treatment – a critical healthcare success factor.

Although several suggestions are put forward, the meeting agreed that there is a need to collect more evidence before it is possible to go into further details as to what the most appropriate system for communication and monitoring could or should be.

Several participants are clearly in favour of using mobile phone networks to improve communications between the diagnostic technologists at lower level and higher levels of the system. The advantage of the SMS is that neither broadband nor a computer is required.

This view is not shared by others who, although conceding that the mobile phone is fast and useful, are currently unsure of its role in collecting large quantities of data that need to be aggregated or when evidence is to be collected.

Maybe there is no “one size fits all” system...

Whatever the technology used for communications (and a mix is most likely) it is important for the healthcare workers to understand how the data is used, why it is required at district level and for them to be incentivized to report in a timely and accurately manner. Furthermore, whatever reporting and communication system is introduced for the purpose of diagnostics, it must be coherent with the overall existing health system.

During the discussion on communications and data reporting the following are some of the points made:

- Before making new proposals, the reasons for the failure of previous data collecting exercises should be studied. One of the main reasons may be because they were isolated initiatives, disconnected from the main healthcare system and that the motivation to sustain them or the understanding of their value was not present.
- What is new about the CLI is that it is a fully integrated approach...a branch of a tree cannot survive without being connected to the trunk and the trunk without being connected to the roots...sustainable funding is also a key requirement, whether from the government or other sources.
- The system proposed has to enable a flow of data from the community to the district, regional and national levels with a rationale for data collecting at every level.
- Today the circumstances are different from the past. There is real time data which can be analyzed at the village level. It possible to act sooner and provoke faster intervention from higher levels.

Key concluding points:

- There must be a clear reporting system which ensures that feedback is also accurate.
- One must be open to the use of new technologies; bearing in mind that training in their use will be a critical success factor.
- Falling into the trap of building a new parallel system to what may already exist and be working well, must be avoided.
- The proposal must be part of the national system for which the government is responsible with the proviso that outsourcing to private or community partners can provide local solutions.
- The supervision procedure must cover sample collection to ensure that policies are correctly implemented. The introduction of new functions at a lower level must not lead to any break or gaps in the QA system.
- It was agreed that there needed to be a decision on whether to recommend that testing be done by a dedicated person or to leave this decision to be taken by governments according to their own criteria or needs.

Preliminary recommendation

- ✓ To refrain from proposing new approaches until the evidence from what is already in place has been gathered. The strengths of what is in place should be leveraged.
- ✓ A core curriculum for governments to adapt should be developed. For this to be possible an evidence gathering exercise is necessary.
- ✓ Whatever the communications technology used, the system proposed has to enable a flow of data from the community to the district, regional and national levels with a rationale for data collecting at every level.

A quote from the Moderator:

Let's get the evidence and come up with what seems workable.

What are the areas of vulnerability in our approach...?

It is not enough for us to recommend. We need to get others who are stakeholders on board such as the doctors, donors, the policy makers and so on. We must spread the advocacy net wide and talk of a glass half full rather than half empty. Be positive.

Advocacy and communication will be an important factor in what happens next – this must be based on a strategy. The example of the 3 by 5 initiative is given as an illustration of what to avoid.

Communicating to and engaging with the global community at the highest level to make the case that the CLI is a revolutionary step is essential.

5. Concluding Session

Overview

The exchanges of experience have provided a solid basis for pursuing this initiative. The privilege of having been able to benefit from the contribution of a Minister from a high endemic country was particularly appreciated. The discussion has not been the realm of theory, but firmly rooted in the realm of reality.

This group must take back a clear message to WHO - an executive summary – which defines exactly what it required from this agency to support this initiative. These discussions have been both detailed, but also lacking in depth in some areas. These gaps need to be filled so as to avoid criticism. A consensus document is required to make the case for the CLI and subsequently obtain the necessary support from WHO.

A two track approach is proposed:

- First, a core group clarifies the outputs of this meeting, formulates the concepts, sets out some minimum criteria and identifies a number of countries in which the approach can be tested. This should be under the umbrella of WHO so that the wider community of stakeholders can move forward with us.
- Second, we engage our respective organizations for support – WHO must do the same with the regions – and then early next year we hold a new meeting to develop the concept we have overviewed today.

Until this process is complete and we have a more tightly packaged “product” it will be difficult to engage our health ministers and other stakeholders such as the Global Fund and PEPFAR. We can only move forward once we obtain buy-in from WHO which will be a key factor in ensuring the process is given the right attention by the funding institutions. This project must be in the “big funding boat”. So the advocacy effort will have to be wide ranging and include Member States who will be a help in convincing WHO.

What we are proposing has been a missing piece of the health world. What do we need to do to convince others that this is not only important, but that it will make a real difference?

Maybe some of the assumptions could be quickly field tested for example in the Millennium Villages project. Uganda, Ethiopia and The Philippines could also provide supporting evidence of a very practical nature. We need to know what the costs would be, what the savings would be, how best to finance and to use technology to make it cheaper than it would have been a couple of years ago.

This meeting has agreed that there is a need to bring diagnostic services closer to the community and we have discussed some of the implementation modalities. RDTs for malaria and HIV diagnostics are already being done at community level. What is new is the intention to systematize and institutionalize the process and roll it out to cover other diseases. A working paper with proposals for implementation will enable countries to say where they require support. FIND and partners can establish pilot projects as to functionality.

The Moderator says it is premature to say that the CLI is being launched. What can be said is that the proposal for the initiative exists and that support and contributions to the debate are still needed.

All these suggestions are useful, but the case still needs to be made. Our proposal must be supported by hard evidence that it is possible and that it will make the kind of difference that we say it will.

The Next Steps

The suggested process is as follows:

- FIND will draft a summary of the discussions within the next four weeks. This is to be circulated so that participants can add comments and elements which are still missing.
- After the summary has been distributed, we could have a teleconference to decide on action steps.
- Each partner organization should define their future role and contribution. Then, with a more robust definition of our concept, we can communicate with countries on the merits of decentralized laboratory services.
- Then next step is how best to approach WHO for guidance/leadership.
- The next meeting (of this group) should include more partners such as Unicef, the development agencies and the funding institutions, even large civil society groups such as MSF can contribute positively.
- The Moderator says that FIND is ready to start collecting evidence for scaling up the approach and that this can be done in parallel with the other policy measures that have been proposed.