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Report of a Meeting: Country Support and Interventions to Improve Use of Medicines in Children

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Summary of discussion

The purpose of the meeting was to address the objective of promoting better use of medicines in children (Objective #4 of the Bill & Melinda Gates Foundation project on Better Medicines for Children). The meeting was attended by researchers and implementers of interventions to improve health service delivery from Africa, Asia, the National Institute for Health and Clinical Excellence (NICE) International, Management Sciences for Health (MSH), UNICEF, and WHO staff from the departments of Essential Medicines and Pharmaceutical Policies, and Child and Adolescent Health, and the regional office of SEARO. The activities discussed were: (1) the identification of effective interventions to improve use of medicines in children and (2) capacity assessment and country selection for a future intervention and evaluation. This included review of options for interventions and review of target country preparedness and interest.

General comments

The Better Medicines for Children project covers not issues related to prescribing and rational use of medicines in children as well as the entire supply chain. The 'supply chain' of essential medicines for children includes upstream issues of policy, medicine selection, and regulation and downstream issues of forecasting, procurement, storage, distribution, human resources, infrastructure and implementation. Interventions at the upstream levels include:

- policies that address inclusion of suitable, safe and efficacious medicines for children in the national Essential Medicines Lists;
- considerations of optimal dosage forms and dosing procedures;
- facilitating priority research into pharmacokinetics, safety and efficacy of essential medicines for children;
- streamlining the processes of licensing, developing and supporting regulators;
- generating guidelines, algorithms and protocols for rational use of essential medicines; and
- facilitating cooperation between drug manufacturers and other stakeholders.

Downstream issues include engaging prescribers, dispensers, academic institutions and countries in adopting and using validated tools for essential medicines, and providing technical support for capacity building (human resources, appropriate investment of in-country resources, and guidance on supply chain systems). On the downstream side, mechanisms to improve patient engagement (parents and children) should also be explored.



Options for country activities include policy formulation, information and advocacy, measurement and data collection, and behavior change interventions. Data to evaluate implementation of an intervention could involve measuring advocacy across different professional and patient groups, the presence of medicines from the EMLc (the existence of an EML), linkage of EML medicines with guidelines, data on licensing, pricing, procurement, storage, distribution, availability, and evaluation of the actual use of medicines in select countries, including identification of stock-out frequency.

The importance of issues related to the supply chain (forecasting, procurement, storage, distribution) was recognized. In Sri Lanka, for example, lack of accurate forecasting has been identified as a barrier to procurement of essential medicines. A current project in Sri Lanka focuses on educating pharmacists about forecasting and minimizing stockouts.

The Better Medicines for Children work is global, but specifically for the Gates project, WHO is planning interventions in two regions: Africa and India. A report on selected country profiles provided background information for African country selection. During the meeting, issues of country preparedness to launch and evaluate a demonstration project were discussed. The final choice of countries was not made as further data gathering from the individual countries identified for a potential high intensity intervention is needed.

Any intervention studies should complement other ongoing studies related to other objectives of the Gates project, for example, reviews of the appropriate dosing regimens of antibiotics in children with malnutrition, a systematic review of dosing aids, testing the cultural suitability of different dosage forms. In addition, there are studies that have been proposed that are not yet funded such as testing a new formulation (dispersible) and packaging for amoxicillin for pneumonia. The planned projects will not overlap with Integrated Management of Childhood Illness (IMCI) which focuses on family and community care for children under five years of age. The IMCI strategy includes three main components: improving case management skills of health-care staff, improving overall health system, and improving family and community health practices. Thus, an appropriate focus for the proposed intervention is in an area where there is an essential medicine for hospital treatment that is connected to a pediatric treatment guideline – such as the Pocket Book of Hospital Care for Children.

Design of intervention

The unique contribution of this project is that it focuses on rational use of essential medicines for children. A major resource for the intervention will be the Second WHO Model Essential Medicines List for children. Ideally, a “demonstration package” of interventions should be designed that addresses different sites in the pathway from policy decisions such as listing of age appropriate formulations of essential medicines in National EMLs and procurement lists to appropriate use of the medicine. The package will be designed in a way that can be implemented across various disease areas.

Key steps in the design of the intervention are identifying priority diseases, identifying key EML medicines that are used to treat the diseases, assessing barriers to use of these medicines, and identifying outcomes that can measure change in use of the medicines.

Matrices for country assessment were proposed, that should identify barriers to use of essential medicines for children by describing 1) important conditions for which there is a relevant EML medicine, 2) steps in improving rational use of the essential medicines for the condition (identifying which steps are not being met), and 3) outcomes that can be measured (including costs as an outcome). See Tables 1 and 2 for draft matrices. The intervention will then be targeted on the steps in access and rational drug use that are not being met in a particular setting. Thus, a first step in evaluating implementation could be an assessment of how many countries have an EML that includes the EMLc medicines; a preliminary comparison of the WHO EMLc with selected country EMLs suggest that there are significant discrepancies. Ghana provided an example of problems with access/availability and suitability of children’s medicines. In Ghana, children’s formularies are not available and tools for administering medicines to children are not available (e.g. dosing spoons).

Refining the research question

The research question was refined using the PICO format (population, intervention, comparison group, outcome).

P: Population

When considering diseases to target, priority was given to major contributors to morbidity and mortality, conditions that are addressed in the Pocket Book of Hospital Care for Children, and conditions with unambiguous diagnostic criteria. The diseases that affect children the most in terms of mortality in under 5 year olds are: malaria, HIV, ARI/pneumonia, diarrhoea and causes of neonatal mortality (e.g.,

sepsis). Other conditions that might be suitable targets, including pain management and treatment of neonatal conditions other than sepsis (e.g., birth asphyxia or neonatal apnea) were also discussed. It was recommended not to focus on children with malaria or HIV in order to avoid duplication of effort with other intervention projects.

The level of the intervention (location of target population) was considered, focusing on a discussion of district hospitals vs. the community level. There were several arguments in favor of district hospitals: a large number of very sick children are seen at this level, training personnel at district hospitals may “trickle down” to other sites, there has been less work at this level and few formal indicators of rational use have yet been developed. It was agreed that the intervention could encompass feeder facilities to the district hospitals in order to reach a greater proportion of sick children who may not reach the hospital (e.g., children with pneumonia). The district level, in most countries, accounts for over 50% of health care personnel. The need to do further assessment to identify districts within a country as sites for the intervention was noted. The SUPPORT Tool¹ or evidence-informed health policymaking related to organizational self-assessment could be used to assess the readiness of countries to participate in the intervention and identify priority areas for intervention. It was anticipated that some of the key issues in district hospitals will be the appropriate use of antibiotics in undernourished children, assessment of whether protocols/guidelines exist in the hospital, whether they align with the EML, and whether they are being followed. Availability of products may also be an issue (stock-outs).

In summary, the population for the demonstration project will be children admitted to district hospitals with pneumonia, diarrhoea, neonatal sepsis, or other high priority diseases.

I: Intervention

To inform the selection of an intervention, the results of two reviews were discussed. Kathleen Holloway summarized the findings of a review of randomized controlled trials and observational studies aimed at changing prescribing in developing countries that was conducted by Dennis Ross-Degnan and colleagues. Lisa Bero summarized the findings of a systematic review of published randomized controlled trials examining methods to change provider prescribing behavior and child health outcome conducted by Michael Cabana and Janet Coffman. Both reviews suggest that the most effective interventions target specific behaviors, assess local barriers to changing the behavior, are multifaceted, and take place at the system level (as

1 Oxman et al. 2009. SUPPORT Tools for evidence-informed health policymaking (STP). *Health Research Policy and Systems*; in press.



opposed to the individual prescriber level). As suggested by intervention-specific systematic reviews conducted by the Cochrane Collaboration Effective Practice and Organization of Care Group (EPOC), effective packages of interventions could include educational materials, conferences, seminars or lectures, educational outreach visits, audit and feedback, reminders, use of opinion leaders, policy changes, and implementation of clinical protocols. The group agreed that a package of interventions would be developed to address the specific barriers identified in rational use of our targeted medicines. Thus, a district hospital “quality improvement package” could include evidence-based interventions that change behavior such as those listed above, managerial and professional advocacy, and supervision and monitoring for sustainability.

Michael English presented the early findings of his study in Kenya of implementation of the Pocket Book of Hospital Care for Children in district hospitals. He described how training was the entry point for the intervention, but that the intervention also included the development of protocols, providing access to protocols and medicines, and supervision and monitoring. The protocols were developed in consultation with the Ministry of Health, Kenya Paediatrics Association and the University of Nairobi. Early results showed benefits in the appropriate use of gentamicin, oral rehydration solution and quinine. Results showed more modest improvements for procedures like performance of lumbar punctures for suspected meningitis. This may have been due to issues of laboratory effectiveness and availability. The discussion highlighted the barrier to change that was created by lack of recommended materials and equipment, for example: oxygen concentrators, appropriate feeds for malnutrition, heaters, laboratory support, medicines such as phenobarbitone injection, caffeine citrate, rectal diazepam and vitamin K.

Noel Cranswick presented the experience of the Centre for International Child Health with implementing the Pocket Book of Hospital Care for Children in the Asia Pacific region. Giorgio Tamburlini presented experiences from Brazil, Angola, Europe and Central Asia, and China regarding the implementation of the Pocket Book and the related assessment of quality of hospital care for children. The main problems addressed by these interventions were over use and misuse of medicines and uncertain availability of essential medicines and supplies.

These presentations highlighted a number of lessons learned about designing and evaluating appropriate interventions. The findings emphasized the importance of considering the role of cultural and social issues as barriers to rational use of essential medicines. The Pocket Book, guidelines, and quality assessment tools were useful as entry points to build awareness, identify priorities, and disseminate good clinical practice. Identification of a driving force for the intervention (e.g., professional organization, NGO, health minister, opinion leaders, etc.) and local



ownership by professionals were also described as key factors in the success of an intervention. Sustainability of any intervention was seen as critical, thus emphasis must be placed on the supervision and support needed to maintain the intervention. Lastly, the role of incentives, such as pharmaceutical company influence on drug use, must also be considered in the design of the intervention. Thus, this project will be aware of the launch of the WHO/Health Action International draft manual *Understanding and Responding to Pharmaceutical Promotion: A Practical Guide* which may be piloted in some of the target countries.

The Pocket Book of Hospital Care for Children was seen as a critical part of the planned intervention for a number of reasons. First, recommendations for medical treatment in the Pocket Book align closely with the EML. Second, WHO could provide copies of the Pocket Book thus making it available in both intervention and control hospitals as an alternate source of information to drug company provided information. Third, many medicines recommended in the Pocket Book are the same as those used in primary care and, thus, could drive demand for essential medicines. The Pocket Book is potentially one place where most WHO guidelines related to children could be published. However, the group noted several improvements to the Pocket Book that are needed. Some sections require updating and an added section on outpatient care would be useful. Updating and expanding the formulary, updating guidelines and recommendations, and linking recommendations to evidence about essential medicines were seen as priorities. In addition, the Pocket Book will need local adaptation to accommodate local protocols and products.

Table 1 summarizes the steps in rational use of essential medicines for each targeted disease. In order to tailor appropriately the intervention to the barriers to use of the essential medicines, each step will be assessed before launching the intervention. Modifiers of responses to medicines, such as malnutrition, will also be assessed, as these may require alteration in the use of essential medicines.

C: Comparison groups

The group agreed that random assignment or modified random assignment of district hospitals to the intervention versus a basic package (e.g., provision of the Pocket Book of Hospital Care for Children) within a country would be the ideal comparison. If there are only a few participating hospitals within a country, for example, a “limited randomization” could be used. All possible combinations of intervention and comparison hospitals would be created and one of these combinations would be randomly selected.



O: Outcomes

The demonstration projects will focus on outcomes that can show measurable improvement within the 3 year time span of the study. The group agreed that process measures (e.g., number of prescriptions, volume of drugs purchased) may be sufficient and more readily obtainable across a wide variety of settings. Although the group will investigate the possibility of obtaining true clinical outcomes (such as mortality), this may not be feasible. Furthermore, many factors other than appropriate use of an essential medicine could affect such clinical outcomes. Process outcomes that could be measured include supply, procurement, distribution, suitability, access/availability, percent of children receiving an appropriate prescription, or appropriate use of the drug. Although measurement should focus on outcomes relevant to the selected diseases, the “spillover” effect of the intervention could also be measured. For example, if the Pocket Book of Hospital Care is part of the intervention aimed at improving use of zinc for diarrhoea, uptake of other guidelines from the Pocket Book not directly related to the selected disease (e.g., tuberculosis treatment) could also be measured.

Table 2 summarizes possible outcomes for each targeted disease. The ability to obtain data to measure each of these outcomes will be assessed before launching the intervention.

Country selection

Overarching considerations

The meeting recognized that the need for appropriate children’s medicines is universal. The countries being considered are heterogeneous with respect to language, political stability, security and health infrastructure. Given the constraints of time and money within the project, it is desirable that countries that participate are reasonably well described in terms of baseline measurements, have existing health systems operating in secure, politically stable environments, have a pool of local experts to carry out implementation and monitoring, and strong administrative support.

The tension between focusing on the countries with the most need that may be the most difficult in which to implement use of essential medicines, versus countries with more preparedness and a greater chance for success was discussed. Thus, the meeting supported the idea of partnering a highly prepared country with a country with less preparation in order to stimulate change in the less prepared setting.



The importance of being able to assess applicability across sites was considered. If the project aims to scale up an intervention across multiple sites within a country, the intervention will be costly. If the project pilots a demonstration project which can be evaluated to determine if an intervention is effective, the costs will be lower.

Africa

The key criteria which must be met in order to consider a country for the demonstration project were identified. Before the launch of the demonstration project, however, it will be necessary to follow up with additional organizational assessments in order to properly tailor the intervention. Multiple systematic reviews suggest that tailored interventions are more effective in producing behaviour change. However, there is a tension between designing the intervention before selecting the countries and gathering additional data to tailor the intervention once the countries have been selected.

The key criteria that were agreed were: political stability, capacity (e.g., existing child health programmes), identification of regional leadership, willingness of influential physicians and other leaders to participate, and availability of data to assess rational use. Based on these criteria, the following countries were grouped according to potential for launching demonstration projects.

- | | |
|------------------------|--|
| High potential: | Ghana, Kenya, Senegal, Uganda |
| Medium: | Cameroon, Eritrea, Ethiopia, Mali, Nigeria, Rwanda, Tanzania, Zambia |
| Low: | Chad, Congo, DRC, Liberia |

An August meeting of 8 African Anglophone countries is planned at which these countries will be reviewing their EMLs. This will be an opportunity to discuss the demonstration project with the participants. An additional meeting in late 2009 will be planned with a group of Francophone countries. A more in-depth assessment of the preparedness and readiness to participate of Ghana, Kenya, Senegal and Uganda may be needed. Although an in-depth demonstration project will be launched in a limited number of countries, it was recommended to provide all countries with a level of activity to promote rational use of medicines for children. This could include advocating for inclusion of children's essential medicines in the country's EML and achieving wider distribution of the Pocket Book of Hospital Care for Children.

India

Kris Weerasuriya, Regional Adviser, HSD/EDM, SEARO described progress on development of the project in India. A person has been potentially identified for possible recruitment to move the project forward in the five target states. Promoting the use of essential medicines is hindered by the complexity of the health care system in India. One challenge is that the regulation of medicines is not overseen by the Ministry of Health. Assessment and data collection are also a challenge in India. Implementation is complicated because health care delivery takes place in three sectors: public, private and informal. The focus of effort will be on creating EMLs that include children's medicines. Currently, the existence of EMLs is variable across states and may or may not be linked to procurement. Strategies for getting access to medicines may differ across states. Identifying similar entry points for an intervention across states is also difficult. These might range from the ministry of health to national rural health missions. Participants at the meeting suggested that the Indian Pediatric Association might have members interested in creating an interest group on medicines for children. The state chapters of this group could sponsor meetings to generate advocacy for children's essential medicines. Advocacy for children's formulations will also be difficult at the level of the national drug authority. Zinc may be an example of a medicine for which practitioners could create a demand for the manufacture and approval of appropriate products. An interesting project in India would be to survey generic manufacturers about their attitudes towards producing EML medicines. Another project could be to ask the Indian Pharmacist Association to conduct an inventory of pediatric formulations.

David Lee described Management Sciences for Health's experience in Rajasthan. A comprehensive pharmaceutical sector study led to a proposal to increase access to essential medicines by establishing a network of sustainable non-profit retail medicine outlets in public facilities. The need to work on multiple levels and stakeholders in parallel was noted, including working with the not-for-profit sector, professional societies, and donor organizations. He discussed successes and challenges in engaging state and national decision-makers to adopt and implement the proposed strategy. The meeting discussed how essential medicines should be branded as the "best" medicine and how opinion leaders are very important for elevating the status of essential drugs.

Future steps

The immediate next steps for the intervention portion of the project are:

- 1) Potentially discuss with Ghana, Kenya, Senegal, Uganda an assessment to obtain more detailed information on barriers to essential medicine use in children, health system infrastructure, data availability, willingness to participate, and to identify collaborators.
- 2) Hold meetings of potential African country participants to discuss potential for participation in pilot project or baseline level of activity to improve essential medicines use in children.
- 3) Draft protocol elements for intervention study and evaluation suitable to be conducted in two countries in Africa. This will include development and completion of a matrix for targeting the intervention according to 1) important conditions for which there is a relevant EML medicine, 2) steps in rational use of the essential medicines for the condition (identifying which steps are not being met), and 3) outcomes that can be measured. See Tables 1 and 2 for draft matrices.
- 4) Following country selection, conduct organizational assessment of district hospitals to identify barriers to use of essential medicines in order to target the intervention.

A number of additional activities were identified that will support the completion of the demonstration project:

- 1) Update the Pocket Book of Hospital Care for Children. Technical assistance will be provided by the International Child Health Review Collaboration, the Cochrane Collaboration and, subject to appropriate funding, by NICE.
- 2) Provide technical support and information to regulators to support the timely approval of quality medicines for children. EMEA committed to fostering this collaboration among country regulators. EMEA can provide technical support by sharing strategies for developing and managing new products, providing data and assessment, and providing training on regulatory evaluation.
- 3) Engage stakeholders. Short courses on rational use of medicines in children could be planned to engage international and local pediatric associations and international associations of pharmacists and pharmacologists.



- 4) Assess patient and health provider attitudes about age appropriate formulations. Sri Lanka has surveyed patients and pediatricians about this topic. The need to be aware of potential risks of solid dosage formulations (e.g., large pills and difficulty swallowing) and beliefs about medicines (e.g., taste of medicines if dispersible tablets are mixed with breast milk) was recognized.
- 5) Strengthen the supply system and procurement. Management Sciences for Health's USAID-supported Strengthening Pharmaceutical Systems (SPS) Programme works in the four countries to be visited and many of the others. There is potential for collaboration with SPS and other MSH programmes, such as the International Network for Rational Use of Drugs (INRUD).
- 6) Develop guidance for ethical issues related to children's participation in clinical trials. This work includes identifying and summarizing all ethics guidelines that exist in relation to children, as well as developing standards and building capacity for ethics committees. The difficulty in harmonizing approaches across numerous legal systems is well recognized.
- 7) Launch a series of national/regional workshops on better medicines for children to be held in collaboration with national pediatric Societies. The series could begin with a workshop at the International Congress of Pediatrics in Johannesburg, 2010.



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Table1:
Country assessment to identify barriers to use of essential medicines
Priority conditions by steps in rational use of EML medicines for the condition

Steps in Rational Use	Priority Condition with EML treatment		
	Pneumonia	Diarrhoea	Neonatal sepsis
EML including treatment exists			
Dosage form exists			
Dosage form available			
Medicine is registered			
Medicine is licensed for indication			
Medicine is procured			
Medicine available at reasonable cost			
Guideline including EML recommendation exists Recommendation included in Pocket Book			
Implementation strategy exists			
Cultural/social issues related to use of medicine			
Incentives/counter incentives (e.g., pharmaceutical industry marketing)			



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Table 2: Priority conditions by outcomes

Outcomes	Priority Condition with EML treatment		
	Pneumonia	Diarrhoea	Neonatal sepsis
EML medicine available in facility			
EML medicine on formulary			
EML medicine prescribed			
EML medicine administered to patient			
EML medicine administered in appropriate dose/duration			
Inappropriate medicine prescribed/administered			
Condition treated according to guideline			
Length of hospital stay			
Hospital readmission			
Resolution of symptoms			
Adverse events associated with medicine			
Mortality			
Cost of treatment			
Unintended effects of treatment			



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