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# contact

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## ACCESS TO MEDICINES: KEY TO MDGS ON CHILD HEALTH



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# ACCESS TO MEDICINES: KEY TO MDGS ON CHILD HEALTH

The 8 UN Millennium Development Goals (MDGs), adopted by 189 governments in the year 2000, target the improvement of health and economic conditions around the world. With MDG 4 on child health, these governments aim to reduce by two thirds, between 1990 and 2015, the under-five mortality rate. As the deadline approaches, we need to evaluate our progress so far. The UN reports that between 1990 and 2009, the number of children that died before their 5<sup>th</sup> birthday has reduced by almost one third. This is a great achievement but a long road lies ahead of us, while not much time remains. Only 9 of the 64 countries with high child mortality rates are on the right track to meet this MDG target.

The MDG on child health is inherently linked to the rights of the child, as declared by the UN and adopted by almost 200 countries worldwide. However, as is the case with so many rights and proclaimed equalities, we still see that some children are less equal than others. Some have a lesser chance at life than others, because they don't have access to essential medicines when they need them the most.

In this edition of *Contact* magazine, several authors talk about the main child-killer diseases, about what is being done to realize the MDGs on child health and on what should be done in the coming years.

When thinking of solutions to solve the problem of limited access to children's medicines, the first thing that comes to mind is more money is needed to bring medicines to the children who need them the most. In the West, children don't normally die from diarrhoea or pneumonia. So why do they die in developing countries, every day? Indeed that is a problem of availability and affordability in particular. But there is more to it than that. As you will read in this

edition, there is also the aspect of appropriate dosage and appropriate formulations, accurate diagnosis, having more clinical trials and knowledge of adverse drug reactions in children, correct prescribing, taking into account the unique physiology of children, among others. And then there is also prevention, through vaccinations and better living conditions.

Clearly, no country can do it on its own. And most certainly the countries with the highest child mortality, can not protect their children without outside help. But even though it looks like, and it is, a lot of work, we can not leave it all to the world leaders, the policy makers and the manufacturers and suppliers of pharmaceuticals. Everybody can contribute, even if only by advocating for the cause and raising awareness so that no one can continue to bury their head in the sand.

If anything, that is what the MDGs have done without failure: they have kept the issues that need to be addressed urgently top of mind. Thanks to the MDGs, those big injustices that perpetuate in developing countries, have remained - or at least resurfaced regularly - on the desks and in the minds of media, international organizations, NGOs and political leaders around the world. They have forced world leaders to admit to the problems and play their part.

We are happy to see that EPN and its members are also playing their part and a lot is being done to work towards the realization of the MDGs on child health. In the section *Experience* in this edition, you will read about Gertrude's Children's hospital who are confident that the programmes, the infrastructures and the interventions they have set up, will contribute to the global objective. Another EPN member, the health department of the Protestant church of Congo is actively involved in vac-

ination activities in the community. Of course many other members, not mentioned here, are working hard towards the same.

We also report on a unique initiative in DRC where radio messages are used to bring health information to the people. The MDGs have definitely made all of us take to action. Let us hope that in the next few years, the successes and the progress towards realization of these targets will happen at a faster pace as the sense of urgency increases.

In 2011, EPN celebrates 30 years of existence. Since the creation of the WCC's pharmaceutical programme in 1981, to the global network that we are now, EPN has been working to strengthen pharmaceutical services in church health systems. At this occasion we celebrate our work, work that contributes to the MDGs and work that goes beyond.

Elisabeth Goffin is the Communications Officer for the Ecumenical Pharmaceutical Network.



## Availability of medicines for children in the church health sector

In 2007, a study was undertaken by WHO in the capital cities of 14 countries in Africa, revealing relatively poor availability of medicines for children in both public and private facilities<sup>1</sup>. Following this, Ecumenical Pharmaceutical Network started in-depth studies on the availability of medicines for children in the church sector and the possible barriers to access.

Studies have so far been undertaken in Chad, Uganda and Kenya. They covered 171 facilities at all levels of care (Hospitals, Health Centres and Dispensaries) representing about 11% of the church-based care in these countries. Data was collected through face to face interviews and physical verification of the availability of the medicines. Availability varied across the 3 countries. In general, Kenya showed the highest availability on average (71%) and Chad the lowest (44%). Availability of certain selected formulations which should be found at the lowest levels of care is shown in the table. The relatively low availability of 1<sup>st</sup> line treatment for malaria (Artemisinin Combination Therapies) in all countries is striking.

Medicine	Chad	Kenya	Uganda
Oral rehydration salts	90%	92%	98%
Cotrimoxazole 200 + 40mg/5ml	39%	95%	57%
Artemether/Lumefantrine (20 + 120mg)	Not stocked <sup>2</sup>	78%	57%
Benzyl penicillin injection 1MU	14%	78%	98%
Zinc tablets dispersible 20mg	32%	56%	64%

Investigations into some of the factors that might impact on availability revealed that

- Standard lists of medicines were available in 38% of Chadian facilities, 69% of the Kenyan ones and in only 32% of the Uganda ones.
- General clinical guidelines were available in 87% (137 of 157) of the facilities but only 35% (59 of 168) of the facilities in the 3 countries had guidelines specifically for management of childhood illnesses.
- Medicine selection is done by individuals, not committees, in at least 60% of the facilities.
- Only 9% (5 of 55) of hospitals employed a pharmacist.
- 60% of the facilities (103 of 171) reported facing occasions where they were unable to buy medicines for children due mainly to lack of funds.

The situation in all 3 countries warrants action to increase availability especially of life-saving medicines such as ACTs and Zinc tablets. Interventions are required from the highest policy making level on such issues as inclusion in national essential medicines lists right through to the facility level where implementation of standard operating procedures, rational selection and prioritization of medicines for children can make a significant difference.

1. Robertson, J et al. 2009. What essential medicines for children are on the shelf? In *Bull World Health Organ*, 87, 231-237.  
2. The first line ACT in use is Artesunate and Amodiaquine which was available in 16% of the facilities.

The financial support from Wemos, United Church of Canada and ICCO/ Kerk in Actie and its partners for these studies is acknowledged.

# CHILDREN'S MEDICINES: INTERNATIONAL EFFORTS AND CHALLENGES

*In 2009, 50 years after the UN's first Declaration on the Rights of the Child, 194 countries have ratified the Convention on the Rights of the Child that was adopted by the United Nations General Assembly in 1989. Some international efforts and pharmaceutical innovations have led to small and big successes. But we are not there yet.*

With regard to health, the convention on the rights of the child states that every child has the inherent right to life and the State has an obligation to ensure the child's survival and development, that a child has the right to the highest standard of health and medical care attainable and States shall strive to see that no child is deprived of access to health care services (article 6 and 24 respectively)<sup>1</sup>. It is therefore not acceptable that year after year almost 9 million children die before they reach 5 years of age<sup>2</sup>. Around 25,000 children each day. Yesterday. Today. Even tomorrow?

## The main child killer-diseases

Pneumonia, diarrhoea, malaria and AIDS accounted for 43% of all deaths in children under 5 worldwide in 2008<sup>3</sup>. Tuberculosis also plays a big part in under 5 mortality. Most of these diseases are preventable and treatable in the community, by trained community health workers in the dispensaries. The need to refocus attention on pneumonia and diarrhoea as leading killers of children is urgent.

### 1. Pneumonia

Pneumonia is the leading cause of death in children worldwide, killing an estimated 1.6 million<sup>4</sup> children every year – more than AIDS, malaria and tuberculosis combined. Vaccination at an early age for pneumococcal disease, which is one of the most common forms of pneumonia, has proved successful at reducing morbidity and mortality. The global roll-out of pneumococcal conjugate vaccine is very welcome and it is hoped that countries all over the developing world will make it part of routine EPI. Even when bacterial pneumonia develops, it can commonly be treated with simple medi-

cines: Amoxicillin for mild or moderate pneumonia, Oxygen/Ampicillin + Gentamycin or Ceftriaxone for severe conditions. But less than 20% of children with pneumonia receive the antibiotics they need.

### 2. Diarrhoea

Diarrhoea is the second leading cause of death in children under 5 years old. The disease kills about 1.5 million<sup>5</sup> children every year, most of them under 2 years old. In many cases, diarrhoea is preventable if access to clean water is secured. It is treatable if simple, inexpensive medicines are used: oral rehydration salt (costs a few cents per treatment) and Zinc supplements which can reduce the duration of a diarrhoea episode by 25% and are associated with a 30% reduction in stool volume.

### 3. Malaria

Malaria kills around 800,000 children every year. Combined efforts and new effective programmes reduced the number of malaria cases by more than 50% in 43 countries over the past decade<sup>6</sup>. Children's medicines recommended in most African countries are Artemisinin Combined Therapy (ACT) for uncomplicated malaria and Artesunate injection or rectal dosage form or Quinine injection for severe or pre-referral malaria.

In many countries ACTs are available almost free of charge via a number of global financing mechanisms such as the Global Fund and PEPFAR. Unfortunately a great number of children and adults are not receiving them. Often Artemisinin is used without the combination of other effective substances, thus supporting resistance development. A new action plan released 12<sup>th</sup> of January 2011 by WHO and the

Roll Back Malaria partnership (RBM) is focusing on proper use of ACT therapy. Quick action is essential. If these treatments fail, many countries will have absolutely nothing to fall back on.

### 4. HIV and AIDS

The estimated number of children living with HIV globally increased to 2.5 million in 2009. During 2009, only 356,400 children, or 28% of the 1,2 million in need in Southern African countries received treatment (adults 35%).<sup>7</sup> The most common fixed dose combination (FDC) regime is still Lamivudine/Stavudine/Nevirapine. The amount needed to treat one child/year decreases to 53 USD if dispersible tabs are taken. If three single suspensions are chosen, the price is threefold (and compliance less). Because of side effects, Stavudine should be replaced. WHO recommends Zidovudine (ZDV) instead. But this increases the cost to 158 USD (Fixed dose dispersible tabs treatment per year).<sup>8</sup>

"Treatment 2.0"<sup>9</sup> is a new approach that could bring down treatment costs, make treatment regimens simpler and smarter, reduce the burden on health systems, and improve the quality of life for people living with HIV and their families. Modeling suggests that, compared with current treatment approaches, Treatment 2.0 could avert an additional 10 million deaths by 2025. UNAIDS calls for the development of new pharmaceutical compounds that will lead to a "smarter, better pill" that is less toxic, longer-acting and easier to use.

### 5. Tuberculosis

The extent of childhood tuberculosis is unknown and is estimated to constitute about 10% of all incident cases. Among many challenges to estimate the burden of TB in children, the following could be listed: the difficulty in establishing a definitive diagnosis (childhood TB rarely presents as smear positive), the presence of extra-pulmonary disease (requiring specialist consultation), and the low public health priority.

All dosages for the 4 TB-medicines currently existing, have recently been increased, based on new scientific knowledge. For better compliance, the combination therapy should be taken in one pill (Fixed dose combination/FDC). But for children, these FDCs do not exist. Today the following regimes are advised for TB treatment in children from 5 to 30 kg:

- Isoniacid 150 mg + Pyrazinamid 400 mg + Rifampicine 250 mg
- Isoniacid 150 mg + Pyrazinamid 400 mg + Rifampicine 250 mg + Ethambutol 250 mg

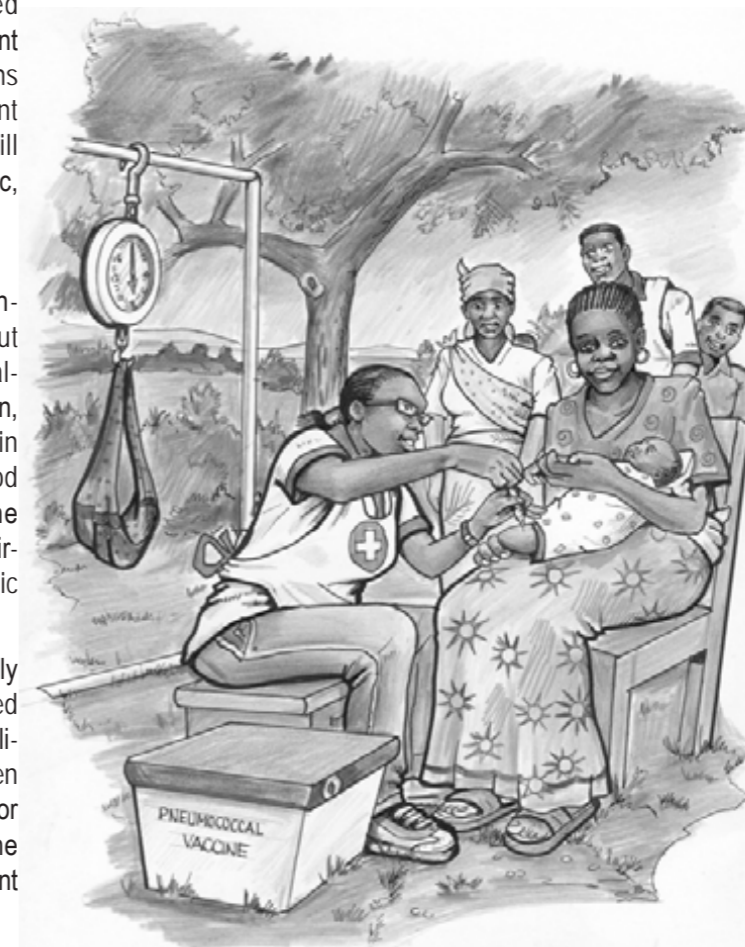
## International efforts

The UN Millennium Development goals (MDGs) adopted in 2000 by the UN Millennium summit are the world's targets for improving various social and economic conditions for people worldwide, especially those in poor countries, by 2015. MDG 4 (child mortality), 5 (maternal health) and 6 (HIV/AIDS) focus directly or indirectly on children's health and access to medicines. Extreme efforts have led to significant successes in the fight against HIV and AIDS, Malaria and TB. However more efforts are needed because the goals set are still far. Although successes have been realized, there are still big discrepancies between children living in very poor conditions and other - more lucky - children in the same country or region.

## WHO campaign

In 2007, the WHO launched its global campaign 'make medicines child size', to raise awareness and accelerate action to address

*Health workers and caregivers require products that are easy to use, and children require medicines that address their special needs.*



the need for improved availability and access to safe child-specific medicines for all children under 12. At present, many medicines are not developed for children or available in suitable dosage forms; and when they are there, they are not reaching the children who need them most. The campaign is an effort to change that reality. Several concrete projects have been launched together with important stakeholders like UNICEF, NGOs, academia, industry and other experts.

#### List of Essential Medicines for children

The WHO Essential Medicines list was developed and updated - specifically for children - in 2009, and was followed in 2010 by the first ever WHO Model Formulary for Children that provides information on how to use over 240 essential medicines for treating illness and disease in children. Indeed, children cannot simply be thought of as 'small adults'. Rapidly changing physiology and co-morbid conditions such as malnutrition mean that what a medicine does in the body and what the body does with

the medicine changes, especially in the first two years of age.

#### International challenges

Continued lobbying and advocacy efforts of several civil society organizations have led to new medicines for children being introduced, especially for HIV and AIDS, Malaria and a few for TB. However, a long list of missing medicines and dosages is still demanded by expert committees.

#### Lack of suitable dosage forms

##### Crushing of tablets

This is not recommended because the dosage may not be accurate, underdosage will minimize effectiveness and can lead to the development of resistance, over-dosage can create strong side effects such as stomach ulcers.

##### Liquids

The liquid dosage form of certain medicines may be an essential dosage form of a medicine for a child, particularly in children unable to swallow, or when titration of dose is needed.



However, the use of liquid forms can be problematic. They should be of appropriate strength and acceptable palatability to the child. Cost is often higher because due to the volumes, logistical infrastructure (e.g. suitable refrigeration, appropriate packaging) is required. In addition to this, there is the problem of excipients, where substances such as alcohol, sugar, colorings, preservatives, propylene and ethylene glycol may be added to liquid preparations of medicines resulting in a wide range of secondary health risks to the child. Syrups often contain a high percentage of sugar. This is problematic because of diabetes, but also in terms of developing fungi if the bottle has been opened and not stored properly for some days or weeks outside a refrigerator, a realistic scenario in developing countries.

#### Dispersible tablets

These tablets can be dispersed in water, milk or breast milk and could potentially be used in very young children (0–6 months). Examples of existing dispersible tablet products suggest that they can be more affordable than standard liquid dosage forms. According to the WHO, dispersible tablets also decreased stigma through removal of high volume and heavy syrups.

The WHO recommends that wherever possible, medicines for children be provided as flexible, solid oral dosage forms such as dispersible tablets and granules in sachets of adjustable size and strength.

#### Medicines are not reaching the children who need them the most

New medicines have to reach health institutions and paediatric patients as quickly as possible but sometimes this takes years. Improvement of compliance, cost reduction, increase of

effectiveness is delayed, often only due to long bureaucratic processes.

The main hitches are:

- Lack of information dissemination
- Slow response e.g. of technical working groups
- National recommendations/guidelines are not quickly updated
- Procurement rules are slow to change
- Policy-making "machinery" moves on its own timeline, independent of new breakthroughs
- Availability

WHO/UNICEF recently researched sources and prices for 240 children medicines in 612 different formulations<sup>10</sup>. For only 75% of the formulations, manufactures could be identified. This survey also proved that paediatric oral dosage forms such as dispersible tablets are generally cheaper than liquid oral dosage forms or powders for oral suspension.

UN Secretary General Ban Ki Moon said: "Meeting the goals is everyone's business ... Billions of people are looking to the international community to realize the great vision embodied in the Millennium Declaration. Let us keep that promise."

It goes without saying that immediate action is needed to take advantage of every opportunity to increase the availability of medicines for children and to improve children's access to those medicines. Each day delayed means hundreds of dying children.

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# PRESCRIBING MEDICINES FOR CHILDREN.

## A DIFFERENT APPROACH IS NEEDED

*It was only at the end of the 20<sup>th</sup> century that the medical society recognized that children are different to adults. Our knowledge of therapeutics in children is languishing, while many effects of our current use of drugs are the consequence of mistakes affecting children (e.g. thalidomide). It is crucial to understand the uniqueness of children and their metabolism and the importance of taking these factors into account so as to avoid medical errors in children.*

*The use of medicines in infants and children presents a unique set of challenges for the prescriber.*

In daily practice, it is difficult to find registered medicines for children, because about 70% of the medicines prescribed in children are not studied, used off-label or unlicensed in this age group<sup>1</sup>. Clinical trials have usually been performed in adults, and then in daily practice dosages are adjusted for children without proper studies in that age group. Factors that complicate finding the correct dosage for children include the heterogeneity between different age groups in the developmental stages of the organs influencing the absorption, distribution, metabolism, and excretion as well as differences in body composition during growth<sup>2,3</sup>. The use of medicines in infants and children therefore presents a unique set of challenges for the prescriber.

### Absorption

The gastrointestinal tract, particularly the stomach, undergoes significant changes from birth until around 3 years of age. Before then, the stomach has low levels of acid; and acid-labile medicines such as penicillin, show enhanced absorption. On the other hand, this depressed level of acidity may result in reduced absorption of weak acids such as phenobarbitone, phenytoin and rifampicin.

Numerous factors, including body composition, plasma-protein binding and the blood-brain barrier influence medicine distribution in the various paediatric age groups.

### Body composition

Total body water and fat composition alter significantly during the transition from birth to adult life. Total body water as a percentage of body weight is approximately 80% at birth, 65% at 12 months and 60% for a young adult. On the other hand, fat content as a percentage of body weight varies with age, being about 3% in premature infants, 12% in full-term neonates, 30% at 1 year of age and about 18% in the average adult.

### Plasma protein binding

Medicine-protein binding is diminished in neonates due to a lower concentration of plasma proteins, particularly albumin, and the lower drug-binding capacity of foetal albumin. This may lead to an increase in the fraction of the unbound, pharmacologically active medicine in the plasma. There may also be competition between endogenous substances, especially free fatty acids and bilirubin, and medicines for albumin-binding sites.

### Blood-brain barrier

The blood-brain barrier is a permeability barrier between the blood circulation and the brain cells bathed in cerebrospinal fluid (CSF). The blood-brain barrier is functionally incomplete in the neonate, and certain substances show increased penetration into the brain. One of the most important factors which determine the rate of transport of medicines across the blood-brain barrier is their lipid solubility.



This gives rise to increased brain uptake of barbiturates and morphine in infants. As meningitis is a relatively common problem in paediatric practice, the extent to which antimicrobial agents penetrate the CSF is an important consideration. Although some agents penetrate poorly under normal circumstances, in the presence of meningeal inflammation, penetration may be considerably enhanced, so that adequate CSF medicine concentrations are attained. Medicines in this category include penicillins, cephalosporins, rifampicin and vancomycin. Medicines which penetrate well even in the absence of meningeal inflammation include chloramphenicol and the combination sulfamethoxazole and trimethoprim.

### Metabolism

The various metabolic reactions that occur in the mature liver are not fully developed at birth. During the first 15 days of life in premature and full-term babies, decreased metabolism is evident, but this is followed by a dramatic increase. Between 1 and 10 years of age, hepatic microsomal oxidation is more rapid than in adults. Therefore phenobarbital, phenytoin and theophylline have shorter half-lives in children than in adults.

Children have a large reserve of hepatic metabolic capacity and modification of the

choice and dosage of medicines is usually unnecessary even in apparently severe liver disease. However, special consideration is required in the following situations:

- liver failure characterised by severe derangement of liver enzymes and profound jaundice; the use of sedative medicines, opioids, and medicines such as diuretics and amphotericin which produce hypokalaemia, may precipitate hepatic encephalopathy;
- impaired coagulation, which can affect response to oral anticoagulants;
- in cholestatic jaundice, elimination may be impaired of medicines such as fusidic acid and rifampicin which are excreted in the bile;
- in hypoproteinaemia, the effect of highly protein-bound medicines such as phenytoin, prednisolone, warfarin, and benzodiazepines may be increased;
- use of hepatotoxic medicines is more likely to cause toxicity in children with liver disease; such medicines should be avoided if possible;
- in neonates, particularly preterm neonates, and also in infants, metabolic pathways may differ from older children and adults because liver enzyme pathways may be immature.



## Excretion

Medicine excretion from the kidney is undeveloped in newborns, below 50% of the adult level up to the age of two to three months. Therefore, the effective dose range and toxic dose range of medicines is closer in such young subjects, but reaches adult level by the age of 1 year. The glomerular filtration rate is low in newborns, and rapidly increases to up to 200% of that in adults in 1 year, and then gradually decreases to the adult level<sup>4</sup>.

## Paediatric medicine dosing

The approach to paediatric medicine dosing needs to be based on the physiological characteristics of the child and the pharmacokinetic parameters of the medicine.

The information about over-dosage and under-dosage of medication in children is associated with the paediatric pharmacovigilance. Whereas severe adverse drug reactions (ADR) from over-dosage of medicines occur in adults and are reported in national pharmacovigilance systems, ADR reports from over-dosage in children seem to receive less attention worldwide, and particularly in developing countries.

The lack of reliable data in the paediatric population is associated with specific problems, including limited availability of safety data due to the lack of clinical trials in the paediatric population and the lack of pharmacokinetics data or dose-finding studies.

During the preparation of this article the *PubMed* database was searched and more than 180 sources of information were analyzed. The result shows that the majority of ADRs reported in young children were reported for vaccines and much less for medicines.

A few examples give the general picture of the situation in ADR caused by over-dosage of medicines in children.

In 2001, according to a US surveillance study, ADRs were the cause of 244,000 outpatient visits of children under 15 years of age. During an active surveillance of 63 US hospitals, the study of NEISS-CADES (National Electronic Surveillance System-Cooperative Adverse Event Surveillance project) reported that among the above mentioned age group, the incidence of ADRs was equal to 2 out of 1000 people<sup>5</sup>. Younger children are at greatest risk. Considering this, half of registered ADRs occur in children younger than 4 years of age and the risk of ADRs among children under 5 years of age is 4 times higher than for those who attend school (5.8/1000 compared to 1.1/1000). For most medicines it is impossible to fully investigate rare adverse reactions prior to authorization, as it is necessary to expose a large number of subjects to a medicinal product to elicit a reaction which occurs with a low probability in the target populations.

Among the major factors that contribute to the occurrence of adverse reactions in children, the off-label use, or unlicensed or unauthorized use in children catches the eye. The limited availability of medicines specifically designed for the paediatric age is a reality which many generations of paediatricians have learned to deal with. It is a reality which the practitioner has to face every time he or she is choosing a medicine grouped with some evidence of efficacy and safety only in adults and not in younger patients. Less than 15% of all medicines currently marketed and less than half of

those specifically intended for children are used on the basis of clinical trials which demonstrate the risk-benefit balance in children<sup>6</sup>.

The risks resulting from the administration of a medicine that has not been tested and proven in the paediatric population may therefore be overdose (increase in adverse reactions), ineffectiveness (for dosing) or use of an inappropriate formulation.

A high percentage of the visits to the emergency room for adverse reactions, after an ingestion of an overdose of medication, has been registered. The main causes of overdose are: accidental ingestion of the medicine arising from lack of adult control or defective inadequate packaging (for example, the lack of safety lock systems), and error in the preparation/dilution of a more concentrated medicine.

A study that was conducted in the Phoenix Children's Hospital, Phoenix, AZ, USA<sup>7</sup> shows that during a 2-year period from 2004 to 2005, emergency departments treated over 1,500 children under the age of 2 years for adverse events related to over-the-counter (OTC) cough and cold medication use. These incidents included 3 infant deaths.

Another study conducted in the US shows the role of parents in over-dosing of medicines in children: parents of 120 children aged

between 6 weeks and 5 years, attending child health clinics answered a questionnaire on their understanding of vitamins<sup>8</sup>. Of fifty four children (45%) who were taking vitamins; 12 (22%) were given the wrong dose. Only 19 parents (35%) knew when to stop supplements and 25 (46%) did not realise over-dosage was potentially harmful, while their children were receiving preparations that contain vitamins A and D, for which harmful over-dosage has been well documented. Only six children (11%) were receiving professional supervision.

## Lessons learnt?

The prescribing of medicines in newborns and children requires the knowledge of physiological variances of metabolism between children and adults. There is a need for a development training programme for public health specialists with a focus on aspects of children's physiology. Studies to examine pharmacokinetics of medicines in children are needed. The paediatric pharmacovigilance should become a priority area as soon as possible.

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*Half of registered adverse drug reactions occur in children younger than 4 years of age.*

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# CHILDHOOD PNEUMONIA: AGE IS CRUCIAL

*Pneumonia and other lower respiratory tract infections are the leading cause of death worldwide. Approximately 150 million new cases of pneumonia occur annually among children younger than 5 years worldwide, accounting for approximately 10-20 million hospitalizations<sup>1</sup>.*

Pneumonia is an infection of one or both lungs which is usually caused by bacteria, viruses, or fungi. The WHO Child Health Epidemiology Reference Group estimated the median global incidence of clinical pneumonia to be 0.28 episodes per child per year. This equates to an annual incidence of 150.7 million new cases, of which 11 to 20 million (7-13%) are severe enough to require hospital admission. Of all episodes of clinical pneumonia in young children worldwide, 95% occur in developing countries<sup>1</sup>.

## Age and symptoms

In children, the age of the patient and any other underlying illnesses can affect the presentation of the condition.

There are many symptoms of pneumonia, and some of them, like a cough or a sore throat, are associated with many other common infections. Often, people get pneumonia after they've had an upper respiratory tract infection like a cold. Symptoms of pneumonia can include: fever, chills, cough, unusually rapid breathing, wheezing, difficulty breathing, chest or abdominal pain, loss of appetite, exhaustion, vomiting.

## Diagnosis and treatment

Full blood count helps in differentiating between the viral and bacterial causes of pneumonia. Chest x-ray is one of the imaging tests that help in the diagnosis of pneumonia. The character of the findings in the x-ray can assist in predicting the organism causing the inflammation. Culture of upper respiratory secretions

or serologic tests are relatively accurate for the diagnosis of viral and mycoplasmal lower respiratory disease.

The appropriate treatment plan depends on the age of the child, the degree of illness, complications and knowledge of the infectious agents or of the agent that is likely causing the pneumonia. Most cases of pneumonia in healthy children can be managed on an out-patient basis.

Although viruses cause most community acquired pneumonia in young children, in most situations, experts recommend empirical treatment for the most probable treatable causes. Treatment recommendations are based on the age of the child, severity of the pneumonia and antimicrobial activity of agents against the expected pathogens that cause pneumonia at different ages.

There are however some factors suggesting the need for hospitalization:

- Age  $\leq$  6 months
- Immunocompromised state
- Toxic appearance
- Sever respiratory distress
- Requirement for supplemental oxygen
- Dehydration
- Vomiting
- No response to appropriate oral antibiotic therapy
- Noncompliant parent

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# GERTRUDE'S CHILDREN'S HOSPITAL: ON A MISSION TO EXCEED MDG 4

*Gertrude's Children's hospital in Nairobi, with its affiliated clinics, attends to an average of 700 patients daily in its out-patient setting; this translates to more than 255,000 children per year. As the only paediatric health care institution in the region, Gertrude's aims to offer equitable access, safe and affordable medicines to all the children seeking health care.*

Over the years the hospital has adopted a Rational Medicine Prescribing programme that has seen the average cost of out-patient prescription fall by no less than 33% between 2008 and 2010. This programme involves audits on the use of medicines such as antibiotic injectables, oral antibiotics, oral anti-histamines and the number of medicines per prescription. The results of the audits are discussed in relation to best practice with all prescribers and recommendations for rational prescribing are made. A notable product of these audits and discussions are the Gertrude's Paediatric Standard Treatment Guidelines (available free of charge on the hospital website and in hospital branches).

As part of its social responsibility, Gertrude's runs two outreach clinics in Nairobi, in the Mathare slum and in the Githogoro slum area. Both clinics provide HIV and AIDS comprehensive care services, baby clinics including immunization and provide health services to both children and mothers free of charge. The clinics attend to an average of 30-50 patients daily. Gertrude's hospital-based Comprehensive Care Clinic provides both ARVs and medicines for opportunistic infections at no cost to patients. The clinic currently has enrolled 1000 children, adolescents and their guardians.

## Extemporaneous compounding

One major challenge with medicines for paediatric use is the lack of suitable formulations. Gertrude's has an established extemporaneous unit with a formulary for several medicines. This unit prepares medicine formulations on a needs basis.

This is especially useful where the patient's dosing requirement cannot be met with available formulations so that a much lower

concentration must be given per unit dose, or where the medicine is unpalatable in its original form or if it must be given in liquid form e.g. in tube feeding.

In the year 2010, Gertrude's prepared 1800 extemporaneous preparations. More than half of these preparations were for treatment and long term management of:

1. Cardiovascular conditions such as pulmonary hypertension, patent duct arteriosus (PDA).
2. Gastro-oesophageal reflux disease (GERD), a major cause of aspiration pneumonia in infants and children with cerebral palsy.
3. Nutritional preparations used to manage severe malnutrition such as Resomal, F100, and F75 milk formulae.

## Patient Safety

In relation to the Millennium development Goal on the reduction of child morbidity and mortality, Gertrude's has an enhanced patient safety programme. As a result, errors have been prevented through interventions, process reviews and system changes. The programme has seen an increase in awareness of risk factors amongst staff, matched with an increase in reporting of interventions on potential errors.

It is our belief that with the above in place and other interventions yet to be fully implemented, including regular medicine use evaluations and research, we will be able to exceed the 4<sup>th</sup> Millennium Development Goal target by reducing child mortality to a minimum, as well as increasing access to medicines for children.

*Dr Berlinda Ng'ang'a is Chief Pharmacist at the Gertrude's Children's Hospital in Nairobi, Kenya.*

# CHILDREN'S HEALTH IN CONFLICT ZONES. THE CHALLENGE OF REACHING PEOPLE CAN BE OVERCOME BY RADIO

*Government hospitals and clinics in the northeast Democratic Republic of Congo ("DRC") are given financial assistance by various international donor institutions. But still there is a lack in initiative to help rural children. It is well known that children are sicker in villages where illiteracy is greatest. Radio broadcasted health messages can help overcome the challenge of reaching people in rural areas.*

Recognized barriers to good medical care for children in the DRC are single mother-figures for large groups of orphaned children, siblings taking on the role of parents, HIV and AIDS, illiteracy in parents and caretakers, and the general discord created by intermittent national conflict. Knowing that health care infra-structures, as well as current local knowledge, were inadequate to meet the needs of the growing population, radio broadcasted weekly health messages were used in 2010 to directly instruct caregivers on how to improve their own health and that of their children. The objective was to empower people to care for themselves.

Radio broadcasted health messages better address questions about health issues than other methods as there is time to explain the natural history of the illness, the consequences of delayed treatment and other illness aspects because people are listening quietly to the information, usually in their homes in the evening. In a busy clinic setting there is not enough time for lengthy discussions to convince a person of the risks and benefits they face. Also, where an audience is mostly illiterate or semi-illiterate, radio broadcasts reach a wider audience.

In a rural village of 500 people, for example, there may be only one or two radios in the entire village. Yet a few people will listen to

that weekly health message and then share the information with others. By September 2010 three men and four women had formed a "Listening Club" in one such village. The radio broadcasting team that visited found that the whole village was motivated to seek better health. Why was radio-broadcasting so successful?

The inspiration for the radio-broadcasts was a similar local radio programme that successfully educated people in cattle care and basic veterinary skills. The results of that programme were profound: individual owners and herdsman began to use the recommended medicines and vaccines on their cattle and their herds prospered. Seeing it work at the village level, a local Christian organization, Association des Chrétiens pour la Lutte contre le SIDA (ACL/SIDA)<sup>1</sup>, decided to use the same approach for children's health and in so doing hurdled several barriers<sup>2</sup>.

**Perceived Action Efficacy:**  
*Can I overcome the disease? Is it easy to do?*

A benefit of the radio health messages is that the illnesses being discussed were not ones that only children experienced. Adults, for years, were suffering the consequences of treatable chronic illnesses, not realizing that their lack of energy and body aches were



*Children caring for children*

directly related. After hearing the radio messages, adults sought treatment, greatly improved their own health and then were motivated to get their children treated as well, since they were convinced of the value of the medication. So convincing the population of the effectiveness of the treatment is pivotal to improving the health of a person, whether adult or child. An adult must be satisfied with the cure before they will give it to a child; children benefit secondarily. Notably, once cured themselves, a parent is willing to spend the necessary money to buy a cure for each child in the family as well.

**Cues for Action:**  
*Can I remember when/how to do the action? Can I remember the steps involved?*

Another barrier to health care for children is that a parent may learn of good, necessary health care but not act on it right away or forget to do it. If an action requires several steps, then a person might hesitate, either due to lack of confidence or not knowing how to carry out all the needed steps. The weekly radio broadcasts address this barrier by repeating a summary of the key ideas at the end of each message and again in the following weeks, but it also gives a mobile phone number where people can call in their medical questions and concerns.

Moreover they tell people where to go to get the needed help in their area via a network of a local clinic/hospital, counselling office or participatory pharmacy that has been instructed ahead of time as to the treatment protocols.

**Perceived Severity:**  
*Is the disease/problem serious?*

Ignorance about the severity of the disease or problem leads to lack of action, specifically the action of seeking help. The radio health messages explain the consequences of the illness in the body, even asymptomatic or hidden inflammatory destruction, so as to motivate the people to seek medical care. People know that malaria, diarrhoea, pneumonia and typhoid fever are serious illnesses but child health remains poor because the chronic conditions of anaemia, worm-burden and poor nutrition are not seen as serious conditions needing care. The broadcast has helped people understand that these conditions could have severe consequences and need to be addressed.

**Perceived Social Acceptability:**  
*Do those who are important to me approve of the behaviour?*

Once a group of people in a village or a population group has experienced the benefits of the treatment, then another barrier to health

*The radio messages serve to inform the population of benefits and availability of certain medicines, as well as where to go to get them.*



care is removed: perceived social acceptability. Since it is often a group that hears the suggestion together by listening to the radio message, seeking medical treatment has a higher chance of being socially acceptable. In a domino effect, the group sees the benefit to those first treated and so approves that the treatment be used by others, including children.

**Perception of Divine Will:**  
*Is it God's (or the gods') will that I prevent or overcome the disease?*

The radio messages explain physical (not spiritual) causes of illness. In one instance, a radio message about chronic gastritis touched the lives of people who thought they had been spiritually poisoned by an enemy. In viewing the condition only from a spiritual dimension, they were missing out on the opportunity to regain their health. By broadcasting the health information directly into the households of these people, they were able to get treatment for family members known to have the same symptoms. This outweighs the odds of waiting for a health practitioner to discover the people that need health care. They also did not need to waste time and money seeking care from

a local witchdoctor, as they understood there was a physical condition that could be treated with affordable medication. Many of the witchdoctors' treatments are very toxic to people's bodies so avoiding consultations there is in the best interests of the ill person who is already physically vulnerable. Because ACL/SIDA is a known Christian organization and they incorporate spiritual messages into their broadcast to help encourage and motivate listeners to better action, people are satisfied that their spiritual concerns have also been considered. Some of the mystery and fear of evil powers are removed as people understand what is happening to their body from a different perspective. It frees them from feelings of oppression, fear, and helplessness.

**Positive and Negative Attributes of the Action:**  
*What are the effects of the behaviour?*

The proven benefits of anti-retroviral use in pregnant women in decreasing the risk of having HIV infected newborns have been around for many years. The medications are now readily available in many cities throughout

Africa but many people remain unaware of the service. The radio messages serve to inform the population of benefits and availability of certain medicines, as well as where to go to get them. As a result, many children have been born to infected mothers, free of the HIV virus. With information provided by the broadcasts, the population is re-connecting with the government health care infrastructure where they can then get more help.

As the health care infrastructure faces a rising population of patients and inadequate numbers of health care professionals to care for the illnesses, it is important to use modern media infrastructure to empower and motivate the people to promote health and prevent disease for themselves and their children.

The radio-broadcasted health messages that continue in the northeast Democratic Republic of Congo have demonstrably overcome many barriers. Furthermore, the radio messages have brought not just information but encouragement, self-empowerment, motivation, direction and above all hope.

Besides the weekly radio messages, the faith-based organization broadcasting the radio health messages sometimes provides literacy materials when visiting villages so that more adults and young adults, whose education suffered during the war years, can begin to read. Literate caregivers are better equipped to provide needed health care to their children, especially the proper use of medications. Many research studies have shown that children improve academically when their chronic anaemia, schistosomiasis and worm infections are treated. So it is not just physical well-being that is the goal, but also the improved academic abilities that can result.



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**Notes**

1. ACL/SIDA is a small grassroots initiative that started in Bukavu, DRC and branched out into northeastern DRC by using the radio messages with first one radio station and later another two stations to include more listeners.
2. An organization called Food for the Hungry has published a manual, written in December 2004, called "Barrier Analysis Facilitator's Guide: A Tool for Improving Behavior Change Communication in Child Survival and Community Development Programs." The manual contains a helpful list of eight barriers to behaviour change, which can be found in Annex 12: Description of Determinants of Behavior Change. <http://www.fh.org/> and <http://barrieranalysis.fhi.net/>

# BETTER MEDICINES FOR CHILDREN SAVE LIVES

*Medicines for children are often unavailable and unaffordable in countries, yet many lives could be saved with access to simple and affordable medicines. The World Health Organization is working to help improve access to and use of the right medicines for children.*

Diseases can affect children differently than adults. Furthermore, children do not respond to medicines in the same way. Yet, many medicines are only available in adult dosage forms. To complicate matters, variations exist between children of different ages, weights and physical conditions.

Many medicines have only been studied in adults, which leads to 'off-label' use in children. This means that medicines are given to children without evidence of their effectiveness or data on their safety. Taking the wrong medicine can cause harm and waste resources.

Children's medicines need to be in a format that is palatable and easy to take. Small children have difficulty swallowing big tablets, whereas flexible oral dosage forms, such as dispersible tablets, are much easier. Some treatments require children to swallow many tablets a day. Current anti-tuberculosis treatment for a 15kg child for example may require 5 tablets and 3 dispersible tablets a day over a 2 month period during the intensive phase of treatment.

## Life or death

Even when a medicine is available in the right dose and the right formulation, the medicine is not always procured or accessible in countries.

Accounts from the largest teaching hospital in Cuttack, Orissa – an eastern Indian state with a population of almost 37 million people – illustrate the impact of the lack of access to essential medicines for children. Recently, a man appeared at the hospital emergency unit at 10 pm with his seven-year-old son who was convulsing uncontrollably in his arms. The

father had carried the boy, walking from a distant village following a referral from the local doctor. The medicine required to treat the boy's convulsions, injectable diazepam, a low-cost medicine, was out of stock at the hospital. After a futile attempt to purchase the medicine at the private pharmacy – long shut – he returned to find his son dead.

This story is not an isolated case. A recent survey conducted by WHO in Orissa, found that of the 34 most essential medicines for children, government hospitals and health centres had only 6, while private hospitals and pharmacies had on average 13.

Even when medicines are available at a public health care facility cost-free, patients are still often directed to a private pharmacy. This was revealed during the WHO sponsored survey undertaken by Dr Trupti Swain, Associate Professor of Pharmacology at the SCB Medical College Cuttack, Orissa.

The results from the survey suggest that corruption is rife, with some doctors receiving payments from pharmacists. When a prescribed medicine is out of stock, the pharmacist may substitute it for something entirely unsuitable – whatever is on hand. In the meantime, the patient believes that the medicine is equally suited to their treatment.

Dr Swain says many patients are illiterate and place trust in their pharmacist. "There is also a belief that medicine supplied by the government is poor quality. The result is catastrophic: unbeknown to their doctor, patients begin a course of unprescribed medicines for which they have over-paid."

Fellow colleague Doctor Gitanjali Batmanabane says over-the-counter pharmaceuticals cost at least twice the price of medicines that government hospitals can source directly from the manufacturer.

"Beyond that however, children's formulations are expensive. This in itself deters public health facilities from stockpiling medicines, specifically suited for children. Instead, doctors prescribe adult formulations for children and ask parents to break a tablet into several pieces, sometimes up to ten portions. What is more troubling is that in many poor households, an elder sibling is entrusted with the task of administering medicine, because the mother is out working."

## A resolution in action

India is one of several countries now implementing the World Health Assembly resolution on Better Medicines for Children and is laying foundations for change. Initiatives such as improving registration procedures and broadening the list of essential medicines available for children at government hospitals are becoming a priority.

Since the World Health Assembly approved a resolution in 2007 on improving access to and use of better medicines for children, WHO has made progress on several fronts. Key tools, such as guides to pricing and sourcing, treatment guidelines and information on the use of more than 240 essential medicines for children have been developed and published. Making this information available to countries helps them to choose, prescribe and administer the right medicines for children.

WHO also advocates for pharmaceutical manufacturers to adapt adult medicines to formulations appropriate for children and to engage in more research and development.

Dr Sue Hill, Scientist at the WHO says, "There is a consensus that the unique treatment needs of children have been ignored for too long. Many countries are joining the effort to support national standards for medicines for children, but more work is needed".

With the countdown to 2015, the Millennium Development Goal 4 target-date to reduce under five mortality by two-thirds, the need for improved access to and use of medicines for children is pressing. More research into determining appropriate dosing and formulations is required; so too is guidance on clinical trials in children, and suitable regulatory pathways to ensure rapid access to medicines. Understanding what is being purchased in countries, advocating for paediatric medicines of good quality and working together is fundamental to this project's ultimate success.

To find out more about Better Medicines for Children visit <http://www.who.int/childmedicines/en/>  
To find out how you can contribute, contact [pedmeds@who.int](mailto:pedmeds@who.int)

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Leading causes of death in children which can be prevented or treated with access to simple, affordable medicines:

Cause of death	Estimated number of deaths
Pneumonia	1,575,000
Diarrhoea	1,336,000
Malaria	732,000
Neonatal sepsis	521,000
HIV and AIDS	201,000

Source: Global, regional, and national causes of child mortality in 2008: a systematic analysis. In *The Lancet*, Volume 375, Issue 9730, 5 June 2010, pages 1969 - 1987.

# ECC CONGO

## INVOLVEMENT OF CIVIL SOCIETY IN VACCINATION ACTIVITIES IN DRC

The SANRU programme aims to promote primary health services through projects and services within the health programme of the Protestant Church of Congo (Direction des Œuvres Médicales de l'Eglise du Christ au Congo - ECC-DOM). The programme partners with Civil Society Organizations to carry out vaccination activities in the community.

The Democratic Republic of Congo, a very large country, spreads over more than 2,345,000 Km<sup>2</sup>, with a border of more than 9,000 Km connecting it to 9 other countries. Congo has 11 provinces with more than 60 million inhabitants, of which more than 80% reside in rural areas.

Only 2 provinces are accessible by roads from the capital. The 9 other provinces can only be reached by air or water, mostly in rather unsafe conditions. The poor state of transport networks (road, air, train and river) strongly affects the movement of people and makes the delivery of goods and follow-up visits between the provinces and even inside the provinces difficult and dangerous.



Transport challenges in DRC

In its post-conflict status, the DRC health system suffers from underdevelopment of health infrastructures, irregularity and low level of staff salaries, limited budget that is allocated to the health sector, weak involvement of the community in organizing health activities in general and particularly with regard to vaccinations. Consequently, the DRC is one of the countries with the highest maternal and child mortality rates (780/100,000 and 127/1,000 < 5 years, ratio of live births respectively)<sup>1</sup> in the world. Sadly, many of these deaths are due to, amongst other factors, illnesses that could be avoided by vaccination. This worrying state of maternal and child health in the Democratic Republic of Congo has justified several funding interventions like the one from GAVI Alliance.

### Vaccination activities

The SANRU programme is a partnership programme between ECC and IMA World Health, designed to provide basic health services, including vaccination, maternal and child health and malaria control among many other interventions, to vulnerable rural populations recovering from years of economic and social collapse. SANRU has been partnering with Civil Society Organizations such as the Red Cross and Rotary to improve access to vaccinations by women and children. This started with the USAID funded AXxes project in October 2006 and was continued with the GAVI Alliance vaccination project that started in May 2008 and will be continued until September 2011.

It is not enough that vaccines are available at the vaccination sites. They also have to be



Delivery of motorbikes to the districts



A vaccination campaign in September 2008

stored correctly, the sites have to be accessible and the vaccination activities must reach as many children as possible, through several different strategies. With funding from the AXxes and GAVI project, the civil society organizations (CSOs) have been able to offer - and still offer - additional support to the vaccination services through the supply of fuel (for refrigerators and freezers) and spare parts for the maintenance of the cold chain to preserve vaccines, donations of management tools and vehicles (motorbikes for the distribution centres<sup>2</sup> and districts<sup>3</sup>, bicycles for the subdistricts<sup>4</sup>), donation of computer tools for the distribution centres, capacity building for the teams working at the districts, financial support to the organization of supervision and monitoring, etc. Through a partnership with Becton Dickinson, the CSOs were also able to provide the districts with syringes for dilution and injection.

At times, the CSOs had to extend their interventions to the transport of vaccines when stock-outs occurred or needs were high, even though this was not part of their mandate. After making the vaccines available in the distribution centres and districts, they also organized activities to increase vaccinations where the limited supplies had earlier strongly reduced the number of vaccinations.

### CSOs making great strides

Within the framework of boosting the involvement of the community in the vaccination

activities, the CSOs took ownership of the vaccination activities and were able to establish roots in the communities by working with community health volunteers<sup>5</sup> and Red Cross volunteers. This way they engaged in awareness creation at household level and were able to identify those children that had not been vaccinated. In the first year of the CSO GAVI project, 22,180 children were identified and vaccinated. They intend to continue these activities, working even more with community organizations and churches within the health zones. Community health volunteers and Red Cross volunteers have all benefited from capacity building with regard to vaccination.

These activities of civil society have contributed to the vaccination of more than a million children with the 3<sup>rd</sup> dose of DTP (Diphtheria, Tetanus, Pertussis). All this in the course of the 4 years of implementation of the AXxes project (October 2006 to September 2010) in 57 districts and the first year of the GAVI CSO project (May 2008 to June 2009) in 65 districts (35 of which were part of the 57 districts receiving global support from the AXxes project).

Moreover, the CSOs have, for the first time in the DRC, also taken to advocacy, targeting the parliament and provincial assemblies in order to raise awareness amongst political decision makers to increase the budget allocated to health and specifically for vaccination. Several provinces have created a budget line for the purchase of vaccines and for the campaign.

*The CSOs took ownership of the vaccination activities and were able to establish roots in the communities by working with community health volunteers and Red Cross volunteers.*

### Strong perspectives

The strong points of this undertaking are the increasing participation of CSOs in important bodies such as the Congolese Inter Agency Coordination Committee on vaccinations, the collaboration at all levels of the civil society with the Expanded Programme on Immunization<sup>6</sup> of the ministry of health, other services of the ministry of health and agencies such as UNICEF and WHO, the involvement of the community in the vaccination activities through community health volunteers and Red Cross volunteers, as well as the experience of the consortium of AXes and GAVI.

Apart from the constraints mentioned earlier regarding the context in which the projects were implemented, it is also noted that the realization of the different activities, has suffered additional constraints. Amongst them are the stock-outs of vaccines and other vaccination materials, the health personnel strike, the removal of the Pentavalent vaccine in the entire country for a duration of 3 months, due to questionable quality, the interruption of GAVI funding to the CSOs for one year and the weak co-financing of the government in the purchase of vaccines.

With the prospect of improving the conditions of staff in the years to come, strengthening the health system with the support of GAVI and Global Fund, improving the acquisition of vaccines in the country through co-financing and increasing the budget allocated to vaccines (thanks to the advocacy by the SABIN institute in the US and civil society), there is a ray of hope for the future.

If the funding by GAVI Alliance as part of its support to the CSOs continues, this remains an opportunity to involve the community even more in health activities in general and vaccinations in particular.

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#### References and notes

1. [http://www.unicef.org/infobycountry/congo\\_statistics.html](http://www.unicef.org/infobycountry/congo_statistics.html)
2. A distribution centre is a logistic division that distributes vaccines to the districts. Each distribution centre is responsible for 5 to 10 districts.
3. Congo is divided into 515 districts. A typical district includes a population of 150,000 people, 200 villages, and 20 health centres. One-half of Congo's districts are co-managed by FBOs/NGOs, especially the Catholic and Protestant churches.
4. A subdistrict is a subdivision of a district. A district normally comprises about 20 subdistricts. A subdistrict has at least one health centre.
5. These are volunteer workers from the community that have received some training allowing them to take up community activities (for example on health education, communication, raising awareness). They are used as a link between the community and the health structures.
6. The Expanded Programme on Immunization (or Vaccination - PEV in French) is a programme of the ministry of health. It determines the national policy and any project within the domain of vaccinations is called to work together with the PEV.

## CHILD SURVIVAL: WHAT HEALTH FACILITIES AND PROFESSIONALS NEED TO DO DIFFERENTLY

*Access to medicines requires that a fine balance is maintained between doctor, pharmacist, and procurement manager. It also presupposes that the right environment exists to produce, purchase and/or procure medicines.*

**B**aby Nabatanzi, a three-month-old child from Uganda is brought into Mityana Hospital, a ninety minute drive west from the capital Kampala. She is diagnosed with malaria. Her doctor knows that the child requires an anti-malarial medicine in the right formulation to ensure compliance, as consistent steady-state medicine concentration in the blood is essential for effective treatment of malaria. The doctor also understands artemisinins are not recommended for children below 5 kg because of limited efficacy and safety information. So he prescribes quinine, the right drug for Nabatanzi, in a liquid form, an appropriate formulation for an infant. Nabatanzi's mother visits the hospital pharmacy to obtain the medicine. The pharmacist informs her that quinine syrup is not available, and there is no dispersible dosage form either. The pharmacist dispenses quinine 300 mg tablets and instructs her to give a quarter tablet every 8 hours, for 5 days.

At home, baby Nabatanzi refuses to take the broken, crushed and dissolved quinine tablet. Her mother tries honey, milk, water and many other solvents to make her baby take the medicine. But Nabatanzi continues to refuse. Worried, Nabatanzi's mother goes to the nearest private pharmacy and asks for quinine syrup. That pharmacy has quinine syrup, but the cost is much too high so she returns home without the medicine for her baby. Nabatanzi has just been denied access to an essential medicine for an important childhood disease.

'Access to medicines' means having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes

of the population. Access encompasses availability (physical access), affordability (economic access) and acceptability (socio-cultural access). In this case, the right medicine in the right formulation was not available in the public hospital; at the private pharmacy it was not affordable for Nabatanzi's parents; and manipulation of the adult dosage form dispensed was of unproven bioavailability and not acceptable for Nabatanzi.

As a doctor, we have many unanswered questions. How many essential medicines are available in suitable paediatric dosage forms? Why is so little attention being paid to studying paediatric formulations? Why are paediatric formulations not issued even to a major hospital? What is the cost difference between the adult and paediatric formulations? What are the storage requirements for paediatric formulations? When a child has malaria, should we be suspicious of the formulation and unproven bioavailability of manipulated medicines for adults? What do we tell the parents?

In 2009, over eight million children under the age of five died<sup>1</sup>. Many of them from conditions that could be treated with safe, effective medicines. Access to appropriate medicines for children is essential for achieving the child health goals including MDG 4 (Reduce child mortality by two thirds) and 6 (Combat HIV and AIDS, malaria, and other major diseases).

#### Limited access

The World Health Organization (WHO) estimates that more than one third of people lack access to essential medicines<sup>2</sup>. Factors may include high prices, systemic inefficiencies, fraud or corruption, lack of quality in the medi-

cine or it may be the promotion of inappropriate products that leads to misspent resources. This lack of medicines for children continues to pose a global problem and acutely affects developing countries.

The challenges with regard to medicines for children are numerous. Very few medicines are specifically formulated for child use, yet children and especially infants and young children have different needs related to their body composition, weight and metabolism. Off-label use, the use of medicines for which effects on children have not been studied and which are not licensed for use in children, is widespread. In certain settings, as much as 90%<sup>3</sup> off-label prescribing in paediatric patients has been reported, as opposed to 40% in adults<sup>4</sup>. Problems of supply and distribution include provision of inappropriately large volumes of suspensions that are difficult to administer and lead to waste or degradation once opened. Storage under harsh conditions, as is the case in many developing countries, requires close attention to shelf-life parameters and heat/stability requirements, which are often overlooked. With regard to quality, substandard or counterfeit medicines pose an additional serious threat to children in these countries. In many developing countries, malaria is one of the biggest killers of children under 5 years of age, but this is precisely where both substandard and counterfeit medicines are most common.

**Remedial action**

What we can do:

- Have separate lists of essential medicines for children that include child friendly dosage forms;
- Advocate for essential medicines for children to be available at the different types of hospitals including district and tertiary hospitals as well as primary care;
- Procurement and distribution of medicines to faith-based hospitals should be based

- on the essential medicines list for children;
- Managers should ensure continuous availability of the medicines for children in faith-based hospitals;
- Research needs to be done on availability, accessibility, affordability, palatability, and bioequivalence of manipulated adult dosage forms, and on the acceptability, suitability, quality and safety of children's medicines;
- Development of financially viable children formulations (e.g. dispersible tablets) needs to be encouraged;
- Manufacturers and suppliers should be encouraged to market medicines for children **as well as adults, irrespective of profit**;
- Policy makers and regulators should be sensitised about the issue of children's medicines;
- Develop guidelines on storage and transport of paediatric medicines (bottles, large volumes, climate, space in stores);
- Establish price controls for children's medicines sold in private pharmacies;
- Professional associations (International Paediatric Association) should take up this issue with relevant stakeholders and contribute to interventions;
- Doctors, pharmacists and nurses should choose not only the right medicine for children, but the right formulation;
- Parents need to be empowered to demand better medicines for their children.

If we are to prevent baby Nabatanzi becoming a statistic, we must all pull in the same direction. Our children are entitled to a healthy childhood.

*Daniel Tumwine works for the Regional Centre for Quality of Health Care and is the Vice President of the Antibiotic Consensus Society of Uganda, General Secretary of the Eastern Africa Paediatric Association and of the Uganda Paediatric Association.*

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# MEDICINES FOR CHILDREN THE MILLENNIUM CHALLENGE

The Psalmist aptly states: *“Behold, children are a heritage from the Lord, the fruit of the womb, a reward”* (Psalms 127:3).

It may be a surprise to know you are given a gift, a heritage from the womb. You need to know it is your responsibility to care for and keep this reward from the Lord.

Despite God's love, we are living in a world that makes many wake daily with a hopeless feeling, despair and fear that the situation will never improve. However, the world is improving faster than what we thought we would see. As we reflect on the progress towards MDG 4 and the other MDGs related to the well-being of children, we realise that although some progress has been made, it is uneven and much more remains to be done. The statistics speak for themselves, and we all know them. Nearly one child, every three seconds dies, before they are five years old. 45% of under-five deaths occur in sub-Saharan Africa.<sup>1</sup>

Children are treated as small adults. Yet it is a Biblical fact that we need to consider their age, weight and physiological condition. As the bible says *“I gave you milk, not solid food, for you were not yet ready for it. Indeed you are still not ready.”* (1 Corinthians 3:2).

**The efforts needed**

The articles in this publication provide lots of insights about what must be done. Efforts must be made towards making flexible solid dosage forms and tailoring specific medicines according to children's age, body weight and physiological condition. The pharmaceutical industries have a great challenge to meet these needs of children worldwide. They must consider formulating the medicines for children in the proper paediatric forms.

We must emphasize the importance of the following:

- Safety of the dosage form designed
- Acceptability of the dose volumes and sizes
- Excipient compatibility
- Taste
- Colour

Of course, efforts must also be made to promote access to medicines worldwide. Even today, if all the medicines available were made accessible to the needy, this could save the lives of millions of children.

So today, we can find great comfort in knowing that we have a compassionate God. God is always willing to come to our aid and supply our needs. Let all the world know that he comes to our aid. When efforts must be made, God makes it possible from us. It actually means to suffer with others and to be in solidarity with sufferers. Remember, compassion asks us to go where it hurts and to focus on the other as a fellow human being, created in God's image and for whom Christ died.

This is how we are able to and why we have to make these efforts for our children.

**Discussion questions**

The Gospel of Jesus tells us about his healing of the sick and suffering. Jesus brings health to those who have lost hope. He shows forth God's grace in the world in radical and unexpected ways.

1. Can the Church following Jesus' example be content with pandemic diseases that can be conquered with the proper amount of resources and goodwill?
2. How we can connect our faith to our advocacy in this regard?

*Reverend Baraka Kabudi is a pharmacist at Mission for Essential Medical Supplies (MEMS), Tanzania.*

**Reference**

1. The Millennium Development Goals Report 2010. United Nations. [http://unstats.un.org/unsd/mdg/Resources/Static/Products/Progress2010/MDG\\_Report\\_2010\\_En\\_low\\_res.pdf](http://unstats.un.org/unsd/mdg/Resources/Static/Products/Progress2010/MDG_Report_2010_En_low_res.pdf)

**The Millennium Development Goals Report 2010**  
2010 assessment of global progress towards the MDGs.  
[http://unstats.un.org/unsd/mdg/Resources/Static/Products/Progress2010/MDG\\_Report\\_2010\\_En\\_low\\_res.pdf](http://unstats.un.org/unsd/mdg/Resources/Static/Products/Progress2010/MDG_Report_2010_En_low_res.pdf)

#### **MDG 4: Reduce child mortality**

Information on the scope of the MDG, a fact sheet and 2010 report.  
<http://www.un.org/millenniumgoals/childhealth.shtml>

#### **Childhood Pneumonia. Scope of the problem**

ReAct Fact sheet  
<http://www.reactgroup.org/files/docs/Fact%20Sheet%20on%20Childhood%20Pneumonia.pdf>

#### **Medicines for children, Fact sheet N°341**

June 2010  
<http://www.who.int/mediacentre/factsheets/fs341/en/index.html>

#### **Sources and Prices of Selected Medicines for Children Including Therapeutic Food, Dietary Vitamin and Mineral Supplementation - 2nd edition**

April 2010  
The second edition of Sources and Prices of Selected Medicines for Children offers up-to-date information on the availability and price of 240 drug items in 612 different paediatric formulations selected from the 'WHO Model List of Essential Medicines for Children', therapeutic food, and vitamin and mineral supplements, to treat major childhood illnesses and disease.  
[http://www.who.int/medicines/publications/sources\\_prices/en/index.html](http://www.who.int/medicines/publications/sources_prices/en/index.html)

#### **WHO Model Formulary for Children**

2010  
The WHO Model Formulary for Children has been prepared based on the Second Model List of Essential

Medicines for Children (2009). For each medicine the Model Formulary provides information on use, dosage, adverse effects, contraindications and warnings, supplemented by guidance on selecting the right medicine for a range of conditions.  
[http://www.who.int/selection\\_medicines/list/en/](http://www.who.int/selection_medicines/list/en/)

#### **"Better Medicines for Children Project" Overview of Methods for Medicines Availability and Pricing Surveys**

September 2009  
This document was prepared by the WHO before the start of surveys on availability and price of paediatric medicines in selected African countries and five Indian states as part of the Better Medicines for Children project. The report describes the key elements of the survey protocol, and includes a more detailed guide for survey preparation and implementation.  
[http://www.who.int/childmedicines/progress/ChildMeds\\_pricing\\_surveys.pdf](http://www.who.int/childmedicines/progress/ChildMeds_pricing_surveys.pdf)

#### **Measuring medicine prices, availability, affordability and price components**

May 2008  
In 2003, the WHO and Health Action International published the first edition of Medicine prices – a new approach to measurement. More than 50 surveys have now been conducted worldwide, and the wealth of experience gained has led to a number of improvements in this second edition of the manual. The survey methodology has been refined based on the lessons learnt to date, and new methodologies and tools have been developed in the areas of price component surveys and routine monitoring of medicine prices and availability. The new edition provides more guidance on policy options and lines of action.  
[http://www.who.int/medicines/areas/access/medicines\\_prices08/en/index.html](http://www.who.int/medicines/areas/access/medicines_prices08/en/index.html)

## NOTES:

*Contact* deals with various aspects of the churches' and community's involvement in health, and seeks to report topical innovative and courageous approaches to the promotion of health and healing.

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