

Situational analysis for policy and practice for Pneumonia treatment in Ethiopia

16 October 2013

1. Background

Pneumonia is the single largest killer of children under 5 as well as the leading infectious cause of childhood mortality worldwide; it accounts for 17% of all under-five deaths, claiming the lives of 1.1 million children under 5 in 2012.¹ Eighty one percent of these deaths occur within the first 2 years of life, highlighting the need for prevention and treatment programmes that emphasise coverage for young children.² According to UNICEF 2013 progress report, pneumonia is the single largest cause of death among children in Ethiopia, causing an estimated 41,000 (20%) of under 5 deaths.³ Seven percent of children under age five showed symptoms of acute respiratory infection (ARI) in the two weeks before the survey and for 27 percent of them, care or treatment was sought from a health care facility or provider.⁴

Pneumonia is a 'disease of poverty'; it is closely associated with factors such as poor home ventilation, undernutrition, and lack of access to quality health services. Pneumonia deaths are largely preventable through optimal breastfeeding practices, adequate nutrition, vaccinations, hand washing with soap, safe drinking water, and access to improved sanitation⁵. Case management is a cornerstone of pneumonia control strategies. It consists of classifying the severity of illness using simple clinical signs such as fast breathing, lower chest indrawing, and general danger signs, and then giving the appropriate antibiotic treatment. Treatment includes home care advice, antibiotics for home use, or referral to a higher-level health facility.⁶

2. Evidence for treatment of pneumonia

In The Lancet, Abdul Bari and colleagues report that in a cluster randomized study undertaken in Haripur District, Pakistan, community

¹ Committing to Child Survival: A Promise Renewed, Progress Report. UNICEF. September 2013

² Executive summary of The Lancet Childhood Pneumonia and Diarrhea series

³ Committing to the Child Survival : A Promise Renewed, Progress Report. UNICEF. September 2013

⁴ Central Statistical Agency [Ethiopia] and ICF International. 2012. Ethiopia Demographic and Health Survey 2011. Addis Ababa, Ethiopia and Calverton, Maryland, USA: Central Statistical Agency and ICF International

⁵ Committing to Child Survival: A Promise Renewed. UNICEF. 2012

⁶ Revisions in Pneumonia Case Management Guidelines: New classification of Pneumonia Severity and a Change in First-line Antibiotic Therapy, Overview of evidence, and implications for policy. WHO. June 2013 (Draft)

case management of World Health Organization (WHO)-defined severe pneumonia in children aged 2-59 months by lady health workers (LHWs) resulted in lower treatment failure than did the current standard of care practice of one dose of oral co-trimoxazole and referral to the nearest health facility for further treatment. The results suggest that community case management of pneumonia could result in standardized treatment for children with severe pneumonia, reduce delay in treatment initiation, and reduce the costs for families and health-care systems.⁷

In other study published in *The Lancet* by Sajid Soofi and colleagues, a cluster-randomized control trial in Matiari district, rural Pakistan, showed that public sector LHWs were able to satisfactorily diagnose and treat severe pneumonia at home in rural Pakistan. LHWs were effectively able to reach children with pneumonia in settings where referrals are difficult, a key component of community detection and management strategies for childhood pneumonia⁸. This study shows that LHWs can correctly identify and treat most of cases of severe pneumonia in children seen in the community, with no increased risk for treatment failure, adverse events, or death. This strategy of devolved care of severe pneumonia cases closer to poorer rural households could potentially allow a larger proportion of children with severe pneumonia to receive appropriate treatment at the community level. The inclusion of community case management of severe pneumonia into the LHW programme addressed several health-system and financial bottlenecks.⁹

Community-based management of severe pneumonia cases with oral amoxicillin can reduce the following:¹⁰

- the risk of complications, including needle-borne infections and unnecessary injections;

⁷ Abdul Bari et al, Community case management of severe pneumonia with oral amoxicillin in children aged 2-59 months in Haripur district, Pakistan: a cluster randomized trial: *Lancet* 2011, published on line November 11, www.thelancet.com (DOI:10.1016/S0140-6736(11)6140-9)

⁸ Sajid Soofi, et al, effectiveness of community case management of severe pneumonia with oral amoxicillin in children aged 2-59 months in Matiari district, rural Pakistan: a cluster randomized controlled trial: January 27, 2012, www.thelancet.com (DOI:10.1016/S0140-6736(11)61714-5)

⁹ Sajid Soofi, et al, effectiveness of community case management of severe pneumonia with oral amoxicillin in children aged 2-59 months in Matiari district, rural Pakistan: a cluster randomized controlled trial: January 27, 2012, www.thelancet.com (DOI:10.1016/S0140-6736(11)61714-5)

¹⁰ Sajid Soofi, et al, effectiveness of community case management of severe pneumonia with oral amoxicillin in children aged 2-59 months in Matiari district, rural Pakistan: a cluster randomized controlled trial: January 27, 2012, www.thelancet.com (DOI:10.1016/S0140-6736(11)61714-5)

- the need for referral or unnecessary admission to the hospital;
- indirect costs for transport, and food, lost income for family members who must travel to a facility;
- and risk of antimicrobial resistance caused by widespread use of inappropriate second-line antibiotics or treatments.

In addition, the study by Soofi and colleagues also shows that community level management of severe pneumonia (defined as children with lower chest indrawing) in children aged 2-59 months with a 5 day course of oral amoxicillin was safe and has also been found to be as safe and clinically similar to treatment of with Co-trimoxazole and referral to a health facility.¹¹

According to the findings, oral amoxicillin is as effective as injectable penicillin in the treatment of severe pneumonia in children 3-59 months of age in a diverse range of regions and countries, including both developing and developed areas. Oral amoxicillin is preferable, however, as it minimizes the risk of injectable-related morbidity, needs fewer medical supplies such as syringes, and is an equally effective alternative to parenteral treatment. A comparison of the use of parenteral ampicillin in hospitals to oral amoxicillin at home found that the two treatments were equivalent with respect to case outcomes. In cases of chest indrawing pneumonia without underlying complications, home treatment with a short course of high-dose oral amoxicillin is preferable to parenteral treatment.¹²

In 2011, WHO updated its recommendations for home treatment of pneumonia in the context of integrated management of childhood illness (IMCI), replacing Co-trimoxazole with Amoxicillin 250mg as the new first-line treatment for childhood pneumonia. The WHO recommendation is that pneumonia without danger signs (no chest indrawing) can be treated at the community level using a simple protocol for diagnosis and administration of oral amoxicillin.¹³

Further evidence shows the effectiveness of oral amoxicillin on a broader range of pneumonia cases. Given the evidence, it is possible to reduce the number of classifications of pneumonia from three to two by combining “chest indrawing” pneumonia and “fast breathing”

¹¹ Sajid Soofi, etal, effectiveness of community case management of severe pneumonia with oral amoxicillin in children aged 2-59 months in Matiari district, rural Pakistan: a cluster randomized controlled trial: January 27,2012, www.thelancet.com (DOI:10.1016/S0140-6736(11)61714-5)

¹² Revision in Pneumonia Case Management Guidelines: New Classification of pneumonia Severity and a Change in First-line Antibiotic Therapy, Overview of evidence, and implications for policy. WHO. June 2013 (Draft)

¹³ Integrated management of childhood illness: caring for newborns and children in the community. Manual for the community health worker. WHO. 2011

pneumonia in the new WHO guidelines for management of childhood pneumonia.¹⁴In 2013, the IMCI guidelines for facility-based classification and treatment of pneumonia were revised; chest indrawing is no longer a sign of severe pneumonia and the first-line treatment for pneumonia officially changed to Amoxicillin for 5 days.¹⁵ In addition, many countries with integrated community case management (iCCM) and community case management (CCM) programs, list Amoxicillin as the preferred first-line antibiotic treatment for pneumonia at community level.¹⁶ Evidence shows that community health workers, when properly trained and supported, can effectively and safely treat lower chest indrawing pneumonia at home with oral amoxicillin.¹⁷Moreover, The UN Commission on Life-Saving Commodities (UNoLSC) for women and children¹⁸ and priority medicines for mothers and children¹⁹ call for improved access to amoxicillin as pneumonia treatment.

3. Amoxicillin

Amoxicillin is an effective broad-spectrum antibiotic for use against bacterial infections and particularly for the treatment of children bacterial pneumonia. It is often used to treat infections in children suffering from severe acute malnutrition (SAM).²⁰Amoxicillin remains a low cost commodity: estimated at just \$ 0.21-0.42 USD per treatment course.²¹ Oral amoxicillin can be easily administered by caregivers in the home with the guidance of trained health workers, making treatment simpler and reducing costs of referral, admission, and treatment associated with injectable antibiotics.²²

3.1. Different Amoxicillin Product Formulations

Amoxicillin is formulated into conventional capsules (Amoxicillin Caps), tablets (Amoxicillin Tab), powder for oral suspension (Amoxicillin OS),

¹⁴ New WHO recommendations for the classification and treatment of pneumonia in children. June 2013 (Draft)

¹⁵ WHO&UNICEF: IMCI generic chart booklet: June 2013

¹⁶ WHO/UNICEF Joint statement : Integrated Community Case Management (iCCM).2012

¹⁷ Revision in Pneumonia Case Management Guidelines: New Classification of pneumonia Severity and a Change in First-line Antibiotic Therapy, Overview of evidence, and implications for policy. WHO. June 2013 (Draft)

¹⁸ Every Woman Every Child, Amoxicillin-Product Profile, United Nations Foundation, Washington, 2012

¹⁹ Priority medicines for mothers and children. WHO.2011

²⁰ UNICEF, Amoxicillin Dispersible Tablets (DT): Product Profile, Availability and Guidance. July 2013

²¹ Every Woman Every Child, Amoxicillin-Product Profile, United Nations Foundation, Washington, 2012

²² New WHO recommendations for the classification and treatment of pneumonia in children. June 2013 (Draft)

and dispersible tablets (Amoxicillin DT). Amoxicillin dispersible tablets are the equivalent of Amoxicillin OS, with each dose compacted into a tablet, dispersible in 5-10 ml of water. Amoxicillin DTs are cheaper than the equivalent OS formulation. DTs also offer logistical and supply chain advantages relative to volume and weight, and are designed to accommodate patients with difficulties in swallowing pills or whole tablets. Moreover, Amoxicillin DTs facilitate and simplify CCM as they are manufactured in set dosages and do not require any manual measuring or mixing, as is necessary with the OS formulation. As a result, the new treatment protocols and the availability of Amoxicillin in DT form simplify the administration and dosage of proper antibiotics and reduce the risk of dosing errors that are correlated with administration of OS. Pilot programs using Amoxicillin 250mg DT have demonstrated safe, effective, and quality treatment of pneumonia through community case management.²³

4. Situation in Ethiopia

4.1. Current Policy and Registration

In Ethiopia, Co-trimoxazole remains the first-line treatment for pneumonia in children under-five years of age. Amoxicillin registration is limited principally to Amoxicillin OS and Amoxicillin Cap and is primarily used to be the second-line for pneumonia and treat other infections. Amoxicillin DT and Gentamycin 20mg are not registered in Food Medicine Health Care Administration and Control Authority (FMHACA).

4.2. Treatment Guidelines

Treatment guidelines for pneumonia are included in various national health system protocols, often in the context of Integrated Management of Newborn and Child Illness (IMNCI) and iCCM guidelines, as well as in Community Based Newborn Care (CBNC) guidelines. However, Co-trimoxazole, is identified as first-line treatment for pneumonia in both IMNCI²⁴ and iCCM ²⁵guidelines. In addition, current guidelines identify chest indrawing as a sign of severe pneumonia and or very severe diseases; therefore according to the guidelines, urgent referral is required, and there is no guidance for treating with Amoxicillin. As noted earlier, ample evidence has shown that severe pneumonia can be treated at community level with Amoxicillin.

²³ UNICEF, Amoxicillin Dispersible Tablets (DT): Product Profile, Availability and Guidance. June 2013

²⁴ FMOH, Integrated Management of Newborn and Childhood Illness, Chart booklet for health workers. Addis Ababa Ethiopia. October 2011

²⁵ FMOH, Integrated Community Case Management of common childhood illness, chart booklet for health extension workers. Addis Ababa, Ethiopia. 2010

4.3. Opportunities

In 2010, the Federal Ministry of Health (FMoH) added community-based management of pneumonia to the HEP. After three years of implementing the iCCM initiative, close to 27,000 community health extension workers (HEWs) have been trained and are currently providing treatment services for childhood pneumonia, diarrhoea, malaria, and severe acute malnutrition at the community level. Through the iCCM program, Co-trimoxazole is being used as the first-line treatment for pneumonia.

In addition, neonatal mortality (death within the first 28 days) accounts for 42% of under-5 mortality. The major direct cause of newborn deaths is infection (36%). In a nationwide effort to reduce neonatal mortality, community based newborn sepsis management was introduced and endorsed earlier this year. This initiative is in a kickoff stage, with the first phase of implementation happening in 7 zones of the Amhara, Oromia, SNNPR, and Tigray regions. As stated in the CBNC Implementation Plan, the recommended treatment of newborn sepsis is Amoxicillin DT and Gentamycin 20mg.²⁶

Moreover, many efforts have been made to train at least two health workers per health centre (HC) and hospital on facility based IMNCI to ensure IMNCI services are initiated and provided in all HCs and District Hospitals. As a result, more than 68% of health facilities are providing IMNCI services²⁷.

5. Major facts for policy change :

- 5.1.** The Cost of Amoxicillin 250mg DT 10x10 strip pack is fairly comparable with Cotrimoxazole 120mg DT 10x10 tab strip pack (table 1):

Table 1: Cost comparison versus Amox and Cotrim DTs

UNICEF Catalogue product	Treatment cost < year olds (US\$)	Treatment cost 1-5 years olds(US\$)
Amoxicillin 250mg DT 10x10 Pack	0.17	0.34
Cotrimoxazole 120mg DT 10x10 Pack	0.164	0.328

²⁶ FMoH, Community Based Newborn Care National Implementation guideline. Feb 2013

²⁷ FMoH,2011 report

- 5.2. The efficacy advantage of Amox for treating pneumonia is recommended by all global authorities (UNoLSC, WHO, UNICEF)
- 5.3. It is already introduced for newborn sepsis management in Ethiopia (2013)
- 5.4. It has been used as the first-line treatment for severe acute malnutrition (SAM) in the out patient therapeutic program (OTP) services by HEW since 2008
- 5.5. The fact that having double antibiotics at health post (Cotrm and Amox) could create confusion among HEW
- 5.6. It has been used by other neighboring African Countries such as Uganda and South Africa

6. Operational issue:

As it has been exercised before, the national quantification to forecast the needs of pharmaceuticals (including Amox DT) required and procurement for effective implementation of iCCM and CBNC will lead by PFSA, and FMoH, in collaboration with UNICEF and other child survival partners. The distribution will follow the already existent PFSA led route of other supplies and drugs. The health posts which going to be started CBNC will be prior targets for distribution of the Amox DT. However, health posts with stock of cotrimoxazole will be made to use it before going to replace Amox DT for pneumonia management; health posts which get out of stock for cotrimoxazole will be refilled by Amox DT.

7. Conclusion

According to WHO recommendations, updating policies and practices for pneumonia treatment can have the following advantages:

- increased access to proper antibiotic treatment closer to home;
- improved follow up care from a HEW in the community;
- streamlining treatments as the same oral antibiotic can be used to treat both fast breathing pneumonia and chest indrawing pneumonia;
- decreased need for referrals to higher level health facilities;
- simplified pneumonia classification and management (two categories instead of three);
- simplified and steamlined training of health workers;
- cost benefits to caregivers, households, communities and health facilities; and
- decreased probability of hospitalization and therefore reduced risk of hospital acquired infection and injection borne diseases.

Further, the ease of using oral amoxicillin and stocking CHWs improves access to care by providing pneumonia treatment at the household

level, leading to improved drug compliance and significantly reducing pneumonia deaths.

As the result all favor the introduction of Amox DT as first-line antibiotics for pneumonia.

8. Recommendation

6.1. Policy:

Evidence shows that a five-day course of oral Amoxicillin is as safe and clinically similar to treatment with Co-trimoxazole and referral, but does not compromise a child or community with possible complications of microbial resistance. As a result, the current policy for the first-line treatment of pneumonia should be revised to reflect global best practices and list amoxicillin as the preferred first line. This change in first line treatment represents major life, resource, and cost-savings to families, communities, and to Ethiopia as a country.²⁸

6.2. Registration:

With amoxicillin DT as the first line treatment, the administration and dosage of treatment is greatly simplified and the risk of dosing errors is significantly reduced. For these reasons, amoxicillin in dispersible table form should be registered in FMHACA to approve and facilitate the procurement and distribution of this essential lifesaving commodity for under-five children.

6.3. Next steps:

The most important first step is that the current policy should be updated to reflect amoxicillin as first line treatment for childhood pneumonia in Ethiopia. Following this change, the current IMNCI and iCCM algorithms, namely the assessment, classification, and treatment of pneumonia sections, need to be revised to align with the new policy and the corollary community based newborn sepsis management. The adaption of the pneumonia classification algorithm for health post setting needs a slight amendment to address the management of wheezing where HEWs are not supposed to handle drugs for wheezing.

Importantly, all health workers (at all levels) and health extension workers will need to be re-trained according to the new guidelines in

²⁸ New WHO recommendations for the classification and treatment of pneumonia in children. June 2013 (Draft)

order to reap full benefits of the new policy²⁹ and ensure that children presenting with pneumonia are properly diagnosed and treated.

In addition, it will be greatly beneficial to develop and implement a behavior change campaign or public service campaign targeted to caregivers in Ethiopia to encourage treatment seeking behavior and request amoxicillin when a child is diagnosed with pneumonia.

²⁹ New WHO recommendations for the classification and treatment of pneumonia in Children. WHO. June 2013 (Draft)