Severe Acute Malnutrition’s Technical Roundtable

INNOVATIONS TO ADDRESS KEY CHALLENGES IN THE TREATMENT OF SEVERE ACUTE MALNUTRITION

This note is the summary report of the technical roundtable hosted by ECHO the 24th November 2015 in Brussels and dedicated to Innovations to address key challenges in the treatment of SAM.

November 2015

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The expansion in the use of the Community–based Management of Acute Malnutrition (CMAM) model by over 70 countries\(^1\) since its endorsement by key UN agencies in 2007 has improved the global coverage of treatment of acute malnutrition in children under five years of age and has contributed to the reduction of childhood mortality. In 2013, 2.9 millions cases accessed treatment representing 17% of the total that needed treatment\(^2\). Policy makers and practitioners working across a wide range of contexts continue facing multiple challenges in the implementation of quality CMAM programmes, its application in emergency contexts and its appropriation by national governments.

A conference was held in 2013\(^3\) bringing together the main stakeholders, to discuss achievements and the main barriers to improving the treatment of Severe Acute Malnutrition (SAM), including coverage, performance and cost–efficiency. Since then a number of initiatives have taken place and are generating ground–breaking knowledge which is critical in the development of future protocols and guidance.

As per its commitment towards the reduction of child mortality and undernutrition, DG–ECHO hosted a technical roundtable on 24th of November 2015. The objective of the roundtable was to share information on current practice and research in the treatment of SAM in order to maintain the growing momentum to address key challenges. The roundtable was structured under two main areas (Please see Annex 1 for the detailed agenda):

- **Potential efficiency gains in the treatment of SAM through innovative approaches**
- **Improving the coverage of SAM through improved diagnosis**

The roundtable was opened by Florika Fink–Hooijer, ECHO Director on Strategy, Policy and International Co–operation welcoming innovation through new ways of recognizing SAM early to avoid complex and heavy medical interventions due to complications. Identification of new ways of monitoring and ensuring emergency actors can exit in order for development actors to be involved earlier to allow greater sustainability and ownership by the governments was also welcomed. In the context of the World Humanitarian Summit, Florika reiterated ECHO’s interest in contributing to aid effectiveness and the importance of innovation in this regard.

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Improving the effectiveness of SAM treatment (Saul Guerrero, ACF-UK)

The sector is good at coming up with new ideas, it is far weaker in terms of making these ideas mainstream. The key is to find balance between effectiveness and scale up.

The issue of how to achieve scale has been seen throughout the history of SAM treatment. From the 1970’s to 2000’s, the inpatient treatment model worked well but the model didn’t enable many children to get treated. The introduction of RUTF changed this and enabled rapid scale-up of services, and increased SAM treatment coverage. However, since 2013, this acceleration is plateauing while the effectiveness of treatment remained inconsistent. 3 areas should be considered to redynamise the scale up:

• Availability– cost is a barrier to treatment. Ways that would decrease the overall cost are to be explored. An important post of expense is RUTF: the cost of production can hardly decrease (already at small margins). Alternatives exploring, for instance, reductions in the amount of RUTF required for treatment (as the MANGO Study looks at) or non–RUTF treatment. Management of supply chain could also be improved to decrease losses at all stages between the producer and the beneficiaries.

• Accessibility– Demand of service is an important component of the scale up process. A key barrier to access is people’s lack of knowledge about malnutrition. Lessons should be withdrawn from programs achieving high acceptability and coverage (e.g. Bangladesh had coverage levels of 89% with an approach where treatment was provided by community health workers). A community level focus is required in this regard. To be understood and accepted, protocols also need to be simplified.

• Quality– quality and effectiveness are important, but should not be reached to the detriment of scale up. We should spend less time collecting new evidence and rather use existing evidence to improve policy and practice.

Discussion points:

• Are we investing in solutions that are effective and scalable? SAM must be seen as a public health intervention that saves lives.

• Participants suggested that there is a need to draw on the efforts of other diseases programmes and collaborate. e.g. malaria– despite the vast amount of money spent, treatment coverage is at about 35%. The lack of strong health systems is a common problem in relation to many diseases, and more synergies can be drawn upon.

• We need to unpack enablers further– why and how did particular countries manage to reach a high level of coverage? e.g. Ethiopia had good infrastructure in terms of health systems and strong integration at the lower level.

• Do we know when the evidence is good enough?
Effectiveness of an optimized Ready to Use Therapeutic Food (RUTF) dosage (Cécile Salpétier, Anne-Dominique Israel, ACF-F)

The MANGO (Modelling an Alternative Nutrition protocol Generalizable to Outpatient care) study has been inspired from an operational adaptation to the protocol due to a shortage of RUTF, in an ACF project in North Rakhine State, Myanmar, in 2009. Different options were discussed to cope with the situation 1) early discharge of beneficiaries 2) restriction in admission criteria and 3) reduced quantity of RUTF per beneficiaries in the course of treatment. After consultation with the ethical committee of the research committee, option 3 was chosen. Children that were the least at risk of mortality received one sachet of RUTF per day until discharge. If they did not show signs of improvement on this alternative protocol, they shifted back to the usual RUTF amounts.

The intervention ran from July 2009 to January 2010, treating 3083 children. One year later, the data was examined and showed a very high cure rate (90.3%) and:

- The non-responder rates decreased rapidly thanks to home visits and caregivers groups
- The alternative protocol enabled the treatment of 1.3 children from a cost perspective compared to 1 child using the previous protocol.

Enabling factors for this success included– the level of food insecurity being lower than typical levels; high community awareness and established local staff. Caregivers were provided with psychosocial care and children within the programme were closely monitored. All these factors resulted in a simple, highly successful, effective programme and thus, it must be noted that it was not simply about reducing RUTF amounts.

A Randomised Controlled Trial, the MANGO project, will take place in Burkina Faso, from April 2016, to assess the impact of the dosage aspect of the previous protocol, without potential interference by the qualitative aspects noted above.

- One research arm will receive the standard RUTF dosage and the other arm will receive a reduced dosage.
- Both groups will receive family food advice and monthly follow-up until four months after discharge.
- Weight gain will be assessed as well as secondary outcomes including cost effectiveness, programme performance (length of stay, relapse rates etc.), body composition as well as outcomes such as leptin, adiponectin, hair (as part of the Opti-Diag study).

The results are expected to be published by 2018.

**Discussion points:**

- What is the acceptable minimum weight gain for SAM children? In global practice, there is still no evidence on an optimal weight gain, study results have been variable. For example, prior to the CMAM model, weight gain of 10kg/day was the norm but the average weight gain is now much lower. It was recommended to consider the impact of this approach on coverage.
- The zero mortality figure of the Myanmar project must be taken cautiously, as only the least vulnerable children have been selected for the application of the adapted protocol.
- The original RUTF dosage amounts prescribed in the CMAM protocols were derived from TFC protocols, and were never challenged. Therefore, it is possible that RUTF dosages used today are too high.

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4 To understand more about this initial protocol change, an article was written for Field Exchange (Magazine 42, Jan 2012) and published in Maternal & Child Nutrition Journal.
• There is a need to think broader and look at prevention of relapse e.g. giving a lower dose for longer to give the body time for metabolic changes to take place.

• A question was raised in relation to outcomes prior to the alternative protocol being implemented. Cecile noted that the recovery rate was similar; the defaulter rate was much higher as well as the non-responder much higher (hence, the broader non-responder strategy being implemented).

• Participants questioned why the alternative protocol did not continue following the 6 months and Anne–Dominique noted that when they were in a position to go back to the normal protocol, ethically they felt they should. Results were only analysed one year later hence, they did not have clear evidence for the project’s success at that stage.

**Spacing of monitoring of SAM cases (Sheila Isanaka, Epicentre)**

This study arose from experiences where weekly visits to the nutrition program were not practical due to geographical constraints, security reasons or when dealing with nomadic populations and because the evidence base for alternative modalities to CMAM is limited. The project aimed to examine an alternative protocol looking at monthly follow-up visits rather than the current recommended weekly visits—assessing the effectiveness and safety of this approach. In order to space out the monitoring visits it was necessary to ensure that this protocol adaptation would not be harmful to the children. Therefore it was important to determine whether caregivers can be trained to monitor clinical signs, have an appropriate reaction when children require medical attention (e.g. visit to the health center), and whether they are able to adequately manage a monthly ration of RUTF.

The initial phase of the study was implemented in 2014. Tools such as postcards outlining clinical signs and MUAC measurement steps were designed and mothers were given short trainings. To test the effectiveness of this strategy, the knowledge of caregivers was assessed before, after and on day 28 following the training based on awareness of clinical signs and agreement with nurse measurements. Unplanned weekly visits were also conducted to assess RUTF utilisation. Results from the pilot study showed that:

• Mothers were able to retain the information from day 1 to day 28 and were able to recognise many clinical signs.

• Mothers awareness of how to correctly measure MUAC was also retained 28 days following initial training.

• A high concordance was noted when comparing MUAC measurements taken by mothers with that of nurses.

• Within this study, a modified MUAC tape was used in which it was clearly marked when a child needed to return to the clinic however, this was difficult to evaluate given that few children needed to return to the clinic.

• Where caregivers were given the monthly ration but were provided with weekly monitoring, children were able to maintain adequate weight gain even when given a monthly ration. This showed that caregivers were able to manage the ration well at home; that it was stored and conserved properly and few cases of over use were reported.

• There were difficulties in recruiting mothers for the study, as some mothers were concerned about storing RUTF at home and needing to ask the head of the household permission to do so. This may have led to some selection bias.

Phase 2 of the study is planned to start in 2016 as a clustered Randomised Controlled Trial to compare treatment outcomes between children paying weekly and monthly visits to the health center for nutrition follow up.
**Discussion Points:**

- Concerns were raised about the mortality implications of the study— if we don’t visit children for long periods of time, there is a potential for at-risk children not being identified in time.

- The potential impact on coverage was debated— Given that children were already identified as being malnourished, it was thought that it would indirectly influence coverage in relation to improving defaulter rates (as it is a huge disincentive having to go each week to the clinic), and the strain on the health system would also be positively affected (which also influences coverage).

- The cost effectiveness must be highlighted— for the caregiver but also from the health system cost saving perspective.

- The profile of those training the mothers was brought up. Within this study, nurses who had the same profile as those who were normally running CMAM programmes in the district were used as they wanted to create tools that nurses could deliver easily.

- The proportion of women who refused to take part was discussed as there was such a high number of refusals and perhaps opportunities for engagement in relation to this are needed. Younger mothers often needed this change to be approved/ validated by head of household and therefore more sensitization with the household heads at the community level is needed to explain the extra dosages. Perhaps more discussions need to occur with caregivers and flexibility should be given e.g. if the caregiver is not comfortable with the monthly schedule, one could have biweekly distribution or a de-centralised distribution point.

- More evidence is needed on how to plan the monthly visits with mothers to ensure high caregiver attendance rates.

- CHWs could also be utilised in this process to train and support mothers.

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**Theme 2**

**Improving the Coverage of SAM through Improved Diagnosis**

Combined Protocol for Acute Malnutrition Study (COMPAS) (Jeanette Bailey, IRC)

The ComPAS study aims at assessing the impact on coverage, quality (to reduce the incidence of SAM), and most critically, the cost effectiveness on the continuity of care between SAM and MAM cases. It is designed in two stages:

- The first stage involves a secondary data analysis of more than 75,000 children under treatment from different operational settings. A plateau is observed, both in the increase of weight and MUAC after a period of time, which could help define when children reach their normal growth potential and how does this differ in different regions. It is hoped that these results can link growth velocity to an optimal dosage of RUTF, and be used for the definition of an optimal discharge criteria, that would help the stabilization of the nutrition status and prevent relapse.

- The second stage is a field pilot in Kenya and South Sudan, which will take place from June 2016 to December 2017. Results are expected in 2018 and it is hoped that it will provide evidence for a simplified MUAC only programme using one Ready to Use Food (RUF).
**Discussion Points:**

- Participants acknowledged the relevance of the RUTF dosage component of the project for the simplification of policy and programming. For example, moving to a simple rule of 2 sachets for MUAC<115 and 1 sachet for MUAC >115. National protocols are too complex and need simplification.

- Furthermore, the current practice is to wait for children to develop SAM before treating them, while the need is certainly more gradual as children deteriorate to or recover from severe acute malnutrition. There is a need to link these interventions to the broader prevention discussions.

- The approach also highlights the limitations of the use of 'traditional' anthropometric indicators, which are re-enforcing the divide between SAM and MAM. The participants discussed the opportunities to move towards other indicators such as weight gain or growth curve for discharge, i.e. using physiological indicators rather than anthropometric indicators. There are still a lot of questions to be addressed on these indicators (early weight gains are usually fat rather than muscles for example). COMPAS is not including body composition analysis but other studies are (MANGO). It was suggested that these two studies work closely in order to result in coherent outcomes to the research. And indeed ComPAS and MANGO are working together under CIFF funding, in a consortium called ‘TOPTI.’

- The presenter stressed that one of the main interests of the research is to analyse sub-characteristics (how does response to treatment differ according to region? Nutritional status on admission? Age? Treatment outcome?). Going beyond traditional indicators to understand the recovery process, for example analysing energy requirements.

- The participants agreed that the origin of the protocol regarding the quantity of RUTF is unclear and therefore this aspect of the protocol could/should be reviewed; critically. Furthermore, if family sharing is ever taken into account in setting such protocols. It was noted that scientists suggest that current dosage is overestimated with the expectation that sharing would occur.

- RUTF is more expensive than RUSF, due to the amount of milk in the product. Yet the cost has to be considered holistically: the use of one product would simplify production/supply chain and management; at program level, the compliance of beneficiaries is expected to be greater (no loss of follow up between one component of the program and the other). These “savings” might be greater than the extra cost of using RUTF versus RUSF.

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**Mothers understand and can do it (MUAC), (Kevin P.Q. Phelan, ALIMA)**

The presentation by Alima outlined a pilot study to determine whether mothers could use MUAC to identify and refer SAM cases for treatment. The study was conducted from September 2011 to April 2012 in Niger. Results\(^5\) showed that:

- There was excellent concordance with CHW measurements and no gross errors were seen (errors were only on the boundaries).

- There was no difference when measuring left and right arms or estimating the middle point by eye or measuring the middle point.

- At a qualitative level, the study resulted in not just others wanting to understand MUAC measurements but in fact, the entire community.

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\(^5\) Results were published in the Archives of Public Health (June 2015).
A larger scale study was conducted from April 2013 to May 2014, where two zones in Niger were compared. The control zone had a traditional CMAM programme with a highly functioning CHW network. Mothers were trained through group sessions followed by individual home visits where they were provided with MUAC tapes. In total, almost 13,000 mothers were trained. Training to mothers focused on what they should do if the child’s MUAC was in the red section of the tape (visit the clinic within 2 days). If the child’s measurement was in the yellow section, they were advised to attend the MAM programme (however, there were differences in the functioning of the MAM programmes within the two zones). The results of the study were:

- Mothers showed a 75% MUAC concordance while CHW’s showed 40% MUAC concordance
- Median MUAC at admission was higher in the Mothers Zone
- Lower hospitalisation rates were evident in the mother group and coverage was similar in both groups.
- There was a higher initial investment with the mothers but overall the intervention cost just over €6,000 in the mothers’ zone and €16,000 for the CHW’s zone (largely due to the provision of cash incentives).
- Comparing the costs per child- within the mother’s zone, it amounted to €0.76 and €2.20 in the CHW zone.

However, limitations of the study included:

- The fact that it only lasted 11 months meant that behaviour changes cannot be fully evaluated.
- Bias was introduced due to the uneven MAM programmes within the two zones.
- MUAC eligibility was restricted due to the height cut-offs of 65/67cm which excluded stunted malnourished children.

The project is now training 40 000 mothers in Burkina Faso, Niger and Mali.

The strategy requires functioning health systems to refer children to but it is a simple and effective tool that mothers can easily use. It could potentially be seen in the same light as thermometers and the ability for non-technical people to use them.

**Discussion Points:**

- There was overall acknowledgement of the appropriateness of the approach and that expansion needs to be accompanied by the systematic use of MUAC for admission and calls for an evolution towards ‘MUAC only’ approaches.
- The approach offers opportunities to integrate SAM and MAM treatment.
- Participants enquired on the way forward to scale up the approach. Kevin noted the main challenges are the protocols and insisted that the approach is not about reducing the needs for CHWs but rather calls for a change in their role (for example from direct outreach to training).
- The approach may reduce the burden placed by acute undernutrition on the health systems, if integrated with other measures such as Seasonal Malaria Chemoprevention (SMC), immunization etc.
- The question remains as to how we can de-centralise without reducing safety, for example, in relation to the lower hospitalization rates, could mothers have missed danger signs?
- This approach is a good example of engaging the community but other community engagement strategies also need to be looked at (e.g. engaging traditional health workers).
OptiDiag-Biomedical Investigations for Optimized Diagnosis and Monitoring of Severe Acute Malnutrition (SAM): Elucidating the heterogeneous diagnosis of SAM by current anthropometric criteria and moving beyond (Trenton Dailey-Chwalibóg, ACF-F)

Given the diagnostic discrepancy between MUAC only and WHZ only measurements (there is only an 18.8% overlap between the two measurements globally), none of the indicators is entirely satisfactory to identify the children considered as acutely malnourished today. There is a need to examine alternative indicators for diagnosing SAM. OptiDiag aims to look at a range of deprived nutritional indicators at physiological level and assess the correlation with anthropometric measurements. Their field use, feasibility and added value will also be considered. Given time implications, this presentation only focused on three indicators out of many that are being considered in the study:

· Stable Isotopes: isotopic ratios for carbon and nitrogen vary with one’s metabolic status (particularly in relation to starvation and nutrition rehabilitation). These isotopic ratios can be measured using hair strands. The analysis of hair follicle can highlight the nutritional history of the individual.

· Leptin Levels: leptin, a hormone secreted in the adipose cells, helps to inhibit hunger. Low levels of leptin highlight fat store adequacy. In a recent study in SAM children in Uganda, mean leptin level at baseline was 250 pg/mL for children who survived but significantly lower for those that died (with the highest level of 35 pg/mL being reported in those that died). Therefore, leptin levels could indicate mortality potential. This can be measured through tests using smartphone chip blood analysis (tests have a long shelf life, can survive high temperatures, and are easy to use).

· Bioelectric Impedance– looks at the resistance of the body to small, harmless electric shocks. Current flows more easily through the parts of the body composed of water (i.e. blood, urine, muscle) and less so through bones or fat. Changes in hydration have been shown to predict survival and hence, this test could be used to indicate mortality potential. This can be measured using a portable battery operated device.

These measurements (as well as the others included in the study) will allow an analysis and diagnostic that will go beyond the MUAC only and WFH/ MUAC dilemma. Other markers that will be assessed include micronutrient status (including Vitamin A & iron), immune status, clinical signs and mortality.

**Discussion Points:**

· Participants further discussed how MUAC and WFH tend to identify different groups (i.e. MUAC tends to identify younger, shorter, female malnourished children and WFH tends to identify older, taller male malnourished children). While this is known we do not know the reasons behind this and perhaps this study can look more into the reasons behind this, and include stunting in the scope of consideration.

· Participants raised many questions on the application of the research and appreciated that this research is being conducted without necessarily having a clear understanding of potential public health implications but rather highlights ‘out of the box’ and innovative thinking.

· The presenter clarified that the main goals of the research are:
  
  - To enhance the understanding of physiological differences among individuals identified through traditional anthropometric indicators (MUAC, WFH)
  - Test the field use/ feasibility of new indicators
Participants made clear recommendations to use the research to increase the understanding of kwashiorkor. But it will require changing the sampling.

Participants also raised concerns regarding the acceptability of the methods by individuals/communities. However, the research lead has taken this into account.

Participants agreed that MUAC is the best indicator of mortality and it does not need to be further proved.

**Conclusions**

The contributions of the presentations highlighted the challenges currently faced in the treatment of SAM, as well as studies synergies and complementarities. The presentations and discussions highlighted that:

- There is a need to be both effective and to reach scale in order to address the key challenges faced in the treatment of SAM.
- Operational constraints are a great motivation for the development of alternative and innovative approaches: there is a need to capitalize on the lessons learned and keep improving practice of the field.
- Community based approaches are required to increase the coverage of interventions, however these need to be matched by quality services.
- There is a general consensus for the need to simplify protocols and approaches.
- Different approaches are required to reduce the cost of treatment while retaining the effectiveness of services.
- The artificial dichotomy between treatment of SAM and MAM needs to be addressed.

It was agreed that the findings of the studies presented during the day would be shared in a follow-up meeting in two years.
## Annex 1. Technical Roundtable Agenda

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<td>9.00 - 9.10</td>
<td>Opening of the Roundtable</td>
<td>Florika Fink-Hooijer</td>
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<td>ECHO Director on Strategy, Policy and International Co-operation</td>
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<td>9.10 - 9.30</td>
<td><strong>Welcome and Introductions</strong></td>
<td>Sophie Whitney</td>
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<td>Humanitarian Affairs Consultant</td>
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<td>9.30 - 10.15</td>
<td>Severe Acute Malnutrition 2.0 improving the</td>
<td>Saul Guerrero</td>
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<td>effectiveness of SAM treatment</td>
<td>Director of Operations, ACF-UK</td>
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<td>10.15 - 11.00</td>
<td>Effectiveness of an optimized RUTF dosage</td>
<td>Cécile Salpéteur &amp; Anne-Dominique Israel</td>
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<td>Nutrition Research Project</td>
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<td>Coordinator &amp; Senior Nutrition and Health Coordinator, ACF-FR</td>
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<td><strong>11.00 - 11.30: Tea/Coffee break</strong></td>
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<td>11.30 - 12.15</td>
<td>Spacing of monitoring of SAM cases</td>
<td>Sheila Isanaka</td>
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<td>Nutrition Epidemiologist, Epicentre</td>
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<td><strong>12.15 - 1.15: Lunch</strong></td>
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<td>1.15 - 2.45</td>
<td>✔ Presentation 1: Simplified and expanded</td>
<td>Jeanette Bailey</td>
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<td>criteria for admissions using MUAC</td>
<td>IRC's emergency nutrition advisor</td>
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<td>✔ Presentation 2: Mothers understand and can</td>
<td>Kevin Phelan</td>
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<td>do it (MUAC)</td>
<td>ALIMA</td>
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<td>✔ Presentation 3: Optimized Diagnosis and</td>
<td>Trenton Dailey-Chawalibog</td>
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<td>Monitoring of SAM (the future?)</td>
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<td><strong>2.45 - 3.15: Tea/Coffee</strong></td>
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<td>3.15 - 4.30</td>
<td>Plenary Session to conclude discussions on</td>
<td>Hisham Khogali</td>
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<td>improving coverage through diagnosis</td>
<td>Humanitarian Affairs Consultant</td>
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<td>4.30 - 5.00</td>
<td>Conclusion &amp; next steps</td>
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