MSF Vaccination Policy Paper

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In the past several years, MSF has focused more on medical activities that involve direct patient care. Vaccination activities have been considered a preventative public health measure deemed to be the responsibility of the Ministry of Health and supported by UNICEF. However, in most MSF contexts the health infrastructure is weak or collapsed and immunization coverage remains insufficient to prevent disease and outbreaks. With the exception of responding to epidemics, MSF has neglected vaccination activities in the projects. This not only relates to traditional and underused vaccines, but also the newer vaccines. As a medical organization that provides health care to populations, it is not acceptable to ignore such an activity that is so effective in preventing significant disease and death.

This vaccination policy describes where MSF aims to be regarding vaccination activities in projects within the next three years. The accompanying strategic document[1] illustrates the framework to reach the policy recommendations. Operationalisation of the policy requires contextualization and design of appropriate/relevant interventions in MSF projects based on this policy position.

Background Information

It is estimated that approximately 2 million deaths annually are due to diseases that are preventable by vaccines currently recommended by the World Health Organization.[2] Of these deaths, approximately 1.5 million occur among children under the age of five. An additional 2.1 million deaths, of which 1.1 million were children, are estimated to be due to pneumococcus, meningococcus and rotavirus.[3] For these infections, a vaccine is either currently available or will be in the near future.

The use of immunization to prevent infectious diseases is one of the most cost effective medical interventions in public health. Over the past decade, global immunization coverage rates have been rising marginally. However, in the poorest parts of the world, the coverage rates for traditional vaccines[4] have been drastically declining since the 1990s. In recent years, MSF has been confronted with outbreaks in open as well as closed situations in these areas.

Inequality remains in access to immunizations. Large population groups do not receive any immunizations or only the first vaccines of a series, remaining partially protected. Vaccines routinely used in industrialized countries like Hepatitis B and *Haemophilus influenza* type b have been slow to be available and used in low-income countries. Newer vaccines (Meningococcal and Pneumococcal) are expensive and in many countries, not affordable. The cost of immunization will only increase as countries include the newer and more expensive vaccines in their programs, further widening the imbalance.

[1] The MSF Vaccination Strategy for Project Level.
[2] Vaccines currently recommended by WHO: Measles, DTP, Polio, Yellow Fever, Hepatitis B, *Haemophilius influenzae* type b (Hib) and BCG
[3] WHO 2002 statistics reported in 2004 Global Immunization Data
[4] see definition section

Definitions

Vaccines can be classified as:

- **'traditional vaccines'** known as the EPI package of BCG, DTP, oral polio and measles vaccine for children and TT for women of childbearing age.
- **'underused vaccines'** which includes Yellow Fever (should be included in the EPI in countries at risk), *Haemophilus influenza* type b (Hib) and Hepatitis B.
- **'new vaccines'** which include the available cholera vaccine and the recently partially available rotavirus vaccine[5]; the meningococcal conjugate A vaccine (2010), the heptavalent vaccine of DTP-HepB-Hib-MenAC and the pneumococcal conjugate vaccine for prevalent strains in developing countries[6] are anticipated to be available within the next 1-3 years. Vaccines for HIV, malaria and TB are under development and are not expected to be available within the next decade.
- **other vaccines:** those that are specific to specific regions like Japanese Encephalitis or specific diseases like Rabies and the current polysaccharide meningococcal vaccines (AC, ACYW135) used during meningitis outbreaks.

Overall Aim – To reduce mortality and morbidity from vaccine preventable diseases, MSF strives to offer effective vaccination (relevant to the country and the context), to susceptible groups within the project's target population as well as respond to outbreaks.

The objectives of vaccination can be summarized as:

1. Vaccination to reduce mortality and morbidity in the individual (individual protection)
2. Improving vaccination coverage to reduce the possibility of outbreaks (dependent on herd immunity)
3. During an outbreak – vaccination to reduce transmission of infection or clinical expression thus preventing / reducing mortality and reducing morbidity

The overall objective of vaccination depends on the context. In closed emergency settings[7] or areas with a high risk of an epidemic (based on epidemiologic assessment), the main objective of vaccination is to prevent outbreaks of communicable diseases with significant mortality by ensuring high immunization coverage. In an open setting where it may not be feasible to reach high enough coverage to achieve herd immunity, maximal individual protection is the aim.

[5] A vaccine for rotavirus is licensed in Mexico and another one in the US.

[6] The 9-valent pneumococcal vaccine, which includes serotype 1 and 5, has already been tested in Gambia and South Africa, but is no longer manufactured. The 7-valent conjugate vaccine (Prevnar) is available and used in industrialized countries.

[7] Closed settings include refugee and IDP camps and therapeutic feeding centres.

Routine (Non outbreak) Vaccination Activities

1. Routine vaccination activities should be an essential and integrated component of all MSF primary health projects as well as stable[8] closed settings (including IPD).

In many MSF projects, even those involved with primary health care where vaccination should be a component, vaccination coverage remains unacceptably low.

- In all MSF projects, the need for vaccination activities should be assessed according to context and subsequent objective of vaccination, the prevalence of vaccine preventable diseases, vaccination coverage rates and the response capacity of the Ministry of Health or other health actors regarding vaccination.
- If there are unmet needs regarding adequate immunization within the target population[9], MSF should takes steps to address this and when necessary directly provide vaccinations.
- The options of support/interventions are detailed in the strategy document.

2. Vaccinate with more antigens – traditional and underused vaccines

National immunization schedules vary between countries with the types of vaccines offered being dependent for the most part on financing. The majority of countries where MSF works are low-income and therefore international recommendations have been slow to be implemented.

- MSF should strive to provide a vaccination package to children, which includes BCG, DTP, measles, polio, yellow fever (in risk countries), hepatitis B and Hib vaccines[10].
- Ideally, combination vaccines should be used – for example, pentavalent (DwPT-HepB + Hib)[11].
- MSF should strive to provide TT and Hepatitis B to women of reproductive age.
- With additional vaccines in schedules, optimal timing and feasibility needs to be reviewed.

3. Introduce new vaccines within identified MSF projects

To gain knowledge on the feasibility of utilization as well as the practicability of scaling up, MSF should plan to pilot new vaccines that are licensed and available according to contextual needs.
For example:

- Two rotavirus vaccines[12] are already licensed – the one in Mexico is expected to be available in Asia, Latin America and Africa by mid 2006 and should be the first new vaccine to be introduced. The other one has recently been licensed in the USA but has yet to be tested in developing countries.

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[8] The situation is considered stable after priorities (which include measles vaccination) have been implemented or mortality rates are under control, usually 2-3 months after the implementation of an emergency response. It is anticipated that the population will remain for a period of time.

[9] The target populations are the beneficiaries of the MSF project. For vertical programs, these are generally the direct beneficiaries of the activities. For non-vertical (primary health care) programs, the beneficiaries are the population in the defined catchment area.

[10] The estimates of Hib incidence in Africa are high (less in Asia) and studies in Africa document significant reduction of Hib meningitis and pneumonia after introduction of the Hib vaccine. WHO/GAVI recommends the assessment of the burden of Hib in developing countries to aid policy makers regarding introduction of the vaccine in the national programs. MSF believes that there is sufficient evidence of the benefit, efficacy and safety of the Hib vaccine to recommend its addition to routine immunization programs in developing countries.

[11] In countries with high prevalence of Hepatitis B (> 8%), then monovalent Hep B vaccines is required within 24 hours of birth.

[12] GSK Rotarix contains only the G1 serotype, which accounts for over half infections worldwide but also provides approximately 80% cross protection against non-G1 strains. Merck RotaTeq contains five serotypes (G1-G4 and P1), which accounts for 75% of rotavirus strains globally.

- MSF needs to proactively monitor the availability of the pneumococcal and meningococcal conjugate vaccines as well as evaluating their applicability in benefiting the target population. MSF should not delay once these vaccines are licensed and deemed safe, in commencing their use in specific projects.

4. Vaccinate more susceptibles – extend targeted age group for vaccination

Most country immunization schedules only include children below 1 year of age, despite many children having low or no vaccination for the previous years[13]. Thus many older children are at risk for vaccine preventable diseases and it is a missed opportunity not to vaccinate above 1 years of age when these children are seen.

- MSF should extend routine immunizations to all children under 5 years of age if local DPT(3) and/or measles coverage is less than 80%
- In case of conducting supplementary immunization activities (campaigns) for measles, the target group should initially include children up to 15 years of age
- Hepatitis B vaccines should be considered up to 15 years (adolescents) – dependent on prevalence.

5. Implement alternative strategies in order to increase immunization coverage and improve vaccine delivery system in MSF contexts

Choice of appropriate strategies and of appropriate antigens depends on the contextual situation and feasibility of implementation. Different strategies of fixed sites, outreach, mobile teams and mass vaccination campaigns should be considered in each MSF setting. More than one strategy may be needed and the choice depends on the population's level of access to health care services.

- Where there is low vaccination coverage and difficulties of access by the population, MSF should consider, if relevant to the context, periodic systemic vaccination campaigns with the targeted vaccines (included in primary health package).
- Flexible cold chain strategies – with vaccine vial monitors (VVM) and open-vial policy (OVP), MSF needs to explore a leaner cold chain that maintains vaccine quality but improves vaccine delivery for MSF activities. The intention is not to take over responsibility for cold chain from the MoH.
- Injection safety and waste disposal systems: new technologies in vaccine delivery need to be followed.

6. Address vaccination in specific groups – including HIV+ individuals, malnourished children, war/natural disaster wounded persons, rabies vaccine in health facilities

- Recommendations on vaccination of infants of HIV+ mothers, asymptomatic and symptomatic HIV+ children and adults should be agreed by the HIV/AIDS working group and implemented in programs.[14]
- In feeding programs – all children should be vaccinated for measles. The other vaccines should be made available so an opportunity for vaccination is not missed. All lactating women and caretakers should be offered vaccine for tetanus to avoid missed opportunities.
- Victims of sexual violence should be vaccinated against hepatitis B and tetanus.
- Projects involved in responding to war wounded, wounded patients from natural disasters (tsunami, earthquake, etc.) should systematically provide tetanus toxoid and immunoglobulin.
- In regions where clinical cases of rabies are seen, MSF should provide rabies vaccine and, if relevant to the context, immunoglobulin for the management of persons with possible exposure to rabies as well as to health care providers and caretakers caring for cases of clinical rabies[15].

[13] WHO's global immunization strategy for 2006-2015 aims to extend immunization services to older children and adults as appropriate.

[14] Questions include issues regarding use of pneumococcal polysaccharide in adults (Uganda paper), when to give vaccines (related to CD4 counts).

[15] For the management of rabies, see the MSF Clinical Guidelines. Rabies immunoglobulin has a short shelf life, is costly and requires a functioning cold chain. It may not be practical to have in projects and will require justification.

7. Monitor MSF vaccination activities

To allow appropriate action regarding vaccination in MSF projects as well as monitoring of activities, certain data is required and should be collected routinely. Assessment and monitoring indicators need to be standardized.

- Vaccine preventable diseases with epidemic potential should be included in a MSF early warning surveillance system.
- Vaccination coverage of the target population should be determined by routine data collection and if necessary, with community surveys.
- Passive monitoring of adverse effects, especially in relation to vaccination of HIV+ individuals and infants born to HIV+ mothers should be considered.
- Evaluations on cost and organizational aspects should be done in selected settings.

Outbreaks of Vaccine – Preventable Diseases[16]

8. During an outbreak, case management (treatment) is the priority for MSF interventions. Mass vaccination campaigns should be done before the epidemic peak to reduce transmission but, depending on disease, can be considered even after the peak to reduce mortality and morbidity

Early detection of outbreaks for a timely response relies on good surveillance.
In closed settings, generally there are an earlier detection and a well-defined population at risk.
In open settings, outbreaks are often reported late and the geographic evolution may be difficult to predict. The choice of strategy depends on the stage of the epidemic, the disease, the vaccine, availability and effectiveness of treatment.

- During the outbreak, the stage of the epidemic needs to be assessed as to whether mass vaccination will affect the evolution and/or have impact on mortality. Epidemiological analysis should be done as early as possible.
- For measles outbreak in an open setting, there should be a clarification of the definitions regarding local epidemic alert level and peak as well as the catchment area[17]. Mass vaccination campaigns should be considered for children up to 15 years old, even late during the outbreak as experience has shown this can still affect transmission.

9. Within MSF projects located in high-risk areas, consider mass vaccinations campaigns aimed at preventing outbreaks

In closed settings:

- Mass vaccination of measles to ensure high coverage (aim for 95-100%) of the target population (6 months – 15 years) to prevent outbreaks is one of the top ten priorities and should be done early during the emergency phase.
- Yellow fever vaccination[18] should be considered in endemic (high risk) areas

[16] Vaccine preventable diseases with epidemic potential and significant mortality include: yellow fever, meningitis, measles, and cholera. Others to consider: pertussis, diphtheria and Japanese encephalitis.
[17] Measles outbreaks in open settings are more difficult to define as there is not a clearly defined epidemic threshold and the evolution often occurs over a prolonged period as transmission spreads through geographic regions. MSF recent experience in measles epidemics show a benefit for mass vaccination at least 6-8 weeks and even longer, after an outbreak has been declared.
[18] Mass vaccination with two antigens usually slows down the speed of the campaign. If yellow fever vaccine is not given with measles vaccine, then 4 weeks is required between the two injections as they are both live vaccines

- There is no consensus on vaccinating against cholera in camp settings and a decision should await more information. Due to logistics and cost constraints and limited data about the duration of immunity, it is not clear whether it just as effective to ensure adequate water and sanitation.

In open settings:
In many countries where MSF is working, recurrent measles, meningitis and sporadic yellow fever epidemics in open settings occur with high mortality and morbidity. In situations deemed high risk, MSF should consider conducting mass vaccination campaigns to avoid such consequences.

- Measles: Within MSF projects, if health facilities are reporting measles cases and measles vaccination coverage is low, MSF should respond with appropriate strategies to increase coverage (e.g. conduct supplemental immunization campaigns). The target group for the vaccination campaign would depend on previous vaccination activities and analysis of the data (age effected).
- Yellow fever: In countries at risk, MSF should strengthen the surveillance including outbreak investigations and be prepared to respond quickly in case of an outbreak.
- Cholera: No conclusive data to make a clear recommendation. Needs to be followed.
- Meningitis: preventative mass campaigns are not considered with the existing vaccines.

10. Implement efficient mass vaccination strategies

It is important, especially during an epidemic, to be able to vaccinate the maximum number of people within the shortest time possible.

- For mass vaccination campaigns, planning and organizational tools that have been developed by MSF should be accessible for all sections. Different strategies should be considered (see strategy document).
- New technology for injection should be followed closely for its use in mass vaccinations.
- Vaccines should be available in multidose vials. Difficulties with obtaining them should be followed up by Access Campaign.

Advocacy and International Issues

11. Advocate for the introduction of underused and new vaccines at affordable cost to low-income countries based on MSF experience

Vaccines need to be available and at affordable costs. Although there are some financial mechanisms in place via the Vaccine Fund, the introduction of underused vaccines is often linked with the performance of EPI and is for a limited time (5 years). Development of vaccines targeted to developing countries may not be considered financially interesting to pharmaceutical industries. Technology for useful vaccines may exist but not progressed further.

Advocate on:

- Inclusion of underused vaccines like yellow fever, Hepatitis B and Hib in national schedules. Vaccines should be more affordable.
- The new and soon to be obtainable vaccines need to be available and at reasonable costs. Specifically – rotavirus vaccine, conjugate pneumococcal vaccines 9 or 11-valent, conjugate meningococcal A and heptavalent including meningococcal A+C.
- The development and availability of combined vaccines (pentavalent at affordable cost) should be promoted in order to reduce the number of child immunization contacts needed and thus reduce lost opportunities, which is key to improving immunization coverage.

12. Proactively monitor new technologies and developments, evaluating usefulness in MSF projects

This includes new vaccines (those being developed), new tools for vaccine delivery (aerosol vaccines, solid vaccines, new needle jet injectors, etc.) and new cold chain technologies.

13. MSF guarantees high standards in vaccine quality and safety and contributes to ensuring adequate vaccine stocks are available.

- MSF uses WHO pre-qualified vaccines, which come with vaccine vial monitors (VVM). Only in the situation of new vaccines, MSF will rely on proper registration/licensing of the vaccine and not necessarily wait for WHO pre-approval.
- MSF is following the bundle policy (vaccines always supplied with auto-disabled syringes and safety containers. Proper waste management is ensure).
- MSF should remain an active member of the International Coordinating Group (ICG) to ensure adequate stocks of meningitis (A&C, and ACW135) and yellow fever vaccines.

14. MSF position on global eradication initiatives

In principle, MSF supports the idea of global eradication of certain diseases. However MSF participation should depend on its contribution to MSF project objectives of reducing morbidity and mortality in the target population.

- If concurrent with MSF objectives, MSF can support with logistical and technical assistance if resources allow. It is not the intention that MSF takes over responsibility of this initiative.
- MSF should encourage National Immunization Days (NIDs) that include measles vaccine in addition to polio vaccine in countries where measles is not controlled.
- In specific situations where NIDs obstruct life saving activities such as mass vaccination campaign as part of a response to an outbreak/epidemic, MSF should engage in formal discussions with WHO/MoH to ensure adequate response to minimize mortality. Public statements should be reserved if these discussions are unsuccessful.

15. All staff within MSF projects (including MoH) should be offered relevant protection

Both expatriate and national staff should be immunized taking into account different susceptibilities to diseases.

- For all national MSF staff and MoH staff working in MSF projects recommended vaccines (minimum TT and hepatitis B vaccines) should be standardized and offered. In the event of outbreaks of vaccine preventable diseases (meningitis and yellow fever) and specific situations (rabies cases, risk of avian flu), additional vaccines need to be available for staff protection.
- For expatriate staff – recommended vaccines pre departure should be standardized among all MSF sections. Vaccines should be available in the field to ensure completion of series or boosters as required.
- Vaccination team should be well informed on how to prevent infectious diseases transmission through the application of standard precaution. Post exposure procedure to be followed in case of accidental exposure to blood have to be known and prophylaxis available.

Each section should have a person dedicated to provide technical assistance to the field for the implementation of the policy in MSF projects. Each member should be an active member of the vaccination-working group.