MEDECINS SANS FRONTIERES
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INTRODUCTION TO THE POLICY:

The **Patient Safety Incident (PSI) Policy** originates in the statement that human activities are prone to error and PSIs are an inherent part of the medical profession[1]. As any medical organization performing medical activities, MSF is not exempted from it. Since 2012, MSF-OCG is committed to assume its responsibilities for the PSIs in projects by learning from them to prevent further harm.

A PSI is defined as an event related to the medical management of a patient, or a healthcare circumstance that could have resulted, or did result, in unnecessary harm and is not linked to the natural progression of the health condition.

This policy is a reference document for managers in charge of health care provision and managers of supporting activities, and it applies to the entire MSF OCG Workforce.[2]

PSI POLICY – MAIN OBJECTIVES

The overall aim of this policy is to reinforce MSF-OCG's accountability toward patients and their families. A systematic approach to the PSIs will enable a learning culture and ultimately reduce their occurrence, while improving the quality and safety of the care provided to patients in MSF OCG's projects.

The policy includes a clear guidance to the immediate response, analysis, reporting and learning processes, and at the same time promotes this integrated management through a non-blaming and supportive frame.

Specific objectives

1. To improve the **systematic approach and immediate management** of PSI cases with:
    a. Clear guidance on the main steps to follow, analysis of the situation, and management of the consequences.
    b. Expert advice on medical, technical, legal, finances, and human resources aspects when needed
    c. Specific support for the disclosure of the PSI to the patient, the family, the community and the health team.
    d. Once the immediate PSI is managed, support to the health team with the follow-up and monitoring of the improvement actions implemented.

2. To get a **global understanding of the main incidents happening in OCG, their impact and the improvement interventions taken** through an internal reporting & monitoring system. The lessons learned in one context can serve others and participate to the global improvement of patient care and patient safety within the organization, in a continuous way.

[1] MSF SAE Guiding Principles, 2012

[2] **MSF OCG's Global Workforce** implies all employees under MSF contract working under the management of MSF OCG. Those MSF contracts include Swiss employment contacts, MSF employment contracts provided by other MSF Operational Centres, MSF Partner Sections, MSF OCG missions or specific employment contracts related to conventions between an external entity and MSF (i.e. HUG), and daily workers. Because of no subordination link, MSF OCG Global Workforce does not imply consultants/independents, sub-contractors and people receiving incentive payments (e.g. MoH staff).

MSF-OCG RESPONSIBILITIES

MSF OCG acknowledges its responsibility towards its global workforce regarding the PSIs occurring in MSF OCG managed structures.

The responsibility that lies within MSF OCG is to work with the health teams on the resolution and mitigation of PSIs incidents. Above all, reporting and learning needs a protective environment for professionals, avoiding blame and retaliation.

Whether MSF is working in a full MSF structure with its own staff, as a support to the Ministry of Health (MoH), or in any other supported structure, with staff from the MSF OCG's Global Workforce or not, the organization will always encourage a systematic and open approach to incidents (if not already the case) and support its implementation. This way, MSF will make sure to support accountability to the patients, wherever the healthcare is provided.

As much as consequences for the patients and their families are of utmost priority for MSF-OCG, consequences for staff (stress, moral distress), the project (community acceptance, security of MSF staff) and for the organization's image are also very important to consider when wanting to maintain continuous security for all, and access to healthcare for the populations.

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POLICY CONTENT AND FRAMEWORK

INTERNAL REPORTING AND LEARNING SYSTEM – WHY, HOW AND WHO

Having an **internal reporting system** allows transparency within projects and in the organization, defining common goals on safety improvement, and sharing lessons learned in a confidential manner by learning from the incidents linked to health care.

> **"PSIs are often provoked by systems or processes errors and often have common root causes and solutions, which can potentially be generalized.**
> **Although each event is unique, it is also likely that there are similarities and patterns in the sources of risk that may be common across different health structures, organizational cultures, and communities."** [3]

To support the reporting, analysis and subsequent responses to a PSI, tools are available within MSF-OCG to help guide and support the field teams:

- **Briefing note and Standard Procedures for the management of a PSI** (Annex 1)
- **Template for the reporting of a PSI** (Annex 2)

The PSI report should be sent to the following email address: **msfch-medical-incidents@geneva.msf.org** (offering a confidential follow-up of the cases).

Reporting a PSI is the responsibility of anybody (medical and non-medical) involved or witnessing an incident. People should feel free and safe to report it.

[3] Larizgoitia, I., Bouesseau, M. C., & Kelley, E. (2013). WHO Efforts to Promote Reporting of Adverse Events and Global Learning. *Journal of public health research*, *2*(3), e29. doi:10.4081/jphr. 2013.e29

The case goes to one person trained (from the Improving Health Care (IHC) team for now). Depending on the specificities of the case and healthcare specialty involved, an advisor or even a wider group might need to be involved to answer the person or the team reporting the incident, to define how best to support the situation. The person from the platform will remain the focal point for communication during the whole process. Answers are usually given during week days.

DEFINITIONS LINKED TO PATIENT SAFETY INCIDENTS

"**Patient safety** is the absence of preventable harm to a patient during the process of health care and the reduction of risk of unnecessary harm associated with health care to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment."[4] [5]

Harm is defined as any impairment of structure or function of the body and/or any further deleterious consequence from it. Harm includes disease, injury, suffering, disability and death. In MSF, we also consider that harm is present when the patient suffers from a longer stay in our project because of a PSI.

Identifying a PSI does not necessarily imply "error", "negligence", or poor-quality care. It just indicates that an undesirable clinical outcome resulted from some aspect of the health care given.

There are **three types of PSIs**

- **A harmful incident:** those that resulted in harm to the patient. MSF OCG describes it as "Any unexpected event happening during the medical management of a patient under the responsibility of MSF OCG that is not due to the normal evolution of the medical conditions of the patient."
- **A no-harm incident**: those that reached the patient, but no discernible harm resulted.
- **A near miss**: those that did not reach the patient and therefore no harm resulted.

Harmful incidents are the visible part of the iceberg, the PSIs that we can actually see happening. Therefore, as much as no-harm or near misses can be reported to the platform to get support on improvement actions**, harmful PSIs need to be reported each time they happen,** for close overall monitoring, and support when needed.

ETHICAL BACKGROUND TO THE REPORTING OF PATIENT SAFETY INCIDENTS

As a humanitarian organization, MSF makes sure ethical principles frame the reasons behind a PSI reporting and learning system.

Two principles from the MSF Charter[6] are linked to the ethical aspects when reporting PSIs.

- **The respect of medical ethics** encompassing "the duty to provide care without causing harm to individuals or group, the respect of patients' autonomy, patient confidentiality and their right to informed consent…". "In accordance with these principles, MSF endeavors to provide high-quality medical care to all patients."
- **The accountability to its beneficiaries**, which is defined as "Aiming at maximum quality and effectiveness, MSF is committed to optimizing its means and abilities, to directly controlling the distribution of its aid, and to

[4] WHO | Patient safety. *WHO* Available at: http://www.who.int/patientsafety/en/ (Accessed: 20th June 2018)
[5] World Health Organization. Patient Safety: Making health care safer. Publication. WHO Geneva. (2017).
[6] Médecins Sans Frontières. Charter and principles. Available at: https://www.msf-azg.be/en/msf-charter-and-principles (Accessed: 21.02.2019)

regularly evaluating the effects. In a clear and open manner, MSF assumes the responsibility to account for its actions to its beneficiaries as well as to its donors."

Reporting about patient safety incidents cannot be disentangled from the notion of **transparency and respect** to patients and their families. Reporting systems in principle look at learning for improvement, whereas disclosure looks at recognizing the incident and informing and communicating about it to the patients, relatives and communities who suffered it.
Other ethical principles must frame the PSI reporting and learning system, such as the "**respect for dignity, autonomy, and privacy.**" Patients are entitled to be informed in case of PSI to make free and informed decisions. People suffering harm due to an incident have a fundamental right to receive transparent information. It is the responsibility of health care providers to inform them and their relatives. This may empower stakeholders including patients, and they may contribute to build a common culture of safety.

Reporting systems must prevent breaches of **confidentiality** and protect all personal data. Anonymity may be preferred for this reason; however, this may need to be balanced with the need to come back to the patient if needed in some instances."
In its MSF Health Data protection Policy[7], MSF defines medical confidentiality as the duty to keep a patient's personal information private which applies not just to doctors but more broadly to all humanitarian workers handling patient and community data.

OCG's vision regarding **disclosure** of the incident to the patient (or family) is linked to the fact that people suffering harm due to an incident have a fundamental right to receive transparent information on what happened, why it happened, and the way MSF is managing the situation.
The only limiting factor to disclosure is if it contrasts with the other ethical duty of MSF, namely the duty of care for MSF staff. If disclosure is deemed to cause a threat to the safety of MSF staff, then the duty of care should be balanced with the obligation to disclose a decision by the relevant managers.

COMMON CONSIDERATIONS FOR THE MANAGEMENT OF HARMFUL INCIDENTS

Patient management

The main and most important aspect of managing a PSI is preventing further harm and dealing with the consequences. In such case, a thorough evaluation of the patient outcome will lead to a comprehensive medical and psychosocial plan that will serve to:

1. Stabilize the patient, when possible, to immediately stop the harmful effects of the PSI.
2. Continue the treatment for the initial sickness if still necessary.
3. Provide counselling and psychological support to the patient and their family. This also means making sure they understand MSF is taking the situation seriously and will come back to them with more information when the situation requires it (see Standard Procedures regarding disclosure)
4. Provide means to cope with the consequences of the PSI if needed (see legal aspects below) and be able to disclose appropriate information to the patient and family.

Security and internal communication

PSIs, especially harmful incidents, can be a potential security risk for a specific person, a project, MSF as an organization or on the image of the organization itself.
Because of this, information needs to be collected as confidentially and thoroughly as possible, by the team and any person supporting the process. This will enable to track down detailed information and will support the internal

[7] Health Data protection Policy, 2018

discussions about the risks and benefits of disclosure of the incident for the patient, project or organization, and how the information will be given.
Communication within the team and with the medical and operations' management lines (PMR, MedCo, FieldCo and HoM) starts as soon as an incident happens, to make sure risks are considered and analyzed, and decisions taken accordingly. The tools used for the PSI reporting system (Annex 1&2) will allow this clear follow-up of decisions and actions taken.

Leadership and creating an open environment

To allow a PSI to become a learning opportunity it is crucial that coordinators, leaders, supervisors, and other team members responsible at all levels, set an environment allowing open discussions. At first and when possible, discussions in group (with the people involved in the PSI) or individually should be preferred to asking for explanation letters, so as to talk about what happened and calm down the tensions.
Blame is the main cause of non-reporting. It is of the managers' responsibility to make sure blame is not used when discussing cases, but instead make sure all people involved in a case can give their point of view, the care provided is analyzed by looking at the causes of problems, and that solutions are discussed in a constructive way.
If any behavior aspect is raised during the in-depth analysis of the PSI, it needs to be discussed among the responsible medical, administrative and human resources people to define any specific follow-up to give, confidentially.

Human resources

MSF Human Resources have a responsibility to protect the staff, but also to participate in the accountability to the patients as the recruitment, evaluations and sanctions processed are part of their portfolio.
Cases of negligence, or deliberate acts of malevolence against patients, though fortunately quite rare, need in-depth analysis to be managed properly. They are in fact difficult to figure out when the person is not caught in the act. This HR part of the case management will need to be done in a concerted manner, with the involvement of the medical managers who have analysed the case, and potentially other people. This management as a team, in the field as well as at HQ level, will need the reporting system's support to guarantee confidentiality and contacts with the right specialists.

Communication, and disclosure to the patient and/or the family

For MSF-OCG, the need for disclosure starts with the belief that the only way to ensure the best possible management of a PSI is to acknowledge it, to manage the consequences in the best interests of the patient, the involved staff and the MSF institution.
Before acknowledging an incident and deciding how to approach the patient or family, thorough analysis is a priority. This will also allow to have a complete and professional understanding of the situation. Being respectful, professional and timely usually allows reducing tensions and enables patients/families to participate to the improvement of patient safety[8,9]. In addition, a transparent disclosure sets a good example to the field team as to how these incidents are managed and how MSF OCG upholds good medical ethics despite the possible consequences of an upset family or community.

MSF recognises that specific communication skills might be needed in certain complicated cases, as well as psychological support for the team. When needed, specific advice will be provided to the team through the PSI reporting system to discuss the best contextual support.

[8] O'Connor, E., Coates, H. M., Yardley, I. E. & Wu, A. W. Disclosure of patient safety incidents: a comprehensive review. *International Journal for Quality in Health Care,* Volume 22, Issue 5, 1 October 2010, pages 371–379, https://doi.org/10.1093/intqhc/mzq042
[9] Clinical Excellence Commission 2014. Open Disclosure Handbook, October 2014. Sydney: Clinical Excellence Commission.

Legal aspects

PSIs may have potential negative consequences for the patient, but also for the staff, the organization and the operations as far as legal aspects are concerned. Those aspects range from the management of confidentiality (medico-legal issues), to the management of information internally (by keeping a timeline of events) and towards the patients and their families, archiving of the documents (to be able to explain or produce proof when taken to court), to the management of requests of compensation and litigation.
Compensation for patients and their families can be considered when it would help the patient or the family to cope with the consequences of the PSI such as further treatment or assistance for any disability encountered.
A compensation is not the decision of one person only but will need to be a consensus between various people in the field (coordinators and HoM) as well as the operations, medical, legal and other specialists from HQ when needed.
The compensation can be monetary, or non-monetary such as further treatment, referral, or equipment (crutches, wheelchair, etc.).

In any case, MSF must act in the best interest of the patient and strictly respect medical confidentiality, and as such refrain from disclosing the names or medical information of the individuals who benefit/have benefited from MSF medical services to any third party, family and authorities, without the consent of the patient or outside a formal procedure by the competent authorities. **Correct management of all these aspects will mitigate the risks of litigation, requests for compensation and secure the environment in which the organization and its staff operate.**

Staff Health

A PSI can be very traumatizing for the staff involved. As much as adequate communication within the team and good management of the incident can help get over part of the stress and reactions linked to it, some people might need individual psychological support to be able to cope with the situation and with going back to their work place.

CONCLUSION

The Patient Safety Incident policy aims to minimize events happening during healthcare by supporting teams on the management and learning processes needed for the incidents encountered.
Through a contextual and detailed analysis of a PSI, measurable and appropriate interventions can be set-up in a systematic way and supported by specialists when needed.

The PSI reporting system, through this multidisciplinary approach, results in the thorough management of the cases, the integration of lessons learned and the essential improvement of health care for the patients we serve.

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ANNEXES

Annex 1:

OCG_PSI_Briefing_
Note_&_Standard_P

Annex 2 :

OCG_Patient_Safety
_Incident_report_-_F