5. RISK-BENEFIT ANALYSIS AND VALIDATION

5.1. Conducting a risk-benefit analysis

Before you start writing up your report for publication, it is important to carry out a risk benefit analysis. In many instances, publishing a case report or a case series for which you have secured informed consent will carry with it no ostensible risks. However, case reports very often have elements which could theoretically lead to patient identification (and possibly to healthcare provider and structure identification), regardless of whether the patient has given his/her consent. So even when you have informed consent, you need to think carefully about any potential risks of publishing your report.

Here are some questions to ask yourself:

Is the health condition being described in any way stigmatizing for the patient or his/her entourage? E.g.:

→*sexually transmitted infection*

→*mental health issue*

→*injury caused by sexual violence*

→*severely ill child brought in by parents "too late" such that death ensues*

Could there be any legal or political dangers for the patient, the health care provider, or the health structure? E.g.:

→*resorting to therapeutic means which are illegal in the country (e.g. use of opioids, termination of pregnancy)*

→*treatment for a victim of torture which could indirectly lead to identification of the perpetrators of that torture*

Are there any elements in the report which could infringe upon the patient's dignity? E.g.:

→***if** photographs are included and even properly de-identified, could they still be embarrassing for the patient?*

→ *is it possible to request informed consent without seeming obtrusive?*

Where appropriate: has the patient's perception been included and presented in a neutral way (i.e. non-judgmental with regard to patient beliefs and actions*)?*

You need then to compare these theoretical **risks** to the **benefits** of publishing the report. Here is a rating grid to help you:

How likely is it that the publication of this report will be of benefit to future patients?

Very likely □ Somewhat likely □ Unlikely □

What does this report contribute to the health sciences?

Very important knowledge □ Somewhat important knowledge □ Not such important knowledge □

Is this report illustrative of a greater need: e.g. clinical management, public health, medical ethics, access to treatment in a resource-limited setting, … ?

Yes, very much so □ Yes, somewhat so □ No, not so much □

5.2. Seeking validation

Once you have determined that there are no risks tied to publishing or that these risks can be managed and that the risk benefit ratio of your report is clearly in favor of publishing, you will always need to validate any manuscript containing patient data with your manager. In an MSF context, this may be your Medical Team Leader or your Medical Coordinator, in other contexts it may be the hospital director or the director of your department. In other words, always seek validation from your hierarchical manager.