Author’s response to reviews

Title: Medical error disclosure: from the therapeutic alliance to risk management. The vision of the new Italian code of medical ethics.

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Author’s response to reviews:

Response to review 1.

1) According to the review’s suggestion we shortened the abstract.

2) As suggested by the review in the section “Honest and correct information as a tool in managing clinical risk” we have extended our considerations to errors (diagnostic and procedural) beyond adverse events. We fully agree with the review that the issue of the disclosure of error is even more thorny than that of the disclosure of adverse events. Every error (diagnostic or procedural) must be clearly disclosed to the patients. We have also included some sentences explaining the difference between error and adverse events. The suggested references were added.

Response to review 2.

We added some sentences explaining the two different approaches to medical errors: the individual one (the so called blame – culture) and the approach focused on the system; some references were added too.

We also added more sentences to explain the meaning of the sentence “... the issue of patient safety and clinical risk management, in which the physician plays a role of primary importance”.

The aim of the document of the Ministry of Health and the code of medical ethics is to highlight that the role of the physician is of paramount importance with regard to the informational burden. It could not be otherwise. It is up to the health care giver, who is, in some way, involved in the health – care – related negative event, to explain to the patient and relatives what happened. The health care givers are the professional who, for competence and preparation, is appointed to do this.

However, the guidelines issued by the Ministry of Health include strategies to furnish a psychological support to the health care giver involved in the negative event who is, literally in the document, defined as the second victim.

The document provides, also, an approach based on the careful and thorough analysis of the adverse event, identification of the root causes and contributing factors and the definition of a plan of action to reduce the probability of
occurrence of an adverse event. It states that to promote the effective 
management of adverse events, it is necessary to make available specific means 
to reduce risk, generate the necessary improvements of the system and to 
promote a culture focused on safety in the provision of essential levels of medical 
care. The role of physicians becomes a part of a complex approach based on a 
system focused approach.

Finally, the review asks if “should the healthcare institution take any 
responsibility?".

In the Italian juridical organization the physician who commits an error have and 
individual responsibility in front of the criminal law. On the other hand, if the error 
causes harm to the patient the duty to compensate economically the damage 
suffered by the patient is satisfied by the insurances companies.

Conciliation through the healthcare institution insurance is implemented by the 
guidelines as a tool for alternative dispute resolution that allows faster definition 
of and a reduction in compensation judicial claims.