Reviewer’s report

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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Reviewer: Murat Civaner

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- Minor Essential Revisions

The authors ask the right question at the end of the piece: “How can a disclosure policy be successful when the healthcare providers’ fear of being sued for medical malpractice makes them view their patients only as plaintiffs?”

And correctly emphasized: “Certainly, the deontological standards which provide for communication as a moment of ‘exclusive technical-professional reflection which is reserved and confidential and aims at correcting the procedure and modifying organizational practices and professional behaviour’ may not be sufficient to reassure physicians with regard to the risks of litigation.”

After asking this question, and making this comment, I think the article might continue by mentioning two approaches to medical errors:

- The “blame-culture”, or the approach focused on the individual:
  o which claims that zero-error is possible
  o automatically blames individual healthcare workers for all kind of harms
  o defends an individual insurance system in order to be able to pay the individual compensations
  o doesn’t reduce errors and harms (since it doesn’t care to reduce them)
  o increases litigations & compensations
  o increases regulary the insurance premiums while decreasing the coverage of insurance packages
  o useful to insurance and law companies, but harmful to patients and healthcare workers.

- The approach focused on the system:
  o which claims that “to err is human”, therefore zero-error is not possible, but the frequency of errors could be decreased
  o the main target should be preventing the harm: we need to focus on how to prevent the harm, instead of automatically blaming the individuals, so we need to ask that which measure(s) should be taken for preventing a possible error that causes harm.
o we need a system that will make the errors easily disclosed without the fear of litigation, by giving a legal protection to healthcare workers who disclose the error (This was actually tried to implemented in US by “Patient Safety Quality Improvement Act” issued in 2005 (Please see Section 922, http://www.pso.ahrq.gov/legislation/act)).

o And when a harm has occurred,

a) we need to compensate it in any case (regardless of its definition: malpractice or complication) by a common pool for compensations,

b) we need to make an analysis backwards: how this error happened and transformed into harm (root-analysis),

c) we need to create the new measure to prevent it next time.

(I personally think that we need to implement the system-focused approach, and we need to re-define the term malpractice, as its universal definition points out the individual and ignore the share of the system. That is why I prefer to use the term “healthcare-related harm”, not “malpractice” or “medical error”)

I think the article would be better if the authors would take an open position regarding those two approaches. In the current text, the sentences such as “(…) the issues of patient safety and clinical risk management, in which the physician plays a role of primary importance.” could make the reader think that they (implicitly) defend the first approach, since they don’t mention much about the share of the healthcare system in the nature of harm. In addition, the steps set out by MoH (lines between 156-177) sound that those steps should be taken primarily by the physician. If it is the case, what authors think about it? Is it possible? Is it fair? Is it the viable solution for exercising the right to truth? Should the healthcare institution take any responsibility, for instance?

Otherwise, the article seems to have mainly an informative character, mentioning about a positive development in the Italian regulations. But comments on its viability / chance to implementation would make the article more valuable to international reader.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.