Informing Patients about Group Adverse Events

Group adverse events are those affecting a multitude of individuals rather than a single patient. Although uncommon a group adverse mishap has the potential to cause widespread patient harm and wreak havoc at the implicated institution. The ensuing investigation and surrounding publicity can impact adversely on public confidence. The quantum of error varies enormously. On the one hand the error may be small and of risk of harm negligible. While on the other hand the risk of injury may be substantial. When an adverse event affecting a group of patients takes place the issue of disclosure is of central importance. It is important to appreciate what the term means. Disclosure is the forthright and empathetic discussion with a patient or group of patients about the clinical facts surrounding a harmful event or an event that could cause harm in the future. In general terms there is an ethical and legal obligation to inform patients about any mishap or potential mishap that has been sustained during their care.

If the likelihood of harm is high the need to contact all patients is clear. However when the risk of harm is small a balance must be struck between the professional and institutional need to be honest and the risk of causing unnecessary anxiety and worry. The approach and attitude to this kind of dilemma has shifted over time. Formerly the common good tended to take precedence particularly in the era of very limited health resources. In more recent years the rights and well-being of the individual have become paramount. However there is every possibility that the philosophy may change again in the future.

The two ethical approaches to a multiple patient adverse event are the utilitarian one and the duty-based one. The utilitarian mechanism involves minimising the overall harm and maximising the overall benefit. Accordingly when the risk of injury to the group is low the decision not to disclose the mishap may be justified. The problem is that it is difficult in advance to quantify the possibility of harm. The level of risk may only emerge following a thorough look-back involving testing and assessment of each affected individual. Trust and transparency are also important components in the decision making process. With a duty-based approach the patients need to be informed irrespective of whether the consequences of the mistake are minor or major.

Doctors and their institutions are faced with a paucity of guidance and information about when mass disclosure is indicated. However the Veterans Health Administration has formulated a policy on disclosure in such situations. Its approach is somewhat different to that advised by most sources. While encouraging honesty and adherence to the truth it also has the view that all of the other factors must taken into account before taking action. It is guided, in part, by the probability and the severity of injury. Its algorithm begins by asking whether the exposure is clinically significant. If the answer is no there is no need to disclose. If the answer is yes the institution is advised to research and calculate as accurately as possible the probability of injury to the involved patients. If the risk of harm is less than 1 in 10,000 patients the VHA debates whether disclosure is indicated. If the likelihood is greater than 1 in 1000 disclosure is recommended. While many commentators would not agree with the VHAS approach it does at least attempt to put some kind of framework on what is a very difficult situation. In particular its approach is to avoid a knee-jerk reaction and panic. A skilled panel must be established. This panel should consist of experts that are capable of assessing the likely risk and formulating a comprehensive disclosure process. Testing and treatment needs to be fast and effective. The panel also requires individuals with the skills to interact with the regulatory bodies. The VHA recommends that sufficient time should be taken to gather all the facts and formulate a comprehensive plan before embarking on disclosure.

Dudzinski et al1 in their discussion of the disclosure dilemma document 21 group adverse events. All the series that are cited are North American apart from one Irish event related to mammography screening. Many of the examples relate to ineffective sterilisation procedures for Endoscopy equipment. In 20 of the 21 cases disclosure to the potentially affected patients was made. In 11 of the 21 cases there was no subsequent harm or harm was not known to have occurred. In the remainder there was a spectrum of adverse consequences. They state that the adverse events are different for each occasion and these differences are important for the disclosure pathway. They feel that disclosure should be the norm even when the risk of injury is small. Temporary anxiety in patients involved in the process is not a deemed sufficient reason not to disclose. However, a possible exception is exposure to CJD where is no testing or treatment to offer the patient. The fear and worry accompanying disclosure may lead to significant morbidity.

Following a group adverse event the first step is to determine how disclosure will be implemented. An effective committee needs to be formed. Expertise will invariably need to be bought in as no institution will have sufficient internal expertise. Epidemiologists and statisticians are needed to determine the size of risk particularly as many of the mishaps relate to infection or disease screening programmes. The specifics of the look-back investigations and the implementation of treatment where necessary should be clearly set down. Counselling for those who ultimately are found to be unaffected should also be provided. All the set goals need to be achieved at the first strike. The drip feed of information is psychologically damaging for patients and undermines confidence in the institution. Despite every effort group adverse events will occur in health services. The imperative is how to ensure that the problem is handled correctly.

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