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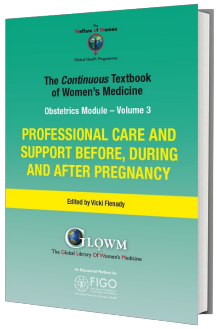

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Chapter

Adverse Event, What Next?

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INTRODUCTION

Unwanted events that result in harm to our patients do occur and probably will keep occurring despite ongoing improvements in the quality of our care. Apart from often unavoidable events, complications such as a urinary tract infection after a catheter insertion, potentially avoidable events occur because humans are wired for making errors and systems do fail in safety checks. The book *To Err is Human*[1] made this painfully clear and started the long-awaited debate on how to cope with medical errors instead of denying them and/or blaming and shaming the offender.

Over the past 20 years increased attention has been given to not only the effects of medical adverse events on the patients, families involved and the care givers, but also policies on management of these events and how to deal with these. Accepting that adverse events do occur and establishing a learning, no-blame environment is the main prerequisite for an effective response to these events. Nowadays, principles of *Just Culture*[2] in organizations are increasingly implemented and serve to raise awareness for a better working environment that will benefit our patients in the future.

This chapter outlines some principles regarding adverse events in healthcare with a focus on maternity care, causes, and how to act. The need to learn from the event with proper attention to the emotional effects on the patients, their family and the care givers is key.

ADVERSE EVENT DISCLOSURE

Several concepts exist when things go wrong in clinical practice: complication, incident, calamity, medical error, adverse event, serious adverse event, mistake, liability, litigation, avoidable, guilt, anger, health care inspectorate, first victim, second victim, third victim, etc.[3] Some concepts are used in different settings which can result in confusion. When a patient experiences harm, neither the patient or the family are interested in how we name the incident. They are mainly interested in two things: (1) “what happened?” including their entitlement to an honest and open answer; and (2) (usually somewhat later in the process) “what are you going to do to make sure this will never happen again?”.

Classification of adverse events is important to have an overview about what happens on your department, and also to prioritize improvement recommendations.[3] The cause of an adverse event resulting in serious harm, and which carries a high probability of recurrence, must be resolved quickly. Two key elements are important to consider as the next step, (1) has the quality of our care failed? and (2) what is the severity of the consequences?

When, after investigation, the conclusion is that the care was consistent with an accepted standard, the event is classified as a complication, even when serious sequelae were encountered. Classification as a complication does not exclude the need for appropriate registration of the event and real-time monitoring of the incidence and causes in order to try to diminish the complication rates. In addition, severe consequences of a complication (i.e. sepsis and death after an uncomplicated urinary tract infection by a catheter insertion) can produce an emotional burden on patients, their family and care givers that needs proper attention. When the quality of clinical care has failed, the adverse event is termed as an incident. Incidents include a range of events and consequences including those which have not reached the patient (i.e. a wrong medication was put forward, but this was recognized before administration) or the patient encountered mild effects only (i.e. administration of an antibiotic with prior known allergic response with only some exanthema rather than full anaphylaxis and resuscitation). Several laws are in place around the world for reporting of serious incidents to external bodies such as an independent or government instituted health inspectorate. In addition, hospitals have systems to report complications and minor or severe incidents to internal committees which will investigate the backgrounds of these incidents and make recommendations accordingly for prevention.

As stated above, the patient (the real victim) is not interested in our classification of the incident. The patient and/or family has the moral right to your full, open and honest disclosure about what happened.[4,5] This is not an easy thing to do. The instigation of court cases about medical errors can often be traced back to the first conversation between the patient and the care provider about what happened, where the patient or family found the conversation unsatisfactory. Talking honestly about what went wrong and apologizing, if appropriate, is the right thing to do. However, this is a very challenging task at this time of maximum clinician and patient vulnerability where there are usual differences between patient and clinician expectations. This conversation requires skills and may benefit from prior advice by an experienced coach. Support for the patient and the care giver is crucial. Potential pitfalls on the part of the care provider may often include denial and defensiveness or on the other hand over-blaming himself or herself and, at the same time, not listening to the patient. The timing of this conversation should be as soon as you are aware of the incident, within reason. Ample preparation, time and a proper setting needs to be arranged. Consultation of experienced patient-affairs personnel beforehand may help. Angry responses from the involved patients and/or family who are immediately searching for someone to blame are understandable and should be properly addressed. The shock for parents losing a baby and their feeling of being powerless adds to the response of looking for who is responsible and liable. Such disclosure is not a single conversation, but rather a process which may involve several meetings with the patient and/or family. This is the responsibility of the senior staff member, and should never be assigned to a junior, inexperienced care provider. During a disclosure conversation it is important to show your empathy (including saying that you are sorry about what happened) and listen to the questions of the patient and/or family. Stick to the facts you know on that moment and avoid speculation what causes could have been present if you are not sure. It is acceptable to say that we do not know all the details of the incident, but a process will follow and explain that process. Ensure the patient and/or family understands that all relevant investigations will be undertaken to identify the causes of the event and confirm when and how you will provide the results (i.e. “I will call you in 2 weeks’ time, what number can I call?”). It is critically important that you deliver what you promise. However difficult it sometimes may be, bring trust back in the system by doing the right thing is a primary aim.

DEBRIEFING

Obstetric emergencies often present themselves out-of-hours, and a team of nurses, both obstetric and pediatric, midwives, obstetricians, pediatricians and registrars or house officers, and anesthetists may be involved. When a baby is involved in an event with poor outcome, it creates an extra dimension to the emotional burden of the patient and the staff. With all the different rosters and shifts, it seems almost impossible to bring all staff together who were involved when a serious adverse event occurred. However, it is important to bring the team together on the day of the incident for a debriefing talk. Similar to the already common debrief by first responders like fire personnel, police or ambulance personnel, this meeting is meant to have people share and express their first emotions about the event in a way they

feel appropriate. Chaired by the senior person involved, it also serves as an opportunity to collect names and contact details (including email) of the persons involved (do not forget the occasional student, or housekeeping) to have the possibility for later contact. Although this is not the moment to start the further investigation, minutes of this meeting can be helpful in getting the facts (including timing of events) for later review. The question should arise whether the people involved are capable to continue to work and whether replacements should be sought immediately or for the subsequent day(s). Decisions should be made regarding how and when the team is to be contacted again, and who will be responsible for the contact with the patient and/or family.

REPORTING AND REVIEW PATHWAY

As mentioned above, according to local laws or regulations, adverse events have to be registered and reported to official bodies, internally in the hospital or care-organization, and to external government or professional bodies. Accordingly, management officials, legal departments need to be notified. Several methods are in place to have a further investigation of the event in order to discover basic causes and to suggest improvements. Healthcare organizations cannot fully prevent adverse events, but they do have the obligation to investigate and to learn from these events. Similar to the airline or off-shore safety investigations, methodology is usually based on root-cause-analysis, like BOW-TIE,[6] TRIPOD,[7] PRISMA,[8,9] with identification of safeguards (which have possibly failed). The approach includes a designated, trained and team not directly involved (2–5 people) examining the patient's medical records, speaking with the personnel involved and the patient. Their task is to produce a report which describes the event in detail and the analysis about which underlying factors played a causative role by asking, in every step, why this happened. Factors may be categorized as technical, human, organization (culture, cooperation) or patient related. The following challenge is to formulate effective improvement suggestions, for example, using the SMART criteria[10] (Specific, Measurable, Acceptable, Realistic, in a Time frame) and to assign a problem owner/responsible person. The final report can be discussed with the involved persons and shared with the patient and/or family. Managerial responsibility will follow by hospital and department management to have the improvements implemented and report on this for further checks. Although the review involves considerable time and resources, it is usually well accepted by all staff involved because of the impact of an adverse event for individuals and their strong commitment willingness to prevent this happening again.[3] At this point it is important to note that although such an investigation team speaks with the patient and/or family, this track of investigation is separated from the after care for patients and/or families and processes for filing complaints or a legal case. These demands should be professionally and empathetically dealt with, but the investigation part as described above is solely focused on learning from the event, without, of course, denying its severity. Patients and/or family should be thoroughly informed about these separate pathways to avoid confusion and perhaps more unnecessary anger.

PERINATAL AUDIT

Apart from the above mentioned investigations more ad-hoc specific-event driven investigation, clinical audits have been developed to improve the quality of care. Countries like the UK, Norway, The Netherlands, Australia, New Zealand, and South Africa[11,12,13,14,15,16,17,18,19] have instituted perinatal audit methodology for review of prenatal mortality or morbidity cases. Methods differ including the use of external experts, confidentiality, participants, and involvement of parents, etc. However, they all share the ambition to learn from adverse events and to improve our obstetric care. WHO adopted several of these principles in registration and classification of perinatal deaths and provides a support-tool for organizing perinatal audit in local facilities.[20,21]

In brief, to organize perinatal audits successfully, there are several prerequisites. Key to success is to have designated personnel to manage the process, the culture and willingness of the management and an involved multidisciplinary group of care givers including nurses, midwives, doctors, etc. Developing good communication skills on how to handle emotions is essential, and teams should preferably be trained in advance about the structure of an audit meeting and how to acknowledge the emotions that may occur when talking about medical errors in a multidisciplinary group. The chairperson is critically important. He or she should have the mandate and undebatable respect of the group. The chair should be independent, so not involved in the patient care of the unit, although some clinical obstetric knowledge is preferable.

In preparation of the meeting, which usually needs 90 minutes per case, the organizers need to construct an (anonymous) narrative of the case. Not only relevant medical information should be included, but also process information such as timing of events, which types of officials were present, or relevant information such as delays in treatment because of weather conditions or that the doctor was having dinner. For a proper discussion during the meeting of the content, quality and sequence of events, several house rules may be adopted. Due to the possible sensitivity of discussion on medical errors, agreement can be made to be fully anonymous regarding the name of the patient and the names of the involved care givers. For an effective audit and the learning process to define improvements, it is not relevant which persons were involved as long as there is enough information to evaluate the care. Of course, these events do have an emotional effect on the persons involved and that should be dealt with separately. Full confidentiality during the meeting is to be expected from the participants and this should be outlined in advance and that post-meeting discussions are not allowed. All participants should feel free to give their opinions and ask questions; however. due to staff hierarchical situations this is sometimes difficult. Respect should be observed for every professional, nurse, midwife or doctor, and their expertise for their own profession should be recognized by not judging other professionals actions, but asking a question about their motivation how to handle in this specific situation.

The care provided should be judged according the adherence to current protocols or guidelines. In addition, during evaluating the course of the case, on every instance it can be asked whether with the knowledge of the case up to then, the next adequate steps have been taken without being biased about the later (bad) outcome. A possible outline of the procedure is listed in Box 1.

Box 1 A possible outline of the perinatal audit procedure

- Identification of cases to be discussed (perinatal mortality, severe perinatal asphyxia, neonatal–maternal morbidity, etc.)
- Compose a written narrative of the case, with attention to procedures. The medical story does not necessarily have to be complete (i.e. “during pregnancy, from 12 to 37 weeks uneventful” instead of reporting all the antenatal checks).
- Pre-meeting with the involved professionals to check whether the narrative is correct and whether all possible learning items can be referred to.
- Perinatal audit meeting, during which factors can be identified that in retrospect were suboptimal; analysis of the basic causes of these factors by asking every time “Why” this happened until no further step down the causative path can be identified (root cause analysis).
- Discussion on possible improvements to prevent the basic causes in the future.
- Assign people responsible for implementing and reporting on these improvements.
- Evaluation on the meeting, possible aftercare for the professionals involved.

The number of audit meetings per year is dependent on the size of the unit, personnel available for organization of these meetings, and number of cases. In general, it seems advisable to organize at least two or three meetings each year to keep the experience and the routine. Some units might organize these meetings every month due to larger numbers.

Recently, the role of the parents whose child has died as a stillbirth or neonatal death in the Perinatal Audit has been raised.[22] Good quality care for parents after the loss of their baby is essential[23] and includes attention to possible questions about the quality of their care including possible complaints or litigation trajectories. As part of the perinatal audit process, it is important to have the narrative as detailed as possible on the course of events to learn from possible errors. Apart from the fundamental question of whether parents should always be involved in reviews of the care provided, they can provide essential information on the course of events which are not necessarily found in the medical notes. Whether parents wish to provide their experiences for the perinatal audit requires careful consideration and evaluation so as not to cause more harm to the parents.

From a review on perinatal audit[17,24] and own experience,[13] review and audit of perinatal mortality cases showed up to 50% of cases with care factors which contributed to the poor outcome, with up to 20%, where suboptimal care factors were directly related to the death. Differences exist in the nature of these factors in maternity care between countries of high- and low-income settings. Inappropriate antenatal care, delays in transportation and inadequate resources for

proper care during labor, are key in poor-resource settings. However, even in high-income settings, delays in diagnosis (i.e. fetal growth restriction) or treatment (i.e. pre-eclampsia, diabetes), failure to act on reduced fetal movements, or failures in fetal monitoring during labor are still large contributors to the number of suboptimal care factors.

HOW TO CHANGE YOUR CARE?

Implementation of changes in healthcare is notoriously difficult. Possible causes for this are that professionals in healthcare have more difficulties in changing their habits because of their more rigid characters and the implicit feeling that this implies they have done things wrong in the past, denying progress in knowledge which may change protocols. A significant amount of literature exists on implementation changes in healthcare.[25,26] After perinatal audit, groups are faced with suggestions for improvement which they themselves defined during the meetings. Motivation to take these further might be higher because of the severity of the consequences (perinatal mortality) and the close relationship to their own care. After evaluation of a 4-year project on the implementation of improvements after perinatal audit in The Netherlands[13], five factors were identified as the main facilitators for successful implementation (Box 2).

Box 2 Five factors for successful implementation of change

Apart from the fact that the suggested improvement is beyond discussion, and its importance, relevance and effectivity is widely accepted (see SMART discussion above) these are:

- A champion person as leader of the group, and is responsible for the overall progress
- Acceptable culture of change in the organization
- Conditions including funding, secretarial support, time
- Continuously evaluation and control of the progress of the process
- External help and support to drive the internal group.

The implementation process can be divided into several sequential steps (Box 3).

Box 3 Steps of implementation process

The following have been found to be helpful:[13]

- Identification of the target groups which are involved in the suggested improvement
- Define how these groups have their interest in the suggested improvement
- Identification of obstructive and promoting factors of influence
- Define strategies, what to achieve and how?
- Who is doing what and when?
- Monitoring of the progress
- Making the change sustainable, routine and evaluable (see PCDA (plan-do-check-act) cycles described later).

In terms of the fourth bullet point above in Box 3 (the strategies), several approaches can be applied alone or in combination including educational (training, E-learning), motivational (personal contact, involving role models), informing (newsletters, presentations), organizational (creating multidisciplinary teams, measuring outcomes and feedback), facilitating (protocol development, advice by telephone), patient-oriented (involving the patients in self-management, patient-feedback analyses), and market-oriented (publish outcome figures, accreditation from external audits).

FAMILY SUPPORT

Every day, for stillbirth alone, more than 7000 families in the world are struck by the loss of a baby, to a total of 4–6

million yearly with more than 95% in low- and middle-income countries.[17,24] With perinatal death, parents lose a child, grandparents a grandchild and often brothers and sisters a sibling too. Aftercare for these families varies widely from non-existent to regular visits with several professionals including counselors, psychologists or social workers. Medical questions and psychosocial needs should be addressed. In general, in many places this care is inadequate. Important aspects with regard to debriefing or perinatal audit have been mentioned above; however, it cannot be stressed enough that parents want, and are entitled to, a central contact person who is preferably the supervising physician. This can be a challenge since this supervising doctor can be held responsible for the tragic outcome which makes the contact with the parents potentially difficult. Nevertheless, the parents should be provided with psychosocial care and clear advice on how the circumstances of their baby's death will be reviewed and fed back to them.

PEER SUPPORT

Although the family should be the primary focus of our attention for caring for their needs, we should not forget the effect of adverse events on our personnel. Fortunately, organizations do invest more and more in a peer support program for their personnel who experienced not only adverse events, but also complaints, litigation of aggressive behavior.[27,28,29,30] Times are gone, when healthcare personnel could not speak about their emotions after experienced an adverse effect where possibly their error had made a contribution. Making an error causes specific stress to care providers that may lead to reactions of fear, anger, doubt in their own capabilities, shame, sorrow and isolation. These reactions may develop into sleeplessness, loss of concentration, feeling tired and feelings of depression, burn-out or even suicide. During this time, the person may perform substandard clinically and is a risk for further medical errors. Apart from caring for our personnel, the organization cannot allow these professionals posing more risks for patients.

QUALITY AND SAFETY MANAGEMENT

Every organization in healthcare spends increasing efforts on their quality and safety management. The above-mentioned topics should be integral part of this and part of the greater plans and efforts to increase the quality of our care. Implementing a just culture, attention to professional behavior of all employees and having functional PCDA cycles, accepted by all, is important.

- Each unit should have a guideline on what to do after an adverse event. The responsible attending staff specialist and the head nurse are responsible for starting the protocol.
- Every obstetric unit should register their severe adverse events and develop a protocol on how to evaluate and produce learning from them.
- Every unit should have a protocol for aftercare for parents who lose a baby as a perinatal death, and a peer-support program for employees in case of severe adverse events.

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PRACTICE RECOMMENDATIONS

- **Form a group in your institution to address and guard the protocol on how to act after adverse events.**

- **Institute pro-active peer-support.**
- **Institute proper after care for the patients after an adverse medical incident.**

CONFLICTS OF INTEREST

The authors of this chapter declare that they have no interests that conflict with the contents of the chapter.

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