

SEVERE ALLERGIES AND THE LAW – THE CASE OF ANAPHYLAXIS

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ABSTRACT

Worldwide, anaphylaxis remains an important cause of sudden death. The crux of the management is immediate administration of adrenaline as part of competently administered cardiopulmonary resuscitation (CPR). The many pitfalls in identifying and avoiding the triggers and in managing the anaphylactic reactions increase the likelihood of mistakes, which place the patients' lives in danger and at the same time expose medical practitioners to the risk of malpractice litigation and even to criminal investigations in certain circumstances.

There are reports that indicate and predict a steep increase in the number of professional insurance claims in South Africa. Therefore, knowledge of the most important legal principles applicable in medical negligence cases empowers practitioners and allows them to formulate, predict and prevent the risks of a certain conduct.

It is important to be aware that civil liability may be incurred when practitioners fail to perform their duties at a reasonable standard of care in the given circumstances. The reasonableness of the standard of care when managing anaphylaxis is established through objective criteria provided by evidence-based research.

Anaphylaxis-related deaths following diagnostic or therapeutic procedures are deemed unnatural and will be investigated by a magistrate in inquest proceedings. If the inquest findings point to the practitioner's negligence, charges of culpable homicide may be brought against him or her. When things go wrong, it is important to express regrets for the suffering and loss, but apologies must be submitted only after seeking advice from the risk managers, insurers or legal representatives.

Of all forms of severe allergy, anaphylaxis is particularly serious because of its rapid onset and progression to a fatal outcome. Although there are no national statistics indicating the overall incidence and the mortality rate of severe allergy, anaphylaxis represents an important cause of sudden death all over the world.^{1,2} The diagnosis of anaphylaxis is based on history of past reactions, evidence of recent exposure to allergens, clinical signs of distributive shock and (or) respiratory difficulty, and

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measurements of serum tryptase concentrations as soon as possible after the episode.^{3,4} The crux of the management is immediate administration of adrenaline as part of competently administered cardiopulmonary resuscitation (CPR).³⁻⁵

When anaphylaxis leads to adverse outcomes, medical practitioners involved become exposed to the risk of malpractice suits and, in certain circumstances, may be subject to criminal investigations. While South Africa has thus far been behind First World countries in terms of medical negligence litigation, there are reports predicting an increase in the number of claims in respect of both the public and the private health sectors.⁶

Establishing liability after adverse outcomes following anaphylaxis is not easy, and even attorneys experienced in medical negligence litigation encounter countless problems in proving a medical negligence case.⁶ This may explain why only a small proportion of the defended claims are eventually resolved in claimants' favour.⁶ However, notwithstanding the favourable outcomes of medical negligence claims, having to deal with a court case remains a cause of major stress even for practitioners who did nothing wrong, and an important reason for this stress is the lack of insight into the nature of the daunting legal process that he or she is facing. Knowledge of the legal principles applicable in medical negligence cases may thus be empowering and may assist those practitioners facing unfounded or frivolous claims while dealing with the stress of litigation.

The purpose of this paper is to provide practitioners with an analysis of the circumstances that can give rise to delictual and criminal liability pursuant to injury or death caused by anaphylaxis. This analysis will be the basis for the formulation and discussion of ways to protect patients and at the same time to prevent litigation.

DELICTUAL LIABILITY: THE TEST OF MEDICAL NEGLIGENCE

Not all adverse outcomes of severe allergy lead to liability for medical negligence in delict. There are several requirements to fulfil the medical negligence test.

First, it must be proven that there was a duty of care on the part of the medical practitioner and that he or she unlawfully failed to fulfil this duty.

Second, and most importantly, it must be proven that the medical practitioner was negligent in that he failed to act as a reasonable medical practitioner in the same circumstances,⁷ failed to foresee harm to the patient and, furthermore, failed to act to prevent such harm with the skill and diligence expected from him in the circumstances.⁸

Third, it must be proven that the conduct of the practitioner was the legal cause of the adverse outcome.

The burden of proving the three legs of the test rests on the plaintiff (the patient or the representatives of the patient's estate). The standard of proof in civil cases is defined by 'the balance of probability'. This means that if both parties' versions of facts are equally probable, the party who had the burden of proof – in this case the patient or the patient's estate – will lose.⁹

In respect of the first leg, the issue of the duty of care arises in the context of public policy as informed by the constitutional provisions that deal with medical emergencies.^{8,10} While there is no 'good Samaritan law' in South Africa, a healthcare provider's legal obligation to intervene in emergencies may arise in certain circumstances.^{10,11} If there is a duty of care, this means that the conduct of the practitioner that led to harm is unlawful.

The second leg of the legal test for liability in delict is to establish whether or not a practitioner was negligent with reference to certain objective criteria that define the standard of care and skill expected from a reasonable nurse, general practitioner or specialist, in the circumstances of the case. This aspect is particularly important, since the negligence test differs substantially between healthcare workers, according to their qualifications, experience and type of practice.^{7,8}

The standard of care in the management of anaphylaxis must be evidence-based and ought to be considered both in respect of prevention of allergic reactions and the treatment of acute attacks.

Thirdly, even when negligence is proven, there is another hurdle to be passed by the plaintiff, who must show that the harm suffered was in fact caused by the practitioner's conduct.

THE STANDARD OF CARE IN ANAPHYLAXIS: REASONABLENESS AND EVIDENCE-BASED CLINICAL PRACTICE

In theory, medical practice must be based on evidence collected through sound research, which is accepted as valid by the medical fraternity. Often in litigation certain guidelines published by organisations or associations in various specialties are accepted as being the reasonable standard of care in the field and may be introduced by expert witnesses as evidence in defence of a healthcare practitioner's conduct. It follows therefore that as long as these management guidelines are followed in the management of severe allergy, there is a strong likelihood that the standard of care satisfies the reasonableness test.

In many situations however guidelines may not be implemented and the standards imposed may not be achievable in practice.⁶ Furthermore, results of medical research may be conflicting, and the experts may support cogently both sides of the argument based on opposing studies. Litigation then becomes a war between the experts, and the winner may not necessarily be the one on the healthcare practitioner's side. In these cases, one must always remember that the required standard of care need not be at the highest level, but simply reasonable in the circumstances.⁸

When appointing the experts, it is useful to choose those who are not only the most competent in their field, but are also capable of persuading the court that the research upon which the practitioner's conduct was based is scientifically validated and is reasonably accepted by the profession. It is not constructive to appoint an expert unable to explain complex medical concepts concisely and in a clear, persuasive fashion, regardless of the expert's professional credentials.

Critical issues, such as the use of adrenaline as first-line treatment in anaphylaxis, are unlikely to be disputed in court.¹² There will also be no debate in respect of the application of CPR manoeuvres according to internationally accepted resuscitation standards in all cases of anaphylaxis.

Grey areas such as the use of glucocorticoids^{13,14} or antihistamine drugs¹⁵ may be points of contention,

where evidence from research is contradictory and may largely depend on the credibility of the expert who provides it.

Standard of care

When the standard of care is established, it does not need to be at the highest level but to the level of the reasonable practitioner in the same circumstances.

Different criteria will be applicable to anaesthesiologists, emergency medicine specialists and intensivists practising in tertiary academic hospitals as compared with general practitioners or nursing staff working in community healthcare centres. The HPCSA considerably lowers the expectations in terms of overall competence and procedural skills for practitioners who act in emergencies outside the field of their specialty, which may give support to an adjustment of standards that makes allowance for the circumstances of medical assistance.¹¹

There are minimum reasonable standards of care that apply to different categories of practitioners in different emergency scenarios, which are based on evidence from peer-reviewed research data and on international or local guidelines.

The **duty of each practitioner** is to:

- Establish what standards apply to the field of his or her practice
- Ensure that these standards are displayed visibly in the form of concise and clear standard operating protocols (SOPs)
- Seek training in areas of weakness
- Ensure the availability and good order of all necessary equipment and medication necessary to intervene in emergencies
- Train all staff in the practitioner's employ
- Adequately supervise staff when performing any procedures, since liability is incurred by the employer for any errors committed by employees while acting within the scope and purpose of their duties, by virtue of vicarious liability.⁸

Record keeping

The importance of keeping **good records** that provide evidence of compliance with the SOPs and/or guidelines at all times, and especially during resuscitation, cannot be overemphasised. During resuscitation, whenever it is possible a member of the team must be assigned to 'real-time' record keeping.

If no staff are available, it is acceptable to make records in retrospect as long as these are written immediately after the adverse event, while memories of all facts are fresh and may be recalled with strict accuracy and completeness. The notes must be dated, and the exact time of recording and of starting and ending the resuscitation must be recorded. It is necessary to make a record of all signs and symptoms that led to the assessment of the patient's condition and to the treatment plan. Vital signs must be monitored often and all measurements recorded. The name and the time of administration of all drugs must be accurately noted and signed clearly and legibly by the person who is in charge of the pharmacological management during resuscitation.

The notes must be written legibly and signed by the author. Nursing notes are critical corroborating evidence in litigation and therefore must be clear and accurate. Immediately after the adverse event, debriefing sessions with the whole team involved in management are useful to explain different versions of the facts

and to clear misunderstandings. This would allow the team leader and risk managers to identify and deal with irreconcilable contradictions between various records that may increase vulnerability to litigation.

Another important point is that very often the signatures are little more than a scribble, both in nursing and doctors' notes. This may raise a hurdle in the path of the patients' attorneys' work, in that it may become difficult to identify the relevant witnesses. However, it must be remembered that ultimately hiding behind anonymity or quasi-anonymity is equally unethical and ineffective, since through the discovery process in civil trials, plaintiffs have access to rosters and staff attendance records which disclose all players and their role in the care of the patient.

Most importantly, adequate records may allow the risk managers and professional insurers to evaluate the strength of a claim at its true value. This is important, since once the commission of a medical error is established, it may be preferable to reach an out-of-court settlement with the plaintiffs rather than defend the claim. One of the main reasons is that settlements are usually confidential, while the record of a court judgement against a practitioner, in case of an adverse finding, is permanent.

WHERE THINGS CAN GO WRONG IN THE MANAGEMENT OF ANAPHYLAXIS

All principles discussed until now are of a general nature, and apply to most fields of clinical practice. There are however risks specific to the management of anaphylaxis that relate to both prevention of the allergic reactions and their management.^{16,17}

Prevention

While the occurrence of anaphylaxis is in theory preventable through avoidance, this is often easier said than done, especially in so far as exposure to foods, insects or latex is concerned. Internationally, prevention of anaphylaxis is regarded as a public health issue and is the subject of legislation that places this responsibility not only on healthcare workers but also on the school system, employers and food industry.^{18,19}

It remains however the duty of healthcare practitioners to identify the allergens likely to cause severe reactions, and to inform and educate the patient and his or her family about the nature and possible consequences of anaphylaxis. An informed patient and family are better equipped psychologically to deal with the inevitability and suddenness of anaphylactic reactions and may be less likely to sue on the grounds of failure to prevent or manage adverse outcomes. Unfortunately, identifying the triggers of anaphylaxis is difficult, and there are reports of skin-prick and intradermal test-related anaphylaxis.^{17,20,21}

Among the most useful prevention measures is providing the patient with a bracelet or pendant inscribing the patient's particulars and the type of allergy. Inter-practitioner communication is also important. Whenever the patient moves to a different locality, the practitioner must accurately inform the new healthcare facility about the patient's allergy profile, level of insight into the disease, compliance with the treatment, management schedules, and all other relevant particulars. There are also occupational health issues that must be addressed, for example when the work environment poses a life-threatening risk to healthcare practitioners allergic to latex.¹⁷

Of all triggers of anaphylaxis, **medication** may be the easiest to control; therefore drug-induced reactions

are preventable through education and avoidance. Prescription errors causing anaphylaxis however still remain a major cause of medical negligence claims internationally.^{17,22}

In South Africa, the only case of mismanagement of severe allergy that ended in a guilty verdict by the HPCSA was that of a general practitioner who chose to ignore the warnings of a history of an allergic reaction to sulpha drugs, and administered co-trimoxazole.²³

In a UK case, a postoperative patient who was allergic to penicillin was administered Augmentin, despite the practitioner having been warned about the allergy by the patient, her son, her records and a red 'allergy alert' bracelet.²⁴

In addition to detailed history-taking and showing respect for the patients and their families, sound clinical judgement is essential to prevent drug-induced anaphylaxis.

Communication between different healthcare facilities and practitioners, conspicuously placed colourful stickers on patients' files, and bracelets or pendants with information about the allergy are all necessary measures to prevent exposure to the potentially harmful drugs.

In addition to avoidance, immunotherapy is another way of preventing anaphylaxis caused by a limited range of allergens. The inherent risks of immunotherapy, which include anaphylaxis, must be discussed with the patient. If available and affordable, the sublingual route should be chosen because of its significantly better safety profile.²⁵ Written informed consent needs to be obtained, and notes relating the content and outcome of the discussion with the patient should be attached to the form for further reference.

Pitfalls of prehospital management of anaphylaxis: the duty to educate and the importance of disclaimers

Anaphylactic reactions can occur anywhere, often far from medical facilities or a healthcare practitioner able to provide emergency assistance. The practitioner in charge of patients with severe allergies has the duty to educate them and their families so that they are able to recognise the symptoms and signs of anaphylaxis and to administer basic life-support measures that sustain the body's vital functions until professional medical help arrives. Patients, their families, friends, teachers and co-workers can be trained to administer adrenaline intramuscularly in emergencies, with prefilled syringes or autoinjector. It is also possible to educate family members and teachers to administer basic CPR, if necessary.

The practitioner must provide all essential information regarding the reasons for the prompt administration of adrenaline, the adrenaline dose, the timing of the repeat injections, the type and structure of autoinjectors and the injection technique. During the training session, it is critical to emphasise two other points: that seeking medical attention after administration of adrenaline is mandatory and that the availability and expiry date of autoinjectors must be checked regularly.

Expectations and fears must be addressed adequately. Placing too much reliance on adrenaline self-administration carries the risk of creating a feeling of false security, and may lead to fatalities following biphasic allergic reactions.¹²⁻¹⁵ At the opposing end of the spectrum, timidity in using adrenaline may delay or prevent life-saving treatment with dire consequences for the patient.^{16,17,21} To deal with this issue, an open discussion about the side-effects of adrenaline and a

careful evaluation of the risks versus benefits must be initiated, and the practitioner must be available for further clarifications or reassurance, if necessary.

The practitioner ought to make sure that there is a reasonable accumulation of knowledge and practical skills before entrusting the patient, the family or the school with autoinjectors. Besides the administrator's technique, the length of the needle and the autoinjector recoil properties may influence the distribution of the drug and consequently the effectiveness of the dose.^{26,27} It is also important to consider the eventuality of device malfunction due to manufacturing defects.

It is therefore prudent to ask the patient to sign a disclaimer in respect of the device malfunctioning, and emphasise the fact that the use of autoinjectors is solely at patient's own risk. Furthermore, to avoid any disputes arising from incorrect self-administration of adrenaline, each training and refresher session conducted with the patients and families should be recorded, and a note regarding the level of insight and proficiency in the use of autoinjectors should be made after each assessment and kept for further reference. The disclaimer may then contain a clause confirming the patient's understanding of the indications, administration technique and the possible outcomes of self-administration of adrenaline, including the rare but possible adverse effects.

Use of printed leaflets or flyers with clear instructions may be useful educational tools, but all written information handed to the patient must be explained. One must remember that patient education about life-threatening allergies is not a once-off task, but rather an ongoing process of transmission of knowledge about the disease, followed by feedback and reinforcement.

Management of anaphylaxis by healthcare practitioners: follow guidelines and keep adequate records

The treatment of anaphylaxis must follow the current, evidence-based guidelines of resuscitation adopted by local and international professional bodies.^{3,4,21,28} Any failure to understand and follow the guidelines complicates the defence, regardless of the justification for such deviation brought by the practitioner involved. Adrenaline remains the mainstay treatment in anaphylaxis and it is safe, provided that the dosage is correct and the concentration of the solution is adapted to the way of administration. Rare side-effects, such as myocardial infarction and arrhythmias, were reported only in instances where adrenaline dilutions of 1:1000 were used intravenously.^{3,4,12}

Any practitioner who administers immunotherapy or performs skin-prick or intradermal tests for allergens known to cause anaphylaxis has the duty to ensure the safety of the patients.

First, all resuscitation drugs (within the expiry date) must be available, and all relevant equipment (oxygen source, laryngoscopes, endotracheal tubes, monitoring devices) must be in good order, since expired or deficient medication stock and equipment failure are always indefensible.

Secondly, adequate knowledge of advanced life support is desirable for general practitioners, physicians or paediatricians who administer or supervise injectable immunotherapy, although basic resuscitation skills may be sufficient for a successful outcome if there is prompt access to an advanced care facility. If things go wrong, however, the level of skill required for managing adverse events after immunotherapy may become a contentious point in litigation.

Thirdly, another important precautionary measure is to monitor the patient for as long as it is necessary to

ensure that the patient will not suffer a reaction on the way home.^{16,21}

In the **emergency room and operating theatres**, important sources of medical errors are the practitioner's failure to take a proper history from the patient if possible, from witnesses, family or ambulance personnel; failure to identify bracelets or pendants with allergy warnings when examining the patient; failure to read the patient's previous records; failure to record an allergic reaction; failure to take into account anaphylaxis as a possible differential diagnosis in patients with history of shock, syncope or unexplained convulsions; failure to manage anaphylaxis according to the guidelines and SOPs, failure to refer to an appropriate level of care.¹⁶

INQUESTS AND CRIMINAL LIABILITY FOR ANAPHYLAXIS DEATHS

In terms of the Inquests Act 58 of 1959, inquests are not criminal proceedings but are aimed at investigating the cause of death when a patient has died of unnatural causes in the opinion of a duly qualified medical practitioner. According to the Health Professions Amendment Act 29 of 2007 (section 48), '[t]he death of a person undergoing or as a result of a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a procedure has been a contributory cause, shall not be deemed to be a death from natural causes', regardless of the time frame between such procedure and death. The investigations into the circumstances and causes of all unnatural deaths in an inquest must be initiated and conducted in terms of the Inquests Act, and the facts are assessed by a magistrate, who then decides whether the healthcare practitioners' negligent conduct was the legal cause of the patient's demise.

It is unclear whether the act of simply prescribing a drug can fit into the concept of 'procedure', and the amended Health Professions Act 56 of 1974 does not provide any definitions to aid the interpretation.²⁹ Whenever a drug is administered parenterally, however, both the prescriber and the person who executes the order may be liable for the adverse events following the administration.

In the event a patient survives the initial anaphylactic reaction but subsequently dies of an infection contracted in the intensive care unit, the causal chain between the administration of the offending drug and the ultimate outcome may not be found to be broken. The same applies if a patient falls while suffering an anaphylactic reaction and dies subsequently not because of the allergy but because of the injuries incurred in the fall. Furthermore, in certain circumstances another practitioner's subsequent negligence may not absolve the practitioner whose conduct caused the anaphylaxis from criminal liability.³⁰

If an inquest finds a link between a practitioner's conduct and the patient's unnatural death, it is important to emphasise that such a finding does not establish guilt or innocence. Criminal liability is a verdict of a properly constituted court of law, arrived at after an open adversarial process where the accused is presumed innocent and is protected by a whole array of rights granted by the Constitution. The presumption of innocence means that the accused needs to prove nothing, but it is the prosecution's duty, as the representative of the State, to prove guilt beyond reasonable doubt.⁹ This burden is a heavy one, and its fulfilment depends on many factors, not least a thorough and competent police investigation and, most of all, convincing expert testimony. Only if the State shows that it has enough evidence to reasonably ensure a

conviction of culpable homicide will the accused need to bring evidence to displace the prosecution case, otherwise the case will be dismissed by the court.^{9,30}

THE IMPORTANCE OF APOLOGIES: IS SAYING 'SORRY' AN ADMISSION OF GUILT?

While a practitioner must never admit guilt or **apologise** before contacting the risk manager, insurer and/or attorneys, showing **empathy** for suffering and loss does not necessarily amount to an admission of liability.³¹ The wording is important, and one must remember that offering an apology and expressing regret are two different things. Apologies always imply an acknowledgement of guilt and therefore must only take place if found appropriate by the risk managers or insurers, especially if the practitioner involved is an employee rather than an independent contractor. On the other hand, expressing regret may have a more circumscribed interpretation, which does not go beyond a natural reaction to any kind of human suffering and loss. However, when liability is beyond doubt, and based on sound legal advice, it is appropriate and ethical to submit apologies.

What is incontrovertible is the importance of allowing clear, open, comprehensive and honest communication with the patient or the family. The availability of the practitioner after an adverse outcome inspires trust and may reduce the likelihood or amount of malpractice claims.³¹

CONCLUDING REMARKS

The management of patients with severe allergies is not for the faint-hearted. It is mired by a multitude of risks and can often lead to undesirable outcomes for everyone involved. For healthcare practitioners, besides the personal feeling of loss, guilt and inadequacy, there may be the added torment of disciplinary hearings before professional boards as well as litigation.

Civil liability is incurred when the practitioner failed to perform his or her duties at a reasonable standard of care in the circumstances. The reasonableness of the standard of care is established through objective criteria provided by evidence-based research in the field of prevention and management of severe allergy.

Anaphylaxis-related deaths following diagnostic or therapeutic procedures are deemed unnatural and must be investigated by a magistrate in inquest proceedings. If the inquest findings point to practitioner's negligence, charges of culpable homicide may be brought against him or her.

When things go wrong, it is important to express regrets for the suffering and loss, but apologies must be submitted only after seeking advice from risk managers, insurers or legal representatives. If mistakes were made however, compensation and forgiveness could provide some relief for everyone involved and prevent litigation.

Declaration of conflict of interest

The author declares no conflict of interest.

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