PMFA News and Hamilton Fraser Cosmetic Insurance have teamed up to provide a series of articles that will give examples of claims that occur from different procedures. The first in the series looks at the use of botulinum toxin.

The case in question

In 2014 a patient underwent treatment using abobotulinumtoxinA with 164u being used in total. The treatment was given in the context of a training course with the practitioner acting under supervision. Prior to the treatment, the patient was counselled thoroughly, with all potential side-effects, risks and complications of the treatment explained during the consultation. The patient signed the consent form agreeing to the treatment which was duly administered.

Unfortunately, within 24 hours of the treatment the patient suffered a reaction which included heart palpitations, chest pains, swollen throat, dizziness and exhaustion. They noticed the practitioner and the organisers of the training course who advised her to attend hospital and to be monitored. The patient was also advised that the reaction was unlikely to be related to the product but the practitioner noticed the manufacturers and completed an incident report. After the incident the patient requested details of the doses and the practitioner provided copies of their training notes to con rm the dosage was within the correct parameters that he had been trained to administer.

It was noted that the patient had received 13 treatments using the same brand of abobotulinumtoxinA over a four-year period prior to this occasion and no adverse effects had occurred. The case was initially denied by the solicitors working on behalf of the practitioner on the basis that none of the reactions suffered by the patient are known side-effects and the additional fact that for four years prior to the incident there had been no issues following treatments. There were comprehensive and legible notes from the practitioner which confirmed that the patient consented to the treatment knowing the possible side-effects, the exact dosages, and the administration areas.

The reserve for the case remained high (£100,000 in damages, £50,000 for the claimant's legal costs and £15,000 in defense costs) due to the nature of the claimed side-effects and the longer-term effect it had on the patient. Five months after the incident the patient formally complained to the practitioner and advised that they still had serious health issues, including heart problems. However, the solicitor's allegations were issued without sight of the patient's records and solely based on what the patient had advised verbally.

Following the initial denial of the claim, it was expected that the patient's solicitors would make one of two potential responses. Either, they would respond to advise they were not pursuing the matter and the file would be closed with just the defense costs being paid, or the solicitors would be required to provide a medico-legal report from an expert on botulinum toxin to confirm that it was the treatment that caused the reaction. If the second option occurred then the case would continue and the insurers would need to decide whether to appoint their own expert to report on the matter.

Editor's comment

I should say that all cases to be featured are suitably anonymised and are historic, i.e. the legal cases have been concluded but the lessons that can be learnt and shared are bountiful. There is a conclusion for this case but I asked Hamilton Fraser not to reveal it at this stage. I hope you, the readers, enter into the spirit of this challenge and do not hold back on your comments, which we will be delighted to publish in follow-up issues.

By way of disclosure I must emphasise that I am not an expert in botulinum toxin but I am concerned about patient safety and maintaining the integrity of the profession. So let me begin! The botulinum toxins are fascinating biological compounds and it is far beyond the scope of this commentary to describe the biology and therapeutic applications. I look forward to suitable review articles in future issues of *PMFA News*.

This is a case involving a practitioner who was attending a training course and presumably did everything 'according to the book'. The patient is counselled and consented and procedure is performed appropriately but within 24 hours the patient complains of a number of rather non-specific symptoms and is advised to attend hospital for monitoring. The symptoms continue for several months.

This is one of those situations in medicine that can happen to anyone: you do everything right but the outcome is not as you or the patient ever imagined. But is the practitioner at fault? What is the relationship between the injection of 164 units of botulinum toxin and the prolonged morbidity experienced by the patient? There was certainly no history of previous adverse reactions, although that does not exclude the possibility of them occurring. The adverse reactions detailed for the combination of cosmetic and therapeutic use of botulinum toxins is extremely long. There are, however, systematic reviews of the cosmetic use of botulinum toxins that report thousands of administrations of the toxin without major adverse events. The very nature of the biological effect of the toxin is that given in appropriate dosage the response is time limited. Whilst there is a temporal association with the administration of the toxin and the onset of symptoms, the symptoms are very non-specific and their prolonged action decreases rather than increases an association with the treatment.

When looking at the cause and effect relationship one must look at other potential factors. The role of the delivery method used and the importance of the right dilution and accurate dosing must be considered. Adopting the role of 'Devil's Advocate' I note that this particular brand of abobotulinumtoxinA typically comes in 300 and 500 unit vials. As only 164 units were used, what happened to the rest? Or was it taken from a previously used vial? Could the vial have been contaminated in anyway?

Please let us have your comments on this case. What is the responsibility / liability of the trainer in such a situation? What about the manufacturer of the drug? What is the responsibility of the profession to a patient or client who develops an objectively verifiable morbidity which is co-incidental to the treatment given? I say 'objectively verifiable' because there are, unfortunately, a small number of patients who make false and malicious complaints. Is it appropriate to make a token payment on a compassionate basis with no liability established?

Let us hear your views and thank you once again to Hamilton Fraser for sharing with us a case from which we can all learn something.