Ampersand Advocates

Summer Clinical Negligence Conference 2018

Case Law update – focussing on the Mesh Debate decision

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18th June 2018

Consideration of AH v Greater Glasgow Health Board and Johnson and Johnson Medical Limited, together with 3 further cases [2018] CSOH 57

Chapter 42A procedure

His Lordship made some *obiter* comments about pleadings and procedure under chapter 42A.

"The purpose of written proceedings is to set out the case so that the defender and the court can understand the basis of the action. It is an exercise in written advocacy. The pleadings should disclose the facts which, if proved, would amount in law to a substantive case and which at the very least require to be answered. In cases such as these, involving medical treatment and the use of a medical product, one would expect to see a narration of the pre-exiting condition, the treatment, the product used in the treatment, the subsequent injury, the duty of care owed by the treating doctor and how that duty of care was breached, the defect in the product and how the breach of duty and product defect in each caused or contributed to the injury. The pleadings need not, indeed should not, be elaborate but they should give fair notice to the defenders of the allegations made against them." (at para [20])

The pursuers suggested that the court should adopt a more modern approach to pleadings, that the record should not be treated like a conveyancing document, and the court should bear in mind its case management powers which allowed practical solutions to concerns about lack of notice eg order production of affidavits, or hearing of evidence on commission.

His Lordship accepted that the record should not be seen as a conveyancing document, but he emphasised the importance of written pleadings, and mentioned the recent Inner House decision in Melville Dow v Amec Group Limited [2017] CSIH 75 which discussed the need for pleadings under the personal injury rules. Whilst elaborate pleading is discouraged, parties still have to give fair

notice of the case which is to be met. Similarly, his Lordship noted that, whilst there are case management powers under Chap 42A procedure, it is still for the pursuer to plead a relevant case, it is not for the court to take over that role:

"Litigation under Chapter 42A is still an adversarial not inquisitorial process" (at para [27]).

He goes on, when setting out the approach that he has taken to the criticisms of the pursuer's pleadings, to state that he will take into consideration what has been plead by the defenders. He acknowledged that it is not usual to look at the defender's pleadings unless debating the pursuer's pleas, however he found it useful to consider the case against the doctors in the context of what they themselves had plead. He was effectively using the defenders' pleadings to help understand the conflict in the factual case. The judge felt that it would be artificial to ignore the defender's pleadings, and he described this as "in accordance with the spirit of chapter 42A, where parties are encouraged to make early disclosure in order to narrow the issues between them".

The 'Montgomery Issue'

The pursuers argued in these mesh cases that in order to obtain their consent properly they ought to have been told about alternative treatments which were reasonable treatment options, and only then could they properly have given informed consent. This flows from the case of Montgomery v Lanarkshire Health Board [2015] UKSC 11 where the Supreme Court held that in obtaining a patient's informed consent a doctor has a legal duty to discuss reasonable treatment options and the material risks associated with those treatment options.

In these debates the doctors argued that properly read, the case of Montgomery did not displace the basic test of medical negligence set out in Bolam v Friern Hospital Management Committee (in England) or, more relevantly for our purposes in Scotland, in Hunter v Hanley. So, in considering what, if anything, might have been offered to the pursuers by way of alternative treatment that was still a matter for the professional judgement of the clinician. The range of alternative treatments which should be discussed with the patient has to be determined by what the doctor considered reasonable, exercising his or her skill and expertise as a reasonably competent doctor.

What the pursuers had to do to make out a relevant case was to show that no ordinarily competent clinician, exercising ordinary skill and care, would have failed to offer those alternatives. There would have to be expert opinion about what such reasonable treatment options would be. The criticism of the pursuers' pleadings was that they said nothing at all along those lines, no averments,

no expert reports, nothing that related the pleadings about informed consent to the proper test for medical negligence.

The defenders argued that in saying that the doctors should have advised of reasonable alternative treatments options the pursuer must offer to prove:

1 what reasonable alternative treatment options should have been advised,

2 the treatment options actually advised, and

3 what the pursuer would have done had proper advice been given

Importantly, it was argued, the court should be careful to distinguish between cases that were "no treatment" cases ie if I had been given proper advice I would never have consented to undergoing that treatment, I would have had no treatment at all, and cases that were "other treatment" cases ie if I had been told about the other reasonable alternative treatment options I would have chosen to go down one of those routes, not the treatment that I actually underwent.

The pursuers approached the matter on a broader basis. It was argued that they had set out in the pleadings the available alternative treatments such as using biological materials rather than mesh in the operations. It was said by the pursuers that Montgomery had displaced the Hunter v Hanley approach to matters of consent. In determining what alternative treatment ought to have been offered the test was whether a reasonable patient would want that treatment. So, the obligation on the clinician is to present a full picture of all treatment options that a patient might find relevant, irrespective of whether the actual doctor was in a position to offer such treatment at that time. The issue was about what the patient would want to know about treatment options, not what the doctor thought was appropriate to tell the patient. What the patient considered reasonable would emerge from the discussions that the doctor would have with the patient.

The question for the judge was how to approach a case where there were a range of alternative treatments which could or should be offered to a patient. In law, how should that range be sensibly defined? The judge considered the case of Montgomery and concluded that it was "a limited, albeit important, innovation on the rule in [Hunter v Hanley]" and he did that under reference to arguments for the appellant which were made to the Supreme Court in Montgomery as follows:

"Decisions about diagnosis and treatment must necessarily, and by definition, be made by the medical practitioners by reference to his special skill, learning and experience in an expert field which is not shared by the patient. By contrast decisions by the patient as to whether to submit to proposed treatment are his to make as of right, and his to make by giving whatever weight he thinks

it right to put upon the risks and benefits which the options available bring." (at para [44] of Montgomery)

Importantly it was noted that this did not mean that doctors could withhold information about a reasonable alternative and its risks based upon their own preference. Any reasonable and available treatment should be discussed with the patient. The dialogue may well include those which the doctor may not consider clinically advisable, but the reasoning for that would form part of the discussion. However, fundamentally, the treatment options had to be those which the doctor, exercising professional judgement, felt was reasonable, not every potential treatment option which the patient might think was reasonable.

The judge found that the pursuer had failed to set out what option they would have taken if properly advised. The defender had no fair notice of what case they were to meet. As a result he excluded from probation those parts of the pursuers' leadings relating to alternative treatments.

What the pursuers in each case were left with was the averment that, had they been properly advised, they would not have had the treatment offered – the "no treatment" option. So, going forward, the pursuers have a relatively simple case for proof. They can argue that if they had been properly informed they would not have had the operation now complained of. What they can't do on the basis of the surviving pleadings is suggest that there were other treatments which should have been suggested to them and which they would have considered instead.

Whilst quite a lot has been trimmed from the original pleadings the court was satisfied that there is still a basic factual dispute between the parties as to what advice was given to the pursuers in obtaining consent. If the pursuers can persuade the court that, despite the version of events given by the doctors, they were not provided with proper advice about the risks of the surgery undergone, then they may prove a breach of duty.

Knowledge of the doctors

The pursuers had plead, in general terms, that the doctors knew or ought to have known about the risk posed by mesh products, and should have warned the pursuer accordingly. The doctors argued that these pleadings were not sufficiently specific.

The court accepted that a doctor cannot advise a patient about a risk if he or she is unaware of it, and reference was made to three potential sources of such knowledge in respect of a medical product, such as mesh:

1 information that the manufacturer brings to the attention of the doctor by way of eg the instructions for use;
2 from the doctor's own skill and knowledge acting as a reasonably competent doctor – investigating areas unfamiliar with where necessary, keeping up to date on potential new treatments through medical journals and studies;
3 warnings from regulatory bodies such as the Medicines and Healthcare Regulatory Authority.

The court was concerned that a number of parts of the pursuer's pleadings in this regard sounded like mere assertions about knowledge rather than being linked in any proper way to how the particular doctor was said to have known information, or ought o have been aware of certain information. The judge excluded some of the pleadings from the record, but is seeking further submissions from the parties about whether other parts of the pursuers pleadings ought to be excluded on the same basis.

Risk and Causation

Based on an Australian case (Wallace v Kam [2013] HCA 19) the defenders tried to persuade the court to knock out parts of the pursuers' claims on the basis that not enough was plead in order to show causation. It was argued that, whilst the pursuers said a great deal about the risks of the mesh operation that were material to them, that wasn't properly linked to the loss claimed and in many instances the potential risks, although numerous, had never in fact come about. The only relevant risks in a negligence action were those where (i) there was a duty to warn about the risk, but there was a failure to do that, and (ii) the risk actually materialised.

In Wallace a surgical procedure involved two distinct risks, A and B. The treating doctor told the patient about risk A but negligently failed to mention risk B. The patient underwent the operation and risk A materialised. The patient argued that he would not have gone ahead with the operation if he had known about both risks (cumulatively the risk would have seemed to him to be too much),

and in that case the risk arising from A would not have come to pass. However, the Australian court held that the claim failed. The policy of the law was to protect patients from physical injury, the risk of which was unacceptable to them. Coming at it from a different angle, if the patient's argument was upheld it would mean compensating the patient for the eventuation of a risk that the patient was willing to accept.

By contrast the case of Moyes v Lothian Health Board 1990 SLT 444 Lord Caplan, in *obiter dicta*, suggested that the important issue was whether, had the risk been known to the patient, they would have agreed to undergo the surgery. The fact that what happened during the surgery resulted from a risk that had been discussed with the patient was neither here nor there, said Lord Caplan.

The judge in this case (at para [89]) described the Lord Caplan approach in Moyes as 'cumulative' risk. What the patient wants to know is whether there is a chance of the operation going wrong, and if it does, what would happen. The Wallace approach considers the existence of two distinct risks arising from the operation, if the patient is willing to consent to the operation despite knowing of one risk which then transpires, that is the end of the story. The second risk, which was not known to the patient and did not transpire, doesn't come into consideration.

Lord Boyd was not satisfied that these mesh cases fell neatly into one category or another. He felt that the position for the pursuer on what she would have done depending on the information given could be quite nuanced, and was not willing to make a decision on the point until having heard evidence. Significantly, in both Wallace and Moyes, the decisions had been reached after evidence was led in each case. So, this is an argument to be resurrected after proof.

Breach of Personal Autonomy

In line with a relatively recent trend in England the pursuers had included in their cases an argument that, as well as the usual breach of duty and corresponding heads of damage, there was, in addition, a further breach – breach of personal autonomy, purely related to the lack of consent. So, for example, if a patient can show that proper consent had not been obtained, but the loss suffered was not causally connected to that breach, there was, independently yet another valid claim – the fact of being robbed of the ability to properly consent to invasive medical treatment in and of itself was a breach of personal autonomy giving rise to damages.

That argument was roundly rejected by the English courts in two recent cases where it was attempted. During the debate in this case the pursuers confirmed that they were not insisting upon that part of their claim. His Lordship declined to pass any comment on the argument.

Case against the Manufacturers

The remaining case in the pleadings is against the product manufacturers under the Consumer Protection Act 1989. Various arguments were made about whether the pursuer's pleadings were sufficient to give notice of the case they sought to make out against the manufacturers. In particular it was argued that the pursuers did not adequately identify the alleged defect in the product. The court was not persuaded to delete any of the pursuer's averments in this regard. Lord Boyd held that the question of what constituted a defect under the Act had to be viewed holistically, and the knowledge of the manufacturers about their own product could not be ignored. He held that proof would be required in order to properly balance the various elements which needed to be considered.

Limitation

Two of the pursuers cases were held to be barred by limitation in relation to the case against the doctors. The other two cases were held to require proof to determine the issue of limitation. All four of the cases required proof so far as limitation was concerned in respect of the manufacturers' cases. The potential application of s19A has still to be determined.

Lord Boyd stated that each case would require to be determined on its own facts. There are limitation pleas in almost all of the hundreds of cases currently sisted – there does not seem to be any prospect of general guidance being issued on the limitation points.

Going Forward

A by order has been set down for 11th July to discuss a number of issues arising out of the judgement, including what, if any, further parts of the pleadings require to be excluded following the judge's decision on the various issues. Only after the by order will there be a complete picture of

how the case will look going forward to proof. What has become clear, however, is that each case will be regarded on its own merits and, despite the huge number of cases, it will be difficult to try to simplify and isolate generic issues which can be determined globally for the mesh cases.