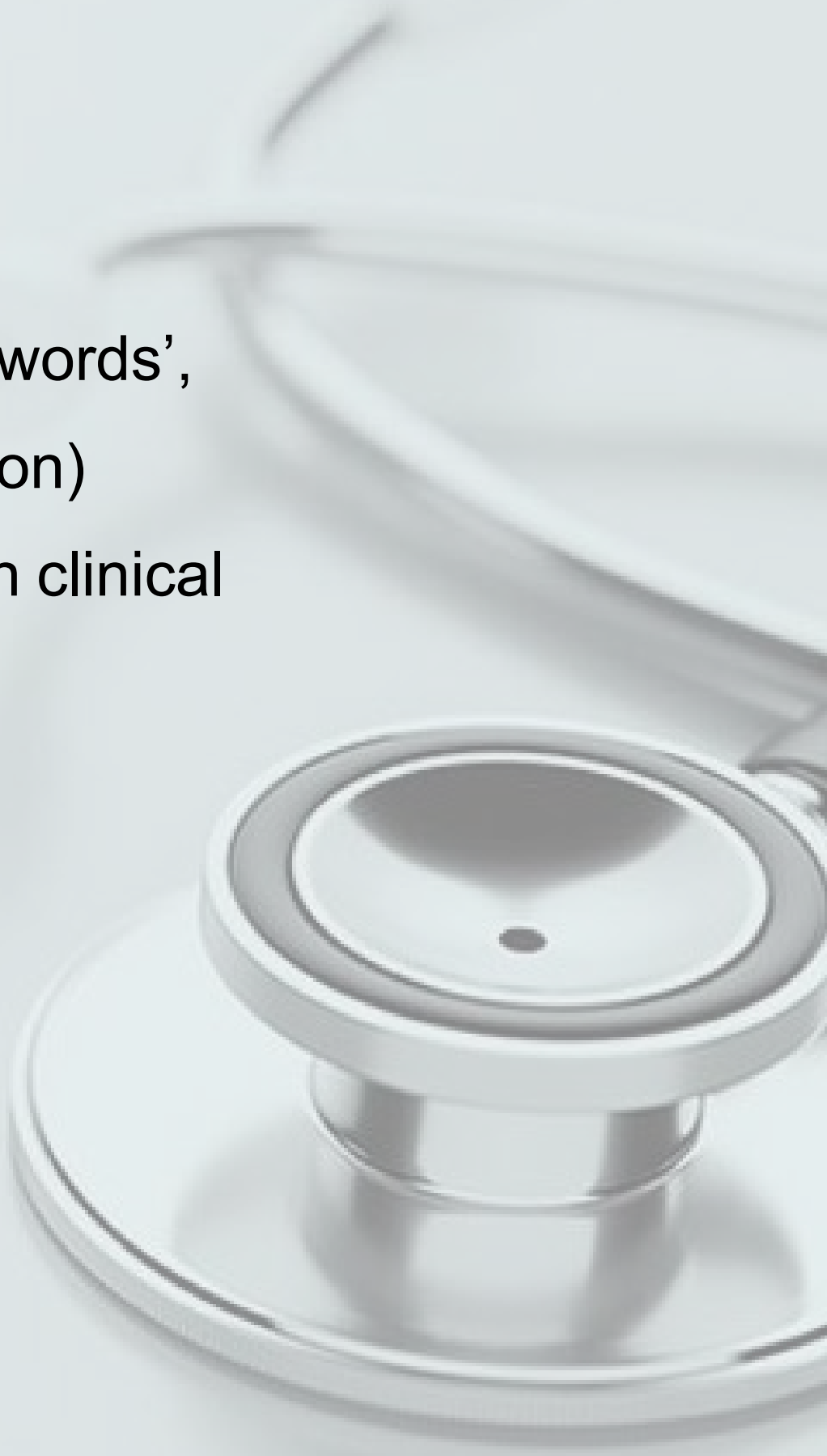
hailshamchambers

Fighting talk: ‘swords’, ‘shields’ and (non) compliance with clinical guidelines



Bramble Badenach-Nicolson

10 November 2022

Fighting talk: 'swords', 'shields' and (non) compliance with clinical guidelines

Bramble Badenach-Nicolson analyses the recent case of *Marion O'Brien (Administratrix of the Estate of Mr John Berry (Deceased)) v Guy's & St Thomas' NHS Trust* [2022] EWHC 2735 (KB).

When considering *Bolam* negligence, what is the relevance of non-compliance with clinical guidelines? Can a Trust's compliance with 'in-house' clinical guidelines act as a 'shield'? These questions were explored and answered by His Honour Judge Tindal, sitting as a Judge of the High Court, in the above case last month.[1]

Background

Mr Berry was admitted to St Thomas' on 28 February 2017 following a heart attack. He had previously undergone a nephrectomy and suffered with end-stage renal failure, with his remaining kidney functioning at 50%. His urine output was minimal and he was dependent on dialysis.

Whilst under the care of the Trust's cardiology team, Mr Berry had an angiogram and stent placement in the left descending coronary artery. Following those procedures, Mr Berry's clinical condition deteriorated and he was found to be at risk of developing sepsis. He was eventually transferred to ICU and prescribed antibiotics.

Mr Berry died in 2019 and whilst there was never any contention by the Claimant that the Defendant Trust's treatment played any part in Mr Berry's death, she sought to argue that the administration of 400mg of the antibiotic Gentamicin in March 2017, when Mr Berry was in ICU, was a negligently excessive dose, considering Mr Berry had no effective renal function and was on dialysis.

It was agreed between the parties that the 400mg dose caused ototoxicity side-effects leading to balance problems, but it was disputed whether the dose also caused Mr Berry's subsequent hearing loss. This, it transpired, was a minor point of contention since the causation of injury was accepted and damages agreed.

Guidance on the appropriate dosage of Gentamicin was available from:

(i) the National Institute for Health and Care Excellence (NICE);
(ii) the British National Formulary (BNF); and
(iii) the Trust's own in-house clinical guidelines.

When considering whether a clinician has been *Bolam* negligent, a Court will consider all the circumstances of the particular case and therefore, clinical guidelines are rarely wholly determinative. However, in this case, the Trust was using its own in-house ICU clinical guidelines as a "*shield"* to the claim, and the Claimant was relying on the Trust's other protocols and the national guidelines as a "*sword*". The terms "*shield"* and "*sword*" were

[1] https://www.bailii.org/ew/cases/EWHC/KB/2022/2735.html - references to specific paragraph numbers are made in square brackets.

used in the 2003 article by Samanta, Samanta and Gunn "*Legal considerations of clinical guidelines: will NICE make a difference?"*, which HHJ Tindal deployed throughout his judgment.

The guidelines

By way of a starting point, clinical negligence practitioners will be aware that in 2021, the GMC issued updated ethical guidance for doctors on "*Keeping up to date and prescribing safely"*: "*You should follow the advice in the BNF on prescription writing… You should take account of the clinical guidelines published by NICE [and]… Royal Colleges and other authoritative sources of specialty specific clinical guidelines".*[2]

This marks a fairly significant change from the 2013 "*Good Medical Practice"* Guidance which instructed as follows: "*You must recognise and work within the limits of your competence and you must keep your knowledge and skills up to date. You must maintain and develop your knowledge and skills that are relevant to your role and practice…".*

The NICE/BNF guideline for Gentamicin (dated 2018 in this case) stated that for serious infections such as pneumonia in hospital and septicaemia, IV Gentamicin for adults should be:

> "*Initially 5-7mg/kg, subsequent doses adjusted according to serum-gentamicin concentration, to be given in a one daily dose regimen"* [all references to the guidelines hereafter are lifted directly from the judgment].

For patients with renal impairment, the NICE/BNF guidelines provided that the Gentamicin dose should be measured by their creatinine clearance rate (CCR). In other words, the rate at which the kidneys clear creatinine from the body:

> "*if there is an impairment of renal function, the interval between doses must be increased; if the renal impairment is severe,* ***the dose itself should be reduced as well****. Excretion of aminoglycosides is principally via the kidney and accumulation occurs in renal impairment. Ototoxicity and nephrotoxicity occur commonly in patients with renal failure. In adults, a once-daily, high-dose regimen of an aminoglycoside should be avoided in patients with a CCR less than 20ml/minute"* [my emphasis].

The Trust's in-house guidelines on Gentamicin applicable *outside of ICU* were similar to the above NICE/BNF approach. Essentially, if there was no renal impairment, the standard dose was 5mg/kg up to a maximum of 480mg and a maximum of one dose per 24 hours, with a second dose not to be prescribed until the 'trough level' of Gentamicin was less than 1mg/l, which is the level at which it is safe to re-dose. As in the NICE/BNF guidelines, if a patient's CCR is less than 20mg/min, clinicians are referred to the more detailed guideline "*Antibiotic Use in Adult Patients with Renal Impairment".* In summary, it indicates that a patient should not be dosed more than once per 24 hours and not again until the Gentamicin level falls

[2] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/keeping-up-to-date-and-prescribing-safely

below 1mg/l.

However, as observed by the Judge, the "*odd guideline out"* [14] was the Trust's ICU Gentamicin guideline. Whilst the guideline semantically distinguished between patients with renal impairment and those without, there was no practical difference in terms of the actual recommended dosage:

> "*Patients with normal renal function*
>
> *Prescribe between 5mg/kg to 7mg/kg (ideal body weight) to a maximum of 480mg […] Please check if previous aminoglycoside therapy has been administered to the patient. If a dose of amikacin or gentamicin has been given within the last 24 hours, the timing of the Gentamicin dose should be confirmed with the ICU medical team*
>
> *Patients with impaired renal function*
>
> *A large first dose is still desirable. In the majority of patients 5 to 7mg/kg (to a maximum of 480mg) should be used. The continuation of gentamicin in renal failure must be reviewed after the initial dose in accordance with the critical care empirical antibiotic guidelines and microbiology. If Gentamicin is still the preferred agent, consider reducing subsequent doses, discuss dosing regimen with critical care pharmacy. Re-dose according to levels (see therapeutic drug monitoring section below) […]".*

Mr Berry's treatment

Mr Berry's weight at the time of admission was 84.5kg, therefore 5mg/kg of Gentamicin would equate to 422.50mg and 7mg/kg to 591.5kg.

Mr Berry underwent an angiogram and stent placement on the morning of 2 March 2017, shortly after which his NEWS score for infection and sepsis was 'Medium Risk'. His NEWS scores fluctuated from that point onwards, reaching 'High Risk' by midday on 3 March 2017. Both parties agreed at trial that, by this stage, Mr Berry was at risk of sepsis.
Mr Berry was initially given 80mg of Gentamicin at lunchtime on 3 March 2017 on the normal hospital ward. That dosage of 80mg was noted by the Judge as being "*significantly **below** the guideline rate in-house and internationally. It is not suggested that such a low dose was itself negligent – Dr Bell* [the Claimant's expert] *says Mr Berry's renal function was so poor that it could have an equivalent effect to a higher dose in a less renally-impaired patient".*

A couple of hours later, Mr Berry was admitted to ICU as a result of his general clinical presentation and increased risk of sepsis. He was also put on Continuous Veno-Venous Haemodialysis (CVVHD), as opposed to straightforward Haemodialysis. The latter form of dialysis is the most common and can be undertaken at home or in a normal hospital ward. CVVHHD is temporary but continuous and is a gentler form of haemodialysis for ill patients who cannot tolerate haemodialysis.

Whilst Mr Berry was doing well on CVVHD and had been generally comfortable during the night of 3 March 2017 in terms of pain and his previously distended abdomen, there were serious concerns the following day on 4 March 2017. His white cell count had not increased since the previous day, his CRP level had almost doubled overnight and his PCT level was 6.6 (normal being 0.05). In short, Mr Berry's infection was progressing.

As noted by the Judge, whilst the experts disagreed as to whether or not Mr Berry strictly met the criteria for sepsis, they both appeared to agree that his infection was progressing by this point, albeit with the Claimant's expert emphasising the possibility that Mr Berry's clinical presentation was due to other factors, such as his arthritis and tissue injury. The Trust's expert, however, was clear that there was systemic infection which risked developing into sepsis and required treatment with antibiotics.

Noting his raised inflammatory markers at 12:30pm on 4 March 2017, Dr Meyer noted that fast dialysis should be attempted, and Gentamicin should be continued "***according to levels**"* and following the in-house guidelines. Mr Berry's drug chart showed that he had been prescribed 400mg of Gentamicin.

Was Dr Meyer negligent?

The Claimant's expert argued that the Trust's ICU guidelines were out of step with the NICE guidelines and were fundamentally flawed, not just in diverging from other guidelines without cogent reasons, but also in not reflecting antibiotics' primary goal as quoted in in its own Renal Impairment guideline: *"To optimise clinical outcomes while minimising unintended consequences of antimicrobial use, including toxicity…"*.

There was also the obvious conundrum that had Gentamicin been administered to Mr Berry at the same time in the normal ward, under the Trust's Renal Impairment guideline, it would have been much less than 400mg.

Although the Judge held that the Trust's ICU guidelines were "*sloppily worded"*, he decided that Dr Meyer, in following those guidelines and departing from the national standard, had *not* been negligent for five key reasons:

(i) Dr Meyer had not blindly applied the ICU guidelines. He had made a note of Mr Berry's tolerance of CVVHD and had deployed a 'mixed clinical strategy' when balancing the need to manage a potentially life-threatening infection with Mr Berry's renal function;

(ii) the Claimant's expert, under cross-examination, clarified that he was not saying the ICU guidelines themselves were negligent, but rather that they were insufficiently nuanced;

(iii) there are cogent reasons for taking a 'one size fits all' approach in ICU, which may mean that a renally-impaired elderly patient might receive the same dose as an otherwise fit young person of the same size. However, as the Trust's expert

emphasised: an ICU needs one guideline and one guideline only. It is a busy environment with a lot of different staff and very ill patients. It needs a simple, clear guideline which is applicable to everyone, not a confusion of different guidelines where applying the wrong one could lead to someone's death;

(iv) the national guidelines constitute a reasonable body of clinical practice generally, but there is another reasonable body on ICU wards. The balance of risk in ICU will often be different to other settings, sometimes almost by definition. As the Judge put it: "'*Intensive Care' means what it says."* The different balance for seriously ill dialysis-dependent patients such as Mr Berry is not something which is taken into account in any of the other guidelines;

(v) the previous 80mg dose had failed and given the fact that Mr Berry had a slow fall to trough level after that dose, Dr Meyer essentially only had 'one shot', as the Judge put it, to stem the rising infection. The risk from that infection outweighed the uncertain risk of ototoxicity. Deferring the dose until the 1mg/l level was reached was "*not closing the door after the ototoxicity horse had bolted, it was trying to secure the door to stop it"* [113.1].

Crucially, however, the Judge held that "*a 'Bolam shield' argument relying on compliance with a NICE, BNF or other 'national guideline' (or even arguably a 'regional one') is one thing.* ***Such an argument relying on an in-house guideline of a particular GP, CCG, hospital or even a large trust of hospitals (as with the Defendant's guidelines here) is quite another****"* [my emphasis added, 78]. This was for three main reasons [78]:

(i) the standard of care in negligence is not subjective but objective. If an in-house guideline could itself amount to a "*responsible body of clinical opinion"* without more, a Trust could effectively determine their own standard of care, which would be wrong in principle;

(ii) the resources and data available to Dr Meyer and his colleauges at a large NHS Trust like the Defendant are not the same as those available to NICE, the authors of the BNF, or any other national professional organisations; and

(iii) it is debatable whether an in-house guideline would impose the same regulatory obligations for an individual clinician under the GMC guidance as NICE and other national guidelines do. A requirement to comply with in-house guidelines would appear to be more relevant to compliance with an employment contract than professional responsibility intrinsically relevant to the *Bolam* standard of care.

Conclusion

The answer to the question 'What is the relevance of non-compliance with clinical guidelines to *Bolam* negligence?' is that a departure from national guidelines will not necessarily constitute *prima facie* negligence. However, an explanation for divergence will be necessary, and the nature and detail required will depend on all the circumstances. If this case is anything to go by, the detail required will most likely be significant and if it is lacking in some way, a Claimant may well be able to use non-compliance as a "*sword*".

As to whether compliance with in-house clinical guidelines can act as a "*shield*": the answer is a clear "no". In-house guidelines are not of the same status as national guidelines and cannot be used to demonstrate that specific conduct would fall within a *Bolam*-compliant practice.

10 November 2022
Bramble Badenach-Nicolson
Hailsham Chambers