Legal implications of deprescribing: a case scenario

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Prescribers are increasingly being encouraged to deprescribe unnecessary medication, but a potential barrier is the worry of litigation. This article presents an illustrative case scenario that examines the legal implications of deprescribing.

The practice of deprescribing medication is being encouraged to support reducing inappropriate polypharmacy. However, the lack of evidence-based guidance can mean deprescribing feels risky. Prescribers may be reticent to deprescribe, as they are wary of the potential legal implications if the decision to stop a medicine causes or contributes to an adverse event. Experience suggests that both prescribing and deprescribing would lead to similar claims of litigation and the same legal tests will apply. A patient is entitled to receive considered medical advice, application of available relevant evidence, full disclosure of all material risks and to be made aware of any reasonable alternative choices of action. This applies equally whether the decision is being made to start, stop or continue a medication.

The concepts of clinical negligence, informed consent and the potential for litigation in deprescribing are discussed in full in a related article. However, in order to illustrate some of the challenges that prescribers face, we describe a clinical scenario, presenting the reader with a number of alternative courses of action involving deprescribing. Different treatment options and potential outcomes illustrate the potential medico-legal consequences of a decision to stop or continue a medication. We have created three versions of one case scenario to illustrate key themes in deprescribing.

Case scenario

Mr A is a 78-year-old man who attends a GP clinic for a scheduled medication review. He lives alone in a third-floor apartment and his wife died six months ago. He has fallen at home a number of times in recent months with no apparent injuries. However, he recently fell while at the supermarket, sustaining bruising with no fractures. He has benign prostatic hyperplasia (BPH) for which he has been taking tamsulosin for the past two years. He also takes furosemide 40mg each morning but cannot remember when this was started or why. The prescriber wishes to discuss the ongoing need for furosemide, given the recent falls and the fact that he has no documented cardiac problems. When this is raised with the patient, he becomes upset and anxious. The patient feels that the furosemide
helps with his BPH symptoms because he is passing urine frequently when taking the drug.

What are the options for the prescriber?

1. **No change to medication**, as the prescriber considers the likelihood of furosemide contributing to the falls as being low.
2. **Withhold furosemide for two weeks.** Agree to a trial of stopping furosemide, after explaining that the furosemide may increase risk of falls, that it is the tamsulosin helping the BPH and why the furosemide seems to confer a benefit. Agree to meet again in two weeks to discuss BPH symptoms.
3. **Stop the furosemide**, telling the patient that there is no clinical indication for this medication.

What are the legal implications for each of these three potential actions?

1. **No change to medication**
   
   **Outcome:** The patient is admitted to hospital one week later following a fall.

   In this situation, would the prescriber be open to a claim of clinical negligence? In order to understand the potential for a clinical negligence claim, we need to apply the four elements of the test for a claim of negligence. All four elements of the test must be met for a claim to succeed (see Box 1).

   If a reasonable prescriber would have deprescribed the furosemide in these circumstances, and if it can be shown that the furosemide contributed to a further fall, eg he fell again and that fall was not due to something unrelated such as tripping on a wet floor, then that prescriber would be open to a clinical negligence claim for not deprescribing. This is because a reasonable prescriber would have done so and because the consequences of that inaction caused harm to the patient. This scenario underlines the need to consider the implications of not deprescribing.

2. **Withhold furosemide for two weeks**
   
   **Outcome:** The patient has undocumented heart failure, which is worsened by stopping the furosemide.

### Duty of care

**Does the prescriber have a duty of care to the patient?** In this case, as the patient has attended a clinical appointment with the prescriber, the duty of care is clear.

| Box 1. Four elements necessary for a clinical negligence claim |
|-----------------|-----------------|
| **Breach of duty** |
| Has the prescriber breached their duty? A breach exists where it can be shown that no other reasonable practitioner of like expertise, skill and experience, faced with the same set of circumstances, would have acted likewise. Therefore, the question to ask in this scenario is: “Would a reasonable prescriber in the same situation have deprescribed the furosemide?” |

| **Harm** |
| Was harm caused? In the first scenario, the patient actually fell and required a hospital admission, which constitutes the harm. |

| **Causation** |
| Did the breach in duty cause the adverse outcome that arose? In the first scenario, “Did the furosemide ultimately cause/contribute to the fall?” |

In this case, the patient is made fully aware of the decision to stop the medication and the potential for symptoms of cardiac failure are discussed. The patient agrees to a trial of stopping the medication as he is worried about his recent falls and agrees with the prescriber’s advice that the potential benefit could outweigh any potential theoretical risk of worsening heart failure.

A claim for clinical negligence is unlikely in this scenario. A prescriber can only be open to a claim of clinical negligence (regardless of any consent from the patient) if the course of action taken was not one that a reasonable prescriber would have taken and if the action caused the harm that materialised. In this hypothetical situation, where it could be shown that no other prescriber acting reasonably would have deprescribed the furosemide in the same circumstances and that the lack of furosemide caused damage such as the worsening heart failure, then a claim of clinical negligence could succeed. It is helpful to note that the law acknowledges that poor outcomes commonly occur for non-negligent reasons. All decisions have the potential to confer benefit but equally all decisions entail risks. As prescribers, we need to consider all options and the clinical implications of stopping or not stopping a medication. Prescribers need to ensure they are acting reasonably and, where possible, in line with evidence-based guidelines.

3. **Stop the furosemide**

   **Outcome:** The patient has no further falls but presents to his GP one month later with shortness of breath.

   In this scenario, the patient is suffering from mild heart failure, which is not documented in the GP record. This is worsened by stopping the furosemide. The patient is fully aware of the decision to stop the medication, but the poten-
Duty of care
Does the prescriber have a duty of care to the patient to obtain the appropriate informed consent to a proposed action? In this case, as the patient has attended a clinical appointment with the prescriber, the duty of care is clear.

and

Lack of informed consent obtained for procedure/treatment
In the third scenario, the prescriber failed to take reasonable care to ensure the patient was aware of any material risks* to him involved in stopping the furosemide, such as breathlessness, which would cause difficulty with access to his home. In this scenario, the prescriber also failed to make the patient aware of any reasonable alternative or variant treatments.

and

Harm
Harm was caused – the risk, which was not outlined, materialised. In the third scenario, shortness of breath occurred.

and

Causation
Causation arises where the claimant can establish that had they been informed of the risk that materialised, then they would have chosen a different option. In the third scenario, if the patient had known of the risk of worsening cardiac failure causing shortness of breath, notwithstanding the continuing falls risk with this medication, he would not have agreed to the deprescribing of furosemide.

*In the UK, the law in relation to informed consent is outlined in the recent Supreme Court decision of Montgomery v Lanarkshire Health Board [2015]. To satisfy the criteria of informed consent, a prescriber must take reasonable care to ensure the patient is made aware of any material risks of a proposed intervention, however small that risk may be, and be made aware of any reasonable alternative or variant treatments. The test of materiality is judged from the perspective of that particular patient, in those particular circumstances. This standard is also explicit in the GMC’s 2013 guidance on consent. Recent case law (Tasmin v Barts Health NHS Trust [2015]) suggests that limits may be put on the duty to make patients aware of alternatives. This should limit the duty to advise of alternatives to those that would be recommended as part of good medical practice and within the confines of existing resources.

Box 2. Four elements necessary for a claim based on lack of informed consent

In addition to (or instead of) a claim of negligence in this instance, the prescriber is also open to an action based on lack of informed consent. A claim for lack of informed consent requires all four elements in Box 2 to be met. (As discussed in scenario 1, a claim for clinical negligence requires all four elements in Box 1 to be met. For clarity it should be noted that a claim for both clinical negligence and informed consent requires all eight to be met.)

In relation to informed consent, as with negligence, poor outcomes can happen and they generally do not give rise to any legal implications. Often a patient agrees to a course of action in the full knowledge of all potential risks and benefits.

Conclusion
We have attempted to outline some key issues concerning reducing the risk of clinical negligence in prescribing and optimising patient consent. This contributes to the continuing discussion in the medical literature around the implications of recent changes in UK law. All decisions have the potential to confer benefit but equally all decisions entail risks. In order to optimise safe practice, a prescriber should always consider two aspects of their actions:

• To avoid a claim of negligence, prescribing decisions must be evidence based and/or in line with the decisions of a reasonable body of their peers.

• To ensure full informed consent, a prescriber must discuss clinically appropriate options with the patient, outlining all the risks relevant to that patient and advise of appropriate alternatives.

Claims for negligence and lack of consent can succeed separately or in addition to each other. If a prescriber can demonstrate that their actions (in deprescribing or not deprescribing) were aligned with those of a ‘reasonable prescriber’ then even if the action (or inaction) contributed harm, then that prescriber is unlikely to be open to a claim in clinical negligence. Provided a patient is made aware of all material risks and reasonable alternatives then a prescriber is likely to satisfy the test for informed consent. While prescribers have access to a variety of tools to support safe deprescribing and alternative treatments are available for many conditions, the challenge is how we identify risks that are material to our patients. Patient-centred conversations in the context of structured review may support embedding this in our daily practice.

References
Screening for pre-diabetes: neither HbA1c nor fasting glucose results are very accurate

Clinical question: Are screening tests for pre-diabetes accurate?

Bottom line: “What’s in a name?” Juliet pondered... to her detriment, as it turned out. So, too, with the diagnosis of ‘pre-diabetes’. In this analysis, an elevated (by various criteria) HbA1c or fasting plasma glucose level only sometimes lines up with impaired glucose tolerance testing results via a glucose tolerance test. If we take an abnormal two-hour glucose tolerance test result to be the true harbinger of eventual type 2 diabetes, an HbA1c level is neither sensitive or specific and a fasting glucose is specific (can accurately rule-in risk) but not sensitive. Depending on the screening test you use (or are required to use), many people will receive an incorrect diagnosis, while others will be falsely reassured. (LOE=1a)


Study design: Meta-analysis (other).
Funding source: Foundation. Setting: Various (meta-analysis).

Synopsis: The authors conducting this systematic review and meta-analysis searched several databases for all research papers that evaluated the diagnostic accuracy of laboratory-based (not office-based) HbA1c or fasting blood glucose tests to identify impaired glucose tolerance, using an oral glucose tolerance test as the reference standard for diagnosis. Heterogeneity among the studies was high, probably due to the differences in populations and settings.

Across all studies the prevalence of impaired glucose tolerance was 27% but varied by study, which will make predictive values bounce around. For HbA1c tests, the sensitivity was 0.49 (95% CI 0.4–0.58) and the specificity was 0.79 (0.73–0.84). For fasting blood glucose tests, the sensitivity was 0.25 (0.19–0.32) and the specificity was 0.94 (0.92–0.96). In other words, neither is very good at predicting oral glucose tolerance test results.