

2

Being accountable for your prescribing

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Learning outcomes

After completing this chapter you will be able to:

- identify the lines of responsibility and accountability for prescribers;
- discuss what it means to 'prescribe within one's area of competency';
- outline key principles involved in dealing with prescribing errors.

Introduction

This chapter demonstrates that with one lapse of judgement the prescriber can fail to fulfil their obligations to the patient, professional colleagues, commissioning body and themselves. It shows how easy it is for the inexperienced prescriber to be deflected from prescribing safely and effectively. It highlights the importance of remaining focused and not being unduly influenced by the expectations of the patient or professional colleagues, whether real or perceived. The desire to please can lead the unwary prescriber to take unnecessary risks, leaving them exposed to criticism or even litigation.

Prescriber

David Mitchell is the pharmacy superintendant of a community pharmacy located within a general practitioner (GP) surgery. The limited company is wholly owned by the partners in the doctors' practice.

2 Developing your prescribing skills

David is responsible for all the professional, ethical, legal and commercial aspects of the business and enjoys a large degree of autonomy in his day-to-day activity. He has recently sought to expand his personal competencies by qualifying as an independent pharmacist prescriber specialising in anticoagulation.

David uses his expertise by running an anticoagulant clinic three afternoons a week at the practice. This is run as a locally enhanced service for the Primary Care Organisation (PCO). There is currently a drive to move this service from secondary care to primary care as demand increases with an ageing population and the desire to make the service more accessible to patients (Department of Health, 2008). David has full access to the GPs' patient records.

Patient background

Graham Rogers is a 53-year-old male self-employed entrepreneur. He lives with his wife and teenage daughter on a smallholding which he purchased for the stabling. His family are keen on horses, and domestic life centres around their hobby. Graham has just purchased a new company installing CCTV cameras. Life at the moment is pretty stressful. He has two ways of winding down at the end of the day. The first is to grab a fork and wheelbarrow and attend to mucking out the stables. This is his only exercise which, like everything else in his life, he does at full speed. Having spent an hour labouring he relaxes with a meal, washed down with a whole bottle of red wine (his second wind-down technique).

Recently he has noticed that he does not have the energy he used to have and has to pace himself to get through his evening's physical work. He will often fall asleep on the sofa when watching the television. He has been on medication for hypertension for two years now and occasionally has to see his GP for treatment for gout, which in his view is a minor inconvenience compared to the benefits he considers he gets from his evening drink.

Taking advantage of his private medical cover Graham arranges for a private health check-up at a time of his convenience to see if he can get to the bottom of his lack of stamina. The results indicate that he has persistent atrial fibrillation.

The diagnosis is reported back to the patient's GP, who in turn sends Graham to see David to arrange anticoagulation with warfarin. He simultaneously refers him to the cardiologist at the hospital for further investigation.

Summary sheet with background information

Name: Graham Rogers

DOB: 29/5/*fifty-three years ago*

Occupation: Self-employed business entrepreneur

Past medical history

Chicken pox aged 5 years

Immunisation status – all available childhood vaccinations had at the appropriate age

Hep A and B and tetanus vaccinations *two years ago*

Hypertension *diagnosed two years ago*

Gout *diagnosed 18 months ago*

Current medication (last dispensed three weeks ago)

Aspirin 75 mg one in the morning

Atenolol 50 mg one in the morning

Nifedipine XL 30 mg one morning and night

Disease monitoring (carried out at private health check one week ago)

BMI: 27

Blood pressure: 157/90 mmHg

Pulse: irregularly irregular, rate 170 bpm

ECG: Shows P wave replaced by rapid oscillations of varying size, shape and timing

Thyroid, liver function test, U&Es, full blood count, cholesterol – normal

Random blood sugar: 7.9 mmol/L

Social history

Married with teenage daughter

Smokes 15 cigarettes per day

Alcohol: ++

Physical activity: mucks out horses every day

Scenario

Because of his work commitments, the first time Graham can keep an appointment is Friday 3 March in the afternoon. As he enters the room it is apparent that he is both apprehensive and very low in mood.

I've been told I've got to go on warfarin. I know that thins the blood, my doctor told me, so that means I'll be even more tired now! And don't you start nagging me about not taking my blood pressure pills, I get enough of that from my wife and I've just had an earful from the doctor.

He then adds, 'Can I still go paintballing with my mates on Saturday?'

As part of the comprehensive patient history, David discovers that Graham has uncontrolled hypertension, poor compliance and a high alcohol intake, all increased risk factors for unwanted bleeding in patients taking warfarin. David is not convinced of the benefits of anticoagulation compared to the risks of a potential major bleed. He attempts to contact Graham's doctor to discuss the case, but the GP is not available until Monday. David decides to postpone starting anticoagulation until after the weekend. He recognises that this could result in a week's delay to starting therapy, as Graham is working until the following Friday. However David discusses this with Graham, who seems unconcerned.

On Monday 6 March, David contacts the GP who is not at all supportive of his actions. The GP points out that National Institute for Health and Clinical Excellence (NICE) guidelines make it quite clear that anticoagulation with warfarin is indicated and that by delaying the start of therapy David has put the patient at risk of stroke unnecessarily for a week. David is now concerned that lack of experience has led him to make a poor clinical decision. He is also mindful of his need to maintain credibility with the doctors' practice both personally and professionally. In an attempt to bring forward the anticoagulation, David telephones the patient. However Graham still cannot commit to the appointments needed for a conventional loading regimen, which would require him to attend the pharmacy over a period of at least two weeks.

David, now feeling under pressure, negotiates with Graham a fast-loading scheme usually used in hospital known as Fennerty. In this regime, the patient is given 10 mg of warfarin each day with daily INR (International Normalised Ratio) checks. The dose is reduced as soon as the patient's INR climbs towards the therapeutic target of 2.5, usually by day 3 (Baglin, 2005). (A variation of 0.5 either side of this target is considered satisfactory.) Graham likes the 'get stuck in approach', as he calls it,

and agrees to call in at 9am sharp to start the regimen before he begins work. However, the first day he can make is Wednesday 8 March. David completes Graham's treatment record card recording the dose of warfarin prescribed. He also gives Graham the National Patient Safety Agency (NPSA) yellow information booklet on anticoagulation (NPSA, 2007), which Graham agrees to read 'when he gets a minute'.

Wednesday arrives and, to David's relief, Graham attends for his appointment. His INR is recorded as 1.1 and David instructs him to take 10 mg of warfarin at 6pm. On Thursday morning, his INR has not changed. David instructs Graham to take another 10 mg that evening. David believes that by Friday morning Graham's INR will be moving rapidly towards the therapeutic target and the time he can tell him to markedly reduce his dose.

Graham fails to keep his Friday morning appointment and upon contacting his office David is dismayed to be told that Graham has left the country for business and will not be returning until the evening of Sunday 12 March.

On Monday 13 March, Graham appears at the pharmacy at 9.00am, pleased with himself for having landed a lucrative business deal. He tells David not to worry. He just carried on taking the 10 mg each day at 6pm. Apart from some bleeding gums and a rather large bruise on his arm, where he must have banged it on something, he feels fine. When David takes Graham's INR, it has climbed to 8.0. Recognising that the patient is now at major risk of a bleed, David instructs Graham to stop the warfarin. David explains to Graham the risk he is now under, informs the GP and arranges for a venous sample to confirm the reading. Point-of-care testing may be inaccurate at this level and the patient's INR may be well in excess of this number. The *British National Formulary* (BNF) recommends stopping the warfarin and restarting when the INR falls below 5, provided there is no, or only minor, bleeding (Joint Formulary Committee, 2010).

Graham finally starts to appreciate the seriousness of the situation and agrees to keep all his future appointments as a priority. After 3 days, with daily INR checks, the level has dropped to 4.7. David gradually reintroduces the warfarin at a daily maintenance dose of 2 mg. David and Graham both recognise that they have had a narrow escape.

David's problems are not yet over. The laboratory results indicated an INR of 8.5. His Primary Care Organisation (PCO) require all critical incidents with warfarin to be reported to them directly and the local enhanced service (LES) which is part of his contract to provide this service for the PCO instructs that vitamin K as an antidote should be given orally to all patients with an INR of 8 or above without waiting for the results of the venous test.

Reflective questions

- 1 To whom is David responsible as a prescriber?
- 2 At what point in this patient's journey does David become responsible and therefore accountable for Graham's treatment? What considerations should David have taken into account before he prescribed for Graham?
- 3 What responsibility does David have to himself in this situation?
- 4 David has experienced a 'near miss' situation in his prescribing. What factors contributed to the error? How should David communicate this incident to the patient and other prescribers? What records does he need to keep? Is there anyone else that David needs to inform about what has happened? How can David reduce the risk of this kind of situation happening again?

Q1 To whom is David responsible as a prescriber?

While David's overriding responsibility must be for the well-being of his patient, it is apparent from the above scenario that the actions taken by a prescriber have far wider implications. In the example above, David's actions have additionally impacted on the patient's GP, upon secondary care laboratory resources and have put him at odds with the advice of the haematologist. He has breached his terms of service with the PCO under the LES. If the patient had come to significant harm, the publicity could have discredited the programme to move the service out into the community. He could potentially have brought his profession into disrepute, as well as damaging his own reputation as prescriber and pharmacist. As an independent prescriber, David is professionally accountable for his prescribing decisions (Royal Pharmaceutical Society Great Britain, 2007). He must make his own clinical assessment of the patient, establish his own diagnosis and formulate a plan for the clinical management of the patient. While he cannot delegate these responsibilities to another person, his employer has vicarious liability for his actions.

David breached one of the fundamental principles of prescribing, in that he prescribed outside his competency. He did not really understand the reason why Fennerty is only used in hospitalised patients where monitoring can be assured. His pharmacological knowledge of the medicine he was prescribing was woefully lacking. He failed to make a proper risk assessment of his initial decision to delay prescribing where the NICE indicates that prescribing an anticoagulant is appropriate. He was clearly acting outside his level of experience.

The Medicines Act 1968 was introduced by the Department of Health and Social Security following a review of legislation relating to medicines prompted by the thalidomide tragedy in the 1960s. It governs the manufacture and supply of medicines and divides them into three categories, Prescription Only Medicines (POM), Pharmacy Only Medicines (P) available for sale only through registered pharmacies and General Sales List (GSL) medicines, which can be purchased through non-pharmacy outlets. In 1999 the Supply and Administration of Medicines report (Department of Health, 1999) (the 'Crown report' – named after its author June Crown and not the Crown as in government) recommended that prescribing of POMs be extended under a supplementary role to professions other than doctors. These so called 'non-medical prescribers' initially included nurses and pharmacists. Section 63 of the Health and Social Care Act 2001 allowed the designation of new categories of prescriber, and set conditions for their prescribing. Amendments to the Prescription Only Medicines Order and changes to NHS regulations to allow the introduction of supplementary prescribing were laid before Parliament on 14 March 2003 and came into force on 4 April 2003. In May 2006, independent prescribing for both nurses and pharmacists was introduced. This expanded the ability to prescribe for any medical condition, but only within the individual's competency. In the above case study, David prescribed outside his competency and has therefore opened up the possibility of prosecution under criminal law. David is also vulnerable to prosecution under civil law by the patient for any consequences arising from his poor prescribing.

As a prescriber, David is subject to both criminal and civil law. Criminal law is the means by which the government identifies and criminalizes behaviour that is considered wrong, damaging to individuals or to society as a whole or is otherwise unacceptable. It is enforced through the criminal justice system. This is the mechanism by which action is taken to deal with those suspected of committing offences and judgment is determined in the criminal courts. Civil law is enforced by private parties.

Prescribers need evidence that they maintain competency, in order to demonstrate that they have acted/continue to act as a professional, using the latest available evidence. Vicarious liability with the employer and personal insurance are essential for all prescribers. David's contract of employment and job description must cover the area in which he is working and should include prescribing as a named activity. The PCO will also have laid down service level agreements and specific competencies for each area of practice.

David has a responsibility for the security of prescriptions. He must record the first and last prescription pad number for each session, in case a prescription pad should go astray. Recording directly onto the surgery

system ensures that a complete audit of his prescribing is maintained and can be accessed by the PCO for monitoring. David should follow best practice, by prescribing all four strengths of warfarin to avoid the need for alternate daily dosing (NPSA, 2007). He must be careful to write '5 milligrams' and '5 micrograms' in full to avoid dispensing errors and ensure that the patient understands the difference between the two. In David's pharmacy, as an additional safeguard, the dispensing of any prescription written by David is carried out independently by an NVQ3 qualified dispenser and checked by a qualified accuracy checker to separate the functions of prescribing and dispensing.

Q2 At what point in this patient's journey does David become responsible, and therefore accountable, for Graham's treatment? What considerations should David have taken into account before he prescribed for Graham?

The decision to prescribe for a patient must be based on a combination of one's own competency in the clinical area, the ability to communicate and the consent of the patient. It is therefore apparent that the prescriber's responsibilities begin long before the patient walks through the door. Before commencing any service, it is essential that David can demonstrate his competency and defend his decisions.

At the point that David achieved his qualification, it is reasonable to expect that his knowledge was up to date or he would not have passed, but knowledge advances continuously and keeping current is a lifelong commitment. New medicines are licensed, existing medicines have their licences amended or withdrawn and protocols are updated. There is, of course, no shortage of ways to continue professional development, including short courses, literature searches and communication with colleagues and peers. It is essential each prescriber has a structure to their learning and that records of CPD are kept. The professional bodies have laid down the minimum standards each prescriber must meet and competency frameworks for non-medical prescribers are available (Department of Health, 2007).

To be competent, a prescriber must deliver a service that is effective, safe and of high quality. A competent practitioner will be able to defend all their decisions to their peers. Competency includes a combination of up-to-date knowledge, the ability to apply that knowledge, an understanding of patients and their motivations, and the ability to work inter-professionally, to provide a cost-effective service to achieve agreed national and local health outcomes. Competency frameworks are available from the National Prescribing Centre, which provides a structured approach to enable practitioners to audit their own performance against defined

standards. To demonstrate his competency to prescribe in the area of anticoagulation, David needs to ensure that he is familiar with national and local guidelines and has a thorough knowledge of the pharmacology and disease processes for which he intends to prescribe (NPSA, 2007). Anticoagulants interact significantly with other medicines. The BNF provides a good summary of the key interactions. However it may not provide sufficient detail on interactions with herbal and alternative medicines. David, specialising in the management of anticoagulation, will need to identify reliable, in-depth and up-to-date sources of information to support his practice.

The moment that David agrees to accept responsibility for treatment, a duty of care exists between himself and the patient. Fundamental to this is communication and, again, this begins before the first word is spoken. David needs to be appropriately dressed, ensure his surroundings are clean and tidy, and watch his body language. Luckily, in this scenario, David and Graham speak the same language, but this cannot be assumed and the interpretation of words needs careful consideration. Graham has already been told that warfarin 'thins his blood'. This may have created images of feeling cold, or not being able to do as much as he should be able to as his blood is not full strength. David would have the job of reassuring him that this is not the case, without undermining Graham's respect for his own GP, who may have used these words to convey the principle of anticoagulation in the limited time available. If Graham thinks that the pharmacist and GP are saying different things, he may be forced into believing one over the other. He may, of course, decide they are both wrong.

When David complied with the GP's request for anticoagulation, he needed to satisfy himself that anticoagulation was appropriate for this patient. NICE clinical guideline 36 lays out a stroke risk stratification to determine if the use of warfarin is appropriate (NICE, 2006). This is a useful tool, but David should have combined this with a complete patient history and a risk assessment of the patient sitting in front of him. Graham's hypertension, his poor compliance with his previous medication, his raised blood sugars and heroic alcohol intake, are all risk factors which may have contributed to his atrial fibrillation. Skilful negotiation would have been needed if the addition of a medicine with such a narrow therapeutic index as warfarin, was to be both safe and effective and to improve his prognosis. David needed to ask himself what the chances were of Graham stopping drinking and smoking. Has he had or does he have any physical injury which would have increased the risk from anticoagulation? He mentioned paintballing with his mates for fun. David needed to address this and consider if Graham's work involved the risk of trauma. Being kicked by a

horse is never a pleasant experience but while anticoagulated could prove fatal. David must recognise that the ramifications of treatment impact on more than just the individual sitting in front of him.

David also had the problem of Graham's current medication. Aspirin and warfarin are sometimes prescribed together under secondary care, but not under the NICE guidelines for atrial fibrillation (AF), as there is an increased risk of bleeding. Stopping the aspirin immediately, before the INR was therapeutic, would put the patient at increased risk. Calcium channel blockers increase the risk of AF and the rationale for the atenolol is uncertain. Clearly communication between David and the patient's GP would be essential at all times.

Q3 What responsibility does David have to himself in this situation?

David needs to ensure his personal protection when handling blood samples. This includes adequate hand-washing facilities and impervious wipeable worktops and floors. All staff handling blood need an up-to-date Hep B vaccination. Protective gloves must be worn at all times and changed between each patient. Professional, single-use lancets which prevent cross-contamination between patients are needed, together with safe disposal facilities to prevent needlestick injuries to David, his dispensary staff and cleaners. Test strips must be date checked and appropriately stored.

One aspect of prescribing which rarely gets consideration in the literature, but is of fundamental importance to the prescriber, is how prescribers can protect themselves emotionally. As a prescriber, you will see some patients on a regular basis, perhaps weekly or monthly for prolonged periods; others you will meet on a single occasion. When you speak to experienced prescribers they all have stories of self-doubt: 'Could I have done more for that patient? Should I have insisted that he was seen by a specialist or a generalist as a matter of urgency?' Your reaction to a particular situation may well be influenced by a previous communication with another professional, who may or may not have been as supportive as you feel they should have been or were even hostile to your intervention, as in David's case. Never get yourself into a position of regret. This may take great courage on your part, but if the worst case happens, can you look a widow or widower in the eye knowing that you could have done more? You could argue that this is just putting the patient at the centre of your work and this is true, but it actually goes one stage further than that, to acting in a way that you can live with yourself. Give your own well-being the same consideration as you give to your patients. This is an example of where can be so helpful to have a mentor.

- Q4** David has experienced a 'near miss' situation in his prescribing. What factors contributed to the error? How should David communicate this incident to the patient and other prescribers? What records does he need to keep? Is there anyone else that David needs to inform about what has happened? How can David reduce the risk of this kind of situation happening again?

In this case study David quickly realised that he had made a mistake in choosing an inappropriate loading regimen for this patient. He allowed pressure from the patient and the GP to influence his decision making. He found himself under a time pressure. He focused his attention on trying to placate the GP and by treating the disease and not the patient. He did not consider the pressures that either the GP or patient were under. David is not responsible for either the GP or the disease, but he is responsible for treating the patient safely and effectively. He is accountable to both the GP and the patient.

David needs to reflect on the undue influences he allowed the GP and the patient to have on his decision making and the factors in their relationships which led him into making a dubious decision. He needs to discuss these pressures with both the other parties who may not appreciate his position. He should reflect on his practice and record this in his CPD record. He failed to understand where his knowledge was insufficient for the actions he undertook (i.e. he acted outside his competence). He should document fully the events which led up to the error, and record in writing his communications with the doctor and patient.

David had the good sense to notify the GP of his error and to explain the situation to the patient. It appeared that Graham recognised ultimately that he too had some responsibility for his potentially fatal event. By implementing concordance, it doesn't mean that David gives into Graham and allows him to do anything he wants. David took some necessary steps, but failed to follow the locally agreed protocol for confirming high INR readings, even though he followed the BNF guidelines for correcting the situation. Local protocols may be based on the personal opinion of a local consultant and may vary from national evidence-based guidelines. This situation could contribute to inadvertent mistakes. The PCO should be made aware of this discrepancy, in David's case, and be able to defend their guidance. David has to be able to live with his decision and answer the question 'If I had followed local protocols, would the outcome have been different?' By accepting his error and taking steps to rectify the situation, he significantly reduced the potential for further action being taken against him. He did, however, also fail to inform his insurance company of the near miss and this could have led him into difficulty had the outcome not been so favourable. This could still happen in the future, should any long-term

adverse consequences arise. His insurance company would have given him advice and guidance on admitting liability, which may affect their willingness to defend his case should litigation follow.

Had David attempted to cover up his mistakes and harm had come to the patient David's position as an autonomous professional would have been indefensible.

While the exact nature of David's mistake may be unique, he is but one of many prescribers facing similar situations. The NPSA has a web-based facility that allows anonymous reporting to collate data on errors, near misses and fatal outcomes. Where common themes can be established, they publish evidence-based guidelines to reduce risk. In anticoagulation they have produced specific guidelines to make anticoagulation safer.

David would also benefit from having a mentor with whom he can meet regularly to discuss general issues related to prescribing. This should be someone David feels happy to talk to about any problems he is experiencing in his prescribing practice. This may be someone different from his clinical mentor who would be able to advise him on matters relating to anticoagulation. Some Trusts encourage new prescribers to 'buddy' up with another prescriber in this way. Some areas offer forums for prescribers.

Scenario conclusion

Several weeks later, David believes he and Graham have established a good rapport. The patients' review period has been extended to four weeks which he can accommodate into his lifestyle.

As Graham is leaving to collect his warfarin he turns to David:

By the way – good news they are going to try cardio version. They reckon I'll need weekly INR checks for at least seven weeks but they'll be lucky. If that doesn't work they are going to give me amiodarone – does that affect the warfarin? And next week I've booked the dentist for a tooth extraction, but that shouldn't affect anything as its not drugs is? I could always try acupuncture if it hurts afterwards and I'm also thinking of starting cod liver oil for my joints. See you – I'm off for a pint.

David believes (and hopes) that Graham is joking, but just in case he has been checking his facts. Cardioversion requires maintaining the patient at a higher INR target, amiodarone interacts with warfarin, as can cod liver oil, dental extraction may require dose adjustment. The biggest

worry for David is that Graham may not behave any differently this time when frequent monitoring would again be required if any of those circumstances arose. What might David do differently should any (or all) of the above occur?

Prescribing pitfalls

- Don't allow yourself to be pressurised by patients, colleagues, receptionists, relatives or anyone else to prescribe outside areas in which you feel competent or that take you outside your legal boundaries.
- Don't make assumptions about your insurance cover – check the details in relation to prescribing.
- Avoid taking on the patient's burden – if you are feeling weighed down seek help.
- Never attempt to cover up mistakes. Be honest with all affected parties.
- When taking blood samples from patients it is necessary to inform your insurance company.
- Never open the door to a patient while wearing a pair of rubber gloves. Always put on a clean pair after they are with you.

Top tips

- Keep up to date with guidelines. Make the most of websites such as NICE, NELM and NPC, who filter information and send you validated links.
- Record everything you do, whether it is issuing a prescription, giving advice or referring.
- Follow your gut instinct when dealing with patients. You get a lot from body language and signals that your conscious may not register.
- Prepare well in advance – the patient contact is the last step.
- Protect yourself – your mental health as well as your patient's health is important. Find a 'buddy' with whom you can talk through issues.
- Accept you will not always be right. Reflect on your practice. The person who never made a mistake never made anything.
- Use competency frameworks if relevant to your role and follow your professional body code of ethics. Read them more than once.
- Be prepared to justify, using evidence base where possible, all prescribing decisions. Ensure you act in a way that a competent prescriber using due care would do or follow well-recognised school of

thought so that your actions would be supported by your colleagues. Read the Bolam case.

- Think outside the box. Who else will your actions affect? What other actions do I need to take? What could the patient be doing to enhance/disrupt treatment?
- Anticoagulants are few in number, but interact with a wide range of prescribed and over the counter medicines and complementary and alternative therapies. A thorough patient history and current medicine regimen needs to be established before agreeing to treat these patients. It is important to establish a rapport and trust with the patient so that they will consult you before self-medicating, come and see you as soon as any medication is changed or doses adjusted, and be honest with you about missed doses and alcohol intake. Patients under the care of renal, hepatic or haemophilia centres may have very different monitoring and dosing requirements.

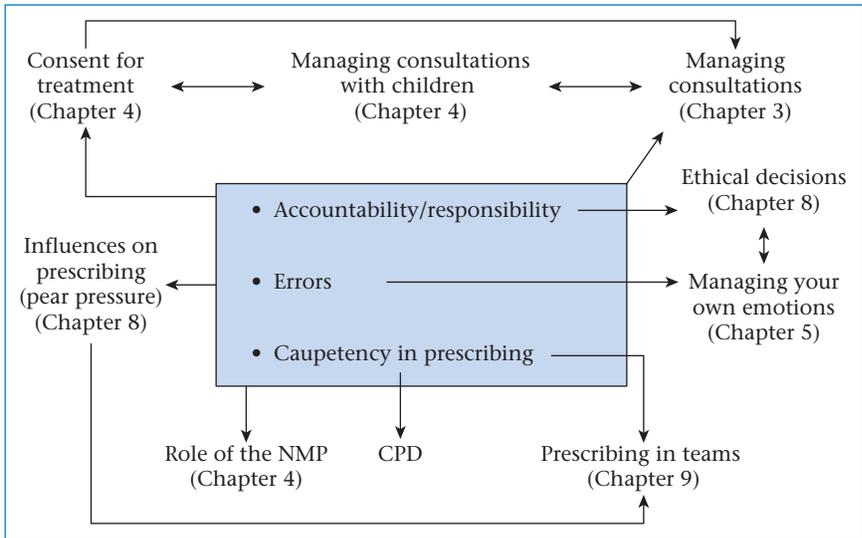
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Mind map



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