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The legal and professional consequences of administering drugs via enteral feed tubes

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Key Points

- Understand the legal implications of manipulating a drug formulation prior to administration.
- Be aware of relevant national guidelines.
- Be aware of relevant local protocols.

When considering the practical and clinical issues associated with the administration of drugs via enteral feeding tubes, the healthcare professional should be aware of legal and professional consequences of altering a drug's formulation prior to administration and the administration of drugs via an unlicensed route. The aim of this chapter is to consider the legal and professional frameworks that govern the practice of healthcare professionals and to relate these specifically to the administration of drugs via enteral feeding tubes. It is appropriate at this point to state that providing the healthcare professional is acting in the patient's best interest, following locally agreed protocols and effecting evidence based practice, it is unlikely that any legal or ethical frameworks will be infringed.

The law and ethics that govern the activities of a healthcare professional are provided in Table 7.1. An activity that transgresses one aspect in Table 7.1 will frequently transgress others and may result in more than one action being taken against the professional. If a pharmacist's action results in serious patient harm or death, then they could find themselves in a court of law to answer a criminal charge, in front of the Royal Pharmaceutical Society of Great Britain's (RPSGB) disciplinary committee, and appropriately sanctioned by their employer. Furthermore, the patient or a relative could take out a civil case in order to obtain compensation for the damage or harm caused.

Table 7.1 Different types of law and ethics that govern healthcare professionals

Type	Description	Relevant standards
Criminal law	Legislation that is used by the state to enforce behaviour; i.e. it is legislation that if contravened generally results in the state becoming the prosecutor and a defendant, if found guilty receiving either imprisonment, community penalty or a fine.	Medicines Act 1968 Misuse of Drugs Act 1972 Data Protection Act 1984
Civil law	Legislation that is used to dispute settlements; i.e. it is used to claim for damages. The claimant is the person or body who has been 'harmed' and the defendant is the person or body who has to prove that they were not liable for the harm caused. The outcome of a successful civil case may be payment of damages by the defendant or an injunction against them.	Applicable to all instances that involve patient care. If you are an employer you may also be liable for any harm that may come to your staff while they are in your employment.
Administrative law	This applies where legislation is devolved from parliament to public bodies to allow them to regulate certain activities. Unlike criminal and civil law, contravention of administrative law will not generally result in a court hearing. It will be dealt with using appropriate mechanisms by the public body and may result in a penalty being imposed, e.g. removal of a care home licence.	The National Care Standards Commission
Ethics	The principles that are accepted in any profession as the basis for proper behaviour. Transgression of the 'ethics' of the profession may ultimately result in the removal of the individual's right to practice.	Nursing and Midwifery Council Code of Professional Conduct, 1 June 2002 RPSGB Code of Ethics

To place the legal and professional issues surrounding administration of drugs via enteral feed tubes in context, a fictitious scenario is provided in Case Study 7.1 and this will be referred to throughout the chapter.

Case Study 7.1

Mr. J.M., 78 years old, has returned to a nursing home from hospital with a PEG tube.

The discharge note states that the medication is as follows:

- Digoxin 62.5 microgram in the morning
- Zopicone 7.5 mg at night
- Warfarin 5 mg in the morning
- Felodipine 5 mg in the morning

There was no guidance provided in the discharge letter as to how to administer these medicines via the PEG tube. The general practitioner prescribes all of the medicines as tablets or capsules and the nurse therefore has to crush or open them all and mix with water before placing them into the tube.

Criminal law

The Medicines Act 1968 governs the supply and administration of all drugs in the UK. The vast majority of drugs prescribed in the UK are 'authorised for marketing' (licensed), under the Medicines Act.¹ A pharmaceutical manufacturer can market the drug solely for the indication for which it has been tested. To remain within the Marketing Authorisation, the drug must be given to the patient in the authorised form, within the authorised dose range and not to a patient with a condition for which the drug has not been tested for safety by the manufacturer. Frequently drugs are not authorised for use in pregnant women or children, not because they are necessarily unsafe but because the manufacturer chooses not to test the drug in these populations.

Administration of drugs via enteral feeding tubes will generally be outside of the marketing authorisation as manufacturers do not tend to test or license drugs to be administered via this route. It could be argued that by circumventing the oral mucosa, the oesophagus in the case of PEGs and additionally the stomach in the case of PEJs, the bioavailability of the drug may be significantly altered. Furthermore, there is limited evidence demonstrating that drug is lost on the tube itself and this again will affect the effectiveness of the therapy.²

The crushing of tablets and opening of capsules prior to administration (which in some circumstances is the only option available for administration via this route) will, in the majority of cases, also place the administration outside of the drug's marketing authorisation. This action will alter the release profile of the drug (to a greater or lesser extent depending on the original formulation) and it is this that is perhaps more likely to cause harm to the patient if not fully considered before being undertaken.

The Medicines Act states that without an appropriate marketing authorisation it is unlawful for any person to sell or supply a medicine in the UK. Doctors, dentists and veterinarians, however, are exempted by the Act from this requirement and can request

that unauthorised medicines be administered to their patients.¹ If this were not the case, it would be impossible for standard treatments to be tested or used in unusual situations or for pre-marketing authorisation clinical trials to take place.

In the case study provided, in prescribing drugs for administration via a PEG tube the doctor is within the law by authorising an unlicensed use of a medication. It is important to note, however, that if the nurse had chosen to crush the tablets without the doctor's prior consent, i.e. if the doctor was unaware of the newly sited PEG tube and prescribed solid dose formulations inadvertently, then the nurse's actions would have been unlawful as nurses are presently not allowed to authorise the use of drugs outside of their marketing authority. Although it is common for nurses to seek advice from other healthcare professionals before undertaking this action, and such actions are completely appropriate, it must also be recognised that healthcare professionals other than doctors or dentists, e.g. pharmacists, cannot authorise such actions under the Medicines Act 1968.

If the nurse's actions were unlawful, in practice it is unlikely that this would be identified or acted upon unless the patient is actually harmed. In such instances, although the transgression of the Medicines Act would be helpful in demonstrating that the person's actions fell below that of a competent professional in a civil case and could be used by the professional body in deciding on its punishment (both discussed later), in itself it would probably be deemed a lesser offence.

Perhaps the greatest concern for any healthcare professional is the likelihood of their actions causing harm and ultimately resulting in a criminal record. For criminal law cases to be successful, the prosecutor would need to prove 'beyond reasonable doubt' that any harm seen was due to the healthcare professional's actions, i.e. in this case drug being crushed prior to administration or drug being inappropriately administered via an enteral feeding tube.

It might be difficult for a prosecutor to argue that a side-effect was a direct result of crushing when the side-effect is an expected occurrence in a percentage of patients receiving the drug in its licensed state. Similarly, it would be difficult for a prosecutor to prove 'beyond reasonable doubt' that the drug had been ineffective owing to the administration via the enteral feeding tube or to crushing, as it is a normal expectation that drugs are ineffective in a proportion of all patients.

Civil law

Providing the healthcare professional uses the drug exactly as the marketing authorisation states, the liability in any civil case will usually lie with the manufacturer. If a drug is tampered with prior to administration in a way that is not outlined in the marketing authorisation or is administered by an untested route, the administering person will be giving an 'unauthorised drug'. Liability would lie with the doctor, with the pharmacist if they are aware of the method of administration when supplying, and with the nurse or carer administering the drug. If the doctor and administrator had received advice from a third party on the unlicensed administration, then the third party, such as a medicines information unit, would also be partially liable.

In the case scenario provided, there are many reasons for questioning the appropriateness of administration of drugs via this route and whether crushing of drugs is the most appropriate action. Administration of warfarin with enteral feeds can result in a significant reduction in the amount of drug absorbed and hence a reduced clinical effect.³ Some zopiclone formulations form a gelatinous mass when mixed with water and may block the enteral feeding tube. Crushing of felodipine, which is a slow-release formulation, may result in J.M. receiving a larger than expected dose initially and subsequently a period of time with no drug in the body. Digoxin has a small therapeutic window and therefore adsorption onto the PEG tube may also alter its clinical effectiveness.

In order for a civil case to be successful, the defendant must be proven to have been negligent. This would require the claimant/plaintiff proving that the defendant had a duty of care to them; that duty of care would need to have been breached; and they would have to provide evidence that they had been damaged as a result of the negligent action. Although all three criteria must be met for a civil case to be successful, unlike in criminal law where a case must be proven 'beyond reasonable doubt', within civil law the case would need to be proven only on the 'balance of probabilities'.

The doctor, the pharmacist and the carer all have a duty of care to J.M. with regard to his drug regimen and it would be more likely that any harm that ensued could be proven 'on the balance of probabilities'.

In order to prove that the duty of care had been breached, the actions of the defendant would be compared with those of a reasonably competent person undertaking a similar role. Consequently, it is worth considering what a 'competent' healthcare professional might do in this situation.

Owing to the relatively frequent nature of this problem, a nurse or at least his or her employer might also introduce a protocol for all staff to follow, thus standardising the approach and level of care. However, blindly following a protocol does not necessarily protect healthcare professionals from liability⁴ and all protocols must be up-to-date and based on expert evidence.⁵

It can probably be assumed that a 'competent' nurse would first check with a suitable information source as to the best approach for administering drugs via this route and it would be appropriate for the nurse to clarify either with the hospital ward or the hospital pharmacy department from which J.M. was discharged how these medicines were being administered on the ward. If they were unsure about the appropriateness of the described actions or were unable to obtain the information from the hospital in time, then telephoning a medicines information department would be a suitable alternative.

The nurse's actions and the information received from the reference source(s) used would be documented in the patient's care plan. If the advice had been against crushing tablets and the general practitioner had asked for this action to take place, then a competent nurse would provide this information to the prescriber.

The issue whether patient consent had been obtained prior to the administration of the unlicensed medication might also be taken into account when considering the appropriateness of the nurses' actions. In order to minimise liability it is believed to be

appropriate when administering unlicensed medicines also to 'tell the person (*patient*) about the risks involved and obtain their consent'.⁵

In summary, therefore, a competent nurse administering drugs to a patient via an enteral feeding tube would be working to an up-to-date protocol, would obtain appropriate guidance, would record their actions and the guidance received, would discuss this with the prescriber, would obtain patient consent, and would then undertake the administration.

If, following the above procedure, J.M. was subsequently harmed by his medication, it might be reasonable to assume that the liability would lie solely with the person authorising the drug administration, i.e. the doctor. There are, however, judgements, that show that this may not be the case.

In *Gold v. Essex County Council (1942)*⁶ the judge stated that 'if a doctor ordered an obviously incorrect and dangerous dosage of a drug a nurse who administered it without obtaining confirmation from a doctor or higher authority might well be found to be negligent'. Furthermore, if the nurse, after confirmation with a higher authority, is still unhappy he or she should refuse to administer any order that is 'manifestly wrong'.⁷

These judgements clearly demonstrate the need for the administrator not to simply accept directions from a doctor, but to question them if unsure and to obtain independent clarification if they are still not happy with what they are being asked to do.

Similarly, the judgements made with respect to nurses could equally be applied to pharmacists when deciding whether or not to supply medication. If the pharmacist believes that administering the drugs according to the doctor's instructions is inappropriate, then there is an opportunity for them to utilise their professional discretion and refuse the supply. In supplying the medication in full knowledge of its intended use, the pharmacist is perhaps accepting a greater share of the liability than the nurse in administering the drug, as they would be deemed to have greater professional competence in this cognitive domain.

In both instances, if the nurse refuses to administer or the pharmacist refuses to supply, they must remember that they still have a duty of care to the patient and should undertake every action possible to resolve the situation and enable appropriate treatment of the patient. Therefore, it is inappropriate simply to refuse to administer or supply. This action should be reserved as a last resort when the healthcare professional feels on balance of all the available evidence that the drug would cause more harm to the patient if administered via the prescriber's intended route/method than if not given.

Administrative law

The body that has been empowered to regulate care in care homes is the National Care Standards Commission (NCSC) and in 2002 it published its national minimum standards.⁸ The standards relevant to this case study would mainly be 9.1 and 9.4.

Standard 9.1 states that

The registered person ensures that there is a policy and staff adhere to procedures for the receipt, storage, handling, administration and disposal of medicines ...

The design of a protocol for the administration of medicines to patients with swallowing difficulties would demonstrate clear adherence to the NCSC guidelines and, providing J.M.'s carer was seen to follow this, there would be no reason for the NCSC to become involved in any dispute that followed.

If the home did not have a protocol, or there was evidence that any protocol was not adhered to by the carer, then NCSC would start to consider the quality of care provided within the home.

Standard 9.4 states that

Medicines in the custody of the home are handled according to the requirements of the Medicines Act 1968, guidelines from the Royal Pharmaceutical Society (RPSGB), ... and nursing staff abide by the Nursing and Midwifery Council (NMC) standards for the administration of medicines.

The Medicines Act has already been discussed and the NMC standards will be covered when considering professional standards. With respect to crushing of medicines, the RPSGB 'strongly recommends that advice on the storage and administration of medicines should be sought from a community pharmacist, preferably the pharmacist that supplies the home' and has informed pharmacists that 'if a formulation is tampered with then the product will be unlicensed. Pharmacists must consider and advise on the potential for distortion in the bioavailability profile of the medicine and whether there is a need for reduction or increase in the dose and how or whether this can be quantified'. Furthermore, 'pharmacists must consider whether alternative licensed products are available, such as the same drug with a different formulation or a different drug for the same indication'.⁹

In the scenario provided, it would be difficult for a pharmacist to identify other 'licensed' products. Even if a licensed liquid formulation were available as an alternative to crushing tablets, its administration via a PEG or PEJ tube would usually be unlicensed. With little quantitative evidence available to determine whether the liquid formulation or crushed tablet would be better for the patient via this route, the pharmacist would need to identify which option was believed to demonstrate best professional practice.

It would be reasonable for the nurse in this instance to ring the local medicines information department. Although the supplying pharmacist will be able to identify which medicines have special coatings and what alternative formulations are available, they would be less likely to be able to provide specialised advice on administration of medicines by PEG tubes.

Professional standards

The NMC is the responsible body in the UK for reinforcing the standards that nurses are expected to meet and these are broadly outlined in its 'Code of Professional Conduct' published in April 2002.¹⁰ Statements such as 1.3, 'You are personally accountable for your practice. This means that you are answerable for your actions and omissions, regardless of advice or directions from another professional', and 8.1, 'You must work with other members of the team to promote health care environments which are conducive to safe, therapeutic and ethical practice', are relevant in this situation. However, the standards found within 'Guidance for the administration of medicines' that came into effect on 1 June 2002 are perhaps the most pertinent.¹¹ These start with the guidance:

The administration of medicines is an important aspect of the professional practice of persons whose names are on the council's register. It is not solely a mechanistic task to be performed in strict compliance with the written prescription of a medical practitioner. It requires thought and exercise of professional judgement.

It would therefore be unprofessional for J.M.'s nurse to accept any direction from a prescriber to crush medication or place it down a PEG tube without first questioning the appropriateness of both of these actions.

Within the principles for the administration of medicines, a nurse is also required to have 'considered the dosage, method of administration, route and timing of the administration in the context of the condition of the patient and co-existing therapies.

Blind administration of medication via a PEG tube, which may require crushing and mixing with water beforehand, may not only result in a civil case, and close consideration of practices within the home by the NCSC, it may also result in the NMC considering the professionalism of the nurse.

Conclusion

This case study demonstrates the need for a good awareness of both professional and legislative guidance with respect to administration of medicines.

For J.M.'s nurse to act both professionally and competently, he or she would need to do the following:

- Ideally work to a protocol written specifically for the administration of medicines outside of their marketing authorisation.
- Seek advice from a pharmacist (preferably working within a medicines information service) on the alternative options available (liquids, alternative routes) and the clinical consequences of crushing and placing medicines down a PEG tube.
- Obtain consent from the patient.
- Record all actions.

- Obtain authorisation, preferably written, from the prescriber if it is decided to administer a medicine outside of its marketing authorisation.

For the pharmacist to act both professionally and competently, they would need to ensure the following:

- That the advice they provided was based on the most up-to-date evidence.
- That the increased risk of harm that would result from administering medicines outside of their marketing authorisation was minimised and justifiable in terms of the potential clinical benefits.

In an ideal world the nurse would have prepared for the meeting with the prescriber in order to have all of the options and relevant information available for this patient at hand and would have obtained this information from an appropriate pharmacist. If the prescriber insisted that the medicines be crushed prior to administration via the PEG tube, it might well be appropriate in this instance for J.M.'s nurse to refuse such a request as it would not be in the patient's best interests and they would not want to be responsible for any harm that ensued.

If the supplying pharmacist was aware of the proposed method of administration and had any concerns regarding its appropriateness, they should also use their professional discretion to refuse the supply. Furthermore, obtaining written authorisation for such action from the prescriber and blindly following it would not be deemed to be professional and would not reduce the level of responsibility that would be attributed to the pharmacist, nurse or carer in a civil court of law.

References

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