Clinical Ethics Committee Case 9:

Should we inform our patient about animal products in his medicine?

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The Clinical Ethics Advisory Group (CEAG) at University Hospitals Bristol NHS Foundation Trust agreed to discuss the following case. The University Hospitals Bristol CEAG was established in 2006 and serves several large teaching hospitals in the South West of England. Group membership comprises representatives from senior and junior medical staff, nursing and midwifery, allied health and healthcare science professions, a non-executive director (lay member), a spiritual adviser and a medical ethicist. The CEAG provides a consultation service, education for hospital staff and offers review of hospital policies where ethics input is required. The Group meets quarterly, but members are also available at times in between to receive referrals and give advice. ‘Live’ consultations may take place at meetings of the group by telephone consultation between members or by email (with anonymized details). Cases have included end-of-life issues, use of new or experimental treatments and children’s issues, sometimes where there has been conflict between clinicians and family. All cases and notes of Group deliberations are recorded and minutes are taken of every meeting.

Referral to the CEAG: deriving drugs from animal sources and considerations of religion

A 70-year-old patient of Middle-Eastern origin (Mr D) is admitted for management of exacerbation of obstructive lung disease. Mr D has capacity to consent to, or refuse, medical treatment. As he is likely to be bed-bound for several days, hospital policy (reflecting national guidance) is that he receives prophylactic heparin to reduce the risk of potentially fatal venous thrombosis. The standard drugs used for prophylaxis against blood clots are various forms of heparin, which is given via subcutaneous injection. All heparins are derived from pigs. A junior doctor has asked her consultant whether she should ask Mr D if porcine-derived heparin is acceptable to him.

We are concerned about how we should proceed. The animal origin of some drugs may not always be known to staff prescribing or administering these drugs. Patients may be even less likely to have this knowledge. Further, information is not easily available to patients or health professionals who may wish to know more. For example, although the ‘Summary of Product Characteristics’ required to be published about any drug includes this information, it is not readily available to prescribers (particularly as Internet
access is not always available on the ward) and would have to be sought on each occasion that a patient is prescribed a new drug.

A proportion of patients will be members of certain religious faiths that prohibit the ingestion of certain foods. While we need to be careful about making assumptions about whether particular patients are members of these faiths (and if so whether they follow its doctrines strictly), religious doctrines may be interpreted by some patients to extend to prohibit the ingestion or other use of pharmaceuticals derived from specific animals. Similar views may also be held by people who choose to follow a vegetarian or vegan diet.

If we talk with Mr D and make the porcine origin of this drug known to him, he may choose to decline this drug. However, to not administer it would be contrary to national guidance (although within Mr D’s legal rights) and could affect clinical outcomes. We could perhaps instead prescribe one of the newer clot-preventing drugs that are entirely synthetic. These may also be easier to administer and monitor, but are more expensive. Some may also have to be prescribed outside of the product licence, with less available evidence of effectiveness.

A further issue is that the use in this case is for prophylaxis as opposed to treatment. Heparin is recommended to prevent a complication which, while potentially serious (including fatal), may also not occur at all. That said, such administration is increasingly viewed as medically essential.

We are approaching the ethics committee with the following questions in mind:

1. Should we feel a moral obligation to disclose the derivation of heparin to Mr D (or indeed to all patients)?
2. If not, is it sufficient to honestly answer questions if he raises them?
3. Is there a morally relevant difference between patients who object to certain animal products on religious grounds and those who have strong concerns about animal welfare?
4. When considering purchasing drugs like heparin, would the ethics committee be happy to recommend the purchase of alternative non-animal-derived products which may be more expensive?

Response from the University Hospitals Bristol CEAG

Thank you for your referral, which we considered at our meeting on 14 September 2009. This case provides an interesting example of a general issue that arises in hospital medicine: that of administering drugs and disclosing the components from which they are developed. How much information should we be required to provide to patients about the origin of the drugs they are receiving? What other limitations might there be? What choices should patients be able to make, and what responsibilities do health professionals have?

Background

Hospital protocols, informed by national guidance, dictate that all inpatients should receive a prophylactic dose of the drug heparin. This drug has proven to be effective in reducing the chances of a blood clot forming during a hospital stay. However, it is produced from a porcine source. The issue that has arisen here is that it appears the junior doctor (and perhaps her colleague) believe Mr D may be a member of the Muslim faith.

Eating certain foods is generally prohibited under Islam. This includes alcohol and pork (including porcine-derived gelatine) and blood; for this reason Halal meat is drained of blood. The Qur’an prohibits
the consumption of pork in four sections: 2.173, 5.3, 6.145 and 16.115: ‘Forbidden to you (for food) are:
dead meat, blood, the flesh of swine and that on which hath been invoked a name other than that of
Allah’ (Al Qur’an 5:3).

The question therefore arises as to whether Mr D, were he to be informed about the porcine origin of
heparin, would choose to refuse this drug. Likewise, as the referrer recognizes, the use of drugs that
have been produced from animal products may also have implications for the increasing number of
people who follow a vegetarian or vegan diet.

However Islam also includes five key legal principles, of which one is that ‘necessity permits the
impermissible’.1 To this end, if there is absolute necessity that a particular treatment course be
followed, and there are no religiously lawful alternatives, the above Sacred Laws may be temporarily
suspended.2 Such a suspension would usually occur following a discussion with a religious leader.3

There is not much information about Mr D’s background or what, if anything has been discussed with
him. We have therefore assumed that as yet nothing has been disclosed to him about how this drug is
made, although he may have been informed that it is standard procedure for him to receive a
prophylactic dose to prevent blood clotting while in hospital. We also do not know anything about Mr
D’s attitudes to diet or indeed whether he is active in his practice as a (presumed) member of the Muslim
faith – a point we will return to below.

Should we feel a moral obligation to disclose the derivation of heparin to Mr D (or indeed to all
patients)?

Before addressing the ethical or moral aspects of this issue, our discussion first turned to a brief
consideration of legal aspects. It is our view that, in general, we have a legal obligation to tell patients
any information about their medical care that they would like (subject to the usual legal doctrine of
informed consent, and its limits). However, we feel that it is less legally certain how much of a legal
obligation we have to tell patients everything they might expect to know, as opposed to their freedom or
responsibility to ask us specific questions for us to then answer?4 At one extreme, if we were to go into
significant detail about drug and treatment origins with every patient, then this will have an immediate
and detrimental impact on hospital operational procedures. On the other hand, patients may not always
have the requisite background information they need to ask us the types of questions they would have
done had they had more information.

The issue of faith-based requirements to avoid ingesting certain products is, of course, not limited to the
Muslim faith. The administration of porcine-derived products is also likely to be relevant to Jewish
patients as well as many Hindus and Sikhs. Patients are encouraged to disclose their religious affiliation
with their care provider and to ask about alternative drugs.5 However, patients are also informed that
the prescribing of porcine-derived medication needs to be sensitive to their religious beliefs.6 Health
professionals are therefore encouraged to give consideration to patient’s religious beliefs before
prescribing drugs or treatment.7–9

We worry that this issue has not yet been discussed in a more open manner within the National Health
Service (NHS) or with different faith groups (and vegetarian activism groups). The doctrine of consent
has changed and developed significantly in recent decades and patients now rightly expect a great deal
more information and consultation regarding their treatment than they did previously. Our challenge is
to determine what individual patients might want and to meet these expectations within the limitations
of busy hospital environments.

In cases like these, it is also important to consider what information staff have available to them. When
we first began to discuss this issue in our own group it came as a surprise to some that heparin was
produced from porcine origin. Ensuring all hospital staff have access to this information will be a significant undertaking. Raising expectations as to information-delivery about the ingredients and methods of production of all hospital medicines may place a significant drain on pharmacy resources and could lead to delays in administering medications as staff take extra steps to ascertain patient questions, obtain the necessary information, go back to the patient and allow the patient time to decide.

Yet, despite these anticipated logistical difficulties, we feel uncomfortable about administering a drug that we know some of our patients might refuse were they to know its origins. While many religious faiths allow the administration of a variety of drugs when medical necessity dictates (such as in an emergency context), not all administration of these drugs occurs in this context and Mr D’s case is an example of this. We were unsure whether prophylactic administration of heparin would be considered as a necessity and how the availability of alternatives would be interpreted. This needs to be taken into account; however, below we also raise the long-term implications of a reduction in prophylaxis in the hospital setting, as there is significant morbidity and mortality from hospital-acquired thrombotic events.

For Mr D we do therefore have an obligation to discuss this with him – but this would also be an obligation that should extend to all patients, as we need to avoid making assumptions based on a particular patient’s ethnic origin or other cultural factors. Such discussions should not commence from the premise that if Mr D is indeed a Muslim he would refuse heparin; rather, he should be presented with the options and allowed to make a choice. We need to be wary about making behavioural assumptions based on a patient’s presumed faith. Mr D may or may not be a devout Muslim; he may also need some assistance to come to a decision about whether to take heparin.

To summarize, our view is that we do have a moral obligation to disclose the derivation of heparin to Mr D and indeed to all patients to allow them to come to a considered and informed choice. We therefore have a responsibility to explore this in a broader way, but if we are to do this we need to be able to accommodate the consequences.

If not, is it sufficient to honestly answer questions if he raises them?

Given our answer to the first question above, it will come as no surprise that we do not believe it is sufficient to honestly answer questions from Mr D if he raises them. It is not up to us as health professionals to make a moral or faith-based judgement on behalf of our patients as to which medications to take and which to refuse. However, information provision is an issue. Patients with strong views about the content of their medicines are perhaps more likely to ‘speak up’ and receive the information they need. For those patients who do not ask questions, it may be paternalistic to make assumptions. We want to give our patients the information they need to make a considered autonomous choice, but we also need to be mindful of ‘overloading’ patients with too much information, not all of which may be wanted. We do need to take care not to upset our patients or simply transfer this problem on to them. This will require health professionals to take a balanced and situation-based approach and to be sensitive to each patient’s needs and preferences.

To adopt the approach of only answering questions as and when they are posed could also be seen to be ‘abandoning’ our patients to rely on their own knowledge. How reasonable is it for us to expect that Mr D will have had access to the necessary background information he needs to ask ‘the right questions’? It will be important to support all patients and provide information in stages to allow reflection, consultation with others and decision-making. However in so doing, the importance of heparin (including its prophylactic use) should be emphasized.

Is there a morally relevant difference between patients who object to certain animal products on religious grounds and those who have strong concerns about animal welfare?
Our view is that there is no morally relevant difference between these groups. As we have discussed above, it will be important not to make general assumptions about patients' religious or other beliefs based on their ethnic or cultural background. It should not matter whether the basis for this objection is based on religious or animal welfare considerations.

There does, however, need to be further consultation with religious and other interested groups to ensure that wider population education can take place; a point we return to below.

**When considering purchasing drugs like heparin, would the ethics committee be happy to recommend the purchase of alternative non-animal-derived products which may be more expensive?**

A Trust may show some resistance to this kind of information being routinely provided to patients, for two reasons. First, Trusts may be likely to emphasize the importance of prophylactic heparin for the safety of inpatients, as an increase in refusal of these drugs may detrimentally impact patient outcomes. Second (and more relevant to the question posed), wide refusal could also mean that a Trust would need to look at alternative, but more expensive, drugs to be administered instead of heparin. The synthetic forms of heparin are about one and a half times as expensive as the porcine-derived version – which if widely adopted would increase this drug budget by at least 50%. If all patients elected to take this form, this could impact on other aspects of patient care.

However, the synthetic forms of these drugs may also offer some clinical advantages. From a clinical perspective, it may actually be better to give all patients (whatever their attitudes or beliefs) the newer form of this drug. If we provide this information to all patients in conjunction with the information about animal origins, many more may want to take the newer, synthetic and potentially more effective form. The question is the amount of information we have the obligation to provide: animal origins only, or clinical effectiveness?

It is also, of course, within Mr D’s right to refuse to take any form of prophylactic drug, even if this would go against what is in his best interests. However, a right to refuse treatment is not the same as a right to demand a particular treatment and in a system of nationalized health-care rationing is always going to be necessary. Yet if we are to ration non-animal-derived heparin, is it acceptable to ration it to particular groups on moral or religious grounds? This would seem to constitute rationing based on religious as opposed to medical interests. The hospital pharmacist could therefore look at the availability of a wide variety of drugs to prescribe as alternatives.

The approach to prophylaxis within the NHS has been to offer a porcine-derived drug. However, the NHS has recently begun to allow patients to privately ‘top up’ the cost of their medicines through choosing and paying for medicines not routinely available within NHS budgets. The practice, which began in oncology, is in itself controversial, but a detailed discussion of the issues goes beyond the scope of this case. Here the reason for private top-up will predominantly be due to drug origin rather than drug effectiveness – should this make a difference? If the non-porcine version of the drug costs the same, then the Trust may choose to purchase it, whereas in oncology the problem is more that the National Institute for Health and Clinical Excellence has not approved the drug for NHS use.

If a Trust or PCT cannot afford an increased drugs bill to cover synthetic forms of heparin then problems may arise. If the medicines or formulary committee vetoes the purchase of synthetic heparin but patient refusals of the animal-derived form increase, problems could arise such as surgeons refusing to operate if no prophylaxis has been taken. So we do need to think about the long-term implications of providing patients with enhanced information about animal origins of drugs.

**Conclusion**
In discussing Mr D’s case, the position we have come to is that when obtaining consent to administer heparin, the health professional treating him needs to ask him whether he has any objections to the use of drugs derived from animals. Such a request would not be based on him being a 70-year-old male of Middle-Eastern origin, but because he is a patient in hospital. This kind of information provision should form part of the work-up for all hospital patients. This approach will obviously have resource implications, but if incorporated into a general approach of openness and information provision, it should be possible to build such a discussion into routine care as much as possible. This would encompass providing information including the availability (or lack thereof) of alternative products and allow Mr D to make a choice according to his beliefs. This decision should then be recorded in Mr D’s notes, or a space could be created in drugs charts to record this information.

We have come to this decision because we do not believe it is appropriate to let the status quo prevail. Changes to models of good practice in patient consent and information provision, as well as an increasingly multi-faith and multi-perspective society, mean we need to reconsider this non-provision of information. Of course, it may be that some followers of the Muslim faith feel comfortable taking heparin. Indeed, the animal origin of heparin may be more of an issue for patients who follow a vegetarian or vegan diet. Wider awareness of the animal origin of heparin may also lead to wider refusal of it in the patient population. However, we cannot make these assumptions and the principle of giving information is arguably no different depending on whether it is grounded in legal, philosophical or religious tenets. Further investigations, together with greater transparency for patients, are warranted. The challenge is to find a way to provide this information in a balanced and supportive way and to offer patients a real choice.

This problem could perhaps be partially resolved by developing initiatives such as information leaflets. For example, our Trust is considering adding a statement to patient leaflets about medicines stating that some drugs may be of animal origin. However, the logistics of ensuring these reach all patients in a timely manner are challenging, particularly the timing of leaflet provision as not all patients will know in advance that they are going to be in hospital. Moreover, the content of such leaflets may be difficult to determine: if a patient is told that ‘some of your medicines’ may contain animal products, in practice if a patient is taking several medications this may give rise to more questions. Informing patients who are unconscious or in other emergency contexts will also be difficult. It will not always be possible to assess patient needs and preferences in advance and sometimes assumptions will need to be made. That said, a leaflet-based approach does go some way to begin to address this problem – particularly if there is a considered approach to leaflet development and perhaps specialist materials for members of particular groups developed with full consultation.

It will also be vital to educate Trust staff about this issue to ensure that all know that this may be a problem. In our own Trust this issue has already been the subject of a Grand Round, and Trust pharmacists will also know the composition of most common drugs (as well as being able to determine this for all other drugs). A list of the most common drugs that are animal-derived could also be developed, which could then be used as a ‘checklist’ to trigger a request for more information such as one of the leaflets described above. These could be made available on the Trust intranet. Issues around animal origins of drugs are also amenable to Trust audits and such practices should be encouraged.

The diversity of approaches to product origins within religious faiths is increasingly being complemented by the escalating prevalence of vegetarianism and veganism, as well as a general upsurge in societal interest as to the origins and safety of all consumer products, including foods and medicines. Therefore, there now needs to be a national focus to develop initiatives to help patients make considered and autonomous choices about consenting to take certain drugs. Health professionals and the NHS need to work with faith and activist organizations to help both ourselves and patients make these decisions.
Some initial reactions from these groups are given in Boxes 1 and 2. Working together in this way will help us determine how best to respond to all patients for whom the animal origin of their drugs will be a relevant consideration to taking them.

**Box 1** Comment from the Muslim Council of Britain

Dr Shuja Shafi, Chair of Muslim Spiritual Care Provision in the NHS at the Muslim Council of Britain, said:

_The MCB continues to work together with health professionals and the pharmaceutical industry to try to increase awareness of this important issue. It is our view that any prescription of porcine-derived medication should be sensitive to the individual's religious background. Taking porcine-derived products into the body (by whatever means) is prohibited in Islam. Health-care professionals should, therefore ensure that all patients are made aware if a drug prescribed to them contains animal products so that they have the opportunity to ask for alternatives. However, in the absence of suitable alternatives, religious leaders can exempt medicines when there is medical necessity. Given that prophylactic heparin is prescribed as a medical necessity, the same principle is applicable. The MCB encourages Muslim patients who wish to discuss this matter to seek advice from their local Muslim Healthcare Chaplain (Imam). The MCB also encourages NHS Trusts to educate their employees about the importance of communicating this information to all patients and to consider making non-porcine anti-clotting and other medications available to those patients who, having considered the alternatives, wish to avoid porcine-derived heparin. The pharmaceutical industry should be urged to consider seeking alternatives to animal-based medications._

**Box 2** Comment from the Vegetarian Society

Annette Pinner, Chief Executive of the Vegetarian Society, stated:

_We very much welcome this issue being raised. The Vegetarian Society receives a lot of queries from vegetarians who need to make a decision about whether to accept various drugs, vaccines or blood products when those products may comprise ingredients that are animal-derived. Strictly speaking, vegetarianism is related to diet and eating. However, many vegetarians choose to take this further and decide to apply the principles of vegetarianism to the medications they take or the clothing they wear. This is therefore an important issue; not only because it is derived from people's personal beliefs but because there may also be legal implications, for example under the Equality Act. It is our view that information about the origins of drugs used in health-care treatment must be made available to all patients, to help them make an informed choice about which medications they choose to take. This responsibility lies with both the companies who manufacture and market the various drugs involved but also the National Health Service. We look forward to further discussion on this important topic._

**Members of University Hospitals Bristol NHS Foundation Trust CEAG who discussed this case**

Jane Buswell, Nurse Consultant, Older People; Chris Davies, Head of Spiritual & Pastoral Care; June Dyer, Clinical Nurse Specialist in Cystic Fibrosis; Dr Ruth Evans, GP Registrar; Professor Karen Forbes, Consultant in Palliative Medicine; Kevin Gibbs, Pharmacist; Phil Hall, Assistant Director, Medical Director Team (Committee Administrator); Dr Ian Jenkins, Consultant in Paediatric Intensive Care and Anaesthesia; Dr Sally Masey, Consultant Anaesthetist (Chair); Ms Peggy Woodward, Midwife; and Sue Yarrow, Superintendent Radiographer.
Also in attendance: Dr Philip Segar, Consultant Paediatric Anaesthetist; Dr Terri Rotchell, GP Trainee.

Notes about the Author

Dr Ainsley Newson is Senior Lecturer in Biomedical Ethics in the Centre for Ethics in Medicine at the University of Bristol. She has a PhD in Medical Ethics and Bachelor degrees in Science and Law. Her research interests include clinical and reproductive decision-making in genetics and synthetic biology. Ainsley is a member of the European Clinical Ethics Network, the Board of Trustees of the UK Clinical Ethics Network and the Editorial Committee of the journal Clinical Ethics. She has been a member of clinical ethics committees for six years, and is currently a member of the CEC at Royal United Hospital Bath.

References and Notes

10. For further discussion, see: Slowther A. Co-payment for medical treatment. Clin Ethics 2008;3:168–70