

Gaining consent for the use of animal-derived medicines, prosthetics and surgical equipment in Otorhinolaryngology: An Ethical Review

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INTRODUCTION

Throughout the history of medicine, there have been numerous developments which have led to changes in public opinion and expectations. A recent shift in public opinion has led to a change in the way healthcare is delivered by doctors and surgeons, with an evolution from frank paternalism to recognising and respecting a patient's autonomy. However, to ensure a patient can make autonomous decisions about their healthcare, they require all of the necessary information to provide their doctor with informed consent. The information that must be communicated to a patient to allow them to provide consent is determined by considering what a reasonable patient would want to be told about that particular intervention; and it is here that some believe we may be failing patients. As clinicians, we have a responsibility to our patients to recognise when public opinion may have changed and when the public may expect us to be providing more information to them when they are considering whether or not receive an intervention.

This review seeks to establish whether we are actually fulfilling our responsibility to patients, more specifically whether we should be informing patients about our use of medical products that contain ingredients derived from animals. Previously, when it is known that a medicine or intervention contains animal-derived ingredients, this information has been provided almost exclusively to patients who we believe may have religious objections to the use of those particular animal products. For example, a study exploring the views of different faiths on the use of animal-derived products in medicine through discussions with religious scholars and searches of religious literature concluded that Judaism and Islam have absolute objections to any porcine products, Hinduism rejects the use of bovine products and Christianity has no restrictions.¹ These views are significant because there are many drugs, grafts and interventions in ENT, and medicine as a whole, that contain animal products. For instance, gelatine is often used to encapsulate medicines for consumption and lactose is used in the manufacturing of medications, but both are often sourced from bovine and porcine ingredients.

Of the 100 most commonly prescribed drugs in the NHS, 74 were found to contain either gelatine, lactose or both, and only 20% of these medicines had supporting documentation that revealed whether their ingredients were synthetic or sourced from animals.² Similarly, the specialty of otolaryngology features numerous examples of animal-based products in its armamentarium. For example, many ear procedures involve the use of GelFoam and Spongostan, which are sterile sponges used to stabilise and reduce bleeding, however both are made using ingredients sourced from pigs.^{3,4} Common operations such as myringoplasties involve the use of dissolvable biomaterials, such as BioDesign grafts that reinforce the tympanic membrane and aid healing, and again these

products are derived from porcine ingredients.⁵ Even vocal cord paralysis, a complication of many neoplasms and cerebrovascular events, is often treated using injections of porcine-harvested collagen to medialise the affected cord and improve symptoms.⁶

Therefore, it is evident from some examples that patients belonging to these religions, a significant proportion of the UK population, may already be unknowingly receiving treatment that they would otherwise refuse – the foundation of a patient's informed consent is being eroded. In addition, there may now be other groups of individuals in the population not being considered in this debate. There has been a consistently growing movement worldwide towards being more conscious of our impact on the environment and global warming, with this trend leading to a significant increase in the number of people who identify as vegetarian or vegan; meaning they may object to the consumption or use of any animal product.⁷

This raises an ethical question for doctors, when gaining a patient's informed consent, do we need to be telling them whether their intervention or medicine will involve the use of animal products? The aim of this paper is to investigate various philosophical viewpoints and apply them to this issue to establish if doctors, in particular ENT surgeons, do have an ethical responsibility to be more considerate of their patient's views towards the use of medicines that contain animal-derived products.

METHODOLOGY

Studies considered for inclusion in this review were found by performing a search of PubMed using the terms: "animal-products", "animal-derived products" combined using the Boolean operator "AND" with "deontology", "consequentialism" and "virtue ethics" respectively. A second search of PubMed was performed to identify previous research on animal-based products in ENT using the terms: "animal-products" with "AND" and "otolaryngology" or "ENT" respectively.

DISCUSSION

Deontological Perspective

Deontology, otherwise known as duty-based ethics, refers to a form of ethics pioneered by philosopher Emmanuel Kant that focuses purely on the ethics of an action, rather than of its consequences. Therefore, from a deontological perspective it is better to do the right thing even if that action could cause some harm or do less good; the end does not justify the means.⁸ It also states that there are set universal rules which must always be followed and that are never morally right to do. For example, a doctor delivering the news of a patient's death to their family member may seek to lessen the blow by not providing absolutely all of

the facts and simply trying to reassure or comfort them. However according to the principles of deontology, this would not be a morally right act as it could be seen as lying or not telling the truth, regardless of whether it produced a more favourable outcome for the family.⁹ Thus, we can summarise that deontology prioritises the principle of autonomy over the principle of beneficence.

As discussed earlier, doctors have many duties to their patients with one of which being a responsibility to provide them with all of the information required to enable them to make an informed decision about their healthcare. The General Medical Council states explicitly in its ethical guidance that when obtaining informed consent, doctors must strive to “*understand the patient’s views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about*”, which may include their views on the use of animal-products.¹⁰ This reinforces the principle of patient autonomy and that patients have a right to consent to or refuse a form of treatment, even if it may result in harm to them. It is immediately apparent that from a deontological perspective, it is morally right for doctors to provide a patient with the relevant information about whether their intervention contains any animal-derived products. This enables them to make an informed decision about whether they want to consent; this remains true even if the patient’s refusal to the intervention due to its constituents results in harm to them.

Consequentialist Perspective

In stark contrast to the deontological perspective, consequentialist ethics states that an action is only deemed as morally right or wrong depending on its outcome, thus the end justifies the means. Consequentialism in medicine would argue that the right action is the one that results in the most positive good for the patient, or the most positive good for the greatest number of people when we refer to utilitarianism, a specific form of consequentialism.¹¹

Before one applies consequentialist ethics to the issue of gaining consent for the use of animal-derived products, firstly it is important to establish what outcomes would be considered the most beneficial. One could argue that the most beneficial outcome is the one that allows a doctor to use the most suitable, innovative intervention for the patient, as that is most likely to result in a good outcome in terms of the patient’s health. For example, the indicated intervention for the patient’s illness may be one that contains animal-derived products, thus by neglecting to inform them of this fact prevents the patient from objecting to the treatment and so would achieve a better patient health outcome.

On the other hand, one may suggest that the best outcome is the one that provides a satisfactory outcome for the patient whilst still respecting their autonomy. As the example above involves not providing all of the relevant information to the patient, their autonomy is not being respected and this can have negative repercussions for the doctor-patient relationship in the future as patients may feel that their doctor is not being honest with them.

Virtue Ethics perspective

Virtue ethics provides a very different viewpoint to both deontology and consequentialism. Based on the ancient Greek philosophy of Socrates and Plato, it states that an act is morally right if that action would be done by one who is a virtuous person, thus it places less emphasis on the goodness of an act and more on the goodness of the person carrying out the act.¹² It is important then to identify what characteristics we are referring to when we describe a virtuous individual, as these virtues have changed over time and can vary depending on the society or culture. In his philosophical work *Republic*, Plato describes a set of four cardinal virtues that must be present for one to be considered virtuous, these are justice, temperance, prudence and fortitude. However, the prominent medical ethicists Beauchamp and Childress propose five different core virtues expected of a doctor in modern society: compassion, discernment, trustworthiness, integrity and conscientiousness.¹³

Applying these qualities to our discussion, one can argue that for a doctor or surgeon to be conscientious and compassionate they must consider their patients’ needs and respect the views they may have towards their healthcare. The doctors should take the time to discuss with the patient any objections they may have, including their views on the use of animal-based products. Similarly, the virtue of trust in doctors and the medical profession develops due to the strong emphasis on positive doctor-patient relationships and an expectation that doctors will want to act in their patients’ best interests. This doctor-patient relationship relies on good communication and honesty, so it is reasonable to suggest that patients would expect their doctor to enquire if they have any objections to the use of animal products.

Perspective of Consultants

Whilst it is important to question the moral nature of informing patients about whether their treatment involves the use of animal-derived products, it is also important to understand the perspectives of the people gaining that patient consent in the first place, the ENT surgeons themselves. A recent survey carried out in 2018 and circulated by the organisation ENT UK aimed to identify under what circumstances an ENT consultant would choose to discuss the possibility of using animal-derived products in an intervention with their patient.¹⁴ ENT consultants nationwide subscribed to the ENT UK mailing list received a link to an anonymous online survey that asked a variety of questions about the topic. These questions included the consultant’s exposure and familiarity with the use of equipment that contained animal-derived products, what patient characteristics would prompt them to want to discuss whether any animal-derived products would be used, what characteristics about themselves would prompt them to have this discussion and whether they have changed their surgical plan based on the outcome of these discussions. One hundred consultants completed the survey and the results highlight a number of key issues for debate. The responses showed that less than half of the ENT consultants reported using any equipment, graft or prosthetic that contained animal-derived products, which

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may be a potential explanation for why this issue has not been addressed sooner. Furthermore, of the consultants who did report frequent exposure to the use of equipment containing animal-derived products, 15% stated that a documented religion of the patient was the only factor that would prompt them to discuss the ingredients of any equipment used, and almost all said that they would change their surgical plan based on the results of their discussion.

Whilst a documented religion is clearly an important reason for discussion of such topics, it creates several possibilities for harm. The most apparent is simply where a patient may have religious beliefs that prohibit the use of certain animal products and it is not documented, thus the surgeon would not feel a need to discuss the ingredients, and however it neglects to account for patients who have strongly held views on the use of animal products without a religious association. As discussed earlier it is becoming increasingly more common for individuals to take issue with the use of animal products in any form; these patients may prefer not to have any animal products used in their treatment if given the proper information and choice, which it seems they are currently being denied. This survey highlights an important question regarding patient consent and the use of animal-derived products and that is whether all patients should be told the origin and ingredients of any medical equipment, grafts or prosthetics used so that they can provide proper informed consent.

CONCLUSION

Even though this review has highlighted a need for more discussion required between ENT surgeons and their patients when involving animal-derived products, a major limiting factor preventing this from taking place is due to faults by the manufacturers themselves. From speaking to ENT consultants, it is apparent that it can be very difficult to obtain any information about the biological origin or ingredients of many products due to several factors. Firstly, there is often poor labelling of ingredients on medication or equipment packaging and in supplementary documentation by manufacturers. Therefore, even if a consultant wished to provide any information on animal-derived products to their patient to allow them to make an informed decision, they are not able to do so through no fault of their own. There is a need to lobby manufacturers of medical products to provide more details on the origin or constituents and make it easily accessible for both doctors and patients to obtain. Efforts have been made in the past to encourage manufacturers to develop alternative products that would be suitable for patients opposing animal-based products, however they were frequently limited due to their increased cost and reduced efficacy. Once comment from ENT surgeons highlighted from the ENT UK survey was, a concern that having to inform every patient about the ingredients of all medicine and grafts used in a procedure would be time-consuming and impractical. However, a simple solution to this could be to alter patient advice leaflets for procedures that would involve the use of animal-derived products, so that patients are passively informed in their own time.

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