

REGULATION Animal-derived medicinal products: community representatives' views of their use

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ABSTRACT

In the UK, there are a variety of religious or cultural beliefs and preferences that guide people in a range of lifestyle decisions. This qualitative study aimed to better understand the views of the public around prescribing animal-derived products, in particular low-molecular-weight heparin (LMWH), from a potential patient perspective. A series of quality improvement focus groups with stakeholders were undertaken to understand perceptions and to evaluate and inform an established treatment pathway. Stakeholders discussed finding out about the porcine nature of LMWH asking 'Why don't they tell us?', suggesting that they 'shouldn't have to give out clues' about their personal preferences. Participants thought about 'how' information be provided, by 'whom' and 'when' were gained. The stakeholders indicated that current practice is unacceptable for patients. They require greater knowledge and transparency regarding product components and recommend that healthcare professionals provide more dialogue and choice to patients.

KEYWORDS: stakeholder engagement, PPI, heparin, qualitative, animal derived

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Introduction

In the UK, there are a variety of religious or cultural beliefs and preferences that guide people in a range of lifestyle decisions. These should be taken into consideration when providing healthcare services. Unless declared incompetent, all adults are considered competent to make decisions about medical treatment. To help patients make informed decisions, healthcare workers provide appropriate and adequate information that helps patients decide whether to accept the recommended treatment.¹

The National Institute for Health and Care Excellence (NICE) recommends venous thromboembolic (VTE) risk assessment in all patients presenting to hospital.² Low-molecular-weight heparin (LMWH), such as enoxaparin (Inhixa®) and unfractionated heparin (UFH), are medication commonly prescribed for the pharmaceutical prophylaxis and treatment of venous thromboembolism (VTE). Both LMWH and UFH are derived from porcine animal products,² and might be unacceptable to those who abstain from the consumption of animal products. A synthetic antithrombotic, fondaparinux (Arixtra®), is available and can be considered as an alternative in many clinical scenarios.

Vegan and vegetarian dietary preferences have increased in popularity, with the number of vegans in the UK quadrupling between 2014 and 2019 to ~600,000, with ~2% of the UK population following a vegetarian diet.^{3,4} However, dietary preference is only one way of acknowledging potential restrictions, with cultural and religious sensitivities also a major consideration. The latest UK Government estimates, taken from the 2021 Census of England & Wales, reported that 6.5% of the population were Muslim, where pork is considered Haram (ie forbidden), 1.7% as Hindu, associated with vegetarianism, and 0.5% Jewish, where pork is not Kosher (ie food that complies with the dietary standards of traditional Jewish law).⁵ Within the food industry, there is widespread acceptance of the disclosure of animal products, and it is commonplace for patients to be asked their dietary preferences for meals when they are in hospital. However currently, there are no legal requirements for pharmaceutical companies to declare animal-derived constituents in medicines.⁶

Drug therapy can be argued to be the most commonly recommended medical treatment. Although some patients refuse medical treatment based on their religious beliefs, most major religions do not prevent their followers from taking medication.^{7–9}

However, medical professionals and patients might not be aware of drugs containing ingredients forbidden to them.

An audit (unpublished data) undertaken in the authors' employing acute hospital Trust, highlighted that most postgraduate doctors were unaware of the porcine content of LMWH (77.0% unaware; 47/61) or the availability of alternatives (44.3%; 27/61). This same audit found that most healthcare professionals (95% (n=41/43) unpublished data) did not routinely consider religious, cultural beliefs or dietary preferences when prescribing medication. Yet, their importance is recognised in the General Medical Council's guidance on personal beliefs and medical practice, which emphasises the importance of taking 'account of spiritual, religious social and cultural factors',¹⁰ and in the Montgomery versus Lanarkshire Health Board ruling,¹¹ about shared decision making having patients discussions at the heart of practice so they (the patients) can make informed decisions about their care.

To date, literature has mainly focussed on the knowledge and acceptability of animal-derived products through surveying doctors or engaging with religious leaders.¹² This qualitative study aimed to better understand the views of the public around prescribing animal-derived products, in particular LMWH, from a potential patient perspective, and seeking their opinions about how we (as clinical professionals) can improve patient experiences when these types of medication are being considered as part of a person's care.

Methods

Study design

A prior consultation with local community representatives suggested that the most meaningful way to improve the discussion and prescription of appropriate LMWH would be to engage with local stakeholders. These representatives were people who represent the population treated within the geographical context of the hospital, for whom this medicinal choice is important. This included religious groups, patient cohorts for whom LMWH is frequently prescribed and also people with dietary restrictions and preferences. The aim of the work was that any change developed would be meaningful to the population served by the hospital and would be sustainable.

The authors held a series of quality improvement (QI) focus groups with stakeholders, to evaluate and inform an established treatment pathway. This work was reviewed and subsequently registered as a service evaluation (NBT Registration number: QI13301) and did not require ethical approval. However, ethical principles and guidelines were followed, and participants were provided with an information sheet and consent forms before their participation.

Setting

The project was undertaken at North Bristol Trust, one of two large hospital Trusts in Bristol, southwest England. It provides community healthcare and hospital services to Bristol, South Gloucestershire and North Somerset, England. It delivers healthcare across Southmead Hospital, Cossham Hospital and the Bristol Centre for Enablement, as well as local communities. Although most of the population is White (71.6%),¹³ all ethnic groups classified by the Office of National Statistics are

represented in the diverse and multicultural population served. For non-planned urgent care, patients are often admitted via the emergency department to the acute medical unit (AMU).

Recruitment

Purposive sampling was used to engage with communities and groups of interest; faith groups where the consumption of animal products is against religious beliefs and individuals/groups who hold lifestyle beliefs, such as vegetarianism and veganism. This was achieved through conversation with trusted community contacts, reaching out via social media channels, encouraged self-identification of groups of interest, and asking individuals and communities to identify other potential groups to approach to be participants.

Data collection

Three 2-h focus group were held, with a total of 17 participants. Groups were facilitated by a clinical member of the study team and a semi-structured topic guide was used (supplementary material S1). Participants were able to join online or in person. Multiple methods were used to collect qualitative data, including Microsoft Teams video recording, an in-room video camera and contemporaneous field notes.

Data analysis

Conventional qualitative content analysis was undertaken by LW and SH.^{14,15} Quotes are presented verbatim.

Results

Participant characteristics

Three focus groups were held between 26 January 2022 and 16 February 2022. In total, 17 people (12 women, five men) took part, with five or six people in each group. In all groups, there was a mix of in-person attendance and those joining via the Microsoft Teams video conferencing platform. Attendees represented a range of ages and nationalities, although demographic details were not specifically recorded. At least two people voluntarily shared they were vegan, as well as several people who were of Muslim or Christian faiths.

Qualitative analysis

Finding out: 'Why don't they tell us?'

During the introduction to the focus group, the issue to be discussed, the porcine content of LMWH, was clearly described. The attendees universally reacted with phrases, such as 'upsetting' and 'worrying', indicating that they were not aware of this before their participation in the group. For some, there was a sense of dismay that information on the origin of medicinal products was not being disclosed, which led to questions such as 'Why don't they tell us?' or 'Don't the pharma companies have to make it clear?'

There was widespread shock at the lack of personal information (eg religion or dietary preference) shared between primary and secondary care, as well as the lack of knowledge among professionals as to the constituents of medications. Analogies were

immediately made to labelling standards in the food industry and how allergies are treated within healthcare.

'but all this type of information is put on menus and food labels, why not on drugs?'

Lack of disclosure, could reinforce the communities' negative beliefs that, because of their religion, ethnicity or language, they were provided substandard care.

'Lots of doctors don't say what it is, when (they) see, (they, the doctor) like to take advantage, experiment on child, that's what it feels like, it is like we just get stuff done to us, without asking (we) don't have a chance to have a choice or to say no, just because they assume they know what's best.' [Sic]

It was widely felt that there would be 'disappointment' if they were not informed of these issues or consent was gained before administration. For some, this extended to 'disrespect' and disregard for their values.

Experiences and impact: 'we shouldn't have to give out clues'

A couple of participants were aware of the porcine content of LMWH before the focus group, but had found out through personal experience after it had been administered. Participants who had been in this situation reported feeling 'guilty' that they had allowed this to happen. They blamed themselves for not volunteering information about their dietary restrictions or taking ownership of their healthcare by checking their medication with the clinicians, suggesting that 'maybe I should have checked that I could have the different medications?'

Being an acute Trust, participants reflected on decision making at times of illness. Although participants reported a desire to be informed, the timing of being given this medical information and the subsequent ability to make decisions were discussed. Participants spoke of a 'vulnerability' that they felt as patients, and that they 'trusted the doctors to act in our best interest'. Finding out that they had not been informed of the nature of LMWH challenged this widely held belief.

Conversely, where participants in the focus group had been in the situation where they were prescribed LMWH and had been informed about the porcine nature of the product, they reported that it improved how they felt they could work with the clinician, because there was the belief that they have 'got patients' interest at heart'.

Communication was an important part of this.

'If get a clinician who doesn't assume something about me, and asks me, (it) instils me with enormous confidence.' [Sic]

Encouragingly, physical, mental and moral wellbeing were seen to be positively impacted if a discussion had taken place and an informed choice given.

'It's about 'mental, moral wellbeing'

A focus of the groups was to explore participants' thoughts about 'how' information should be provided, by 'who' and 'when'.

How

Upon introducing the topic of how best to communicate the porcine nature of LMWH, participants almost universally reported

the belief that their medical records from their general practitioner would easily share this information. They were surprised by the gap between how they believe their medical details and care preferences were stored and used by their general practitioners and acute hospital systems, and the reality.

'Are you telling us that the hospital doesn't have access to our GP records? My GP knows all this stuff about my dietary preference'

Following on from this, participants suggested that it would make sense to have the non-animal derived products as first line, rather than the current practice, and, if not clinically appropriate, a discussion with the patient could occur.

'So, why aren't the vegetarian versions the ones used as standard?'

'If they don't work as well then isn't that when the doctor should talk to us about it and what the different options are?'

Participants felt strongly that everyone (the public) should know about this medication, and that this knowledge could help empower individuals to engage in prescribing conversations with medical teams. However, it was also recognised that this should start in the hospital setting, with participants suggesting that anything developed (eg educational materials) be accessible and inclusive for all, irrespective of age, education or literacy. Audio was popular, as was a preference for verbal over written information.

'The challenge is when do you have the conversation in an emergency, but if it isn't an emergency then the information needs to be available in a range of different ways, but I guess a video in multiple languages might be best, then you can have sub-titles too.' [Sic]

Who

Participants felt that it was the clinician's responsibility to share the information about medical constituents, but that the issue needs to be known by all healthcare professionals and be supported by in-hospital (NHS) policy makers to ensure supportive, effective systems and training.

'Obviously the doctor needs to prescribe the drugs, but if everyone knows about the issue then if I tell a nurse she would know to tell the doctor'

'It sounds like a lot of change needs to happen in the hospital for everyone to know about heparins not being suitable for Muslims. Doesn't that mean a policy needs to change?'

There was recognition that, overall, clinicians are doing the best for their patients in situations where vast amounts of information are required to be known and communicated to patients or their families.

When

Participants were clear that it was difficult for medical staff and patients to make decisions during an acute medical admission. The degree of information sharing and potentially any decisions made were acknowledged to be contextually dependent on the acuity of their illness and whether urgent or lifesaving care was needed.

'If it is lifesaving or an emergency, then I can understand the doctors not asking, but they should raise it as soon as stuff has settled down'

Where there was time, participants were keen for the situation to be discussed with them. There was recognition that there may be times where, because of the physical or emotional impact of illness, making an informed decision would be more difficult and that prior knowledge or advanced plans would be helpful.

Discussion

Qualitative focus groups with stakeholders were held to better understand the views, experiences and impact of prescribing animal-derived products, in particular LMWH, from the perspective of potential patients. Universally, participants in the focus groups were upset or worried about finding out about the porcine nature of LMWH. It was suggested that people 'shouldn't have to give out clues' about their personal preferences. Participants' thoughts about 'how' information be provided, by 'whom' and 'when' were gained.

Despite it being nearly 2 decades since the UK Government's Medicines Taskforce supported work on increasing the knowledge of porcine-derived medication,^{16,17} our work with stakeholders adds weight to the importance of being informed and being given choice.¹⁶ How this is delivered needs consideration, specifically related to the beliefs and choices of individuals, as well as the fundamental concepts of good clinical practice, such as patient-centred care, informed consent and shared decision making.

Patient-centred care must consider identity as part of ethnic, religious, cultural or philosophical contexts, which can be key components in the social constructs of patients. This diversity requires the medical community to be cautious of using collective identity. In choosing interventions that aim to support improvements to equity, especially for minority groups, we must be mindful of taking an overly reductive approach to solutions that use group identity to infer beliefs.

As noted by the participant stakeholders in this study, public understanding of information sharing between healthcare contexts is flawed. Despite attention to the subject literature, there has been slow progress to date, with few shifts in prescribing practice, whether at an individual, organisational or national level.

The current work was driven by a prior consultation with local community stakeholders following their suggestion that the most meaningful way to improve the quality of LMWH prescribing was through talking with potential service users for whom their dietary restrictions would make some LMWH undesirable. The insights gained through involving public engagement have reinforced the value of this type of collaboration. However, despite attention to the subject at hand, there has been slow national progress to date, with few shifts in prescribing practice.¹⁸ The variety of interventions suggested by the participants in this work highlights the importance of looking at approaches to change at individual, societal and environmental levels, and those that align to well-known behavioural change theories.¹⁹ Although behavioural changes in the prescription of LMWH are required of healthcare professionals, the understanding of behavioural drivers, especially with respect to policy measures²⁰ and system restrictions, is also key.

Cultural competence and humility²¹ are likely to be key enablers of widespread practice change; however, we noted minimal discussion related to such. Recognising the nature of debate in society, it is imperative that we support the development in

healthcare of psychologically safe environments that enable us to talk and learn safely, compassionately and curiously about one another, without fear of criticism, judgement or exclusion.

Looking ahead, several issues require further attention. First, the matter of disclosure of the constituents of medication and informed consent. Specifically, where the extent and responsibility of that lies. We noted the varying voices and opinions of our focus group participants as to what might be 'reasonable', whether legally or ethically, with regard to expectations of professional knowledge and extent of responsibility. Heparins are only the tip of the iceberg, and Hassanein and Anderson found that these issues are present across healthcare settings and the problem of animal-derived components within the healthcare sector extends down as far as product materials, such as wound dressings.¹⁰

Improved disclosure is linked to knowledge, which must be supported through increased transparency in product constituents and labelling. Although the nature of active ingredients, such as heparin, must be disclosed, under EU laws there are no current legal requirements for pharmaceutical companies to declare the nature or extraction methods of commonly used excipients (inactive medicinal components), such as gelatine, lactose and magnesium stearate. Information on such is often difficult to obtain, inconsistently reported, unclear or inaccurate.⁶ Where it is known, or clear, labelling regulations forbid the use of terms such as vegetarian on packaging, although active ingredients must be disclosed in product information.

Although the least restrictive solution would simply be to avoid the use of any animal-derived products across the medicinal and healthcare field, current laws applicable in the UK make this more challenging to do in practice because European legislation mandates listing all the contents of medication in often lengthy patient information leaflets accompanying products. However, the origin of the contents is not required to be specified.⁶

There are limitations to the findings presented within this report; as a qualitative project, we do not contend that our data are generalisable, but they are likely to be transferable to both other acute hospital settings and other medicinal products that contain porcine parts. By not formally collecting demographic data on the focus group participants, it is not possible to consider the specific biases that they might bring. However, the range of ethnicities and dietary preferences represented provided balanced discussion, where each participant was facilitated to challenge the status quo with other members' understanding and their own experiences.

The insights gained through the current stakeholder engagement have provided a foundation for building interventions and shaping changes relating to the prescribing of LMWH. The engagement of stakeholders in providing the data undoubtedly makes the findings richer, and more valid to patient cohorts. The suggestions regarding ongoing education and dissemination of the issues around LMWH are also likely to be more sustainable because they come from service users, patients, public and staff. What the present work does not investigate is the gap in healthcare professional knowledge and how to best address this. Patient perspectives, such as those given in the current work, can feed into educational packages to fill this need.

Conclusion

The work presented demonstrates that the current practice of LMWH prescribing is unacceptable for patients. They require greater knowledge and transparency regarding product

components. It might be time for medical labelling to be changed to provide this level of detail.

As we look ahead to a more diverse, equitable society, our collaborations with service users remind us how little we know about the breath of one another's culture, values or beliefs, but that asking is the most important thing. ■

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Supplementary material

Additional supplementary material may be found in the online version of this article at www.rcpjournals.org/content/futurehosp/S1. Semi-structured topic guide used in the study.

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