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Does the current regulation of assisted reproductive techniques in the UK safeguard animal welfare?

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Abstract

Reproductive medicine is one of the fastest-developing fields of veterinary medicine, Regulation of veterinary assisted reproductive technologies (ARTs) is currently divided between the Animals (Scientific Procedures) Act (1986); the Veterinary Surgeons Act 1966, and the Animal Welfare Act (2006). None of those pieces of legislation was purpose designed to protect the welfare of animals undergoing ARTs, either directly or by determining which veterinary ART procedures may or may not be performed. Consequently, due to the lack of reference to such procedures, the welfare protection aims of the legislation are sometimes ambiguous. It is therefore difficult to ascertain whether the aims of the legislation are being fulfilled, but, in the opinion of this author, the legislation is anyway inadequate in scope, most particularly because it fails to provide a reporting function.

It is unclear whether all or any veterinary ART procedures being undertaken on post-natal animals are associated with suffering. Some ARTs may cause discomfort, stress or pain: study or review of the welfare effects of these would be valuable. Any future review of the legislation regulating veterinary ARTs, be that an overall review or a review of one of the relevant statutes (for example the VSA), should take into account the interface between research and clinical medicine; the potentially welfare-compromising gaps between the Acts; the need to introduce reporting functions in order to build an evidence base, and the issue of veterinary specialisation and whether specialised techniques should be carried out only by those with specialist post-graduate qualifications.

Keywords

Assisted reproduction; animal welfare; Veterinary Surgeons Act; Animal Welfare Act; Animals (Scientific Procedures) Act; veterinary specialisation

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Conflict of interest statement

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Introduction

In November 2012, the Farm Animal Welfare Committee (FAWC) published its opinion on the welfare implications of breeding and breeding technologies in commercial livestock agriculture (FAWC, 2012). Though the FAWC noted that the regulation of genetic material has not kept up with advances in biotechnology, it failed to address the broader question of whether the regulation of the entire, fast-developing field of veterinary assisted reproductive technologies (ARTs) is adequately protecting animal welfare. This paper attempts to answer that subject by assessing first what the current regulation of ARTs aims to do to protect animal welfare and whether those aims are fulfilled, and secondly whether, even if the aims of current regulation are being fulfilled, they are adequate to protect animal welfare in the twenty first century.

Assisted reproduction is the most tightly regulated area of human medicine, being governed by primary legislation in the form of the Human Embryology Act (1990, as amended) and by a statutory body (the Human Fertilisation and Embryology Authority). The underlying reason for the extraordinary level of regulation of assisted reproduction in human medicine is concern that the techniques which are being used potentially affect not only the individuals demanding treatment but also other potential and existing individuals, and society as a whole. Veterinary assisted reproduction is regulated much less tightly than human assisted reproduction, but at a level which is more consistent both with all other human medical specialities and with all areas of veterinary medicine. The purpose of this paper is not to argue that assisted veterinary reproduction deserves special regulatory consideration. Creation of human:animal admixed embryos does require special regulatory consideration, because of the impact which it has on society and on very essential moral questions such as what qualifies a being to be considered human. However, that it already provided for in the HFE Act (2008, as amended). Rather, I hope to show that current regulation of ARTs fails to protect animal welfare adequately, and that the reasons for that failure are not particular to assisted reproduction but are rather associated with a more general lack of safeguards relating to , training, specialisation and the legal framework of veterinary regulation, which apply also to and ought also to be considered in relation to other veterinary specialities.

There are three main areas of concern about animal welfare and the regulation of veterinary assisted reproductive technologies. The first is the technologies themselves. Protection of animals being used for and produced by ARTs, and indeed protection of veterinary surgeons undertaking ART procedures and of fee-payers commissioning those procedures, can only be achieved if we understand the welfare implications, efficacy and safety of veterinary ARTs. Such understanding is crucial to the protection against unnecessary suffering afforded by the Animal Welfare Act (2006), and yet is currently lacking, in part due to the failure of the current legislation to provide a reporting function. The second area of concern relates to the regulation of persons undertaking ARTs, since protection of animal welfare is dependent not only upon the potential for pain and distress inherent in ARTs themselves, but also upon the competence of personnel performing ART procedures. Animal welfare could be compromised by features of the current regulation which allow non-veterinarians to undertake certain ART procedures without supervision, and veterinarians to undertake all

ART procedures without post-graduate training. The third concern is that protection of animal welfare provided by current regulation of veterinary assisted reproductive technologies is not as good as it should be because the regulation is not coherent: the division of regulation between three statutes results in a dilution of welfare standards and a lack of clarity about which enforcement regime applies in some cases, which compromises animal welfare.

This paper considers only mammalian animals (which are the species most commonly dealt with by veterinarians in Practice), and does not consider fish or birds.

What protection for animal welfare does current regulation of veterinary ARTs in the UK aim to provide?

The welfare of animals undergoing ARTS is protected by a combination of regulation of ART procedures and regulation of those performing ART procedures. Unlike regulation of human ARTs (which falls under the Human Embryology and Fertility (HFE) Act (1990, amended in 2008) regardless of the purpose for which the ART is being undertaken), the legislation regulating veterinary ARTs differs according to whether the ART is being undertaken for research or clinical purposes. Experimental ARTs (i.e. those which are not part of 'recognised veterinary practice'¹) are licensed under the Animals (Scientific Procedures) Act (A(SP)A) (1986), as amended. Clinical ARTs are regulated by a combination of the Veterinary Surgeons Act (1966) (VSA) and the Animal Welfare Act (2006) (AWA)². The VSA applies to England, Scotland, Wales and Northern Ireland, as does the A(SP)A³. The AWA extends to England and Wales only, with some parts applicable in Scotland and Northern Ireland⁴.

Regulation of procedures and direct protection of animals

No legislation exists which is purpose-designed either to determine which veterinary ART procedures may or may not be performed, or to protect animals undergoing ARTs. Protection of animal welfare by regulation of procedures and by direct protection of animals being used for or produced by ARTs is therefore provided by legislation which is general rather than specific in its application. Thus research ARTs are governed by general research regulation provided by the A(SP)A, which provides both for prospective assessments of harms to animals (s) via the project license system (s5) and for retrospective reporting on a project (s5(f)) and on the severity of actual harms which did occur to animals (s21a). The aim of the A(SP)A in affording protection to animals relating to ARTs is limited by section (1b(2)), which excludes embryos/foetuses in the first two thirds of gestation. The A(SP)A does protect post-natal animals having ARTs performed on them and also places some

¹See paragraph 1(g) Part 1G of the Guide to Professional Conduct; Annex B to the Guide to Professional Conduct (A(SP)A and VSA interface) and RCVS Advice Notes 9 (joint RCVS and Home Office advice on A(SP)A interface) and 12 (the use of new technology tests).

²The AWA (2006) was preceded by the Protection of Animals Act (1911). For a historical perspective on the development of animal welfare legislation in Britain and discussion of the related case law see Radford, M (2001) *Animal Welfare Law in Britain: Regulation and Responsibility* Oxford University Press, Oxford. Section B and Appendix 2.

³The A(SP)A contains enactments relating to pre-existing legislation in Scotland and Northern Ireland.

⁴E.g. ss 67(1-3) and s48(12). There is an Animal Health and Welfare Act (Scotland) (2006) and a Welfare of Animals Act (Northern Ireland) 2011.

restrictions on ARTs being performed if the result of the ART is likely to be the birth of an animal which will experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice (s2c(1)). The premises on which A(SP)A-regulated procedures are undertaken have to be licensed and regulated (s2) and there is a requirement (s2c(5a-b)) for ‘a person to be responsible for overseeing the welfare and care of the animals kept at the place specified in the licence and (b) a veterinary surgeon with expertise in laboratory animal medicine, or other suitably qualified person, to provide advice on the welfare and treatment of those animals. 2012 amendments to the A(SP)A (1986) make breeding of an animal a regulated procedure if the animal is bred or descended from an animal which has been genetically modified, has been allowed to live past the stage of gestation at which it becomes a protected animal, and is likely to experience pain, suffering, distress of lasting harm as a result of the original genetic modification (s3b(a-c)).

The regulation of clinical ART procedures, like the regulation of research ARTs, is non-specific, and is covered by a combination of the VSA and the AWA. The aims of the VSA in affording protection to animals involved in ART procedures are difficult to determine since they are implicit rather than explicit. ART procedures are not mentioned directly in the VSA, but are covered by the definition of veterinary surgery in s27(1): ‘the art and science of veterinary surgery and medicine...shall be taken to include (c) the medical or surgical treatment of animals and (d) the performance of surgical operations on animals’. The VSA contains no definition of which clinical veterinary ARTs are permitted or prohibited. ‘Animals’ are defined as including birds and reptiles (s27), but is unclear whether ‘animals’ is meant to include foetuses/embryos, or only animals after birth. No mention is made of gestational age. There is an equal lack of definition of gestational age in the Federation of Veterinarians of Europe’s ‘Veterinary Act’ (2009), s8.

The aims of the AWA in providing protection for animals involved in ART procedures are explicitly limited by the fact that the AWA does not apply ‘to an animal ...in its foetal or embryonic form’ (s(1)(2))⁵. The AWA does, however, aim to protect animals against ‘unnecessary suffering’ (s4(1-2)). This affords protection to animals undergoing clinical ART procedures and presumably (like the A(SP)A) could also include an animal suffering after birth as a result of an ART which created it.

Protection of animal welfare via the regulation of persons undertaking ART procedures

The competence of those undertaking ARTs is an important factor in protecting the welfare of animals having ARTs performed on them. Regulation of such competence depends upon whether the procedures are for research or clinical purposes. Persons undertaking research ART procedures are regulated by the general terms of the A(SP)A, which requires that only procedures specified in project licenses be carried out, and then only by someone holding a personal licence which permits them to carry out specific procedures on specific animals

⁵s16(3) of the Animal Health and Welfare Act (Scotland) (2006) gives Ministers power ‘...to extend the application of such provisions...to an animal from such earlier stage of its development’ if science proves that ‘creatures of the kind concerned are capable of experiencing pain or suffering’. The Welfare of Animals Act (Northern Ireland) 2011 excludes “foetal or embryonic form(s)” (s1(2)).

(s3-4). Regulation of who may legally perform clinical ARTs falls under the VSA. Such persons are veterinarians admitted to the Royal College of Veterinary Surgeons (RCVS) (s3-8), and doctors who perform operations on animals either to benefit humans or at the behest of a registered veterinarian (s19(4)). S19(4)(e) of the VSA allows ministers to permit non-veterinarians to undertake ‘any minor treatment, test or operation specified in an order made by the Ministers’. This power has created ‘exemption orders’ which allow non-veterinarians to undertake specified procedures. The ARTs covered by an exemption order (The Veterinary Surgery (Artificial Insemination) Order 2010) are artificial insemination (AI) in cattle and in mares⁶.

Does the current regulation of veterinary ARTs in the UK fulfil its aims in terms of protecting animal welfare?

The aims of the A(SP)A, the VSA and the AWA differ, and it is therefore easiest to consider each Act separately when assessing whether the current legislation fulfils its own aims for protecting animal welfare.

Regulation of research ARTs

The aims of the A(SP)A are to regulate any procedure which may cause a protected animal or embryo/foetus of more than two thirds of its gestation or incubation period ‘pain, suffering, distress or lasting harm’ (s2c(1)), and to allow such procedures only where the perceived benefits outweigh the animal welfare costs (House of Lords, 2002). There have been no prosecutions under the Protection of Animals Act (1911), the AWA (2006) or under A(SP)A (1986) relating to animals which were harmed whilst the subject of an A(SP)A license involving ARTs (Dolan, 2007). This might suggest that the A(SP)A is achieving its objectives of regulating procedures and protecting animals, or that non-compliance is being dealt with via the mechanism of compliance notices and revocation of licences (A(SP)A s11) rather than by prosecution.

It is also possible that ARTs are being performed which ought to be licensed under the A(SP)A but are instead being undertaken as unlicensed, clinical procedures. The A(SP)A may not be doing what it aims to do simply because those performing experimental ARTs are not applying for an A(SP)A licence, thus leaving the animals involved unprotected. Theoretically, any ART which is not ‘accepted clinical practice’ is by default experimental (FAWC, 2004), and thus regulated by A(SP)A. Only once a technique is accepted clinical practice is it regulated by the VSA. However, recent discussions about prosthetic limbs in animals (Harvey 2010) have demonstrated the potential for a veterinarian to successfully argue that a procedure (even if novel) is clinical rather than experimental, particularly if it is already clinical practice overseas (FAWC, 2004). The protection afforded to an animal by A(SP)A (under which a procedure likely to cause “pain, suffering, distress or lasting harm” (s2c(1)) can only be undertaken if the benefits are deemed to outweigh the animal welfare

⁶The Veterinary Surgery (Epidural Anaesthesia of Bovines) Order 2010 and the Veterinary Surgery (Rectal Ultrasound Scanning of Bovines) Order 2010 and are also relevant to the practice of veterinary ARTs. The former permits people who are not veterinary surgeons to administer epidural anaesthesia to bovines for the purpose of embryo collection or transfer, and the latter permits non-veterinarians to undertake per-rectum ultrasound scanning of cows for the purposes of pregnancy detection.

costs) is greater than that afforded by the VSA (which ensures simply that the procedure is undertaken by a MRCVS to a sufficiently proficient standard to make the procedure 'efficient' (s5:1)). Animals being used for scientific procedures are thus likely to be afforded greater protection than those being used for other purposes. Consequently, if an ART is undertaken under the VSA when in fact the procedure is such that it should qualify as a scientific procedure and be regulated by the A(SP)A, the animals involved are being afforded less protection than they arguably should be. This is not a failure of either piece of legislation *per se*, but rather a reflection of the blurring of the boundaries between research and clinical practice, which allows for the possibility that veterinarians may use an "accepted practice" argument to justify the importation and application of commercially developed techniques, the welfare implications of which have not been assessed by regulation of the procedure under A(SP)A (FAWC, 2004). The potential for animal welfare to be compromised by veterinary procedures falling between the two Acts is not unique to ARTs, and how best to regulate the clinical practice/research interface should be considered as part of any future legislative review of the VSA.

Regulation of clinical ARTs

Because there is no specific legislation relating to veterinary clinical ARTs, what the legislation says it will do to protect animal welfare is a matter either of omission or of interpretation. I shall consider what the legislation says it will do and whether it does so in relation (a) to embryos and fetuses and (b) to post-natal animals undergoing clinical ARTs.

(a) Does current regulation of veterinary clinical ARTs fulfil its own aims in terms of protecting the welfare of embryos and fetuses?

(i) The Animal Welfare Act: The AWA excludes embryos and fetuses from its provision (s(1)(2)) and thus does not aim to protect the welfare of embryos and fetuses.

(ii) The Veterinary Surgeons Act: Any protection conferred upon an animal at any stage of life by the VSA is indirect, rather than a direct aim of the statute, since the primary aim of the Act is to limit the right to provide veterinary medical and surgical treatment, diagnosis and advice (s27(1)) to those registered with the RCVS (s19(1)), and to ensure that such individuals practice to an 'efficient' standard (s5(1)). Whether the limitations on who can practice veterinary medicine and the regulation of an 'efficient' standard are meant to apply to embryos or fetuses is unclear, because the omission of any mention of embryos or fetuses in the VSA could be interpreted either as an assumption that they *are* or *are not* included in the definition of 'animals' in s27(1). Such an interpretation has not to date been tested in Law.

In human medicine, the protection afforded to embryos by the HFE Act applies to embryos only in so far as they exist *outside of the body*. The VSA says no more about embryos/fetuses outside of the body than it does about them inside the body. The implication of this omission may be that it is perfectly legal for veterinarians and non-veterinarians to create animal embryos *in-vitro* and treat them as they wish providing that the embryos remain outside an animal body. It seems unlikely that this was what those who drafted the VSA intended. However, for such actions to contravene the VSA the definition of 'animal' in the

Act would have to include embryos/foetuses *themselves*, outside of an animal body. If it does not, the VSA does not limit ‘treatment’ of embryos and foetuses to MRCVSs, and thus the VSA is not failing in an intended aim of preventing non-veterinarians creating and manipulating embryos outside of the body, but rather never aimed to do so (either deliberately or, more likely, because such possibilities were not considered in 1966).

Until such time that a legal test of definition of ‘animal’ in s27(1) of the VSA defines whether or not ‘animal’ is meant to include an embryo or foetus, it is impossible to be sure whether the aim of the VSA was to restrict ‘treatment’ of those pre-natal forms to MRCVSs. Until the aim of the VSA in this respect is clarified, it is difficult to know whether or not the VSA is fulfilling its aim. Were a complaint made to the RCVS about veterinary mistreatment of an animal embryo/foetus, it is unlikely that the veterinarian would be found guilty of serious professional misconduct unless the procedure was not normal veterinary practice and had no peer support. Any complaint against a non-veterinarian for harming an animal embryo would be outside the jurisdiction of the RCVS, and it is hard to see how such a complaint would be otherwise pursued since the AWA does not apply to embryos.

(b) Does current regulation fulfil its own aims in terms of protecting the welfare of post-natal animals undergoing veterinary clinical ARTs?

(i) The Animal Welfare Act: The AWA aims to protect animals against ‘unnecessary suffering’ (s4(1-2)). Presumably (like the A(SP)A) this could include an animal suffering after birth as a result of an ART which created it. Since its enactment in 2006, there have been no prosecutions under the AWA for causing unnecessary suffering by undertaking an ART on an animal. This absence of prosecutions could reflect the fact either that there is no suffering associated with veterinary ARTs; or that there is no *unnecessary* suffering associated with the clinical practice of veterinary ARTs, or that the AWA is simply failing to protect the welfare of animals involved in ARTs.

Do veterinary ART procedures cause suffering?: Suffering in animals involves negative mental states such as pain, fear, frustration, anxiety and nausea. Whether a veterinary procedure is causing suffering may be assessed based on clinical observations or measurements of adverse effects (for example bleeding; infection; wound break-down) and by observational assessment of recognised species-specific behavioural changes which are indicative of pain (Prunier, et al., 2013). Though there are reports of embryo transfer causing pain in rats (Krueger and Fujiwara, 2008) and mice (Jirkof, et al., 2013), there are no peer-reviewed papers in the literature assessing the negative mental and physical effects (if any) associated with different ARTs in mammalian species. Personal experience suggests that some ARTs, such as transcervical insemination in mares which are used to being handling and restrained, are associated with negligible stress, discomfort or pain (if any), whereas other procedures, such as ovum recovery using ultrasound-guided transvaginal needle aspiration in mares, are associated with behavioural changes indicative of discomfort. This is consistent with reports in the literature of pain associated with oocyte retrieval and embryo transfer in women (Emanuel, 2013, Vlahos, et al., 2009). The use of sedation and local anaesthetics can ameliorate such problems, but application of such medications can itself cause temporary pain. There is a lack of evidence on which to base a judgement about

whether or not the majority of veterinary ARTs do in fact cause stress, discomfort and/or pain, and further research is required to explain whether either a true or a perceived lack of suffering associated with veterinary ARTs is one explanation for the lack of prosecutions under the AWA for welfare problems related to ARTs. Ovum recovery using ultrasound-guided transvaginal needle aspiration in mares is not currently a commonly used clinical technique in the UK, and is unlikely to become so since it requires not only expertise but also (which is more likely to act as disincentive in Practice) highly specialised and expensive equipment, and the clinical indications for its use are few. However, the two examples of transcervical artificial insemination and ovum recovery using ultrasound-guided transvaginal needle aspiration in mares are used here as two examples to illustrate the dearth of knowledge about potential discomfort or pain associated with veterinary ARTs, be they fairly basic or very advanced.

Do veterinary ART procedures cause unnecessary suffering?: Suppose for the sake of argument that at least some veterinary ART procedures can cause suffering. If that is indeed the case, could the lack of prosecutions under the animal welfare act for welfare problems resulting from ART procedures reflect the fact that such suffering is necessary / not unnecessary? Section 4(3) of the AWA defines ‘unnecessary’ dependent upon whether the suffering could have been avoided or reduced, was in compliance with relevant legislation, or was for a defined legitimate purpose. In relation to some veterinary ARTs, particularly where the science is not yet perfected, this definition can be difficult to apply. Take, for example, reproductive cloning⁷: if a surrogate dam suffered from dystocia caused by foetal oversize (a recognised side-effect in some species), would that be unnecessary suffering (because it was predictable and there are methods of reproduction other than reproductive cloning), or would it be necessary (because reproductive cloning is the only way of reproducing an individual almost identically, and the state of the science is such that it is impossible to avoid occasional foetal oversize)? Arguably, any suffering associated with veterinary ARTs is by definition unnecessary under section 4.3 of the AWA because it could always be avoided by simply not undertaking the ART procedure. That being so, can ARTs ever be justified if there is suffering associated with them? Under Section 4(3)(c) of the AWA suffering can be justified as being ‘necessary’ if it is for a “*legitimate purpose, such as*

- (i) the purpose of benefiting the animal, or
- (ii) the purpose of protecting a person, property or another animal”

This is particularly interesting in relation to ARTs because arguably no ART is ever undertaken for the benefit of the animal on whom it is performed. ARTs are frequently undertaken for the economic benefit of the owner or breeder of the animal; one might make an argument that a healthy animal born successfully as the result of an ART benefited from being alive, and in examples involving endangered species there might be some benefit in terms of preserving biodiversity. However it is difficult to think of any benefit to the animal itself in having procedures such as artificial insemination, embryo transfer and oocyte

⁷Reproductive cloning is being offered as a clinical service in the USA and within Europe. The author is not aware of any veterinarian currently undertaking reproductive cloning for clinical purposes in the UK.

recovery performed on them, other than an argument that those animals which actually give birth as the result of an ART might derive pleasure from interacting with their offspring (if they are allowed to). That seems a weak argument since we are unable to prove whether an animal would consider such an interaction a fair trade-off for having had to endure the ART at the outset, and anyway many of the animals who are having ARTs performed on them repeatedly, for example embryo donor mares, are undergoing the procedures exactly to avoid them ever giving birth to and raising their own offspring.

Could it be argued that suffering associated with ARTs is ‘necessary’ because it is ‘*protecting a person, property or another animal*’ (AWA Sec 4.3 (c)(ii))? Unless ‘property’ is meant to include protecting a person’s financial or commercial interest, or unless there is some direct protection conferred on the owner’s animal property as the result of having the ART performed on it, it is hard to see how suffering associated with ARTs could be justified on the grounds of protecting property. An argument could be made that suffering associated with veterinary ARTs is ‘necessary’ to protect a person if veterinary ARTs were being undertaken to provide a medical benefit to humans. To revert to the extreme example of reproductive cloning, whilst the use of this ART simply to re-create a competition animal for financial gain could not be justified under the AWA s4(3), if the reason for cloning was to produce heart valves from transgenic pigs for human transplantation an argument could be made that the suffering was ‘necessary’ because its function was to ‘protect a person’ (assuming that life-saving surgery falls within the meaning of ‘protect’). This argument depends upon the assumption that xenotransplantation is beneficial to the recipient and other humans, which is not clear-cut (Fovargue 2007; Fovargue and Ost 2010) In individual cases, it might be possible to argue that any suffering associated with an ART procedure in one animal was ‘necessary’ because it conferred a benefit upon another animal – for example if one animal underwent an embryo transfer procedure and acted as an embryo recipient in order to avoid a donor animal with a condition which would prevent her carrying a foetus successfully to term herself being endangered by the pregnancy. However, the validity of such arguments as a justification for suffering being ‘necessary’ under the AWA is undermined by the argument that such suffering (for either animal) could be avoided entirely by simply not requiring the donor animal to reproduce.

It seems, therefore, hard to argue for the majority of ART procedures that any suffering associated with veterinary ARTs could be defined as ‘necessary’ under the AWA since (a) such suffering could usually be avoided by not undertaking the ART procedure at all (b) the suffering would not be associated with any benefit to the animal who suffered and (c) for the majority of examples (though not all) there is no convincing argument that the procedure is being undertaken to protect ‘*a person, property or another animal*’ (Sec 4.3(c)).

Is the AWA simply failing to fulfil its aim of protecting animals undergoing ART procedures against unnecessary suffering?: If, for the sake of argument, we suppose that at least some ARTs are associated with suffering, and if, as argued above, in the majority of examples any suffering which might be associated with ART procedures cannot be considered necessary under the AWA (Sec 4), then does the lack of prosecutions for animal welfare problems involving ARTs reflect the fact that the AWA is simply failing in its aim of protecting animals against unnecessary suffering?

One possible explanation for the lack of prosecutions (never mind successful prosecutions) is not so much that the AWA is failing as that it is not being made use of in relation to ARTs, for reasons revolving around prosecution criteria. The majority of ARTs being performed on animals, and certainly the more invasive ARTs such as ovum pick up and electro-ejaculation of male animals, are being performed by veterinary surgeons working under the VSA. For that reason, such ART procedures may not be being considered by those organisations (such as the animal charities) which usually instigate prosecutions under the AWA. If the AWA is not being used in relation to ARTs then whether or not current legislation as a whole is succeeding in its aims of protecting the welfare of animals undergoing ARTs is heavily dependent on the aims of the VSA, and whether they are fulfilled.

(ii) The Veterinary Surgeons Act: The aims of the VSA are to ensure that no-one other than a MRCVS undertakes ARTs which are acts of veterinary surgery ((s27(1); s(19(1)), and that the performance of ARTs by MRCVSs is to an 'efficient' standard (s5(1)). No guidance is offered in the Act on what 'efficient' means. The mechanism by which the VSA aims to protect animal welfare, including the welfare of animals undergoing ARTs, is thus an indirect one. Such aims of the VSA should be achieved for ARTs (as for all acts of veterinary surgery) by dealing with complaints about such procedures via the RCVS's professional conduct department. However, the function of the VSA has been compromised in recent years by the mechanism of 'exemption orders' (Veterinary Surgery [Artificial Insemination] Order 2010),, which allow non-MRCVSs to perform specified ARTs and ART-related procedures, and in so doing establishes a group of people who operate outside of the jurisdiction of the RCVS (FAWC, 2004), and to whom the VSA does not apply should they operate to an unacceptable standard. The regulatory control of the standard of competence of persons undertaking artificial insemination of cows and mares was further weakened in 2010 by the government's decision that it was necessary in order to comply with Directive 2006/123/EC and the Provision of Services Regulations 2009 to drop the requirement for persons undertaking such activities to undertake a Defra-approved training course, pass an exam and be licensed in the UK. Since 2010, the definition of "approved course" in the exemption orders relating to artificial insemination, bovine epidurals and rectal ultrasound scanning of bovines enables persons who have undertaken training courses in other EEA States which would permit them in those states to undertake the procedure to work under the relevant exemption order in the UK. There is no regulatory mechanism for controlling the equivalence of UK and EEA State courses, nor for objectively ascertaining the competence of those who have undertaken an EEA course. Because Defra ceased to keep a central register in 2010 the number of equine "Artificial insemination technicians" in the UK is not known. The number who have trained in the UK is probably approximately 1000 and the likelihood is that fewer than 50% of those regularly undertake inseminations (Richard Matson, personal communication). The number of 'technicians' practicing AI in cattle is similarly not known (personal communication, British Cattle Veterinary Association).

Persons undertaking acts of veterinary surgery who are not registered with the RCVS and not working under an exemption order can be prosecuted as a criminal offence under the VSA, usually at the instigation of the police, or of the RCVS working with the police. See,

for example, <http://www.southportvisiter.co.uk/southport-news/southport-southport-news/2009/11/20/whistleblower-how-i-exposed-southport-fraud-vet-russell-lewis-oakes-101022-25209814/>. However, a complaint of substandard practice made against someone performing an ART under an exemption order could be pursued only either under the AWA (in which case ‘unnecessary suffering’ rather than ‘acceptable standard’ would have to be proven) or under the Supply of Goods and Services Act (1982) if the local Trading Standards Authority believed that section 13, which states that ‘*where the supplier is acting in the course of a business, there is an implied term that the supplier will carry out the service with reasonable care and skill.*’ had been breached by sub-standard practice. There are no examples of prosecutions relating to artificial insemination of mares or cattle under the Supply and Goods Act (1982). Under the AWA, non-veterinarians undertaking ARTs under exemption orders could be prosecuted if they could be shown to have caused ‘unnecessary suffering’ as the result of incompetence in procedures not normally associated with suffering. This re-emphasises the importance of an evidence base to establish whether ARTs are usually associated with suffering even when practiced to an ‘efficient’ standard (discussed above), and also highlights the issue of whether those who typically instigate prosecutions under the AWA consider ART procedures as part of their remit. The experience of the British Equine Veterinary Association (BEVA) and the British Cattle Veterinary Association (BCVA) is that although members of the public do complain to veterinary professional bodies about substandard practice by non-veterinarians, they are usually unwilling to pursue such complaints through the courts (David Mountford, CEO BEVA, personal communication 2012; J Fishwick, Past-President BCVA, personal communication 2012). This suggests that the lack of case law on unnecessary suffering being caused by ARTs being undertaken to an insufficient standard by non-MRCVSs reflects unwillingness by the public and by Defra to pursue such cases, rather than the fact that no substandard practice occurs.

Even if organisations such as Defra, the Trading Standards Authority and the animal charities were prepared to instigate prosecutions against non-veterinarians who were practicing ARTs to a standard low enough to cause suffering which could be shown to be unnecessary⁸, the fact that there is no requirement under the exemption orders to the VSA for non-veterinarians to be supervised by a veterinarian or by anyone else makes it unlikely that evidence of substandard practice would be easily acquired unless the animal owner themselves reported the non-veterinarian to a relevant organisation with the aim of instigating a prosecution. Given that the animal owner might feel embarrassed about having employed a sub-standard person to inseminate their animal, and particularly given that the animal owner could potentially also be held liable for allowing unnecessary suffering to occur to the animal as a result of having instructed the person to undertake an ART on the animal (AWA Sec 2(a-b)⁹), such reports are not likely to be frequent.

⁸Veterinary surgeons who practiced to an unacceptable standard which caused unnecessary suffering *could* be prosecuted under the AWA, but the more usual recourse would be for a complaint to be made to the RCVS under the VSA.

⁹AWA (Sec 2) A person commits an offence if—

- (a) he is responsible for an animal,
- (b) an act, or failure to act, of another person causes the animal to suffer.

The current regulation is failing in its aims (limited as they are) of protecting the welfare of animals undergoing ARTs because of a lack of evidence relating to whether ARTs are associated with suffering which makes interpretation of the AWA problematic; because exemption orders cause the VSA to fail in its purpose of ensuring that ARTs are only undertaken by MRCVSs working to an acceptable standard, and because the fact that regulation is divided between the A(SP)A, the AWA and the VSA creates confusion about which Act is applicable and where the responsibility for prosecution and enforcement lies.

Is the current regulation of veterinary ARTs adequate to protect animal welfare?

No legislation exists which was purpose-designed to regulate veterinary ARTs, and two of the non-specific pieces of legislation which currently perform this function (the VSA and the A(SP)A) pre-date the development of many technologies which are now commonly used in veterinary reproductive medicine practice. This section of the paper asks whether, putting aside the failures identified in the previous section and even if it was working as it was meant to when it was enacted, the current regulation of ARTs is adequate to protect animal welfare in the twenty-first century? This question will be answered with reference to the protection of animal welfare provided by regulation of ART procedures; regulation which directly protects animals involved in ART procedures; the regulation of persons performing ART procedures, and the scope of the current regulation.

Is the current regulation of ART procedures adequate to protect animal welfare?

There is no legal or regulatory specification of which veterinary ARTs may or may not be undertaken, in either a clinical or a research context. This is in striking contrast to the regulation of ARTs in human medicine, where the 1990 HFE Act specifies prohibited practices on embryos and gametes (Sec 3), and where no research or clinical ART procedure may be legally undertaken unless it is the subject of a Human Fertilisation and Embryology Authority license (Sec 4). Whilst it might be that the protection of animal welfare would be enhanced by a regulatory specification of permitted and prohibited ARTs based on a cost/benefit analysis of individual techniques, such a system falls outside the scope of the current VSA, and would probably require new primary legislation. It would also impose on the field of veterinary reproductive medicine a regulatory burden in excess of that imposed upon any other branch of veterinary medicine or surgery. This could only be justified on animal welfare grounds if ARTs presented a significantly greater threat to animal welfare than did other types of veterinary medicine and surgery. Unless that could be proven, it is hard to make a welfare-based argument for ARTs being the subject of more precisely formulated and draconian regulation than, for example, complex orthopaedic surgery or oncological treatments.

Is the current direct protection of animals involved in ARTs adequate to protect their welfare?

Current regulation provides either no or very limited protection to animal embryos and foetuses (see above). Should the regulation therefore be updated to provide better welfare protection for these animal forms? In the human HFE Act, such protection as is provided for

embryos derives from the notion that a human embryo is somehow worthy of moral ‘respect’ (House of Commons 2005). Animal welfare legislation is generally based not in concepts of the moral worth of animals, but in concepts of pain, disease, and the avoidance of ‘unnecessary suffering’ (AWA s4(1-2)). In the clinical context, the failure of the combined legislation and regulation to provide protection for animal embryos and fetuses would only matter in welfare terms if unnecessary suffering was occurring as a result of that failure. In humans, a 2010 review by the Royal College of Obstetricians and Gynaecologists into foetal awareness (<http://www.rcog.org.uk/fetal-awareness-review-research-and-recommendations-practice>) concluded that it was difficult to extrapolate and apply the findings of work on neonatal pain (Derbyshire and Fitzgerald 2010) to fetuses because, though nervous connections from the periphery to the central cortex are present from 24 weeks of development onwards, fetuses remain in a “continuous sleep-like (state of) unconsciousness or sedation” and are therefore unlikely to perceive pain. Research suggests that foetal or embryonic animal forms do not feel pain, distress, or suffer (Mellor and Diesch 2006; Mellor 2010). If this is indeed the case, the (non-existent or limited) protection of animal embryos and fetuses provided by the current regulation is adequate in welfare terms, and there is no need to revise the regulation to create specific protection for pre-natal animal forms. Whether animal embryos and fetuses should be afforded moral respect, independent of welfare considerations, is a separate issue which is outside the scope of this paper.

Is the regulation of persons undertaking ARTs adequate to protect animal welfare?

As discussed above, the existence of ‘exemption orders’ in their current form represents a threat to animal welfare because it allows non-veterinarians with poorly specified and controlled qualifications to undertake ARTs unsupervised and without regulatory oversight by a professional body. This issue could be addressed by revoking the exemption orders and re-instating all ARTs as acts of veterinary surgery, so that the standard of those practicing them was consequently regulated under the VSA by the RCVS. However, such action is unlikely in the current political climate of deregulation (Liddon et al., 2011; Lowe, 2009) and also perhaps because such revocation would seem to contravene EU Directive 2006/123/EC, which provides for free movement of services between member states. Alternatives which would adequately protect animal welfare by safeguarding the clinical standard of those practicing veterinary ARTs under exemption orders are either for Defra or Trading Standards to prosecute cases of sub-standard practice under the AWA (again unlikely in the current economic climate), or for non-veterinarians to voluntarily submit themselves to regulation by the RCVS. Since the VSA does not confer such a function upon the RCVS, this would probably require amendment of the VSA. The problem of the RCVS apparently being unable to regulate non-veterinary surgeons is not unique to the practice of ARTs – it exists also, for example, for musculoskeletal ‘paraprofessionals’ working under the Veterinary Surgery (Exemptions) Order 1962. Although a key difference is that non-veterinarians working under this exemption order (unlike those working under the 2010 artificial insemination exemption order) are meant only to work under the direction of a veterinary surgeon who has previously examined the horse and made a diagnosis. It may be that the type of solution currently being sought by some musculoskeletal ‘paraprofessionals’ of establishing and maintaining a voluntary list of those practitioners who fulfil certain

training and qualification criteria (see, for example, <http://www.beva.org.uk/useful-info/Directories/Musculo-Skeletal-Paras>) could also be adopted by non-veterinarians undertaken ARTs. Such a system should improve animal welfare by at least allowing animal owners to more easily distinguish between those who they may wish to treat their animals, based on qualification. However, the impact on animal welfare of any voluntary system will necessary be limited if that system lacks a regulatory body and a disciplinary process which provides a mechanism from banning those who practice to an insufficient standard from continuing.

Even where ARTs are being undertaken by a MRCVS rather than by a non-veterinarian working under an exemption order, the welfare of the animal(s) involved is dependent upon clinical competence (as it is for any clinical procedure), which the VSA aims to ensure (s5:1). However, there are currently no formal mechanisms of reviewing efficacy or welfare impact of such practice (FAWC, 2004), and indeed 'efficient' is not defined in the VSA. The issue of the need to ensure clinical competence is one which occurs at all levels of veterinary practice and which has been reflected in the RCVS' increased emphasis on 'Continued Professional Development' and the introduction of a compulsory 'Professional Development Phase' (see <http://www.rcvs.org.uk/education/professional-development-phase-pdp>) In the absence of a register of procedures performed or of those undertaking such procedures, the number of animals being subjected to ART procedures in the UK is unclear. The more technically difficult the procedure, the less often it is likely to be performed. Thus personal experience suggests that embryo transfer as a method of breeding horses remains uncommon, and equine ovum pick-up very rare (possibly not used at all for clinical purposes) in the UK. Similarly, whilst about 2/3rds of British dairy cows and 10% of beef cows are bred by AI, the number of cows being bred by embryo transfer is probably less than 2% of the national herd per annum, and the number undergoing ovum pick-up significantly lower than that (A Taylor, personal communication). Whilst it is true that some procedures routinely performed in veterinary practice - such as ovariohysterectomy and castration - probably have greater potential to cause suffering than some very technical, advanced ART procedures, it is also true that overall animal welfare could be enhanced by the introduction of a requirement for a post-graduate qualification for veterinarians undertaking ARTs in clinical practice. Where procedures are highly technical, and dependent upon experience (as ARTs are), the interests of the animal(s) involved are likely to be best served by a specialist. For example, frozen semen insemination followed by embryo recovery in a mare involves restraint of the animal, *per-rectum* examinations, transcervical uterine flushes and hormonal treatments, all of which are either stressful or transiently painful. The number of stressful or painful procedures which an animal is subjected to could be minimised if the procedures were performed by Specialists rather than by (to take an extreme example) new veterinary graduates, because the superior training and experience of the specialist makes it likely that the specialist would achieve a pregnancy in a lesser number of reproductive cycles. Yet there is nothing in the regulation to say that ART procedures should be performed by specialists, nor indeed that any other treatments which in human medicine would only be undertaken by specialists (for example major abdominal surgery) should be. This fundamental question of the welfare and ethical implications of veterinary specialisation vs standard qualification is one which is not particular to ARTs (see the RCVS Consultation on Specialisation <http://www.rcvs.org.uk/news-and-events/news/the->

future-of-veterinary-specialisation-a-consultation) Although post-graduate qualifications in veterinary reproduction exist (for example the European Diploma in Animal Reproduction), holding such a qualification is not currently a prerequisite for undertaking clinical ARTs. Introducing such a requirement, even on a voluntary basis – perhaps as part of the RCVS' Practice Standards Scheme - would impose a standard higher than that currently imposed upon Practices which, for example, undertake major abdominal surgery in horses. However, this is not a reason not to adopt such a system for ARTs, but rather a reason to adopt a similar system for other areas of veterinary medicine too¹⁰. Indeed, it would be consistent with the support for post-graduate specialisation implicit in the RCVS's aim that all "Hospitals" under its Practice Standards Scheme have at least one surgical diplomate by 2015. An overall regulatory strategy which provided recognised, approved pathways for procedure-specific training of specialists - and thereby promoted the practice of specialised techniques by specialists would more adequately protect animal welfare than the current regulation of ARTs does, by increasing the chances of acts of veterinary surgery being undertaken not only to an 'efficient' standard (VSA s5:1), but to an excellent standard.

Is the scope of the regulation adequate to protect animal welfare?

The current regulation of clinical veterinary ARTs safeguards animal welfare directly, via the protection of post-natal animals against unnecessary suffering provided by the AWA, and indirectly, via the provision made by the VSA to ensure that those undertaking ARTs practice do so to an 'efficient' standard. Neither of these two pieces of legislation provides for the reporting function which is imbedded in the equivalent human legislation by section 13 of the HFE, which requires collection of data about success rates, adverse events and best practice. The lack of a regulatory reporting mechanism is not limited to ARTs: the same deficit is encountered in all areas of clinical veterinary practice. This may be partly because 'clinical audit' is not yet fully accepted practice in veterinary medicine, and partly due to fears that sharing information with a third party breaches client confidentiality and thus contravenes the RCVS' Professional Code of Conduct (Campbell 2013). For these fears to be allayed, regulatory systems need to be established which are designed to enable clinicians to report not only side-effects of medication¹¹ but also perceived risk factors and factors associated with successful outcomes without breaching client confidentiality. Without effective and transparent reporting functions evidence-based analysis of the animal welfare implications, efficacy and safety of veterinary procedures (something which is desirable to protect animals, fee-payers and veterinary surgeons) is impossible. Such an analysis is particularly important in a speciality such as reproduction where novel techniques are constantly being developed and modified. A reporting function could be incorporated into the current regulation of veterinary ARTs without the need for new primary legislation, by adopting a voluntary reporting system for veterinarians practicing ARTs which could be adapted to fit within and be administrated under the RCVS' existing Practice Standards Scheme (<http://www.rcvs.org.uk/practice-standards-scheme/about-the-practice-standards-scheme>

¹⁰There is an associated issue of who trains the specialists in a country where there are very few specialists. Historically, many current clinical specialists in veterinary ARTs have benefited from self-organised periods of training in international centres of excellence. It could be that formalisation of such arrangements would complement existing arrangements for post-graduate veterinary examinations.

¹¹Adverse reactions to *drugs* (only) may currently be reported under the voluntary system of the Veterinary Medicines Directorate: www.vmd.defra.gov.uk/adversereactionreporting. Accessed 08.03.2012

scheme). Providing that data collection was sufficiently detailed, problems of the kind encountered under the Human Fertilisation and Embryology Authority's system (whereby some of the best clinics appear to be achieving the lowest success rates because they treat the most difficult cases) could be avoided. Centralised collection and collation of data about procedures performed, success rates and adverse events would benefit veterinarians by enabling them to publicise their certified-standard services and to adapt their practices according to what was shown to be most efficacious; animals by providing an evidence base from which to improve best practice and identify and address welfare issues; and clients by identifying veterinarians with appropriate skills who were prepared to submit their work for scrutiny.

Conclusions

In contrast to human medicine, little consideration is given in the regulation of veterinary ARTs to the protection of embryos and fetuses. This may reflect the fact that the desire to protect human embryos and fetuses which runs through the human legislation reflects a desire to 'respect' them because they are 'potential humans' (Warnock, 1984), and society does not feel the same degree of moral concern about animals or, consequently, about 'potential animals' (i.e. animal embryos and fetuses). There are also considerations which occur in relation to human embryos (for example parental and posthumous rights relating to embryos created by *in-vitro* fertilisation) which do not directly apply to animal embryos¹². On purely welfare grounds, however, such protection as is currently afforded to animal embryos and fetuses is nonetheless adequate if embryos and fetuses cannot feel pain, distress, or suffer.

It is unclear whether all or any veterinary ART procedures being undertaken on post-natal animals are associated with suffering, because an evidence base detailing the welfare implications, efficacy and safety of such procedures does not exist. The lack of an evidence base is in itself partly the result of the inadequacy of the regulation of veterinary ART procedures, which does not provide for a reporting function. The lack of evidence about the welfare effects of veterinary ARTs makes it difficult to know whether the lack of prosecutions under the AWA relating to ARTs is indicative of a lack of suffering, a lack of substandard practice, or the fact that ART procedures are not much considered by those organisations which typically instigate prosecutions under the AWA.

The fact that regulation of veterinary ARTs is divided between three statutes – the A(SP)A, the VSA and the AWA - results in inconsistent provision of protection which could mean that the same animal undergoing the same procedure would be afforded varying levels of protection according to which Act was being applied. Although this might sometimes be to the benefit of experimental animals, the overall impact of the legislation on animal welfare is weakened since it makes it possible for individuals to "fall between acts". Hence non-veterinarians working under exemption orders to standards which compromised animal welfare are outside the remit of the RCVS and the VSA, and might not be "on the radar" of

¹²Issue relating to the human (rather than parental) rights of ownership of animal embryos do, of course, occur, but these are, in practical terms, matters of contract rather than of moral consideration.

animal welfare organisations interested in enforcing the AWA. Similarly, veterinary surgeons working at the research: clinical medicine interface may, deliberately or otherwise, be undertaking procedures under the VSA which ought in fact to be licensed under the A(SP)A. There is a danger that animal welfare may be compromised if ARTs are undertaken as clinical procedures when they ought to be classed as research procedures, and this danger exists also in other types of veterinary medicine.

The indirect protection for animal welfare provided by the regulation of persons performing ART procedures is currently inadequate, partly because it has been undermined by the creation of 'exemption orders', and partly because there is no requirement for post-graduate training in ARTs for veterinarians wishing to undertake such procedures. Any future review of the legislation regulating veterinary ARTs, be that an overall review or a review of one of the relevant statutes (for example the VSA), should take into account the interface between research and clinical medicine; the potentially welfare-compromising gaps between the Acts; the need to introduce reporting functions in order to build an evidence base, and the issue of veterinary specialisation and whether specialised techniques should be carried out only by those with specialist post-graduate qualifications.

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