Protecting Animals within a revised Radiological Protection Framework

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Abstract- Diagnostic and medical monitoring procedures are now escalating, and their number is also rapidly increasing within veterinary medicine, raising concerns about the lack of advice with respect to the exposure of animals as patients. This fact has now been recognised by the ICRP, and its current strapline is that of '*Protecting people, animals and the environment around the world from the harmful effects of radiation*'. But if that is the case, what revisions to the framework are necessary in order to achieve it? And what other exposure situations need to be considered?

The overall scope of radiological protection certainly needs to be redefined, and an overall ethical framework drawn up to underpin it, particularly in relation to justification of exposures. At present, the ICRP has recently reviewed its ethical basis for human radiological protection, but that in relation to the environment is somewhat different, and that with respect to veterinary medicine will be found to be different again. More important, however, is the need to examine the science base upon which radiological protection is founded across these three areas. DRLs are available for patients, based on Reference models and data bases, and Reference models and data bases also exist for fauna and flora in an environmental context from which DCRLs have been derived. Both DRLs and DCRLs serve to aid optimisation of protection. The latter are, admittedly, very crude in many respects, but there will be little improvement until radiobiology/radioecology provides the science in order to do so. But there are as yet no Reference models or data bases for animals in relation to veterinary medicine. The risks of concern for individual animals receiving such exposures are also different from those of concern in relation to populations of animals in an environmental context.

The focus in the past has been on how the effects of radiation on animals can be interpreted in a human context, particularly with respect to dogs. Large data bases exist on them, and one might now even consider it a moral duty to use these data for the benefit of dogs themselves. This could be done, but the ability to interpret such data in the context of other animals is extremely poor, and often unreliable.

Much could therefore be achieved within a revised framework. There are various dosimetric models available, and reference data bases that could be compiled in order to provide draft diagnostic reference levels for animals (DRLAs) relevant to veterinary medicine. Avenues could also be developed to gather, collate, and interpret new data bases. The chance to do all of this within a revised ICRP set of Recommendations should not be missed.

Keywords: Protection of animals; Veterinary medicine; DRLAs

1. Introduction

Since its inception almost a century ago, radiological protection has gone through many phases. Initially concerned with the application of ionising radiation in medicine, its framework developed in a stepwise fashion to embrace other categories of exposure and novel exposure situations. And yet the only major change since the introduction of the concept of collective dose has been that of a sub-framework to enable sensible decisions to be made in relation to the protection of fauna and flora in the environment under different exposure situations, thus enabling the nuclear industries to be regulated on the same basis as any other (ICRP, 2008).

For much of the western world medicine is again the principal source of additional exposures for humans, and virtually all of the sources used in diagnostic, interventional, and therapeutic medicine are now being applied in veterinary practice. Because of this, the issue of the protection of 'animal as patient' was raised a few years ago (Pentreath, 2016), and an ICRP Task Group (TG 107) then explored the subject further (Pentreath et al, 2020). The topic is still a matter of deliberation, and is being further addressed as part of the work of another Task Group (TG 110), set up to consider radiological protection in veterinary medicine as a whole. This is a welcome step. But there are still other exposure situations that involve animals, as mentioned in the first of these papers, including exposures relating to their commercial use, and of course their use as experimental material. It would therefore be short-sighted simply to fold into the existing ICRP radiological protection framework the exposure of animals in the context of veterinary medicine (although this in itself has considerable challenges, as discussed here) without at least giving some thought to these other exposure situations.

It is also important to note that radiological protection, as envisioned by the ICRP, is that of an overall systematic framework. When previously expanding it to include an explicit means of demonstrating that the environment could be protected, this was an important consideration (Pentreath, 2009). It acknowledged that the advantage of such an approach is that, as the needs for change to any component of the system arise (as in the acquisition of new scientific data, or changes in societal attitudes, or simply from experienced gained in its practical application) it is then possible to consider what the consequences of such a change may have elsewhere within the system, and thus upon the system as a whole. Such a system would not work unless it was based on a numerical framework that contained some key points of reference, particularly with respect to how best to relate exposure to dose, dose to the risks of radiation effects, and the consequences of such effects. A key step in developing this scientific framework was the creation of an entity originally known as 'Reference Man', which has served as a conceptual and analytical tool for many of the ICRPs numeric analyses and resulting conclusions. This systematic approach was then extended to include a small set of 'Reference Animals and Plants' to serve as the basis for producing and analysing numerical data in order to provide advice with regard to protection of the environment. The result was a set of dose rate bands (Derived Consideration Reference Levels, or DCRLs) that could be used to help manage, and thus optimise, situations where the environment was contaminated as a result of planned, existing, or emergency exposure situations.

The current systematic approach has thus evolved over many years. It is based on an enormous range of knowledge on the effects of radiation on human beings, supplemented by other data from studies on animals, and more recently on studies on biota in an environmental context. The ICRP attempts to convert all of these data, together with their errors, uncertainties, and knowledge gaps, into pragmatic advice that will be of value in managing different exposure situations. It bases this advice on a number of principles relating to the justification of the origins and purpose of exposure; the need to constrain the doses that may be received from individual sources, together with dose limits, where relevant; and the need to optimise the level of protection. In expanding the system even further in order to meet the ICRP's current strapline of '*Protecting people, animals and the environment around the world from the harmful effects of radiation*' it would therefore seem to be important to do so in a manner that complements and reflects the elements that the radiological protection framework already contains.

2. Scope, ethics, and their relevance to radiological principles in the context of protecting animals

Incorporating the protection of animals within the framework of radiological protection raises interesting questions about its overall scope. Animals are not only subject to ionising radiation in veterinary practice, but also for 'commercial' reasons, such as CT scanning of sheep to determine their meat content, or the examination of, particularly, horses, in relation to their sale or to attain a licence to race. And thousands of animals are used in experiments under laboratory conditions in relation to learning more about the effects of radiation and its use in various spheres. All of these practices relating to such deliberate exposures may well be reasonably defensible but, if so, it is important to be able to explain why – essentially their 'justification', a key component of the radiological protection framework. If such practices are to remain outside of the framework, then again such a decision needs to be based on a reasoned argument, not just because the subject was too difficult to address. All of which, in turn, relates to the underlying assumptions being made in relation to the framework as a whole.

The practical application of radiological protection has evolved in parallel with considerations of the morals and ethics relating to it. Thus the primary aim of radiological protection, as currently expressed (ICRP, 2007), is that of "….*contributing to an appropriate level of protection for both people and the environment against the detrimental effects of radiation exposures without unduly limiting the desirable human actions that may be associated with such exposures*….". Behind these principles lie a set of ethical values relating to human protection that are based on the objectives of the promotion, or the actual doing, of 'good' ('beneficence') and, simultaneously, the avoidance of causing 'harm' ('non-maleficence'). They are also based on the concepts of prudence, justice, and dignity. Thus the concept of prudence allows uncertainties to be taken into account; that of justice ensures that social equity and fairness in decisions are considered in relation to radiological protection; and that of dignity recognises the respect that one must have for people as individuals.

Ethical values relating to protection of the environment are altogether more complex and difficult to articulate. They differ from one society to another, and within any given society. They can be grouped in many ways, but the ICRP has essentially accepted (ICRP, 2003, 2008) that of the following: anthropocentric, in which human beings are the main or only thing of moral standing, and thus the environment is of concern only as it affects humans; biocentric, in which moral standing can be, and usually is, extended to individual members of other species, and thus obligations pertaining to such individuals arise as a consequence; and ecocentric, in which moral standing can be extended to virtually everything in the environment but the focus lies more on the entirety and diversity of the ecosystem rather than, say, the moral significance of each and every individual component of it. There are practical implications arising from these ethical values and, notwithstanding the biocentric view, the focus is usually that of attempting to protect populations of animals rather than specific individuals within it.

The ethical basis underpinning veterinary practice is somewhat different. As with the case of human medicine, there are the basic principles of beneficence and non-maleficence. And, again in line with human medicine, it operates under 'Aesculapian authority' that licenses a medical (or veterinary) practitioner (a 'healer') to handle their patients and treat them in various ways. But in veterinary medicine there are the added issues of 'animal ethics' and 'animal welfare', which often have a bearing on the objective of preserving life. This is essentially an all-pervading one in medicine, but in veterinary practice such decisions are also tempered by the different life expectancies, quality of life, or even assumed purpose in life - as in the case of livestock - of the animal in question: and, of course, they critically depend on where the onus for making these key decisions lie.

The practical relevance of these ethical values relates to how they are reflected in the fundamental principles of justification of exposure; optimisation of protection; and the application of dose limits. The first requires that any decision that alters the exposure situation should do more good than harm. The second requires that all exposures should be kept as low as reasonably achievable, taking economic and societal factors into account. And the third states that individual exposures, other than medical exposures of patients, should not exceed the dose limits as recommended at any one time by the ICRP. Patients are exceptions from this third principle because generic dose limits might well reduce the effectiveness of the diagnosis or treatment, thereby doing more harm than good. Emphasis is therefore placed on the justification of the procedures in the first place, on the optimisation of protection in relation to the source and, for diagnostic procedures, on the use of diagnostic reference levels (DRLs).

But even the justification principal in the radiological protection of patients is somewhat different from other exposure situations in that, generally, the benefits and the risk relate to the same person (although other aspects may apply – such as doses to medical staff). And it is also the case that any specific method or procedure that can be regarded as 'justified' does not necessarily imply that its application to a specific patient is in itself fully justified.

The principal of optimisation of protection for patients is also unique. Thus in diagnostic procedures it is the same person that gets the benefit but suffers the risk, and the imposition of individual restrictions on patient dose could also be counterproductive to the medical purpose of the procedure. Source-related individual dose constraints are therefore also not relevant and thus Diagnostic Reference Levels (DRLs) that relate to a particular procedure, which applies to groups of similar patients rather than individuals, are used. Radiation therapy is also very different from other situations in that the dose is intentional and its potentially cell-killing properties are the very purpose of the treatment. In this case optimisation therefore becomes an exercise in minimising doses (and/or their deleterious effects) to surrounding tissues without compromising the pre-determined and intentionally lethal dose and effect to the target volume.

With regard to the basic principles of radiological protection, therefore, there are clearly specific issues to be considered when animals are irradiated. In terms of justification, the 'risk' is always born by the animal, but the benefit may fall entirely to the animal's owner (as, for example, in multiple x-ray or CT scans of an animal for prospective buyers of that animal, or of livestock to assess their meat content). This then leads to a dilemma with regard to who makes the decision with regard to the justification of exposure. In medicine there are usually two parties involved: the health professional and the patient. But in certain cases there are three: the health

professional, the patient, and the patient's guardian, carer, or parent - although it may be assumed that all of those parties are acting in the highest moral way. Differences of opinion may nevertheless emerge - such as between the views of the health professional and the parent or guardian of a small child on what to do in the best interests of the child. In such cases, mechanisms usually exist such that the final decision may be made by a court of law, but the overall aim is not usually in dispute: the well-being, and thus 'good' of the patient.

In the case of veterinary medicine there are almost always three relevant parties: the veterinarian, the animal patient, and the animal's owner or guardian. But considerable differences may exist between the value judgements applicable to each party: in particular who reaps the benefit, and why. This dilemma has often been central to the development of ethics within the veterinary profession. The problem is often exacerbated by the fact that, in the law of many countries, a person may hold '*property rights'* over animals, which implies that they may own animals as private goods, make use of them for economic gains, and dispose of them in a manner deemed 'fit' within the law. This view of animals as a 'property' is thus a source of some of the ethical dilemmas faced by veterinarians and has an effect on the vet-animal-client (owner) relationship. The owner may demand that the veterinarian opinion should be secondary, because he/she owns the animal and may thus ask the veterinarian to comply with his/her decision. This may particularly be the case with regard to livestock. Different again is recognition of the extremely strong bonding between owners and their domestic (pet, or companion) animals that may create a psychological barrier between the veterinarian and the client, especially in issues connected with euthanasia. And a further consideration may be the owners' willingness and ability to pay.

4. Natural susceptibility to cancer in domesticated animals

Bearing in mind that the principal concern in veterinary medicine relates to an individual animal rather than a population, the focus is likely to be that of the risk of that individual developing cancer as a result of the exposure. And this, in turn, raises the question as to how prevalent cancer is in animals, particularly 'domestic' animals. There do not appear to be any international registers of such information, although there are a number of national data compilations, particularly on dogs. Thus a UK study of purebred dogs by Adams et al (2010) found that cancer was one of the major causes of death, accounting for 27% overall, and increasing with age. It is however difficult to determine long term trends, although it is likely that improvements in health and the welfare of animals, leading to greater longevity, plus improved diagnostic techniques, are likely to result in an increasing rate of diagnosis. And as observed by Dobson (2013), there are some interesting similarities and differences when compared with human data. Thus mammary glands are a common site for tumour development in bitches, although the risk is reduced in those that have been spayed at a young age, inferring the importance of endogenous hormones in the development of this disease. But in contrast, carcinomas of the prostate, a common condition in men and also associated with hormonal stimulation, appears to be relatively uncommon in dogs and occurs more frequently in neutered animals. It also seems that carcinomas of the large bowel, which are fairly common in humans, do not feature highly in dogs, whereas some tissue sarcomas that are rare in humans, are relatively common. A rough ranking order for malignant cancer in dogs is that of mast cell tumours, soft tissue carcinoma, lymphoma, osteosarcoma and mammary sarcoma.

Dogs have been considered to be interesting models for the development of cancer (Gardner et al 2016). Probably evolving from grey wolves of Europe or the Middle East, and becoming domesticated some 20 to 30,000 years ago, different types were gradually established for different purposes. In fairly recent times, however, selective breeding practices have resulted in over 300 discrete breeds worldwide. The establishment of breed 'standards' has resulted in reduced genetic diversity within breeds and greater genetic divergence amongst breeds. Thus although the average nucleotide heterozygosity across all dog breeds is comparable to the human population **(**Lindblad-Toh et al 2005) the level of genetic diversity within any single breed is considerably less than the species as a whole. Indeed, it has been estimated that whilst domestication of wild canid populations resulted in a 5% loss of nucleotide diversity, the establishment of specific breeds conforming to strict standards caused a 35% loss (Gray et al., 2009). In view of the fact that mutations in a small number of genes are responsible for many breed characteristics, selective breeding for exaggerated traits further reduces genetic diversity, and perhaps risks the selection of mutations that predispose to disease, for it is certainly the case that differences exist between breeds of dog and their risk of developing certain types of

cancer, although there are few large scale epidemiological studies on the incidence of different types of cancer in the canine population which document such variation.

With respect to other animals, cancer is common in domestic cats, though less commonly reported than in dogs. There do not appear to be any comprehensive registers at national level. There are however interesting differences from cancers in dogs. Thus, for example, the vast majority of mammary gland tumours are malignant, and multiple tumours and metastasis are common at diagnosis. There also appears to be a breed predisposition in Siamese cats, which are more likely to develop mammary tumours, and at a younger age than in other cat breeds. And, in contrast to breast cancer in women, feline mammary tumours are more likely to be hormone (oestrogen and progesterone) receptor negative (Cannon, 2015). Horses are different again. Particularly common are squamous cell carcinomas, that can affect the eyes and eye lids in particular, melanomas, sarcoid tumours, lymphosarcoma, and cancers of the reproductive system. But again, there do not appear to be any national registers of the prevalence of the disease.

5. Effects and risks of radiation

There is, again, much information on dogs. Large data bases derive from the use of dogs in experiments during the cold war, from about 1950 to 1980 (Spatola et al, 2021), in order to inform on the effects of radiation on people, but there were only limited publications in the open literature arising from them. Dogs were irradiated by intravenous injection, inhalation, ingestion, external irradiation, implants and so on. Large numbers of healthy dogs were exposed to ^{60}Co and x rays at dose rates from a few mGy day^{-1} to several Gy, under different exposure regimes, from continual, multiple, to single exposures. Probably dozens of studies were made in different countries. One large scale study in the USA involved 1,500 dogs exposed *in utero*, exposure terminating at various ages up to a year post-conception. The occurrence of various cancers were then recorded later in life. Frequent effects in all of these experiments are haematological changes, infertility, and cancers of the bone, liver and lung. None of these data seem to have been interpreted with regard to their potential utility for guiding advice on the consequences of exposures to dogs in the context of veterinary medicine (or in any other context) and it would seem that, in view of their sacrifice, there is now a moral duty to do so!

Extrapolating and interpolating radiation effects amongst different vertebrate species is, however, not straightforward. In considering differences amongst different types of animals, particular interest has focused on stem cells. Thus if one considers the apparent natural rate of cancer occurrence in different human tissues, they differ by up to 10^6 orders of magnitude. It seems that the lifetime risk of cancer correlates reasonably well with the total number of divisions of the normal 'self-renewing' cells that maintain any particular tissue's homeostasis. But there are many other factors to consider, as discussed elsewhere (Pentreath, 2021) including metabolic rate, the number of different stages in the life cycle, and how they transform from one to another, or just the total life span. And yet no common framework for examining these basic and obvious factors that might influence the effects of radiation on organisms in general has ever emerged. Correlations (or the lack of them) between large and small animals with regard to their potential to develop cancer have primarily focussed on the basis of the differences in the number of cells that they contain. Thus it has been noted that not only are humans about 3 10^3 times larger than mice, and thus formed from a proportionately larger number of cells, but they also live very much longer: their cells should therefore undergo about 10^5 more divisions in a lifetime (Rangarajan & Weinberg, (2003). Thus if the risk of genetic damage, including the creation of mutant alleles that lead to cancer, increases in proportion to the number of cell divisions, this implies that humans should experience much higher rates of cancer incidence than mice. Yet epidemiological studies reveal that the lifetime risk of developing cancer is roughly comparable in both species.

There are, however, several other factors to consider. One is the difference in basic metabolic rate, plus the fact that many carcinogens are activated or neutralised quite differently in mouse and human tissues. Furthermore, the spectrum of age-related cancers in these species is quite different: whereas many strains of laboratory mice tend to develop cancer in the cells of mesenchymal tissues (such as lymphomas and sarcomas) most age-related cancers in humans arise in epithelial cell layers and lead to carcinomas. The cytogenetic profiles of mouse and human tumours also present other key differences. Thus despite the overall similarities in organ systems between mice and humans, subtle differences with respect to physiology and tissue architecture can drastically alter the types of tumours that form.

6. So what needs to be done?

Obviously the first step is to be clear about the scope of radiological protection, as envisioned by the ICRP, over the next decade or so. This is important because different international organisations currently have different views as to what it does, and does not, encompass. And once articulated, the scope needs to be underpinned by a single, comprehensive ethic. This currently does not exist, even for the areas within the ICRP's existing framwork.

But more importantly, there are several areas that need to be addressed, including the following.

6.1 Quantities and units

The scientific framework upon which radiological protection is based makes use of various quantities, and uses specific reference models and data sets in order to relate exposure to dose and dose to biological effect. These have all been primarily developed for human radiological protection (ICRP, 2007), but a similar 'reference' approach has also been developed for some animals and plants in order to help manage radiation exposures in the context of protection of the natural environment (ICRP, 2008).

The basic physical quantity of absorbed dose, the gray (Gy), is a measurable quantity. In order to relate a radiation dose to a radiation risk (or detriment), however, it is also necessary to take into account differences in the biological effectiveness of radiations of different quality and differences in the sensitivity of different (human) organs and tissues to ionising radiation. These necessities are met by the use of ICRP 'protection quantities' that have been derived using voxel phantoms of a Reference Male and a Reference Female. Radiation weighting factors (w_R) have been derived for human organs and tissues to produce an equivalent dose, for both males and females; and reference phantoms have been used to allow for differences in sensitivity to radiation by the use of tissue weighting factors (w_T) for a 'sex-averaged' human being, resulting in another protection quantity, the effective dose. Thus, by definition, the terms equivalent dose, effective dose, and thus the Sv, are unique to humans. They do not apply to animals.

In practical radiological protection applications, effective dose is used for managing the risks of stochastic effects and is therefore only applicable to dose rates of < 100mSv. But in medical practice the relevant quantity for planning the exposure of patients and risk-benefit assessments has been the equivalent dose, or the absorbed dose, to irradiated tissues, not the effective dose. This is because the use of effective dose has severe limitations that must be considered when quantifying medical exposures (ICRP, 2007). Indeed the assessment and interpretation of effective dose from medical exposure of patients is very problematic when organs and tissues receive only partial exposure, or a very heterogeneous exposure, which is often the case, especially with x-ray diagnostics. The effective dose can nevertheless be of value for comparing doses from different diagnostic procedures, and for comparing the use of similar technologies and procedures in different hospitals and countries, as well as the use of different technologies for the same medical examination. However, for planning the exposure of patients and risk-benefit assessments, the equivalent dose or the absorbed dose to irradiated tissues is the relevant quantity. For therapeutic medical applications, where the objective is deliberately to cause tissue reactions to specific areas or volumes, the quantity used is the Gy.

Radiation doses for any animal can therefore only be expressed in terms of absorbed dose (Gy), and there are no parallels to the equivalent or effective dose, and hence no parallels to the Sv, for any animal. Recommendations have however recently been made by the ICRP to the effect that an RBE weighted absorbed dose should be used for radiological protection purposes for biota in an environmental context, with an RBE weighting of 10 for alpha particles (it is 20 for humans) and 1 for all low-LET radiations. The use of a single value of 1 for all low-LET radiations is consistent with the approach currently taken for the protection of humans. It is however conceded that under certain circumstances of exposures to tritium, in particular, the use of higher RBE values may be warranted (ICRP, 2021).

For animals, a number of ICRP Reference types (Reference Animals and Plants, or RAPs) for relating exposure to dose, and dose to biological affect, have been described at the taxonomic level of Family, two of which are for big and small mammals - Cervidae and Muridae. The reference dosimetric models initially used were simple, but some voxel phantom models have since been developed. Data on biological effects relating to external and internal sources of radiation were drawn from a wide range of literature on non-human biota (ICRP 2008).

There are, however, no reference models or data bases for animals of primary interest in veterinary practice (Equidae, Canidae, Felidae) although there are many computational anatomical animal models available that are suitable for dosimetric modelling (Zaidi 2018), including at least five for canines (Padilla et al. 2008; Kramer et al. 2012; Stabin et al. 2015) and, as already noted, data bases exist on the effects of radiation on such mammals.

6.2 Optimisation

There is a lack of accurate information regarding doses used in veterinary practice, particularly for diagnostic purposes. This is a particular problem with the use of CT scanners designed for human use that are programmed to provide doses per examination in mSv (effective dose). This is an issue, as already identified, that needs to be resolved (Pentreath et al, 2020). There is also a lack of data on doses used in therapeutic veterinary practice, and no numerical guidance is available. It is also worth noting in passing that although by far the vast majority of such procedures are performed on dogs, cats, horses, and cattle, other animals may also be examined – of which some examples are given in Figures 1 to 3.

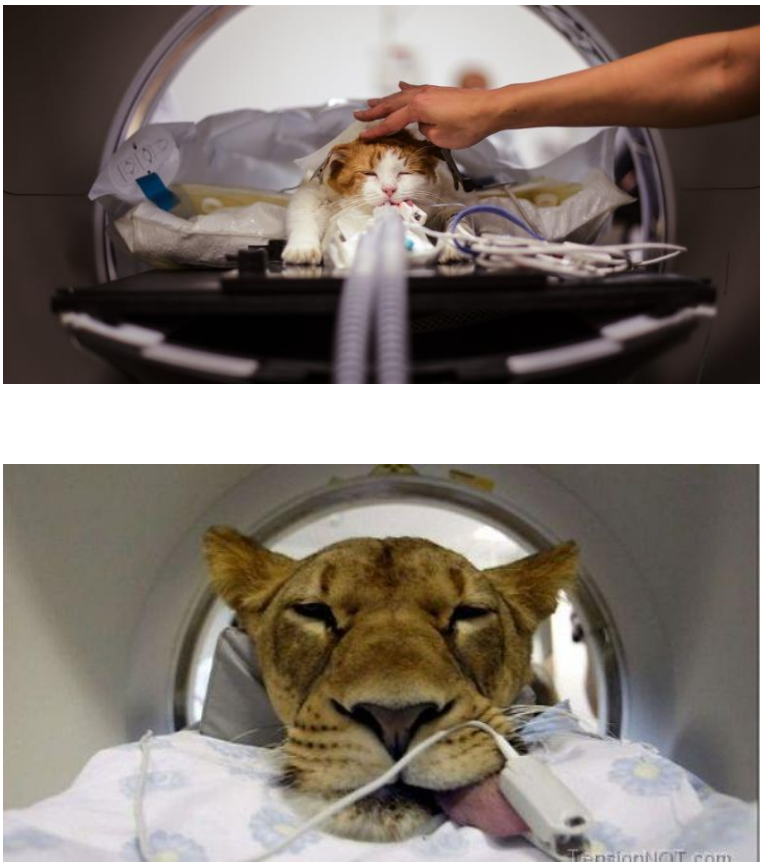

Figure 1. CT scanning of cats big and small [Origin, copyright?]

There are many facets to optimisation, in human and veterinary medicine, but of particular value has been the development of Diagnostic Reference Levels. If animals are to be brought within the overall ICRP framework, then it is obvious that it would also be sensible to draw up a sub framework that complements that already established for humans and animals in an environmental context – namely the development of reference dogs, cats, and horses from which a set of Diagnostic Reference Levels for Animals (DRLAs) could be drawn up. This has the advantage that once a set of numerical information exists, however preliminary, then it encourages the compilation of other data to challenge or confirm the initial set. But without such a set, there will be no urgency to standardise procedures or to compare and learn from different experiences worldwide.

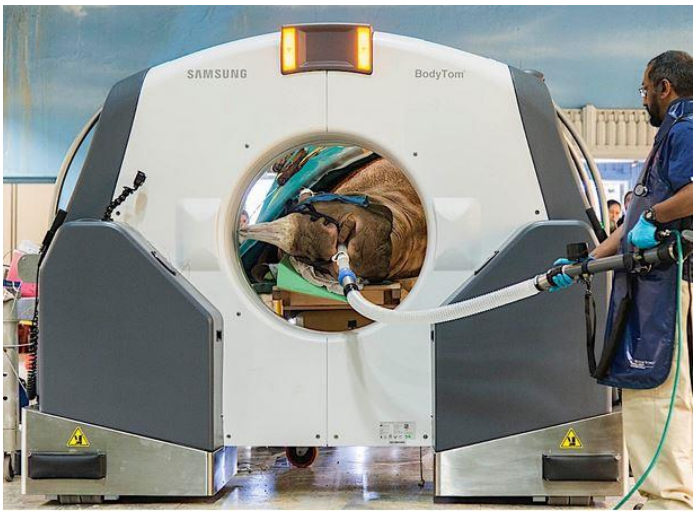

Figure 2. An eight year old rhinoceros, Layla, undergoing a CT scan at Brookfield Zoo, Chicago, USA (Photo credit Chicago Zoological Society).

Figure 3 CT scan of an injured python. [Origin, copyright?]

Optimisation in therapeutic treatments is primarily focussed on minimising damage to healthy tissue. Thus although these are less common procedures, the potential for unnecessary damage and distress to animals is considerably greater. Linear accelerators are now used routinely to provide therapeutic treatment. Doses delivered can be up to 70 Gy (to dogs) (Coomer et al., 2009), and there is already some concern about the

knowledge upon which such treatment is based. There are not many published scientific reviews of the damage incurred to healthy tissues, and very few of the consequences of errors in therapeutic treatment. Late effects are also known but not well recorded, although a review of acute and chronic effects published over 20 years ago stated that severe reactions occurred in less than 5% of treated animals (Harris et al., 1997).

Amongst the problems arising, as previously discussed (Pentreath et al 2020) the following have been identified. First, a lack of the completeness of reporting (in published studies) of treatment planning, radiation dose, treatment delivery, quality assurance, and adjunctive therapies. By and large, information is lacking or insufficient to allow complete interpretation of results, or the reproduction of how treatments were planned or delivered, and fall short of ICRU guidelines for humans (ICRU, 2010) that emphasise the importance of standardisation in reporting for optimal interpretation of clinical results and for the repeatability of treatments. There is therefore a clear need for the adoption of standards for the reporting of clinical studies, as well as for the reporting of details of radiotherapy planning and delivery if progress is to be made.

Another serious concern was that of inconsistencies in the definition of target volumes during the treatment planning process. The accurate reporting of margins around a target is obviously necessary for any useful exchange of information between centres, and to ensure repeatability of results. And as in human radiotherapy, fractionation has been a mainstay in veterinary practice, but protocols differ considerably, even for the curative intent of the same condition In general, therefore, there are many areas of interest, such as the uncertainties over the reconstruction of dose and how this relates to the risks of late effects in different types of animals, which are essentially similar to those arising from the treatment of human patients (Vu Bezin et al., 2017).

Clinical trials are also imperative to progress veterinary radiation oncology, but there appears to be an over-reliance on retrospective studies (considered to be a poor basis for evidence) to assess clinical outcomes. One important limitation is the issue of incomplete or missing data. A recent review (Kent et al., 2018) referred to various studies relating to intracranial tumours in dogs, and concluded that prospective clinical trials are needed to answer lingering questions about efficacy outcomes, such as survival. Case selection to identify patients best suited for different procedures is also seen as an area requiring more attention with regard to the adoption of newer approaches (Kubicek et al., 2016). Arkans et al. (2015) discussed the common issue of the risk of potential sources of error arising, and thus of potential harm to the patient, simply because of the increasing complexity of the treatments that may now be used.

Other matters arising were those relating to the certification of radiation therapists with respect to veterinary medicine, licensing, error reporting (or the lack of error reporting), the need for more guidelines to be drawn up, and so on. There has also been an increase in the use of radiation for palliative care, particularly for cats and dogs, but there appears to be a lack of agreed protocols with respect to such use, such as for nasal tumours in dogs (Tan-Coleman et al., 2013), in order to do so.

6.3 Data bases

With the principal sources of exposure for people and animals now arising from medical and veterinary practice, one no longer looks to the traditional sources of data such as UNSCEAR and the IAEA for numerical information, but to national reports on such exposures in the relevant public health reports and related compilations. With the development of a more formal approach to the protection of animals within a broadened ICRP framework, it is likely that such data bases would become more available and be collated at international level plus, most importantly, subject to some form of scrutiny and intelligent interpretation. This is unlikely to occur, however, unless some data bases are compiled by the ICRP, albeit on a preliminary basis, in order to derive sets of values that are of practical use, worldwide, within veterinary medicine.

7 Broadening, but maintaining, a Radiological Protection Framework

As argued above, it is clearly very opportune to revise the current ICRP radiological protection framework, both to reflect the changes that have already occurred since 2007, and to prepare for the future. In this respect the major task would seem to be that of broadening the framework in order to achieve the current objectives,

as set out in it current strapline to include "… *the protection of animals … around the world from the harmful effects of radiation*" but simultaneously maintaining the framework's overall outline and internal structure. In order to do so, it obviously needs to reconsider its scope with regard to what practices are included and which, if any, are not, and why. Such decisions need to be based on a clear rationale, and thus transparent ethical basis. There is no doubt, however, that it will include protection of the animal as patient in veterinary medicine, and this alone brings with it many challenges, but none that cannot be addressed by expanding the current system, and creating a sound numerical basis, founded on models and data bases, that can be used in a practical and useful way around the world.

It also surely makes sense to view the subject of the exposure to radiation and its subsequent effects on all animals, particularly mammals, in a collective way, and to learn how this knowledge can be used for the protection of humans and animals in medical and veterinary practices. There are data that can only arise from experience with animals that could be of value to improve human radiological protection, and vice versa, but this is only likely to arise within a framework that has a sound numerical basis. There is so much that could be learned from each other, and the combined data arising would be highly beneficial to all.

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