LES DÉPOUILLES : LES TISSUS HUMAINS, LA COMPÉTENCE ET LE CONSENTEMENT DANS UNE ÈRE DU PROFIT

Eike-Henner W. Kluge, PhD, département de Philosophie, University of Victoria, Victoria (BC). M. Kluge était le premier témoin expert en éthique médicale reconnu par les tribunaux canadiens et le directeur fondateur du département des affaires éthique et judiciaires de l'Association médicale canadienne. Le professeur Kluge a été conseiller de l'Association médicale du Commonwealth et expert-conseil du ministère de la Santé (sous-direction de la protection de la santé), du ministère de la Justice du gouvernement canadien et des provinces de l'Ontario et de la Colombie-Britannique. Il s'est aussi présenté devant le Comité permanent de la Chambre des communes sur les affaires judiciaires et a témoigné devant la Commission royale. Le Comité sénatorial spécial sur l'euthanasie et le suicide assisté a également demandé son témoignage.

Il est l'auteur de six œuvres en éthique biomédicale, a préparé une étude sur les banques de tissus humains commandée par la sous-direction de la protection de la santé du ministère de la Santé et a rédigé plus de quatre-vingt articles sur des sujets aussi variés que l'attribution des ressources en soins de santé, les politiques de don d'organes, la génie génétique, le système de soins de santé canadienne et la mort voulue en milieu de soins de santé.

RÉSUMÉ

Depuis plusieurs décennies les tissus et les fluides humains intéressent de plus en plus les chercheurs en santé en raison de leur rôle potentiel dans le développement de nouveaux outils diagnostiques, médicaments et traitements. Ils sont également devenus substances de valeur jouant de grands rôles dans la récupération de protéines ainsi que d'hormones pour procédures cosmétiques. Ils sont également fréquemment utilisés dans l'industrie bio-phramacologique. Malheureusement, la compréhension actuelle du statut éthique et légal des tissus et fluides humains, ainsi que des conditions de récupération et d'utilisation appropriées, est peu uniforme. L'objectif de cette présentation est de brosser un tableau des considérations juridiques et éthiques à envisager lors de la création d'un protocole de récupération et d'utilisation répondant aux normes appropriées.

THE REMAINS OF THE BODY: HUMAN TISSUE, COMPETENCE AND CONSENT IN AN AGE OF PROFIT

Eike-Henner W. Kluge, PhD, Department of Philosophy, University of Victoria, Victoria, BC. Mr. Kluge was the first expert witness in medical ethics recognized by Canadian courts and was the founding Director of the Canadian Medical Association's Department of Ethics and Legal Affairs. Prof. Kluge has acted as an advisor to the Commonwealth Medical Association and as consultant to the Ministry of Health (Health Protection Branch) the Ministry of Justice of the Canadian Government and the Ontario and British Columbia Ministries of Health. He has appeared at various times before the House of Commons Standing Committee on Judicial Affairs, has presented testimony to the Royal Commission, and was invited by the Special Senate Committee on Euthanasia and Assisted Suicide to give testimony.

He is the author of six books in biomedical ethics, has prepared a commissioned study on human tissue banking for the Ministry of Health, Health Protection Branch and has authored more than eighty articles on subjects on such subjects as health care resource allocation, organ donation policies, genetic engineering, the Canadian health care system, and deliberate death in the health care setting.

ABSTRACT

Over the past few decades human tissues and fluids have increasingly become of interest to health-oriented research due to their potential use in the development of new diagnostic tools, drugs and treatment modalities. They have also become valuable commodities that figure prominently in the recovery of hormones for cosmetic purposes, the production of proteins and in a whole range of uses in the bio-pharmacological industry. Unfortunately, current understanding of the ethical and legal status of human tissue and fluids, and of the conditions under which they may be recovered and used, is somewhat uneven. The aim of this presentation is to outline the ethical and legal considerations that must be met if a recovery and use protocol is to meet appropriate standards.

Introduction

For most of history, human fluids and tissues were of interest to health care professionals only for pathology purposes. Interest expanded, however, into the therapeutic field with the advent of transfusion and transplantation. As biological sophistication increased, researchers became more interested in human biological materials (biologicals) for their potential usefulness in developing new diagnostic tools, drugs and treatment modalities, and the bio-pharmacological industry began to consider them valuable commodities for the recovery of hormones for cosmetic purposes, the production of proteins and a whole range of other uses.

Historically these developments occurred in parallel with an increasing societal concern for the ethical and legal issues that centre around autonomy, privacy and informed consent. As a result, the right to self-determination came to include the right to decide what happens not only to one's body, as a whole, but also to one's body parts and products;[1,2] privacy issues expanded to encompass personal genetic information;[3] and the notion of informed patient consent was adapted to include not only the right of the patient to decide on medical treatment but also the right to be given, prior to making a decision, all the information that an objective reasonable person would require before making the decision about treatment.[4]

These developments occurred independently of each other, but their intersection gave rise to a series of considerations that centre around the recovery, storage, manipulation and use of human biologicals. The situation was further complicated by the fact that research, delivery of health care, industrial usage, and data handling/manipulation had become transborder enterprises that straddled countries and legal systems.

Unfortunately, these developments have not been paralleled by a corresponding increase of their nature and importance within the perioperative profession. The aim of this discussion is to outline some of the more salient factors that are involved, with special focus on the recovery, storage and handling of human biologicals in the OR setting. Legal considerations will be important to this discussion, but it will be suggested, however, that ultimately, because of the international context of contemporary health care delivery, consultation and research, and because of the global field-of-operation of the bio-pharmacological industry, it is ethical considerations that should be at the core of any protocols that might be devised. This is the only way that inter-jurisdictional conflicts can be minimized.

Autonomy and informed consent:

Patients have a right to autonomy — which is to say, they have the right to decide what shall happen to them.[4,5] Since patients are physical beings, this includes not only the right to make informed consent about any intervention, but also the right to decide what shall happen to their bodies, their body parts, or the products of their bodies. The easiest way to conceptualize the implications of this, for the OR setting, is to distinguish between the right of ownership and the right of disposition.

Ownership

Legally, the term 'ownership' refers to the bundle of rights that someone has in relation to a particular thing, entity, substance or process.[6] This includes the right of possession, control, use, benefit, and exclusion, as well as the right to transfer or sell what is thus owned.

In Canada, as in most countries,[7] there is no ownership recognized in relation to human bodies or body parts. The implications of this are

clearly expressed in the British Columbia *Human Tissue Gift Act*,[8] which stipulates at Section 10 that, "A person must not buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or parts other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research."

There are three major reasons for adopting this stance. *First*, if ownership in human bodies were allowed, then bodies could be sold. This would mean that slavery would become legal. *Moreover,* it would legalize commercial trade in body parts. The individuals most likely to be affected by this practice would be socioeconomically disadvantaged persons. As examples from the uncontrolled blackmarket industries in India, Pakistan and Turkey show, it is invariably poor people who sell their organs for use in what is euphemistically referred to in the media as 'transplant tourism'.[9,10] *Third,* to treat human bodies, body parts and tissues as property is to adopt a perspective that treats human beings as mere biological machines. This would undermine the principle of the dignity of the human person that is affirmed in the International Declaration of Human Rights.[11] It should also be noted that neither the BC statute, nor its analogues in other Canadian jurisdictions, distinguishes between living and dead human bodies or body parts.

There is, therefore, no recognized ownership of, and no legal commerce in, human bodies, body parts or tissues. And while blood, placentas, foetuses and other biologicals that are replaceable by normal bodily functions and repair are not specifically mentioned in the statutes just referred to, most jurisdictions specifically prohibit the sale of these items (with the exception of blood) in separate and distinct clauses and for similar reasons.

Disposition

The absence of ownership does not, however, mean an absence of control over bodies, body parts, and tissues. This is usually expressed by saying that all persons have a right to the control over the disposition over their own bodies, body parts and tissues.[12] The reason for this is again threefold. *First*, as biological entities, all human beings are presumed to have an abiding interest in what constitutes their unique physical being. This, among other things, is what underpins the right to the inviolability of the person, the right donate organs, the right to decide how one shall be buried, etc. *Second*, the biologicals themselves have been produced by their human originators and no-one else. There is a standard presumption that whoever has produced something has a right of control over it, as underlies patent law. *Third*, all human biologicals contain genetic markers that are unique to their originators. The right to privacy that surrounds all persons, and the right to decide who shall have access to information about oneself,[13] therefore entails that the originator of the biologicals has a privacy-grounded right of control over them.[1]

By way of filling out the picture, it should be noted that the right of disposition does not lapse when their biological originator is incompetent (or dead). It devolves onto the duly empowered substitute decision-maker. The only exceptions are coroners and pathologists engaged in the execution of their legally mandated duties. Moreover, the order of duly empowered substitute decision-makers is fixed by law and goes as follows: patient-appointed substitute, spouse, child, parent, sibling, anyone else related by birth or adoption. Priority in this list confers exclusive decision-making power — unless it can be shown in a court of law that the higher-ranked person would violate the wishes or values of the incompetent person. The ranking reflects the standard assumption that, all other things being equal, the higher in the list would be more likely to know the originator's values than someone ranked lower. There is case law to this effect.[14]

Guidelines

The preceding considerations are clearly accepted by the Interagency Panel on Research Ethics (IPRE)[13] and the Canadian Institutes of Health Research (CIHR)[14]. These bodies have

Continued on Page 10

promulgated guidelines against which the ethics of all publicly funded research in Canada is measured. Failure to adhere to these guidelines entails not merely censure of the implicated individuals or institutions but, in the most egregious cases, will result in withdrawal of accreditation and loss of public funding. Moreover, while the private sector is not directly subject to these guidelines, they may apply indirectly because, in any litigation affecting human biologicals, they are the standards that are applied to all actions irrespective of whether these actions are carried out in the public or the private sector.

Both IPRE and CIHR subscribe to, and follow, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.[17] This policy states that the collection of human tissue shall be undertaken only with the free, competent and informed consent of the originator of the tissue; that gametes, foetuses and other biologicals (including fluids) are included; and that in the case of deceased donors, consent must be acquired from the duly empowered substitute decision-makers of the individual in question.[17] In addition, the consent process must disclose the proposed use, any known or expected commercial potential and any known or reasonably expected privacy implications.[17] The only exception to this is when the use is for pathology purposes and other exemptions provided by law. Collection for the destructive disposal of biologicals does not require consent, since patients generally assume that unless their consent is explicitly requested, the biologicals in question will be destroyed after an operation. It is also worth noting that donorship must never be a condition of treatment.

Traditional arguments against informed consent

Despite the clear position of IPRE, the Tri-Council, and CIHR on this matter, it is often assumed that informed consent for the collection and use of human biologicals is unnecessary in the OR. This stance, insofar as it has been defended at all, usually involves an appeal to one or more of the following four legal arguments: the argument from *laches*, the argument from adverse possession, the argument from abandonment, and the argument from *res nullius*.

The **argument from *laches*** is based on the legal doctrine that whoever is negligent in asserting their ownership or dispositionary power, when it was possible to do so, loses that power to anyone who cares to assume it. By way of example, this doctrine was taken to ground in what historically came to be called "squatter's rights" in the domain of real estate. However, even if one ignores the fact that human biologicals are not property and therefore could not, strictly speaking, be covered by this doctrine, there is also the fact that in order for the argument to be acceptable in a court of law, the owner of the property must have been aware of the right of ownership and disposition. This is not usually the case with patients whose biologicals are removed in the operating room. Consequently, the patients' failure to assert their dispositionary power is not indicative of negligence but is a consequence of ignorance. In other words, this argument would apply if, and only if, the medical staff had previously informed the patients of their rights — which is not generally the case.

The **argument from adverse possession** is based on the legal doctrine that if someone is visibly and openly in possession of something that belongs to someone else, and if the legitimate owner does not challenge that possession or assert a right of disposition, then the current possessor acquires the right of ownership and disposition. Legal technicalities aside, therefore, the human-tissue argument that is based on this doctrine is essentially similar to the argument based on the doctrine of *laches* — and it fails due to essentially the same reason. It applies only if the originator of the biologicals was aware that s/he had dispositionary power and, moreover, was aware of the unconsented-to recovery and use of the tissue. Again, this is not usually the case with biologicals that are taken from the OR. The patient's usual presumption is that, pathological examination aside, the biologicals will be destroyed.

The **argument from abandonment** is based on the legal doctrine that if someone abandons something, the act of abandonment extinguishes all rights of control and possession. The doctrine of abandonment, however, only applies if the abandonment was intentional. Consequently, in order for this argument to apply to biologicals from the OR, the patient would have to be aware that there was a right of ownership or disposition and, moreover, that the biologicals would not in fact be destroyed but would be retained and used. Again, this is not usually the case. The standard assumption of patients undergoing removal of tissues or fluids in the OR is that these will either be destroyed directly upon completion of the procedure or that they will be destroyed after an examination for pathological indicators. Consequently, the argument from abandonment also fails because the presuppositions on which it is based are not met.

The **argument from *res nullius*** is based on the old Roman maxim that "Res nullius fit primi occupantis," or "What belongs to no-one falls to the dispositionary power of whoever first takes possession of it." The argument holds that since human biologicals are not property, there is no ownership or dispositionary right over them; consequently, whoever recovers them in the OR thereby acquires dispositionary power over them. In order for the argument to work, however, it has to make two assumptions: *first*, that only ownership can ground dispositionary power; and *second*, that the dispositionary power that the biologicals' originator has, prior to the removal, is extinguished upon removal of the biologicals. The first assumption is simply false. As diverse statutes and legal cases attest, everyone has a dispositionary power over their own body despite the fact that they do not own it. The second assumption simply asserts what the argument is supposed to prove. That is to say, it simply assumes that once tissue has been removed from the body of the patient it no longer falls under the control of the patient and therefore may be used without the patient's permission. Consequently, the argument from *res nullius* also fails.

Given the failure of these arguments in favour of non-consensual recovery and use of human biologicals, given also that these biologicals contain the potential for tremendous financial profit, and given further that the patient has ethically and legally recognized privacy interests in the information that can be derived from such materials, it would seem reasonable to conclude that consent must be acquired for any use of human biologicals taken from the OR, beyond those taken for pathological examination or destruction.

Conclusion

During the gold rush of the 19th century, the lure of profit gave rise to practices that ignored both ethics and law. "Claim jumping," where miners simply worked property that legally belonged to other miners, was not uncommon. In some instances, current practices surrounding the retrieval and use of human biologicals in the OR — the surgical "leftovers" — follow a similar pattern.

It is dangerous to assume that if the matter ever came to litigation, Canadian courts would follow the ruling in *Moore v. Regents of the University of California*.[16] In that case, the Supreme Court of California held that the patient whose spleen was removed as part of his treatment for hairy cell leukemia had no proprietary or dispositionary right in the tissue and therefore had no right to a share in the hundreds of millions of dollars of profit that flowed from the subsequent use of the MO cell line. In the first place, this is a US case and hence not binding on Canadian courts. Given that the Supreme Court of Canada refused to follow US precedent when it rejected a patent application for genetically modified animals,[19] it cannot be assumed, as a matter of course, that the Supreme Court would slavishly follow *Moore* in this instance. Secondly, the *Moore* case was decided without taking into account the patient's legally protected privacy interests. The Supreme Court of Canada, however, has repeatedly signalled that it places tremendous importance on these interests.[1,2] It is likely, therefore, that, at a minimum, the Court would require that these interests be protected.

Continued on Page 13

Thirdly, and perhaps most importantly, the Tri-Council Guidelines that are subscribed to by IPRE and CIHR make it very clear that non-consensual use of human biologicals is ethically unacceptable. These Guidelines, and the principles that underlie them, form the basis for all ethical review of contemporary Canadian research. Violating them runs the risk of severe administrative, financial and legal repercussions. Therefore even if institutions and researchers are not persuaded by ethical considerations, purely prudential considerations should persuade them to follow at least the spirit of the Guidelines. This holds true especially if the partners involved in any such recovery, research or use are international — as is the case in many research and commercial ventures. Not only are the Guidelines considered a model of research ethics, they also reflect international Conventions such as the Oviedo Convention.[20] Given the variations among legal provisions in different jurisdictions the only guarantee that one's practice will survive concerted scrutiny is to follow ethical principles.

REFERENCES

1. *R. v. Dyment* [1988] 2 S.C.R. 417

2. *R. v. Pohoretsky*, [1987] 1 S.C.R. 945.

3. *Personal Information Protection and Electronic Documents Act*, Statutes of Canada. 2000, c. 5.

4. *Reibl v. Hughes* (1980) 2 S.C.R. 880.

5. T. L. Beauchamp and J. F. Childress, *Principles of Biomedical Ethics (5th ed.)* (Oxford: Oxford Univrsity Press, 2001).

6. D.A. Dukelow, *The dictionary of Canadian law (3rd ed.)* (Scarborough, Ont. : Thomson Carswell, 2004).

7.G. Dworkin and I. Kennedy, Human Tissue: Rights in the Body and its Parts. *Medical Law Review* 1993 1: 291-319.

8. *Human Tissue Gift Act* [RSBC 1996] CHAPTER 211.

9. I. Husain, Transplant tourism. *Khaleej Times Online*, January 11, 2007 accessed at . http://www.khaleejtimes.com/DisplayArticleNew.asp?xfile=data/opinion/2007/January/opinion_January36.xml&section=opinion&col=

10. *Sydney Morning Herald,* April 1, 2007. (Associated Press) Transplant Tourism is on the Rise.

11. United Nations (1948). Universal Declaration of Human Rights: General Assembly Resolution 217 A (III). Accessed at http://www.un.org/Overview/rights.html

12. Uniform Law Conference of Canada. Human Tissue Donation Act (April, 1990) available at http://www.ulcc.ca/en/us/index.cfm?sec=1&sub=1h1

13. *McInerney v. McDonald* [1992] 2 S.C.R. 138.

14. Mawdsley v . Austin [1985] 1 W.W.R. 369 (B.C.S.C.).

15. Interagency Advisory Panel on Research Ethics, home pagehttp://www.pre.ethics.gc.ca/english/aboutus/aboutus.cfm

16. Canadian Institutes of Health Research, home page at http://www.cihr.ca/

17. *Tri-Council. Policy Statement: Ethical Conduct for Research Involving Humans*, accessed at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

18. *Moore v. Regents of U. of California* 793 P.2d 479 (Cal. 1990).

19. *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45

20. Council of Europe (1997). ETS no. 164: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, #25, 26, accessed at http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm