EDITORIAL

Ethical Issues Surrounding Body Integrity and Research

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In 'ethics', we are always guided by certain principles regarding how we should conduct ourselves in certain circumstances. Some professional organizations (*eg* doctors, nurses, lawyers) have developed *Codes of Ethics* that provide guidance (and reference points) on how their professionals should conduct themselves in certain situations. But what do we do when there are no written guidelines, and more than one ethical principle or theory may apply to our undertaking, and rather than being in concord, they are in opposition? The issue I examine here accords to human body tissue, and the approach pits deontological (duty-based) ethical theory against utilitarianism (the principle of utility – maximizing the good, happiness, or benefit).

Human body tissue and ethical considerations

Ethical issues surrounding human body tissue or fluid are good examples of this dilemma. Often bodily fluids and tissue (blood, serum, urine, stool and biopsy specimens) are collected normally for surveillance in public health or for testing in the clinical care of patients. However, the collection, storage and release of information regarding bodily tissue all carry ethical components (1). Of pivotal importance here, is the 'purpose' for which the bodily sample was taken from the individual in the first place. Was it taken on the basis of trust in the relationship between the doctor and the patient for his or her healthcare, or was it taken on the basis of a relationship between the researcher and the research participant?

These two conditions are underpinned by different ethical dictums. The relationship between the doctor and patient is underpinned by the dictates and obligations of *clinical ethics,* which is undergirded by Kant's ethical theory [duty-based dictates] (2). The relationship between the researcher and the research participant falls under the rubric of *research ethics* (3). Within the latter, the ethical concerns are particularly with notions of justice for the research participant (fair subject selection, protection from harm and proper compensation if harm occurs), matters of informed consent and a favourable risk/benefit ratio for the research endeavour.

The particular context and jurisdiction in which the bodily sample was taken also matter. The cultural value attached to tissues and samples may vary from country to country, and so the export of samples from one jurisdiction to another (*eg* across member states of the English-speaking Caribbean) raises several ethical issues, not the least of which is the matter of control over subsequent use. The absence of agreed-upon policies for tissue and sample export, sample handling and sample destruction can have deleterious repercussions (4). Further, fears that samples may take on monetary value in international research may aggravate such concerns.

Specific material transfer agreements (MTAs) that describe in detail the nature of the work to be carried out in foreign laboratories, as well as the procedures for the return of sample or sample destruction at the end of the particular project (whether sample testing or research) are therefore instrumental in reducing these concerns (5). Such MTAs not only protect the laboratory staff as well as researchers, but may also be beneficial in addressing the concerns of ethics committees regarding ownership, long-term storage and sample re-use.

The use of surveillance data and human tissue

Many persons are concerned about the issue of consent and the collection and use of surveillance data (4). In this regard, the paramountcy of the matter of consent in the areas of clinical care medicine and participation in research is widely acknowledged and accepted. However, some persons believe that it is far less clear whether people should necessarily have a similar authority and control over, for example, biological samples or medical data, particularly where these are anonymized, because it is more difficult to identify relevant harms under those circumstances. They think there are no significant harms involved when the data are suitably anonymized (6). For example, when blood is taken and screened for surveillance purposes, *eg* for HIV prevalence in newborns, there is controversy whether such blood can be stored and used for research without consent, after being unlinked and anonymized. There has also been some debate over whether a parent's consent should not also be required for any storage of blood (6).

This issue is very important, as often many persons do not conceive that any harm occurring or potential harm can be more than physical. Harm and potential harm to participants, whether in research or healthcare, may run the gamut of physical (as in pain or injury), psychological/emotional (as in guilt, anxiety, fear of needles or injection, or the potential loss of privacy or confidentiality), social (as in damage to

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one's network of friends, relationships, stigma and discrimination), legal (*eg* discovery of illegal substance abusers and prosecution for criminal conduct) and financial/economic [*eg* loss of earnings, employment, or access to insurance benefits] (7).

This ethical quandary regarding the possible use of blood from newborns has been addressed in some jurisdictions, *eg* in Scotland, by legislation that specifies that a parent's consent is required for each step of the process, from the taking of blood, its screening, its storage and any possible research on the stored blood tissue [or bodily fluid] (6). When this change in Scotland's legislation came about, however, more parents began to refuse the blood screening of their offsprings altogether, which became a cause for concern. Subsequently, new guidelines were issued stating that newborn blood may be used for research without individual informed consent where the samples have been anonymized and the research project has received ethical approval (6).

Research with body tissue and research ethics committees

A similar issue arose regarding research with human tissue, namely tonsils that were archived from individuals undergoing routine tonsillectomy in the United Kingdom (6). A Human Tissues Bill was drafted that required the consent of patients for storage and use of leftover tissue, but a lobby by the British Medical Association and the Royal College of Pathologists occurred, stating that such requirements were too costly in terms of money and the human resources required for administration, and so could jeopardize the future of this form of surveillance. The Bill was subsequently amended to allow such storage and use without consent, although with safeguards, including the requirements that the research be first approved by a research ethics committee, and that the samples be anonymized.

It is now well established and widely accepted that data-gathering activities about human beings which result in individuals being personally identifiable carry intrinsic risks that need specific safeguards. Where such activities will result in the generation of new knowledge, then they are classified as 'research.' However, whether samples to be taken will be anonymized, or the data of persons are to be securely stored, all research that involves human beings should be submitted to an independent research ethics committee for their determination of the risk/benefit ratio for the potential participants in the research (3). The challenge then for the research ethics committee will be to decide which ethical theory or dictum will dominate their decision-making.

Ethical theories in conflict

Kantian ethics, a deontological theory, says that some features of actions make them right or wrong, regardless of the outcomes they produce (2). So the means or 'route' taken to achieve a good outcome is more important than the good outcome itself. As a result, we *ought* to act in ways that we would want everyone to likewise act (the *maxim* rule), since such actions have moral worth and are based on *goodwill.* Further, we are obligated (duty-bound) to treat every person as having *moral worth* and so persons should be treated as 'ends' in themselves and never as a 'means' to a further end. Certainly, according to the dictates of Kantianism, we should respect people and never 'use' anybody for our own personal benefit or for the benefit of others (8).

Utilitarianism (a *consequence-based* ethical theory) holds that actions are right or wrong according to the *outcomes* or consequences they produce (9). It makes no moral provisions for the 'means' undergone to obtain that 'end'. Under this disposition, one has to balance possible good and bad consequences to determine the moral worth of an action. Utilitarianism therefore provides much strength and ethical justification in the formulation of public policy. It is *beneficence-based,* as it sees morality mainly in terms of the goal of promoting welfare (10). This ethical theory's main weakness in criticism, however, is that it does not cater to the needs or welfare of the individual or the minority [which is a 'justice' issue] (11).

The concept of moral harm

The approach of not seeking further consent for use after tissue storage has been criticized in certain quarters, particularly by people who place a greater emphasis on human dignity and perceived body integrity [the moral worth of a human being] (12). Whilst these various concepts are subject to cultural interpretation and varying actualization, in our Caribbean societies, we generally highly respect body integrity, as illustrated by many persons wishing to bury their deceased loved ones with all their organs intact [that is, families' reluctance to support organ donation] (13).

Aligned with the notion of moral worth, some people believe that individuals should have full control and determination over the use of their personal information (even if anonymized) and body tissue, and so informed consent should be sought for any use of these, otherwise *moral harm* or lack of respect for the dignity and integrity of the person occurs. In alternative bioethical language, these persons have been *wronged* if use is made of their tissue or personal information without their consent. Under this concept, the harm is not physical or social, as may occur when these persons are personally identifiable, but *moral*.

The approach of using anonymized data or body tissue for further testing and research is founded in the ethical theory of utilitarianism, which is primarily concerned with usefulness and outcomes, whether physical or social and maximizing benefit to large groups of persons (9, 10). This latter approach that is focussed solely on end results, however, does not take cognizance of the *means* to the end and the concept of 'respect for persons', with consequential *moral* harm occurring if permission was not obtained for use of their body tissue or personal information.

The ethical theory of deontology, on the other hand,

supports the approach of permission-seeking. Under this theory, you have the duty or obligation to respect the dignity of the individual and their body integrity, and not use them toward some perceived greater good. In other words, it dictates that persons should be viewed as 'ends' in themselves and not as a 'means' to a further end (where the end is maximizing benefit to others, according to utilitarianism).

Deontological theory would thus require that we seek further permission from people if we wish to do further tests or research on their stored body tissue. They have the ethical right to determine what happens to their personal information and parts of their body at every step of the process.

CONCLUSION

Ethics aims to tell us the best way of proceeding in a matter, and to provide us with strong ethics-based reasons for doing so. The ethical issues surrounding the use of human body tissues are complex. These include the particular context within which the body sample is taken, the ethical requirement to minimize harm at all times, the various possible types of consequential harms, the strategies undertaken to address ethical concerns and whether these are acceptable, and the predominant ethical theories or principles that will underpin decision-making.

In ethics, the ethical way forward depends on determining the specifics of each case, within the particular context. Therefore, whether it is ethical for stored body fluid or tissue to be used for research without the individual's informed consent will be determined by the particulars of the case, with the pertinent ethical principles applied. Ethicists or properly constituted research ethics committees may be consulted in such cases. Crucially, we should be aware of the various ethical issues involved and be guided to think deeply on such matters.

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