CHAPTER 2

PUBLIC HEALTH

Abraham Wai

2.1 INTRODUCTION

2.1.1 The concept of "public health"

Over the years, improvements in the health of the population have been achieved by a wide range of measures. These have included those delivered within a healthcare context, such as vaccination programmes, and those delivered in other ways, such as in the workplace, home and general environment. Infectious disease legislation[1] and improved housing and sanitation considerably reduced morbidity and mortality in Hong Kong in the nineteenth and twentieth centuries.

Internationally a number of academic institutions defined "public health". For example, the Faculty of Public Health of the Royal Colleges of Physicians, the United Kingdom (UK) defines public health as:

> "the science and art of preventing disease, prolonging life and promoting health through organized efforts of society".

World Medical Association, in its Statement on Health Promotion stated that:

> "the key functions of public health agencies are assessing community health needs and marschalling the resources for responding to them, developing health policy in response to specific community and national health needs, and assuring that conditions contributing to good health, including high-quality medical services, safe water supplies, good nutrition, unpolluted atmospheres and environments that offer opportunities for exercise and recreation are available to the individuals".[2]

CEA Winslow, professor of Public Health in Yale University reiterated it more clearly:

> "The science and art of (1) preventing disease, (2) prolonging life, and (3) organized community efforts for (a) the sanitation of the environment, (b) the control of communicable infections, (c) the education of the individual in personal hygiene, (d) the organization of medical and nursing services for the early diagnosis and preventive treatment of the disease, and (e) the development of the social machinery to ensure everyone a standard of living adequate for the maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity."[3]

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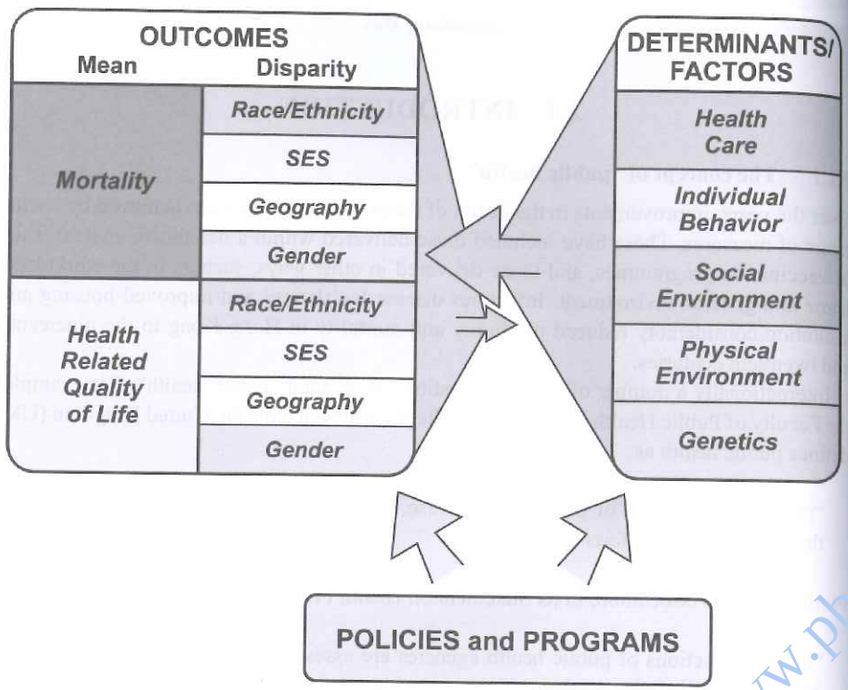
1 For example, the Contagious Diseases Ordinance 1867. Further example of early Hong Kong legislations related to health includes Dangerous Goods Ordinance 1873, Good Order and Cleanliness Ordinance 1844, Cattle Disease Ordinance 1885, Chinese Hospital Incorporation Ordinance 1870, and Oral Examination of Prisoners Ordinance (No 18 of 1873).

2 World Medical Association, World Medical Association Statement on Health Promotion (1995).

3 CEA Winslow, "The Untilled Field of Public Health". *Modern Medicine* 1920; 2:183–191.

2.1.2 Health determinants

Health outcomes, however defined and measured, are produced by determinants or factors. They often are sorted into the five categories presented on the right of the following model.



Source: http://www.improvingpopulationhealth.org/blog/what-are-health-factorsdeterminants.html

Healthcare determinants generally include access, cost, quantity and quality of healthcare services. Individual behaviour determinants include choices about lifestyle or habits (either spontaneously or through response to incentives) such as diet, exercise and substance abuse. Social environment determinants include elements of the social environment such as education, income, occupation, class and social support. Physical environment determinants include elements of the natural and built environment such as air and water quality, lead exposure and the design of neighbourhoods. Genetic determinants include the genetic composition of individuals or populations.

In the model above, each category is depicted as the same size, implying that they each contribute equally to health outcomes. Although useful for illustration, in reality those determinants will carry different weights (and hence would be different sizes). Differences exist depending on the population studied and because cross-sectoral analysis is complicated by interactions between determinants and the latency over time of their effects.

It is important, too, to realise the presence of "reverse causality", which is why there is a small arrow in the above model going from outcomes to determinants or factors. This reflects the fact that outcomes such as morbidity can produce a change in a determinant or risk factor. For example, childhood illness can be responsible for lower educational attainment. In this case, the definitions of outcomes and determinants are reversed; morbidity would

be the determinant or factor and educational attainment the outcome. Separating out the different directions of causality is an important and difficult research challenge.

2.1.3 Public goods and public services

In economics, a "public good" is a good ie, both non-excludable and non-rivalrous in that individuals cannot be effectively excluded from use and where use by one individual does not reduce availability to others.[4] Gravelle and Rees states:

> "The defining characteristic of a public good is that consumption of it by one individual does not actually or potentially reduce the amount available to be consumed by another individual."

Public goods have, for centuries, been part of the economic analysis of government policy at the national level. As globalisation progresses, it is becoming clear in many areas that matters which were once confined to national policy are now issues of global impact and concern. The term "public good" is also often used to denote what is better described as "public services": resources or institutions that respond to important needs of members of the population, and that are managed by the state in a way that ensures that the needs are addressed in a fair and effective manner. In this sense, public services are a facility or resource ie, valuable to all citizens, although its availability is not necessarily unlimited or free of charge.

The public health system in Hong Kong is provided by the Department of Health (DH) and the Hospital Authority (HA). Although part payment is required for some services, currently a wide range of core public health services are provided "free at the point of need" to all, irrespective of sex, age, risk assessments or socio-economic status, which is not available in many jurisdictions whose health system is heavily privatised. Universal access to healthcare services, however, is one of key roles of the public health system.

2.2 AN ETHICAL FRAMEWORK

Public health programmes focus on the population level. These are usually preventive measures. The affected population usually does not perceive themselves in any health issues. As a result they raise issues about the responsibilities and authority of the state and other agents whose policies and actions shape or affect people's lives, depending on the kind of intervention, the situation of those most directly affected by it and the seriousness of the risks involved in implementing, or not implementing, a certain programme.

Public health practitioners make ethical decisions with significant implications, knowingly or otherwise, from time to time. For example, allocation of resources to disadvantaged groups, mass health programme design or service reprovision, are all ethical decisions. We are probably acting because we think it is "the right thing to do" or "just common sense". Each of these actions can be linked to a well-established set of moral ideas: respectively, the importance of distributive justice or fairness, a commitment to achieving the greatest good for the greatest number and the

4 For current definitions of public goods, see any mainstream microeconomics textbook, eg Hal R Varian, *Microeconomic Analysis* (New York: W. W. Norton & Company, 3rd ed., 1992); Andreu Mas-Colell, Whinston and Green, *Microeconomic Theory* (Oxford: Oxford University Press, 1995) or Gravelle and Rees, *Microeconomics* (Essex: Prentice Hall; Finanacial Times, 3rd ed., 2004).

belief that we have a right to limit someone's freedom if he is doing harm to others. These ideas are deeply embedded in our social and professional culture but are rarely made explicit.

2.2.1 State–citizen relationship

Political philosophy helps understand the relationship between the state, the government, the intermediate bodies, such as institutions and companies governed, and the public. A number of schools of thought exist. The *libertarian* perspective affirms what are classically regarded as the universal "natural" rights of man, including life, liberty and property. States are there only to ensure that people enjoy these rights without interference from others. The state's legitimate activities comprise only political institutions, which provide authoritative statements of individual rights; judicial institutions, which determine when these rights have been violated and penal institutions to punish those who are found to have committed such violations. The promotion of the welfare of its population is not regarded as a proper role for the libertarian state.

Collectivist view, however, includes utilitarianism and social contract theory. Utilitarian traditions aim primarily to maximise utility by focusing on achieving the greatest possible collective benefit, meaning that actions or rules are generally measured by the extent to which they reduce suffering and promote overall "good health". Hence, when choosing between several competing public health programmes, states and policymakers should prioritise them according to their likelihood in producing the greatest aggregate benefit.

Social contract theory suggests that the state's authority is based on the collective will of a community to cohabit as an enduring nation state, which in turn determines the extent of rights of individual citizens. On this view, these rights do not constitute a limit to the state's authority to intervene in the lives of its citizens; instead, the state's authority is properly exercised in that it realises the collective will of the community. This position will typically favour measures to promote the welfare of its citizens, including public goods and services of all kinds.

In liberal states, the protection of individual freedom constrains the state's authority, as suggested by libertarians. Instead of agreeing that legitimate state power is restricted to protection of these freedoms, liberal states adopt the social contract version of collectivism that the state's power may rightly be used to advance the welfare of its citizens. The liberal will generally reject the utilitarian claim that it is acceptable, without further argument, to pursue beneficial interventions, even if these significantly affect the liberty of some individuals. Thus, for the liberal state, some interventions to promote the interests of the population may be acceptable without providing further justification (such as ensuring opportunities for health for the disadvantaged and vulnerable), whereas other interventions require explicit justification or may simply not be acceptable at all.

One way to start thinking about resolving the tension between the promotion of public health and the protection of individual freedom is provided by the famous "harm principle" advanced by John Stuart Mill in his essay *On Liberty*:

> "The object of this Essay is to assert one very simple principle, as entitled to govern absolutely the dealings of society with the individual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties, or the moral coercion of public opinion. That principle is, that the sole end for which mankind are warranted, individually or collectively in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil, in case he do otherwise. To justify that, the conduct from which it is desired to deter him must be calculated to produce evil to someone else. The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. Over himself, over his own body and mind, the individual is sovereign."[5]

Even in an approach that seeks to ensure the greatest possible degree of individual liberty and the least possible degree of state interference, where the purpose is to prevent harm to others, coercive, liberty-infringing state intervention is still acceptable.

2.2.2 Liberalism in public health issues

Mill's harm principle has its own limitation, and public health policy may extend beyond merely preventing harm to others. While Mill stated that his principle was applicable only to "human beings in the maturity of their faculties", and he goes on to say:

> "We are not speaking of children, or of young persons below the age which the law may fix as that of manhood or womanhood. Those who are still in a state to require being taken care of by others, must be protected against their own actions as well as against external injury."[6]

So Mill recognises that the state can rightfully intervene to protect children and other similar vulnerable people. Mill also believed that the individual liberty is secured to enhance "utility", or "the interest of society".[7] In the context of public health policy, this provision is especially important as such policy is often directed at public good and services.

Although Mill's harm principle strongly opposes public health programmes which simply aim to coerce people to lead healthy lives, it also recognises the importance of making an informed decision on their public and private life, through education and information. Therefore, programmes that "advise, instruct and persuade"[8] the public for an informed decision align with Mill's harm principle.

Mill's emphasised the exercise of freedom in the construction of one's personal life. All interventions in personal life, even with good intention to reduce health risks to others, carry a significant ethical cost. The public authority should therefore scrutinise its initiative or intervention for minimal intrusion and directive to individual's freedom.

Based on these rationales, in its report in 2007, the Nuffield Council on Bioethics proposed an initial liberal ethical framework for public health programmes, which includes certain goals and constraints which cover Mill's harm principle and the limits.[9] Having considered

5 JS Mill, "On Liberty" in S Collini (ed), *On Liberty and Other Essays* (Cambridge: Cambridge University Press, 1989) p.13.
6 *Ibid.*
7 *Ibid.*, p.14.
8 *Ibid.*, p.95.
9 Nuffield Council on Bioethics, *Public Health: Ethical Issues* (London: Nuffield Council on Bioethics, 2007) pp.17–18.

various factors, including individual autonomy, social inequalities, the changing habits and the limits of information-only approaches and the social consideration, it further suggests the stewardship model, which means liberal states have responsibilities to look after important needs of people both individually and collectively, to improve the initial liberal framework. Therefore, they are stewards both to individual people, taking account of different needs arising from factors such as age, gender, ethnic background or socio-economic status, and to the population as whole, including both citizens of the state and those who do not have citizen status, but fall under its jurisdiction. The World Health Organization (WHO) explained the concept of stewardship:

> "Stewardship is the overarching function that determines the success or failure of all other functions of the health system. It places the responsibility back on government and calls for the strengthening of ministries of health. However, it does not call for necessarily a hierarchical and controlling role of government but more of that of overseeing and steering of the health system. It calls for vision, setting of regulations and implementing them, and the capacity to assess and monitor performance over time. A strong stewardship should in fact permit a more efficient use of the private sector to meet the needs of the health system."[10]

Therefore, the notion of stewardship gives expression to the obligation on states to seek to provide conditions that allow people to be healthy, especially in relation to reducing health inequalities. In fact, the state needs to take a more active role in promoting the health of the population than was envisaged in the initial liberal framework. Health-promoting public policies should include appropriate access to medical services, programmes to help people combat addictions and support to healthy lifestyles. Democratic and transparent decision-making procedures can often ensure an appropriate balancing of the interest of individuals and those of society.

This stewardship model is not paternalistic because it is less likely to support highly coercive universal measures. Instead, it is more sensitive to the need to respect individuality, by seeking the least intrusive way of achieving policy goals, taking into account also the criteria of effectiveness and proportionality. It is also more sensitive than paternalism to the concept of mandate, and the need for policies to be adequately justified. It recognises the importance of open and transparent participatory processes as a necessary condition for public health policymaking, but it is also clear that these are not sufficient by themselves. Stewardship is not exercised simply by following the public vote, especially where issues involve complex scientific evidence. Under the stewardship model, public health policy should be compatible with the views of the public, and the government should create conditions that allow the public to scrutinise and judge the appropriateness of proposed polices.

While Mill's harm principle is a central part of the approach and usually provides the strongest justification for public health interventions, several important issues in public health can be addressed by referring to the classical harm principle alone; however, there is also a range of cases where the classical harm principle is of limited use, and this is where the stewardship model as a whole provides a particularly suitable reference framework.

10 WHO, *World Health Report 2000* (Geneva, Switzerland: WHO, 2000).

"Concerning goals, public health programmes should:

- aim to reduce the risks of ill health that people might impose on each other;
- aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;
- pay special attention to the health of children and other vulnerable people;
- promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;
- aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;
- ensure that people have appropriate access to medical services; and
- aim to reduce unfair health inequalities.

In terms of constraints, such programmes should:

- not attempt to coerce adults to lead healthy lives;
- minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements (such as democratic decision-making procedures) which provide adequate mandate; and
- seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values."[11]

2.3 POLICY FRAMEWORK AND PRACTICE

Seeking change in public policy is a key public health strategy to protect and promote the health of the public. The policy advice and analysis provided by public health must be premised on the best available evidence. However, as "health is largely constructed outside the health sector",[12] any health policy decisions on public health that is seeking to influence often involve multiple levels of government and other organisations. The main elements that need to be considered in any public health policy include the nature of evidence, the perception of risk and the notion of a precautionary approach.

2.3.1 Evidence

The concept of evidence-based medicine (EBM) has grown in prominence in recent years.[13] According to one definition, EBM is:

> "the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. Current best evidence is up-to-date information from relevant, valid research about the effects of different forms of

11 Nuffield Council on Bioethics, *Public Health: Ethical Issues* (n.9 above).
12 E Ollila, "Health in All Policies: From Rhetoric to Action". *Scand J Public Health* 2011; 39(6 Suppl):11–18.
13 G Taubes, "Looking for the Evidence in Medicine," *Science* 1996; 272:22–24; DL Sackett *et al.*, "Evidence-based Medicine: What It Is and What It Isn't". *British Medical Journal* 1996; 312:71–72.

health care, the potential for harm from exposure to particular agents, the accuracy of diagnostic tests, and the predictive power of prognostic factors."[14]

EBM involves the delivery of optimal individual patient care through the integration of current best evidence on pathophysiological knowledge, cost-effectiveness and patient preferences. Necessary EBM skills include the ability to track down, critically appraise and rapidly incorporate scientific evidence into a clinician's practice. Key steps in the EBM process[15] include the abilities to:

(1) convert information needs into answerable questions;
(2) track down, with maximum efficiency, the best evidence with which to answer these questions (from the clinical examination, the diagnostic laboratory, the published literature, or other sources);
(3) critically appraise that evidence performance for its validity (closeness to the truth) and usefulness (clinical applicability);
(4) apply the results of this appraisal in clinical practice; and
(5) evaluate performance.

Brownson[16] define evidence-based public health (EBPH) as:

"the development, implementation, and evaluation of effective programs and policies in public health through application of principles of scientific reasoning including systematic uses of data and information systems and appropriate use of program planning models".

In EBPH, the most viable approach to a public health problem is chosen from among a set of rational alternatives. This process relies on several related disciplines including epidemiology, biostatistics, behavioural sciences, health economics and healthcare management. Any process or method that is established should recognise that public health practitioners often have substantial administrative duties; therefore, EBPH must be time-efficient.

Public health interventions such as education and behavioural change programmes are not invasive and might be viewed as unlikely to cause any harm on first impression. However, there is evidence that some may do so.[17] There is a duty on those introducing such measures to monitor their actual impact over appropriate time frames, rather than simply assuming they are beneficial.

14 National Institute of Public Health, Oslo, Norway, First Annual Nordic Workshop on How to Critically Appraise and Use Evidence in Decisions about Healthcare (1996).

15 DL Sackett and WMC Rosenberg, "The Need for Evidence-based Medicine". *Journal of the Royal Society of Medicine* 1995; 88:620–624.

16 RC Brownson, JG Gurney and GH Land, "Evidence-based Decision Making in Public Health". *J Public Health Management Practice*, 1999; 5(5):86–97.

17 For example, training children in bicycle safety has been shown in some instances to have increased accident rates among children who cycle (probably because they or their parents became more confident after the training and they were then exposed to more risks). The "Bike ed" programme in Australia, designed to reduce cycle injuries, actually increased the risk of injury overall, doubling it in boys. Furthermore, the most adverse effects were observed among younger children, children from families with lower parental education and children who lacked other family members who cycled, thereby increasing socio-economic and gender inequalities which are particularly marked in any case for childhood injuries. The implications of this observation are that well-intentioned and plausible interventions, even of a non-invasive kind involving only education, can do unanticipated harm.

Moreover, the design of such interventions, where the exact weight and role of different factors may not be clear-cut from the outset, often requires a different kind of approach to evidence-gathering. The assessment of both evidence about causes and evidence of effective interventions needs to be sensitive to the specific issues raised in that particular area of public health.

The adoption of an evidence-based approach brings with it certain assumptions as to what constitutes good evidence, and it is important to scrutinise carefully any source of evidence. The minimum hurdle for evidence to be reported (or to be considered in public health policy more generally) is that it should be published in the peer-reviewed literature or it must have been subject to an equivalent scrutiny by expert peers, which suggests a certain robustness as findings are scrutinised by experts in the field and research is repeatable. It is important to understand that "the absence of evidence" is not equivalent to "the evidence of absence". It is generally accepted that it is very difficult to prove a negative, and the "no evidence" proposition should always be accompanied by both a summary of what has been done to look for a risk and the qualification that there can be no absolute certainty. Even where every reasonable step has been taken to ensure that evidence is robust, in practice, it is often incomplete or ambiguous and usually will generate doubt from some stakeholders. Thus, scientific evidence does not necessarily lead to the most crystal clear and effective policy. Decision to choose among competing public policy options are often needed to be made in rush, allowing little time for bureaucratic rationality, not even a thorough reassessment of evidence or more information gathering.

2.3.2 Risk

In addition to evidences, the decision maker has to consider the nature and the extent of the risk involved, which is the probability of an event occurring in relation to the severity of the impact of the event. He should estimate the magnitude of the risk by means of scientific and technical assessment. However, it is noted that statistical measures of risk is only part of the consideration. In fact, perceptions of risk always vary with people's value judgements.

Public perception of a risk is influenced by how familiar is the topic to the population. The subjectivity of public perception may go opposite to the scientific evidence. For example, the higher cancer risk of smoking has been accepted by the public, but the low risk of Guillain-Barré syndrome from vaccination generated great public concern. Where hazards are familiar; are perceived as being under the individual's control; are natural rather than man-made; or the consequences are only seen much later, they are often considered to be more acceptable.[18] Two particularly important factors are the possible scale of harm, for example where consequences are perceived as "catastrophic", and "unknowable risks", where people feel insufficiently qualified to judge the likelihood of the occurrence of a bad event.

The base-rate fallacy influences the risk perception as well. Risks are often misinterpreted when presented as percentages or probabilities. For example, if a cancer-screening programme is reported to reduce the risk of dying from breast cancer by 25 per cent, how many lives are saved? Is it 25 out of every 100 women? In reality, the correct answer depends on the overall frequency of deaths from breast cancer in the female population (the base rate). If, for example, the overall mortality rate is four in 1,000, the 25 per cent reduction in risk from screening is from four to three per 1,000 women, or 0.1 per cent.[19]

18 House of Commons Science and Technology Committee, Scientific Advice, Risk and Evidence Based Policy Making (2006), available at http://www.publications.parliament.uk/pa/cm200506/cmselect/cmsctech/900/900-i.pdf, p.95; SE Hampson, HH Severson, WJ Burns, P Slovic and KJ Fisher, "Risk Perception, Personality Factors and Alcohol Use among Adolescents". *Personality and Individual Differences* 2001; 30:167–181.

19 G Gigerenzer, *Reckoning with Risk* (London: Penguin Books, 2002) pp.59–60.

CHAPTER 5

CONFIDENTIALITY

David Wong

5.1 WHY IS CONFIDENTIALITY RELEVANT TO HEALTHCARE?

It is general knowledge and understanding as well as trite law that there is a common law duty for a doctor to respect the confidence of his patients. This is an obligation that applies to all confidential information and is not restricted only to medical material.

The duty is not only due to the protection of patient's right to privacy. Patients deserve confidence in providing healthcare personnel their personal and private matters. For many types of treatment, full disclosure and cooperation by the patient are essential which can only be found in a well-established doctor–patient relationship.

It is illustrative to start with a real example. In *HKSAR v Tsun Shui Lun*,[1] a research assistant was convicted of obtaining unauthorised access to a computer with a view to dishonest gain for himself, contrary to s.161(1)(c) (access to computer with criminal or dishonest intent) of the Crimes Ordinance (Cap.200) and was sentenced to six months imprisonment. He later appealed against both conviction and sentence. What transpired concerned the radiology report of the then Secretary for Justice, who was undergoing treatment for a condition at Queen Mary Hospital. The report exposed the diagnosis of the condition from which the Secretary was suffering to the *Ming Pao* and *Apple Daily* newspapers, which they published the following morning. Although it was found that there was no financial or proprietary gain or loss to others, there was no doubt a breach of trust, breaching of the patient and doctor confidentiality and what was done seriously undermined public confidence in the medical profession. There was also intrusion into the privacy of a patient. Patrick Chan CJHC did not allow the appeal against conviction.

The potential seriousness of a breach of the confidentiality obligation can thus be appreciated.

5.2 WHAT IS CONFIDENTIALITY?

The medical practitioner enjoys privileged rights to gain information of patients that are strictly private and personal. This may be understood to be a result of necessity because of the obligation of the doctor or healthcare worker to offer the most appropriate advice or treatment. It is essential for a doctor to have full knowledge of the patient's health-related matters so that an accurate decision could be made for treatment. Management also often entails tailoring of a treatment programme to the particular needs of the patient.

A good example would be a microbiologist asking about travelling history in a patient with a suspected unusual infection, a gynaecologist digging into the sexual aspects of the past history in a patient with pelvic inflammatory disease, a doctor might need to know if a gentleman with

1 [1999] 3 HKLRD 215.

micturition problems have had urethritis from past venereal exposure or a psychiatrist may need to learn about the childhood upbringing of a client with neurotic problems.

In disclosing private personal history to a healthcare worker, the patient bases his reliance on trust and confidence.

5.3 THE BASIS OF THE DUTY

5.3.1 The ethical sources of the duty

The basis of the duty of confidentiality originated from ethical principles. The latter were later reinforced by the common law.

5.3.1.1 *The Hippocratic Oath*

The obligation was evidenced in the Hippocratic Oath of 500 BC. The last of the several listed covenants in the original version of the Oath stated:

> "Whatever, in the course of my practice, I may see or hear (even when not invited), whatever I may happen to obtain knowledge of, if it be not proper to repeat it, I will keep sacred and secret within my own breast".[2]

This promise survived the 1948 modification of the Hippocratic Oath in the Declaration of Geneva as its fifth requirement:

> "I will respect the secrets that are confided in me, even after the patient has died".[3]

The modified document is sometimes also referred to as the Physicians' Oath. This statement has remained unchanged in the latest 2006 version, despite amendments to the rest of the oath.

The Hippocratic Oath and the Geneva modification represent today's declaration of the physicians' dedication to the humanitarian goals of medical science and practice.

To modern-day healthcare workers, it is the professional conduct guidelines issued by the regulatory bodies overlooking the professions that are the most directly ethically binding.

5.3.1.2 *International Code of Medical Ethics*

The latest version of the International Code of Medical Ethics,[4] as adopted and published by the World Medical Association in 2006, has the following to say under the duties of physicians to patients:

> "A PHYSICIAN SHALL respect a patient's right to confidentiality. It is ethical to disclose confidential information when the patient consents to it or when there is a real and imminent threat of harm to the patient or to others and this threat can be only removed by a breach of confidentiality".

2 C James, "The Hippocratic Oath". *The London Medical Repository* 23(135):258, also available at https://en.wikipedia.org/wiki/Hippocratic_Oath (visited 19 April 2016).

3 *Ibid.*

4 Adopted by the 3rd General Assembly of the World Medical Association (London, England, October 1949) and subsequent amendments.

The International Code of Medical Ethics is endorsed by the Medical Council of Hong Kong, except where the contrary intention appears from the context of the Code of Professional Conduct.[5] The Council will have regard to the International Code in the exercise of its disciplinary power.

5.3.1.3 *Code of Professional Conduct of the Medical Council of Hong Kong*

The regulatory body of each country or region is responsible for the registration, licencing and discipline of members under its jurisdiction. The General Medical Council (GMC) of the United Kingdom (UK) has very comprehensive stipulations on the issue of patient confidentiality. A strict duty is imposed on all registered medical practitioners to refrain from unauthorised disclosure of information of patients acquired in the professional setting to any third party.

Similarly, the Medical Council of Hong Kong has its own stipulations in the Code of Professional Conduct for the Guidance of Registered Medical Practitioners (the Code). The 2009 version of the Code was updated since by a number of revised provisions via the Council's newsletters and website. In January 2016, these revisions were all incorporated into an updated print version of the Code 2016.

The Code has stipulations on confidentiality in Pt.II Sections A and I. The relevant statements in Section A are as follows:

> "A. PROFESSIONAL RESPONSIBILITIES TO PATIENTS
>
> 1. Medical records and confidentiality
>
> 1.1 Medical records
>
> 1.1.1 The medical record is the formal documentation maintained by a doctor on his patients' history, physical findings, investigations, treatment, and clinical progress. It may be handwritten, printed, or electronically generated. Special medical records include audio and visual recording.
>
> 1.1.4 All medical records should be kept secure. This includes ensuring that unauthorized persons do not have access to the information contained in the records and that there are adequate procedures to prevent improper disclosure or amendment. Medical records should be kept for such duration as required by the circumstances of the case and other relevant requirements.
>
> 1.1.5 Doctors should have due regard to their responsibilities and liabilities under the Personal Data (Privacy) Ordinance (Cap.486), in particular, patient's rights of access to and correction of information in the medical record and the circumstances under which doctors may refuse to entertain such requests.
>
> 1.2 Medical examination and subsequent reporting
>
> 1.2.1 Whenever a doctor conducts a health check-up on a person there exists a doctor-patient relationship which should be respected at all times. The medical information should not be disclosed to a third party without the prior consent of the patient. If consent is withheld or withdrawn, the doctor must respect this except in the circumstances set out in section 1.4.2.

5 Code of Professional Conduct of the Medical Council of Hong Kong (January 2016).

1.3 Handling of medical records upon transfer or cessation of practice

1.3.3 The doctor who assumes custody of the medical records has a responsibility to inform the patient of the transfer of the record to him either upon enquiry or upon the patient attending his practice. He must seek the patient's consent to his taking over the patient's medical care and his custody of the medical record. Before such consent is obtained, the succeeding doctor should not make reference to the patient's medical record under his custody unless it is in the best interest of the patient to do so.

1.4 Disclosure of medical information to third parties

1.4.1 A doctor should obtain consent from a patient before disclosure of medical information to a third party not involved in the medical referral.

1.4.2 In exceptional circumstances medical information about a patient may be disclosed to a third party without the patient's consent. Examples are: (i) where disclosure is necessary to prevent serious harm to the patient or other persons; (ii) when disclosure is required by law.

1.4.3 However, before making disclosure without the patient's consent a doctor must weigh carefully the arguments for and against disclosure and be prepared to justify the decision. If in doubt, it would be prudent to seek advice from an experienced colleague, a medical defence society, a professional association or an ethics committee".

And in Section I,

"I. SERIOUS INFECTIOUS DISEASE

32. Confidentiality

32.1 In any given case when it appears that others, i.e. spouses, those close to the patient, other doctors and health care workers, may be at risk if not informed that a patient has a serious infection, the doctor should discuss the situation fully and completely with the patient laying particular stress, in the case of other medical or allied health staff, on the need for them to know the situation so that they may, if required, be able to treat and support the patient. In the case of spouses, or other partners, similar considerations will apply, and the doctor should endeavour also to obtain the patient's permission for the disclosure of the facts to those at risk.

32.2 Difficulties may clearly arise if the patient, after full discussion and consideration, refuses to consent to disclosure. If mutual trust between doctor and patient has been established such a case will, hopefully, be rare. In this case, it is covered by the general ethical standards of the profession and the refusal should be respected. Should permission be refused, however, the doctor will have to decide how to proceed, in the knowledge that the decision reached, may have to be justified subsequently. If the welfare of other health workers may be properly considered to be endangered, the Council would not consider it to be unethical if those who might be at risk of infection whilst treating the patient were to be informed of the risk. They in their turn would, of course, be bound by the general rules of confidentiality.

32.3 In the exceptional circumstances of spouses or other partners being at risk, the need to disclose the position to them might be more pressing, but here again the doctor should urgently seek the patient's consent to disclosure. If this is refused, the doctor may, given the circumstances of the case, consider it a duty to inform the spouse or other partner.

32.4 Doctors involved in the diagnosis and treatment of HIV infection or AIDS must endeavour to ensure that all allied health and ancillary staff, e.g. in laboratories, fully understand their obligations to maintain confidentiality at all times".

5.3.2 Local institutional policies

In addition, it is common to have institutional guidelines and policies adopted that are regularly updated, eg hospitals under the Hospital Authority (HA), private hospitals and clinics, and government-run healthcare delivery facilities under the Department of Health. Statements to the effect of the confidentiality requirements are usually also present either in the contract of employment or in codes of conduct for staff in various institutions. For more senior positions, further restrictions may be stipulated when staffs leave the service and sometimes there are litigations on whether restraints imposed are reasonable as to the time duration or the geographical extent and so forth.

5.3.3 Equity and the common law

The law of confidence originated from the principles of equity. The Lord Chancellor in *Prince Albert v Strange*[6] granted an injunction to restrain the publication of a catalogue which would have exposed details of the original etchings of Prince Albert stolen from him. Lord Cottenham noted: "But this case by no means depends solely upon the question of property; for a breach of trust, confidence, or contract, would of itself entitle the plaintiff to an injunction". The Lord Chancellor reckoned that there was a public interest in keeping confidential information secret.

The common law on the topic of confidentiality is very rich and informative. The substance in those judgments provides pervasive elaborations as to the requirements under the duty.

AB v CD[7] is an often-quoted old-time case to start with. A claim was made against a medical practitioner for divulging the confidential nature of the findings of a medical consultation to the church committee resulting in the dismissal of an elder. The elder had a child born to him six months after marriage and wanted to arrange for baptism for the child. He tried to retain the defendant doctor to certify that it was a case of prematurity. The latter was actually of the opinion that the child was conceived before the marriage and he recorded so faithfully in his report. That report was delivered to the Church Minister instead of the elder and the information therein was recorded in the minutes of the Church's meetings. The action was an alleged breach of professional confidence for damages. Lord Cowan decided

6 (1849) 1 Mac & G 25, 41 ER 1171.

7 (1851) 14 D 177.

that the doctor's findings were of confidential nature and since "secrecy was an essential condition of the contract between a medical man and his employers, the breach of secrecy afforded a relevant ground for an action of damages".

Another later *AB v CD*,[8] was also a decision of the Court of Session of Scotland. Here a doctor was asked by a lady to testify for her physical health to support her argument of having been ill-treated by her husband with a view to obtain a divorce. In the consultation, the doctor obtained information concerning the past health of the woman, including her habit of opiate consumption, and opined to refer her to a nursing home. Two years later, the same doctor accepted the instruction of the woman's husband to be his expert witness in court and arranged to examine the woman. The applicant's contention was that the doctor had communicated her confidential matters to the husband and then openly disclosed the same in court. The Law Justices stated unanimously that statements made when under examination as a witness in the witness box were absolutely privileged, including answers to the questions posed. The exception would be where the witness gives expression to a calumnious statement altogether irrelevant to the subject matter of the case in which he was being examined. As to the release of confidential information to the husband, it was remarked that not every breach of confidence was actionable. Lord Trayner explained:

> "A statement… may be indiscreet, but not actionable. For example, if a medical man said to A that he had been called in to see B, and on being asked by A what was the matter with B, he replied that he was labouring under a severe cold - that would not be actionable. On the other hand, if he stated that B was labouring under some malady, the consequence of misconduct, that would or might be actionable".

In this case, it appears that Lord Trayner was indicating that only slanderous remarks were potentially actionable breaches.

Sir Nicolas Browne Wilkinson V-C said in *Stephens v Avery*:[9]

> "The basis of equitable intervention to protect confidentiality is that it is unconscionable for a person who has received information on the basis that it is confidential subsequently to reveal that information".

In a much more recent case, *Campbell v MGN Ltd*,[10] Baroness Hale's speech further elaborated on the point:

> "It has always been accepted that information about a person's health and treatment for ill-health is both private and confidential. This stems not only from the confidentiality of the doctor-patient relationship but from the nature of the information itself. As the European Court of Human Rights put it in *Z v Finland* 25 EHRR 371, 405-406, para 95:
>
> > 'Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention. It is crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general. Without such protection, those in need of medical assistance may be deterred from revealing such information of a personal and intimate nature as may be necessary in order to receive appropriate treatment and, even, from seeking such assistance, thereby endangering their own health and, in the case of transmissible diseases, that of the community'."

8 (1904) 7 F 72.
9 [1988] Ch 449.
10 [2004] 2 AC 457.

In *Douglas v Hello! Ltd*,[11] the approach of Lindsay J at first instance was endorsed by Lord Hoffmann and Lord Brown in the House of Lords:[12]

> "111. Lindsay J held Hello! liable for breach of confidence. He applied the well-known criteria summarized by Megarry J in *Coco v AN Clark (Engineers) Ltd* [1969] RPC 41, 47:
>
> > 'First, the information itself… must "have the necessary quality of confidence about it". Secondly, that information must have been imparted in circumstances importing an obligation of confidence. Thirdly, there must be an unauthorised use of that information to the detriment of the party communicating it'".

It is important to distinguish breach of confidence from breach of privacy as the two are often mixed up. Readers will recall that *Douglas v Hello! Ltd* referred to a series of cases concerning the argument between two magazines over the right to publish the wedding party photographs of Michael Douglas and Catherine Zeta-Jones, as the Douglases had contracted beforehand with *OK! Magazine* giving the company exclusive rights to publish those pictures. The explanation of Lord Hoffmann is illuminating:[13]

> "118. It is first necessary to avoid being distracted by the concepts of privacy and personal information. In recent years, English law has adapted the action for breach of confidence to provide a remedy for the unauthorized disclosure of personal information: see *Campbell v MGN Ltd* [2004] 2 AC 457. This development has been mediated by the analogy of the right to privacy conferred by Article 8 of the European Convention on Human Rights and has required a balancing of that right against the right to freedom of expression conferred by Article 10. But this appeal is not concerned with the protection of privacy. Whatever may have been the position of the Douglases, who, as I mentioned, recovered damages for an invasion of their privacy, *OK!*'s claim is to protect commercially confidential information and nothing more. So your Lordships need not be concerned with Convention rights. *OK!* has no claim to privacy under Article 8 nor can it make a claim which is parasitic upon the Douglases' right to privacy. The fact that the information happens to have been about the personal life of the Douglases is irrelevant. It could have been information about anything that a newspaper was willing to pay for. What matters is that the Douglases, by the way they arranged their wedding, were in a position to impose an obligation of confidence. They were in control of the information".

11 [2008] 1 AC 1.
12 *Ibid.*, [111].
13 *Ibid.*, [118].

5.3.4 Treaties and statutes

5.3.4.1 *European Convention on Human Rights*

Douglas v Hello! Ltd[14] touched on the influence of human rights considerations. The European Convention on Human Rights (ECHR)[15] was incorporated into UK law by the Human Rights Act 1998. The relevant provision in the European Convention is art.8 (the right to respect for private and family life):

> "(1) Everyone has the right to respect for his private and family life, his home and his correspondence.
> (2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others".

Paragraph 2 of art.8 thus provides for the exceptions allowed under the Convention which would override the interest in upholding the fundamental right to enjoy respect for private and family life.

The right to freedom of expression in art.10 says:

> "(1) Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.
> (2) The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary".

Again, art.10 comes with a para.2 which provides for the exceptions allowed, the most relevant of which here would be "for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence".

5.3.4.2 *Personal Data (Privacy) Ordinance*

The ethical requirement has now been supplemented by the Personal Data (Privacy) Ordinance (Cap.486) (PD(P)O). The statute prohibits the use of information for any purpose other than that at the time of collection. It therefore includes in its ambit the restriction of subsequent communication of confidential information to a third party.

14 [2008] 1 AC 1.
15 Convention for the Protection of Human Rights and Fundamental Freedoms, also known as the European Convention on Human Rights.

It is important to start with a clarification of words. The word "privacy" has entered everyday language and sometimes there is a tendency to simply take it as meaning the same as confidentiality. It is true that both privacy and confidentiality restrict the flow of secretive information in relation to an individual or entity. Privacy is, however, concerned with rights particularly in relation to freedom from surveillance and decision on how private information should be managed. Confidentiality, as discussed in our context, is an obligation owed. It should also be noted that there are different spheres of privacy. Physical privacy is concerned with the freedom from intrusion into one's physical territory in a broad sense; organisational privacy is related to measures and strategies on confidentiality within institutions and informational privacy refers to the collection of personal data, right to access, data amendment and the confidentiality associated with such data.

The PD(P)O is a statute governing personal informational privacy. It was first enacted in 1995 after initial proposals published by the Law Reform Commission of Hong Kong and subsequent public consultation. The Personal Data (Privacy) Amendment Bill 2011 suggested updates to the legislation and the result was the Personal Data (Privacy) Amendment Ordinance 2012, which came into effect on 1 October 2012. The Privacy Commissioner's power to grant legal assistance, Pt.6A provisions on direct marketing, and provisions on court jurisdiction took effect from 1 April 2013.[16]

The statute deals systematically with collected retrievable personal data. Although it can be regarded that the PD(P)O in a sense is a statute protecting personal data privacy, it is equally true to say that it is not a law on privacy in general. The statutory protection of privacy in general in English law and in Hong Kong law, such as media intrusion and stalking, is actually very primitive. Thus, it was confirmed in *Wainwright v Home Office*[17] that, in England, while privacy was a value underlying the common law of breach of confidence, it was not a principle of law and nor was there a tort of invasion of privacy.

The statute is built on the data protection principles (DPPs), which are found in its Sch.1. The different parts and sections detail the stipulations based on the data principles in addition to provisions related to the regulation of such practices.

All parts of the statute are important to healthcare personnel and institutions. Part V concerning data access is of particular relevance to front-line healthcare workers.

The PD(P)O consists of 10 parts followed by 6 schedules.

(1) Part 1 contains the standard preliminary provisions of statutes.
(2) Part 2 concerns establishment of the Privacy Commissioner for Personal Data and his functions and powers.
(3) Part 3 is on codes of practice.
(4) Part 4 is on data user returns and the register of data users.
(5) Part 5 concerns access to and correction of personal data. Division 1 is access to personal data. Division 2 is correction of personal data. Division 3 is miscellaneous, eg erasure of personal data no longer required, keeping of logbook by data user, imposition of fees by data user and so forth.
(6) Part 6 relates to the prohibition of matching and transferral of personal data outside Hong Kong.

16 New Guidance on Direct Marketing, Office of the Privacy Commissioner for Personal Data (Hong Kong, January 2013).
17 [2004] 2 AC 406.

(7) Part 6A concerns the use of personal data in direct marketing and provision of such. Division 1 is interpretation. Division 2 is use of personal data in direct marketing. Division 3 is provision of personal data for use in direct marketing.
(8) Part 7 is on inspections, complaints and investigations.
(9) Part 8 is on exemptions.
(10) Part 9 is on offences and compensation.
(11) Part 10 is on miscellaneous matters, eg form specification, service of notices, fees and so forth.

Schedule 1 is the most important of the six because it is where the DPPs are elaborated. These principles are as follows:

(1) Purpose and manner of data collection: must be fair, for a relevant and necessary purpose, lawful and not excessive. The data subject must be informed of his rights.
(2) Accuracy and retention of personal data: accuracy to be ensured and retention not be longer than is necessary for the purpose of collection, by taking all practicable steps.
(3) Use of personal data: not for any other purpose from that for which it is collected unless with further consent.
(4) Security of personal data: all practicable steps should be taken to ensure protection against unauthorised or accidental access, processing and erasure.
(5) Information to be available: as to the data user's policies and practices in relation to personal data.
(6) Access to personal data: the right of a data subject to ascertain whether a data user holds his personal data, to request access, to be addressed within a reasonable time and at a reasonable fee, to make corrections, to be provided with reasons if rejected and to object to rejections.

A number of sections also deserve attention.

Section 2 defines a "data user" to be a person who, either alone or jointly with other persons, controls the collection, holding, processing or use of the data, whereas a "data subject" means that individual who is the subject of the data.

Section 4 states that a data user shall not do an act, or engage in a practice, that contravenes a DPP as stipulated in Sch.1 of the PD(P)O.

Section 18 concerns data access requests (DARs). An individual, or a relevant person on behalf, may make a request for data access. Such a person is entitled to be informed by the relevant data user whether the individual is a data subject and, if his data is held, to be supplied with a copy of it. Section 19 requires that the supply of personal data held to be made available within 40 days or a written notice of explanation why compliance cannot be met.

Section 20 contains grounds for the refusal of a DAR. These include failure to prove the identity of the individual requesting,[18] compliance not be possible without revealing data of others[19] (subject to exceptions in s.20(2)); not supplying such necessary information for

18 PD(P)O s.20(1)(a)(i) and (ii).
19 *Ibid.*, s.20(1)(b).

the retrieval;[20] request not in the specified format;[21] entitlement under statute[22] and Pt.VIII exemptions.[23]

Section 22 provides for correction of inaccurate data.

Section 26 requires data no longer required for the purposes of its collection to be erased unless erasure is prohibited by law[24] or in the public interest.[25]

Section 28 allows for a reasonable fee to be imposed for making a data access or correction request.

The PD(P)O aims at the regulation of data collection and protection of individuals whose information is being collected. An aggrieved person from practices that violate the stipulations of the Ordinance may lodge a complaint to the office of the Privacy Commissioner. The Commissioner will coordinate with the parties for a resolution through mediation if the case satisfies the requirements. The Commissioner may also initiate a formal investigation where a breach is considered serious, to be followed by measures for enforcement. An enforcement notice would specify steps that the data user must take in order to remedy the breach and, if appropriate, prevent any recurrence of the contravention.

A data user contravening an enforcement notice is an offence in law which is punishable by a fine or imprisonment.[26] A person who fails to comply with the requirements of the Commissioner is similarly liable.[27]

When a data subject's rights are infringed in violation of the six data principles, he can also resort to the statute and seek remedy through the court according to its provisions.

5.3.4.2.1 Personal Data (Privacy) Amendment Ordinance 2012

A number of new changes were brought about by the Personal Data (Privacy) Amendment Ordinance 2012.

There were new provisions concerning the handling of DARs. The data user is required under s.19 to inform the DAR or in writing if he has such data.[28] A new additional ground for refusal to comply with a DAR is if it is a requirement under the law.[29] The Hong Kong Police Force can choose to provide an oral response only of a clear criminal conviction record[30] on request.

The most notable of the new changes was the creation of a new offence in s.64 (offence of disclosure of personal data obtained without consent from data users). This refers to disclosure of personal data obtained from a data user without consent with the intention to: gain[31] or cause loss[32] or psychological harm.[33] Four defences are available:[34] prevent or

20 *Ibid.*, s.20(3)(b).
21 *Ibid.*, s.20(3)(e).
22 *Ibid.*, s.20(3)(ea).
23 *Ibid.*, s.20(3)(f).
24 *Ibid.*, s.26(1)(a).
25 *Ibid.*, s.26(1)(b).
26 *Ibid.*, s.50A.
27 *Ibid.*, s.50B.
28 *Ibid.*, s.19(1)(a) and (b).
29 *Ibid.*, s.20(3)(ea).
30 *Ibid.*, s.19(2)(1A).
31 *Ibid.*, s.64(1)(a).
32 *Ibid.*, s.64(1)(b).
33 *Ibid.*
34 *Ibid.*, s.64(4).

CHAPTER 8

END-OF-LIFE ISSUES

Helen Chan

8.1 INTRODUCTION: CONCERNS CENTRED ON END-OF-LIFE ISSUES

Death is a natural part of life but, with medical advances in recent decades, it is often viewed as a failure of medicine. Hence, treatment decisions always tend to err on the side of saving life. Undeniably, "saving the dying and helping the injured" are among the main duties of health professionals. Yet, every coin has two sides and we should reflect on our decisions and evaluate whether maintaining life of every patient regardless of their condition is our absolute duty. For example, if clinical experience suggests that the patient has received a grave prognosis, should we try every means to fight against death? The phenomenon of the "medicalisation of death" raises a question for the conventional cure-oriented culture: "Is medical intervention always in the best interests of the patient?"

The prevalence of frailty and chronic, progressive, deteriorating conditions are increasing in developed regions; Hong Kong is no exception. In such clinical conditions, debate over treatment decisions is often stirred up as, in the current pluralistic society, the benefits and risks of treatments are subject to interpretation. Disputes often become heated if they are left in the hands of family members or the healthcare team if individuals have not expressed their care wishes at an earlier time and subsequently lack mental capacity. It is anticipated that there will be growing awareness of ethical quandaries related to end-of-life issues. This chapter attempts to use various case scenarios that commonly arise in end-of-life care in current practice to illustrate the dilemma and then outline the existing guidelines or legislation that are important in supporting the clinical decision-making process.

8.2 BREAKING BAD NEWS: RIGHT TO KNOW VERSUS DUTY TO PROTECT?

According to the principle of respect for autonomy, patients obviously have the right to know their health condition so that they can make informed decisions about their treatment. However, what happens if the prognosis is grave? One may then hesitate as the patient may lose all hope of recovery when they learn the news; the health professional may feel obliged to protect the patient from potentially sensitive information. This gives rise to situations in which health professionals and family members have to collude to hide information from the patient.

Case scenario 1

Mrs Wong, a 68-year-old retired teacher, noticed that she has lost 5 kg in 2 months and had become tired easily. Her daughter worried about her and accompanied her to seek medical advice. During a physical examination, the doctor noted that there was a lump in her right breast; a biopsy was performed for further investigation. Eventually, the result confirmed the diagnosis of breast cancer and, indeed, it had metastasised to the bone which implied a poor prognosis. The doctor was afraid that this news would be devastating to Mrs Wong.

The Patients' Charter clearly stated that patients have the right to information.[1] All relevant information that may affect the patient's decisions concerning their treatment should be provided. This should include, but not be limited to, a clear explanation about their diagnosis, prognosis, the purpose and potential risks of the treatment or medication proposed and any alternative.

A recent study reported that most oncologists in China are used to disclosing the patient's cancer diagnosis to the family first; half of them disclosed the diagnosis to the family only.[2] Such practice raises two issues. First, the physicians have breached the duty of confidentiality by disclosing the patient's information to a third party (ie family members) without seeking their prior consent. Second, when the patient asked about their medical condition, the health professionals and family members would inevitably deceive the patient and that definitely undermines the duty to be honest and jeopardises the trusting relationship between health professionals and patient.

By adopting this avoidance approach, does non-disclosure mean the patients would not be aware of their failing health? In their early work, Glaser and Strauss revealed that patients might have intuitively suspected that they were nearing the end of their life but pretended that they were doing well.[3] Non-disclosure would eventually lead to the patient being isolated and, thus, deprive them of the opportunity to plan for their remaining days as well as their end-of-life care. Hence, the central issue here is not about "should we" disclose the information but "how to?" The healthcare team has to be tactful and empathetic in the communication process to avoid causing feelings of abandonment in the patient and family.

8.3 LIFE-SUSTAINING TREATMENT: DOING GOOD OR DOING HARM?

Life-sustaining treatment (LST) refers to any treatment which has the potential to postpone the patient's death, such as cardiopulmonary resuscitation, pacemakers and vasopressors.[4] In other words, it is a means of maintaining the patient's life.

Case scenario 2

Mr Yung, an 85-year-old man, had chronic obstructive pulmonary disease (COPD) and required long-term oxygen therapy. He developed dyspnoea easily on exertion and so he needed support in most of his activity of daily living. One night, he had severe shortness of breath and was sent to hospital. Due to his respiratory failure, he was admitted to the intensive care unit and, eventually, the doctor placed him on a mechanical ventilator to assist his breathing.

Mr Yung was in a life-threatening situation and he might have died without medical intervention. In this case, a mechanical ventilator, which is used to maintain sufficient airflow and oxygenation, is one of the examples of LST. The paradox is that the treatment

1 Hospital Authority (HA), "Patients' Charter" (1999), available at http://www3.ha.org.hk/twh/ui/patient_charter/Patient%20Charter.pdf (visited 18 April 2016).

2 Ying Pang *et al.*, "Breaking Bad News in China: Implementation and Comparison of Two Communication Skills Training Courses in Oncology". *Psycho-Oncology* 2014; 24(5):608–611.

3 Barney G Glaser and Anselm L Strauss, *Awareness of Dying* (New York: Aldine Publishing, 1965).

4 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (2015) Section 4.1, available at https://urldefense.proofpoint.com/v2/url?u=http-3A__www.ha.org.hk_haho_ho_psrm_ENG.pdf&d=CwIDaQ&c=4ZIZThykDLcoWk-GVjSLm9hvvvzvGv0FLoWSRuCSs5Q&r=0U04L7Q9npvtq5cWKTDrQRFTANFMzhpnSeiNN8BW4B_1yHPtzFf457aQrJ9a0hWY&m=OtZxnxydLNyyoqe9HEId0K9A9tgs4JP-ikjXdr4ZNx4&s=uBzJEoIR-u0enyvKrMdL2ohV_8-dClE6uoAsfBnqI0s&e= (visited 18 April 2016).

was used to maintain the patient's life, but it could not reverse his underlying health problem (ie COPD) and may have resulted in complications that add further burdens to the patient. Evidence suggests that the use of mechanical ventilation is associated with complications, including respiratory muscle weakness, aspiration, ventilator-associated pneumonia and sinusitis.[5] Due to pathological reasons, a considerable number of patients with severe COPD fail to resume independent respiratory control; they cannot be weaned off the ventilator.[6] This poses the question whether continuing mechanical ventilation support, notwithstanding further resulting complications, is in the best interests of the patient?

8.3.1 Withholding and withdrawing life-sustaining treatment

Withholding treatment means the medical team does not provide the treatment from the outset, whereas withdrawing treatment means the medical team discontinues the treatment after its initiation.[7] The latter option is allowed because the medical team can give a timed trial to the treatment if its benefit is uncertain. The Hospital Authority (HA) Guidelines highlighted that the decision to withhold, as well as to withdraw, LST is serious and may be unethical and legally not acceptable if not carried out appropriately.[8]

Concern about whether withdrawing and withholding LST were lawful and ethical had been clarified through prolonged legal battles involving the perspectives of family members and experts including physicians, philosophers, religious leaders and politicians.[9]

This originated from landmark court cases in the United States (US). *Re Quinlan*, was the first that sparked the debate. Karen Ann Quinlan, a 21-year-old college student, suffered cardiopulmonary arrest after taking a mixture of alcohol and drugs at a party. Resuscitation successfully saved her life but she sustained severe brain damage that resulted in a persistent vegetative state (PVS), a clinical condition of complete unawareness of the self and the environment despite wakefulness.[10] Mechanical ventilation and nasogastric tube feeding were given as life support. Having witnessed their daughter living in such conditions for months, her parents requested the removal of the ventilator, which was seen as an extraordinary means to maintain life, and allow her to die naturally. As withdrawing a LST may result in death and the medical team may be civilly or criminally liable for such an act, the medical team sought the Court's decision.[11] Eventually, the New Jersey Supreme Court ruled that an individual's right to privacy, including the right to refuse medical treatment, would be passed to the family or a surrogate when the patient became mentally incompetent.[12] With this decision, the endotracheal tube and the ventilator were then withdrawn from Karen.

5 Anahita Rouze *et al.*, "Chronic Obstructive Pulmonary Disease and the Risk for Ventilator-Associated Pneumonia". *Curr Opin Crit Care* 2014; 20(5):525–531.

6 Karen EA Burns *et al.*, "Noninvasive Ventilation as a Weaning Strategy for Mechanical Ventilation in Adults with Respiratory Failure: A Cochrane Systematic Review". *CMAJ* 2014; 186(3):E112–E122.

7 Lawrence O Gostin, "Deciding Life and Death in the Courtroom: From Quinlan to Cruzan, Glucksberg, and Vacco – A Brief History and Analysis of Constitutional Protection of the 'Right to Die'". *JAMA* 1997; 278:1523–1528.

8 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above).

9 Jim Howe, "The Persistent Vegetative State, Treatment Withdrawal, and the Hillsborough Disaster: Airedale NHS Trust v Bland". *Practical Neurology* 2006; 6:238–246.

10 The Multi-Society Task Force on PVS, "Medical Aspects of the Persistent Vegetative State". *NEJM* 1994; 330:1499–1508.

11 Gostin, "Deciding Life and Death in the Courtroom" (n.7 above).

12 *Re Quinlan* 355 A 2d 647 (NJ 1976).

In *Cruzan v Director, Missouri Department of Health*,[13] the family's request to withdraw the feeding tube was even more contentious. In 1983, Nancy Cruzan, who was 25 years old, was involved in a car accident in Missouri. Again, resuscitation restored her respiratory and cardiac functions, but she was also in a PVS which meant she did not regain consciousness due to brain damage. A feeding tube, known as percutaneous endoscopic gastrostomy (PEG), was inserted into her stomach to sustain her. With minimal hope of rehabilitation, her parents believed that their daughter would not want to live in this way and so, four years later, they requested the removal of the feeding tube. Although recognising that the parents were entitled to the right to refuse treatment on behalf of their daughter, the Missouri Supreme Court did not approve the feeding tube withdrawal until 1990 when there were witnesses to give "clear and convincing" evidence to prove that Nancy would not want to be kept alive by treatment of this kind in the event of mental incapacity.[14]

In current practice, there are no legal or moral differences between withholding and withdrawing LST.[15] Forgoing treatment in either way is ethically and legally acceptable when (1) a mentally competent and properly informed patient refuses the treatment or (2) the treatment is futile.[16] The purpose of forgoing treatment is to avoid prolonging the dying process but not to hasten death.[17] Therefore, the term "passive euthanasia" should not be used to avoid confusion about its intent and motive.[18]

8.3.2 Treatment futility

Plainly speaking, futility means a treatment that is highly unlikely to achieve its intended purpose.[19] In some situations, clinical evidence clearly showed that certain treatments were futile in a particular situation, known as physiologic futility and, thus, healthcare teams had no ethical obligation to provide that treatment. But, for most of the time, clinical situations are not so clear-cut. Often, the treatment brings both benefits and burdens to the patient. By taking *Re Quinlan* and *Cruzan v Director, Missouri Department of Health* as examples, the treatments can achieve the purpose of maintaining life, but they cannot ameliorate the damage to the brain; the patients remained in a PVS condition. So, in these cases, what would be the right decision: prolonging life by all means available or letting the patient die without intervening? The decision-making process is, indeed, subject to how one interprets the benefits and burdens resulting from the treatment.[20]

8.3.3 Which is more important: quality of life versus length of life?

The debate between quality of life and the value of life of severely ill patients is underscored in one notable court case in the United Kingdom (UK). Tony Bland, an 18-year-old football

13 497 US 261 (1990).
14 Sara Taub, "Departed, Jan 11, 1983; At Peace, Dec 26, 1990". *AMA Journal of Ethics* 2001; 3(7) (Virtual Mentor), available at http://journalofethics.ama-assn.org/2001/07/imhl1-0107.html (visited 18 April 2016).
15 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above); American Medical Association, "Opinion 2.20 – Withholding or Withdrawing Life-Sustaining Medical Treatment" (2015), available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion220.page? (visited 18 April 2016); British Medical Association, *Withholding and Withdrawing Life-Prolonging Medical Treatment: Guidance for Decision Making* (Oxford: Blackwell Publishing, 2007).
16 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Section 4.2.
17 British Medical Association, *Withholding and Withdrawing Life-Prolonging Medical Treatment* (n.15 above).
18 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Appendix 2.
19 *Ibid.*
20 *Ibid.*

fan, was one of the victims of the Hillsborough disaster in 1989. He suffered crushed ribs and punctured lungs. The deprivation of oxygen to his brain caused severe damage. In the following three years, he was left in a PVS condition and he relied on PEG for nutritional and hydration support. The medical team, with the support of Tony's parents, applied to the High Court for an order to allow the lawful withdrawal of the feeding tube from the young man.[21] The judges of the High Court considered that being kept alive in a PVS condition was of no benefit at all to the patient and his family, and the use of life-sustenance measures in this case was not in the "best interests" of the patient.[22] Sir Stephen Brown, President of the Family Division of the High Court, concluded that "[h]is spirit has left him and all that remains is the shell of his body". The ruling implied that tube feeding was considered futile for Tony Bland. The court's decision was supported by the Court of Appeal and the House of Lords which is the highest level of legal appeal in the UK. Tony Bland died nine days after the PEG was withdrawn. This was the first time in English legal history that a court allowed withdrawing LST and let the patient die. Yet, since the court decision involved subjective evaluation of the quality of life of a patient in a PVS, it invited extensive criticism of whether the intrinsic value of life would diminish when a patient had limited hope of recovery and whether the value of one's life can be judged by third parties.

8.3.4 Artificial nutrition and hydration: treatment or basic care?

In *Cruzan v Director, Missouri Department of Health* and *Airedale NHS Trust v Bland*, tube feeding was withdrawn after balancing its benefits and risks. Tube feeding, or in technical terms, artificial nutrition and hydration (ANH), broadly refers to the techniques that bypass the swallowing process to provide nutrition or hydration. This includes the use of a nasogastric tube, PEG, intravenous or subcutaneous infusion and parenteral nutrition.[23] By definition, ANH is also a kind of LST to support the patients if they are at risk of aspiration through oral feeding or their nutritional intake is insufficient to meet their needs. Providing nutrition and hydration is the basic care required to fulfil fundamental needs; therefore, the debate about whether ANH can be withheld or withdrawn as in the case of other LST is more controversial.

Case scenario 3

Mrs Chow was diagnosed with dementia eight years ago. Over these years, her functional and cognitive ability declined progressively. She could no longer communicate or recognise her family members and she became dependent for all activities of daily living. After a swallowing assessment, the speech therapist recommended tube feeding and the discontinuation of oral intake to prevent recurrent aspiration pneumonia. Her husband agreed with the suggestion believing that it was the best way to ensure adequate nutritional support for his wife. Her daughter, however, rejected it and insisted on hand feeding. She considered tube feeding was inhumane and deprived her mother of life quality.

21 Howe, "The Persistent Vegetative State, Treatment Withdrawal, and the Hillsborough Disaster" (n.9 above).
22 *Airedale NHS Trust v Bland* [1993] AC 789.
23 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Section 8.1.

In this case, it appears that ANH is a means to ensure adequate nutrition and hydration to meet the physiological needs of the patient and thus prevent dehydration. Yet, empirical studies have shown that the use of ANH may not necessarily prevent patients from developing aspiration pneumonia or increase their survival rate, and its application also leads to issues concerning the quality of life and dignity.[24] For example, the procedure of inserting the tube may be a painful and traumatising experience for the patient and, in order to prevent the feeding tube being pulled out, some patients are physically restrained. Rather, careful hand feeding has been advocated widely in the US and Australia as an alternative to ANH in situations like Mrs Chow's.[25]

Despite the evidence, a recent large-scale survey found that doctors in Asia are less likely to withhold or withdraw ANH in current practice.[26] One possible explanation is that feeding is often seen as a filial act in Asian culture.[27] Yet, consensus has not been reached in Western countries as well. In *Schiavo v Schiavo*,[28] a case concerning whether a PEG should be withdrawn from a person in a state of PVS, Pope John Paul II expressed his view that the provision of food and water should be maintained to preserve life, even by artificial means. Based on the sanctity of life principle, life is precious regardless of its condition and potentiality. Consistent with this perspective, tube feeding and mechanical ventilation were administered for life sustenance in his final phase of life when John Paul II had difficulty in eating and breathing due to Parkinson's disease. Hence, treatment decisions regarding ANH are often challenging because of the ways benefits and risks are interpreted which may also involve cultural and religious considerations.[29]

On this issue, the HA Guidelines on LST in the terminally ill have provided a full discussion about feeding issues in patients with advanced dementia to elaborate the approach to feeding in patients with feeding difficulties that suits the local context.[30] In particular, it highlights that the decision-making process on feeding options should be through consensus-building among the healthcare team and the patient's family, with the patient's prior care wishes and preferences and best interests being taken into consideration.

8.3.5 Treatment decision: who can decide?

The consensus-building process on treatment decisions can be very straightforward if the patient has clearly stated their preferences or their family members know the patient's care wishes. Basically, patients have the right to choices, which means they can accept or refuse any treatment provided if they are mentally competent and have been given sufficient

24 Howard Brody *et al.*, "Artificial Nutrition and Hydration: The Evolution of Ethics, Evidence and Policy". *J Gen Intern Med* 2011; 26(9):1053–1058.

25 American Geriatric Society, "American Geriatric Society Feeding Tubes in Advanced Dementia Position Statement". *J Am Geriatr Soc* 2014; 62(8):1590–1593.

26 Jason Phua *et al.*, "Withholding and Withdrawal of Life-Sustaining Treatments in Intensive Care Units in Asia". *JAMA Intern Med* 2015; doi:10.1001/jamainternmed.2014.7386.

27 Helen YL Chan and Samantha MC Pang, "Cultural Aspects of Forgoing Tube Feeding in American and Hong Kong Chinese Patients at the End of Life" in Victor R Preedy (ed), *Diet and Nutrition in Palliative Care* (Boca Raton, FL, US: Taylor & Francis Group, LLC, 2011) pp.145–155; Samantha MC Pang *et al.*, "Comparing the Ethical Challenges of Forgoing Tube Feeding in American and Hong Kong Patients with Advanced Dementia". *Journal of Nutrition, Health and Aging* 2007; 11(6):495–501.

28 403 F 3d 1289 (2005).

29 Cynthia MA Geppert *et al.*, "Ethical Issues in Artificial Nutrition and Hydration: A Review". *J Parental and Enteral Nutrition* 2009; 34(1):179–188.

30 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Section 8, Appendix 4.

information for making informed decision.[31] Their decisions should be respected unless their mental capacity has been affected by illness or medication, by false assumptions or misinformation, or by due influence by others.[32] However, it is unusual for patients to have planned ahead for end-of-life care as they tend to defer the discussion until the actual crisis or believe erroneously that their family members would be able to predict their care wishes.[33] Given that the weighing of treatment benefits and risks is subject to interpretation, it can be hard to determine what would be in the best interests of the patient. So, who should have the final say in these difficult situations?

8.4 ADVANCE DIRECTIVES

Advance directive is a means for mentally competent individuals to indicate the form of healthcare they would like to have in the future should they become incompetent.[34] The concept of advance directive, sometimes known as a living will, is underpinned by the principle of respect for autonomy, in which contemporaneous autonomy is extended to a prospective one for future care. For both Mr Yung and Mrs Chow, we do not know whether the patients themselves would have wanted to receive ventilator support and ANH, respectively, in such illness conditions. Since it is unclear whether the treatments would be considered as futile or unacceptable by the patients, the administration of these LSTs may be contrary to their care wishes for end-of-life care. So, if they had formulated an advance directive for themselves at an earlier stage, before they lost their decisional capacity, their care wishes would have been known.

The development of advance directive was related to the US court cases aforementioned. Following *Re Quinlan*, the "Natural Death Act", also known as Death with Dignity Acts or Living Will Acts, was enacted in all states in the late 1970s and 1980s to acknowledge a constitutional right to forgo LST according to the patient's wish in the event of a terminal condition or irreversible coma through advance directive.[35] It was further clarified in *Cruzan v Director, Missouri Department of Health* that the advance directive should be supported by clear and convincing evidence that specified the clinical situation and the particular treatment considered for refusal. To meet this requirement, the US Congress passed a federal law, the Patient Self-Determination Act in 1990, that requires healthcare institutions, including hospitals, skilled nursing facilities, home health agencies, hospices and health maintenance organisations, to provide patients with written information about the right to self-determination in end-of-life care, provide staff education on advance directives, maintain policies and procedures related to advance directives and promote documentation for informed decision by completing written advance directives.[36] All these are to ensure patients are informed of

31 HA, "Patients' Charter" (n.1 above).

32 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Section 5.1(b).

33 Helen YL Chan and Samantha MC Pang, "Quality of Life Concerns and End-of-life Care Preferences of Aged Persons in Long-Term Care Facilities". *Journal of Clinical Nursing* 2007; 16:2158–2166.

34 Law Reform Commission of Hong Kong, "Report on Substitute Decision-Making and Advance Directives in Relation to Medical Treatment" (2006), available at http://www.hkreform.gov.hk/en/docs/rdecision-e.pdf (visited 18 April 2016).

35 Bernard Towers, "The Impact of the California Natural Death Act". *Journal of Medical Ethics* 1978; 4:96–98.

36 Bernard Lo and Robert Steinbrook, "Resuscitating Advance Directives". *Arch Intern Med* 2004; 64(14):1501–1506; American Bar Association, "Health Care Advance Directives" (2015), available at http://www.americanbar.org/groups/public_education/resources/law_issues_for_consumers/patient_self_determination_act.html (visited 18 April 2016).

their rights regarding decision-making for their future care and assured that their decisions would be acknowledged and respected by their healthcare providers.

8.4.1 Development of advance directives in Hong Kong

Advance directives are recognised under the common law framework, although there is no specific legislation on them.[37] A valid and applicable advance directive should be respected provided that the patient is properly informed about the treatment and is able to envision the clinical situations and treatment concerned. The family has no authority to override an advance directive and the healthcare team is liable to legal action for battery or assault if they knowingly provide treatment against the advance refusal.[38]

Dating back to 2004, the Law Reform Commission launched a public consultation with regard to substitute decision-making and advance directives in relation to medical treatment.[39] With this exercise, the Commission concluded that the concept of advance directives was new to society and that it was premature to introduce a statute in this regard. Hence, the Commission recommended public education pertaining to the concept of advance directives by non-legislative means and put forward a model form of advance directive for reference.[40] The form requires the presence of two witnesses who have no interest in the estate of the person making the advance directive, one of whom must be a medical practitioner. Such requirement is not mandatory under common law principles but this can prevent uncertainty or disputes concerning its validity in the future. The medical practitioner, as a witness, can also assess the mental competence of the patient to understand the nature and effect of making an advance directive and provide information for the decision-making.

In 2009, the Food and Health Bureau also published a Consultation Paper on the "Introduction of the Concept of Advance Directives in Hong Kong".[41] Subsequently, the HA issued the "Guidance for HA Clinicians on Advance Directives in Adults" for reference in 2010 and updated the Guidance in 2014.[42] The Law Reform Commission model form was subsequently modified to enhance its comprehensiveness and flexibility. Figure 8.1 shows the full HA advance directive form. This modified form covers three clinical conditions, namely: (a) terminally ill, (b) PVS or a state of irreversible coma and (c) other end-stage irreversible life-limiting conditions. In addition, the patient can opt for ANH only if clinically indicated but may refuse all other LSTs. Furthermore, there is a short form specifically designed for terminally ill patients to refuse cardiopulmonary resuscitation only (see Figure 8.2). In addition, the order of "Do not attempt cardiopulmonary resuscitation (DNACPR)" was extended to non-hospitalised patients with advanced, irreversible illness (see Figures 8.3 and 8.4). All these help to clarify common misunderstandings and uncertainty with regard to its implementation.

37 HA, "Guidelines on Life-Sustaining Treatment in the Terminally Ill" (n.4 above) Section 5.2.

38 *Ibid.*

39 Law Reform Commission of Hong Kong, "Consultation Paper on Substitute Decision-Making and Advance Directives in Relation to Medical Treatment" (2004), available at http://www.hkreform.gov.hk/en/docs/decision-e.pdf (visited 18 April 2016).

40 *Ibid.*

41 Food and Health Bureau, "Introduction of the Concept of Advance Directives in Hong Kong: Consultation Paper" (2009), available at http://www.gov.hk/en/residents/government/publication/consultation/docs/2010/AdvanceDirectives.pdf (visited 18 April 2016).

42 HA, "Guidance for HA Clinicians on Advance Directives in Adults (Version 2)" (2014), available at http://www.ha.org.hk/haho/ho/cc/CEC-GE-1_en.pdf (visited 18 April 2016).

Figure 8.1: The Full Version of Hospital Authority Advance Directive Form—HA 9610/MR[43]

醫院管理局 HOSPITAL AUTHORITY

ADVANCE DIRECTIVE[1]

Please Use Block Letter or Affix Label
SOPD / Hospital No.:.....
Name:.....
ID. No:..... Sex:.....Age:.....
Dept::.....Team:..... Ward/Bed:.....

Section I : Personal details of the maker of this advance directive

Name : ..... *(please use capital letters)*

Identity Document No.: .....

Sex : Male / Female

Date of Birth : ____ / ____ / ____ (Day) (Month) (Year)

Home Address : .....

.....

Home Tel. No. : .....

Office Tel. No. : .....

Mobile Tel. No. : .....

Section II : Background

1. I understand that the object of this directive is to minimise distress or indignity which I may suffer or create when I am terminally ill or in a persistent vegetative state or a state of irreversible coma, or in other specified end-stage irreversible life limiting condition, and to spare my medical advisers or relatives, or both, the burden of making difficult decisions on my behalf.

2. I understand that euthanasia will not be performed, nor will any unlawful instructions as to my medical treatment be followed in any circumstances, even if expressly requested.

3. I, _____ *(please print name)* being over the age of 18 years, revoke all previous advance directives made by me relating to my medical care and treatment (if any), and make the following advance directive of my own free will.

4. If I become terminally ill or if I am in a state of irreversible coma or in a persistent vegetative state or in other specified end-stage irreversible life limiting condition as diagnosed by my attending doctor and at least one other doctor, so that I am unable to take part in decisions about my medical care and treatment, my directives in relation to my medical care and treatment are as follows:

(Note: Complete the following by ticking the appropriate box(es) and writing your initials against that/those box(es), and drawing a line across any part you do not want to apply to you.)

[1] The Form was proposed by the Law Reform Commission on 16 August 2006; amended as in Food and Health Bureau Consultation Paper on 23 December 2009; modifications made and footnotes added by the Hospital Authority in May 2010 and in June 2014.

ADVANCE DIRECTIVE HA 9610/MR

(Continued)

43 *Ibid.*

Figure 8.1 (*Continued*)

(A) **Case 1 – Terminally ill**

(Note: In this instruction –

"Terminally ill" means suffering from advanced, progressive, and irreversible disease, and failing to respond to curative therapy, having a short life expectancy in terms of days, weeks or a few months; and the application of life-sustaining treatment would only serve to postpone the moment of death, and

"Life-sustaining treatment" means any of the treatments which have the potential to postpone the patient's death and includes, for example, cardiopulmonary resuscitation, artificial ventilation, blood products, pacemakers, vasopressors, specialised treatments for particular conditions such as chemotherapy or dialysis, antibiotics when given for a potentially life-threatening infection, and artificial nutrition and hydration. (Artificial nutrition and hydration means the feeding of food and water to a person through a tube.))

☐ **I shall not be given the following life-sustaining treatment(s):**

☐ **Cardiopulmonary resuscitation (CPR)**

☐ **Others:** _____

_____

☐ **Save for basic and palliative care, I shall not be given any life-sustaining treatment[2]. Non-artificial nutrition and hydration shall, for the purposes of this form, form part of basic care.**

☐ **However, I want to continue to receive artificial nutrition and hydration, if clinically indicated, until death is imminent and inevitable.**

(B) **Case 2 – Persistent vegetative state or a state of irreversible coma**

(Note: In this instruction -

"Life-sustaining treatment" means any of the treatments which have the potential to postpone the patient's death and includes, for example, cardiopulmonary resuscitation, artificial ventilation, blood products, pacemakers, vasopressors, specialised treatments for particular conditions such as chemotherapy or dialysis, antibiotics when given for a potentially life-threatening infection, and artificial nutrition and hydration[3]. (Artificial nutrition and hydration means the feeding of food and water to a person through a tube.))

☐ **I shall not be given the following life-sustaining treatment(s):**

☐ **Cardiopulmonary resuscitation (CPR)**

☐ **Others:** _____

_____

☐ **Save for basic and palliative care, I shall not be given any life-sustaining treatment[4]. Non-artificial nutrition and hydration shall, for the purposes of this form, form part of basic care.**

☐ **However, I want to continue to receive artificial nutrition and hydration, if clinically indicated, until death is imminent and inevitable.**

[2] Care should be taken to ensure that the patient has really decided not to consent to receive "all" life-sustaining treatment.

[3] Note that to withdraw artificial nutrition and hydration (ANH) in a non-terminally ill patient who is in a persistent vegetative state or a state of irreversible coma (PVS/IC) can be contentious even in the presence of an advance directive. For patients presenting with such a directive and in PVS/IC, advice should be sought from the HCE/CCE and HAHO to consider whether an application to the Court is required. A patient wishing to make a directive to withdraw ANH, or to withdraw all life-sustaining treatments under this Section, should be alerted about this special caution.

[4] Care should be taken to ensure that the patient has really decided not to consent to receive "all" life-sustaining treatment.

(C) **Case 3 – Other end-stage irreversible life limiting condition, namely:**

_____

(Note: In this instruction -

"Other end-stage irreversible life limiting condition" means suffering from an advanced, progressive, and irreversible condition not belonging to Case 1 or Case 2, but has reached the end-stage of the condition, limiting survival of the patient. Examples include:

(1) patients with end-stage renal failure, end-stage motor neuron disease, or end-stage chronic obstructive pulmonary disease who may not fall into the definition of terminal illness in Case 1, because their survival may be prolonged by dialysis or assisted ventilation, and

(2) patients with irreversible loss of major cerebral function and extremely poor functional status who do not fall into Case 2.

"Life-sustaining treatment" means any of the treatments which have the potential to postpone the patient's death and includes, for example, cardiopulmonary resuscitation, artificial ventilation, blood products, pacemakers, vasopressors, specialised treatments for particular conditions such as chemotherapy or dialysis, antibiotics when given for a potentially life-threatening infection, and artificial nutrition and hydration. (Artificial nutrition and hydration means the feeding of food and water to a person through a tube.))

☐ **I shall not be given the following life-sustaining treatment(s):**

☐ **Cardiopulmonary resuscitation (CPR)**

☐ **Others:** _____

_____

☐ **Save for basic and palliative care, I shall not be given any life-sustaining treatment[5]. Non-artificial nutrition and hydration shall, for the purposes of this form, form part of basic care.**

☐ **However, I want to continue to receive artificial nutrition and hydration, if clinically indicated, until death is imminent and inevitable.**

5. I make this directive in the presence of the two witnesses named in Section III of this advance directive, who are not beneficiaries under:

(i) my will; or
(ii) any policy of insurance held by me; or
(iii) any other instrument made by me or on my behalf.

6. I understand I can revoke this advance directive at anytime[6].

_____ _____

Signature of the maker of this advance directive Date

Section III : Witnesses

Notes for witness :

A witness must be a person who is not a beneficiary under –
(i) the will of the maker of this advance directive; or
(ii) any policy of insurance held by the maker of this advance directive; or
(iii) any other instrument made by or on behalf of the maker of this advance directive.

[5] Care should be taken to ensure that the patient has really decided not to consent to receive "all" life-sustaining treatment.

[6] A written revocation can be directly signed on the advance directive form, or written and signed on a separate piece of paper and attached to the advance directive form.

(*Continued*)

Figure 8.1 (*Continued*)

Statement of Witnesses

First Witness

(Note: This witness must be a registered medical practitioner, who, at the option of the maker of this directive, could be a doctor other than one who is treating or has treated the maker of this directive.)

(1) I, _____ *(please print name)* sign below as witness.

(a) as far as I know, the maker of this directive has made the directive voluntarily; and

(b) I have explained to the maker of this directive the nature and implications of making this directive.

(2) I declare that this directive is made and signed in my presence together with the second witness named below.

_____ _____

Signature of 1st witness Date

Name: .....

Identity Document No. / Medical Council Registration No. [7]: .....

Office Address: .....

.....

Office Tel. No. : .....

Second Witness

(Note: This witness must be at least 18 years of age)

(1) I, _____ *(please print name)* sign below as witness.

(2) I declare that this directive is made and signed in my presence together with the first witness named above, and that the first witness has, in my presence, explained to the maker of this directive the nature and implications of making this directive.

_____ _____

Signature of 2nd witness Date

Name: .....

Identity Document No.[8]: .....

Home Address / Contact Address : .....

.....

Home Tel. No. / Contact No. : .....

[7]. It is not necessary for HA staff to provide the Identity document No. / Medical Council Registration No. since staff code or address of hospital ward/unit would be sufficient for the identification of the 1st witness.

[8]. It is not necessary for HA staff to provide the Identity document No. since staff code or address of hospital ward/unit would be sufficient for the identification of the 2nd witness.

Figure 8.2: Advance Directive to Refuse Cardiopulmonary Resuscitation When Suffering from Terminal Illness—HA9612/MR[44]

醫院管理局 HOSPITAL AUTHORITY

ADVANCE DIRECTIVE
(TO REFUSE CARDIOPULMONARY RESUSCITATION WHEN SUFFERING FROM TERMINAL ILLNESS)

Please Use Block Letter or Affix Label
SOPD / Hospital No.:.....
Name:.....
ID. No:..... Sex:..... Age:.....
Dept:: Team: Ward/Bed:

Section I: Personal Details of the Maker of this Advance Directive

Name:..... Identity Document No.:.....

Sex: ..... Date of Birth:..... Tel. No.:.....

Home Address: .....

Section II: The Directive

1. I, _____, being over the age of 18 years, revoke all previous advance directives made by me relating to my medical care and treatment (if any), and make the following advance directive of my own free will.

2. If I am **terminally ill**[#] as diagnosed by my attending doctor and at least one other doctor, so that I am unable to take part in decisions about my medical care and treatment, my directive in relation to my medical care and treatment is as follows:
I shall not be given cardiopulmonary resuscitation (CPR).

3. I make this directive in the presence of the two witnesses named in Section III of this advance directive, who are not beneficiaries under my will, or any policy of insurance held by me, or any other instrument made by me or on my behalf.

4. I understand I can revoke this advance directive at any time.

_____ _____

(Signature of the maker of this advance directive) (Date)

[#] "Terminally ill" means suffering from advanced, progressive, and irreversible disease, and failing to respond to curative therapy, having a short life expectancy in terms of days, weeks or a few months; and the application of life-sustaining treatment would only serve to postpone the moment of death.

Section III: Statement of Witnesses

Notes for witness: A witness must be a person who is not a beneficiary under the will of the maker of this advance directive, or any policy of insurance held by the maker of this advance directive, or any other instrument made by or on behalf of the maker of this advance directive.

(*Continued*)

44 *Ibid.*

these means can be expensive, the use of performance enhancing agents make no difference from the conventional means.[87] Similarly, health risks are inherent in many forms of sports training, banning performance-enhancing agents based on safety concern is not a strong argument. An objective assessment on the inherent risk is needed before a decision of prohibition is made. However, the risks of human gene therapy today have not been adequately understood in healthy subjects. As not as the risk is acceptably low and does not affect germline, prohibition is not obviously grounded. At the moment gene therapy is at the cutting edge of medical science, its application to enhance performance has important financial implication, leading to unfair competition due to lack of means. However, with technology maturity and consensus adoption among the group, the cost of such intervention will drop by economy of scales.[88] Thus, gene doping could become widely accessible to athletes regardless of their financial situation.

87 A Miah, "Rethinking Enhancement in Sport" (n.85 above); BM Kious, "Philosophy on Steroids: Why the Anti-doping Position Could Use a Little Enhancement". *Theor Med Bioeth* 2008; 29:213–234.

88 B Bayus, "An Analysis of Product Lifetimes in a Technologically Dynamic Industry". *Management Science* 1998; 44(6):763–775.

CHAPTER 13

MEDICAL RESEARCH ETHICS

Gavin Joynt

13.1 INTRODUCTION

Medical research refers to systematic investigations designed to contribute to or extend generalisable medical knowledge. This chapter will focus on research involving human subjects, or the use of human tissue. Medical ethics describes a system of evaluating and developing moral principles that inform values and judgments in medical practice, including research. Although Hong Kong is a predominantly Chinese city, and its people overwhelmingly Chinese in ethnicity and culture, medical research is implemented in a manner entirely consistent with current Western medical codes and procedures. Thus, the understanding of medical research from a Western perspective of ethics is necessary to describe practice in Hong Kong.

Medical research is conducted in many forms. Basic or preclinical research studies biological mechanisms, and it may or may not involve human tissue or cells. Some clinical studies aim to gather knowledge from human subjects by observation, or gather information through surveys and questionnaires. Others measure the effects of routine treatments and interventions, while some involve the development and testing of new and innovative treatments. Clinical trials involve the testing of interventions, whether biological, mechanical or behavioural, on human subjects. Commonly clinical trials investigate the effects of new vaccines, drugs and devices, or new delivery methods. The results of the clinical trial should assist the medical community to determine if the intervention is effective and safe. Different types of research are governed by different moral rules and requirements, generally proportional to the risks posed to human (or animal) subjects, or issues related to the use of tissue specimens.

There is a general recognition, by both medical researchers and healthcare providers, as well as by the patients and the public, that the ongoing conduct of research is essential for the advancement of medical knowledge. Therefore, most of us accept that clinical trials are necessary and that the results will benefit individuals within society. In this regard, patients and the public also accept that some risk to individuals exposed to research can be justified in order to promote a common good. However, the exposure to risk should usually be small in magnitude, and justified by the likely beneficial gain in knowledge produced by the trial. Researchers, supported by the structures in place to supervise and regulate medical research, have a responsibility to always ensure that subject risk is minimised as much as possible by good trial design.

13.2 THE ETHICS OF MEDICAL RESEARCH

While not universally endorsed by ethicists and healthcare professionals, using the "principled" approach to justify the ethical and moral basis of the conduct of research remains informative. Beauchamp and Childress introduced the moral principles of

autonomy, beneficence, non-maleficence and justice to facilitate the description of a moral framework within which medicine can be practiced.[1] Briefly, the principle of autonomy states that healthcare providers should respect a patient's right to "self-rule", or more simply put, have the right to decide on the type and quantity of medical care they are willing to accept. Beneficence states that healthcare providers should provide care that is for the patient's benefit, and non-maleficence is that care should do the patient no net harm. The principle of justice implies that healthcare providers promote a fair allocation of the medical resources available to them. These principles have also been used to assist the examination of the ethical and moral framework within which clinical research operates.

At the centre of the moral justification for the legitimate conduct of medical research is the principle that every individual research subject should be able to exercise their autonomy by being given the opportunity to freely agree, or refuse, to be a part of a research project. This is generally achieved through the requirement for a medical researcher to obtain "voluntary informed consent" from all potential subjects. Special protection is provided to individuals with diminished mental capacity, as their ability to assert their autonomy is reduced, and the risk of exploitation is greater. This extra protection is often provided for by the requirement that individual consent be enhanced by the participation of a guardian or equivalent in the consent process. Children, impoverished individuals, prisoners and individuals with impaired mental capacity may fall into this category and are considered vulnerable.

Medical research subjects also have a general right to confidentiality and respect for their privacy. It is expected that as part of voluntary informed consent, subjects are made fully aware of how much information about them will be revealed during the process of the research, and under what special circumstances, if any, personal information will be revealed.

In meeting the requirements of the principles of non-maleficence and beneficence, it is particularly important that the medical research should not directly harm the study subject. Considering individual risk in clinical trials, the risk of the intervention under investigation should always be considered to be at least on par with the risk of conventional therapeutic interventions. When comparisons of interventions are made, the risks patients are exposed to by the comparator agents should be substantially similar, a condition called clinical equipoise. In reality, risk and reasonable side effects are inevitable in many medical settings, it is understood that a limited risk for participants in research may be carefully balanced against the potential gain. It is being increasingly recognised that scientific knowledge gained through medical research that carries risk is important, but not sufficient, and therefore the research should have appropriately important potential medical benefits to society to be considered morally justifiable. For example, the Belmont Report states that good medical research "makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous".[2]

1 TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 5th ed., 2001).

2 Department of Health, Education and Welfare (DHEW), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report, Washington, DC: United States Government Printing Office (30 September 1978).

It is more recently that the principle of justice has been systematically used to enhance our understanding of the ethics and morals of medical research. When applied to the setting of clinical trials, the principle of justice informs us that that the benefits and burdens of research should be fairly distributed. Thus, research participants should normally be recruited from those groups who will benefit from the research in question, not simply compliant populations, especially those disadvantaged by local social, demographic or financial circumstances. Similarly the benefits of research should be distributed fairly, both in terms of access to results and other beneficial outcomes. This principle has implications for researchers and institutions, who may conduct medical research in other parts of the world, or in Hong Kong, but on behalf of others from outside Hong Kong.

The responsibility for ensuring these principles are not violated during the conduct of research primarily lies with the individual researcher conducting a study, guided by regulatory structures designed to oversee the conduct of research, such as ethics committees and review boards. Much thoughtful guidance from reputable international bodies on the proper ethical and moral conduct of research exists.[3] The Medical Council of Hong Kong (MCHK) provides some guidance through its "Code of Professional Conduct".[4] Institutions responsible for research also have statements and guidance to ensure the responsible conduct of research.[5] The remainder of the chapter will provide a brief summary of the principles of ethical conduct as they apply to current practice of research, and where available reference to available local institutional guidance and legal codes will be made.

13.3 THE CHECKERED HISTORY OF MEDICAL RESEARCH

Some knowledge of the recorded history of the abuse of human subjects in medical research serves as a strong reminder to contemporary researchers of the need to protect research subjects, especially the vulnerable. Although honour codes such as the Hippocratic Oath, stretch back to antiquity and have always stressed the need for doctors to be honest, act with integrity and to put patient interest first, clinical trial investigators have not always adhered to the apparently sound principles of ancient (or modern) honour codes when conducting research.

3 World Medical Association, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, 64th WMA General Assembly (2013), available at http://www.wma.net/en/30publications/10policies/b3/; US Department of Health and Human Services, Basic HHS Policy for Protection of Human Research Subjects, 45 CFR 46 (2009), available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (visited 2 May 2013); Council for International Organizations of Medical Sciences, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice E6(R1) (10 June 1996), available at http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf; Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects (Revised Draft 2002), available at http://www.cioms.ch/images/stories/guidelines_demo/AllGuidelines-1-25.pdf.

4 Medical Council of Hong Kong, Code of Professional Conduct for the Guidance of Registered Medical Practitioners (2009, amended 2014), available at http://www.mchk.org.hk/Code_of_Professional_Conduct_2009.pdf.

5 Chinese University of Hong Kong, Policy on Research, Intellectual Property and Knowledge Transfer (2015), available at https://www.orkts.cuhk.edu.hk/images/Research_Funding/The_Policy_Paper_1b.pdf; University of Hong Kong, Policy on Research Integrity (2013), available at http://www.rss.hku.hk/integrity.

The beginning of serious efforts to regulate and control modern research arises from the aftermath of the appalling abuse of research subjects during the Second World War. These abuses were investigated at the Nuremberg Doctors' Trial, soundly condemned, and led directly to the publication of the Nuremberg Code in 1947,[6] the first complete set of written rules for guiding the conduct of research. At about the same time, in a linked document, the "Code for Human Experimentation, Principles of Medical Ethics" was published by the American Medical Association. The later actions of "respected" researchers conducting the Tuskegee trial in the United States (US), during which subjects were kept ignorant of, and denied known effective therapy in the interests of securing knowledge of the disease process, again strongly illustrated how respected researchers could fall short of the requirements of accepted moral behaviour and codes of conduct.

The fallout from the Tuskegee trial and the many cases of morally doubtful research brought to light by Beecher in the 1960s, were pivotal in demonstrating the need for the medical community to develop not only a set of clear and widely promulgated rules to govern research, but also to institute some method to ensure the oversight of researchers.[7] Beecher's observations, supported by others, thus led progressively to the requirement for greater oversight and governance in research.[8] As a result, in most countries, including Hong Kong, all current research should be scrutinised and approved by an appropriate Ethical Research Committee prior to commencement.

Many countries or jurisdictions have subsequently developed written requirements and guidelines governing the ethical conduct of research. Research Ethics Committees (RECs) and Institutional Review Boards, eg the Ethics Committee of the University of Hong Kong, and the Chinese University of Hong Kong (Human Research Ethics Committee (HREC) of the University of Hong Kong, the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee) have such requirements. Other international examples of such documents include the Belmont Report,[9] the implementation of good clinical practice in the conduct of clinical trials in Europe,[10] the international ethical guidelines for biomedical research involving human subjects,[11] the requirements for responsible conduct in research (RCR) in the US, and Basic HHS Policy for Protection of Human Research Subjects,[12] as well as the Declaration of Helsinki,[13] and the international "Good Clinical Practice" Guidelines.[14] The MCHK Code of Conduct specifically refers to the need that research follow codes as outlined in the International Conference on

6 E Shuster, "Fifty Years Later: The Significance of the Nuremberg Code". *New Engl J Med* 1997; 337:1436–1440.

7 HK Beecher, "Some Fallacies and Errors in the Application of the Principle of Consent in Human Experimentation" (1962) 2 *Clin Pharmacol Ther* 141–146; HK Beecher, "Ethics and Clinical Research". *N Engl J Med* 1966; 274:1354–1360.

8 J Horner and D Minifie, "Research Ethics I: Responsible Conduct of Research (RCR) – Historical and Contemporary Issues Pertaining to Human and Animal Experimentation". *J Speech Lang Hear Res* 2011; 54:S303–S329.

9 DHEW, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report (n.2 above).

10 Directive on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use, Directive 2001/20/EC, Offic J Eur Commun: 0034–0044, 4 April 2001.

11 Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects (n.3 above).

12 US Department of Health and Human Services, Basic HHS Policy for Protection of Human Research Subjects (n.3 above).

13 World Medical Association, Declaration of Helsinki (n.3 above).

14 Council for International Organizations of Medical Sciences, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (n.3 above).

Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines for Good Clinical Practice, and be in accordance with the Declaration of Helsinki.

13.4 THE ROLE OF ETHICS COMMITTEES IN HUMAN RESEARCH

In the absence of specific legislation, or any detailed overarching policy or guideline governing the conduct of medical research, existing RECs play a pivotal role in the regulation and governance of medical research. The major universities, the Hospital Authority (there is one REC in each major hospital cluster—a geographical grouping of hospitals) and some private hospitals have appropriately instituted, and functional medical research ethics committees. The existing professional guidance from the MCHK on clinical research provides a brief summary of the general principles that should be followed. Regarding ethics committees, it indicates that, "A trial should be conducted in compliance with the protocol that has received prior approval from an appropriate ethics committee or mechanism of similar standing", and that "The formation of an ethics committee in all institutions where researches on humans are undertaken should be encouraged."[15] It is, therefore, largely up to these individual committees to determine the moral and ethical standards that must formally be met by the researchers.

A brief description of the function of RECs is as follows. The primary role of RECs is to review and approve, or reject medical research proposals. Some RECs review specific types of research on human subjects, such as human studies in social sciences and psychology, or clinical trials. Others have a general function and review all types of medical research. Generally protocols for animal studies, intended to provide scientific information to advance science related to human conditions, are reviewed by specific animal experimentation RECs. This section will concentrate on human RECs.

All RECs should have documented requirements for composition, frames of reference and standard operating procedures. Generally the major functions of RECs are to:

(1) protect the rights of research participants through ensuring the respect of each individual's dignity, as well as their rights, safety and well-being;
(2) recognise that research is essential to society to improve collective current and future health, and should therefore facilitate researchers and enhance justified research; and
(3) promote public confidence in the integrity and conduct of researchers and the net benefits of research to society.

Practically it falls to RECs to conduct a formal ethical assessment of individual research projects to ensure that they meet recognised moral standards, that the research is worthwhile and safe, and that the risks, burdens and intrusions to patients are acceptable and justified by the expected benefits to society.

15 Medical Council of Hong Kong, Code of Professional Conduct for the Guidance of Registered Medical Practitioners (n.4 above).

As with REC reviews internationally, reviews in Hong Kong are generally proportionate to the scale/complexity of the proposed research. For example, the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee categorises risk by the following criteria:

(1) involvement of human subject recruitment;
(2) subject vulnerability;
(3) subject assignment methods;
(4) involvement of medical products;
(5) involvement of clinical procedures; and
(6) complexity of the study design.

Some institutions have separate RECs that review non-clinical research. An example is the REC governing survey ethical conducted at the Chinese University of Hong Kong (ie Survey and Behavioral Research Ethics Committee of the Chinese University of Hong Kong). Such arrangements may facilitate the review of research protocols by members with more intimate knowledge of corresponding research methods and with ethical issues related to the specific form of research being conducted.

Although research may not start until a favourable REC opinion has been given, the principal researcher retains primary responsibility for the design, conduct and reporting of the research. Thus, the researcher always remains responsible for the scientific and ethical conduct of the research. While RECs are not primarily responsible for enforcement of research conduct, if the research turns out to be unsafe, or is not carried out as agreed, they are empowered to investigate the circumstances of possible breaches of integrity (eg approval conditions not followed, or follow up public or participant complaints). Annual or more frequent updates from researchers on the progress of research are required, and high-risk studies may require monitoring by a specially designated safety monitoring committee, not normally linked to the REC, but independently constituted by knowledgeable and reputable individuals. The role of such committees is to monitor for the presence of unexpected harmful effects.

RECs retain the right to report violations to relevant authorities for action, and suspend or terminate approved clinical studies if unacceptable risk to subjects occurs. RECs have the right to audit clinical studies to assess compliance with study protocols, the REC's requirements and other applicable standards.

The composition of RECs is not regulated, however in line with international standards, RECs generally include lay members (up to 30 per cent), medical members (usually active researchers), ethicists and lawyers.

Multi-centre research has many ethical challenges, and generally such research should meet standards in all countries and sites within countries.[16] The participating centres that are that are taking part in multi-centre research must obtain approval from the relevant local or cluster REC prior to commencement of the research.

16 LA Jansen, "Local IRBs, Multicenter Trials, and the Ethics of Internal Amendments" (2005) 27 *IRB* 7–11.

13.5 SELECTED ETHICAL ISSUES IN CLINICAL TRIALS

13.5.1 Voluntary informed consent

To be considered valid, voluntary informed consent has four main components. These are as follows:

(1) the participant must have the mental capacity to make the decision;
(2) must receive sufficient information on the proposed experimental intervention in question (including the probability of expected benefits and risks);
(3) must be capable of comprehending the information; and
(4) must be able to provide his consent free of duress or coercion.

Section 2 of the Code of Professional Conduct[17] gives guidance on the requirements for valid consent to medical treatment. While not addressing medical research directly, many of these principles remain valid in the setting of research, in particular Sections 2.7–2.10 regarding the validity of consent and the requirements for proper explanation of treatment and risks as outlined earlier. In the context of medical research there are, however, some controversial issues that remain.

Effective communication is a key to ensuring that patients receive comprehensible information. Known barriers include language and cultural biases,[18] and this remains a risk, where medical training, case records and descriptions of medical conditions are largely in English, while the vast number of research subjects are Chinese speaking. This potentially creates a barrier to good quality communication during consent processes. Addressing these linguistic issues carefully is a pre-requisite to ensure the validity of research. Generally RECs require researchers to present consent forms in both Chinese and English.

It is also known that researchers may find it difficult to explain many of the technical aspects of research that include the process of randomisation, magnitude of risks, side-effects and the "real" concept of voluntary participation.[19] Some studies are technically complex, and potential risks and outcomes difficult to comprehend, even for medical professionals. In this context it is difficult to understand what "adequate information", sufficient for decision-making really is.[20] Thus whether subjects, unfamiliar with much of the knowledge base and concepts required to fully understand the complexity of a study to which they may be enrolled, are genuinely capable of providing "informed" voluntary consent, in many cases is unclear.[21] A classic example is known as therapeutic "misconception", when a research subject fails to understand the distinction between the purpose of clinical research (which is to gain generalisable knowledge), and of ordinary treatment (which is to cure a patient), and therefore incorrectly attributes therapeutic intent to a research procedure.[22] Despite

17 Medical Council of Hong Kong, Code of Professional Conduct for the Guidance of Registered Medical Practitioners (n.4 above).
18 E Etchells, G Sharpe, C Elliott and PA Singer, "Bioethics for Clinicians: 3. Capacity". *CMAJ* 1996; 155(6):657–661.
19 A Karim, S Qurraishi, H Coovadia *et al.*, "Informed Consent for HIV Testing in a South African Hospital: Is It Truly Informed and Truly Voluntary?". *Am J Publ Health* 1998; 88:637–640.
20 O Corrigan, "Empty Ethics: The Problem with Informed Consent". *Sociol Health Illn* 2003; 25(7):768–792.
21 J Flory and EJ Emanuel, "Interventions to Improve Research Participants' Understanding in Informed Consent for Research: A Systematic Review". *JAMA* 2004; 292(13):1593–1601.
22 CW Lidz and PS Appelbaum, "The Therapeutic Misconception: Problems and Solutions". *Med Care* 2002; 40(9 Suppl):V55–V63.

these problems, the need for obtaining voluntary informed consent from subjects remains an imperative, if only to prevent the possibility of either coercion or deceit in the research process.[23]

One of the underlying principles justifying the need for obtaining voluntary informed consent in medical research is autonomy. In Western cultures autonomy has become a dominant principle informing bioethical reasoning,[24] partly reflecting the importance being awarded to individualism in Western liberal societies.[25] The Chinese perspective of personhood, and by extension autonomy, is somewhat different. The Chinese idea of personhood emphasises individual rights and self-determination less, and places a greater emphasis on the individual as a member of a family group.[26] The Chinese family, therefore, plays a very important role in healthcare decisions.[27] Thus, the concept of individual autonomy is replaced in many instances by a concept of "familial" autonomy. In the author's experience, this altered perception of autonomy is as important in decision-making regarding participation in medical research as it is in therapeutic decision-making, and voluntary informed consent frequently involves broad family discussion with the researcher prior to individual decision-making regarding participation.

13.5.2 Voluntary informed consent in urgent or emergency settings

The ability of medical researchers to achieve valid voluntary informed consent in the emergency setting is often difficult, and frequently impossible. When the research investigation or treatment is urgent, there is little or no time for proper provision of information regarding of risks and benefit. Subjects often have reduced mental capacity as they may be distracted by pain, the need for therapeutic analgesic/sedative drugs, or in an incapacitated condition of as a result of brain injury or the use of recreational drugs. In this setting the risk of coercion is also high, as conscious patients may perceive the need for urgent decision-making while they are acutely ill and vulnerable.

Thus, although we ought to always obtain consent prior to the institution of medical research, it is not always possible that we can. This leaves two options:

(1) to abandon research in emergency settings; and
(2) to explore methods that may allow the conduct of clinical trials without prior consent in special circumstances.[28]

A number of proposed solutions that allow subjects to be safeguarded, while permitting medical research to proceed without prior consent have been proposed. Obtaining consent from close relatives or subject "surrogates" may allow the retention of a degree of autonomy

23 O'Neill, "Symposium on Consent and Confidentiality: Some Limits of Informed Consent". *J Med Ethics* 2003; 29:4–7.

24 PR Wolpe, "The Triumph of Autonomy in American Medical Ethics: A Sociological View" in DeVries R and Subedi J (eds), *Bioethics and Society: Sociological Investigations of the Enterprise of Bioethics* (New York: Prentice Hall, 1998).

25 F D'Agostino, "Two Conceptions of Autonomy" (1998) 27 *Economy and Society* 28–49; Corrigan "Empty Ethics" (n.20 above).

26 Y Cong, "Ethical Challenges in Critical Care Medicine: A Chinese Perspective". *J Med Philos* 1998; 23:581–600; Y Cong, "Doctor-Family-Patient Relationships: The Chinese Paradigm of Informed Consent". *J Med Philos* 2004; 29:149–178.

27 MD Feldman, J Zhang and SR Cummings, "Chinese and U.S. Internists Adhere to Different Ethical Standards". *J Gen Intern Med* 1999; 14:469–473.

28 GM Joynt, "Obtaining Informed Consent for Clinical Trials – Seldom Easy, Often Difficult, and Sometimes Impossible". *Int J Obstet Anesth* 2012; 21:4–6.

for incapacitated subjects. However, this solution is problematic as surrogates are also often not available. There is recent precedent for subjects being entered into emergency clinical trials without consent, but with strict safeguards designed to protect research subjects. While there is some jurisdictional variation, the type of safeguard required by RECs to allow such studies has been broadly similar. A list of requirements, based on previously published international guidance for exception from the need for prior voluntary informed consent is collated in Table 13.1.[29]

Table 13.1 Some Suggested Requirements That Must Be Met in Circumstances Where Waiver of Informed Consent Is Necessary because of the Urgent/Emergency Nature of the Research.[30]

• The nature of the research is such that "voluntary informed consent" from the patient cannot be achieved. This generally means emergency, life-threatening situations in which the subject lacks sufficient capacity to give informed consent, and appropriate surrogate decision-makers cannot be reached within in the time frame that the intervention must be applied.
• The research must be scientifically sound, and the investigation or the intervention being studied must be sufficiently established that justification for the research can be made.
• The risk to subjects from the investigation or intervention must be sufficiently small, given the clinical circumstances and standard clinical treatments.
• There should be at least some potential benefit to be gained from the trial by the subject, and the possible knowledge gained for society must be meaningful from a scientific and social perspective.
• The research study should be approved by the relevant REC/s and authorities.
• Subjects or their representatives should always have the opportunity to complete the "voluntary informed consent" process at the earliest opportunity and withdraw from the study if desired.
• A Research Study Monitoring Board, composed of members independent of the research team, should closely monitor the progress of the trial.
• Some guidelines require that the community within which the research is being conducted be consulted about the research study as well as the consent conditions, prior to commencement and be formally informed of the results of the study.

29 The Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects (n.3 above); US Food and Drug Administration, Protection of Human Subjects; Informed Consent and Waiver of Informed Consent Requirements in Certain Emergency Research, Federal Register 61(192) (1996); Panel on Research Ethics, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) (Ottawa, Ontario, Canada: Government of Canada, 2nd ed., 2010); J Thompson, "Ethical Challenges of Informed Consent in Prehospital Research". *Can J Emerg Res* 2003; 5:108–114; GM Joynt, Rainer, "Ethical Issues in the Conduct of Clinical Trials in Trauma Patients" in Papadakos PJ and Gestring ML (eds), *Encyclopedia of Trauma Care* (Berlin Heidelberg: Springer-Verlag, 2015).

30 Adapted from GM Joynt and T Rainer, "Ethical Issues in the Conduct of Clinical Trials in Trauma Patients", in Papadakos PJ and Gestring ML (eds), *Encyclopedia of Trauma Care* (Berlin Heidelberg: Springer-Verlag, 2015) pp.551–555, also available at https://urldefense.proofpoint.com/v2/url?u=http-3A__link.springer.com_referenceworkentry_10.1007-252F978-2D3-2D642-2D29613-2D0-5F214&d=CwIFaQ&c=4ZIZThykDLcoWk-GVjSLm9hvvvzvGv0FLoWSRuCSs5Q&r=0U04L7Q9npvtq5cWKTDrQRFTANFMzhpnSeiNN8BW4B_1yHPtzFf457aQrJ9a0hWY&m=RIpusIfwz3wQW0ER30z6p_IrINioufw8AR8NMo_IQWA&s=QAL2raMrTsLz4e9Iz2ooUpvEkdljTr1f4cjqMzIFHRQ&e=.

This approach appears reasonable; however, to maintain the trust between research subjects and society on the one hand, and the research community on the other, careful exercise of good judgment is required by all parties. Thus investigators, IRBs and regulatory bodies need to ensure adequate checks and balances are in place when exception from informed consent is considered necessary.[31]

From an ethical and moral perspective, it seems that the key objective to meet in the setting when subjects are asked to forfeit their autonomy is to avoid unacceptable harm to the patient, by paying special attention to the principle of non-maleficence. It follows that the research should carry minimal net risk to the subject.[32] In comparative clinical trials, "clinical equipoise" is thus one requirement necessary if consent is to be waived. Clinical equipoise in a human study may be accepted as existing "when a reasonable number of medical professionals believe the experimental investigation or intervention would be as good as, or better than the standard treatment, taking account of all risks and benefit". Establishing that equipoise exists between existing treatments and an experimental treatment can be difficult, as existing scientific data can be minimal, or challenging to interpret. The requirement for societal transparency, sometimes dictated by RECs, would mean the need for the development of appropriate methods for consulting the community, and while apparently not yet attempted in Hong Kong, attempts at implementation in other countries have been accompanied by several reports of the extreme difficulties involved achieving this goal.[33]

13.6 THE VULNERABLE SUBJECT

The vulnerable subject is anyone who is at risk of being unduly influenced to agree to take part in medical research. Different categories of subjects may meet the definition of vulnerable.[34] Patients with intellectual disability, those in emergency situations or those who have an incurable disease are potentially at increased risk of therapeutic misconception and form one category. A second category is those who are at risk of retaliation from authority and may be coerced. Examples include students (especially medical or allied health), military personnel, prisoners or other confined persons. Third category is of those whose legal or social positions are precarious such as ethnic minorities, refugees and the impoverished. Lastly, children (minors) may fit one or more of the above-mentioned categories and are automatically classified as vulnerable. Although there is no strict definition of vulnerable subject, or specific guidelines for their protection in medical research, through adherence to international guidelines, RECs are cognisant of the need for added safeguards, and requests for approval in such circumstances are strictly scrutinised. The status of the foetus must be considered when research in pregnancy is

31 KB McClure, NM Delorio, TA Schmidt, G Chiodo and P Gorman, "A Qualitative Study of Institutional Review Board Members' Experience Reviewing Research Proposals Using Emergency Exception from Informed Consent". *J Med Ethics* 2007; 33:289–293.

32 EA Largent, D Wendler, E Emanuel and FG Miller, "Is Emergency Research without Initial Consent Justified? The Consent Substitute Model". *Arch Intern Med* 2010; 170:668–674.

33 AA Ernst and S Fish, "Exception From Informed Consent: Viewpoint of Institutional Review Boards–Balancing Risks to Subjects, Community Consultation, and Future Directions". *Acad Emerg Med* 2005; 12:1050–1055; JM Baren and MH Biros, "The Research on Community Consultation: An Annotated Bibliography". *Acad Emerg Med* 2007; 14:346–352.

34 P Shivayogi, "Vulnerable Population and Methods for Their Safeguard". *Perspect Clin Res* 2013; 4:53–57.

contemplated, placing pregnant subjects in the vulnerable group, deserving of special consideration and protections.

Considering adult subjects with mental incapacity, Hong Kong's statutory adult guardianship scheme may be found in Pt.IVB of the Mental Health Ordinance (Cap.136) and it's subsidiary instruments. The Ordinance is aimed at extending the subject-person's basic human rights through the appointment of a legal guardian. The terms of guardianship include the provision of consent to medical or dental treatment by an appointed guardian if the person concerned is incapable, but no mention is made of the possibility of consent for medical research. Researchers, RECs, guardians and other stakeholders, when contemplating essential research in such subjects, should take great care to meet all the moral and ethical requirements of research, particularly the protection of the rights and well-being of the subject.

13.7 THE PRINCIPLE OF JUSTICE IN RESEARCH ETHICS

In research ethics, justice refers to the fair selection of research participants to participate in research projects or clinical trials. Fair selection should ensure an optimal balance of the risks and benefits when researchers are recruiting subjects, and be based on strictly scientific principles, not vulnerability or privilege.[35] For example, rates of disease are sometimes higher in countries or regions that are developing, but remain disadvantaged for historical reasons. For scientific reasons medical research in such populations is attractive, however, research in these populations is potentially problematic. Impoverished or poorly educated subjects are prone to coercion and therapeutic misconception. Local RECs and research governance may not be well-developed. In addition, testing on a disadvantaged population may reap benefits primarily for people living in more advantaged settings. This is especially true if the intervention being tested is expensive and unlikely to be available in the population in which the clinical testing was performed. Thus, there is a societal mismatch between those exposed to risk and those receiving benefit. Relatively advantaged societies like Hong Kong should guard against such exploitation, both within disadvantaged sections of Hong Kong society and when Hong Kong researchers are contributing internationally. It should be noted that even when involved in research projects outside Hong Kong, university medical faculty researchers are required to receive approval for participation from their designated local REC.

13.8 CONFIDENTIALITY

The right of a patient to confidentiality of their personal and medical information arises from respect for the principle of autonomy. Control of personal information and right to privacy extend from this principle. The Personal Data (Privacy) Ordinance (Cap.486) protects subject privacy, and all research must meet this minimum standard. Section 23.13 of the MCHK Code of Professional Conduct states that, "The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the

35 EJ Emanuel, D Wendler and C Grady, "What Makes Clinical Research Ethical?". *JAMA* 2000; 283:2701–2711.