



An Roinn Sláinte
Department of Health

Ethical Framework for Decision-Making in a Pandemic

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Introduction

The occurrence of a pandemic will inevitably result in considerable burdens being placed on human health and could cause significant social and economic disruption. The dilemma facing public health officials is how to implement public health measures in response to a pandemic in a manner that is equitable, reasonable, proportionate, in compliance with national and international legislation and which does not discriminate against particular groups or individuals. The main goals of the public health response to a pandemic should be to minimise the negative health impacts of the pandemic (i.e. the number of hospitalisations and deaths) and to maintain a functioning society. This goal may be achieved through the use of effective management and containment strategies and the prudent stewardship of resources.

Many of the issues encountered in planning and responding to a pandemic involve balancing rights, interests and values. A consistent feature of any public health crisis, such as a pandemic, is that the resulting treatments and interventions will place severe strain on the national healthcare system's already limited human and material resources. Difficult decisions will, necessarily, have to be made regarding how these limited resources can and should be utilised and distributed. The principles which inform resource allocation decisions should be applied consistently to avoid creating inequity. The move from patient-centred practice to practice guided primarily by public health considerations can cause tension for clinicians, because ensuring the health of the population often entails imposing limitations on the rights and preferences of individual patients. Managing an outbreak of infectious disease may require reviewing the standard of care it is possible to provide to patients and justifying a different approach to the allocation of resources, including medications, hospital beds, ICU equipment and clinical personnel.

We all have a role to play in minimising the impact of a pandemic in Ireland. This involves caring for ourselves and for others. As individuals we can express our solidarity with others by supporting those in need of help and making joint efforts to avert/reduce the threat. Protecting the public, and hence ourselves, will require society-wide collaboration e.g. practicing good respiratory etiquette, hand hygiene or staying at home when ill. In a public health crisis, just as clinicians may need to reconsider the needs and preferences of individual patients in order to prioritise the well-being of the population, members of the community need to review their own private interests in the light of a greater societal good.

This may involve accepting restrictions on individual liberty and privacy until the point at which the crisis is resolved. Pandemics by their nature transcend national boundaries. Mounting an effective response, therefore, involves international cooperation and a need for global solidarity in addressing threats posed by a pandemic.

While we are all vulnerable during a pandemic, some groups are likely to be particularly vulnerable because of biology, pre-existing medical conditions or social disadvantage. The implementation of public health measures during a pandemic should pay special attention to protecting the interests of these vulnerable populations and seek to ensure that such measures do not increase health inequalities. While the principle of equity or fairness requires that like cases are treated alike in accordance with transparent criteria, avoiding inequity requires ensuring that public health measures which are implemented during a pandemic focus on protecting the interests of populations who are considered vulnerable, including those who typically encounter barriers to accessing care.

Increased public awareness about a disease, how it spreads and its associated health risks will enable people at an individual and societal level to prepare for and respond to a pandemic. Pandemics may result in situations of increased uncertainty and fear when individuals are required to accept extraordinary measures e.g. voluntary/involuntary quarantine. Clear and regular communication, based on an understanding of risk perceptions, may address public concerns and alleviate fears which may result in more people cooperating with the necessary public health measures. It is essential that information be made available through a variety of sources for both healthcare professionals and the public, and that recipients should know where and from whom information is coming. It is also important to have information available in different languages and for people who face communication challenges (e.g. hearing or visual impairment) so that the entire population can make informed decisions about what actions to take during a pandemic.

Need for an Ethical Framework for Decision-Making

Planning for, and responding to, a pandemic requires reflection on values because scientific/clinical information alone cannot drive decision-making. Shared values give us a shared basis for decisions. Using ethical principles to guide decision-making can enhance

trust and solidarity, and can strengthen the legitimacy and acceptability of measures put in place. While healthcare ethics may not always be able to offer precise answers to every difficult question arising in the context of a pandemic, it can provide useful tools to help address the issues involved, to weigh up competing interests and to reach appropriate decisions. An ethical framework enables aspects of a particular decision to be teased out and deliberated upon, before a final decision is made.

This ethical framework includes a number of substantive ethical principles and procedural values that can be applied to, and employed during, the decision-making process in a pandemic. Ethical principles apply to the decisions that are made, whereas procedural values relate to the manner in which those decisions are made.

This high-level framework is intended for policymakers and healthcare planners and providers in acute and community settings. It is also designed to assist clinicians in implementing the ethical principles outlined below in their clinical practice. It is not designed to guide individual clinical decisions but to assist healthcare workers in thinking through the difficult decisions that will need to be made.

Ethical Principles

The framework identifies seven key ethical principles that should inform the pandemic planning process and decision-making during a pandemic. It is important to recognise that there is a degree of interaction between these principles and they cannot simply be applied or implemented in isolation. Decisions made to safeguard one principle may conflict with another principle, for instance, measures taken to minimise harm may result in limitations being placed on privacy. When values are in tension with each other, the importance of having ethical decision-making processes is reinforced (Table 1.). The importance assigned to particular ethical principles can vary depending on the cultural context and/or the local circumstances. All of the principles are important and the appropriate emphasis given to each is context dependent. Crisis conditions may place constraints on the extent to which principles can be applied, but every effort should be made to utilise them to the fullest extent possible under the specific circumstances. A pandemic develops in stages and that may give rise to different ethical issues. At different stages of a pandemic, the relative importance of each principle may shift.

Table 1. Ethical Principles to Guide Ethical Decision-Making During a Pandemic

PRINCIPLE	DESCRIPTION
Minimising Harm	<p>A foundational principle of public health ethics is the obligation to protect the public from serious harm. Harm is a broad concept, but includes physical, psychological, social and economic harm. In a pandemic, restrictions to individual liberty (e.g. asking people to self-isolate), access to services (e.g. cancellation of elective procedures/out-patient clinics) or service areas (e.g. limiting visitors to hospitals/residential facilities), as well as the imposition of infection control practices (e.g. restricting public gatherings), may be necessary to protect the public from harm. Where such restrictions are being considered, decision-makers should provide reasons for the public health measures to encourage compliance and should establish a mechanism to review decisions.</p>
Proportionality	<p>Proportionality requires that restrictions to individual liberty and measures taken to protect the public from serious harm should not exceed what is considered necessary to address the actual level of risk to, or critical need of, the community. The least restrictive measures to achieve public health goals should be employed, and more coercive measures should only be used in circumstances where the least restrictive measures have failed or may fail to achieve the public health goal.</p> <p>A proportionate response also involves communicating information in a way that neither exaggerates nor understates the situation. At the start of a pandemic much will remain unknown about how it will affect individuals and society as a whole. Those communicating decisions and the media have a responsibility for accurate and proportionate reporting.</p>
Solidarity	<p>Solidarity calls for a collaborative approach to pandemics that sets aside conventional ideas of self-interest or territoriality at every level of society, e.g. between individuals, healthcare institutions, governments and nations. Solidarity requires working together to respond to a pandemic; sharing of information that will help others; coordination of planning and response activities at local and national level, including those related to health care delivery; transfer of patients; and deployment of human and material resources.</p>

Fairness	<p>In a pandemic situation, when healthcare resources may be in short supply, available resources should be distributed fairly, effectively, and in ways that recognise the moral equality of all persons. Fairness requires that resource allocation decisions are not made arbitrarily. A fair decision is one that gives people with an equal chance of benefiting from health resources an equal chance of receiving them. A fair decision is also one that might treat some people differently but for clinically sound reasons e.g. it requires those who could get the same benefit from an intervention at a later date, to wait.</p> <p>Procedural fairness in decision-making is also vital and should be guided by the values contained in Table 2.</p>
Duty to Provide Care	<p>The duty to provide care and alleviate suffering is inherent to all codes of ethics and professional standards for healthcare professionals. Healthcare professionals will need to weigh the demands of their roles against other competing obligations e.g. their own health and the health of their families. In a pandemic situation, we may need many different types of carers. Non-clinical healthcare workers have a significant role in mitigating the negative impacts of a pandemic and sustaining the healthcare system, and could also be considered to have a duty to care. Individuals outside the healthcare system may also be involved in providing care for family members and other members of the community in line with the principle of solidarity.</p>
Reciprocity	<p>Measures to protect the public good are likely to impose a disproportionate burden on healthcare workers, patients and their families. Workers may have to face increased workplace risks as well as additional or expanded duties. Individuals in isolation or quarantine, and families of ill patients may experience significant social, economic and emotional burdens. Reciprocity requires that society supports those who face a disproportionate burden in protecting the public good, and takes steps to minimise the risks and burdens as far as possible.</p>
Privacy	<p>Individuals have a right to privacy and confidentiality with respect to their health information. However, a person's right to privacy is not absolute and it may be necessary, in extenuating circumstances, to restrict this right. Any disclosure of personal information to a third party must be limited to pertinent information that is absolutely necessary to avoid serious harm to the broader population, and there is no less intrusive means to protect public health.</p>

While each pandemic has its unique characteristics, experience shows there are predictable issues which arise and require ethical deliberation, including the duty of healthcare workers to provide care; restriction of individual liberty; priority setting and allocation of scarce resources; and conducting research during a pandemic. These issues are included in this framework and, while not intended to be exhaustive, serve to illustrate how the values and

principles in the ethical framework can be used to identify key ethical aspects of decision-making.

Procedural Values

Good decision-making processes show respect for people and ensure procedural fairness, as well as confer legitimacy on the decisions made. Communicating decisions and the rationale behind them in an open and transparent way is one of the crucial factors in increasing the acceptance and cooperation of those who will be affected by these decisions, *i.e.* frontline healthcare professionals, patients and the general public. Where possible, the participation and inclusion of multiple stakeholder groups, including members of the general public, in the formulation of a preparedness plan will increase the likelihood of its acceptance. It is often not feasible or appropriate to carry out extensive consultation during the response to a pandemic. This increases the need to be responsive to new information which may not have been considered during the initial decision-making. Judgements about the implications of a particular measure are likely to change over the course of a pandemic outbreak as more up-to-date information becomes available. Planning is, thus, an ongoing process and the ability to adapt a pandemic preparedness plan in light of new information is of particular importance.

Good decision-making is maintained by using explicit and transparent processes and having clear lines of accountability. Decisions may have to be made despite considerable uncertainty about relevant facts. Whether a decision is ethically appropriate and justifiable has to be judged in relation to the situation and information that exists at the time the decision is made, rather than by reference to facts which only become apparent at a later time point.

The values outlined below aim to enhance the ethical quality of decision-making processes.

Table 2. Procedural Values to Guide Ethical Decision-Making During a Pandemic

Reasonableness	Decisions should be based on best available evidence at the time, be the result of an appropriate process (taking into account the speed and context in which a decision is made), proportionate to the threat, and should have a reasonable chance of working. The decisions should be made by people who are credible and accountable.
Openness and Transparency	The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.
Inclusiveness	Stakeholders are consulted (to the greatest extent possible in the circumstances), views are taken into account, and any disproportionate impact on particular groups is considered
Responsiveness	There should be an opportunity to revisit and revise decisions as new information becomes available, as well as mechanisms to address disputes and complaints.
Accountability	Decisions made in the emergency setting must comply with these procedural requirements. There should be mechanisms in place to ensure that ethical decision-making is sustained at all stages of the pandemic. Those responsible for making the decisions are answerable for the decisions they did or did not take, within a multi-level network of accountability relationships. Within all accountability relationships, it must be clear who is accountable to whom, what they are accountable for, how accountability will be evaluated and the consequences of failures of accountability. Knowing what the goals of an accountability system are prevents those working within the system from “losing sight of what they are working towards with respect to accountability.” ¹ Appropriate records should be kept of decisions taken and the justification for them.

Duty to Provide Care

RESPONSIBILITIES AND OBLIGATIONS

The duty of care is foundational to healthcare practice. At its heart is the obligation to alleviate suffering, restore health and respect the rights and dignity of every patient.

¹ Christie NV (2018) A Comprehensive Accountability Framework for Public Administrators, Public Integrity, 20:1, 87.

Healthcare workers must balance their duty to care for patients, their obligations to their colleagues and family members with their obligations to self. In a pandemic, healthcare workers who are trained to provide patient-centred care for individuals must shift their practice to provide patient care that is also guided by the duty to steward scarce health resources such as medications, interventions and the time they can spend with patients. Under these crisis conditions, healthcare workers may experience serious moral and emotional distress. Meeting this challenge, healthcare workers play an essential role in responding to a pandemic and in maintaining a functioning and compassionate healthcare system. Clinical staff, as well as management, administrative and support staff also have a significant role in mitigating the negative impacts of a pandemic and sustaining the healthcare system. Accordingly, such non-clinical staff can also be said to have a duty to care.

During a pandemic, care may also come from a number of sources other than healthcare workers. There will be those in the community caring for older persons and those with disabilities, as well as people caring for family members, friends and neighbours who become ill. This care will be important for society to function and is also an expression of solidarity and part of the broader consideration of what we owe to each other.

Government has a crucial role to play in supporting healthcare workers in their duties by providing leadership in forming pandemic policies, providing public health guidance to frontline staff and the public, using its regulatory powers and by providing the necessary resources to mount an effective and humane health response. In addition, every member of society has a duty to follow public health advice and to adhere to all necessary instructions and restrictions.

Counteracting the effects of a pandemic represents part of an implicit contract between healthcare workers and society to use their expertise to respond during an emergency. A vital component of this social contract requires healthcare workers to recognise their responsibility to help society by showing solidarity and a commitment to care by continuing to work despite the potential risks involved. In turn, healthcare workers, whether clinical staff or otherwise, should be provided with support structures and resources to undertake their duties i.e. ensuring regular breaks during and between shifts as well as access to appropriate emotional supports in recognition of the psychological burdens they will face.

There may be a need for staff redeployment during a pandemic. Such redeployment measures are an important aspect of the response to a pandemic, particularly in relation to augmenting a healthcare institution's surge capacity and in offsetting inevitable staff absences. Redeployment may require healthcare professionals to be flexible and to work beyond their normal scope of practice or in different environments. Where this is the case, workers should be supported to undertake new or additional duties supported by training and supervision in so far as possible. For instance, "in-house" training when feasible should be offered for junior team members and clear lines of communication should be provided. Nevertheless, healthcare professionals should remain mindful of their obligations and responsibilities set out in their professional standards and the prevailing guidance and should continue to use their professional judgment in the delivery of care. In the interest of the procedural value of accountability, outlined in Table 2, there is still a responsibility to explain decisions and the rationale underpinning those decisions. In response to the provision of care, there is a reciprocal obligation on healthcare managers to be mindful of the burdens of redeployment and to minimise the risks to workers by providing additional support to those who accept extra responsibilities during a pandemic.

It is equally important that a healthcare worker's duty to care and obligations towards patients, as well as towards society overall, are not considered in isolation. Numerous factors need to be taken into account when determining the full extent of an individual healthcare worker's duty to care including:

- The necessity for that individual's services and expertise
- The degree of difficulty in replacing him/her
- The individual's duty of care to (present and future) patients
- The risks to the individual and his/her family
- Potentially competing obligations, e.g. family caring responsibilities.

An individual's duty to care is not absolute. For example, the virulence of a pathogen could place healthcare workers with certain pre-existing conditions at an increased risk of serious complications should they contract it. In such cases, it would be unfair and disproportionate to expect these individuals to undertake such heightened health risks to uphold their duty of care. While recognising that exceptions may have to be made under these circumstances, such "at risk" healthcare workers should also remain amenable to continuing to work in another capacity in a low risk environment. Exceptions or exemptions

from certain tasks may also be appropriate for healthcare workers with specific family caring responsibilities, having taken account of the individual's personal and professional obligations.

RECIPROCITY

Reciprocity, in the case of healthcare workers, can mean taking all reasonable precautions to prevent illness among healthcare workers e.g. through appropriate infection control measures. Healthcare workers should be provided with the necessary personal protective equipment (PPE) required to facilitate the completion of their tasks safely, as well as training in its use. Where any additional training and guidance is required to ensure such PPE is used in the appropriate and most effective manner, this should also be provided.

Showing support and solidarity by protecting healthcare workers from infection could also involve prioritising them to receive a vaccine if/when it becomes available. Immunising healthcare workers as a priority could be deemed equitable and proportionate, given the heightened risks they are exposed to during a pandemic and the vital role they play in mitigating the effects of a pandemic. Notwithstanding such preventative and protective measures, healthcare workers may still fall ill while upholding their duty of care. In such cases, decisions may be taken to expedite their testing and treatment, through priority access to anti-viral medicines or other interventions.

Illness and the resultant absence from work among healthcare workers during a pandemic will have a significant impact on the health response and is likely to require the redeployment of healthy staff to roles outside their normal remit. Employers and healthcare institutions should try to reduce the pressure and stress associated with such transfers. As an initial step, institutions should, where possible, aim to redistribute staff according to their relevant skills and experience to ensure the most efficient and effective continuation of services. Where staff must be redeployed to areas outside of their normal scope of practice or working environment, reciprocity requires that any decisions or actions taken by such healthcare workers would have to be assessed in the context of the challenging contemporaneous circumstances rather than with the benefit of hindsight. Such assessment must take cognisance of information relating to resources, guidelines or protocols in place at the time. The importance of ongoing (psychosocial) support for staff is also an issue which falls under the heading of reciprocity.

Restrictions of Individual Liberty

Restrictive measures, such as limiting freedom of movement of individuals and/or introducing social distancing measures, may be necessary in the management of a pandemic. This could include closing schools, cancelling public gatherings and sporting events, limiting travel, and imposing quarantine and isolation measures². Such measures illustrate the potential tension between individual rights and the collective good, and require consideration of how justifiable it is to restrict individual rights and freedoms in order to achieve certain public health goals. The principles of minimising harm, proportionality, solidarity, reciprocity and privacy are relevant in this context. The five procedural values are of special importance in ensuring compliance with any decision taken to restrict the liberty of individuals. Transparency about the process for making such decisions is key. The public should be clearly informed that restrictions on personal freedom may be instituted, and that these limitations may be important for their own protection and for that of others (in that it may limit transmission of disease in the community).

Restrictions on freedom of movement, in the interest of public health, place a considerable burden on individuals and communities, therefore, such measures must always be carefully considered and justified. Legitimate restrictions on an individual's freedom can be justified in cases where exercising that freedom places other people at significant risk. In enacting any measure where personal freedom is limited, the least restrictive effective measure should be adopted. For example, home-based quarantine/isolation may be appropriate, provided that adequate clinical and logistical support can be provided.

Decisions to limit individual liberty should be introduced only if the best available scientific evidence indicates that the measure(s) considered will achieve the intended goal; that the limitation(s) planned is proportionate to the anticipated benefit; that no less restrictive measure would be effective; and that failure to implement the measure would result in significant harm. Restrictions should apply without unfair discrimination, and the need for measures which limit individual liberty should be continually reviewed and assessed in light of emerging evidence. Reciprocity can be expressed by ensuring people who are

² Quarantine is used to separate and restrict the movement of well persons who may have been exposed to a communicable disease to see if they become ill. Quarantine can be voluntary or involuntary. Isolation is used to separate ill persons who have a communicable disease from those who are healthy.

subject to liberty-limiting measures are given extra support and are well looked after, in exchange for the extra burden they are carrying for protecting others.

PRIVACY AND THE PUBLIC INTEREST

An important feature of the Irish healthcare system is that patients' privacy is upheld and their information is treated as confidential. However, a person's right to privacy is not absolute and it must be balanced against the needs of society overall (*i.e.* the public interest)³. A well-recognised exception to the obligation of confidentiality is that decision-makers may be entitled to override personal privacy rights in cases of serious public health risks, if revealing limited amounts of personal information would help to protect the health of the general population.

Decision-makers also have an obligation to protect citizens from stigmatisation and discrimination. This can be achieved by respecting individual privacy as far as possible by only providing information that will give a realistic view of the extent of the pandemic's impact, a requirement of the principle of proportionality. The information shared with the public should be enough to make them aware of the facts, but not enough to accurately identify individuals. Such information might include: the general region the patient comes from (*e.g.* province or whether s/he comes from the east *etc.*); the patient's gender; whether the patient has an underlying health condition; and the age range of the patient (*e.g.* under 14 years, over 65 *etc.*).

In order to contain the spread of the infection and/or to monitor its advancement, it may also be necessary for healthcare professionals and public health policymakers to share personal information with each other. Where information sharing amongst professionals is deemed necessary for protecting public health, strict safeguards must be in place to ensure that: information sharing is done in accordance with data protection legislation; there is no unwarranted invasion of privacy and only those with specific authorisation have access to personal information; and the mechanisms for maintaining confidentiality of

³ Processing data necessary to perform a task in the public interest is one of several legal grounds provided for in Article 6 and Article 9 of the General Data Protection Regulation (GDPR). Article 89 of the GDPR provides for processing of data in the public interest subject to appropriate safeguards. In addition, Article 9 recognises that processing may be justified to protect the vital interests of the data subject. Recital 46 expressly recognises that the monitoring of epidemics may involve data processing that is justified by reference to both the public interest and the vital interests of data subjects.

patients are secure (e.g. databases containing personal information should be password protected and the information contained be encrypted).

Allocation of Scarce Resources

Pandemics place a considerable strain on health systems and can further exacerbate resource limitations. Decisions in relation to the allocation of scarce resources e.g. PPE⁴, hospital beds, medications and other interventions, will have to be made at the individual, organisational and population level. The principles most applicable to this issue are fairness, minimising harm, solidarity and reciprocity. It is particularly important that the process by which resource allocation decisions are made is reasonable, transparent and accountable, and that the rationale underpinning those decisions is communicated to the public, especially each person and family impacted by a clinical decision.

The principle of fairness means that everyone matters equally, and under normal circumstances all individuals have an equal claim to healthcare. During a pandemic, however, healthcare resources, particularly critical care resources, are likely to become limited over time. Once the healthcare system reaches capacity, everybody will be cared for, but may not have the same access to different levels of medical intervention. Decisions will, therefore, have to be made regarding who should be prioritised to receive intervention. These decisions should be based on the underlying rationale of maximising the benefit that can be gained from the limited amount of resources available and giving due attention to the fair distribution of benefits and burdens⁵. Consideration of how benefit can be maximised will include reference to the best clinical evidence available at the time.

Patients with Covid-19 as a cohort should not be given preferential treatment over other patient cohorts requiring acute care; neither should they be treated any less favourably.

SURGE CAPACITY

Efforts should be made to augment capacity to help accommodate the surge in patients requiring care as much as possible. However, since overall healthcare resources are finite,

⁴ The most protective equipment should be reserved for those performing interventions which present the highest risk (e.g., intubations, monitoring persons on BiPAP) (Hicks et al, 2020).

⁵ This reflects the WHO 2016 *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks*, which recommends that resource allocation decisions should be guided by balancing utility and equity considerations.

it must be recognised that efforts to increase care capacity will have a knock-on effect on other resources and services in the healthcare system. This will, ultimately, require difficult decisions to be made in relation to which services to maintain and which to defer. The impact of the pandemic, in terms of the number of individuals requiring hospitalisation and critical care, will not be uniform and it will affect different regions and institutions to a greater or lesser degree at different times. Given the temporal and geographical variation in the impact of the pandemic it is crucial that institutions develop a phased response to increasing surge capacity, which can be implemented gradually as demand for critical care increases. It will be important that institutions across regions collaborate and cooperate with each other, in so far as possible, in order to maximise the utility of scarce material and human resources. Taking a stepwise approach to augmenting surge capacity will facilitate normal healthcare functioning to continue for as long as possible. This conforms to the ethical principles of fairness, equity and proportionality as normal services should not be deferred unless it is deemed necessary in the face of critical care requirements.

As the situation with regard to a pandemic worsens and demand for critical care intensifies, there will be greater justification in adopting more extensive deferment of healthcare services. When deciding which services to postpone, an institution should take account of the relative risks and benefits for the patients affected in conjunction with the resources available and, ultimately, adopt measures based on the principles of proportionality and fairness.

Certain services will have to be maintained during a pandemic, e.g. emergency treatment, obstetrics. Other services (*i.e.* those whose postponement would not be deemed life-threatening and would not adversely affect the patient's health) could potentially be deferred either in the short-term, until a specific surge in demand has passed, and/or in the longer-term until the pandemic itself is over. As an expression of solidarity, each institution has a responsibility to try and rearrange appointments for these services as soon as possible once the requisite resources are no longer needed to supplement the critical care demand, and/or once the level of risk to patients in attending the institution for the treatment has lessened.

PRIORITISATION OF MEDICATION AND CRITICAL CARE

In cases where all patients cannot be treated, notwithstanding surge capacity, it is essential that the *process* of differentiating between those individuals who should and should not receive a particular intervention is conducted in a consistent manner, taking account of the local context. Decisions will have to be made about the level of care offered e.g. admission to ICU, initiation of life-sustaining treatment e.g. ventilation, as well as withholding or withdrawal of life-sustaining treatment, necessitating referral to palliative care services. Fairness dictates that these decisions should be based on the underlying rationale of maximising the benefit that can be gained from the limited amount of resources available.

Decisions should be principally based on the health-related benefits of allocation mechanisms. Thus, the starting point for any rationing decision is to consider which patients are most likely to benefit from the intervention. Consideration of the patient's pre-morbid health status, their will and preferences (if known), the presence of co-morbidities and their frailty status (independent of age) are all relevant in this context.

A multi-principled approach takes into account estimates or projections of: the total number of lives saved; the total number of life years saved; and long-term functional status should patients survive; these estimates or projections may be made based on empirical data if they are available, or on sound clinical rationale. Such an approach can act as a tool to facilitate fair decisions, as it seeks to balance utility and equity considerations. Utilising a multi-principled approach can temper the classic utilitarian approach of the allocating resources based on 'the greatest good for the greatest number', taking into account a fair distribution of benefits and burdens. Categorical exclusion e.g. on the basis of age should be avoided as this can imply that some groups are worth saving more than others and creates a perception of unfairness. The principle of solidarity dictates that while all patients may not receive critical care, those who do not should continue to be cared for with alternative levels of care, including palliative care.

It is not appropriate to prioritise based on social status or other social value considerations e.g. income, ethnicity, gender. However, it may be ethical to prioritise certain at-risk groups and those essential to managing a pandemic for treatment. This conforms with the principles of minimising harm, fairness and reciprocity.

Certain groups of individuals are more likely to need anti-viral medication as part of their treatment regime, assuming that an anti-viral medication that is safe and effective is available for use. These groups include those who develop severe symptoms and also those individuals who are considered to be at higher risk of complications should they contract the illness. Given the more serious medical implications for these individuals, it is considered fair, equitable and proportionate to prioritise anti-viral treatment for them. Priority access to anti-viral medications by persons who assume risk to their own health or life in responding to the pandemic e.g. healthcare workers is also ethically justifiable, on the basis of the principles minimising harm and reciprocity.

Once a pandemic becomes established and the causative virus has been identified, development, testing and production of an appropriate vaccine will begin. However, given the processes involved and the production time required, a vaccine may take a number of months to produce. Moreover, since the vaccine will be delivered in batches, overall supplies will be limited at a given point in time, therefore, decisions will have to be made in relation to who should be prioritised to receive the vaccine. Vaccine allocation policies consistently focus on defined cohorts within the population, namely; healthcare workers, at risk groups, children, the elderly, and the remainder of the adult population. While the exact order that these different groups receive the vaccine may change depending on the specific nature of the pandemic virus involved, prioritisation decisions generally incorporate the same basic set of factors:

- They are based on objective medical evidence;
- They take account of the ethical principles of fairness, equity and proportionality; and
- They aim to minimise harm and achieve the most good with the available resources.

Research During a Pandemic

In order to inform the public health response to a pandemic and to provide for appropriate scientific evaluation of any new intervention or medicine, research will be required. Data from such research plays a crucial role in mitigating mortality and morbidity during a pandemic. Research should not, however, divert human and/or material resources away from the public health response, or from the provision of care. In pandemic situations the usual protections afforded to research participants should be upheld, as should standards

for research integrity. The principles of fairness, reciprocity and privacy are most relevant in this context. The five procedural values apply.

The research should offer a means of developing information not otherwise obtainable; the design of the research should be scientifically sound; duplication of effort should be avoided; investigators and other research personnel must be qualified; there should be fair selection of research participants; participation in research should be voluntary; and research proposals should undergo independent ethical review.

Special consideration should be given to the informed consent process when conducting research during a pandemic. Participants may be particularly susceptible to therapeutic misconception⁶ and efforts should be made to correct any misunderstanding on the behalf of participants as to the purpose of the research.

Confidentiality of the personal information of research participants should be protected to the greatest extent possible. Information collected as part of a research project should be shared with public health authorities if it is deemed important for the response effort e.g. information regarding transmission chains. Participants should be informed about the circumstances under which information might be shared with others as part of the informed consent process. Every researcher involved in the generation of information related to a pandemic has an ethical obligation to share preliminary data once they are adequately quality controlled for release⁷.

Mechanisms should be available to allow for the accelerated review of research proposals in a pandemic, without undermining any of the substantive protections that ethics review is there to provide.

Collaboration nationally and internationally between research groups is crucial in order to avoid research silos.

⁶ Therapeutic misconception exists when individuals do not understand that the defining purpose of clinical research is to produce generalisable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study, Henderson, G.E *et al* PLoS Med. 2007 Nov; 4(11): e324.

⁷ WHO 2016 *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks*, p.33