ITEM 9C



COVID-19 Guidance: Ethical Advice and Support Framework

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Key Summary

- 1. The COVID-19 epidemic may result in changes to healthcare scope and delivery across the UK, for all patients.
- 2. This guidance on ethical advice and support should be read alongside national decision-making and escalation guidance, produced by senior clinical experts, to help to make decisions in difficult circumstances. It applies at all levels of healthcare delivery.
- Clinical decisions should continue to be guided by the principles of GMC Good Medical Practice, and available evidence¹. Clinical teams have responsibility for decisions about their patients.
- 4. In the small number of situations beyond the scope of national guidance or the experience of clinical teams, ethical advice and support must be available to aid decisions at all levels including individual, group or population level.
- 5. This guidance aligns with the work of the UK Medical Ethics Advisory Group, taking a coherent approach across the UK, adapted to the Scottish context ².
- 6. Doctors should be assured that decisions taken in good faith, in accordance with national actions and guidance to counter COVID-19, will not be held against them.

The current COVID-19 pandemic in the UK may result in increased patient demand for NHS care in Scotland, along with a high level of staff absence. This may impact the entirety of the healthcare system, and its capacity to meet the increase in demand in the community and in secondary care ³.

The Scottish Government, along with NHS Boards across Scotland, are working hard to ensure that the NHS has the available resource to care for the people of Scotland. However, if the immediate need for healthcare resource exceeds what is required, and there is no additional capacity available within the system, changes to healthcare delivery and scope may be necessary. The four Chief Medical Officers of the UK are working to ensuring a collective approach to managing the COVID-19 outbreak across the four nations, and guidance developed specifically for Scotland is closely aligned with the rest of the UK.

This document forms part of a suite of guidance to help support the delivery of healthcare in Scotland, which includes clinical guidance and escalation plans ⁴. Ethical advice and support will not be needed in most cases; clinicians will be able to apply their knowledge and experience as well as refer to clear national guidance. However, where there is need for ethical advice and support it is crucial that it is accessible, timely, and useful.

Purpose

Clear decision-making guidance to assess individual cases, and advise on appropriate management and escalation, can help clinicians make difficult clinical decisions. Clinical decision-making guidance for Scotland has been produced by a senior clinical team, chaired by Professor Tom Evans. This guidance is considered both clinically sound and on firm moral ground.

However, there may be a small number of complex situations in which additional ethical advice or decision-making support may be useful for healthcare workers and clinical teams, as well as Health Boards and senior teams. This document will set out the approach to ensuring that this is accessible to all staff who need it, and able to deliver useful in put in challenging circumstances.

Scope

It is important that the right care be delivered to the right patient and the right time ⁵. Under normal circumstances, these decisions would be made of the basis of patient choice and anticipated clinical benefit to the patient. In the context of increased demand, it may also be important to consider fairness of healthcare distribution within the wider population and how finite resources can be most appropriately used. Because of this, there may be some complex or challenging decisions where ethical advice or decision-making support will be useful. The impact of the COVID-19 pandemic is challenging to predict, and different approaches may be needed at both regional and national levels at different stages of the response across Scotland. This may result in a departure from usual clinical practice and will need clear national guidance to help the NHS in Scotland respond.

Clinical decisions should be based on assessment of the patient and application of clinical judgment, further guided by national guidance where appropriate. Healthcare staff will need psychological support when making difficult, complex or challenging decisions outside of their normal practice, which the ethical advice and support groups should be available to offer. The role of the ethical advice and support groups will need to evolve as the clinical context changes, and any guidance on this will be communicated clearly.

Ethical Advice and Support Groups

- Ethical advice and support groups will be established as a priority in each Health Board in Scotland, to deliver useful, timely and pragmatic ethical support for complex or difficult cases.
- A national ethical advice and support group will be established to offer advice and support to local groups, as well as to consider national ethical issues and offer advice.
- 3. Mutual aid agreements will offer access to immediate support, where the Health Board ethical advice and support group is unable to offer advice in a clinically useful timeframe. This may be delivered through existing clinical networks or expert groups, or through local agreements. This will allow access to independent advice around complex clinical, ethical and logistical challenges as they arise.

Ethical considerations

It is important that patients are treated independent of suspected or confirmed COVID-19 status, and that any clinical decision guidance applies equally to all patients ^{2,6}.

Doctors should act in accordance with professional guidance including the GMC's guidance *Good Medical Practice* (2013) ¹, as well as on *Consent: patients and doctors deciding together* (2008) ⁷ and *Treatment and care towards the end of life* (2010) ⁸, and in accordance with their legal obligations.

The ethical framework developed by the Committee on Ethical Aspects of Pandemic Influenza was first published in 2007 and revised by the Department of Health and Social Care in 2017¹⁰. This framework outlined the fundamental principles that all people should be treated with equal concern and respect:

- Everyone matters
- Everyone matters equally but this does not mean that everyone is treated the same ¹¹
- The interests of each person are the concern of all of us, and of society
- The harm that might be suffered by every person matters, and so minimising the harm that a pandemic might cause is a central concern ¹⁰

These principles continue to underpin the work of the UK Medical Ethics Advisory Group, but more recent guidance reflects changes in society and thought since the Influenza pandemic guidance was published in 2007.

The ethical approach to decisions in Scotland will be consistent with the UK framework, but will be adapted to the Scottish context.

Respect

• All patients should be offered good quality and compassionate care ^{1,8,11}

Fairness

• Patients should be treated as individuals, and not discriminated against ¹¹

Minimising harm

- Where there is a decision that a treatment is not clinically appropriate there is not an obligation to provide it, but the reasons should be explained to the patient and other options explored ⁸
- No active steps should be taken to shorten or end the life of an individual ⁹, however the appropriate clinical decision may be to withdraw life prolonging or life sustaining treatment, or change management to deliver end of life care

Working together

- The present and past wishes and feelings of adults should be taken into account so far as they can be ascertained by any means of communication ¹²
- Clinicians should act with honesty and integrity in their communication with patients and should communicate clinical decisions and the reasoning behind them transparently. This should be documented appropriately ¹

Flexibility

• As the clinical situation evolves both at the individual and population level, decisions will need to be kept under review with clear guidance at the national level ¹⁰

Reciprocity

- Wherever clinicians are expected or asked to take increased risks, they must be supported in doing so ¹⁰
- Where there are resource constraints, patients should receive the best care possible, while recognising that there may be a competing obligation to the wider population⁸

Capacity and consent

The approach to assessing, supporting and recording decisions about capacity and consent remains the same during the COVID-19 pandemic. Clinicians should continue to apply the ethical, professional and legal frameworks clarified below to interactions with patients.

- All patients over 16 years old are considered under Scots Law as adults and are presumed to have capacity. All practical steps should be taken to support patients in being able to input into decision making 1,8
- Where adult patients are found through medical assessment to lack capacity, decisions should be based on whether any proposed treatments are of overall benefit to the patient, and if so, consideration of which option would be least restrictive on the patient's future choices in accordance with the Adults with Incapacity Act (2000) ¹²
- Where patients have delegated legal authority through Power of Attorney, views of the patient and their attorney(s) should be considered where appropriate as described in the Adults with Incapacity Act (2000) ^{12,13}
- Below the age of 16 individuals have the capacity to consent to medical treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment ¹⁴
- Assessments of capacity should follow the principles outlined by the General Medical Council in guidance Consent: doctors and patients making decisions together and 0-18 years: guidance for all doctors, which provide context on the law in Scotland ^{7,15,16}

Logistical considerations

National ethical advice and support group

This should include healthcare professionals, academics, legal professionals, religious group representatives, senior social work officer, and lay representation.

The Scottish ethical advice and support group will be available as a point for escalation for the Board level groups. This group will meet to review challenging system based challenges or complex individual cases that have already been discussed at the local level, to review the common challenges that are being encountered and to consider whether review of or additional guidance would be useful.

The Scottish ethical advice and support group will meet on a regular basis and will report to the Chief Medical Officer in Scotland or to a delegated responsible officer. A written summary of items discussed, and any recommendations made by the group, should be reported to the CMO or the delegated responsible officer after each meeting.

Board level ethical advice and support groups

NHS Board groups should be considered as a point of contact for ethical advice, and not an alternative to existing clinical national guidance or to replace team based clinical decision making for the provision of good clinical care.

These should be appointed locally, with a diverse range of backgrounds and expertise. This should be a small group that reports directly to the Board through the Chief Executive, or a delegated responsible officer. The ethical advice should be independent of senior decision makers within the Health Board senior management team, to ensure that it is able to offer independent advice. It is expected that there should be provision for daily meetings, including on weekends.

Membership should include:

- lay representation
- experienced clinical, public health and social work input
- multi-disciplinary perspective

It is important that Board ethical advice and support groups have a flexible approach, are readily available and able to offer timely support. Examples where this group may usefully be able to offer insight include:

- Complex decisions around withdrawal of care
- Situations where clinical decision makers feel uncomfortable with the application of national guidance
- Challenging decisions around escalation planning and ceilings of care
- Complex decisions related to patient discharge due to high clinical demand
- Challenges related to reduced ability to provide normal standards of care, in particular in the community or for patients at the end of their lives

The number of cases referred may change during different phases of the COVID-19 pandemic, and groups may need to adapt their ways of working. It is expected that only a small minority of cases will need to be referred to and discussed by the groups. At each NHS Board level, there must be a:

- Clear route to contact for the ethical advice and support group, publicised to staff
- Clear structure for sharing information with the ethical advice and support group, such as SBAR
- Clear process by which discussions by the ethical advice and support group are documented and fed back to the responsible clinical team
- Clear process for ongoing learning and review

Governance structure:

The Board ethical advice and support groups should report directly to the Chief Executive, or to a delegated responsible officer, to ensure that they are aware of ethical challenges within the Health Board. The ethical advice and support groups will provide a written summary report.

Mutual Aid Agreements

Where immediate advice is needed to aid urgent or critical decisions, it is important that this is available and accessible. These decisions may be:

- a) Related to decisions about the care of individual patients
- b) Related to the ability to deliver appropriate or necessary care

In both instances it is important that conversations are clearly documented and communicated with the rest of the clinical team.

The Care of Individual Patients

Mutual aid agreements between hospitals or Health Boards should include access to independent advice or support for clinical decisions in urgent or emergency situations, from the relevant clinical experts. This might include decisions around an immediate need to admit to intensive care. This may include the use of existing clinical networks or expert groups, such as the Critical Care Delivery Group.

These discussions should be communicated with patients and their families as appropriate.

The Ability to Deliver Patient Care

Where a clinical team or hospital is no longer able to deliver the quality of care, or access to resources, that they feel is appropriate ethical challenges will arise for the individuals, team and management. There must be immediate access to ethical advice if this occurs, to offer an independent view and support in difficult circumstances. This may include discussion of the risks and benefits related to transfer of patients. Access to ethical advice and support should be through mutual aid agreements, managed through national networks or agreed

locally between hospitals or Health Boards. These discussions should be highlighted to senior hospital management at the earliest available opportunity.

Research

There is current national interest in COVID-19 research, across the UK.

Research and appropriate use of available data is key to helping deliver the best care at the patient and population level and is an important part of the national and global response to the COVID-19 pandemic. This requires a collaborative approach, avoiding silo working, to ensure that effort and resource is used most effectively. The use of resource such as staff time, equipment, and funding, for research should be balanced against the needs of the wider healthcare response, and the normal standards of research must continue to be upheld.

To ensure that appropriate ethical standards of research are met for the safety of patients and the population, any research should meet the appropriate standards and approvals.

The Medicines and Healthcare Regulatory Authority has a framework for prioritising research submissions around COVID-19 in the context of the pandemic, available online¹⁷. The Health Research Authority is working to expedite Research Ethics Committee Reviews as part of this¹⁷. The Health Research Authority UK has produced an expedited standard operating procedure to help researchers in submitting to ethical review ¹⁸.

Authority for Research on Adults with Incapacity

The considerations for ethical research involving adults with incapacity are outlined in section 51 of the Adults with Incapacity (Scotland) Act 2002 (Authority for Research)¹². No research can be carried out on an adult who lacks the capacity to decide whether to participate in research, unless the conditions contained in section 51 are satisfied. For approval, the research must be approved by "the Ethics Committee" constituted by Scottish Ministers under Regulations made under the Act. The Health Research Authority Central Booking Service should allocate all such applications to the designated Research Ethics Committee in Scotland, which will review the application under section 51 of the AWI Act^{12, 19}.

Research across the UK

Where research involves participants across the UK, the NIHR regulations state that applications should be made separately to Research Ethics Committees in England (or Wales) and Scotland, but a favourable decision from whichever is asked for approval first should be sent with the application if this is already available¹⁶. Where the study involves adults who lack capacity, separate decisions about the application must be made in Scotland and England or Wales due to differences in the legal framework¹⁶. Any changes related to AWI specifically after initial approval would only need to be resubmitted to the Scotland A Research Ethics Committee¹⁹.

Review

It is important that given the rapidly evolving and unpredictable nature of the COVID-19 pandemic, that the structures remain flexible and that advice given is reviewed in the light of the current clinical and healthcare context. This may change, and clinical teams should apply appropriate judgement as to whether they should review patient care in the light of any developments. Where these changes happen, these should be clearly communicated to patients and their families.

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Further Resources

Teaching seven principles for public health ethics: towards a curriculum for a short course on ethics in public health programmes, Schröder-Bäck et al. BMC Medical Ethics 2014, 15:73 (<u>http://www.biomedcentral.com/1472-6939/15/73</u>)

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