

# COVID-19 guidance: ethical advice and support framework



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## COVID-19 guidance: Ethical advice and support framework

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Version 2.4	Version updated to reflect comments regarding Human Rights and Equality after stakeholder feedback <ul style="list-style-type: none"><li>• New section added on Equality and Human Rights</li><li>• Language throughout document altered to reflect shared decision making</li><li>• Welsh and Irish documents, and NHS E&amp;I documents reviewed</li><li>• Updated to better reflect current position of UK MEAG</li></ul>
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Version 2.62	Changes reviewed by SG Policy Teams
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Version 2.71	Pre-EQIA feedback from stakeholders added
Version 2.72	Updated to reflect feedback from EQIA, in particular to clarify that membership of groups should be as reflective as possible of the community that they serve, acknowledging the constraints of a limited membership.

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## Summary

1. During the COVID-19 pandemic, clinical and healthcare decision-makers continue to be duty-bound to respect, protect and fulfil human rights, prevent discrimination and ensure equality and human dignity are at the heart of clinical practice
2. Increased pressures on healthcare systems and resources due to the COVID-19 pandemic may result in changes to healthcare scope and delivery across the UK, for all patients.
3. This document outlines structures and principles for ensuring an ethical approach to decision making, and for ensuring that ethical advice and support is available if needed through clear structures at the local and national level. It is for clinical and healthcare decision-makers in Scotland and should be read alongside Clinical Pathways guidance, produced by senior clinical experts.
4. Clinical teams have responsibility for decisions about their patients care. Clinical decisions should continue to be guided by relevant legislation, including equality and human rights law, the principles of GMC Good Medical Practice, and available evidence<sup>1</sup>.
5. 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.
6. This guidance aligns with guidance produced by the UK Moral and Ethical Advisory Group, taking a coherent approach across the UK, adapted to the Scottish context<sup>2</sup>.
7. 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 as individuals.
8. This guidance applies to the care of all patients during the COVID-19 pandemic and is not specifically related to a single diagnosis.

## Background

It is important that given the rapidly evolving nature of the COVID-19 pandemic, that this ethical advice and support framework is viewed in the current clinical and healthcare context. Scottish Government will aim to keep this guidance up to date, and the need for ethical support at local and national level will be kept under review.

The Scottish Government, along with Health Boards across Scotland, are working hard to ensure that we have the resources, guidance and advice needed to care for the people of Scotland during the COVID-19 pandemic. An increase in demand on healthcare resources, along with high levels of illness among staff, may affect the care that the NHS in Scotland is

able to deliver for patients. If the immediate need for healthcare resource is more than it is possible to deliver, and there is no additional capacity available within the system, changes to healthcare delivery and scope may be necessary. It is possible that this could affect all aspects of the healthcare system, in the community and in secondary care<sup>3</sup>.

It is important that if this happens, decisions are made fairly, equitably and prudently to minimise the loss of life, in a manner that is non-discriminatory and consistent with equality and human rights obligations. The healthcare response is crucial to ensuring that the rights to life and to health continue to be respected, without discrimination, and that resources reach those who are most likely to clinically benefit.

All individuals should be treated with care, compassion and respect, following the professional guidance outlined by the General Medical Council and the relevant human rights and equality legislation. Practising Realistic Medicine means finding out what matters to people and providing them with the information they need to make an informed choice about their treatment and care.

There is currently no preventative or curative treatment, outside of evidence-based good clinical care, that has been proven effective for the COVID-19 virus. Active research into vaccination and therapeutics is ongoing across the UK and rest of the world. As treatment options become available and new evidence emerges, the approach to management of the SARS-CoV-2 virus and the COVID-19 disease at the individual, local and national level will need to be reviewed to ensure that it remains proportionate to the stage of the pandemic response, and that any guidance remains useful, appropriate, ethical and grounded in equality and human rights.

The four Chief Medical Officers of the UK are ensuring a collective approach to managing the COVID-19 outbreak across the four nations, and guidance developed for the Scottish healthcare context is informed by that.

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<sup>4</sup>. 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 high quality, accessible, timely, and useful.

## Purpose

Clear decision-making guidance to assess individual cases, and advice on appropriate management and escalation, can help clinicians make difficult clinical decisions. It is important that this guidance is equitable, proportionate to the stage of the response to the pandemic, and uses the best available evidence. Clinical decision-making guidance for Scotland has been produced by a senior clinical team, in the Clinical Pathways guidance.

However, there may be a small number of complex situations in which additional ethical advice may be useful for healthcare workers and clinical teams, as well as Health Boards and senior teams. This guidance sets out the approach to ensuring that ethical advice is accessible to all staff who need it, and able to deliver useful input in challenging circumstances.

## Scope

It is important that the right care is delivered to the right patient at the right time<sup>5</sup>. Clinical decisions are made on the basis of patients' wishes, anticipated clinical benefit, and minimising the risk of harm. Clinical decisions should continue to be informed by assessment of the patient and application of clinical judgment, aided by national guidance, available evidence, and relevant legislation. 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.

Increased healthcare demand and system challenges may result in a departure from usual clinical practice and will need clear national guidance to help the NHS in Scotland respond. In the context of increased demand, it is important that decisions are made fairly, equitably and prudently to minimise the loss of life, in a manner that is non-discriminatory and consistent with equality and human rights obligations. The healthcare response is crucial to ensuring that the rights to life and to health continue to be respected, without discrimination, and that resources reach those who are most likely to clinically benefit. There may be some complex or challenging decisions, beyond the normal experience of clinical teams, where ethical advice will be useful. The purpose of this framework is to support health systems in delivering this advice and support across Scotland.

Healthcare staff will need psychological support when making difficult, complex or challenging decisions outside of their normal practice. The ethical advice and support groups should be available to offer support where it is needed, and signpost to other resources available nationally and locally. The role of the ethical advice and support groups will evolve as the clinical context changes, and any guidance that is needed will be communicated clearly.

## Ethical Advice and Support Groups

This guidance outlines the structures that will be introduced across Scotland to help ensure that there is available ethical advice and support when required at the individual, system and population levels. These will complement existing support mechanisms. The Terms of Reference of the National Group will be published separately.

1. 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.
2. 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.

## Legal considerations

Additional pressures on healthcare resource, staff and systems may necessitate a change in the way that we deliver care to patients across Scotland and result in a change to normal practice. However, clinicians **must** continue to act within the law during the COVID-19 pandemic and should ensure that they are continuing to meet their obligation to uphold it.

## Equality and Human Rights

The Human Rights Act 1998 (“the 1998 Act”) incorporates certain rights under the European Convention on Human Rights into the domestic legal order<sup>6,7</sup>. Section 6(1) of the 1998 Act provides that it is unlawful for a public authority to act incompatibly with these rights, which include the right to life and a requirement that all rights must be protected without discrimination. The Equality Act 2010 (“the 2010 Act”) provides a legal framework to protect the rights of individuals and advance equality of opportunity for all. It prohibits both direct and indirect discrimination on the grounds of any protected characteristic, such as age, disability or sex.

There is also a national commitment to respecting, protecting and fulfilling human rights across Scotland in line with international human rights conventions. These explicitly include the rights of disabled people and of children and young people, as outlined in the National Performance Framework (<https://nationalperformance.gov.scot/national-outcomes>). This is further underpinned by guidance issued as part of the COVID-19 response. In this context, the right of every individual patient to the highest attainable standard of physical and mental health is especially important to the healthcare response.

During the COVID-19 pandemic, clinical and healthcare decision-makers continue to be duty-bound to respect, protect and fulfil human rights, prevent discrimination and ensure equality and human dignity are at the heart of clinical practice.

These principles are embedded in medical ethics and are embedded in professional guidance and training for doctors<sup>1</sup>. There must be equity of access for people who could benefit from treatment escalation, and respect for autonomy and the right for people to be involved in decisions which affect them<sup>8</sup>.

Clinicians and decision makers must be mindful of how changes can impact on people with different characteristics. It is important to ensure that groups are not affected disproportionately or unfairly. Taking the time to understand how some characteristics, including protected characteristics, impact on individuals can help them decide the treatment

and care options that are right for them. This can be achieved through shared decision making and supporting people to make an informed choice. For example, clinicians should not suggest a course of treatment on the basis of an arbitrary age limit or on the presence of a disability that is not clinically relevant to the potential benefits of treatment. Taking a human rights approach requires each person to be considered and treated as an individual. It means ensuring that people understand their rights, are fully supported to participate in decisions which affect them and are assisted to overcome additional barriers they face. It also means that those decisions are made with human rights standards in mind and that there are remedies if things go wrong.

## Ethical considerations

*Patients must be treated independent of suspected or confirmed COVID-19 status, and any clinical decision guidance must apply equitably to all patients<sup>6,7,9</sup>.*

Doctors should act in accordance with professional guidance which set out the core principles underlining the approach to challenging decisions, including the GMC's guidance *Good Medical Practice* (2013)<sup>1</sup>, as well as on *Consent: patients and doctors deciding together* (2008)<sup>10</sup> and *Treatment and care towards the end of life* (2010)<sup>11</sup>. In responding to the COVID-19 pandemic it remains essential that established legal obligations continue to be complied with, including those set out in the 1998 Act and the related non-discrimination requirements put in place by 2010 Act<sup>6,7,12</sup>.

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 2017<sup>16</sup>. This framework outlined that all people should be treated with equal concern and respect and highlighted the following fundamental principles:

- **everyone matters** - *This means that healthcare decisions should respect the principles set out in human rights and equality legislation*
- **everyone matters equally** – *but this does not mean that everyone is treated the same<sup>12</sup>*

*Decision making processes should be fair and equitable, as well as transparent.*

*Decision makers need to be honest with patients and the public about how decisions are made, in a way that they are able to understand*

- **the interests of each person are the concern of all of us, and of society** - *Decision makers at all levels should find out what matters to those that their decisions impact, including individual patients and healthcare staff, and support them in playing an active role in shared decision making processes*
- **the harm that might be suffered by every person matters and so minimising the harm that a pandemic might cause is a central concern**<sup>9,13</sup>

It is of vital importance that all patients receive the compassionate care that they need.

Patients must not be subjected to treatments that are likely to cause harm, or where there is limited chance of benefit.

Every effort is being made to ensure that our health and care system in Scotland has the capacity and capability to deal with this pandemic effectively. However, should resources become scarce, it is important that decisions are made fairly, equitably and prudently to minimise the loss of life, in a manner that is non-discriminatory and consistent with equality and human rights obligations. The healthcare response is crucial to ensuring that the rights to life and to health continue to be respected, without discrimination, and that resources reach those who are most likely to clinically benefit.

The National Clinical Pathway Guidance should help to support clinical decision making and national and local ethical advice and support groups will provide additional ethical support should the need arise.

The ethical approach to clinical decision making in Scotland will be consistent with the UK framework, but will be adapted to the Scottish context. This will ensure that the principles of equity, respect and fairness are upheld across Scotland throughout this pandemic.

### Respect

- All patients should have access to good quality and compassionate care<sup>1,7,12</sup>

### Fairness

- Patients should be treated as individuals, with respect for their autonomy, and not discriminated against<sup>12</sup>

## 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, or their attorney or guardian where appropriate, in a way that they are able to understand, and other options explored in accordance with the patient's wishes<sup>9,11, 13</sup>
- No active steps should be taken to shorten or end the life of an individual, however the appropriate clinical decision may be to withdraw life prolonging or life sustaining treatment, or change management to deliver end of life care<sup>7</sup> Clinicians are already familiar with the need to make ethically-based decisions where further treatment simply will not deliver medical benefit to the patient, and/or it runs the risk of being inhumane, degrading or violating fundamental human dignity
- Where a treatment is likely to cause significant harm or have a limited chance of benefit, clinicians, in discussion with patients and those closest to them, may decide that this treatment or course of action is not in the patient's best interests. This could include deciding against transfer to hospital or admission to intensive care or may reflect a decision to a withdraw life prolonging or life sustaining treatment. In all circumstances, patients should continue to be provided with the best possible care, as close to their wishes as possible

## Working together

- Where possible, people should be actively involved in decisions about their health and wellbeing<sup>1, 9</sup> with the assistance of full and accessible information. People's present and past wishes and feelings should be taken into account so far as they can be ascertained by any means of communication<sup>10</sup>. Tailored support should be provided to those who need assistance to participate in decisions.
- Clinicians should act with honesty and integrity in their communication with patients, and those closest to them. This should be documented appropriately<sup>1</sup>
- Clinicians should maintain confidentiality in line with GMC guidance<sup>14</sup>

## Flexibility

- As the clinical situation evolves both at the individual and population level, decisions will need to be kept under review with clear clinical pathway guidance at the national level<sup>4,11</sup>
- All individuals have the right to change their minds about the care and treatments that they would choose, for example, patients may wish to review advanced decisions or care plans in light of new treatment options.

### Reciprocity

- Wherever clinicians are expected or asked to take increased risks, they must be supported in doing so, for example there must be adequate supplies of appropriate PPE<sup>8,13</sup>
- Where there are resource constraints, patients should receive the best care possible within those constraints and making use of the maximum available resources<sup>8,13</sup>

### 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 aged 16 years or over are presumed to have capacity<sup>15</sup>
- All practical steps should be taken to support adults in being able to be active participants in making informed decisions about their health and wellbeing<sup>10, 16</sup>
- Where adult patients are found through medical assessment to lack capacity, decisions should be based on the patient's past and present wishes where these can be ascertained through any means, whether the treatments are of overall benefit to the patient, and which option would be least restrictive on the patient's future choices in accordance with the Adults with Incapacity (Scotland) Act 2000 ("the 2000 Act")<sup>16</sup>. If there are changes to healthcare scope and delivery, decisions should be made fairly and equitably, and not impact any group disproportionately. This means that any changes should equally relate to adults who lack capacity but must not discriminate against individuals because of their lack of capacity.

- Where patients have delegated legal authority, the views of the patient and any guardian, continuing attorney or welfare attorney should be considered as described in the 2000 Act.<sup>16</sup>
- 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<sup>15</sup>
- 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<sup>10,17, 18</sup>

## Logistical considerations

### National ethical advice and support group

This should include healthcare professionals, academics, legal professionals, a representative of all faiths and none, social care professionals, and lay representation.

The national ethical advice and support group will be available as a point for escalation for the Board level groups. This group will meet to review 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 group should be guided by a principle based approach and an awareness of the equality and human rights obligations.

The national 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. This group is not intended to replace existing ethical structures within Scotland that are set out in statute, such as the Research Ethics Committee or Mental Welfare Commission, and will work in a complementary way.

## Health Board level ethical advice and support groups

This group should be considered as a point of contact for ethical advice and support, to give advice on applying ethical principles to difficult or challenging decisions, and not an alternative to existing clinical national guidance or to replace team based clinical decision making for the provision of good clinical care.

Membership of Health Board level groups should be appointed locally, with a diverse range of backgrounds and expertise. This should be a small group that reports directly to the Health 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 and public health input
- multi-disciplinary perspective
- social care input
- member of the Spiritual Care Team

Local group membership should be reflective of the population they serve as best it can, given the relatively small membership of these groups.

It is important that Health 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 moral distress regarding 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 due to competing need for resource

The number of cases referred to Health Board ethical advice and support groups 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 Health Board level, there must be a:

- Clear route to contact the ethical advice and support group, publicised to appropriate groups. Members of staff, patients or those closest to them should all be able to refer an issue for consideration by the group to ask for their advice
- Clear structure for sharing information with the ethical advice and support group, such as SBAR (Situation; Background; Assessment; Response Requested)
- 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

It is expected that this advice will be explained as appropriate to other people involved – such as patients. The process should be transparent and honest.

### Governance structure

The Board ethical advice and support groups should report directly to the relevant Health Board through the Chief Executive, or to a delegated responsible officer, to ensure that they are aware of ethical challenges within the Board. The ethical advice and support groups will provide a written summary report, which will be submitted to the Health Board as set out in locally decided Terms of Reference.

### 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. Wherever possible, these discussions should involve patients and those that they choose to involve.

### 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 are 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 online<sup>19</sup>. The Health Research Authority is working to expedite Research Ethics Committee Reviews as part of this<sup>20</sup>. The Health Research Authority UK has produced an expedited standard operating procedure to help researchers in submitting to ethical review<sup>21</sup>.

#### [Authority for research on adults with incapacity](#)

The considerations for ethical research involving a Clinical Trial of an Investigational Medicinal Product (CTIMP) are outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004.

Further rules in relation to the approval of research involving adults with incapacity are outlined in section 51 of the Adults with Incapacity (Scotland) Act 2000 (“the 2000 Act”) (Authority for Research) and in regulation 6 of The Adults with Incapacity (Ethics Committee) (Scotland) Regulations 2002<sup>16,22</sup>. 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 the relevant legislation are satisfied.

Under the 2004 Regulations, where a CTIMP is conducted at one or more trial sites in Scotland involving participants who are adults who are incapable of consenting to participation in the clinical trial; and the chief investigator is professionally based at a hospital, health centre, surgery or other establishment or facility in Scotland, the application for an ethics committee opinion in relation to that trial must be sent to the Scotland A Research Ethics Committee.

Under section 51 of the 2000 Act, the research must be approved by (that is to say, receive a favourable ethical opinion must be received from) “the Ethics Committee” constituted by Scottish Ministers under the 2002 Regulations. This is the Scotland A Research Ethics Committee. The Health Research Authority Central Booking Service should allocate all such applications to the Scotland A Research Ethics Committee in Scotland, which will review the application under section 51 of the 2000 Act<sup>168, 22</sup>.

### Research across the UK

Where a CTIMP does not meet the criteria set out above that would require it to be considered by Scotland A REC, then consideration by Scotland A REC is not required and the application can go to any “flagged” REC in the UK. The favourable ethical opinion from that REC is sufficient even if Scottish AWI participants are to take part in the CTIMP<sup>16</sup>.

Where the study is not a CTIMP and involves adults who lack capacity, separate decisions about the application must be made in Scotland and England or Wales and Northern Ireland, as appropriate, due to differences in the legal frameworks applicable across the UK. In these cases, any amendments related to AWI in Scotland specifically after initial approval would only need to be resubmitted to the Scotland A Research Ethics Committee<sup>22</sup>.

### 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, they should be clearly, sensitively and accessibly communicated to patients and those closest to them.**

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21. Standard Operating Procedures for Research Ethics Committees, Health Research Authority, June 2019 (version 7.4)
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## Further Resources

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