Rapid development of a Clinical Decision-Making Committee in a UK paediatric hospital during the COVID-19 pandemic

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Abstract
To date, the Government has not issued any national ethical guidance to support clinical decision-making in England during periods of potentially reduced healthcare resources in the context of the evolving COVID-19\(^1\) pandemic at the time of writing. In the ensuing vacuum left by a lack of national guidance, ethical frameworks and approaches have been drafted by professional bodies, individual hospitals and trusts. It is clear that in delivering healthcare during this pandemic, more specific guidance is needed to ensure fair and consistent allocation policies, to attain public trust and confidence and to support clinicians so that decisions do not fall on them to make alone and unsupported. This article sets out how we in our institution, a UK tertiary and secondary level stand-alone paediatric provider Trust, set up a Clinical Decision-Making Committee to inform proactive

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1. COVID-19 is referred to as the official term for the disease which can be caused by coronavirus.
clinical and ethical decision-making, to ensure that all patients are treated appropriately and fairly during these unprecedented times.

Keywords
Clinical decision-making, COVID-19, COVID, pandemic, coronavirus, ethics

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Introduction
We are currently amidst an unprecedented crisis and the COVID-19 virus has now spread to almost every country in the world. There is currently no effective vaccine or specific proven pharmaceutical treatments available to treat COVID-19. At the outset of the outbreak, in March 2020, the World Health Organisation warned countries that health-care facilities should prepare for a significant increase of COVID-19 cases and advised governments to immediately begin to test, track and trace citizens with the virus, so as to contain and prevent community transmission.

In the United Kingdom, it appears that the Government’s initial strategy to minimise the impact of COVID-19 was to ‘allow the virus to pass through the entire population so that we acquire herd immunity’. There was a shift from the ‘contain’ phase of the outbreak to the ‘delay’ phase in early March when the death toll for UK citizens was at 12. In the same month, the UK Government published its plan to delay and mitigate the crisis and advised citizens across the country to begin working from home where possible and to minimise social interactions. Those with symptoms were asked to self-isolate for 7 days and shielding was introduced for the most clinically vulnerable (including those aged 70 and over, those with specific chronic pre-existing conditions and pregnant women) who are deemed at higher risk of severe illness from the virus.

The Prime Minister addressed the nation on 23 March 2020 and announced the need for further restrictions, and the ‘Stay at Home’ policy, together with stricter social distancing measures, was introduced. As part of the ‘lockdown’ phase, schools, places of worship, entertainment and hospitality and indoor leisure venues were

2. See BBC News, ‘Coronavirus Is Continuing Its Spread Across the World, With More Than 4.7 Million Confirmed Cases in 188 Countries’, 18 May 2020.
3. World Health Organisation, ‘Responding to Community Spread of COVID-19’, Interim Guidance 7 March 2020; S. Boseley, ‘WHO Urges Countries to “Track and Trace” Every COVID-19 Case’, The Guardian 13 March 2020.
4. R. Horton, ‘Comment: COVID-19 – A Reckoning’, The Lancet 395(1022) (2020), p. 935.
5. H. Stewart, K. Proctor and H. Siddique, ‘Johnson: Many More People Will Lose Loved Ones to Coronavirus’, The Guardian 23 March 2020.
6. Department of Health and Social Care Policy Paper, ‘Coronavirus Action Plan: A Guide to What You Can Expect Across the UK’, 3 March 2020. Available at: https://www.gov.uk/government/publications/coronavirus-action-plan/coronavirus-action-plan-a-guide-to-what-you-can-expect-across-the-uk (accessed 25 August 2020).
Citizens were prohibited from leaving the place where they were living without reasonable excuse (examples of reasonable excuse specified in the regulations include the need to provide care or assistance, or to travel for the purposes of work and to access critical public services). Public gatherings of more than two people were banned. Anyone who contravened these rules committed an offence, punishable by a fine. The legislative powers to enact these measures stemmed from the Public Health (Control of Disease) Act 1984 (‘the 1984 Act’) and regulations which provide a legislative framework for health protection in England and Wales. Part 2A of the 1984 Act provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation and includes powers to impose restrictions or requirements on people, and in relation to things and premises, for use in rare circumstances where voluntary cooperation cannot be obtained. On 26 March 2020, The Health Protection (Coronavirus, Restrictions) (England) Regulations 2020 came into force which allowed the Government to make these public health measures in response to the serious and imminent threat to public health posed by the incidence and spread of COVID-19.

To help tackle the outbreak, the UK Government also passed the Coronavirus Act 2020. Among a raft of measures, the 2020 Act introduced new registration powers for the Registrars of the Nursing and Midwifery Council (‘NMC’) and the Health and Care Professions Council (‘HCPC’) to help to deal with the increase in those needing medical care and the shortage of approved staff to help. The 2020 Act also includes powers to provide indemnity coverage for clinical negligence of healthcare workers and others carrying out National Health Service (NHS) activities (and for Northern Ireland, health and social care activities) connected to care, treatment or diagnostic services provided under the arrangements for responding to the COVID-19 outbreak.

7. As inserted by the Health and Social Care Act 2008 (‘the 2008 Act’). Amendments to the 1984 Act made by the 2008 Act were intended to comprehensively modernise the legal framework for health protection.
8. The Health Protection (Coronavirus, Restrictions) (England) Regulations 2020, section 6.
9. Op. cit., section 7.
10. Op. cit., section 10. A person who commits an offence under these Regulations may be issued a fixed penalty notice of £60. A fixed penalty notice is a notice offering the person to whom it is issued the opportunity of discharging any liability to conviction for the offence by payment of a fixed penalty to a local authority specified in the notice.
11. The amended 1984 Act sets out a framework for health protection which requires much of the detailed provisions to be delivered through regulations. Section 45C of the 1984 Act provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat can come from outside England and Wales.
12. The Regulations were passed under the emergency procedure set out in section 45R of the Public Health (Control of Disease) Act 1984 (c. 22). See Explanatory Notes of the statute.
13. The Coronavirus Act 2020 received Royal Assent on 25 March 2020. The legislation is time-limited to 2 years.
14. The Coronavirus Act 2020, sections 2–5.
15. The Coronavirus Act 2020, sections 11–13. See NHS Resolution for more information on the special scheme established to meet liabilities arising from the special healthcare
In May 2020, the Government changed the policy from ‘Stay at Home’ to ‘Staying Alert and Safe’.

16. England began lifting the lockdown restrictions and in June 2020 outdoor markets, car showrooms and non-essential retail premises opened. On 4 July, pubs, restaurants, hairdressers, cinemas and theme parks reopened with social distancing rules.

17. The NHS test and trace service was finally introduced on 28 May 2020 to control the spread of the virus, although it has attracted much criticism as to how effective it has been in practice.

18. As lockdown measures have begun to be lifted, COVID transmission has once again increased raising concerns of a second wave. An outbreak of COVID-19 identified in parts of Greater Manchester, East Lancashire and West Yorkshire resulted in restrictions being imposed on residents in those areas on 30 July 2020. Professor Sutherland has warned ‘if we return to operating as we did before the pandemic, there will be a second wave of the virus’.

19. Notwithstanding the containment measures, the United Kingdom is at the epicentre of the virus in Europe. The European Centre for Disease Prevention and Control (an agency of the European Union (EU)) reported that the United Kingdom has the highest

arrangements being put in place in response to the coronavirus outbreak and in accordance with new powers from the Coronavirus Act 2020. Available at: https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-coronavirus/ (accessed 25 August 2020).

16. Cabinet Office, ‘Guidance Staying Alert and Safe (Social Distancing)’, 11 May 2020. Available at: https://www.gov.uk/government/publications/staying-alert-and-safe-social-distancing/staying-alert-and-safe-social-distancing-after-4-july (accessed 25 August 2020).

17. The Government published practical guidelines to help restaurants, pubs and hairdressers reopen safely, provided they meet Government criteria for keeping staff and customers as safe as possible. See HM Government, ‘Keeping Working and Customers Safe During COVID 19 in Restaurants, Pubs, Bars, and Takeaway Services’, COVID 19 Secure Guidance for Employers, Employees and the Self Employed 31 July 2020. Available at: https://assets.publishing.service.gov.uk/media/5eb96e8e86650c278b077616/working-safely-during-covid-19-restaurants-pubs-takeaway-services-200812.pdf (accessed 25 August 2020).

18. https://www.nhs.uk/conditions/coronavirus-covid-19/testing-and-tracing/ (accessed 25 August 2020).

19. R. Vize, ‘Too Slow and Fundamentally Flawed: Why Test and Trace Is a Weak and Inequitable Defence Against Covid-19’, BMJ 369 (2020), m2446, pp. 1–3.

20. See Department of Health and Social Care, ‘North of England: Local Restrictions’, 31 July 2020. Available at: https://www.gov.uk/guidance/north-west-of-england-local-restrictions-what-you-can-and-cannot-do (accessed 25 August 2020).

21. W.J. Sutherland et al., ‘Informing Management of Lockdowns and a Phased Return to Normality: A Solution Scan of Non-Pharmaceutical Options to Reduce SARS-CoV-2 Transmission’, 2020. DOI: 10.17605/OSF.IO/CA5RH. A peer reviewed paper published on the Biosecurity Research Initiative at St Catharine’s College, Cambridge website. Available at: https://covid-19.biorisc.com/ (accessed 25 August 2020).

22. See European Centre for Disease Prevention and Control, ‘COVID-19 Situation Update for the EU/EEA and the UK’, 4 August 2020. Available at: https://www.ecdc.europa.eu/en/cases-2019-ncov-eueea (accessed 25 August 2020).
number of COVID cases and deaths in Europe. They report that as of 4 August 2020, 1,755,809 cases have been reported in the EU/European Economic Area (EEA) and the United Kingdom: United Kingdom (305,623), Spain (297,054), Italy (248,229), Germany (211,281), France (191,295), Sweden (81,012), Belgium (70,221), Netherlands (55,415), Romania (54,009), Portugal (51,569), Poland (47,469), Ireland (26,208), Austria (21,341), Czechia (17,008), Denmark (13,996), Bulgaria (11,955), Norway (9268), Finland (7466), Luxembourg (6864), Croatia (5296), Greece (4737), Hungary (4544), Slovakia (2354), Slovenia (2181), Lithuania (2120), Estonia (2080), Norway (1246), Cyprus (1155), Malta (809) and Liechtenstein (89). 

As of 4 August 2020, 182,833 deaths have been reported in the EU/EEA and the United Kingdom: United Kingdom (46,210), Italy (35,166), France (30,294), Spain (28,472), Belgium (9850), Germany (9156), Netherlands (6140), Sweden (5744), Romania (2432), Ireland (1763), Portugal (1738), Poland (1732), Austria (718), Denmark (616), Hungary (597), Bulgaria (388), Czechia (386), Finland (329), Norway (256), Greece (209), Croatia (153), Luxembourg (118), Slovenia (117), Lithuania (80), Estonia (69), Latvia (32), Slovakia (29), Cyprus (19), Iceland (10), Malta (9) and Liechtenstein (1). 

As winter approaches, there remains real concerns that as COVID-19 affects a large proportion of the population and given the lack of pre-existing immunity, that seasonal flu will exacerbate the COVID 19 crisis and that the virus will produce enough severe illness that it could quickly overwhelm England’s publicly funded NHS. The British Medical Association (BMA) noted that as mortality rates for those with the virus are estimated to be between 0.5% and 3.4%, that a considerable percentage of the population may seek and require medical attention. While the COVID-19 pandemic raises a host of ethical questions, key among these is the real possibility that healthcare systems will need to ration scarce critical care resources.

In the United Kingdom, despite the increase in NHS staff and the availability of intensive care beds, there has been an ongoing shortage of vital personal protective

23. Op. cit.
24. Op. cit.
25. Op. cit.
26. The healthcare systems of the four nations of the United Kingdom (England, Northern Ireland, Scotland and Wales) have been devolved to each of their jurisdictions. For more on how health infrastructures may be overwhelmed, see E.J. Emanuel, P. Govind, U. Ross et al., ‘Fair Allocation of Scarce Medical Resources in the Time of COVID-19’, The New England Journal of Medicine 382 (2020), pp. 2049–2055.
27. BMA, ‘COVID-19 Ethical Issues – A Guidance’, p. 1. Available at: https://www.bma.org.uk/media/2360/bma-covid-19-ethics-guidance-april-2020.pdf (accessed 25 August 2020).
28. A. McGuire et al., ‘Ethical Challenges Arising in the COVID-19 Pandemic: An Overview From the Association of Bioethics Program Directors (ABPD) Task Force’, American Journal of Bioethics 20(7) (2020), pp. 15–27.
29. Extra capacity was created via establishment of Cardiff’s Dragon’s Heart Hospital, Glasgow’s Louisa Jordan Hospital, and the Nightingale Hospitals in London, Belfast, Birmingham, Exeter, Harrogate, Sunderland, Bristol and Manchester. The Government
equipment\textsuperscript{30} and there are real fears that serious health needs may outstrip availability and difficult decisions will be required about how to distribute scarce life-saving resources. Global experience from the COVID-19 pandemic, and previous planning for pandemic flu,\textsuperscript{31} suggests that scarcity of resources may give rise to difficult triage decisions for both clinicians and hospitals. The BMA specifically acknowledged that it was ‘important that we begin to think now about how we would respond should that situation arise in the future’.\textsuperscript{32}

Unlike in Scotland,\textsuperscript{33} the Government has not issued national ethical guidelines in England to help support decision-making on the many ethical questions the pandemic raises, such as how resources should be allocated should demand outstrip supply. Huxtable persuasively notes how authoritative national ethical guidance is needed to bring clarity, consistency and fairness to decision-making.\textsuperscript{34} Doctors’ defence bodies and health lawyers’ arguments that national guidance was needed have gone unheeded by the Government.\textsuperscript{35} In the ensuing vacuum left by a lack of national guidance, ethical frameworks and approaches have sprung up in individual surgeries, hospitals and trusts, and from professional bodies, such as the

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\textsuperscript{30} R. Horton, ‘COVID-19 and the NHS – “A National Scandal”’, The Lancet (2020) p. 395, The Comment, published 28 March 2020.

\textsuperscript{31} A.K. Thompson, K. Faith, J.L. Gibson et al., ‘Pandemic Influenza Preparedness: An Ethical Framework to Guide Decision Making’, BMC Medical Ethics 7 (2006), p. 12; Emanuel, Persad, Upshur et al., ‘Fair Allocation of Scarce Medical Resources’; D.B. White and B. Lo, ‘A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic’, JAMA 323(18) (2020), pp. 1773–1774.

\textsuperscript{32} See ‘COVID-19 Rapid Guideline: Critical Care in Adults NICE Guideline’ [NG159]. Published date: 20 March 2020. Last updated: 29 April 2020. Available at: https://www.nice.org.uk/guidance/ng159 (accessed 25 August 2020).

\textsuperscript{33} See Scottish Government, ‘COVID-19 Guidance: Ethical Advice and Support Framework’. Available at: https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2020/04/coronavirus-covid-19-ethical-advice-and-support-framework/documents/covid-19-cmo-ethical-advice-and-standards-3-april-2020/covid-19-cmo-ethical-advice-and-standards-3-april-2020/govscot%3Adocument/COVID-19%2BCMO%2Bethical%2Badvice%2Bsuction%2Bcovid-19%2Bv2.2%2B-%2BApril%2B2020.pdf (accessed 25 August 2020).

\textsuperscript{34} R. Huxtable, “COVID-19: where is the national ethical guidance?” BMC Med Ethics 21 (2020), p. 32.

\textsuperscript{35} C. Dyer, ‘COVID-19: Guidance Is Urgently Needed on Who Should Be Treated in Event of Shortages, Say Lawyers’, BMJ 369 (2020), m1503, p. 1.
BMA, the Royal Colleges and the General Medical Council (GMC). This piecemeal approach to responding to the pandemic is confusing both for clinicians and the public. As Huxtable notes:

...the proliferation of guidance from various sources and its frequent updating risks either contradiction or duplication of effort. Rather than being guided, professionals confront information-overload, which might leave them distrustful of issuing agencies and, fundamentally, unsure of which guidance to follow and, correspondingly, of their obligations.

One example of the ethical guidance offered is that issued by the National Institute for Health and Care Excellence (NICE). NICE issued a series of rapid guidelines on COVID-19, developed in collaboration with NHS England and NHS Improvement. In its guidance on COVID critical care clinical decision-making, NICE advises clinicians in England to ‘base decisions on admission of individual adults to critical care on the likelihood of their recovery, taking into account the likelihood that a person will recover from their critical care admissions to an outcome that is acceptable to them’.

The guidance imposes a heavy burden on the treating clinicians and makes it clear that:

When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

36. For instance, see ethical guidance issued by the Royal College of Physician, Ethical Dimensions of COVID-19 for Frontline Staff (London: Royal College of Physicians, 2020). Available at: https://www.rcplondon.ac.uk/news/ethical-guidance-published-frontline-staff-dealing-pandemic; British Medical Association, COVID-19 – Ethical Issues. A Guidance Note (London: British Medical Association, 2020). Available at: https://www.bma.org.uk/advice-and-support/covid-19/ethics/covid-19-ethical-issues; Royal College of General Practitioners, ‘Ethics, Challenging Conversations and Health Inequalities’. Available at: https://elearning.rcgp.org.uk/mod/page/view.php?id=10556 (accessed 25 August 2020).

37. Fritz Z., Huxtable R., Ives J., Paton A., Slowther AM., Wilkinson D., et al. ‘Ethical road map through the covid-19 pandemic’ BMJ 369 (2020), p. m2033; see also A. Paton, ‘The Government Can’t Just Follow the Science – We Need Ethics to Guide Us Out of Lockdown’, The Independent 23 May 2020.

38. R. Huxtable, “COVID-19: where is the national ethical guidance?” BMC Med Ethics 21 (2020), p. 32.

39. Op. cit.

40. Op. cit.

41. See NICE ‘COVID-19 Rapid Guideline’.
Similarly, ethical guidance has been published by the BMA, the Royal College of Physicians, the GMC and the Royal College of Paediatrics and Child Health. Despite the aforementioned guidance, a large onus is still placed on healthcare professionals to use their subjective clinical judgment to make determinations regarding a patient’s ability to benefit from treatment. Leaving front-line clinicians unsupported in the forefront of this decision-making could be disadvantageous, leading to them potentially:

Facing untenable personal, ethical and moral conflict.

Experiencing reduction in the implicit trust between themselves and their patients and families.

Making inconsistent clinical decisions, leading to inadvertent bias and prejudice being introduced into the process.

Exposing themselves to legal liability for decisions made in the absence of specific immunity from legal suit for decisions made during the pandemic.

In the absence of clearer national guidelines on how to allocate scarce resources during the COVID-19 pandemic, development of ethical frameworks to aid clinical decision-making is necessary in order to ensure the fair allocation of scarce resources within a clinical setting.

**Paediatric delivery of care**

Although the vast majority of individuals diagnosed with COVID-19 are adults, it is clear that the pandemic also increases pressure on paediatric and neonatal services. This article is written to offer some insight into how paediatric healthcare has been delivered on the front line in the United Kingdom and outline how we have made clinical and ethical decisions during these unprecedented times in our institution, which is a UK tertiary and secondary level stand-alone paediatric provider Trust.

In light of the demands placed on the NHS, free-standing children’s hospitals and hospitals with paediatric and neonatal environments were called upon to share needed resources, and most exist in isolation with no true paediatric expertise or experience. Newborns in the NICU who would normally be cared for in the paediatric ward were being cared for in the NICU. Many NICUs were in a state of flux as they tried to manage patients who were critically ill and who may have been tested positive for COVID-19. The NICUs were on the front line, but had no guidelines to manage these patients.

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42. BMA, ‘COVID-19 Ethical Issues’.
43. RCP, ‘Ethical Dimensions of COVID-19 for Frontline Staff’, 7 April 2020.
44. https://www.gmc-uk.org/ethical-guidance (accessed 25 August 2020).
45. See RCPCH, ‘Ethics Framework for Use in Acute Paediatric Settings During COVID-19 Pandemic’. Published date: 16 April 2020. Last updated: 16 April 2020. Available at: https://www.rcpch.ac.uk/resources/ethics-framework-use-acute-paediatric-settings-during-covid-19-pandemic (accessed 25 August 2020).
46. Moral distress emerges when providers believe that the right course of action is not taken because of institutional or other factors – A. Jameton, Nursing Practice: The Ethical Issues (Englewood Cliffs, NJ: Prentice-Hall, 1984) cited in McGuire et al., ‘Ethical Challenges Arising in the COVID-19 Pandemic’.
47. See O. Bowcott, ‘Union Seeks Legal Immunity for NHS Medics in Pandemic’, The Guardian 19 April 2020. Available at: https://www.theguardian.com/society/2020/apr/19/coronavirus-nhs-risks-facing-billions-of-pounds-in-negligence-claims (accessed 25 August 2020).
resources. From the onset of the pandemic, while offering primarily paediatric care, as part of our role in the wider regional network, we offered provision for a limited number of critically ill adult patients, from neighbouring trusts, in the event of ‘surge’ demand across the local system. While the ‘surge’ to date has not yet overwhelmed available resources in the United Kingdom, there is an ongoing debate surrounding how children should be prioritised in allocation protocols.48

Acknowledging ethical guidance that has been issued, and cognisant that competing demands for resources may lead to difficult decisions, it was clear that in delivering healthcare during this pandemic more specific guidance would be needed to attain public trust and confidence and to support clinicians, so that they never had to make decisions alone and unsupported. When implementing rationing policies, Emanuel et al. highlight ‘the need for fair and consistent allocation procedures that include the affected parties and that these procedures must be transparent to ensure public trust in their fairness’. 49 Furthermore, they identify the importance of ensuring that ‘individual physicians are not faced with the terrible task of improvising decisions about whom to treat or making these decisions in isolation’. 50 They note how placing such burdens on individual physicians could exact an acute and lifelong emotional toll and that even well-designed guidelines can present challenging problems in real-time decision-making and implementation. 51

To navigate these challenges and relieve individual front-line clinicians in our hospital of that burden, we made the early decision to institute an overarching Clinical Advisory Board with three constituent bodies to provide overall support, guidance and a framework for clinicians to facilitate clinical decisions, both proactively and reactively in the face of the pandemic.

The three bodies were:

(i) A Clinical Ethics Committee (CEC) to temporarily replace the Trust’s existing Clinical Ethical Support Group.
(ii) A Clinical Decision-Making Committee (CDMC).
(iii) A Protecting Vulnerable Patients Forum.

This article concentrates primarily on (ii), the rapid development of our CDMC.

**Developing a CDMC**

The aim of the CDMC is to inform proactive clinical decision-making to ensure that all patients are treated appropriately and fairly. 52 It also provides sufficient guidance and support for clinicians making difficult decisions, aided by the use of a real-time hospital dashboard regarding current and predicted limitations on healthcare resources.

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48. McGuire et al., ‘Ethical Challenges Arising in the COVID-19 Pandemic’.
49. Emanuel, Persad, Upshur et al., ‘Fair Allocation of Scarce Medical Resources’.
50. Op. cit.
51. Op. cit.
52. Guidance issued by the BMA discusses the importance of fair process making decisions amidst the COVID – 19 pandemic – see BMA, ‘COVID-19 Ethical Issues’, p. 9.
Method

This required the rapid development of a clinical template underpinned by a robust ethical framework, which was then used as a basis to discuss difficult clinical decisions and provide high-level support for individuals and teams making such decisions.

Necessarily, the CDMC uses a live dashboard which takes into consideration other factors such as limitations on hospital and region-wide healthcare resources, including bed escalation status, emergency department and intensive care unit (ICU) pressures, staffing and equipment levels, including ventilators, renal replacement, consumables and so on. In addition, the CDMC actively seeks information about potential shortage of resources from a variety of sources, including front-line clinical teams, Trust Command leadership and others, so that help may be given to prevent and/or alleviate shortages wherever possible before having to define alternative standards of care.

All discussions take place through the medium of a daily, multidisciplinary ‘virtual’ forum meeting, chaired by a senior clinician in a managerial position. It is essential that this meeting is open to all clinical staff, although in practice it is largely attended by senior clinicians, supported by a leadership team. It helps to support front-line clinicians in providing best possible care for patients when potential limitations of resources may require an alteration in practice from the usual framework of care. In these situations, it helps to define and ensure fair, transparent and implementable allocation rules to support the right and safe decision. These rules are primarily patient-centred and rooted in established ethical principles common throughout healthcare systems. For instance, the four guiding principles of Beauchamp and Childress of (i) Respect for Autonomy, (ii) Beneficence, (iii) Non-Maleficence and (iv) Justice were incorporated into decision-making discussions and brief ethical training was offered to all on the CDMC.53

It is essential that the CDMC can respond without delay when addressing and supporting any such decisions, recognising that time may often be limited in such circumstances.

CDMC structure

To gain the confidence of front-line clinicians, the CDMC needed to be recognised as being fit for purpose; able to react to their potential dilemmas in a timely fashion and be supported at Board level. The Chair is a senior clinician nominated by the Trust Medical Director (MD). The rest of the leadership is drawn from senior clinicians holding formal managerial positions within the Trust; these included the MD and Deputy MD (ex officio Chair of the Clinical Ethical Committee [CEC] vide infra), the Divisional Directors of Medicine and Surgery and the Chair of the Clinical Ethics Support Group (CESG). This team is actively supported by a senior manager drawn from the Trust Tactical Command, and a senior project manager. Other individuals deemed essential to the team’s success are senior nurses and Allied Health Professionals, along with individuals who have had both training and experience in bioethical principles and the process of ethical decision-

53. T.L. Beauchamp and J.F. Childress, Principles Biomedical Ethics. 8th ed. (Oxford: OUP, 2019).
making – some of whom are paediatric trainees and the Trust’s legal adviser. All clinical staff are invited to join the daily meetings.

**Development of the referral process**

As the CDMC was set up, it quickly became apparent that a structured referral process was required, and would be dependent on clear, intuitive and easy-to-use documentation that would double up as the documentation needed for recording purposes. Thus, a senior ICU clinician and the long-standing Chair of the former CESG were tasked with formulating a referral document with an underpinning ethical framework (Online Supplemental Appendix 1). The document was finalised within a matter of days and, after Trust-wide dissemination, was actively trialled in the CDMC, using a mix of simulated clinical dilemmas and actual patient scenarios.

A further issue that quickly arose once we had implemented the urgent referral process was around the compassionate use of novel therapies outside formal research protocols. On occasion, this might also need completion of a ‘sign off form’ to be issued to any pharmaceutical company involved, if requested.

**Recording decisions**

Robust recording of the decision-making process and of all decisions made is mandatory in all cases. This is achieved by insisting all referrals are documented using the standard template described above. In addition, videoconferencing software is used to digitally record meetings.

**Referral process**

Referral of cases is facilitated by following one of three routes:

1. Urgent cases requiring an immediate decision, including potential compassionate use of novel therapies.
2. Cases to be considered within 24 h or longer, including consideration of those entering formal research trials.
3. Through the Protecting Vulnerable Patients Forum (see below).

The referral template (Online Supplemental Appendix 1) mandates completion of the clinical section before any referral, urgent or otherwise, can be accepted. Completion of the ethical section can be delayed until after full discussion of the case, but some prior ethical consideration is felt to be essential in aiding the decision-making process. The Regional Paediatric Network, covering Cheshire, Merseyside and the Isle of Man, have been informed of the process, and referrals can be made by district general hospitals directly to the CDMC.
Urgent cases requiring an immediate decision

It was essential that an urgent referral mechanism, to operate 24 h a day, 7 days a week, was established as a matter of priority. A 1st on call rapid response hotline rota was established among the leadership team identified above. This provides telephone advice to senior clinicians regarding any cases or situations deemed to pose an urgent problem that cannot wait until the following day. The 1st on rapid responder also has access to 24 h (2nd on call) experienced ethical support advisers from both in and outside of the Trust, and to a legal advice hotline provided by the Trust’s legal representatives. In addition, urgent consideration and approval of initiating compassionate use of novel therapies outside of formal research trial protocols can be undertaken.

Early feedback from clinicians has been very favourable; they appreciate that they may be asked to make potentially difficult decisions in the face of scarce resources out of hours, and welcome this senior clinical managerial input supported through the office of the MD.

Cases to be considered within 24 h or longer

All other non-urgent cases are referred directly by email to the Chair (or deputy) and to the project administrator of the CDMC, using the agreed referral template. A decision is then made as to whether the referral falls within the scope of the CDMC, and if so, the urgency for discussion. The case is then added to the agenda of the relevant daily meeting. In addition, consideration of patients for entry into formally approved clinical research trials are discussed.

If the issue is not deemed within the scope of the CDMC, then the clinical decision-making reverts to the relevant clinicians or other appropriate decision-makers. All cases considered through the 1st on call rapid response hotline will automatically be reviewed as a priority at the meeting the following day.

Protecting Vulnerable Patients Forum

This forum exists to identify vulnerable cohorts of patients in a standardised fashion. The membership encompasses representatives from a wide spectrum of clinical specialities and disciplines, chaired by the Divisional Director for Medicine. Its remit is to consider the following aspects of care, so that if required, cases can be escalated to the CDMC for further consideration:

(i) Key co-morbid risk factors.
(ii) Other considerations affecting the current pathway of care (including anaesthetics, diagnostics, pharmacy, therapies, ward availability, outpatient availability).
(iii) Alternative ways in which assessment, treatment and aftercare could be provided, including a standardised risk assessment of available pathways of care.
(iv) Identification of patient subgroups at the highest risk of critical deterioration, to allow conversations with vulnerable families and development of bespoke advanced plans of care.
Format and outcomes of the daily CDMC meeting

Cases listed for discussion are presented by the Lead Clinician who had completed the referral template; in addition, all other clinicians involved in the patient’s care are expected to attend the meeting. Discussion firstly ensures clarification of the relevant clinical detail and potential outcomes, followed by ethical consideration of all possible interventions, and if deemed relevant, a legal opinion on the case. Underpinning the ethical decision-making process, values of reasonableness, candour and transparency, inclusivity, responsiveness and accountability are applied.

Generally, it is expected that a consensus view is expressed by the majority of those present and agreed. If needed, a vote can be taken at the Chair’s discretion and the result of any such vote recorded. In other circumstances, it might be appropriate for more information to be obtained, or other action, such as seeking an external clinical review. If no consensus can be reached, then the case can be considered further at the CEC.

Clinical Ethics Committee

It was felt essential that there was regular oversight of the CDMC’s activities, and that the existing Trust CESG was not in a position to offer the necessary degree of such oversight – primarily, as it only formally met on a monthly basis, with a remit to offer considered ethical advice to clinicians in individual cases and to support an ethical education facility. The CEC was therefore set up to temporarily supersedae the CESG during the duration of the pandemic. It will meet weekly throughout this period and will support more urgent ethical considerations by the daily CDMC.

The primary role of the CEC is to provide a weekly review of all cases referred to the CDMC for their consideration and to assist in ensuring consistency of the ethical support and advice given, along with any additional learning or educational input required. It may also consider less urgent cases after discussion with the Chair/Deputy Chair or referred by another member of the CDMC. Discussion may include appropriate legal advice.

The CEC will also provide educational resources in the form of appropriate online resources and access to relevant articles, publications and teaching. It will also submit minutes of its meeting to the Trust Board on a monthly basis. Any items of specific concern or which require Trust Board approval will be the subject of a separate report.

It is expected that the CEC will be disbanded after the end of the pandemic and any duties replaced by the pre-existing Clinical Ethical Support Group. It is anticipated that the CDMC will continue to function after the end of the pandemic.

Conclusion

The Clinical Decision-Making Committee is part of a concerted effort across our institution to support clinical decision-making during the COVID-19 outbreak. The CDMC was rapidly created to engage a multidisciplinary team of experienced clinicians, supported by an ethical and legal framework, to aid clinical decision-making in periods of potentially reduced healthcare resources in the context of the evolving COVID
pandemic. It follows pre-established processes of decision-making, documentation and reporting of all decisions, and has created a forum for both education and guidance in addition to a necessary support framework for front-line clinicians, many of whom are facing unprecedented stress. It is hoped that such a robust framework will provide both the short-term support required and the long-term protection both to individual clinicians and the Trust as difficult decisions may be scrutinised and challenged by families and patients in the aftermath of the crisis.

Authors’ note
The lead author (the manuscript’s guarantor) affirms that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Supplemental material
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