

Who gets the ventilator? Important legal rights in a pandemic

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INTRODUCTION

COVID-19 is a highly contagious infection with no proven treatment. Approximately 2.5% of patients need mechanical ventilation while their body fights the infection. Once COVID-19 patients reach the point of critical illness where ventilation is necessary, they tend to deteriorate quickly. During the pandemic, patients with other conditions may also present at the hospital needing emergency ventilation. But ventilation of a COVID-19 patient can last for 2-3 weeks. Accordingly, if all ventilators are in use, there will not be time for patients to 'queue up' to wait for those who arrived earlier to recover. Those who need a ventilator will die if they do not receive access to one quickly.

Many nations now face the prospect that they failed to prepare appropriately for this foreseen risk of pandemic (another issue worthy of legal analysis) and that their populations will need far more ventilators than the health service can supply. For many weeks, the UK has been anticipating a surge of COVID-19 infections that could leave patients queuing in hospitals for ICU care. Luckily, social distancing has 'flattened the curve' and this problem might not arise. There is still a degree of risk, however, and other countries will not be so lucky.

At some point, during this pandemic or the next, all countries will need to answer hard questions about whether and when scarce ICU resources (such as ventilators, beds and staff) should be either withheld or withdrawn from certain groups of patients solely for the purpose of providing them to others. Attempts to answer these questions can be found in a wide range of ICU triage protocols and ethical guidance documents, many of which embrace the foundational principle of 'save the most lives'. Unfortunately, this worthwhile goal has generated many suggestions that could violate the law.

This article identifies ten ways in which the withholding or withdrawal of a clinically indicated ventilator might violate a patient's rights, along with recommendations on how to avoid doing so. While our analysis is based on UK law, it is relevant for other countries with similar legal systems. If the issues we identify are not addressed, doctors may act unlawfully. Worse, patients may die unlawfully.

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CURRENT POLICIES AND GUIDANCE

The UK government controversially abandoned its plans to create a national policy for triage decisions during the COVID-19 pandemic.² As a result,

at present, the only central guidance comes from the 'COVID-19 Rapid Guideline' issued by the National Institute for Health and Care Excellence (NICE), which recommends triaging admission to the ICU based on frailty assessments, but provides little concrete guidance on how to allocate or re-allocate ventilators once a patient is in the ICU. Thus, if there is a ventilator shortage, these decisions will need to be made at the local or regional level by doctors, hospitals and the National Health Service (NHS) Clinical Commissioning Groups (CCGs) that are responsible for health service management and procurement. This could lead to 'postcode' lotteries where patients have different rights to ventilators in different hospitals, not to mention insufficient clarity for patients about their rights to life-saving treatment.

There are many sources that one could draw on in developing a local, regional or national policy to govern the withholding and withdrawal of ventilation.4-10 There are triage policies that set out detailed protocols for the use of ventilators, as well as ethical guidelines created by professional bodies, governments, and medical ethicists. Problematically, many of these sources pay insufficient attention to legal requirements.

For example, NICE suggests that 'decisionmaking support' can be found in a guidance note published by the British Medical Association (BMA)—a trade association for doctors.³ This is concerning, given that in our view, some of the BMA guidance fails to sufficiently acknowledge patients' legal rights. Regarding the withholding of treatment, the BMA suggests that decisions be based on a patient's relative 'capacity to benefit quickly', which could result in the denial of treatment to patients with poorer prognoses—patients who are also more likely to be elderly, disabled or chronically ill. Regarding the withdrawal of treatment, the BMA adopts the same approach, acknowledging that this could 'involve withdrawing from an individual who is stable or even improving but whose objective assessment indicates a worse prognosis than another patient who requires the same resource'. 11 The only time the BMA departs from this approach is for patients who work in 'essential services', including healthcare workers, who it suggests might be given priority if so authorised by the government.

While the various guidelines that we have reviewed differ in many ways, they are generally infused with the same ethical principle: 'save the most lives possible'. They take the view that when





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there are multiple critically ill patients, each with an equal ethical claim to be ventilated and not enough ventilators for all, doctors should prioritise patients who are more likely to recover swiftly (thereby clearing the ventilators for other patients in need).

Saving as many lives as possible is a worthy goal, but this principle can occlude the consideration of patients' legal rights—rights that are not suspended merely because a crisis has occured. So even if the principle is used as the primary touchstone, the goal should be: 'save the most lives possible without violating the rights of patients.' Of course, this should go without saying, but many legally enforceable rights have been overlooked in the ethically focused guidelines that have been produced thus far.

UNAPPRECIATED COMPLEXITIES

When analysing how ventilators should be allocated or re-allocated in the COVID-19 pandemic, medical ethicists often appeal to simplified cases, such as Taurek's famous lifeboat thought experiment.¹² Another thought experiment cropping up is the trolley problem: should one pull the lever to divert the trolley so that it kills one rather than five?

While these simplified cases can be useful for exploring our ethical intuitions, they can also be dangerous, as they erase important details that make a significant difference to ethical and legal analysis. For example, as outlined below, a policy for ventilator allocation needs to take account of: (1) clinical implications, (2) evidentiary weaknesses, (3) ethical controversy, (4) subjective judgements and (5) organisational complexity.

1. Clinical implications

Ordinarily, when a ventilator is withdrawn, the patient is extubated and turned over if prone (face down). This action could constitute a battery if done without consent to a patient who still has a fair chance of survival. Merely detaching the ventilator machine as a modular unit might avoid this, with a legal sleight of hand that every subsequent action would be medical management for the patient post-withdrawal. However, the patient will need to be brought out of sedation in order to activate his (or her) respiratory reflex. Continued sedation would hasten death and this could constitute unlawful killing unless it is clinically indicated, which is inherently not the case if withdrawal is based solely on resource grounds. As ventilator treatment for the patient is still indicated, the clinical team should try to bring the patient out of sedation and help the patient survive until another ventilator is available. During ventilator withdrawal, however, there is a strong chance the patient will be confused, anxious and distressed, particularly if still face down. He will likely cough and claw at the tube that is left in his throat (since the doctors may not have consent to remove it) and experience a feeling of suffocation. The patient will need to be calmed by medical staff, who may offer non-sedating pain therapy. They will also need to tell the patient that he still needs a ventilator, that it was withdrawn to help another patient, and that he can rejoin the ventilator wait-list.

2. Evidentiary weaknesses

A task force of ICU experts on mass critical care concluded in 2014: 'Critical care triage is a complex process that requires significant planning, preparation, and infrastructure for it to be conducted ethically and efficiently. At present, the prognostic tools required to produce an effective decision support system (triage protocol) are lacking along with most of the infrastructure, processes, legal protections, and training for critical care triage.' 13 It is difficult to attribute relative probabilities of

survival to patients, or to anticipate length of bed stay, with a novel disease like COVID-19.14 Data are emerging from China, Italy and Spain, but are limited. Inferences can be made from more established data on acute respiratory distress syndrome (ARDS) and viral pneumonia, but the data thus far on COVID-19 suggest that it might differ in important ways from these other diseases. While clinical physiological tools such as SOFA (Sequential Organ Failure Assessment) and APACHE (Acute Physiology and Chronic Health Evaluation) help predict clinical outcomes, they may not be practical under pandemic conditions (eg, SOFA requires laboratory tests for which there may be shortages or delays). Furthermore, studies have shown that even the best tools for predicting clinical outcomes during the H1N1 pandemic were satisfactory, but not good. SOFA assessment is vulnerable to clinicians' subjectivities, and missing data points create added uncertainty. Stratifying patients into priority groups is not a clear science; if the criteria are too strict, resources will be wasted, yet if they are too loose, the increase in lives saved will be limited. Change in SOFA score over time may be a useful predictor of clinical outcomes for patients with ARDS and pneumonia, but its predictive value is low when the intervals are too short. A common proposal in ventilator triage policies is to re-assess patients after 48 hours of ventilation, but this may not be enough time to observe change that would be a meaningful predictor of outcomes.¹⁵

3. Ethical controversy

There is considerable disagreement about the ethics of resource allocation. The principle 'save the most lives' is intuitively appealing, but translating it into a policy that allocates ventilators to patients who are expected to make faster recoveries puts those who have pre-existing health conditions at a disadvantage. Poor health is affected by, inter alia, age, disability, socioeconomic status and genetic luck (eg, ACE2 polymorphisms), 16 which may not themselves be fair grounds for rationing. Focusing instead on 'save the most life years' is another option, but it faces many of the same objections and deprioritises the elderly even if they are expected to make a fast recovery. The argument that the elderly should be deprioritised on the basis that they have 'had a fair innings' aligns with some conceptions of fairness, but not all. Perhaps we should make reasonable adjustments for the less privileged or to save people judged to have special value (eg, those who help maintain essential services) or to be more deserving (eg, those who shouldered extra risks treating infectious patients), but such adjustments would depart from the egalitarian idea that everyone should count for one and only one, given the difficulties of comparing and valuing lives. ¹⁷ In addition, it is difficult to show that withdrawal policies actually benefit the public interest, as they could lead to loss of trust in the NHS and the range of societal costs that this could bring. 17

4. Subjective judgements

If decisions are made by doctors on a case-by-case basis, without reference to an agreed and detailed policy, they may be inconsistent, arbitrary, unfair and/or discriminatory—and thus, potentially illegal. It is easy for clinicians' personal subjectivities, and even their broadly accurate clinical generalisations, to improperly influence their clinical judgements about individual patients. The fact that the average 68-year-old may be less fit than the average 50-year-old should not supplant a particularised assessment of the individual 68-year-old patient. Likewise, patients with disabilities should not be reduced to stereotypes about their 'probable' quality of life.

5. Organisational complexity

The organisation of medical care, including the provision and distribution of critical care services, spans many parties beyond the patient's medical team, both within the hospital (eg, the ICU's director and the hospital's director of clinical services) and beyond. 18 Hospitals are commissioned to provide care by CCGs and (to a lesser extent) NHS England. 19 NHS England has published a standard operating procedure (SOP) for the management of surge and escalation in adult critical care, but it does not detail withholding or withdrawing ventilators. 19 The SOP states that the procedure should be read in conjunction with local and site-specific escalation plans, along with 'other critical care service operational policies together with national and professional bodies' guidance'. 19 Managing a surge of patients is not straightforward to organise centrally because it depends on case-mix, availability of staff and equipment, the disease's impact on critical care admission rates, and other factors. 19 Directions can be given by NHS England Strategic Command, the NHS England Region, local Critical Care Networks, CCGs, and local and site-specific management. 19

RELEVANT AREAS OF LAW

The COVID-19 dilemma is unprecedented—and the legal issues untested. In most countries, there will be numerous relevant areas of law, all with nuances that need to be analysed. In the UK, for example, one needs to consider the following:

Criminal law

- The criminal offences related to patient death (murder and gross negligence manslaughter) and patient care (assault, battery, ill-treatment, or willful neglect), both of which allow liability for omissions.

► Human rights law

- Article 2 of the European Convention on Human Rights (ECHR): the right to life (which includes an obligation on the State to make regulations compelling public and private hospitals to adopt appropriate measures for the protection of their patients' lives). 20 21
- Article 3 of the ECHR: the right not to be subject to inhuman or degrading treatment.
- Article 8 of the ECHR: the right to respect for one's private and family life (which includes the duty to consult with patients when denying them life-sustaining treatment).²²
- Article 14 of the ECHR: the right to the protection of the above rights without discrimination.

Civil law

- The law of battery and negligence, including:
 - The duty of care that applies when withholding or withdrawing treatment under Bolam²³/Bolitho.²⁴
 - The duty to disclose material risks when obtaining consent for intubation and ventilation under *Mont-gomery*.
- The potential defences to tort claims based on the exceptional circumstances created by the pandemic.

▶ Public and administrative law

- The National Health Service Act 2006 requirement that CCGs provide health services 'to the extent they consider er necessary to meet the reasonable requirements of the persons for whom they have responsibility'.
- The administrative law principles that prohibit public authorities from making irrational decisions or decisions that disproportionately affect the rights of individuals.

- The Equality Act 2010 provisions that prohibit direct and indirect discrimination.
- The case law on the rationing of scarce resources such as drugs, therapies and organs.

Professional regulations

- The rules and guidelines created by professional organisations and regulators, such as the General Medical Council (GMC).
- ▶ Laws on decision-making for incapacitated adults
 - Protections under the Mental Capacity Act 2005, which requires that incapacitated patients be treated in their best interests.
- Derogations from the current law
 - Potential legislative indemnities (eg, the discretionary indemnity provided by the Coronavirus Act 2020).
 - Potential legislative immunities from criminal and/or civil liability.²⁶
 - Potential derogations from the ECHR pursuant to Article 15.²⁷

POTENTIAL VIOLATIONS AND RECOMMENDATIONS

Given the numerous and complex areas of law that are applicable to a decision to withhold or withdraw ventilation, it is crucial that debates about ventilator allocation policies engage directly with these legal issues. Ethical guidance from clinicians and ethicists cannot be translated into operational guidance without proper consideration of the myriad legal duties of the various individuals and institutions involved. Many of the policies that have been proposed could result in unlawful behaviour by hospitals and doctors and unlawful loss of patient life.

The legality of withholding or withdrawing ventilation that is clinically indicated will depend on many factors, including the details of the triage policy and who authored it. There is an important legal difference between: (1) a policy adopted by the government, the NHS, NICE, a CCG, the doctor's hospital, or a professional regulator (eg, GMC, Royal College of Anaesthetists, etc); and (2) a policy suggested by the BMA, the Intensive Care Society, medical ethicists, or similar sources. This is not because information disseminated by any of the latter is inherently flawed, but rather because it is unauthoritative. As such, relying on it exposes doctors to legal risk.

For doctors, hospitals, CCGs and others who want to know what to do, we have investigated the law applicable in the UK. While there is some legal uncertainty that can only be resolved by courts, our current view is that the best interpretation of the legal landscape is as follows.

Withholding ventilation

Recommendation 1

Doctors should not withhold a ventilator from a patient for whom it is clinically indicated based on predictions of relative clinical effectiveness, unless:

- a. they apply a publicly available policy that has been issued or approved by an organisation with legal authority to direct doctors how to distribute limited resources among their actual and potential patients; or
- b. they are faced with multiple patients presenting at the same time and not enough ventilators for all.

Rationale: Doctors cannot be forced to provide treatment contrary to their clinical judgement, 28 29 but they have a duty to treat their patients with reasonable care and skill. Thus, if ventilation is clinically indicated, it is doubtful that doctors can unilaterally decide to withhold care on the grounds that a scarce

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resource would be more effectively used on future (anticipated) patients. Doctors are generally permitted, and expected, to make decisions in line with lawful policies adopted by the NHS, their CCGs or their hospitals.³⁰ But they take substantial legal risks if they apply guidelines that are not publicly available (see recommendation 9) or that were created by individuals or bodies that lack legal authority over medical practice and healthcare rationing. The only exception is if a doctor has multiple patients presenting at the same time and not enough ventilators for all; in this case, it will be necessary to withhold treatment from some even if a governing policy has not been established. Although doctors may not face personal civil liability for withholding care—as they will generally be indemnified by their hospitals or possibly the Coronavirus Act 2020—some patients could lose their lives unlawfully if doctors follow advice from unauthoritative sources.

Recommendation 2

NHS England, CCGs and hospitals should familiarise themselves with the limits of the data that support current triage policies, as these limits cast doubt on the possibility of reliably predicting patient outcomes.

Rationale: Public authorities must ensure that their decisions are rational and, where they engage the rights of individuals, proportionate. The Human Rights Act 1998 requires that they comply with the incorporated ECHR rights. Thus, those that are creating triage policies must carefully assess whether the evidence behind their policies is truly robust. Small differences between patients may not be clinically meaningful, and a decision to withhold ventilatory care could be legally challenged by patients or their families on the grounds that it is irrational, arbitrary or disproportionate in light of the limited evidence. Decisions that affect human rights and patients who are comparatively powerless are subject to greater scrutiny by the courts. ^{31 32} Thus, the authorities—and non-authoritative organisations—that are creating triage policies must be careful to avoid encouraging flawed decision-making at the institutional or individual level.

Recommendation 3

Priority should not be given to particular groups of patients based on instrumentalist grounds, such as the social value of their jobs.

Rationale: As a matter of public law, this type of prioritisation could be challenged for being irrational and/or disproportionate when the evidence is inspected. For example, the evidence might not support the assumption that a doctor who has just recovered from a critical COVID-19 infection will recover the strength to work in time to save additional lives during the pandemic, or that a worker helping to maintain critical infrastructure like electricity services is contributing more to society than a person caring for their friends and family. Furthermore, as a matter of civil law and professional regulation, it is unlikely that doctors' duty of care can be modified based on their view about the social value of a patient's job or lack of employment. This could amount to negligence, or even gross negligence manslaughter if the patient dies.

Recommendation 4

Although assessment of what is appropriate for a given patient must be based in clinical judgement, triage policies should not rely too much on the discretion of doctors. Policies should set out a standardised method to stratify patients' relative priorities, with tie-breaker principles if necessary (eg, time on the ward, or random selection).

Rationale: A triage policy that relies on discretion may result in arbitrary and inconsistent allocation decisions. This approach could breach Article 2 of the ECHR, which requires that States take appropriate steps to safeguard patients' lives, including through the creation of effective regulatory regimes. 20 21 This approach could also engage Article 8, which requires that decisions to deny life-saving treatment be made in accordance with a set of criteria that are clear and accessible (see recommendation 9). The Secretary of State for Health and Social Care could be failing in his overarching responsibility for healthcare if he does not take sufficient steps at a national level to protect patients' rights in the allocation of ventilators during the pandemic, particularly if the absence of a national policy results in widespread violations of patient rights. 34

Recommendation 5

If a ventilator is clinically indicated for a patient, it should not be withheld because the patient has a disability, which includes a substantial and long-term impairment such as a chronic illness (e.g. diabetes, pulmonary hypertension, COPD, cystic fibrosis). It might be permissible to withhold treatment based on the more general criterion that a poor outcome from COVID-19 is predicted, but this approach should be evaluated to determine whether it effectively disadvantages those with specific chronic illnesses or other disabilities. If so, the approach should only be used if there is strong evidence that reliably predicts poor outcomes and alternative non-discriminatory criteria could not be used instead. (The same restrictions apply to age-based criteria). Reasonable adjustments for disabilities may also be required, such as altering the prioritisation criteria or lengthening time-limited ventilation trials, if a patient with a disability does not have the same capacity to benefit as quickly as a patient without that disability.

Rationale: Many chronic illnesses and impairments satisfy the definition of 'disability' in the Equality Act 2010.³⁵ If treatment is denied because of disability—or if the disability is an 'effective cause' of the denial—this would constitute direct discrimination in violation of the Act. There is no defence for this. If instead, ventilation is denied on the basis of physiological criteria that predict poor outcomes (eg, oxygen saturation, organ failure, blood pressure, etc), the question becomes whether the criteria place patients with a disability at a particular disadvantage or treat them unfavourably because of something arising from their disability. If so, the use of the criteria is only lawful if it is 'a proportionate means of achieving a legitimate aim'. Otherwise, it constitutes indirect discrimination in violation of the Act. While the 'legitimate aim' requirement will likely be satisfied by the aim of allocating limited NHS resources efficiently, the 'proportionate means' requirement will only be satisfied if there is evidence that the criteria are sufficiently precise and accurate to achieve the aim and that they are reasonably necessary to do so.³⁶ (Age is also a protected characteristic, and age-based discrimination is likewise only lawful where it is a proportionate means of achieving a legitimate aim). For those with disabilities, the Equality Act 2010 also includes a duty to make reasonable adjustments so that they are not placed at a substantial disadvantage.³⁵ Furthermore, CCGs, hospitals and NICE must consider how disabled patients might be adversely impacted by their guidance (including, for example, NICE's endorsement of the BMA's guidance).

Withdrawal of ventilation

Recommendation 6

Clinically indicated ventilation should not be withdrawn before a trial of treatment has been completed, and it should only be done pursuant to a triage policy that satisfies the above requirements for withholding treatment.

Rationale: Withdrawal that does not comply with this recommendation would arguably constitute inhuman or degrading treatment in violation of the State's obligations under Article 3 of the ECHR. The act of withdrawing a ventilator from a patient for whom it is clinically indicated, in conjunction with the actions associated with this step (eg, un-sedating the patient so that his respiratory reflexes can kick in), would constitute active "treatment" for the purpose of Article 3.37 This cannot be justified on the basis of resource constraints. While resource constraints can limit the State's affirmative duty to protect a person from inhuman and degrading treatment, 38 they are irrelevant to the State's negative duty. This type of withdrawal could also engage the State's obligations under Article 2, for although it may not constitute intentional deprivation of life. it could breach the State's positive obligation to adopt appropriate measures to protect patients' lives and to have a clear legal framework regulating the medical profession. ²⁰ ²¹ The European Court in *Lambert* acknowledged that the margin of appreciation is not unlimited.²¹

Doctors may also be held directly liable for this type of withdrawal, which could constitute a breach of their duties of care under civil law (eg, battery, negligence) and criminal law (eg, gross negligence manslaughter, criminal battery, ill-treatment or willful neglect), as well as their professional duties. It is important to remember that when doctors withdraw a ventilator on resource allocation grounds, they are dealing with a patient for whom a ventilator has been judged to be clinically indicated-a judgement that has been based on factors including the patient's chance of recovery, the quality of life he may enjoy afterwards, and the patient's expected reaction to the invasiveness of mechanical ventilation and other ICU supportive therapies. Thus, whenever possible the patient should be un-sedated to give him a chance of surviving until another ventilator is available; otherwise, the doctor would be hastening his death. While withdrawal should of course be permitted where ventilation is no longer clinically indicated, doctors may need to provide patients with a sufficiently long trial to develop a robust assessment of how they respond before reaching this conclusion.^{28 39}

Recommendation 7

Unreasonably short time-limited trials should not be implemented to enable the withdrawal of treatment that remains clinically indicated.

Rationale: Although time-limited trials of ventilation may be clinically appropriate to determine how a patient responds, and although it might be permissible to provide shorter trials than would be provided outside the COVID-19 crisis, the trial periods should be clinically meaningful. The UK Supreme Court has warned against making decisions to withdraw life-supportive treatment when a patient's condition is unpredictable or fluctuating. If doctors unilaterally impose a time limit that is too short to be clinically meaningful, they may be in breach of their duty of care. If an authority (eg, government, hospital, CCG) specifies such a limit, it could be challenged on evidentiary grounds under administrative law for irrationality. Imposing unreasonable time limits or assessment criteria on ventilation trials could also be unlawful if they amount to constructive withdrawal of ventilation.

Recommendation 8

If, contrary to recommendation 6, a policy is adopted that allows a ventilator to be withdrawn based solely on relative prioritisation of patients (or if a doctor adopts such an approach in the absence of a policy), this decision must be proactively disclosed to potentially affected patients as a material risk before obtaining their consent to intubation and ventilation.

Rationale: Failure to inform the patient that ventilation may be withdrawn even if it is proving effective would breach the doctor's duty of disclosure under Montgomery.²⁵

Public availability of ventilator triage policies

Recommendation 9

Policies that direct doctors to withhold or withdraw life-saving treatment must be clear and publicly available.

Rationale: The ECHR's requirement that any interferences with the Article 8 right to privacy be 'in accordance with the law' has been interpreted as meaning that policies governing the denial of life-saving treatment must be clear and accessible.³³

Patient consultation

Recommendation 10

If a decision is taken to deny a patient life-supportive treatment (through withholding or withdrawal), the patient and/or the patient's family members must be consulted.

Rationale: The duty to consult arises from Article 8 of the ECHR and the common law, and it is required even when consultation would cause the patient to suffer distress (short of actual harm). As the court explained in Tracey, this duty protects patients' autonomy, integrity and dignity in the final days and moments of their lives, and it provides patients and family members with an opportunity to challenge the decision. To be clear, this does not mean that the doctor must obtain the patient's or family's consent to the decision. Denial of life-supportive treatment can be lawful even without consent (see recommendations 6 and 7), but the duty to consult beforehand remains effective.

CONCLUSION

If a ventilator triage policy is going to be based on the principle of 'save the most lives,' it must pay close attention to the legal rights that might be violated by this approach. An individual or family who believes that a ventilator is being unlawfully withheld or withdrawn deserves to have the issues discussed in this article considered by the British courts, at least as a test case. ²¹ Pushing ahead with a general ethical principle rather than carefully scrutinising its operation in the complex clinical environment could be deeply problematic, especially for the elderly and people with chronic illnesses and disabilities. Doctors who follow such proposals may act unlawfully. Worse, patients may die unlawfully. Patients' legal rights matter. Currently they are not being given the attention they deserve.

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