The legal and ethical implications of rationing critical clinical services - particularly in relation to Swine Flu

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Introduction

1. This paper examines the problem of the provision of critical care services at times when those services are sufficiently in demand it is necessary for rationing to take place on the basis not of clinical need but of benefit: in other words, for a system of triage to be implemented. Such times pose acute ethical dilemmas and legal problems. The ethical dilemmas have been the subject of considerable examination by both international and national bodies (both governmental and non-governmental); the legal problems have not been the subject of such scrutiny.

2. The structure of the paper is as follows:

    a. the context: the need for rationing of critical care services;

    b. ethical issues arising;

    c. legal considerations.

3. A health warning: this paper is drafted from a legal perspective; the author does not make any claim to be a specialist ethicist.

The context

4. The NHS works at or near capacity; in 2005/6 the NHS in England had an average overall staffed bed occupancy of 85%.[1] There are currently 3,637 adult critical care beds and 320 paediatric critical care beds.[2] It is overwhelmingly likely that in the event of a flu pandemic the demand for critical care beds will significantly outstretch this capacity, even when capacity is expanded by making use of non-critical care beds,

[1] Department of Health*: Pandemic Flu: Managing Demand and Capacity in Health Care Organisations (Surge)*, April 2009 (Available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_098769), para 4.1. This Guidance is referred to below as the *Pandemic Flu Guidance*.
[2] *Ibid* para 4.1

suspending elective procedures and so forth.[3] This is particularly so because, unlike an isolated disaster, a flu pandemic will continue to produce large numbers of sick people for a considerable period of time and over a large area. Over the entire period of a pandemic, up to 50% of the population may show clinical symptoms of flu, resulting in the total health care contacts for flu-like illness increasing from a 'normal' 1 million up to 30 million; at the peak of a pandemic, the Department of Health estimates that 110 per 100,000 population could require access to critical care services.[4] Further, given the pan-national extent of the epidemic, it will not be possible (or only possible to a limited extent) for patients to be transferred so as to spread the critical care load more evenly.

5. A national framework is in place for responding to a flu pandemic, drawn up in November 2007.[5] This has been supplemented by a raft of further documentation including, with particular relevance to the current talk, the *Pandemic Flu Guidance* issued in May of this year. International bodies including WHO have also produced guidance,[6] and state and federal bodies in the United States, Canada and Australia have produced further guidance.[7] Finally, assistance can be gleaned from the work of non-governmental bodies which have convened discussion groups to consider and advise as to planning for pandemics.[8]

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[3] The Department of Health considers that it should be possible to increase current critical care capacity by 100% from normal bed availability: *Pandemic Flu Guidance* at paragraph 10.1.

[4] *Pandemic Flu Guidance* at paragraph 4.2.

[5] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080734

[6] See, in particular, *Ethical Considerations in developing a public health response to pandemic influenza* (available at http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2/en/index.html). This guidance does not sit entirely comfortably with the guidance produced by the Department of Health, as it appears to suggest that the priority in the operation of any triage system remains the treatment of those most severely ill.

[7] See, for instance, the detailed guidelines produced in July 2009 by the Queensland Government in July 2009: http://www.health.qld.gov.au/swineflu/documents/icu_guidelines_v3.pdf; also

[8] See, for instance, *Definitive Care for the Critically Ill During a Disaster: A Framework for the Allocation of Scarce Resources in Mass Critical Care*: http://www.chestjournal.org/content/133/5_suppl/51S.full. This is of particular relevance as one of the participants was Dr Michael D Christian, whose views have played an important role in framing the *Pandemic Flu Guidance*.

6. The common theme to all the guidance is that a flu pandemic will inevitably create situations in which it is not possible for conventional allocation of critical care resources to take place. In the *Pandemic* Flu guidance, this is defined as "Surge – extreme." At this point, there will be no more capacity, the priority will be to maintain services for life-threatening conditions, with triage for all treatment.[9]

7. The Department of Health, in its *Pandemic Flu* guidance, identifies the need for national agreement on the prioritisation of service provision,[10] but then makes it clear that primary care trusts will have to take the lead in implementing the guidance. In line with this approach, the Department of Health identifies a range of tools that PCTs can use to determine admission to, utilisation of and discharge from services, but does not definitively identify which tools should be used.

8. In the critical care context, the Department of Health appears to advocate (albeit does not definitely endorse) the protocol for triaging patient access to critical care during a pandemic drawn up by Christian and others.[11] Such a protocol applies both to determine entry to critical care, and to continuation of the provision of critical care services. It has the following features:

    a. inclusion criteria: in other words, criteria to establish that the patient actually requires active critical care intervention;

    b. exclusion criteria: i.e. criteria to exclude the following categories of patients:

        i. those with a poor prognosis even if cared for an intensive care unit;

        ii. those who require resources that will not be available during a pandemic; and

[9] *Pandemic Flu Guidance* Paragraph 7.2
[10] Which has the following benefits, according to the Department of Health: (1) reassurance of a consistent clinical approach across England; (2) transparency and clarity in the approach to be adopted; (3) public and professional discussion and sign-up in advance of a pandemic; (4) support for clinicians during a pandemic; and (5) an opportunity for appropriate indemnity and professional support to be agreed and in place beforehand. *Pandemic Flu Guidance* at paragraph 7.3.
[11] See footnote 8 above for a convenient summary of this approach.

iii. those with advanced illness whose underlying illness means that they have a high likelihood of death even without their current, concomitant critical illness[12]

c. a prioritisation tool.

9. Critical to any triaging protocol is the tool used for scoring illness. The *Pandemic Flu Guidance* discusses at some length the Sequential Organ Failure Assessment tool endorsed by Christian et al, but with a number of caveats. In particular, the *Guidance* emphasises that the SOFA system has not been validated, and should not be used as a primary or exclusive triaging tool.[13]

10. In line with the approach outlined above to the division between national and local responsibilities, the relevant chapter of the *Pandemic Flu Guidance* concludes in this respect as follows:

> *"The required strictness of triaging decisions will vary according to the scale of the problem and its geographical extent. The necessity for triaging patients will also be influenced if additional critical care capacity exists elsewhere and if transport logistics allow these to be accessed. Accordingly, a staged triaging structure should be created, with the progression criteria being agreed by local consultation"*[14] (emphasis added)

11. The *Guidance* provides an approach to staged triage in Appendix 3 which provides as follows in respect of the stage with which we are currently concerned (i.e. one prior to an event causing the collapse of some or all hospital infrastructures):

> "*Stage 3*
> *Even with maximally expanded critical care capacity, it will only be possible to treat a limited proportion of the patients who may require Level 3 care as it is likely that all available Level 3 beds will be in use as a result of a progressively increasing referral rate. Consequently, many potentially preventable deaths may be inevitable. New referrals will only be able to*

[12] *Pandemic Flu Guidance* paragraph 10.2
[13] Ibid; also Appendix 14.
[14] Ibid.

receive Level 3 care if a bed becomes available because a patient has died or recovered sufficiently to be discharged.

Staffing and equipment limitations will be such that critical care interventions will have to be restricted. Mechanical ventilation, fluid therapy (+/- vasopressor support), intravenous antibiotics and enteral nutritional support may be provided, but treatment will not be further escalated if deterioration occurs despite these interventions. In patients considered to be at risk of peptic ulceration, H2 receptor antagonist therapy may be considered appropriate.

The over-riding principle will be that only patients who are thought to have a good chance of survival with a reasonable life expectancy should receive Level 3 care. In patients who progress to multiple organ failure despite full supportive care, treatment interventions may have to be withdrawn, or non-escalation strategies agreed on the basis that other less sick patients are more likely to benefit from receiving Level 3 care. Use of the SOFA scale to assist in non-escalation/withdrawal decisions will ensure consistency for all patients.

The decision to withdraw or limit interventions earlier in the course of a patient's treatment than would be considered under normal circumstances is likely to cause distress to relatives and critical care staff, and the ability to continue functioning as a cohesive team will require careful attention to staff communication and morale.

As there is likely to be extreme distress, anger and even a risk of aggressive behaviour from family and friends of those in whom withdrawal of treatment interventions must be considered, it may be advisable to rely on non-escalation (eg not commencing vasopressor support or renal replacement) in many situations. Lack of availability of drugs, equipment or expertise may independently restrict such interventions.

Nursing and medical resources are likely to be under such pressure that the normal standards expected of critical care will inevitably be compromised and hence close teamwork and mutual staff support will be of crucial importance. Failure to preserve staff morale is likely to lead to increased absenteeism, and consequently increase staffing problems and reduce bed availability.

In the face of high demand there may be patients that the clinicians cannot differentiate between on the basis of benefit. At this stage, allocation of ICU treatment may required to be made by a clinically based selection process, taking into account the principles of the ethical framework (Appendix 2)."

12. However, in line with the approach set out above to the division between national and local responsibilities, the ball is placed very firmly in the court of Primary Care Trusts and Strategic Health Authorities to determine precisely the trickiest elements of the triaging process.

Ethical considerations

13. The Government has convened a Committee on the Ethical Aspects of Pandemic Influenza ('CEAPI'), which in turn has helped draw up an ethical framework for policy and planning responses to pandemic flu ('the *Framework'*).[15] The *Framework* needs to be approached correctly; as outlined in the introduction:

> "*The framework is designed for use by planners and strategic policy makers at national, regional and local level, both before and during a pandemic. It is also designed to assist clinicians and others (who will also be guided by their own professional codes) in developing policies on clinical issues for use during a pandemic. Although not designed to address individual clinical decision-making, clinicians and members of the public who want to think about the ethical implications of their own behaviour during a pandemic are welcome to use it for such purposes*" (emphasis added).

14. The *Framework* identifies a number of key principles, underpinned by a central principle of equal concern and respect. The individual principles are outlined as follows (they are expressly not ranked in order of significance)[16]:

    a. respect;

    b. minimising the harm that a pandemic could cause;

    c. fairness;

    d. working together;

    e. reciprocity;

    f. keeping things in proportion;

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[15] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_080751. This should be read together with CEAPI's "approach to ethical issues," which places the framework in its context: http://www.dh.gov.uk/en/Publichealth/Flu/PandemicFlu/DH_065163.

[16] *Framework* at p.2.

g. flexibility;

h. good decision-making, to include:

i. openness and transparency;

ii. inclusiveness;

iii. accountability;

iv. reasonableness.

15. It is perhaps of some interest to compare these principles with those derived at the Mass Critical Care Summit meeting convened in Chicago in 2007.[17] The participants there identified three key principles underpinning an ethical approach to triage:

a. a limitation of individual autonomy;

b. transparency;

c. justice/fairness.

16. Whilst the latter can be seen to be a compressed version of the former, the emphasis on the limitation of individual autonomy is an important factor that perhaps does not receive sufficient emphasis in the *Framework*. Triage in a Stage 3 situation represents in an extreme form a departure from the principle of individual choice that is enshrined in modern medical culture. Whilst necessary, it is vitally important that it is recognised as such.

17. The extent to which triage is a departure from the normal principles governing the allocation of scarce clinical resources is further emphasised in a useful passage from

[17] *Definitive Care for the Critically Ill During a Disaster: A Framework for the Allocation of Scarce Resources in Mass Critical Care*, available at http://www.chestjournal.org/content/133/5_suppl/51S.full

one of the leading text books on medical ethics and the law, Mason and McCall Smith's *Law and Medical Ethics*:[18]

> "*Triage is a curiously derived expression meaning, in the present context, the separation of casualties into priority treatment groups. It is basically a military concept, the current British policy being to allocate four categories of casualty, ranging from those whose slight injuries can be managed by self-care to those who cannot be expected to survive even with extensive treatment and who are, therefore, treated on a humanitarian basis only; the policy is closely associated with casualty evacuation. Triage in this sense is not only good emergency surgical practice but is also ethically acceptable because it is directed to a single discernable end – that is to win the war or the battle, and we accept that this is, in itself, a morally acceptable objective with which the medical branch of the armed services can quite properly associate itself. But can we, in ethical terms, simply transfer the concept of triage, which is an emergency procedure, to elective civilian practice? It may be possible to do so in special circumstances – it is, for instance a recognised practice following a major disaster, when the single most pressing objective is to mitigate the effects of that disaster..."*

Legal considerations

18. It is a slightly curious feature of the extensive documentation produced by the Department of Health and CEAPI that none of it makes reference to legal principles, most notably the principles enshrined in the European Convention on Human Rights ('ECHR'). To a lawyer reading the documents, the suggestion would almost appear to be that the ethical considerations underpinning the operation of a triage system are separate to the legal considerations. The limited judicial consideration that has been given to triage (or triage equivalents) in the civilian context would suggest that this is wrong and that – unsurprisingly – the principles set down in the *Framework* sit entirely comfortably within the standard legal framework governing the taking of clinical decisions.

19. That legal framework must be analysed from two perspectives: (1) the responsibility of the State, in the guise of the Secretary of the State and (at a local level) the Primary

[18] 7th Edition, OUP 2006.

Care Trust to ensure the provision of healthcare to patients; (2) the responsibility of individual clinicians to discharge the duties of care that they owe to their patients.

The responsibility of the State to ensure the provision of healthcare

20. The Secretary of State's general duty is to be found in s.1(1) of the National Health Service Act 2006 ("the 2006 Act"), which provides as follows:

> *Secretary of State's duty to promote health service*
>
> *(1) The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement –*
>
> *(a) in the physical and mental health of the people of England, and*
>
> *(b) in the prevention, diagnosis and treatment of illness.*
>
> *(2) The Secretary of State must for that purpose provide or secure the provision of services in accordance with this Act.*
>
> *(3) The services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed.*

21. Section 2(1) of the 2006 Act provides that:

> *The Secretary of State may—*
>
> *(a) provide such services as he considers appropriate for the purpose of discharging any duty imposed on him by this Act, and*
>
> *(b) do anything else which is calculated to facilitate, or is conducive or incidental to, the discharge of such a duty.*

22. Section 3(1) of the 2006 Act provides that:

> *The Secretary of State must provide throughout England, to such extent as he considers necessary to meet all reasonable requirements—*
>
> *...*
> *(c) medical, dental, ophthalmic, nursing and ambulance services,*

...

(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness as he considers are appropriate as part of the health service,

(f) such other services or facilities as are required for the diagnosis and treatment of illness.

23. The general duties of the Secretary of State under s.3 of the 2006 Act are delegated to Primary Care Trusts and Strategic Health Authorities, by virtue of s.7(1) of the 2006 Act read together with Regulation 3 of the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 (SI 2002/2375) (as amended).

24. Whilst (as far as I have been able to tell) the Courts in this country have never had to consider the question of triage, it has long been recognised by the Courts that the duty imposed upon the Secretary of State (and thence upon PCTs and SHAs) is not an absolute one. In other words, the Courts have long recognised that health bodies are required to make difficult decisions about the allocation of scarce resources. In *R v Cambridge Health Authority ex parte B* [1995] 1 WLR 898, Sir Thomas Bingham MR observed at 906D to F:

> "*I have no doubt in a perfect world any treatment which a patient, or a patient's family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make*."

25. In similar vein are the comments of Auld LJ in *R v North West Lancashire Health Authority ex p A* [2000] 1 WLR 977 at 991E to F:

> "*As illustrated in the Cambridge Health Authority and Coughlan cases, it is an unhappy but unavoidable feature of state funded health care that Regional Health Authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each Authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each Authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose – indeed, it might well be irrational not to have one – and it makes sense too that, in settling on such a policy, an Authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure*."

26. The cases set out above were decided before the Human Rights Act 1998 was enacted (which allows the ECHR to be raised directly before courts in England and Wales). However, in cases decided subsequent to the enactment of the 1998 Act,[19] the Courts have continued to decide cases in a similar fashion, and have not had recourse to Article 2 ECHR (which enshrines the right to life). This Article does, however, merit a brief detour because of its central significance in the ECHR.

27. The European Court of Human Rights has accepted that Article 2 of the ECHR at least raises the question of the state's duty to provide the healthcare necessary to save life.[20] For instance, in *X v United Kingdom* 14 DR 31 (1978), E Com HR, the complainant sought to challenge a vaccination programme for children. The European Commission on Human Rights accepted that a state was under an obligation to take adequate measures to protect life, and suggested that this might raise issues with respect to the adequacy of medical care. However, on the facts of the case, the Commission found that there was evidence to suggest that the vaccinations had been administered poorly

[19] For instance *R(Rogers) v Swindon NHS PCT* [2006] 1 WLR 2649); R*(Otley) v Barking and Dagenham NHS Primary Care Trust* [2007] EWHC 1927 (Admin); and *R (Ross) v West Sussex Primary Care Trust* [2008] EWHC 2252 (Admin), all of which concerned funding for expensive drug treatments for terminal illnesses.

[20] See Lester, Pannick and Herberg, *Human Rights Law and Practice*, paragraphs 4.2.13 et seq.

or that proper steps had not been taken to minimise any risks. The European Court of Human Rights has also found that Article 2 requires that states pass regulations compelling hospitals, whether public or private, to adopt appropriate measures for the protection of their patients' lives.[21]

28. In my view, though, it is highly unlikely that a Court (either a domestic Court or the European Court of Human Rights) considering the imposition of a triage system (either by way of a challenge to the system as a whole or by reference to a particular case) would find that the imposition of an appropriate triage system at stage 3 of a pandemic would breach Article 2 ECHR. In other words, I consider that it is highly unlikely that a Court would find that the health authorities were under an obligation by virtue of Article 2 to treat all those who presented themselves as requiring critical care facilities if this is impossible. I note here, by analogy, the South African case of *Soobramoney v Minister of Health, KwaZulu-Natal* (1997) 4 BHRC 308. Here, a challenge was brought following the refusal of dialysis treatment due to insufficient hospital resources. The claim was brought upon two sections in the South African constitution which provided (s. 27(3) that: "No one may be refused emergency medical treatment" and (s. 11) that "everyone has the right to life." Rejecting the claim (and relying on the passage from *B* set out above) the Court held that:

> "*31. One cannot but have sympathy for the appellant and his family who face the cruel dilemma of having to impoverish themselves in order to secure the treatment that the appellant seeks in order to prolong his life. The hard and unpalatable fact is that if the appellant were a wealthy man he would be able to procure such treatment from private sources; he is not and has to look to the state to provide him with the treatment. But the state's resources are limited and the appellant does not meet the criteria for admission to the renal dialysis programme. Unfortunately, this is true not only of the appellant but of many others who need access to renal dialysis units or to other health services. There are also those who need access to housing, food and water, employment opportunities and social security. These too are aspects of the right to '… human life: the right to live as a human being, to be part of a broader community, to share in the experience of humanity' (see S v Makwanyane 1995 (4) BCLR 665 (para 326) per O'Regan J). The state has to manage its limited resources in order to*

[21] See, for instance, Calvelli v Italy (17 January 2002, unreported), at para 49.

address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society."[22]

29. Where a triage system would be open to challenge, however, would be if it was operated in such a way as it discriminated against any patient on the basis of anything other than criteria that were developed solely by reference to a clinical comparison of that patient with others with a similar level of need. Framed in legal terms, this would amount to a breach of Article 2 of the ECHR read together with Article 14 (which prohibits discrimination in the enjoyment of the rights and freedoms set forth in the Convention on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status[23]).

30. A triage system could also – potentially – be challenged[24] on the following grounds:

    a. that it has not been implemented following suitable consultation. The *Pandemic Flu Guidance* expressly states that the staged triaging structure for any particular locality should be created following local consultation. The requirement for consultation is well-recognised in public law, and requires, inter alia, that the decision maker must carry out the consultation with an open mind, and that those consulted must be provided with sufficient information to enable them to express their views, and they must be allowed sufficient time in

[22] See also *Shortland v Northland Health Ltd* (1999) 50 BMLR 255, in which the New Zealand guidelines as to the allocation of restricted publicly funded resources were considered. A decision was taken to discontinue interim dialysis in respect of a patient with end-stage renal failure and dementia; it was justified both on the basis that the moderate dementia suffered by the patient placed him outside the group of those considered suitable for treatment and also by reference to a pure 'best interests' test. The High Court and Court of Appeal both strove officiously to avoid considering the status of the guidelines, and to decide the question on the basis of the exercise of clinical judgment. However, neither Court sought to impugn the guidelines or the reasoning process underpinning them.

[23] On the face of it, it might appear that one could argue that "other status" included the severity of the condition of the particular patient. However, if the triage system differentiated between patients on the basis of clinical criteria, then this would not amount to "discrimination" within the meaning of Article 14 as interpreted by the Strasbourg Court, which has held that Article 14 is only violated if by a difference in treatment between persons who are in comparable situations which has no objective and reasonable justification: *Belgian Linguistics Case (No 2)* A 6 (1968), 1 EHRR 252, ECtHR, para 10.

[24] Most likely by way of judicial review; it is likely that the considerations of time would mean that aggrieved persons would not seek to follow standards complaints procedures.

which to do so.[25] Here, there is a difficult line to tread between providing sufficient information to enable consultees to participate and being alarmist. However, as the *Framework* emphasises, transparency is of signal importance in the implementation of any triage scheme – and this goes both for its implementation in any specific case, and for its implementation as a scheme more generally;

b. that its implementation is unnecessary given the actual state of the demands upon the critical care services. Such a challenge would be difficult to mount, and it is likely that any Court would be very hesitant before engaging in a detailed assessment of the actual stage of the flu pandemic.

31. Turning to the treatment of specific individuals, it is easy to imagine that those who have been declined treatment (or perhaps, even more agonisingly, those who have been given treatment but whose treatment has been withdrawn following a triage re-assessment) will seek to challenge the decision. From what I have seen, there does not appear to be any suggestion in the Department of Health guidance that PCTs/SHAs should implement an internal appeals process against triage decisions. In the abstract, such would have a great deal of merit. However, there may well be substantial practical problems which would arise, in particular in terms of delay, when the essence of the triage system is that critical care resources are deployed as swiftly and as efficiently as possible. [26]

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[25] See, in particular, *R v Brent London Borough Council, ex p Gunning* (1985) 84 LGR 168.

[26] I note the discussion of this in the Mass Critical Care Summit proposals, which reads as follows: "*In order to ensure "procedural justice," a standardized and equitable practice that conforms to the rules in place, any triage operation should be regularly and repeatedly evaluated to guarantee that the process has been followed fairly. This evaluation process will promote medical provider compliance; eliminate administrator, governmental, or physician overrule (special pleadings or "favors"); and facilitate consistency. Owing to the critical illness of patients and the limitations of the scarce resource(s), this evaluation process will need to be efficient and frequent. Direct appeals to the triage procedure may be impractical based on the urgency with which the allocation decision must be made. Individual physicians, administrators, or government officials should not be able to overrule a "good faith" decision made by a triage officer in compliance with the triage process. Because all patients will share the same pool of resources, the standard of care and triage process should apply to all patients, whether their condition is directly attributable to the mass casualty event or results from other underlying pathology or circumstances. If there is a challenge to procedural justice (ie, the process was not followed according to established criteria), then an appeal is indicated.*"

32. Absent such an ability to launch an internal appeal (and/or in any event, in the case of those disappointed with the outcome of an internal appeal), PCTs must prepare themselves for challenges to be brought by those affected by triage decisions by way of judicial review proceedings. Potential grounds for such a challenge (and hence matters that those making triage decisions must consider) are:

    a. a breach of the right to life under Article 2 (or potentially of the right not to be subject to torture, inhuman or degrading treatment enshrined in Article 3 ECHR). As set out above, it is unlikely that such a challenge would succeed absent very clear evidence of an error in the triage assessment process, for instance in the interpretation of the clinical evidence, which rendered the decision irrational;

    b. discrimination: i.e. differential treatment without an objective and reasonable justification;

    c. that the decision is not adequately reasoned. Such rationality challenges are common in the public law field; whilst I would anticipate that a Court would be willing to give significant leeway when examining the precise wording of the reasons given for a triage decision taken under pressure, it would nonetheless require sufficient reasons to be given for the patient/their family to be able to understand (and, if necessary) to challenge a decision which would have the effect – most likely – of meaning that they will die;

    d. that the decision to refuse or terminate treatment was taken by too strict a reading of the SOFA score (if this adopted), in other words without exercising the discretion that the *Pandemic Flu Guidance* makes clear clinicians must exercise.

Individual clinical responsibility

Civil responsibility

33. Individual clinicians, and in particular those charged with making the triage decisions in any particular case, are going to be placed in an entirely invidious situation, at every level. Not the least of their concerns will be a concern that they may face a claim would be brought against the clinician (and the hospital as his employer) on the basis of a negligent triage assessment leading either to death or personal injury, and it is for this reason that PCTs should offer indemnities to doctors who are required to carry out triage assessments.

34. However, in my view is that it is unlikely that a claim in any individual case would succeed absent very clear evidence of a departure from reasonable clinical practice. A number of points can perhaps be made in this regard, however:

    a. the suggestion that triage decisions are carried out by more than one clinician, of more than one discipline, is an entirely prudent one, not just in terms of defending the PCT from a judicial review challenge to the triage decision, but also in terms of defending any potential civil claim;

    b. it is clearly envisaged that practitioners will have to work outside their usual areas of expertise. At common law, the standard of duty of care owed by a doctor is that of a reasonable and careful practitioner of his grade or level of experience; it is highly likely that any court asked to examine the actions of a clinician required to practice outside his usual area of expertise would be very slow to criticise those actions barring clear evidence that the clinician acted inappropriately (for instance, perhaps, by failing to seek appropriate guidance from a practitioner experienced in the area if he was unclear about a particular clinical criterion to be applied in the SOFA assessment);

    c. a 'blind' adherence to the SOFA scores at the expense of clinical judgment as to the appropriateness of refusing or continuing treatment would potentially

ground a claim against an individual clinician (or group of clinicians), as this would represent an abdication of clinical judgment;

d. in any case, any patient (or family member claiming as dependent/family member of a deceased patient) would have to establish that any negligence on the part of the clinician(s) involved in the triage decision in fact caused the death or personal injury of the person concerned (and that this was foreseeable). This would be a question of fact in each case.

Criminal responsibility

35. Theoretically, a sufficiently gross lapse of clinical judgment could open the way to a prosecution for manslaughter in the event that a patient refused treatment (or from whom treatment was withdrawn) subsequently died. Again, however, requiring triage decisions to be taken by more than one person would have the very significant benefit of – hopefully – protecting against such an eventuality.

36. Whilst dealing with criminal responsibility, I note as a final point that it there is a good argument that the corporate manslaughter provisions do not apply vis-a-vis the PCT and/or the relevant hospital in the application of triage decisions. The provisions of the Corporate Manslaughter and Corporate Homicide Act 2007 do not apply in respect of the allocation of public resources of the weighing of competing public interests (s.3); moreover, by s.6, emergency situations are excluded (and, by ss.6(3) and (4) such emergency situations include decisions as the order in which persons are to be given medical treatment).

Conclusion

37. The rationing of critical care services raises complex ethical and legal questions; whilst considerable attention has been dedicated to debating some of the ethical questions (albeit frequently and, of necessity, at a high level of generality), there appears to be a curious dearth of consideration of the legal questions raised by rationing. However, as this paper has attempted to show, approaching the ethical

dilemmas in an appropriate fashion is likely to mean that the best (or, perhaps, least worst) answers can be given to the legal questions.

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