Public healthcare resource allocation and the Rule of Rescue

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Received 1 June 2007
Revised 30 October 2007
Accepted 16 November 2007

ABSTRACT

In healthcare, a tension sometimes arises between the injunction to do as much good as possible with scarce resources and the injunction to rescue identifiable individuals in immediate peril, regardless of cost (the "Rule of Rescue"). This tension can generate serious ethical and political difficulties for public policy makers faced with making explicit decisions about the public funding of controversial health technologies, such as costly new cancer drugs. In this paper we explore the appropriate role of the Rule of Rescue in public resource allocation decisions by health technology funding advisory bodies such as the National Institute for Health and Clinical Excellence. We consider practical approaches to operationalising the Rule of Rescue from Australia and the UK before examining the relevance of individual moral imperatives to public policy making. We conclude that that whilst public policy makers in a humane society should facilitate exceptional departures from a cost effectiveness norm in clinical decisions about identified individuals, it is not so obvious that they should, as a matter of national public policy, exempt any one group of unidentified individuals within society from the rules of opportunity cost at the expense of all others.

> Our moral response to the imminence of death demands that we rescue the doomed. We throw a rope to the drowning, rush into burning buildings to snatch the entrapped, dispatch teams to search for the snowbound. This rescue morality spills over into medical care, where our ropes are artificial hearts, our rush is the mobile critical care unit, our teams are the transplant services… Should the Rule of Rescue set a limit to rational calculation of the efficacy of technology? Should we force ourselves to expunge the Rule of Rescue from our collective moral conscience? […] Might a world with less cost-effective healthcare be a morally better place to be? –Albert Jonsen[1]

In healthcare, a tension sometimes arises between the injunction to do as much good as possible with scarce resources ("cost-effectiveness") and the injunction to rescue identifiable individuals in immediate peril, regardless of cost (the "Rule of Rescue").[1–3] The rescue imperative is a powerful motivation for individual behaviour, which is sometimes known in psychology as the "identifiable victim effect".[4] Typically the "immediate peril" in question involves imminent death; though the rescue imperative can also apply to other dramatic cases of immediate peril involving severe non-fatal harm.

The tension between cost effectiveness and the Rule of Rescue can generate serious ethical and political difficulties for public policy makers faced with making explicit decisions about the public funding of controversial health technologies, such as costly new cancer drugs. On the one hand, funding the technology may rescue patients facing imminent death (eg, by giving them a small number of extra months of life). On the other hand, the cost of funding the technology may divert resources away from care of other patients that—according to the best available evidence—would do more good (eg, by giving them a large number of extra months of life).

In the UK, the National Institute for Health and Clinical Excellence (NICE) sometimes wrestles with dilemmas of this kind.[5] The dilemmas are brought into sharp focus, because NICE pays close attention to cost-effectiveness evidence, such as the cost per quality adjusted life year.[6] However, although the Institute has published guidance on the "social value judgments" that employees and affiliates are expected to adopt, it currently takes no official position on the Rule of Rescue.[7] It currently has no view on whether the Rule of Rescue is a relevant consideration; let alone how it might be defined and weighed in the balance with other considerations. This may change, as the Institute is to review its guidance later this year.

Our intention in this paper is to explore the appropriate role of the Rule of Rescue in public resource allocation decisions by NICE and comparable health technology funding advisory bodies across the world. In the next section we examine how one country, Australia, has attempted to make explicit use of the Rule of Rescue. Section three goes on to examine the NICE Citizens Council Report and recommendations on the use of the Rule of Rescue.[5] The final section explores the relevance of individual moral imperatives to public policy making.

THE AUSTRALIAN DEFINITION—A RARE, SEVERE CONDITION WITH NO ALTERNATIVE TREATMENT

An important pragmatic concern about the Rule of Rescue is that it should not become a "catch-all" basis for special pleading by patient advocates and manufacturers in seeking funding for their own favoured form of cost ineffective care. One way of avoiding this would be to restrict application of the Rule of Rescue to a tightly defined set of specific requirements. The Australian Pharmaceutical Benefits Advisory Committee (PBAC) specifies three requirements for the application of the Rule of Rescue to national pharmaceutical coverage decisions, as follows[8]:

> Three factors, which apply in exceptional circumstances, are particularly influential in favour of

J Med Ethics 2008;34:540–544. doi:10.1136/jme.2007.021790

> listing. When all three factors apply concurrently, this is called the "rule of rescue". The three factors are as follows.
>
> No alternative exists in Australia to treat patients with the medical condition meeting the criteria of the requested restriction. This is an absolute requirement. It means that there are no nonpharmacological or pharmacological interventions for these patients.
>
> The medical condition defined by the requested restriction is severe, progressive and expected to lead to premature death. The more severe the condition, or the younger the age at which a person with the condition might die, or the closer a person with the condition is to death, the more influential the rule of rescue might be in the consideration by PBAC.
>
> The medical condition defined by the requested restriction applies to only a very small number of patients. Again, the fewer the patients, the more influential the rule of rescue might be in the consideration by PBAC. However, PBAC is also mindful that the PBS [Pharmaceutical Benefits Scheme] is a community-based scheme and cannot cater for individual circumstances.

The most remarkable thing about this Australian operationalisation of the Rule of Rescue is that it does not focus on identifiable individuals in imminent peril and hence bears little relationship to the original Rule of Rescue concept discussed in the literature. The only mention of imminent peril is in the third sub-clause of the second of three requirements, which states that "the closer a person with the condition is to death, the more influential the rule of rescue might be". Although the term Rule of Rescue is used, it does not invoke the sense of desperate urgency that looms behind Jonsen's examples.[1]

The first requirement—no available alternative treatment—is a peculiar one. It is not clear why the availability of an alternative treatment should make any difference from a moral perspective. It might be argued that availability of a treatment offers hope to the patient, which is valuable over and above any health benefits. However, all patients in immediate peril value the hope offered by a better treatment than the one currently one offer—it is not clear why this hope is more valuable for some patients rather than others. Furthermore, the alternative treatment of "best supportive care" is always available, so what this requirement is really driving at is the availability of an effective man-made disease-modifying technology—which amounts to a "fetishisation of technology".[9] This fetishisation implies that it is worth reducing total population health in order to make available at least one effective man-made disease-modifying technology for every condition. This is a peculiar policy objective, with implications that seem counterintuitive and unfair. For example, imagine there are two patients with two different conditions who are both suffering equally—the first patient receiving "best supportive care" and the second patient receiving a disease-modifying treatment with limited effectiveness and severe side-effects. Imagine that a new treatment comes along that is effective for both conditions but not cost effective. Is it fair that the first patient should receive this treatment but not the second? Is the "hope" provided to the second patient less important than the hope provided to the first?

The second requirement focuses attention on severity of illness and, more specifically, on severe and progressive conditions expected to lead to premature death. Concern for severity of illness can be grounded in generalisable philosophical principles of justice: first, a principle of priority to the worst off in terms of health; second, a principle of equality in terms of health; and third, a principle of distribution according to need, where need is a function of health as well as capacity to benefit from treatment. In each case, "health" here refers to the individual's health at a point in time, rather than an aggregation of the individual's entire lifetime experience of health. These principles will all give priority to the severely ill, defined as individuals in poor health at a particular point in time in terms of proximity to death and/or poor health-related quality of life. In their general forms, "priority", "equality" and "need" principles have all received extensive consideration in the philosophical literature[10–13] and numerous health-specific variants have received attention in the health literature.[14–16] Generalisable principles of this kind also fulfil the important desideratum of being in principle quantifiable in a form that allows them to be weighed up against cost-effectiveness concerns. For example, Nord has developed a workable system of severity weighting that allows concerns for severity to be quantified in the form of a generalised version of the standard cost per quality adjusted life year approach that he refers to as "cost-value analysis".[17 18] Nord's proposal is to value all gained life time equally—whether in full health or severe ill-health, so long as the person wishes to continue living—and to apply a simple transformation function to quality of life scores that gives greater weight to gains and losses at the severely ill end of the quality of life scale. This approach is recommended as a supplementary analysis in submissions to the Norwegian Medicines Control Agency in making pharmaceutical reimbursement decisions.[19]

One problem with defining a generalisable principle of justice in terms of severity of illness is that it seems myopic: why focus on a snapshot of ill-health at a particular point in time rather than a person's whole lifetime experience of ill-health?[20] However, even if one accepts the case for severity weighting of the kind advocated by Nord, it is important to recognise that concern for severity, and the philosophical principles of justice that underpin it, is quite different from the Rule of Rescue. There is an important difference between concern for severity and concern for identifiable individuals in immediate peril. Concern for identifiable individuals in immediate peril implies less concern for unidentifiable individuals in future peril; whereas concern for severity applies to all severe illness—whether suffered by identified or unidentified individuals and whether suffered now or in the future. So, for example, Nord's system of severity weighting would give high priority to preventive public health programmes designed to prevent severe illness in the future; whereas the Rule of Rescue would give low priority to preventive programmes of this kind—since they target people who are currently relatively healthy and not in any immediate peril. Similarly, the Rule of Rescue implies giving low priority to treatment for patients at mild to moderate stages of a progressive condition, and instead waiting until the condition becomes sufficiently severe to constitute immediate peril—by which time, of course, treatment may be less beneficial and/or more costly. So the Rule of Rescue is quite different from severity weighting, and cannot be justified with reference to any of the standard principles of justice.

Finally, the third requirement restricts the applicability of the Australian Rule of Rescue to conditions that affect a very small number of people—often termed "orphan" conditions. Whilst this restriction prevents the Rule of Rescue from becoming a routine "catch-all", it is hard to defend. The moral imperative behind Rule of Rescue relates to the fact of imminent peril. It is not clear why it should make any difference from an ethical point of view whether the cause of imminent peril is rare or common.[21]

Thus, each requirement is flawed, and may introduce greater inequity than equity. However, the most striking characteristic of the Australian implementation of the Rule of Rescue is that it is almost completely independent of the concept of the Rule of Rescue as described in the literature. The patient is not facing immediate peril; there is no sense of urgency to this story. The Australian definition is more reminiscent of American and European Orphan Drug legislation.[22 23]

THE UK NICE CITIZEN'S COUNCIL DEFINITION—A MIXED BAG OF 11 CONSIDERATIONS

The NICE "Citizen's Council" is a group of 30 members of the public drawn from a broad cross section of the general UK population in order to give their views and opinions on issues of social value judgement relating to the work of NICE. Although it has no mandatory authority, it is a unique collection of lay members of the public, brought together to immerse themselves in the social value judgements that cannot be avoided in healthcare resource allocation. One of their recent reports addresses the issue of the Rule of Rescue.[5]

NICE asked the Citizen's Council to address its deliberations to the following questions:

1. Is there a preference to save the life of people in imminent danger of dying instead of improving the life of other people whose lives are not in immediate danger?

or

2. Saving the lives of many people in the future through disease prevention programmes (such as treating high blood pressure or lowering blood cholesterol levels)?

   If the Council considers that NICE should ignore the Rule of Rescue—why?

   If the Council considers that the Rule of Rescue should be applied—when?

   And what limits are there?

Box 1 NICE Citizen's Council checklist of questions for implementing the rule of rescue[5]

1. Is the intervention required to avoid immediate loss of life?
2. Is there a good chance of an increased life expectancy?
3. Will it result in a significant improvement in quality of life? Are the treatment's side effects very severe and do they outweigh the good the treatment would do?
4. What will be the consequences should the treatment not be received?
5. What are the alternative treatments and how do they compare?
6. Are future medical gains probable because of the research engendered by the treatment?
7. Are the costs prohibitive to the NHS? To what extent does it increase the burden of costs on the NHS and society at large?
8. To what extent is cost effectiveness demonstrable
9. Are there good grounds for believing it would set a precedent for other patient groups lobbying for less cost effective treatments?
10. Will it avert danger to public health—eg, threat of an epidemic
11. Will people feel society's worth is diminished if it appears to be acting inhumanely by ignoring the Rule of Rescue?

At the end of their deliberations the Citizen's Council felt that the:

> Majority group were able to specify when NICE should apply the Rule of Rescue and define what these limits should be.

Box 1 reproduces the questions that the Citizen's Council considered central to the application of the Rule of Rescue in NICE's deliberations. The majority view was that NICE should take into account the Rule of Rescue, but only in "special circumstances". The report proposes a checklist of 11 questions, the answers to which, it is implied, will allow NICE's advisory bodies to assess whether there is case to be made under the broad heading of the Rule of Rescue. The report is to be commended for attempting to specify the conditions under which Rule of Rescue is to be applied. On close examination, however, this attempt suffers from three major shortcomings.

First, there is no clear guidance about how the answers to the 11 questions are to be used. Does the Rule of Rescue apply if the answer to just one of the 11 questions is "yes"? If so, it would apply to virtually all technologies assessed by NICE. If not, how many "yes" answers are required, and are some "yes" answers more important than others? Furthermore, does the Rule of Rescue always carry the same weight whenever it applies, or is it a matter of degree that carries more weight in certain cases (eg, when more of the answers are more emphatically "yes")?

Secondly, the checklist lacks coherence and focus. For example, question 5 (about alternative treatments) overlaps with questions 2 and 3 (about gains to life expectancy and quality of life), since NICE always evaluates gains incrementally, that is, in comparison with alternative treatments. And question 4 (about consequences should the treatment not be received) overlaps with question 1 (is the intervention required to avoid immediate loss of life). Worse, at least two of the questions bear no relationship to the Rule of Rescue concept of rescue from immediate peril as originally coined[1] or as subsequently elaborated in the literature.[22] Question 6 (about future medical gains) raises an important general set of issues about the value of research. Issues of potential gain from continuing research (or potential loss from ceasing research) arise in all resource allocation recommendations made by NICE, and are not restricted to special cases involving Rule of Rescue. It would seem unhelpful to deal with this important general issue in the context of a special case. Question 10 (about epidemics and other dangers to public health) raises another tangential issue. Issues of contagious disease, anti-microbial resistance and other "externalities" are best treated separately and explicitly, using appropriate modelling tools from epidemiology and economics, rather than muddled together with the Rule of Rescue. Finally, the report also considers the argument that it is sometimes not possible to demonstrate cost effectiveness for specific therapies because the evidence for effectiveness falls below some arbitrary quality threshold. This again raises a general set of issues—about standards of evidence and how to deal with a weak evidence base—which are at best tangential.

A third shortcoming is that many of the questions leave key parameters so vaguely defined that either a "yes" or a "no" answer could usually be justified, depending on the decision-maker's own subjective value judgement (or, indeed, on how far he/she is swayed by the lobbying of vested interests). The worst offender in this respect is perhaps question 2—what is a "good chance": 25%, 50%, 75%? And how large does the "increased life expectancy" have to be: 1 day, 1 month, 1 year? Other instances of vagueness include question 1 (how soon is "immediate"?), question 3 (how large is a "significant" improvement in quality of life?) and question 7 (how large is a "prohibitive" cost?).

The report notes that "at the beginning of the meeting, most of us tried to circumvent the law of opportunity cost".[5] In question 7, however, the Citizen's Council implicitly admit that the implementation of the Rule of Rescue cannot be done in denial of opportunity cost: the cost of doing so must be balanced against the value attached to it. This brings into sharp relief the fact that any implementation of the Rule of Rescue has to be explicit in defining the exceptional case—in particular, the explicit identification of "a good probability of increased life expectancy" and "significant improvement in quality of life". Until these definitions have been established, it will not be possible to assess the cost of implementing this Rule of Rescue or to assess whether society values its implementation more highly than its cost.

INDIVIDUAL MORAL IMPERATIVES AND PUBLIC POLICY MAKING—THE RELEVANCE OF "EXCEPTIONS"

The Citizen's Council report demonstrates the conflict between wanting to promote what is the instinctively right thing to do, but at the same time not wanting to lose sight of the opportunity costs of doing so. In this section, we consider whether the instinctive appeal of the Rule of Rescue reflects an appropriate moral foundation for public policy.

It might be argued that people have a self-evident "human right" to be rescued from peril by the state. However, it is not self-evident that the state violates a person's human rights by failing to pay for a benefit, in the same way that it might violate that person's human rights by (say) torturing them. Furthermore, a "human right" suggests an inviolable side-constraint on decision making, rather than a value to be weighed in the balance and traded off at the margin against other policy goals such as maximising population health.[6] Resource constraints are likely to prevent any Rule of Rescue from assuming the rigidly inviolable character of a human right, as it will never be possible to afford all technologically feasible medical rescues. Another, less demanding, possibility is that the state may have a *prima facie* duty to rescue its citizens from immediate peril—that is, a duty that is defeasible under certain circumstances.[7] The difficulty with this, of course, is how to specify the defeasibility criteria. One simple criterion would be cost-effectiveness—society has a duty to provide cost-effective rescues. Going beyond that, however, is problematic. Is it self-evident that society has a *prima facie* duty to provide non-cost-effective rescues? If so, under what circumstances is this duty defeasible? This suggestion thus raises more questions than it answers—it is in danger of becoming merely a re-statement of the problem rather than a principled justification for the rule of rescue that might provide guidance in determining its applicability to specific cases.

A more promising line of argument is that application of the Rule of Rescue by public policy makers can have "symbolic value". Some actions by the state may have indirect and/or long-term benefits in making citizens feel better about the society in which they live, in promoting trust and co-operation, or simply as "the mark of a civilised and humane society".[5] Unlike human rights, symbolic value can be weighed in the balance and traded off against other values.[24] This has the important practical implication that not all medical rescues are equally morally obligatory—and that, other things equal, cost-effective rescues are to be preferred to cost-ineffective rescues.

However, there are problems with this line of argument. First, it is hard to form even the vaguest guess about the magnitude of "symbolic value"—not only because effects are indirect and long-term but also because the same action may symbolise different things to different citizens. Second, there is a danger of costly and irrational "gesture politics" replacing rational decision making. Third, it is not clear there is any "symbolic value" in proactive policy decisions. We can distinguish two scenarios. First, where society is willing to accept diversions from the general cost-effectiveness norm by applying "exceptional circumstances" reactively on a case-by-case basis (eg, the rescue team going over budget to save the life of a trapped miner). A second scenario, closer to the NICE case, is where society specifies beforehand the particular types of incidents where the general cost-effectiveness norm is to be relaxed (eg, to invest in disproportionate levels of specialist safety provision in mines, but not in railway tunnels). A society that does not accommodate the former type of exception does indeed seem to be inhumane. However, it is not obvious that a society that accommodates the latter type of exception is necessarily humane: it is not clear why certain groups (eg, miners) should get special priority at the cost of everyone else (eg, train staff and passengers).

More fundamentally, the case against applying the Rule of Rescue to public decisions is that it is based on a natural human emotion that is irrelevant to public decision making and should be kept firmly in the private sphere. According to this view, the primary virtues of public decision making are impartiality and justice in balancing the interests of different population groups, rather than partiality and compassion towards particular identifiable individuals. The role of the public decision maker is to make impartial, dispassionate judgements about resource allocation between groups of unidentified people and their "statistical" lives.[25 26] Partiality and compassion towards particular identified individuals are inappropriate considerations that the public decision maker should not allow to interfere with his decision making, as it is arbitrary and unfair to discriminate in favour of people who happen to be identified and against those who have not yet been identified.

Classic examples of the Rule of Rescue talk about specific individuals, drowning in the water or entrapped in fire. In the medical context, this corresponds to the clinical, bedside level. The appropriate parallel in a medical context, therefore, is whether an individual or a team of medical staff who went beyond their usual call of duty to save a specific life should be praised for doing so. The appropriate parallel in a medical context is not whether or not NICE should put in place systematic provision for those cases where individual lives will be threatened. The remit of NICE does not cover individual cases: it is a body set up to make recommendations at the national policy level.

There is also a fundamental objection to any definition of the Rule of Rescue as an exceptional case involving imminent death. Human beings are mortal. Sooner or later, all lives will pass through the stage (however defined and operationalised) where death is "imminent". Some deaths are unexpected and quick (eg, traffic accidents) so that this window happens very suddenly and is so narrow that there is no scope for medical intervention. However, in a large number of cases, death is more or less predictable and before death will be a stage where the patient will be regarded as facing imminent death. It is problematic to regard falling within this window as constituting something "exceptional" and being worthy of special consideration; it is not something exceptional, but something we will all pass through in some form or other.

Having set aside those for whom no rescue is possible, and those for whom the state of imminent death arrives predictably at the end of a pathway of increasing and appropriately managed ill-health, we are left with a group of people for whom the transition to the state of immediate peril (whether fatal or non-fatal) was unexpected and for whom treatment, although not cost effective, is possible. This group is defined by what it is not, and implicit in that definition is the challenge of devising pro-active policy statements for them. Further, it is a group most likely to be concentrated in those who enter the healthcare system through the emergency department, which is designed and funded for the purpose of rescuing those whose ill-health is unexpected and potentially life threatening. The appropriate public policy expression of the moral imperative to rescue those who unexpectedly fall into immediate peril may well be the emergency healthcare services.

This raises interesting and important questions about how the Rule of Rescue might be applied in a practical and quantifiable manner to the context of the emergency services—for instance, to determine whether the emergency services are "under-funded". There are also equivalent questions about the applicability of the Rule of Rescue to other health contexts that currently lie outside the remit of NICE and equivalent health technology funding bodies around the world—such as prioritisation on waiting lists for organ transplant services and other "exotic lifesaving medical therapies".[27] These questions are beyond the scope the current paper, but are important topics for future research.

CONCLUSION

The Rule of Rescue is a description of a common and shared individual response to people in immediate peril. Because we all share this response, academics and policy makers have struggled to implement it in the context of healthcare policy. The central problem has been to operationalise the underlying concept and only two organisations have explicitly accepted the challenge. The Australian policy on Rule of Rescue in pharmaceutical coverage decisions is in fact almost completely divorced from the original concept of immediate peril, and focuses instead on a different set of issues surrounding the problem of orphan drugs. The NICE Citizen's Council report provides a useful rehearsal of the issues but in the final analysis their solution is so vaguely defined that it fails to provide clear operational guidance.[5]

The Rule of Rescue—the moral imperative to rescue identified individuals in immediate peril, regardless of cost—is distinct from the general issue of concern for the severely ill, which does not attach special importance either to the immediacy of illness or to the identifiability of the individual concerned. Unlike the Rule of Rescue, concern for the severely ill can be grounded in generalisable (if questionable) philosophical principles of justice and quantified in a form suitable for economic evaluation.[18 19]

Reflecting upon the possible moral foundations for the use of Rule of Rescue in public resource allocation by NICE type bodies, it is difficult to find a convincing argument for developing pro-active social policies on the foundation of individual moral responses to exceptional circumstances. The appropriate role for the public decision maker is to ensure impartiality and justice in balancing the interests of unidentified individuals belonging to different population groups. It is likely that public policy makers in a humane society should facilitate the exceptional departures from a cost effectiveness norm that will sometimes quite rightly be made by health professionals operating at the clinical, bedside level in making decisions about identified individuals. But it is not so obvious that they should, as a matter of public policy, exempt any one group of unidentified individuals within society from the rules of opportunity cost at the expense of all others.

Acknowledgements: The authors would like to thank K Claxton and E Nord for helpful comments.

Funding: CMcC was partially funded by the National Institute for Health and Clinical Excellence between 2002 and 2006. RC is funded by MRC Health Services Research Special Training Fellowship G106/1145.

Competing interests: RC was a member of the NICE Appraisal Committee 2002–2007.

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