

## It's money that matters: the financial context of ethical decision-making in modern biomedicine

Article (Unspecified)

Hedgecoe, A. M. (2006) It's money that matters: the financial context of ethical decision-making in modern biomedicine. *Sociology of Health and Illness*, 28 (6). pp. 768-784. ISSN 0141-9889

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## **It's money that matters: the financial context of ethical decision-making in modern biomedicine.**

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**Article for** 'The view from here: Bioethics and the social sciences', *S of H&I* monograph.

### **1. Introduction:**

The issue of autonomy has long been a site of tension between bioethics and the social sciences. A wealth of studies suggest that informed consent, so vital to respect patients' and research participants' autonomy, is extremely hard to obtain in a meaningful sense (Gray, 1975; Lidz, Meisel, Osterweis, Holden, Marx, and Munetz, 1983; Fox and Sawzey, 1984; Harth and Thong, 1995; Corrigan, 2003). Yet the chronological and topical range of these studies has done little to persuade bioethicists to alter the central role autonomy plays in modern western ethical thinking. For sociological sceptics about bioethics, one question raised by this data is, Does autonomy, in fact, exist? Or is it a construct created by philosophically oriented bioethicists and used by researchers and clinicians to get their work done?

Yet while bioethics has traditionally, and correctly, focused on patient autonomy and the protection of the vulnerable, an equally important but less studied topic involves the autonomy of doctors and their freedom to make clinical decisions. Traditionally bioethics conceptualises the clinical encounter in terms of *clinical* autonomy, "the classical fiduciary ideal" that "Physicians should do whatever is in the best interests of their *individual* patient" (Khushf 1999, p.43). Such autonomy depends upon "the discretionary space normally afforded professionals" since "the nature of professional judgement and making right and good decisions requires a degree of responsible freedom in clinical matters" (Pellegrino and Thomasma 1981, p.xii). Through a case study of the breast cancer drug Herceptin, this article proposes that economic pressures in modern healthcare mean that this 'discretionary space', so vital for clinical autonomy, has ceased to exist. As a consequence, the current bioethics model of clinical decision making is out of step with social reality.

In many ways, this model has much in common with what we might term 'prescriptive' approaches to medical decision making which explain "how medicine ought to be practiced" (McKinlay, Potter and Feldman, 1996, p.769) as opposed to the 'descriptive' approach which "highlights the influence [on clinical decisions] of a range of social factors that are logically unrelated to the etiology or course of illness" (ibid). Both bioethics and the prescriptive approach tend to assume:

"that physicians are autonomous decision makers practicing in socially insular clinical settings...[But in reality]...Clinical decision making invariably takes place in a social relationship that is penetrated and shaped by patients' age, gender, socio-economic status, and race, physicians' professional training and clinical experience, and bureaucratic features of the organized settings of clinical transactions" (Clark, Potter and McKinlay, 1991, p.861)

The 'bureaucratic features of the organized setting of the clinical transaction' that I focus on in this article are rationing decisions about a drug called Herceptin. Thus I am less interested in rationing in the sense of the social and political reasons underlying exactly which patients are allowed specific treatments, and more focused

on the impact particular rationing decisions have on clinician decision making. More specifically, I am interested in the way in which rationing impacts on clinical autonomy by following a particular rationing decision, made at a national level, and showing how it impacts on clinical decision making in breast oncology in the UK. Thus I use rationing as a tool to explore the problems and limits of current bioethical thinking about medical decision making.

My intent here is not to weigh in on traditional bioethical debates over the rights and wrongs of rationing healthcare and the particular mechanisms by which this should be done (e.g. Daniels, Light, and Caplan, 1996; Harris, 1987; Rawles, 1989; Mooney, 1989; Singer, McKie, Kuhse and Richardson, 1995). These discussions tend to be 'top down', in that there is little bioethical discussion of *how* rationing decisions get implemented and their effect on how clinicians treat patients. The assumption seems to be that either a particular treatment is funded or it is not. As Samia Hurst and colleagues, among the few bioethicists to address these issues, note in their recent survey of this area, "Two commonly held assumptions seem to be...: first, physicians are making these decisions on their own, and second, the decisions to ration are simple dichotomous choices" (Hurst, Chandros Hull, DuVal, and Danis, 2005, p.643). As they go on to note, "physicians' experiences in situations of resource constraints appear to be more complex than the normative literature assumes" (ibid, p.644).

My point is not that there is no discussion of the effect of rationing on clinical autonomy in the literature, but rather that it occurs almost exclusively among medics, and in medical journals, and is largely missing from bioethics debates.<sup>1</sup> Thus despite ethical discussion of 'just' health care and the roles of rationing and economics, there is a blind spot in bioethical discussion in this area, a failure to note, in Lindsay Prior's elegant phrase, that "Rationing principles...are woven like a fine thread through the broad tapestry of [clinical] action" (Prior, 2001, p.571). In this case Prior is referring to the oncological genetics unit, yet as the remainder of this article shows, the 'fine thread' of rationing also binds the hands of clinicians dealing with more conventional breast cancers, and in turn raises questions about the bioethical model of medical decision making.<sup>2</sup>

## **2. A case study in clinical rationing: Herceptin**

Trastuzumab is a monoclonal antibody marketed under the brand name Herceptin developed for the treatment of the around 30% of breast cancers that produce too much of a particular protein, HER2. Before a woman receives Herceptin, a series of diagnostic tests are run on her tumour tissue, one of which is to determine the levels of HER2. Because too much HER2 protein ('over-expression') is deemed to be the result of a genetic fault in the tumour tissue, many commentators present Herceptin as one of the first widespread examples of 'pharmacogenetics', the use of genetics to help develop and prescribe drugs. The research presented below was carried out as part of a Wellcome Trust funded study of the clinical development of pharmacogenetics (Hedgecoe, 2004). But since the focus of this paper is the relationship between clinical decision-making around Herceptin and rationing, the novel, pharmacogenetic aspects of this drug will remain in the background, except when they are directly relevant to these narrower concerns.

My case study is based on qualitative semi-structured interviews carried out between January 2002 and July 2003 with 25 UK-based breast cancer specialists (2 Clinicians,

20 Clinician Researchers, 1 Researcher, and 2 Oncological Pharmacists. Self-selected categories), identified through publications in this area, lists of those involved in clinical trials, and snowball sampling. In addition, interviews were carried out with 2 policy makers at a local healthcare level, one representative of NICE (the central body that approves drugs for the NHS), one representative from Roche (the company that markets Herceptin in Europe), and two people from breast cancer charities.<sup>3</sup>

A second round of interviews were carried out in Spring 2005 as part of a European Commission funded project comparing, among other things, Herceptin use in different EU member states. These interviews covered 6 clinician researchers (three oncologists and three histopathologists) and a re-interview with one of the previously interviewed oncological pharmacists. These interviewees were chosen to complement the first round of interviews and update information on clinical practice, economic issues and testing issues.

***The Institutional Context:*** Although Herceptin was approved for use in the UK in 2000, this did not guarantee that the drug would be made available on the National Health Service (NHS). One of New Labour's first decisions upon coming to power in May 1997 was the creation of NICE, the National Institute for Clinical Excellence, which opened in April 1999.<sup>4</sup> NICE issues guidance on new and established technologies and interventions, and whether they should be funded by the NHS. (Birch and Gafni, 2002). NICE is a 'fourth hurdle' to drug regulation; after the traditional three hurdles of safety, efficacy and quality of manufacture comes the fourth hurdle of clinical and cost effectiveness (Paul and Trueman, 2001).

The exact mechanism by which NICE reaches its decisions is largely irrelevant to the concerns of this paper, as are the details of the controversy that surrounded the NICE guidance on Herceptin (see Hedgecoe, 2004, p.131-139). The main point of interest is that the NICE approval took an unexpectedly long time. Although the NICE appraisal process for Herceptin began in September 2000, when the drug got its EU license, the Institute's guidance was not published until March 2002. This 18-month delay, perhaps half as long again as most other NICE decision, meant that while it was legal to prescribe Herceptin in the UK, there was no obligation on the part of NHS healthcare providers such as Primary Care Trusts (PCTs), which oversee primary care services in a given area and can commission services from NHS acute trusts (Hospitals), to actually pay for the drug, or for the testing. A partial solution to this latter problem was provided by the company Roche which, through three 'reference centres' funded HER2 testing in the UK between October 1999 and March 2003: any clinician who wanted to could send a tissue sample to one of the three labs and Roche would cover the cost of the testing.

***"As good as I possibly can be": clinical decision making before the NICE decision:*** This still left the issue of how to fund Herceptin, with the essential clinical decision being, is Herceptin even an option? Obviously, this is only a problem for patients seeking treatment on the NHS. As one of my interviewees put it, "Here it's a funding issue; if patients are privately covered, insured they receive it" (CR3). But for the NHS, prior to the publication of NICE's appraisal of Herceptin, whether a clinician could prescribe the drug depended on local factors determined by their hospital or health authority. As one of my interviewees put it:

a number of my colleagues in other major centres around the country who have been using Herceptin for maybe a year prior to NICE Guidance... somehow they persuaded their purchasers to pay for it... and that has not happened in [city name]. I would estimate that probably about 50% of the country are like us and unable to fund it - prior to NICE Guidance (CR16).

This figure of around 50% coverage was supported by other interviewees, and thus raises the issue of why some healthcare providers decided to fund Herceptin and some did not. Clinician Researcher 13, who *was* allowed to prescribe Herceptin at this time suggested that it was, in part, on the basis of a scientific case made by clinicians:

Based on the evidence, we sped ahead of NICE and thought we can't deny our patients this and it was very strict in terms of the evidence, we used it well before. But that's the post code prescribing - we happened to be able to do it, eeked money out of our health authority.<sup>5</sup>

Yet even this decision was partly based on idiosyncratic, local factors, since the hospital concerned "had a very forward thinking clinical director who recognised that this was a drug that was going to be approved and we shouldn't get into these situations and having some patients catch up" (CR13).

But beyond individual hospitals, clinicians attempted to allow some Herceptin use at a regional level, often running into structural problems within the NHS. For example, one interviewee described the attempt by:

our own network...[where]...we have a new drug group...[which]...came down using the same format as NICE effectively but we came down and decided that we felt it was justified to use Herceptin for a limited number of people... and what's happened is that within our own cancer network, patients who lived within [one] Health Authority can get it, the ones in [a neighbouring Health authority] can't. So we've got postcode prescribing within our own network. (CR2).

The exact mechanism by which the cancer network managed to get some Herceptin funded revolved around certain clinicians having greater expertise than others, manifesting itself in the form of a 'named prescriber' system, where only a limited number of clinicians were regarded as 'expert' enough to indicate HER2 testing and prescribe Herceptin. The need for this was highlighted by Clinician Researcher 6, who talked about running a clinic in another location, where "there's somebody else up there who's.... been sending people he thought were HER2 positive, sending samples for testing". Such decisions would be based on severity of the disease, age of the patient and various other features of the cancer that would lead one to think that the tumour was HER2 overexpressing. But in this case, of the samples sent to the lab, "he's had about a 15% hit rate which goes to show that actually the prediction of who is positive and who is not positive is not that good on the basis of other histological features" (CR6). The implication is that working out which patients' samples to send for HER2 testing is a skilled job, not to be undertaken by just any oncologist.

Although Roche was underwriting testing costs in the UK when this policy got off the ground, Herceptin was funded by individual healthcare providers.<sup>6</sup> Therefore: "Within the network, we've actually said that the only two people who should instigate prescribing are [CR2] and [CR6]. So, we're actually trying to control the initiation of Herceptin so that we make sure that people are actually FISH 3 positive [i.e. clearly

over-expressing HER2], have been properly tested, have been through the other options” (Pharmacist 1). The clear aim of this named prescriber system is to ensure that Herceptin is “not being prescribed willy-nilly” (Policy 2). Set up as a means of responsibly using the limited budget provided for Herceptin use prior to the NICE guidance, this sort of mechanism underlines clinicians’ practical response to rationing decisions. As Hurst, and colleagues note in their recent work, such decisions are not made by individual clinicians, nor are they dichotomous ‘fund’ or ‘do not fund’ decision. But rather it is about trying to provide care to as many patients as possible, given the financial restrictions imposed from above, and the consequent impact on clinical autonomy.

The point about these attempts by individual Trusts and cancer networks to pre-empt NICE’s decision is, of course, that the decision makers at NICE were not the only people with access to data on Herceptin and its cost. Oncologists were just as capable of reading the clinical reports and drawing their own conclusions, yet their expertise in oncology was often of little importance in a situation where decisions about prescribing practice were being made at a level higher than that of the individual doctor. While some clinicians managed, through various mechanisms, to prescribe Herceptin, others couldn’t, with a consequent impact on their clinical autonomy. As one oncologist said: “I’m being seen to be as good as I possibly can be by our Trust people, by not using drugs in advance of NICE approval when they’re expensive drugs but I know that I’m flying in the face of the increasing body of evidence because I can read the papers just as well as NICE can” (CR8).

***“A much stickier wicket legally”:* clinical decision making after the NICE decision**

When the NICE guidance was published in March 2002, the guidance document was presented to a professional community frustrated by the patchy availability of Herceptin over the previous 18 months, and showing signs of considerable antipathy towards NICE due to its perceived lack of expertise and susceptibility to political pressure. The NICE guidance document states that Herceptin is recommended as an option to treat women whose tumours express high levels of the HER2 protein measured by a test called Immunohistochemistry (IHC). It should be used in combination with a chemotherapy (paclitaxel) in patients who have not received chemotherapy for their metastatic breast cancer or on its own, in women who have received at least two courses of chemotherapy, without effect (National Institute for Clinical Excellence, 2002). A number of features of this guidance are open to question, including the reliance on IHC testing rather than the more advanced FISH test and the tight restrictions on who should get Herceptin as a monotherapy. Yet in terms of clinical decisions, none of this matters, since once NICE issues its guidance on a particular piece of technology, healthcare providers in the UK are legally obliged to make that treatment available, whatever the feelings of individual clinicians might be. One effect of such a requirement is to erode clinical autonomy:

if NICE say it’s okay, we’ve got to give it even though we actually would rather spend a bit more money on the dialysis machines than not be restricted ourselves because the patient can say: ‘Look, if NICE says that I can have Herceptin, why aren’t you giving it to me?’ *There may be reasonable clinical judgement against it [i.e. prescribing Herceptin] but you’re in a much stickier wicket legally as a doctor to then deny the patient Herceptin.* (CR7; emphasis added)

And the NICE rules do not just require clinicians to prescribe Herceptin to women who, in clinical terms, might not be good candidates, they also force delays on the use of Herceptin on women who are suitable. One interviewee suggested that the health care providers were “being advised by people who are reading the NICE Guidance to the letter of the law...[i.e. that]... you cannot give Herceptin until post three lines of metastatic chemotherapy which, from a clinical point of view, doesn’t make sense” (CR16). For this clinician, the NICE rules make no sense since Herceptin would presumably also be of benefit to these women at an earlier stage in their treatment.

Another example of the restrictions the NICE guidance puts on the autonomy of clinical decision-making mentioned by this interviewee is the way in which managers require the strictest definition of HER2 over-expression before allowing the prescription of Herceptin. The NICE guidance requires only that patients who score highly (3+) on IHC testing should necessarily be treated, although research has shown that some people who score lower (2+) may benefit from Herceptin and that further (FISH) testing can identify them. But a strict reading of the NICE guidance excludes this group of patients, and allows these guidelines to serve as a means of controlling clinical decision-making regarding this drug. This means that, whatever an individual’s clinical opinion may be, they may not be able to exercise it when prescribing Herceptin.

It should not come as a surprise to find that even within the tight constraints placed on practice by NICE guidance clinicians attempt, on a number levels to exercise some kind of control over clinical decision making. Yet what is clear is that the kinds of clinical decisions that are made are phrased in terms of further rationing. Clinician-researcher 16 notes that:

all of us have been very conscious about the resource issue...we’re still at the point of requesting the test individually when the number of all-risk features make us feel that we would want to offer the patient either the HERA Trial<sup>7</sup> or the drug in the metastatic setting.... So we have looked at ways ...of not introducing HER-2 as an across-the-board test, but rationing it...and I would definitely use age, myself, as a rationing tool...and I don’t have a big problem in saying that the 75-year old with 20 Node positive, ER negative, grade three disease, needs anything, except lots of alcohol and morphine. I don’t have a problem with that....

Although this kind of decision is phrased in terms of ‘clinical judgement’, it is, explicitly, a rationing decision, a choice focused on the costs incurred rather than the clinical outcome for a specific patient. This becomes clearer when one thinks about Herceptin’s very usefulness as a treatment, its low toxicity and limited side effects, which can make choices harder than they might be with a ‘conventional’ chemotherapy: ‘the major issue with them is going to be cost, and I think that unlike conventional chemotherapy where you get a lot of side effects from the treatment, then it can limit their use by the toxicity and here you cannot use that. And the spectrum of ages you can use it in is wide’ (CR3). Thus when thinking about the possibility of Herceptin in the case of the hypothetical 75-year old woman, the clinician cannot ‘ration by toxicity’ as they might with a conventional chemotherapy. A decision not to treat becomes explicitly about ‘rationing’. In the context of broader discussions this is clearly an example of ‘bedside rationing’ (Hall 1994), the “withholding by a physician of a medically beneficial service because of that service’s cost to someone other than the patient” (Ubel and Goold 1997: 74). In the context of

US healthcare, such behaviour on the part of clinicians generates much discussion, upto and including debates about the Supreme Court's view of its legality (Blochce and Jacobson 2000). In the UK however, as discussed below, within the context of a socialised system of medicine such as the NHS, doctors have always been aware of the wider financial impact of their choices.

Moreover, the grounds on which these oncologists made these decisions, age, are not exceptional. Social scientists have explored clinical rationing on the basis of age in a number of other conditions such as end stage renal dialysis (Varekamp, Krol and Danse, 1998) and Myocardial Infarction (Elder and Fox, 1992). So ubiquitous are clinical rationing decisions based on age, that it is described as 'the factor most often invoked to deny treatment. It provides an automatic pilot for doctors, so simplifying the perplexities and avoiding the agonies, of choosing between different lives' (Klein, Day and Redmayne, 1996, p.87)

When age is not an option, other solutions present themselves. The following case illustrates the way access to testing is used as a means of restricting access to the drug:

One case that had prolonged discussion associated with it was this particular girl, 30 years old, who was severely mentally impaired, with a huge breast tumour which had obviously been ignored because she didn't talk about breast lumps having a mental age of five, as she did, and she turned up with anaemia and the bone marrow showed almost complete replacement with tumour cells. We couldn't give her a cytotoxic; the question is, is it the appropriate use of Herceptin to treat her, and we said if it is an appropriate use, then test her. If it's not an appropriate use, then we won't test her, or test the tumour. That's the one real debate we've had (CR8).

As suggested above, the decision is phrased as being about rationing. The context for the interviewee introducing this case was the suggestion that: "I think our Trust takes a positive approach to funding issues saying things that are approved by NICE must be funded *but there has to be proper case selection*" (CR8; emphasis added). Thus the decision whether to treat the 30 year-old mentally impaired patient is not to do with the safety of the treatment concerned<sup>8</sup> but whether this is an appropriate use of resources. The second point to notice is that the discussion here is not over whether to prescribe Herceptin or not, but whether to test this patient's tumour for HER2 status. While the reason for this might be to do with the cost of HER2 testing, IHC is not expensive and can be carried out at almost any pathology lab. A more likely explanation is that NICE rules specifically require health providers to prescribe Herceptin to those women whose tumours overexpress HER2; but if a HER2 test is not run on a patient's tumour, then no obligation is incurred by the healthcare provider.

This sort of situation was described in an early (pre-NICE decision) interview by Clinician Researcher 1 who faced:

"An interesting dilemma here...although the Trust has given us funding for the drug, they haven't given us any funding for the HER-2 testing so they don't seem to have taken a global view of this and so we're struggling at the moment to try and get some funding for our pathology department to go on to do the HER-2 testing"



This situation was presented as an example of bureaucratic mismanagement, with the healthcare provider willing to pay for the expensive drug, but not for the (comparatively) cheap testing. This may be too generous an interpretation. Given that restricting access to HER testing has become the main way healthcare providers avoid the NICE requirement to provide Herceptin to women who over-express HER2, this looks like an early indication for how things have developed. Controlling access to HER2 testing serves as a way of rationing the total number of patients who might be eligible for Herceptin. Surveys carried out by breast cancer charities (Breast Cancer Care, 2004) and follow up interviews with other clinicians conducted 18 months later suggest that the restriction of HER2-testing as a form of rationing has become more widespread and seems to have become informal policy for a number of healthcare providers in the UK, reinforcing the idea that clinical autonomy is constrained by rationing systems.

The NICE guidance impacts on clinical autonomy in two ways. First, and most obviously, it clearly restricts the kinds of decisions open to clinicians, the patients they can and cannot treat. Second, when clinicians do exercise their autonomy, the ‘discretionary space’ within which they make their decisions is structured in terms of further rationing, rather than other clinical features.

**“Our inability, as doctors, to give the therapy that we believe is right”:** It is commonly assumed that there is a tension for clinicians in modern health care systems, between their duty to do the best for an individual patient, and a broader concern towards society, as articulated in terms of cost containment. Yet for many of my interviewees, this dilemma was not an issue. As some economists have noted (e.g. Weinstein 2001), a central problem for the individual clinician weighing up the ethical aspects of rationing healthcare is that, for all their expertise, they lack the kind of bird’s-eye-view required to assess the consequences of their decisions. As one interviewee suggested:

If the money is [from] a new source of money you take it and you give that treatment. But if someone said to you, ‘oh you can have this treatment but you can’t have your radiotherapy machines’, obviously you wouldn’t do that. But there is no central way of actually seeing that if you were to get this extra money, that if somebody else is going to lose are you robbing Peter to pay Paul. The budget which these things come from are so vast, and so inaccessible to us, we don’t know where they will have come from (CR3).

To some extent, oncologists’ views about budget limits, which tend to be sceptical, are shaped by their experience with a series of expensive drugs; “in the beginning when we started using Taxol it was extremely expensive, carboplatin was extremely expensive, it’s less expensive now but it’s still kind of expensive. These drugs will continue to be expensive” (CR11). Yet these drugs are still used. When it comes to the family of drugs known as taxanes (of which Taxol is one), “we spend hundreds of thousands now on taxanes which 5 years ago we couldn’t spend because we were told the money doesn’t exist for that. And were told, if you have the money for taxanes somebody has to do without...I mean have some beds been closed because of that? I don’t know” (CR3).

Thus, in the case of Herceptin at least, clinicians do not face an ethical dilemma since a dilemma implies choice: two or more possible courses of action. Yet, partly because

of their experience of using expensive drugs, and partly because their actions are so financially restricted anyway, these clinicians are not ethically troubled by the need to constrain costs for the sake of wider society. Rather rationing serves as part of the structure, a 'fine thread' in the tapestry of clinical decision making. This limits ethical debates in Herceptin use to issues around informed consent and whether patients are told about HER2 testing prior to it taking place (Hedgecoe, 2005).

But more than this, such rationing is in keeping with the broader culture within the UK's NHS, which acknowledges that "decisions to treat one patient...may mean that others are denied care" - even if one is not in a position to know if this is the case or not (Newdick 1995:21). While the origins of such beliefs may lie partly in economics, they also have strong cultural foundations, based on the postwar origins of the NHS, and its link to the welfare state. DeVries is correct to say that medical sociologists need to pay greater attention to broader cultural themes if they are to provide a full explanation for why healthcare practices and system differ between states. He convincingly shows how the Dutch preference for midwife-led home births has its roots in Dutch cultural features including the role of women in the family and home, thriftiness, solidarity and Dutch dislike of heroics (DeVries 2004). We might speculate about US clinicians resistance to rationing by reference to the primacy of the individual in US public life, a feature of American culture than has been the subject of discussion since at least Alexis de Torqueville.

In the case of the UK, understanding the cultural roots of NHS rationing is necessarily reflexive, given the iconic role the NHS plays in British public life. It is hard to overestimate the cultural impact of this "anomaly, not to say...anachronism" whose "overall architecture and method of funding have remained largely unchanged in a rapidly changing society", an institution whose popularity derives from its anomalous status, its position as "an exercise in institutionalised nostalgia" symbolising "a simpler warmer world of camaraderie, solidarity and national success" (Klein 2001: vii). How we in the UK view healthcare rationing has its cultural roots in wartime Britain, where rationing of food and clothes "became a symbol of social solidarity and of shared commitment to a national enterprise" and where the "black market was synonymous with spivvery" (Klein, Day and Redman 1996: 7-8). But this not to say rationing is always acceptable. Its acceptability "seems to depend on its perceived reasonableness, which, in turn, appears to depend on the form it takes" (Klein, Day and Redman 1996: 8). Thus clinicians' willingness to ration Herceptin use beyond the restrictions placed by NICE, depends on the (culturally mediated) view of what counts as reasonable grounds.

Of course, at the broadest level, clinicians' tales about the use of this new drug should alert us to a very simple state of affairs: if a hospital or healthcare funder does not allow the prescription of Herceptin, then the ethical issues surrounding clinical-decision making about this drug are rather limited. And this is in keeping with the binary model of rationing that bioethics uses when it considers the effects of economics on healthcare provision: either a treatment gets funded or it does not (Harris, 2005).

My research has exposed the inadequacy of thinking simply in such dichotomous terms. But even when bioethics engages with these issues in a more complex way, something is missing. This is highlighted by the Nuffield Council on Bioethics' report

on the ethical issues involved in the clinical use of pharmacogenetics, which provides one of the few discussions of Herceptin and rationing available. They admit that “bodies such as NICE may provide guidance about the circumstances in which medicines may be provided...as in the case of Herceptin”. But they imply that “Although not formally binding on health professionals...physicians may feel obligated to restrict prescription to those individuals who...meet the necessary criteria...and indeed, health providers may impose such requirements” (Nuffield Council on Bioethics, 2003, p.66). This picture is not wrong so much as incomplete. There is no *legal* requirement for clinicians to only prescribe in accordance with NICE; they could offer the drug ‘off label’ to women at an earlier stage of breast cancer.<sup>9</sup> It is just that for most clinicians that sort of autonomy in their clinical decision making is simply not available; ‘may feel obligated’ and ‘may impose such requirements’ do not do justice to the relationship between clinicians and the restrictions imposed on their autonomy by health care providers.

When we think about autonomy, we usually think about the choices patients have to make, the information provided to them, and their ability to make a free, informed decision. But of equal importance, though of far less prominence in the literature, is clinicians’ autonomy, the freedom of doctors to choose the best treatment for the patient. Yet it is clear that in the case of Herceptin in this particular health system that such autonomy is in short supply. As Clinician Researcher 16 put it: “It’s very difficult, I think, if we work within a system that has an enormous amount of regulation and an enormous amount of rationing, and there’s no getting away from our inability, as doctors, to give the therapy that we believe is right”.

**Conclusion: Towards an ethics of decision making at the margins.**

In the light of the Herceptin story it is worth thinking about whether bioethicists are asking the wrong questions, or asking the right questions wrongly? If they are asking the wrong questions then by focusing on autonomy bioethicists are relying upon a concept so sociologically complex that the solution is to abandon autonomy as a useful way of thinking about clinical decisions. The problem with such a point of view is that it does not offer an alternative, a way forward for discussing the clinical encounter. ‘Bioethics knocking’ is great sport for social scientists, yet perhaps the time has come to offer more constructive criticism. If we suggest that the problem with bioethics is that it asks the right question wrongly, we may be able to see a way to proceed: if we don’t just throw out autonomy, but use sociology to appreciate what it means and how it really functions, we do have a way forward. Because at the same time as this story undermines the myth of clinician autonomy, and hence the bioethical model of medical decision making, it also suggests productive areas for bioethical inquiry. These are at the margins of clinical practice, and centre on the ways in which clinicians try to ‘get round’ the restrictions imposed on them. While there is some discussion of the legal issues surrounding such practices in US medicine (for example, underbilling in the case of uninsured patients; Weiner, 2001), the range of clinicians’ ingenuity and the ethical aspects of the strategies remain underexplored.

Two examples from the case of Herceptin may prove useful. In the first case, in one of the follow up interviews conducted in early 2005, one clinician, claimed that because his local healthcare provider would not supply Herceptin while NICE was deliberating: “We had to go through the process where one of my patients had to go to the media and eventually the health authority did give us the money to give people

Herceptin. After a lot of publicity...This is the normal route in view of the way NICE behaves, and I think we can expect more of that in the future". This prediction has proved accurate, with recent controversy over the NHS's willingness to pay for Herceptin to treat early stage breast cancer (Meikle, 2005).<sup>10</sup> Supporting or even organising these sorts of actions allows clinicians to exercise their autonomy in order to get individual patients the best possible treatment. But clearly there are ethical elements to such 'guerilla' healthcare that need to be thought through. What are a clinician's duties regarding his or her employer, and how do these relate to their responsibility towards patients. Do clinicians have a moral obligation to wage these sorts of campaigns, or are they beyond what we can reasonably expect? Social scientists in turn might seek to show how these issues fit within the broader culture of the NHS, which traditionally has steered away from the kind of Hippocratic individualism that characterises the US healthcare system (Zussman 1997)

The second example is the interviewee who told me that because "With the new drugs, it's a lot harder [to get access]. My approach is to put patients into clinical trials wherever possible" (CR8). The point is that the control arm in such trials are not given placebos but often receive a standard of treatment which exceeds that normally agreed by the health care provider, perhaps because the drugs concerned have not yet received NICE approval. By entering patients into trial, this clinician is ensuring that they receive the best drugs available, thus circumventing financial restrictions on their clinical use. Obviously a number of interesting ethical issues are raised by this practice including what counts as research and what counts as treatment, whether this behaviour counts as deception (and if so, is this wrong?), and whether there are obligations on clinicians to seek out and use such tactics to ensure their patients get best treatment.

I stated at the beginning that this article is not about rationing but rather about what rationing tells us about the limits of the bioethical model of clinical decision making. This model which requires a 'discretionary space' for the clinician to act in a patient's best interest is undermined by the way rationing decisions permeate the clinic, and restrict clinicians' autonomy. At the same time this case provides an opportunity for bioethics to explore the margins of clinical decision making, where there is space for autonomy. It is beyond the remit of a single case study to prove whether this is an isolated case or indicative of modern medicine as whole, but should clinical autonomy be restricted by rationing on a wider basis, then the challenges presented to bioethics and the way it tackles clinical decisions need a vigorous and comprehensive response.

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<sup>1</sup> For example while Povar and Moreno's 1988 article 'Hippocrates and the Health Maintenance Organization' is a classic contribution to debates in this area, it is largely ignored by bioethicists. It has been cited 51 times in the ISI database, only three of which are published in bioethics journals (based on a list of top 9 bioethics journal by impact factor) and the large majority of the remaining 48 articles were not written by bioethicists (based on affiliation). The assumption, that ethical discussions among medics, in medical journals, are not the same thing as 'bioethics', cannot be defended in full here (see Cooter 2000). It rests upon a view of bioethics as a very specific ideology rooted in time and place, rejecting the potentially anachronistic position that counts all medical ethical debates as 'bioethics'.

<sup>2</sup> For an excellent introduction to the emerging sociology of rationing, see Light and Hughes, 2001.

<sup>3</sup> In the UK there are a number of breast cancer charities (which in the US might be term activist groups), non-governmental organisations largely supported by public donations which provide support and information for women with breast cancer. They also, to varying degrees, combine these roles with political lobbying and the funding of scientific research.

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<sup>4</sup> In April 2005 NICE joined with the Health Development Agency to become the new National Institute for Health and Clinical Excellence, also called NICE.

<sup>5</sup> 'Post-code rationing' is the controversial situation whereby different regions have access to different medical services and treatments. The idea that people in another part of the country, or even in the next street, could get access to drugs denied you by your local health provider 'offended against the equity principle' at the core of the NHS (Klein, 2001, p.200-201). One of the apparent aims in setting up NICE was to reduce this kind of variability.

<sup>6</sup> I deliberately use this vague, broad term because of the complex nature of healthcare funding in the UK. Depending on the situation, the organisation responsible for funding Herceptin in any one case might be a Strategic Health Authority (responsible for strategic planning within regions), a Primary Care Trust (PCT, which provides primary care services in local areas), a Hospital trust (which are commissioned by PCTs to provide acute services - such as oncology) or a cancer network (Kewell, Hawkins and Ferlie, 2002), 34 of which were set up in 2001 to provide cancer services in England (James, 2002).

<sup>7</sup> The HERA trial is testing Herceptin's suitability in the adjuvant (post-operative) setting, and thus makes the drug available to women far earlier than the metastatic stage. Since the trial is industry funded, patients entered into it do not cost healthcare providers money.

<sup>8</sup> Most professionals regard Herceptin as far less toxic than standard chemotherapies.

<sup>9</sup> From my follow-up interviews it is clear that a small number of clinicians have convinced healthcare providers to fund this.

<sup>10</sup> The research for this paper was carried out before the recent controversy over access to Herceptin for pre-metastatic patients blew up.

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