



# Non-professionals' evaluations of gene therapy ethics

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## Abstract

Although the moral responsibilities of clinicians and researchers in the new genetics are exhaustively reflected upon, much less attention has been paid to the factors affecting the moral reasoning of non-professionals when they reflect on genetic issues. In this paper, we compare the moral evaluations of somatic gene therapy (SGT) made by some of its potential consumers (patients) and its providers (medical professionals). The results highlight significant differences between professional opinion and non-professional evaluations. Medical professionals shared a moral evaluation of SGT that (a) based its acceptability on a strong therapeutic imperative, (b) grounded this in an unproblematic separation of identity and disability/illness, and (c) generally did not see SGT as ethically different from other medical interventions. Prospective patients (a) often questioned the effectiveness of “therapeutic” interventions, (b) could derive a strong sense of identity from disability/illness, and (c) sometimes saw genetic interventions as changing a person's identity, either directly (through the genes) or indirectly (through altered life experience). We discuss the implications of these differences for the professional and public debate on the ethics of gene therapy. Our results highlight the need to take into account non-professionals' views of SGT.

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## Introduction

Many recent developments in the new genetics have raised ethical dilemmas that have been extensively discussed by medical professionals and ethicists. However, although the moral responsibilities of clinicians and researchers in contemporary biomedicine are reflected upon exhaustively, much less attention has been paid to the moral responsibilities and vulnerabilities of potential patients. In recent years bioethics has shown increasing interest in the potential of empirical studies to complement its analytic, normative work (e.g. Haimes, 2002; Bosk, 1999; Christakis, 1999; Kleinman, 1999; Gallagher, 1998; Hoffmaster, 1992; Marshall, 1992; Jennings, 1990; Lieban, 1990), but most of the relevant sociological data has been primarily concerned with lay understanding of genetics (e.g. Henderson &

Maguire, 2000; Kerr, Cunningham-Burley & Amos, 1998; Richards, 1996; Richards & Ponder, 1996) or with surveying lay attitudes towards specific issues in genetic ethics (e.g. Macer, 1992; Macer et al., 1995; Michie, McDonald, & Marteau, 1996; Holm & Jayson, 2001). Relatively little attention has been paid to examining the factors affecting the moral reasoning of non-professionals when they reflect on genetic issues.

Somatic gene therapy (SGT) involves introducing an exogenous gene sequence into an organism, to act as a substitute for an endogenous gene that produces inadequate or aberrant protein (see Walters & Palmer, 1997, chap. 2). SGT currently lies in the uncertain grey area between novel research topic and therapeutic reality. Clinical trials began in the early 1990s, and attempts to provide SGT for a number of conditions—notably cancer, acquired immune deficiency syndrome and inherited diseases—are underway. The clinical efficacy and safety of SGT, however, remain disputed (Stephenson, 2000), and no form of SGT is yet in routine use. In the years of professional discussion of

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human genetic manipulation, an ethical consensus has evolved (Abramowicz, 2001; Leclerc, 2001; Fletcher, 1990). This views SGT as an extension of conventional medical interventions, and identifies the predominant ethical issues associated with SGT as: (i) the anticipated risk/benefit balance, (ii) the selection of appropriate patients, (iii) the provision of information to patients so that informed consent can be given, (iv) the preservation of patient confidentiality, and (v) the cost to the healthcare system (see Reiss, 2001; Scully & Rehmann-Sutter, 2001; Graumann, 2000; Rehmann-Sutter, 1999; Walters & Palmer, 1997; Juengst & Walters, 1995; Clothier, 1992).

In this paper, we report on an attempt to explore and compare the moral evaluations of SGT made by some of its potential consumers (patients) and providers (medical professionals). Our starting point was the assumption that people's moral understandings, and hence their evaluations of a morally difficult situation, reflect their perception of the situation, which in turn is shaped by their understanding of their life world, and particularly by their own life experiences. The aim was therefore not simply to reanalyse the ethical problems of gene therapy that are given in the medico-ethical literature—which has already been extensively done—but to compare the moral frames of reference of different agents in relation to gene therapy. Since people with disabilities and chronic illness have experiences of health, medical intervention and embodiment that differ from and may be far more extensive than those of people who can identify as able-bodied or healthy, our question was whether and how these differences influence the moral construction of a situation.

Our approach in this study was phenomenological, in that it was based on participants' descriptions of their subjective experience rather than making any attempt at an objective description (Rapp, 2000; Van der Zalm & Bergum, 2000). Participants' ethical statements were often more implicit than explicit, and our approach was necessarily also hermeneutic; we acknowledged our interpretative activity in producing our accounts of the participants' reasoning (Nicholson, 1997; Smith, 1996).

## Study design

### Sampling

We selected groups that we anticipated would provide a range of experiences and descriptions. Rather than providing a representative or statistically randomised group, this sampling is intended to uncover a greater diversity of accounts to be interpreted and elements to be incorporated into the theoretical framework. For the patient groups, we eventually focused on four conditions: two chronic illnesses, one with a well-charac-

terised genetic basis (cystic fibrosis, CF) and one without such a basis (multiple sclerosis, MS); and two conditions normally classed as disabilities rather than illnesses, again one with a strong genetic component (skeletal dysplasias, primarily achondroplasia, A) and one without (Deafness, D).<sup>1</sup> We analysed a total of 35 questionnaires; 17 of these respondents were then selected to be interviewed in depth. This dual approach was chosen so that questionnaires could be used to identify respondents for further interview. We found that some participants would complete a questionnaire very fully but did not wish to be interviewed, while others became more willing to be interviewed after completing the questionnaire had engaged their interest. The data used for analysis came primarily from the interviews, but some of the more extensive questionnaire responses were also used.

We also interviewed a smaller group of medical professionals(m), ranging from basic scientists with little or no contact with patients or prospective patients, to clinicians whose primary focus was patient care and who had an interest in the future use of gene therapy. These participants were identified either because they were known to be involved in SGT research or genetic research in the University of Basel, and/or through their membership of the Swiss National Science Foundation's *Nationales Forschungsprogramme 37* which focused on SGT. All were therefore familiar with the concept of SGT and its limitations; some were involved in basic or clinical research into SGT, others were clinicians specialising in conditions that could, in principle, be candidates for future gene therapy. Ten medical professionals were approached by letter or telephone, and eight eventually agreed to be interviewed; the remaining two were unable to find time.

We used questionnaires and interviews to probe peoples' ideas about crucial ethical issues in SGT, and to ask why they considered these issues to be the crucial ones, without leading them to give what they thought were the "right" answers instead of their real opinions. The questionnaires and interviews were designed to encourage discussion of a topic that the participants might not have considered in depth before. Since we were particularly interested in the relationship between the life world experiences of disease/disability and if these modify attitudes to the ethics of gene therapy, the questionnaires and interviews explored these areas.

<sup>1</sup> Participants with several different skeletal dysplasias were interviewed, all of whom self-identified as being of restricted growth or as dwarves. For ease of reference in this paper they are all denoted as achondroplastic. People who identify themselves with "deaf culture" and those who do not are conventionally distinguished by using Deaf or deaf, respectively. All the hearing impaired participants of this study identified themselves with Deaf culture, hence we use D here.

Apart from a section collecting details about the participant's gender, age, religious affiliation, etc., the questionnaire used open questions and participants could write as much as they wanted in their replies. Interviews were semi-structured. Both questionnaires and interviews covered the patient's current health status and medical history, their feelings about their condition and its relationship to their identity, and what they understood by the term "gene therapy". The interview questions were devised following a review of the bioethics literature and identification of the existing professional consensus on ethical issues in SGT, and after the interview protocol had been piloted. We used the professional consensus as a starting point because we wanted to see how the non-professionals' approaches to ethical evaluation compared with that given in the literature: the professional literature provided a framework for comparison, while two pilot interviews showed that similarities and differences could be identified. The vignette presented a story about an individual with the interviewee's own condition, who is offered a new "gene therapy" by his/her physician. The vignette gave details about the character's personal and professional circumstances, and interviewees were asked whether they thought the character would opt for or against a trial of gene therapy; who were the key figures in the situation; what factors the character would take into account when making the decision; and whether there were other pieces of information, not given in the vignette, that the interviewee would have found useful. We took care to emphasise that the vignettes were fictitious, and that no effective gene therapy for any condition is available yet.

The questionnaires and interviews took place mostly in Switzerland (Basel, Zurich, and Lausanne), and in one case in the United Kingdom, between January 2000 and July 2001. The design of the study, questionnaire, interview outline and informed consent documents were reviewed and approved by the *Ethikkommission beider Basel*. Most of the patient interviews were carried out in German, and the medical professional interviews in English. In this paper, quotations from patients have been translated from the original German where necessary.

### Data analysis

Transcript content was analysed quantitatively to identify themes (Mayring, 2003; Krippendorff, 1980). As is usual in qualitative methodologies, data analysis was ongoing, and the emerging themes were allowed to shape subsequent data collection as the interview questions were modified. Sections of transcripts identified as containing particular themes or categories were then isolated and analysed for their content, context and meaning. Particular attention was also paid to issues of

ethical concern that were explicitly identified by participants. In a third stage, the dominant ethical issues identified were analysed in greater detail, looking especially for commonalities or differences between groups.

In presenting quotations from the interviews as data, we are aware of the inherent risk of misunderstanding or instrumentalising the quotes out of context. The limits of space in this paper made it necessary to present these data as succinctly as possible, but the full textual content of the interview was taken into consideration in the analysis and when selecting the quotes.

## Results

### Areas of ethical concern

Level 2 coding of questionnaire and interview data led to the identification of 11 major themes of concern for the evaluation of SGT by participants. These are listed below, together with examples (not exhaustive) of the content of these categories:

1. *Body and identity*: the body perceived as an enemy or as a source of weakness, as satisfactory as it is, or as perfectible by technology.
2. *Disability and identity*: disability interpreted as a disruption of the "real" identity, versus disability as an integrated aspect of a person's identity.
3. *Role of genes*: whether genes are understood as the primary cause (*Ursache*) of disease, or if gene therapy alters the fundamental being (*Wesen*); how regulatory guidelines should reflect the significance of genetic information.
4. *Eugenics and intolerance*: the impact of gene therapy on social attitudes to disability, illness and human variation in general.
5. *Risk and unpredictability*: of the course of a disease or disabling condition, of the outcome of an experimental therapy, of the effects (financial, psychological or social) of therapy on the patient's social or psychological equilibrium, of the extent of future social or financial support to those embarking on an innovative therapy.
6. *Timescale and the lifecourse*: patients make their ethical evaluation over a longer timescale compared to professional providers; awareness of different priorities of people at different stages of their lives.
7. *Financial issues*: ability to pay for experimental therapy, long-term financial dependency.
8. *Emotional factors*: factors such as guilt (at "causing" the disease in a child, at making a wrong therapeutic decision), and disappointment (having hopes raised and then dashed if the therapy does not work).

9. *Powerlessness*: of the non-professionals against the perceived power of the medical profession, transnational pharmaceutical companies, and the overall drive of “scientific progress”; inability to prevent genetic manipulation being used for undesirable or irresponsible ends; powerlessness to control any technology by democratic means.
10. *Trust/mistrust*: of authorities such as the medical profession: the fear of being exploited purely as experimental guinea pigs.
11. *Information*: paucity of accessible, unbiased information: patients did not see medical professionals, the government or pharmaceutical companies as providers of neutral information.

The first five of these categories (body and identity; disability and identity; the role of genes in human lives; eugenics and intolerance; and risk and unpredictability) were taken for more detailed conceptualisation. We were particularly interested in seeing how concepts of embodiment (body and identity, disability and identity) were related to ethical issues (eugenics and intolerance, risk and unpredictability). Our discussion focuses on the differences between patients taken as a group and the medical professionals, and then on the differences between patient groups.

### Major differences between medical professionals and patients

One of the clearest differences was the use that the medical professionals made of the *therapeutic imperative* as an over-riding, positive value in their ethical evaluation (“I think there is no major concern in the public...as long as we are trying to cure diseases it’s fine”). The patients showed more variable responses. These included statements about the value of diversity (“If there were no disabilities, society would be impoverished”; CF) or the possibility that disability could have some benefits (“Without the hearing impairment my life would have been different, but not necessarily better...I would have missed out on lots of encounters, never have got to know the *Gehörlosenkultur* [Deaf culture] and everything that goes with it”; D). Some also expressed scepticism about the use of the therapeutic imperative: “I think that ‘to cure severe disease’ is not grounds for doing everything.” (CF)

Medical professionals also presented a more *geneticised* view of human health, as their discussions rarely alluded to other potential aetiologies. Patients, on the other hand, were often explicitly critical of this approach: “Here’s the problem gene, we take it out and put in a healthy one, and there you are, a healthy person.” (CF, sarcastically) Some patients were con-

cerned that genetic research is too one-sided: “Really I’d prefer it, even if it’s a bit idealistic, if people did research today on how we could live together better.” (CF)

In general, medical professionals did not give either genes or gene therapy a *special status*, often stating that gene therapy is “no different from giving a drug.” By contrast, the majority of patients expressed the belief that the genes have special significance in forming personal identity: “If I have gene therapy it is changing the building blocks of who I am.” (A) There were however exceptions to this, notably among the MS patients who were already being treated with recombinant beta-interferon. This is a conventional medication that happens to be manufactured by recombinant genetic methods. In the course of interviews with MS patients, it became apparent that some of them believed that in taking recombinant beta-interferon they were receiving gene therapy. They therefore equated gene therapy with their routine drug therapy, based on their understanding of their experience.

None of the medical professionals suggested that disability or illness could be part of a person’s *concept of self-hood*, or that removing it might change a person’s or family’s identity: “If you have a family...characterised by very early loss of hearing or something like that, then this would certainly lead to try[ing] early therapies that would prevent such a condition...” (M). In contrast, this point was made by several patients, who said things like, “I identify exclusively with my hearing impairment.” (D), or “If you take these elements away from me I wouldn’t be (*subject’s name*), I would no longer be that person.” (A) Thus these patients expressed a sense that despite its negative aspects, disability or illness forms an irreplaceable component of a person’s identity. This is consistent with evidence in the sociological literature of a strong, but complex, relationship between illness, disability and identity formation (e.g. Ahmad, Atkin, & Jones, 2002; Marks, 1999; Shakespeare, 1996; Charmaz, 1993). This may lie behind the unexpected observation that some patients found SGT of a child or adult to be *less* morally acceptable than termination of a pregnancy:

- “I can’t deny the mother the right to terminate. But using gene therapy there, I have real problems with that.” (A)
- “It’s the biggest decision you can make, to change a life, *even bigger than ending a life.*” (A) (emphasis added)

Statements like these contradict the standard ethical view, which usually argues that gene therapy is *more* ethically acceptable than prenatal screening coupled to elective termination, because it does not involve the death of the affected individual and therefore is not discriminatory or selective (Walters & Palmer, 1997; Post, 1991). The medical professionals in this study tended to follow this line: “[Prenatal diagnosis] is

obviously of course a selection against handicap...[but this] would no longer be true if we had the therapeutic means...because *this selection thing is only valid as long as we terminate pregnancies.*" (M, emphasis added).

In their interviews, the medical professionals were asked directly what they perceived to be the major ethical problems to do with SGT. The two issues that were identified by all medical participants here were the risk of side-effects of an experimental treatment to the individual patient, and the healthcare costs to society of high-technology medicine.

- "Gene therapy is very different because of the safety issues and the long-term risks."
- "You have to compare on the one hand the...danger, and on the other hand the benefits."
- "The time will come when we won't be able to say that everyone can have access to all that's available in medicine, because the sophistication of medicine will just keep increasing the cost and society won't be able to keep up...I don't like that but I don't see how it can be avoided."
- "Of course gene therapy is extremely expensive and it is not going to be available for everybody, so there [are] all the problems with who is going to get it and who is not going to get it."

Although prospective patients showed concern about both these issues they were not the dominant ones. Patient evaluations of SGT incorporated a broader spread of ethical issues. In addition to those mentioned by medical professionals, they added *the effect of novel therapeutic interventions on the equilibrium of their day to day lives*: "[If the character in the scenario accepted gene therapy] she would become dependent on regular therapy. Before, she was healthy and independent" (D); "I need so much intelligence, so much brain, to keep going and somehow to cope with the constant day to day problems." (MS); *the personal as well as the social financial burden*: "Gene therapy will surely be terribly expensive" (MS); "There is also the question, when someone could get it (SGT) abroad but hasn't enough money—then there's a two or three-class society, and that shouldn't happen" (CF), and *the eugenic impact on society*: "...society will say, if you have a disabled child when you could have aborted it, it's your own fault" (CF); "Possibly long term it will become very elitist, between those who have been gene manipulated and those who haven't" (A).

### Major differences between patient groups

The four patient groups we studied differed substantially in their approaches to SGT. The major differences identified are listed below. The order of priority given was estimated qualitatively from the interview tran-

scripts and questionnaires, and is intended to indicate general trends non-quantitatively.

First, the patients differed in their overall *attitude towards gene therapy*. MS patients were notably the most positive in their evaluation; the CF patients expressed more ambivalence, followed by Deaf and achondroplastic participants who were more negative.  $MS > CF > D = A$ .

Second, there were differences in their assessment of *the role of genes in disease*. Participants with MS were most likely to ascribe a predominant genetic role in disease causation. CF patients again showed a more ambivalent response. Achondroplastic and Deaf participants were least likely to see genes as "the" cause of disease. Note, however, that the achondroplastic participants were fully aware of the strong genetic component to the *condition*, but they did not consider achondroplasia to be straightforwardly a *disease*.  $MS > CF \gg A > D$ .

Third, patients differed in how they *related condition to identity*. Some perceived their own condition as a disruption of their identity, something that posed a threat to their sense of being who they wanted to be. Of all the groups, patients with MS were most likely to see the disease in this way. These respondents universally described their condition as unwanted, negative, and not part of the self. Once again, some CF patients showed the greatest ambivalence, on the one hand seeing CF as negative and something they would get rid of if they could, on the other questioning the utility of eliminating one disease "when another would take its place".  $MS > CF \gg A > D$ .

Other participants saw their condition as an integral and inescapable part of their identity, as something without which they would no longer be the person they now felt themselves to be. Deaf participants who completed the questionnaire were most likely to describe the condition as an integral component of their identity. All the Deaf participants in this study responded that they saw their deafness as a *positive* part of themselves. Participants with achondroplasia also described it as an integral part of their identity. However, unlike participants in either the MS, CF or D groups, some achondroplastic participants were careful to distinguish between different aspects of the condition, e.g. describing reduced stature as an integral part of their identity whereas the joint or vertebral pain that is frequently associated with skeletal dysplasia was not.  $D > A \gg CF > MS$ .

Whether someone understands a condition as either a disruption to, or as a fundamental component of, an established identity might depend on how old the person was when the condition developed. The older the age at onset, the greater the disruption to a firmly established sense of self. Although qualitative and based on a small sample, our data however suggest that *stability of the*



Table 1  
Comparison of perceived ethical issues in SGT across participant groups

Issue	Medical professionals	MS	CF	A	D
Risks to patient	X	(X)			
Destruction of culture					X
Component of identity				X	X
Slippery slope			X	X	X
Eugenic effects in society				X	X
Increased intolerance in society			X	X	
Disruption to life situation		X (incl side effects)	X (incl side effects)		X (incl loss of independence, loss of relationships)
Moral value of disability/diversity			X	X	
Autonomy/consent			X		
Healthcare costs	X	X	X		
Lack of information		X	X		X
Power differential between patients and providers			X		
Exploiting sickness for profit		X	X		

Crosses indicate issues that were mentioned by patient groups. Crosses in bold indicate the predominant issue for that group.

*condition* over time may play a more significant role than age. Thus, the Deaf and achondroplastic participants were quite similar in their description of the condition as a component of themselves, and both deafness and achondroplasia are relatively stable conditions. But there was no marked difference between participants who had been Deaf since birth/early childhood and those who had lost their hearing at a later age in terms of their incorporation of hearing impairment into their sense of identity. Similarly, the responses of MS and CF participants also resembled each other more than they did the other two groups; both of these are progressive conditions even though CF is present from birth while MS has a later onset. These data suggest that a condition that deteriorates over time constitutes a persistent challenge to an existing identity which makes it less easily assimilated into a person's self-concept.

#### Comparison of patients' views on ethical issues in gene therapy

We next turned to the points raised by each patient group in the ethical evaluation of SGT. Many of these were common to more than one group, but there were noticeable differences in the relative significance attached to certain issues. In the summary below, the order of each issue indicates non-quantitatively its relative importance within the group, i.e. how often and how strongly it was mentioned (see Table 1).

- *Multiple sclerosis*: Disruption of personal equilibrium, including the financial consequences of long-

term treatment and the emotional consequences of potential disappointment ("How can I continue my life with minimum disruption—will I have to cut back on work, what will it mean for my personal finances?" "Do I have enough strength for a long-term treatment?"); the patient's lack of information/competence to decide for or against gene therapy ("People must have the opportunity of being well informed...you hear things here and there, but it's very scrappy"; "Of course it's already difficult, getting hold of information when you're disabled"); the exploitation of sickness for profit by pharmaceutical companies, or of patients as experimental guinea-pigs by medical research; the financial burden on society of expensive healthcare; the risk of potentially harmful side effects to the patient (although this point was mentioned, it should also be noted that in this group it was usually accompanied by statements that *minimised* these risks).

- *Cystic fibrosis*: The moral good of disease or disability, i.e. "learning from" the illness, or the social value of diversity as well as potential individual gains ("[Scientists] just want to get rid of suffering and death, and for me that's not right"; "I don't think that 'to heal severe illnesses' is a reason for doing absolutely everything"); the burden of healthcare costs to the individual or to society ("The money would be better used, if people were told beforehand how much they had to pay themselves"; "There are already medications that are terribly expensive, and you ask yourself who should pay for it"); the possibility that gene therapy of disease would be the start of a "slippery slope" towards greater

uniformity in society; the importance of patient autonomy and informed consent, and how this was reduced by a lack of accessible information; the patient's relative powerlessness within medical culture; the exploitation of sickness for profit by pharmaceutical companies, or of patients as experimental guinea-pigs by medical research; disruption of personal equilibrium, including the financial consequences of long-term treatment and clinical side effects.

- *Deaf*: The risk that gene therapy and genetic manipulation will lead to the eradication of Deaf culture (“[Eradication] would be very sad! Deaf culture and sign would disappear, and that would be a real loss”; “Is hearing impairment something that has to be ‘fixed?’”); the importance of Deafness as a component of identity (“The transition to being able to hear again would be a heavy psychological burden”; “Isn’t the hearing impairment a part of me, something that constitutes my being too?”); the possibility that gene therapy of disease would be the start of a “slippery slope” to other, less acceptable forms of gene technology and to greater uniformity in society; disruption of personal equilibrium (especially the destruction of relationships within the Deaf community, and loss of independence from medical culture); increasing the acceptability of eugenic attitudes within society; the patient's inability to make an informed decision due to the lack of information (especially in *gehörlosengerecht* or Deaf-appropriate form).
- *Achondroplasia*: The risk that gene therapy (and other forms of genetic manipulation) will lead to increased acceptability of eugenic attitudes within society (“[People will say] oh, dwarf, we can correct that, it's going to be manufactured babies”; “[It will lead to] perfectionism, that everything is excluded, that only the perfect Super-Type comes into the world”); the possibility that gene therapy of acknowledged disease would be the start of a “slippery slope” to greater uniformity in society (“I think society needs a variety of people, including disabled people, to be a whole society, to be accepting of each other, and I think to totally abolish disability is, well it's wrong”; “And it just goes further and further all the time, until you have the perfect human being”); the moral good of disease or disability, i.e. the value of having diversity in societies; the importance of achondroplasia as a component of identity.

Patient groups differed from each other in how much weight was given to particular issues, and how they were expressed. For example, participants with achondroplasia were most likely to raise the issue of the risk of “eugenics” and of a slippery slope towards a decreased

tolerance of diversity. This aspect was not volunteered by any of the MS patients, and was sometimes explicitly repudiated when suggested by the interviewer. However, both MS and CF patients generally considered the exploitation of disease for (excessive) profit by the medical and pharmaceutical professions to be a major ethical issue, while Deaf and achondroplastic participants, with probably less day to day exposure to medical intervention, did not raise it except as part of a more general worry about the values of science and medicine. Finally, while the other groups noted the possible disruption of the familial, social, financial or psychological equilibrium as an ethical issue, Deaf respondents uniquely focused on the potential damage to relationships with D/deaf family and friends, whether through being “cured” or simply because an individual could be judged as rejecting Deaf culture by seeking a therapy. Such a response is consistent with the negative attitude towards prenatal diagnosis for inherited deafness shown by some studies (e.g. Middleton, Hewison, & Mueller, 2001, 1998; Stern et al., 2002).

## Discussion

In this study we attempted to compare the moral frames of reference of different agents thinking about SGT, noting that the ethical discussion of gene therapy has been dominated by the perspective of medical and ethical professionals. The results highlight some differences between the professional opinion on the ethics of SGT and non-professionals' evaluations of it. Our small but diverse sample of medical professionals shared a moral evaluation of SGT that (a) based its acceptability on a strong therapeutic imperative, (b) grounded this in an unproblematic separation of identity and disability/illness, and (c) generally did not see SGT as ethically different from other medical interventions. The moral evaluations of the prospective patients on the other hand (a) often questioned the actual need for or effectiveness of “therapeutic” interventions, (b) could derive a strong sense of identity (even a negative one) from disability/illness, and (c) sometimes saw genetic interventions as changing a person's identity, either directly (through the genes) or indirectly (through altered life experience).

Some of these differences may be related to variations in the understanding of the concept of SGT. The medical professionals were all either directly or indirectly involved in SGT research. Their understanding, e.g. drawing a clear distinction between somatic and germline gene therapy (GGT), is the conventional biomedical one. By contrast the non-professionals showed more variation in their grasp of SGT. When asked to define SGT, only two (both were CF patients) seemed clear about the distinction between SGT and GGT. Most of the other participants gave descriptions

of a process that changed all an individual's genetic material throughout their body, and which could be inherited by their descendants. This difference in what professional and non-professional participants understood by the topic under discussion raises ethical issues which need to be addressed.

The medical professionals also drew on a more restricted range of issues as relevant to ethical evaluation than the patients. Issues that were consistently raised by our patient participants, such as (i) disruption to personal equilibrium, (ii) the exploitation of sickness for profit, (iii) the potential for the condition to be an integral part of the identity, and (iv) the eugenic consequences, both in terms of increasing intolerance of difference and of the real "erasure" of disability, are rarely if ever mentioned by the ethical literature on gene therapy. Nor were these points raised by the medical professionals in our interviews. This suggests a bias of the professional ethical discussion towards the perspectives of medical professionals.

Although the medics had both medical and non-medical information available to them, they demonstrated clear "discursive boundaries" (Kerr, Cunningham-Burley, & Amos, 1997), as shown by the relative paucity of the ethical issues they raised as relevant to SGT (risk, in terms of the potential side effects of novel therapy, and the societal burden of healthcare costs). Thus, in making their moral evaluations, medical professionals focused on recognised areas of their own professional responsibility. While these issues were clearly of importance to patients, in many cases they were not their *primary* concern. It may be that these discursive boundaries were retained because the participants perceived themselves as being interviewed in their professional roles, and consciously or otherwise restricted themselves to this approach, especially as all were interviewed at or near their place of work. All eight were interviewed by one of us (JLS) who was known to them as a molecular biologist, although not a clinician. This might have had an influence in reinforcing discursive boundaries. The interviews included some direct questions about how they might respond to SGT if they were potential patients, but interestingly several of the medical interviewees resisted responding to this line of questioning.

Differences in the experience of disability and illness in the lives of medical professionals and patients, and of people with different kinds of disability, also appear to affect their consideration of the moral difficulties involved (Shakespeare, 1999). Western medicine and the medical ethics associated with it are based on the belief that the suffering experienced by the sick or disabled person requires clinical intervention; it is also based on assumptions about exactly what constitutes the suffering in illness or disability (i.e. disruption of a biomedical norm). However, these assumptions may not

match the subjective experience of illness or disability, or of medical intervention, since relatively few medical or bioethical professionals will have had extensive personal experience of disability (Lupton, 1994). These differences in subjective perception become morally important, because the doctor–patient encounter is one that embodies a significant power differential; fairness requires the articulation of the concerns of both agents.

Some limitations of this study should be borne in mind. First, patients were mostly self-selected by responding to advertisements and personal contact. Therefore, we do not claim that they are representative of everyone who shares the same condition, or even of disabled or chronically ill people in general. Second, the two sources of data (written questionnaire answers and interviews) were not identical: questionnaire responses were usually shorter and gave less insight into the participants' life worlds than the interviews. As our approach was content-based and interpretative we felt it legitimate to use both, for the advantages of extending our relatively small data base and to capture those participants who felt most comfortable responding in writing.

A particular difficulty of our study is that SGT is not currently a reality, which means that the participants were being questioned about their attitudes to a *hypothetical* situation. This might have contributed to the doctors' reluctance to move out of the one domain (medicine) where there were some solid facts on which to base their opinions. Nevertheless, despite posing a hypothetical issue, we can say that for the four patient groups examined there were clearly observable differences in their evaluations of this hypothetical situation, based on their interpretation of the vignette mediated through their own experience of disability and illness.

The study originated in the desire to see whether the moral evaluations of gene therapy made by non-professionals would differ from what had been identified as the professional consensus. Therefore, we did not attempt to problematise the separation of interviewees into medical professionals or people with particular conditions, as the study itself was intended to illuminate at least one aspect of this. Our interpretation of the results is that non-professionals tend to draw on a wider range of factors than professionals, who are trained to remain within tacit discursive boundaries; and that one of these factors in the moral evaluation of gene therapy is the individual's *experience* of their embodiment as normative or non-normative, and how it has been integrated into their sense of self. We are not however suggesting that this is the only or the most important factor, nor that, because the importance of embodiment is strikingly apparent in the non-professionals' discourse it is therefore always of less relevance to the medical professionals. This is where the professionals' implicit acceptance of discursive boundaries, "knowing what



they were supposed to say”, is likely to be important. Furthermore, we would distinguish the subjective experience of embodiment from the objectifying grouping of disabled people into categories of conditions. In trying to explore whether having/being a non-normative body has an impact on the perception of gene therapy ethics, we noted commonalities that cut across the medical categories, and aspects that appeared distinct to particular conditions. And, as subjectivity is a complex and often contradictory phenomenon, participants’ responses were not always straightforward. The commonalities, differences and contradictions all need to be investigated more fully.

### Implications

Our results highlight the need to take into account non-professionals’ views and arguments about SGT. The differences between these and the professionals’ views were great enough to indicate that assuaging the ethical concerns of medical professionals and ethicists may not address the chief worries of non-professionals. As we have seen, patient participants were less concerned about the potential side effects of gene therapy or the burden on healthcare resources than with the anticipated disruption to their (sometimes precariously managed) lives, the eugenic consequences for future societies, and the integration of genes and therapy into their conceptualisation of the relationship between their condition, their bodies and their self-hood. If, as our study suggests, these questions do not immediately present themselves to medical professionals, lack of understanding about different priorities may be a barrier to effective communication.

In addition to improving communication between patient and healthcare provider, greater clarity about patients’ or prospective patients’ beliefs may also encourage ethicists to tackle questions that patients themselves define. It is important that public views are taken into account when formulating policy, and to do this the views of the public need to be taken seriously. Equally, the misgivings of sections of the public need to be given thorough discussion and debate rather than treated as uninformed fears to be allayed as rapidly as possible. To foster public involvement in democratic debate about genetic policy and regulation, it is important that these issues be conscientiously uncovered.

For the foreseeable future, human gene therapy will be limited to the particular social setting of clinical studies that use patients as volunteers. The free and informed consent of the research subjects (or their legal representatives) is considered to be a key prerequisite for the ethical legitimacy of such trials (Smith, 1999). However, the validity of consent is dependent on the

subject’s understanding of the significant issues. This understanding is in turn dependent on the patients’ access to accurate and comprehensive *information* about the study and its implications. For physicians and research ethics committees to provide such information presupposes that they have adequate insight into what might be the important issues and questions for the non-professionals. Yet the results of this study show that many of these issues are not even included in the standard professional understanding of the ethics of SGT, let alone adequately addressed. Examples of these “extra issues” have been given here, and others will undoubtedly arise once we take moral partnership with potential patients as research subjects seriously. Simply to theorise about the “potential patient’s perspective” is no replacement for a genuine investigation into their real points of view. This means *asking* them about how gene therapy interacts with their life histories, their day-to-day experiences, and their self-understanding and self-concept. And since life histories, day to day experiences and identity issues differ according to the medical condition, the ethical priorities will also differ depending on whether we are talking about CF, skeletal dysplasia, or some other condition. There is no *one* gene therapy ethic.

Variation among potential consumers of gene therapy or other forms of therapeutic genetic intervention is frequently ignored in ethical discussion, where they become conflated into an undifferentiated mass of “the disabled”. Yet we have found differentiation to be critical to an understanding of the varying stances towards gene therapy, and—importantly—the basis of the arguments used in each case. When an ethical understanding of SGT is reconnected with the diversity of human biographies, differences between perspectives can be seen as a source not just of a differential balance of interests, but of radically different experiences of the situation. Given the amount of diversity found even within this small study, which was undertaken within a relatively homogeneous society, we would argue that bioethical debate and policy making need to accommodate greater diversity and ambiguity than it currently does.

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