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INFORMED CONSENT AND MEDICAL ORDEAL

A QUALITATIVE STUDY

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ETHICAL APPROVAL

Ethical approval for this study was obtained from Westmead Hospital Research Ethics Committee and the Research Ethics Committee of the University of Sydney.

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COMPETING INTERESTS

None declared.

ABSTRACT

Background Informed consent is a mainstay of clinical practice, with both moral and legal force. Material disclosure about extreme treatments, however, is unlikely to convey the full impact of the experience of treatment. Informed consent may be flawed under such circumstances.

Aims To compare expressed satisfaction with pre-treatment information to satisfaction after experiencing autologous stem cell transplantation (ASCT) for recurrent lymphoma.

Methods A qualitative, narrative-based cohort study has been conducted in a Teaching hospital Bone Marrow Transplant unit at Westmead Hospital, Sydney, Australia. The cohort

consisted of ten transplant recipients and nine of their nominated lay carers. The Outcome measure was satisfaction expressed in narrative interviews at the time of transplantation and three months later. We used discourse analytic techniques to examine the narratives.

Results Both patients and carers expressed high satisfaction with the information given by individual clinicians and by speakers at a formal Information Day held before transplantation. At the first interview, neither patients nor carers commented much on the forthcoming ordeal of chemotherapy and bone marrow ablation, although all patients had undergone previous chemotherapy. At the second interview, the ordeal dominated the narratives, and retrospective dissatisfaction with information was common.

Conclusions This study suggests that information about treatment theories and protocols can be satisfactorily communicated, but personal experience of suffering defies communication. This finding has serious implications for the practices involved in obtaining informed consent and for the very notion of informed consent.

KEY WORDS

Autologous stem cell transplantation; haematological malignancies; extreme treatment; medical communication; informed consent.

INTRODUCTION

Informed consent is one pillar of modern clinical practice¹⁻¹⁷. It is meant to confirm a relationship of trust and understanding between patient and doctor. Complete information is supposedly provided in spoken and/or written form, so that the patient knows the nature of her treatment, its risks and benefits, and its possible outcomes. Informed consent is itself supported by moral and legal pillars. It is morally good because ideally it involves truth, relationship, trust, free choice and exchange of knowledge – all construed as ‘goods’ in the context of medical practice and within the context of Western liberalism. It is legally good because the patient must have a general understanding of what will be done, otherwise the treating doctor is open to a charge of battery.

There are, however, some who doubt the validity of informed consent on both moral and legal grounds. Some moralists believe that it represents an unattainable ideal, particularly in the context of serious illness and extreme treatment^{6 18 19}. The High Court in Australia does not consider informed consent to be a clear and distinct concept, nor helpful in cases involving alleged negligence²⁰. Despite these misgivings, however, conventional text-books of bioethics from different English-speaking countries emphasize its importance as a mainstay of respect for autonomy and of sound medical practice^{21 22}.

Its place is therefore well-established. This article examines its efficacy among patients undergoing the taxing and debilitating treatment of autologous stem-cell transplantation (ASCT) for recurrent lymphoma in a bone-marrow transplant unit at Westmead Hospital, western Sydney, Australia. It is a purely qualitative study that concentrates, not on recall of detail of the information given, but on the satisfaction expressed by patients and their carers before and after the transplant.

MATERIAL AND METHODS

This study examines the appraisal by patients and their carers of the medical information provided individually by clinicians, and at the Information Day run by the Westmead Hospital for all bone-marrow recipients and their nominated carers. It does so by drawing on results from a prospective, ongoing, two-year study of a sequential sample of patients and their carers treated at the BMT Unit at Westmead Hospital, Sydney, Australia. All patients had recurrent lymphoma following chemotherapy, with or without radiotherapy. All were assessed as suitable for autologous stem cell harvest, and for stem cell transplantation after high dose chemotherapy (ASCT). All patients and their carers gave consent to interviews during hospital admission for transplantation, at three months after transplantation, and at six month intervals for two years.

The study received ethical approval from the University of Sydney and from Westmead Hospital. Informed consent was obtained from all participants. All names have been suppressed, and pseudonyms used. Table 1 shows demographic data about the patients and their matching carers. The sample represents well the ethnic diversity of Western Sydney.

Table 1: Demographic data of the patients and their matching carers*

Patients	Sex	Decade	Ethnicity	Occupation	Carers	Sex	Decade	Ethnicity	Occupation	Relationship
Abby	F	3	White Australian	Office manager	Bronnie	F	6	White Australian	Housewife	Mother
Colin	M	7	Mixed-race South African	Small business owner	Delia	F	6	Mixed-race South African	Marine underwriter	Wife
Evelyn	F	4	Chinese	Health translator	Francis	M	4	Chinese	Alternative medical practitioner	Husband
Grace	F	7	White British	Office worker	Henry	M	7	White Australian	Retired	Husband
Ingrid	F	7	White Australian	Volunteer health support worker	Justin	M	4	White Australian	Radiation oncology technician	Son
Kevin	M	6	White Australian	Business director and manager	Louise	F	6	White Australian	Animal breeder	Wife
Norah	F	4	Chinese	IT recruitment	Marvin	M	4	Chinese	IT manager	Husband
Pegah	F	4	Lebanese	Housewife	Omar [#]	M	ND	Lebanese	Small business assistant	Husband
Quentin	M	4	White Australian	Business manager	Ruby	F	4	White Australian	Nurse	Wife
Tony	M	7	Italian	Businessman	Sigrid	F	6	White Australian	Housewife	Wife

*Ages are given by decade only.

[#] The carer code-named Omar declined interview. F, female; IT, information technology; M, male; ND, not determined.

The cohort consists of 10 patients (six female; four male) and nine carers (five female; four male). Carers were nominated by the patients. One carer declined to participate in the study because he deemed his English language ability to be too poor. Interviews were conducted by two non-medical academic researchers (CFCJ and CM). Two sets of interviews have been analysed. The first set of interviews, conducted at the time of admission (Time 1), consists of ten interviews with patients and eight interviews with carers. One carer was not available for interview at Time 1. The second set of interviews was conducted three months after discharge from hospital following the ‘transplant’ (Time 2) and consists of six interviews with patients and seven interviews with carers. Two patients had died since the first interview, one was too ill to be interviewed, and one had received his ‘transplant’ too recently to qualify for a second interview. One carer was excluded for the same reason, and one carer’s transcript of his second interview was not available at the time of review. Interviews at Time 1 were designed to elicit illness narratives. Interviews at Time 2 were semi-structured.

The discourse analytic methodology and its theoretical basis have been set out in some detail elsewhere²³. The methodology is based on theories of the evolution and practices of discourse communities²⁴⁻²⁶. Transcripts in this part of the study were read for two specific themes – 1) appraisal of the quality and content of medical information given by the clinical staff both individually and during the Information Day; and 2) perceptions of the impact of the ‘transplant’ episode and its aftermath as an ordeal²⁷ for the ‘transplant’ recipient. Each ‘instance of mention’ of these two themes was coded and extracted into a separate file. We emphasise that we have examined the satisfaction that patients and carers express about the information proffered, rather than the accuracy of its recall and understanding.

Material quoted in the results section has been minimally edited for sense and punctuation. Italics have been used for emphasis.

RESULTS

INTERVIEW AT TIME 1

Medical information

Six of 10 patients commented specifically on the excellence of the medical information, saying that they felt well prepared for their transplantation experience. Colin (patient), for example, described the Information Day as

“...very informative. I was very impressed, actually”.

No patient commented adversely on the quality or content of the Information Day.

Five of the eight carers made eight specific comments, three carers praising without reservation and two balancing their approval with minor reservations.

Ordeal

Both patients and carers all had previous first or second hand experience of the unpleasant side effects of chemotherapy. Despite this, only one of 10 patients specifically dwelt on

chemotherapy as an ordeal, and extrapolated that experience to the forthcoming transplant. Colin (patient) said

Devastating. Yeah. It all depends what degree of chemo I was given, you know...sometimes the chemo is very strong, and it really puts me down.

Four of eight carers, however, recorded the severity of chemotherapy's impact on their charges. Delia (carer) made a typical comment:

And I don't know much about what sort of chemo but it has knocked him.

INTERVIEW AT TIME 2

Medical information

In the interviews at Time 2, all six patients commented on the quality and content of the medical information, but the appraisal was now overwhelmingly negative. The six patients made between them 25 comments, of which 20 were critical.

Colin (patient), who found the Information Day so helpful at the first interview, said at the second:

No I was not prepared, I mean I was not prepared...I never thought how bad it could be or how dangerous it could be, how life threatening it could be...I could never ever comprehend what I was going through at the time.

Six of seven carers spoke about the quality and content of the medical information, addressing the issue on 14 occasions. Four appraisals were supportive and 10 critical. A typical comment was offered by Henry, who cared for Grace. When asked whether he had been prepared for Grace's suffering and death, he answered:

No, didn't have a clue. I must say that it was mentioned that there were risks involved, but I just didn't think this would happen to us.

Ordeal

All six patients made multiple mentions of ordeal, on 20 occasions. Colin (patient), for example, says of the transplantation experience that it was:

Very traumatic, and very frustrating, and it was not a pleasant thought at all, or feeling... I just wasn't functioning.

There was agreement that no one would want to go through the same experience once its severity has been understood. Abby (patient), who has experienced chemotherapy before, said

Y'know, I just cannot go through this again. Y'know, it was way too much. It was just more than I ever expected, y'know.

All seven carers similarly commented on their charges' ordeals. Comments referred in the same way to how much worse the transplant experience had been, compared to previous episodes of chemotherapy. Ruby, who cared for Quentin, commented that

I think he was a lot sicker than he thought he was going to be.

Bronnie (carer) complained that information about the ordeal of transplant and its aftermath was, in retrospect, too vague and non-specific:

...because all we were told, the exact words that that one of the ladies in the hospital said was “You are going to feel like a washed out dishrag for about three to four months,” and I thought “Okay,” but that can cover a lot of things, and it didn’t really specify anything, so *without anything being specified it is hard to know what it is...*

RELATIONSHIP BETWEEN DISSATISFACTION AND ORDEAL

Pooling the instances of mention in all interviews – those of patients *and* carers – we noted that in the first set of interviews dissatisfaction with medical information was coded twice in the first interviews among the 18 interviewees (10 patients and eight carers). There were five instances of mention of ordeal in the first interview.

In the second interviews, there were 31 instances of dissatisfaction offered by 13 interviewees. There were 30 mentions of ordeal by the 13 interviewees. These observations suggest that personal experience of the ordeal of transplantation increases awareness of the limitations of conventional medical information.

DISCUSSION

The results of this small qualitative study demonstrate that the experience of ASCT can cause a radical reappraisal of the adequacy of the information provided before the procedure. The ordeal of treatment changed approval to disappointment at the inadequacy of preparation. We conclude that, at least in this small cohort of patients, ASCT is not something that *could* be adequately communicated. It is not, indeed, possible to convey the experience of any extreme treatment, however conscientiously the clinical staff may try. No amount of telling can create the experience in the listener. Only the experience itself can take the patient through its threats, its pain, loneliness, despair and degradation^{28 29}.

Informed consent in such contexts is therefore flawed. One of the basic requirements for adequate consent is *material disclosure*²¹, but material disclosure of the details of the transplant experience does not achieve the purpose of preparing patients and carers for what it is actually like to go through the ordeal.

We suggest that clinicians consider changing the nature and purpose of the consent process. They need, of course, to respect all the present criteria of competence, voluntariness, material disclosure, recommendation, understanding, voluntary decision and autonomous authorisation^{21 22}, but there is also a clear need to go further. What seems to have been missing from the present process was a commitment to provide the support that patients and their carers needed during the ordeal. Informed consent, as presently construed, is only a reasonable beginning. We believe that it should be supplemented by an implicit contractual undertaking to be *present* throughout the ordeal²⁷. If clinicians are to be judged as sincere in their commitment to providing good care for patients undergoing major treatment, we argue that they will need to provide information and assurances that would allow a patient to sign a document containing something along these lines:

The procedure that I will undergo has been explained to me by the clinician primarily responsible for my care to a level with which I am satisfied.

I have raised my particular concerns, and they have been adequately discussed.

I understand that no one can completely convey what I will experience during treatment, but the responsible clinician and his team have undertaken to continue to explain – to the best of their ability and knowledge – what is happening to me, what needs to be done to help me, how long each episode will last in the course of my illness and treatment, and what its outcome is likely to be.

I understand that the experience of treatment may be different to anything that I can imagine. The clinician and team have contracted to answer my ongoing questions and those of my designated family member(s) and/or carer(s) to the best of their knowledge and ability as the treatment course evolves, and as they deliver appropriate and competent care.

CONCLUSION

If this qualitative study can be further generalised, informed consent might become a part of an implicit contract between patient and clinician, in which the clinician undertakes the heavy responsibility of providing expert care and compassionate support throughout any extreme treatment. We do not believe that this commitment is too much to expect of those who routinely use dangerous and debilitating treatments. In the present study, it is noteworthy that the clinical staff was praised in the interviews before the transplant, but not after the transplant. This is not to say that they failed to deliver excellent care. It does suggest that patients and their carers perceive a need for clinicians to offer more specific support for each issue – such as severe mucositis, the need for strict isolation, severe pain, debility – as it arises, offering comfort, explanation, and the reassurance that each encountered threat is familiar and temporary. They need to offer choices and make recommendations about ways to relieve symptoms and deal with crises, and they need to do these things personally and with their team, showing their physical presence²⁷, their concern for the welfare of patients, and their familiarity with each issue that arises during the disturbing process of treatment. Informed consent to disruptive treatment should not be an end in itself. It is better construed as the beginning of a complex relationship that places heavy responsibility for continuing care on clinicians who undertake extreme treatments. It may not be possible to prepare people adequately by giving information before the ordeal, but it should be possible, by attending to the specific experiences of each patient, to forestall the patient Colin's complaint that

I could never ever comprehend what I was going through at the time.

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