Human functioning of patients after hematopoietic stem cell transplantation displayed with the International Classification of Functioning, Disability, and Health: a Delphi study

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Introduction

The number of patients undergoing hematopoietic stem cell transplantation (HSCT) is growing worldwide. Between 1970 and the present, the number of successful stem cell transplants for people with blood cancer has increased from hundreds to several thousand per annum worldwide.[1] In the Netherlands 1,230 HSCTs were performed in 2014.[2] HSCT is the intravenous infusion with stem cells of a donor (allogeneic) or patients' own stem cells (autologous). This therapy is widely used in the treatment of blood cancers, including leukemia, lymphoma, and multiple myeloma, to restore the stem cells when the bone marrow or immune system is damaged or defective or to allow the patient to receive high doses of chemotherapy and/or radiotherapy whereby previously harvested stem cells are replaced after the therapy.[3,4]

Although HSCT treatment can cure or achieve long-term remission of hematologic diseases, it is not without risks for patients.[5,6] Patients undergoing autologous or allogeneic HSCT run the risk of early complications, such as bacteremia/sepsis and mucositis, and late effects, including endocrine, pulmonary, and immune effects.[6] For the allogeneic HSCT, there is the risk of an attack of the newly transplanted donor cells on the patients' cells, known as graft versus host disease (GVHD), which affects multiple organs and can be either acute or chronic.[7] Because of this potential risk, the allogeneic HSCT is seen as a more intense treatment than the autologous treatment.[8–10] In addition to the physical problems, the treatment is associated with a heavy physiological burden and effects on the quality of life.[11] Patients undergoing HSCT are admitted to a hospital for days or weeks and have to return to the hospital regularly for outpatient visits after discharge. The majority of these outpatient visits continue at least until one year post-transplantation.[2] Concluding, a HSCT has a major impact on the daily functioning of patients, wherein the impact of the allogeneic is considered stronger than the autologous.

The International Classification of Functioning, Disability, and Health (ICF) describes human functioning from a holistic, bio-psychosocial perspective.[12] The ICF was developed by the World Health Organization (WHO) as the international standard terminology for functioning, together with the conceptual model of health.[12] In the ICF, all aspects of health and well-being are described in terms of human functioning within the components "body functions and body structures", "activities and participation", and "environmental factors". These components are divided into chapters and each chapter consists of categories. Over 1,400 categories are included in the classification. The interaction between a health condition, functioning and contextual factors is represented in the conceptual model of health (Figure 1).[12]

*Figure 1

During the last decade, there has been an increasing focus on functioning, which has led to changes in perspectives on healthcare.[13] For example, a new definition of health has been proposed: “health is the ability to adapt and self-manage in the face of social, physical and emotional challenges”.[14] In this definition, functioning, resilience, and ability are the central themes, instead of the disease or disability as in the WHO’s current definition of health. The new definition of health and the focus on functioning are two pillars in recent formal advice to the Dutch Minister of Health aimed to prepare healthcare professionals and health education for future challenges in healthcare.[15,16]

To address functioning in the health care practice, a paradigm shift from the biomedical model of care toward the bio-psychosocial model is required.[15] Within this approach nurses support the patient in self-management and apply shared decision making to maintain or improve daily functioning in relation to health and quality of life.[13,17] However, health care professionals deliver their care by using tools and skills mainly based on the biomedical model.[18] The use of ICF in clinical practice can be a tool to achieve a shift toward the bio-psychosocial model.

Within the hematology sector in the Netherlands, there is a demand to describe functioning of HSCT patients and to implement the ICF in clinical practice. To facilitate this demand, an ICF core set, a selection of ICF categories most relevant for describing functioning of a particular health condition or in a specific healthcare context, can be used.[13,19,20] The core set can serve as a guide for reporting a patient’s health status or as an evidence-based basis for developing patient-centred outcome measures.[21–23] In the past years, several core sets have been developed and published.[24] However, a core set for the HSCT patient population has not yet been developed.

Aim

The aim of this study was to identify the most relevant categories of the International Classification of Functioning and Health to describe functioning of hematology patients after autologous and allogeneic stem cell transplantation in the period up to one year post-transplantation based upon patients and nursing input. Identifying these categories is a major step in the development of an ICF core set.

Method

Design

An exploratory, sequential mixed methods design was used to identify relevant ICF categories related to functioning of HSCT patients using the Delphi technique (see Figure 2). The Delphi technique is an organized process with different rounds among a panel of experts to reach consensus on a specific topic.[25] The Delphi technique is an efficient means to combine the expertise of a geographically dispersed group without the necessity of a formal meeting.[26] Therefore, it was possible to combine the expertise of nurses from hospitals located in different areas of the Netherlands and patients from different parts of the country. This Delphi study consisted of two rounds, based on the guidelines of Keeney et al.[27] In both rounds a paper questionnaire was used: in the first round the questionnaire consisted of a quantitative and qualitative section, in the second round solely of a quantitative section. This study was performed from January 2016 to April 2016.

*Figure 2

Domain, Setting and Participants

The population of interest were nurses working with HSCT patients and patients who underwent an HSCT. Nurses were eligible if they were currently working as registered nurses and had least two year of experience in taking care of HSCT patients. Nurses were recruited from the Department of Hematology of the eight university hospitals in the Netherlands. Furthermore, nurses working in the outpatient setting of those eight hospitals were also invited to participate since care for HSCT patients continues after hospital discharge.

Patients were recruited via the hematology patient association in the Netherlands. Patients were eligible if they underwent autologous or allogeneic HSCT, aged 18 years and over, and could speak and write Dutch.

Sample Size

There is no universal agreement on the sample size of an expert panel for a Delphi study; the sample size is often based on practical logistics and common sense.[28] In line with this, the intended sample consisted of 32 ward nurses (four per included hospital), 24 outpatients' nurses (three per included hospital), and ten patients.

Sampling

Nurses and patients were selected through purposive sampling in order to obtain the required level of expertise.[26] The chief nurses of the eight Departments of Hematology and

one outpatient nurse per hospital were invited to participate with their team by email. More detailed information was given by telephone to the chief nurses and outpatient nurses. The patient association was contacted by telephone. A request for participation was submitted for approval to the board of the patient association. The board agreed to participate, and subsequently, a contact person passed on patients' names and addresses.

Primary Outcome

The main study outcome was a selection of relevant aspects of human functioning of post-HSCT patients displayed with ICF categories, obtained through questionnaires in a two-round Delphi study.

Questionnaire First Delphi Round

The content of the questionnaire of the first Delphi round was based on previous research: (i) content analysis of nursing reports of 31 HSCT patients admitted to a hematology unit of a University Medical Centre in the Netherlands[29] and (ii) literature review on important aspects of functioning for HSCT patients[30]. This research led to 66 ICF categories (Appendix A).

These 66 ICF categories were presented in the questionnaire, accompanied by a description from the WHO.[32] The questionnaire contained two rows for each category, one for autologous and one for allogeneic HSCT, both with similar answer options. Nurses were asked to complete the row for the type of transplantation they were most experienced in and patients for the type of transplantation they underwent. It was possible to complete both rows for each category.

The nurses and patients were asked to rank each ICF category on a five-point Likert scale, ranging from "not relevant" to "very relevant"; an ICF category could be considered relevant when (i) the category was believed to be important or (ii) if the category was deemed to have considerable effect in the functioning of post-HSCT patients. The five-point Likert scale method was chosen over a dichotomous scale in order to provide the respondents with increased optionality in answering the questions.[26]

The qualitative section of the first round consisted of open-ended questions. For each chapter of the components ("body functions", "activities and participation" and "environmental factors"), nurses and patients could name and describe aspects they wished to include that were not included in the 66 ICF categories of the quantitative section.

Consensus

The Delphi technique is an iterative process for combining expert opinion into group consensus.[27] There are no recognized guidelines for an appropriate level of consensus; many Delphi studies employ arbitrary levels.[31] In the present study, a consensus level of 70% was applied based upon other research.[27,28] An ICF category reached "high consensus" when ≥ 70% of the participants rated the category as relevant, "moderate consensus" was associated with a level of relevance between < 70 to ≥ 50% and levels < 50% were labelled as "no consensus". 'High consensus' categories were included in the final selection. "Moderate consensus" categories were submitted again in the second Delphi round, and "no consensus" categories were excluded.

Procedure

First Delphi Round.

Nurses and patients were asked to complete the quantitative and qualitative sections of the questionnaire.

Second Delphi Round.

In the second round, the results of the first round were presented to the nurses and patients. They were asked whether they agreed (agree/disagree) with the exclusion of the "moderate consensus" categories in the final selection to test whether these categories were incorrectly removed from the final selection. In addition, categories added by nurses and patients in the qualitative section of the first round were included; nurses and patients were asked whether they agreed (agree/disagree) with the inclusion of these categories in the final selection. The response of each individual participating nurse and patient and the group mean response on each ICF category were reported back in order to enable nurses and patients to carefully reconsider or modify their responses. For both Delphi rounds, nurses and patients had two weeks to respond. A reminder was sent by email three days before each deadline.

Data analysis

Data were analysed using SPSS Statistics version 22.0 (IBM Corp., New York, U.S.A.). Descriptive statistics were used to present demographic characteristics and ICF categories; continue variables were expressed as means and standard deviation and categorical variables as frequencies and percentages. No sub-analysis was conducted between the answers of the nurses and patients.

The type of missing data was analysed if it was completely at random (MCAR), random at (MAR), or not at random (MNAR). Afterward, a technique to handle the missing data was

determined.

For the analysis of the data gathered in the first round, the researchers decided that an outcome of 4 (relevant) or 5 (very relevant) on the Likert scale indicated that the participant was willing to include the ICF category in the final selection. Outcomes 1,2 or 3 were considered signals for exclusion of the ICF category from the final selection. For each ICF category, frequencies of scores 4 and 5 were calculated and categorized as a “high consensus”, “moderate consensus” or “no consensus”. The qualitative data were linked to ICF categories by means of the linking rules, in close collaboration with another independent person trained in using the ICF linking rules.[32] Differences were discussed with an ICF expert. The ICF categories added by four or more participants were submitted in the second Delphi round, and participants were asked whether they agreed or disagreed with the inclusion of these categories in the final selection.

After the second Delphi round, the frequencies of the nurses and patients who agreed or disagreed with the exclusion of the moderate consensus categories were calculated. If ≥ 70% of them disagreed with the exclusion of an ICF category, the category was included in the final selection. The other moderate consensus categories were excluded. Second, the frequencies of the nurses and patients who agreed or disagreed with the inclusion of the categories from the qualitative section of round 1 were calculated. If ≥ 70% of them disagreed with the inclusion of an ICF category, the category was excluded from the final selection. The other categories were included in the final selection.

Ethical issues

This study was conducted according to the principles of the WMA Declaration of Helsinki.[33] Participants who agreed to participate signed an informed consent. Only participants who returned the questionnaire of the first Delphi round were included in the second Delphi round. Quasi anonymity was used: participants were known to the researcher but their answers remained anonymous to others.[34] This paper is written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.[35]

This research method did not require approval from the Medical Ethical Review Committee on Research on Humans.

Results

Participants

Thirty-five nurses representing the eight university medical centres agreed to participate. Ten patients agreed to participate. The response rate in the first round was 73% (n = 33), of which 22 were nurses and ten were patients. The response rate in the second Delphi round was 85% (n = 28) and consisted of 18 nurses and ten patients. Baseline characteristics, divided into autologous and allogeneic, are presented in Table 1 (nurses) and Table 2 (patients).

*Table 1

*Table 2

Missing data

Nurses and patients were contacted to supply missing information that occurred in both rounds. After these attempts, the percentage of missing data remained at less than 2%. Missing values of the questionnaires were not replaced because they were considered completely at random (MCAR).

First Delphi round

High consensus

In the first Delphi round, 16 categories reached “high consensus” for the autologous HSCT and 34 categories for the allogeneic HSCT. For the autologous HSCT, the category with the highest consensus (96%) was “e310 Immediate family”. For the allogeneic, “b455 Exercise tolerance functions”, “b545 Water, mineral and electrolyte balance functions”, “b810 Protective functions of the skin”, and “e310 Immediate family” reached high consensus (96%).

Moderate consensus

For the autologous HSCT, 30 ICF categories reached “moderate consensus” and 19 ICF categories for the allogeneic HSCT and were submitted again in the second Delphi round (Appendix C).

No consensus

The remaining categories did not reach consensus: 20 ICF categories for the autologous HSCT and 13 ICF categories for the allogeneic HSCT. These categories were excluded from

the final selection (Appendix D). The categories with the lowest level of consensus were the same for the autologous and allogeneic HSCT: “b310 Voice functions” (15% and 20% respectively) and “b235 Vestibulair functions” (19% and 28% respectively).

Qualitative data

Nurses and patients added 59 new subjects that were deemed relevant in the functioning of post-HSCT patients. These subjects varied from “problems with concentration” to “return into community”. The linking procedure resulted in 18 ICF categories, which were submitted to the questionnaire of the second Delphi round (Appendix E). Thirteen of those categories were in the component “activities and participation”, three in the component “environmental factors”, and two in the component “body functions”.

Second Delphi round

Moderate consensus.

The second Delphi round started with the 30 ICF categories with “moderate consensus” of the first Delphi round for autologous HSCT and 19 ICF categories for allogeneic HSCT (Appendix C), as well as, for both groups, the 18 ICF categories added by nurses and patients. For the autologous HSCT there was no ICF category with ≥ 70% disagreement; hence, all ICF categories were excluded from the final selection.

For the allogeneic HSCT 82% of the nurses and patients disagreed with the exclusion of the ICF category “d570 Looking after one's health”; hence, this ICF category was included in the final selection of relevant categories.

Added categories.

For both autologous and allogeneic HSCT, there was no ICF category with ≥70% disagreement for the categories that were added in the qualitative section. Therefore, all these ICF categories were included in the final selection of relevant categories.

Final selection of relevant categories

After the two Delphi rounds, the final selection of relevant ICF categories for the autologous HSCT patient totalled 34 and, for the allogeneic HSCT 53. Of these categories, ten are related to the component “body functions” for the autologous HSCT and 27 categories for the allogeneic HSCT. Participants added two categories.

For the autologous HSCT, 17 categories are related to the component “activities and participation”, and 19 categories for the allogeneic HSCT. Participants added thirteen categories.

Seven categories are related to the component environmental factors, for both the autologous HSCT and allogeneic HSCT. Participants added three categories.
The final selection of relevant ICF categories is presented in the ICF framework in Figure 3. Those ICF categories, together with the WHO description, are presented in Table 3.

*Figure 3
*Table 3

Discussion

The aim of the study was to identify the most relevant ICF categories in nursing care for functioning of hematology patients after HSCT in the period up to one year post-transplantation. The results demonstrate that 34 ICF categories are considered relevant for the functioning of autologous HSCT patients and 53 categories for the allogeneic HSCT patients. The 34 categories of the autologous HSCT are also deemed relevant for allogeneic HSCT as these are also represented in the final selection of 53 categories of the allogeneic HSCT. Most differences between the autologous and allogeneic HSCT were found in the component “body functions”. Most added categories in the qualitative section were related to the component “activities and participation”.

The difference in relevance of categories between autologous and allogeneic HSCT (mostly related to “body functions”) can be explained by the risk of the occurrence of GVHD for allogeneic HSCT patients. The clinical manifestations of GVHD occur mostly in the skin, gastrointestinal tract and liver.[36] This may explain why nurses and patients included categories such as “b525 Defecation functions”, “b820 Repair functions of the skin”, and “b860 Functions of nails” as relevant for the allogeneic but not for the autologous patients. More in-depth research is required to confirm the suggested relationship.

Most of the subjects added by nurses and patients in the qualitative section were related to the component “activities and participation”. This is in line with several studies published in recent years in which the importance of similar themes came to light.[38–41] The study of Johansson et al.[37] describes patients’ goals in the first thirteen months after allogeneic HSCT, and one of the important goals was “to participate in normal life”. Two other studies[39,40] describe the experienced difficulties of HSCT patients in returning to and participating in normal life as a result of economic and work concerns and financial hardship. However, all three studies confirmed that health care providers do not include these themes focused on activities and participation in their assessments of health care provision.
Recent literature reviews showed that many of HSCT patients’ needs, in psychological, physical, informational, financial, and spiritual domains, are unmet.[38] The researchers

describe that the improvement of patient-healthcare-provider communication could help to ensure that the treatment team is aware of patient's needs.
The use of the ICF could be a tool (i) to improve the assessments of health care providers and (ii) to align treatments with the need of the HSCT patients by improving communication between the health care provider and the patient because the ICF was developed to capture the overall health status of a patient.[41]

More than 25% of the nurses and patients added subjects related to concentration and memory in the qualitative section, resulting in the inclusion of the ICF categories "b140 Attention functions" and "b144 Memory functions" in the final selection. The relevance of these categories is underlined by two recent studies, published in 2016.[38,42] The review of Barata et al.[38] concluded that the most prevalent unmet needs for HSCT patients are psychological in nature, including cognitive problems. The study of Mayo et al.[42] shows that neurocognitive impairment is a major issue among HSCT patients and other cancer survivors and that the everyday functional impact of neurocognitive impairment remains relatively vague. This could explain why those subjects were added and were not found in the literature and report analysis.

To appreciate this study's findings some aspects require further consideration. First, nurses and patients were not selected randomly; all patients were selected via the patient association and the number of nurses and patients might be too few to sufficiently represent the HSCT population in the Netherlands. However, all eight universal medical centres of the Netherlands are represented in this study. Future research should investigate whether the outcomes of this study are generalizable to the HSCT population in the Netherlands and abroad. Secondly, all the "no consensus" level categories were removed from the final selection without further in depth consultation of the nurses and patients. However, from the "moderate consensus" level only one ICF category was ultimately added to the final selection. Lastly, no subgroup analysis was conducted between nurses and patients. Further research should investigate whether there is a difference between the opinions of nurses and patients.

The strength of this study is the participation of patients because their voice and views are of utmost importance in health care research. Secondly, many of the included nurses in the study had working experience in hematology-oncology nursing for at least 15 years, so the results are based on proven experience. Thirdly, reliability was achieved by giving nurses and patients the opportunity to review their individual responses in relation to the group response and to participants the opportunity to amend their response in favor of group

consensus. A further strength of the Delphi procedure is that nurses and patients anonymously completed the questionnaire to reduce social desirability.

Conclusion

This research provides a first step in the development of a core set for health professionals, which could be a standard for describing HSCT patients' functioning in clinical practice and research or evaluation of health care focusing on what really matters to HSCT patients.

Based on this study's findings the final selection of relevant categories consists of 34 ICF categories for the autologous HSCT and 53 categories for the allogeneic HSCT.

Pilot testing in clinical practice is the next step to confirm the core set's validity and applicability in clinical practice.

References

1. Leukemia & Lymphoma Society. Facts 2014-2015 [Internet]. [cited 2015 Oct 15]. Available from: https://www.lls.org/sites/default/files/file_assets/facts.pdf

2. European Society for Blood and Marrow Transplantation. Data Management [Internet]. [cited 2015 Oct 28]. Available from: https://www.ebmt.org/Contents/Data-Management/Pages/Data-Management.aspx

3. Gratwohl A, Baldomero H, Aljurf M, Pasquini MC, Bouzas LF, Yoshimi A, et al. Hematopoietic stem cell transplantation: a global perspective. JAMA. 2010 Apr 28;303(16):1617–24.

4. Ljungman P, Bregni M, Brune M, Cornelissen J, de Witte T, Dini G, et al. Allogeneic and autologous transplantation for haematological diseases, solid tumours and immune disorders: current practice in Europe 2009. Bone Marrow Transplant. 2010 Feb;45(2):219–34.

5. Lennard AL, Jackson GH. Stem cell transplantation. West J Med. 2001 Jul;175(1):42–6.

6. Mohty B, Mohty M. Long-term complications and side effects after allogeneic hematopoietic stem cell transplantation: an update. Blood Cancer J. 2011 Apr;1(4):e16.

7. Ferrara JLM, Levine JE, Reddy P, Holler E. Graft-versus-Host Disease. Lancet. 2009 May 2;373(9674):1550–61.

8. Horne B, Gilleece M, Jackson G, Snowden JA, Liebersbach S, Velikova G, et al. Psychosocial supportive care services for haematopoietic stem cell transplant patients; a service evaluation of three UK transplant centres. Eur J Cancer Care (Engl). 2014 May;23(3):349–62.

9. Champlin R. Selection of Autologous or Allogeneic Transplantation. 2003 [cited 2016 May 24]; Available from: http://www.ncbi.nlm.nih.gov.proxy.library.uu.nl/books/NBK12844/

10. Poloméni A, Lapusan S, Bompoint C, Rubio MT, Mohty M. The impact of allogeneic-hematopoietic stem cell transplantation on patients' and close relatives' quality of life and relationships. Eur J Oncol Nurs Off J Eur Oncol Nurs Soc. 2016 Apr;21:248–56.

11. Prieto JM, Blanch J, Atala J, Carreras E, Rovira M, Cirera E, et al. Psychiatric morbidity and impact on hospital length of stay among hematologic cancer patients receiving stem-cell transplantation. J Clin Oncol Off J Am Soc Clin Oncol. 2002 Apr 1;20(7):1907–17.

12. World Health Organization, editor. International classification of functioning, disability and health: ICF. Geneva: World Health Organization; 2001. 299 p.

13. Stallinga HA. Human functioning in health care: Application of the International Classification of Functioning, Disability and Health (ICF). Groningen: Rijksuniversiteit

Groningen; 2015.

14. Huber M, Knottnerus JA, Green L, van der Horst H, Jadad AR, Kromhout D, et al. How should we define health? BMJ. 2011;343:d4163.

15. Kaljauw M, van Vliet K. Naar nieuwe zorg en zorgberoepen: de contouren - Rapport - Rijksoverheid.nl [Internet]. 2015 [cited 2015 Nov 8]. Available from: https://www.rijksoverheid.nl/documenten/rapporten/2015/04/10/naar-nieuwe-zorg-en-zorgberoepen-de-contouren

16. Jambroes M, Nederland T, Kaljouw M, van Vliet K, Essink-Bot M-L, Ruwaard D. Implications of health as “the ability to adapt and self-manage” for public health policy: a qualitative study. Eur J Public Health. 2015 Dec 24;

17. V&VN. Leren van de toekomst. Verpleegkundigen & Verzorgenden 2020. Available from: http://www.venvn.nl/Portals/1/Nieuws/Ouder%20dan%202010/306254_1_Nl.pdf

18. Pruitt SD, Epping-Jordan JE. Preparing the 21st century global healthcare workforce. BMJ. 2005 Mar 19;330(7492):637–9.

19. Selb M, Escorpizo R, Kostanjsek N, Stucki G, Üstün B, Cieza A. A guide on how to develop an International Classification of Functioning, Disability and Health Core Set. Eur J Phys Rehabil Med. 2015 Feb;51(1):105–17.

20. Bickenbach J, Cieza A, Rauch A, Stucki G. ICF Core Sets: Manual for Clinical Practice For the ICF Research Branch, in Cooperation with the WHO Collaborating Centre for the Family of International Classifications in Germany (DIMDI). Hogrefe Publishing; 2012. 1559 p.

21. Stucki G, Cieza A, Ewert T, Kostanjsek N, Chatterji S, Ustün TB. Application of the International Classification of Functioning, Disability and Health (ICF) in clinical practice. Disabil Rehabil. 2002 Mar 20;24(5):281–2.

22. Cieza A, Ewert T, Ustün TB, Chatterji S, Kostanjsek N, Stucki G. Development of ICF Core Sets for patients with chronic conditions. J Rehabil Med. 2004 Jul;(44 Suppl):9–11.

23. Bartoszek G, Fischer U, von Clarenau SC, Grill E, Mau W, Meyer G, et al. Development of an International Classification of Functioning, Disability and Health (ICF)-based standard set to describe the impact of joint contractures on participation of older individuals in geriatric care settings. Arch Gerontol Geriatr. 2015 Aug;61(1):61–6.

24. ICF RESEARCH BRANCH - ICF Core Sets [Internet]. [cited 2015 Dec 12]. Available from: https://www.icf-research-branch.org/download/category/4-icf-core-sets

25. McKenna HP. The Delphi technique: a worthwhile research approach for nursing? J Adv Nurs. 1994 Jun;19(6):1221–5.

26. Polit DF, Beck CT. Nursing research: generating and assessing evidence for nursing

practice. Ninth Edition. Philadelphia: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2012. 802 p.

27. Keeney S, Hasson F, McKenna HP, Wiley InterScience (Online service). The Delphi technique in nursing and health research. Chichester, West Sussex: Wiley-Blackwell; 2011.

28. Keeney S, Hasson F, McKenna H. Consulting the oracle: ten lessons from using the Delphi technique in nursing research. J Adv Nurs. 2006 Jan;53(2):205–12.

29. Werf, van der S, Stellingwerf, B. Een weergave van het functioneren van patiënten op de verpleegafdeling Hematologie in ICF-categorieën. 2014.

30. Hagedoorn, K., Touw, van der M. ICF Core-Set na stamceltransplantatie. Een literatuurstudie. 2015.

31. Evans C. The use of consensus methods and expert panels in pharmacoeconomic studies. Practical applications and methodological shortcomings. PharmacoEconomics. 1997 Aug;12(2 Pt 1):121–9.

32. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustün B, Stucki G. ICF linking rules: an update based on lessons learned. J Rehabil Med. 2005 Jul;37(4):212–8.

33. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects [Internet]. [cited 2016 May 30]. Available from: http://www.wma.net/en/30publications/10policies/b3/index.html

34. Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000 Oct;32(4):1008–15.

35. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies. PLoS Med [Internet]. 2007 Oct [cited 2016 May 30];4(10). Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2020495/

36. Vogelsang GB, Lee L, Bensen-Kennedy DM. Pathogenesis and treatment of graft-versus-host disease after bone marrow transplant. Annu Rev Med. 2003;54:29–52.

37. Johansson E, Larsen J, Schempp T, Jonsson L, Winterling J. Patients' goals related to health and function in the first 13 months after allogeneic stem cell transplantation. Support Care Cancer Off J Multinatl Assoc Support Care Cancer. 2012 Sep;20(9):2025–32.

38. Barata A, Wood WA, Choi SW, Jim HSL. Unmet Needs for Psychosocial Care in Hematologic Malignancies and Hematopoietic Cell Transplant. Curr Hematol Malig Rep. 2016 Apr 25;

39. Sheldon LK, Kazmi M, Klein C, Berry DL. Concerns of stem cell transplant patients during routine ambulatory assessment. Patient Prefer Adherence. 2013 Jan 3;7:15–20.

40. Abel GA, Albelda R, Khera N, Hahn T, Salas Coronado DY, Odejide OO, et al. Financial Hardship and Patient-Reported Outcomes after Hematopoietic Cell Transplantation. Biol Blood Marrow Transplant J Am Soc Blood Marrow Transplant. 2016 May 13;

41. Nederlandse WHO Collaborating Centre for the Family of International Classifications. ICF: Nederlandse vertaling van de International Classification of Functioning, Disability and Health. Houten [etc.]: Bohn Stafleu Van Loghum; 2007.

42. Mayo S, Messner HA, Rourke SB, Howell D, Victor JC, Kuruvilla J, et al. Relationship between neurocognitive functioning and medication management ability over the first 6 months following allogeneic stem cell transplantation. Bone Marrow Transplant. 2016 Feb 29;

Figures and Tables

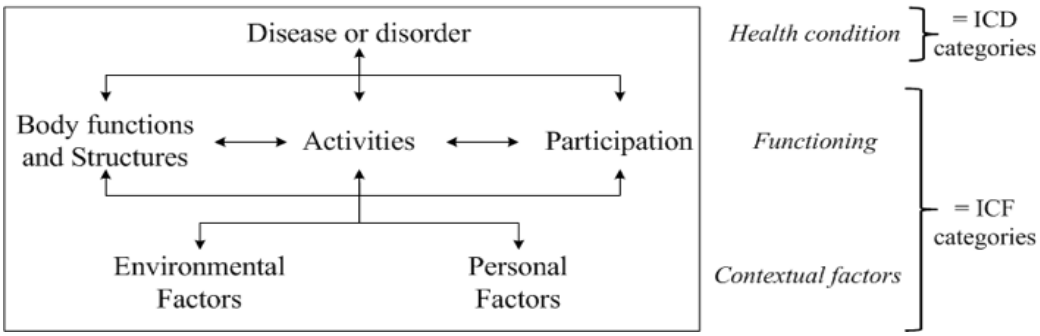

Figure 1. WHO's conceptual model of health representing the interactions between the components (disease, body functions and structures, activities, participation, environmental and personal factors) of the health status.[12]
Note: ICD: International Classification of Diseases; ICF: International Classification of Functioning, Disability and Health.

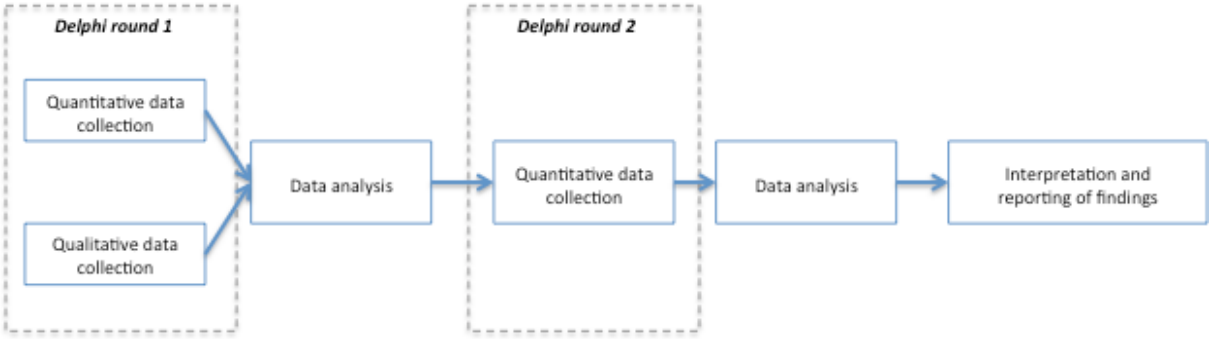

Figure 2. Design of the two-round Delphi study.

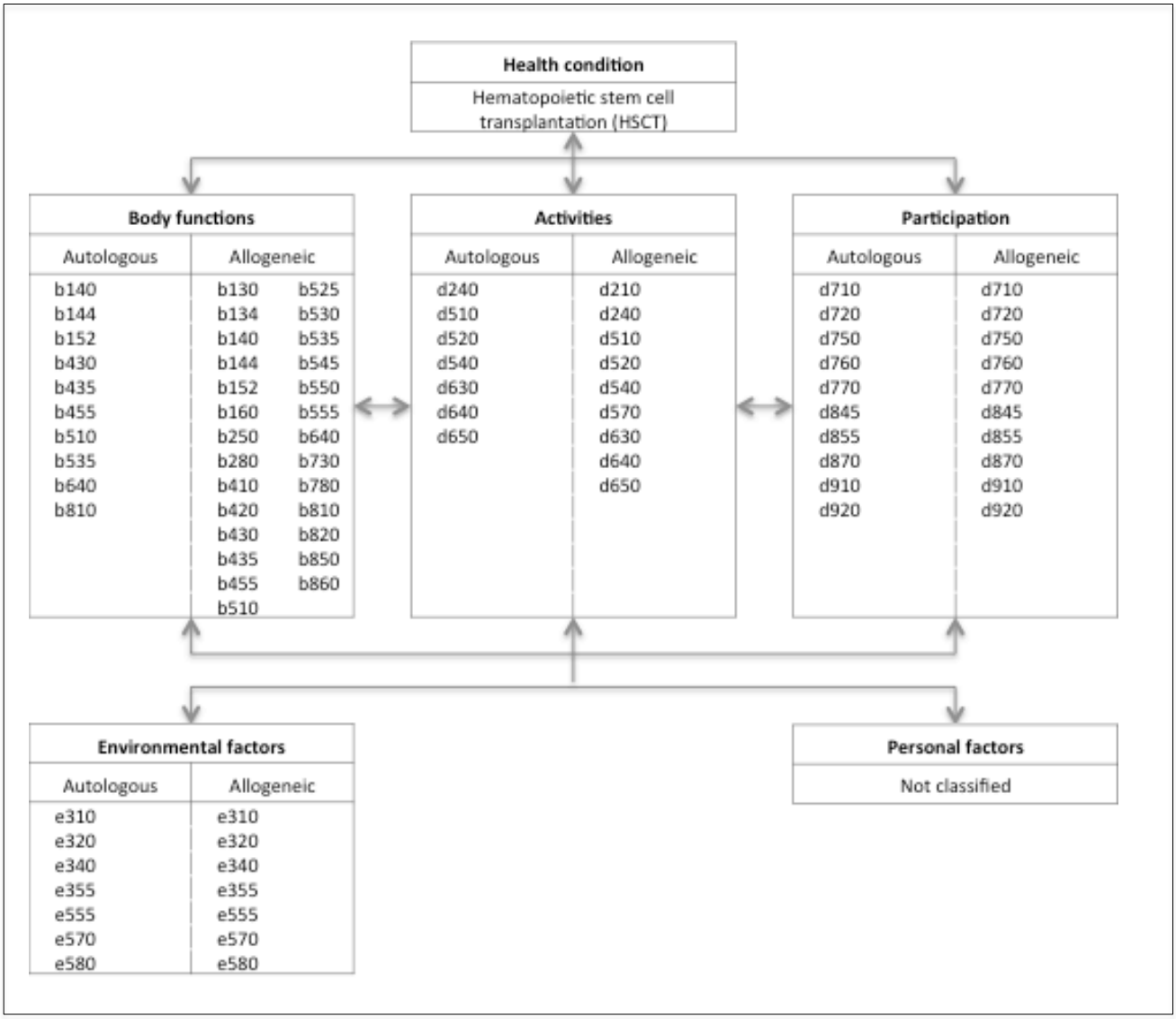

Figure 3. Relevant ICF categories for autologous and allogeneic hematopoietic stem cell transplantation (HSCT) displayed in the conceptual model of Health, developed by the WHO.[12]

Table 1

Baseline characteristics nurses

	Delphi Round 1				Delphi Round 2			
Type HSCT*	Autologous n = 20		Allogeneic n = 19		Autologous n = 16		Allogeneic n = 16	
Gender	n	%	n	%	n	%	n	%
Female	17	85	15	78.9	14	87.5	13	81.3
	M	SD	M	SD	M	SD	M	SD
Age	41.4	10.7	41.2	11.7	42.6	10.5	42.2	11.5
	M	SD	M	SD	M	SD	M	SD
Working experience in hematology-oncology (years active)	15.3	9.5	15.1	9.8	16.6	9.9	16.4	10.0
Setting	n	%	n	%	n	%	n	%
Hospital	11	55	10	52.6	8	50.0	7	43.8
Outpatient clinic	9	45	9	47.4	8	50.0	9	56.3

Note. HSCT = Hematopoietic stem cell transplantation, M = mean, SD = standard deviation.
* In the first Delphi round 17 nurses completed the questionnaire for both autologous and allogeneic, in the second Delphi round 14 nurses.

Table 2

Baseline characteristics patients

	Delphi Round 1 & 2			
Type HSCT*	Autologous n = 6		Allogeneic n = 6	
Gender	n	%	n	%
Female	4	66.7	3	50.0
	M	SD	M	SD
Age	61.5	8.2	58,8	5.6
Years after HSCT (post-HSCT)	n	%	n	%
0-1 year	1	16.7	-	-
1-2 year	2	33.3	-	-
2-3 year	1	16.7	3	50.0
> 5 year	2	33.3	3	50.0

Note. HSCT = Hematopoietic stem cell transplantation, M = mean, SD = standard deviation.
* First and second Delphi round: 2 patients completed the questionnaire for both autologous and allogeneic.

Table 3

Final selection of relevant categories for the autologous and allogeneic HSCT accompanied by a description of the World Health Organisation.

ICF code	ICF category	Autologous	Allogeneic
Component Body Functions			
Chapter b1 Mental functions			
b130	Energy and drive functions		X
b134	Sleep functions		X
b140	Attention functions	X	X
b144	Memory functions	X	X
b152	Emotional functions	X	X
b160	Thought functions		X
Chapter b2 Sensory functions and pain			
b250	Taste function		X
b280	Sensation of pain		X
Chapter b4 Functions of the cardiovascular, haematological, immunological and respiratory systems			
b410	Heart functions		X
b420	Blood pressure functions		X
b430	Hematological system functions	X	X
b435	Immunological system functions	X	X
b455	Exercise tolerance functions	X	X
Chapter b5 Functions of the digestive, metabolic and endocrine systems			
b510	Ingestion functions	X	X
b525	Defecation functions		X
b530	Weight maintenance functions		X
b535	Sensations associated with the digestive system	X	X
b545	Water, mineral and electrolyte balance functions		X
b550	Thermoregulatory functions		X
b555	Endocrine gland functions		X
Chapter b6 Genitourinary and reproductive functions			
b640	Sexual functions	X	X
Chapter b7 Neuromusculosketal and movement-related functions			
b730	Muscle power functions		X
b780	Sensations related to muscles and movement functions		X
Chapter b8 Functions of the skin and related structures			
b810	Protective functions of the skin	X	X
b820	Repair functions of the skin		X
b850	Functions of hair		X
b860	Functions of nails		X
Component Activities and Participation			
Chapter d2 General tasks and demands			
d210	Undertaking a single task		X
d240	Handling stress and other psychological demands	X	X
Chapter d5 Self-care			
d510	Washing oneself	X	X

d520	Caring for body parts	X	X
d540	Dressing	X	X
d570	Looking after one's health		X
Chapter d6 Domestic life			
d630	Preparing meals	X	X
d640	Doing housework	X	X
d650	Caring for household objects	X	X
Chapter d7 Interpersonal interactions and relationships			
d710	Basic interpersonal interactions	X	X
d720	Complex interpersonal interactions	X	X
d750	Informal social relationships	X	X
d760	Family relationships	X	X
d770	Intimate relationships	X	X
Chapter d8 Major life areas			
d845	Acquiring, keeping and terminating a job	X	X
d855	Remunerative employment	X	X
d870	Economic self-sufficiency	X	X
Chapter d9 Community, social and civic life			
d910	Community life	X	X
d920	Recreation and leisure	X	X
Component Environmental Factors			
Chapter e3 Support and relationships			
e310	Immediate family	X	X
e320	Friends	X	X
e340	Personal care providers and personal assistants	X	X
e355	Health professionals	X	X
Chapter e5 Services, systems and policies			
e555	Legal services, systems and policies	X	X
e570	Social security, services, systems and policies	X	X
e580	Health services, systems and policies	X	X

Note. 'X' = category is included in the final selection of relevant categories. Shaded rows represent the categories added by participants.

Abstract

Background: The number of patients undergoing hematopoietic stem cell transplantation (HSCT) is growing worldwide. The treatment has a major impact on the daily functioning of patients. In improving one's health, patients' functioning should be included as a focus in health care. Functioning can be described with the International Classification of Functioning, Disability, and Health (ICF). The ICF describes all aspects of health and well-being in terms of human functioning within the components "body functions and body structures", "activities and participation", and "environmental factors".

Aim: To identify the most relevant ICF categories for the functioning of hematology patients after autologous and allogeneic stem cell transplantation.

Method: A two-round Delphi study was performed with an exploratory, sequential mixed methods design to reach consensus on relevance of ICF categories. Participants were 33 nurses of the eight universal medical centres in the Netherlands and 10 patients via a patient association. In both rounds participants ranked the relevance of ICF categories in a quantiative section. In the first round participants could add aspects (qualitative section) they missed in the quantitative part of the first round.

Results: After two rounds consensus was reached on 34 categories for the autologous and 53 categories for the allogeneic HSCT. All 34 categories for the autologous HSCT are also represented in the 53 categories for the allogeneic HSCT. Most categories added by participants were related to the component "activities and participation".

Conclusion and implications: This research provides a step toward the development of a core set for health professionals, which could be a standard for describing HSCT patients' functioning in clinical practice, and research or evaluation of health care focusing on what matters to those affected. Pilot testing in clinical practice is the next to step to confirm the core set's validity and applicability.

Key words: hematopoietic stem cell transplantation, functioning, International Classification of Functioning, Disability and Health, ICF

Dutch summary

Achtergrond: Wereldwijd is er een groeiend aantal patiënten die een hematopoietische stamceltransplantatie (HSCT) ondergaat. Deze behandeling heeft grote impact op het dagelijks functioneren van patiënten. Voor het bevorderen van gezondheid van patiënten is het belangrijk om functioneren als focus van zorg te nemen. Functioneren kan beschreven worden met behulp van de International Classification of Functioning, Disability and Health (ICF). In de ICF worden alle aspecten van gezondheid en welzijn beschreven in termen van menselijk functioneren, binnen de componenten 'lichaamsfuncties en lichaamsstructuren', 'activiteiten en participatie' en 'omgevingsfactoren'.

Doel: Het identificeren van de meest relevante ICF categorieën voor het functioneren van hematologische patiënten na autologe en allogene stamceltransplantatie.

Methode: Exploratief, sequentieel mixed methods design. De Delphi methode is gebruikt om met behulp van twee rondes overeenstemming over relevantie in ICF categorieën te bereiken. Deelnemers waren 33 verpleegkundigen van de acht universitaire medische centra in Nederland en 10 patiënten via een patiëntenvereniging. In beide rondes beoordeelden deelnemers de relevantie van ICF categorieën. In de eerste ronde konden aspecten toegevoegd worden die werden gemist in het kwantitatieve deel van de eerste ronde.

Resultaten: Na twee ronden was consensus bereikt over 34 categorieën voor de autologe en 53 categorieën voor de allogene HSCT. De 34 categorieën voor de autologe HSCT waren ook vertegenwoordigd in de 53 categorieën van de allogene HSCT. De meerderheid van de door het panel toegevoegde categorieën was gerelateerd aan de component 'activiteiten en participatie'.

Conclusie en implicaties: Dit onderzoek is een volgende stap in de ontwikkeling van een kernset als standaard voor het beschrijven van het functioneren van HSCT patiënten in de klinische praktijk, en voor onderzoek en evaluatie van de gezondheidszorg zodat die zich focust op wat patiënten belangrijk vinden. Een pilot in de praktijk is een volgende stap om de validiteit en toepasbaarheid van de kernset te onderzoeken.

Trefwoorden: hematopoietische stamceltransplantatie, functioneren, International Classification of Functioning, Disability and Health, ICF

Appendix A: 66 ICF categories questionnaire first Delphi round

ICF code	ICF category
Component Body Function	
Chapter b1 Mental functions	
b110	Energy and drive functions
b114	Orientation functions
b117	Intellectual functions
b126	Temperament and personality functions
b130	Energy and drive functions
b134	Sleep functions
b152	Emotional functions
b156	Perceptual functions
b160	Thought functions
b164	Higher-level cognitive functions
b180	Experience of self and time functions
Chapter b2 Sensory functions and pain	
b210	Seeing functions
b235	Vestibular functions
b240	Sensations associated with hearing and vestibular function
b250	Taste function
b265	Touch function
b270	Sensory functions related to temperature and other stimuli
b280	Sensation of pain
Chapter b3 Voice and speech functions	
b310	Voice functions
Chapter b4 Functions of the cardiovascular, haematological, immunological and respiratory systems	
b410	Heart functions
b420	Blood pressure functions
b430	Hematological system functions
b435	Immunological system functions
b440	Respiration functions
b450	Additional respiratory functions
b455	Exercise tolerance functions
b460	Sensations associated with cardiovascular and respiratory functions
Chapter b5 Functions of the digestive, metabolic and endocrine systems	
b510	Ingestion functions
b525	Defecation functions
b530	Weight maintenance functions
b535	Sensations associated with the digestive system
b540	General metabolic functions
b545	Water, mineral and electrolyte balance functions
b550	Thermoregulatory functions
b555	Endocrine gland functions
Chapter b6 Genitourinary and reproductive functions	
b610	Urinary functions
b620	Urination functions
b640	Sexual functions
Chapter b7 Neuromusculosketal and movement-related functions	
b730	Muscle power functions
b760	Control of voluntary movement functions
b770	Gait pattern functions
b780	Sensations related to muscles and movement functions

Chapter b8 Functions of the skin and related structures	
b810	Protective functions of the skin
b820	Repair functions of the skin
b830	Other functions of the skin
b840	Sensation related to the skin
b850	Functions of hair
b860	Functions of nails
Component Activities and Participation	
Chapter d2 General tasks and demands	
d210	Undertaking a single task
d240	Handling stress and other psychological demands
Chapter d3 Communication	
d330	Speaking
Chapter d4 Mobility	
d410	Changing basic position
d415	Maintaining a body position
d450	Walking
Chapter d5 Self-care	
d550	Eating
d560	Drinking
d570	Looking after one's health
Chapter d7 Interpersonal interactions and relationships	
d770	Intimate relationships
Chapter d8 Major life areas	
d845	Acquiring, keeping and terminating a job
Chapter d9 Community, social and civic life	
d920	Recreation and leisure
Component Environmental Factors	
Chapter e1 Products and technology	
e165	Assets
Chapter e3 Support and relationships	
e310	Immediate family
e320	Friends
e355	Health professionals
Chapter e4 Attitudes	
e410	Individual attitudes of immediate family members
Chapter e5 Services, systems and policies	
e580	Health services, systems and policies

Appendix B: Categories with high consensus after the first Delphi round

ICF code	ICF category	Autologous (consensus in %)	Allogeneic (consensus in %)
Component Body Functions			
Chapter b1 Mental functions			
b130	Energy and drive functions	X	72
b134	Sleep functions	X	72
b152	Emotional functions	73	80
b160	Thought functions	X	72
Chapter b2 Sensory functions and pain			
b250	Taste function	X	72
b280	Sensation of pain	X	72
Chapter b4 Functions of the cardiovascular, haematological, immunological and respiratory systems			
b410	Heart functions	X	80
b420	Blood pressure functions	X	72
b430	Hematological system functions	85	80
b435	Immunological system functions	89	92
b455	Exercise tolerance functions	81	96
Chapter b5 Functions of the digestive, metabolic and endocrine systems			
b510	Ingestion functions	81	88
b525	Defecation functions	X	80
b530	Weight maintenance functions	X	88
b535	Sensations associated with the digestive system	81	80
b545	Water, mineral and electrolyte balance functions	X	96
b550	Thermoregulatory functions	X	76
b555	Endocrine gland functions	X	80
Chapter b6 Genitourinary and reproductive functions			
b640	Sexual functions	73	76
Chapter b7 Neuromusculosketal and movement-related functions			
b730	Muscle power functions	X	72
b780	Sensations related to muscles and movement functions	X	72
Chapter b8 Functions of the skin and related structures			
b810	Protective functions of the skin	73	96
b820	Repair functions of the skin	X	84
b850	Functions of hair	X	80
b860	Functions of nails	X	76
Component Activities and Participation			
Chapter d2 General tasks and demands			
d210	Undertaking a single task	X	72
d240	Handling stress and other psychological demands	81	92
Chapter d7 Interpersonal interactions and relationships			
d770	Intimate relationships	89	88
Chapter d8 Major life areas			
d845	Acquiring, keeping and terminating a job	77	88
Chapter d9 Community, social and civic life			
d920	Recreation and leisure	85	88
Component Environmental Factors			

Chapter e3 Support and relationships			
e310	Immediate family	96	96
e320	Friends	92	92
e355	Health professionals	77	84
Chapter e5 Services, systems and policies			
e580	Health services, systems and policies	77	80

*Note: '*X': category did not reach the 'high consensus' level

Appendix C Categories with moderate consensus after the first Delphi round and applied in the second Delphi Round

ICF code	ICF category	Autologous (disagreement with exclusion in %)	Allogeneic (disagreement with exclusion in %)
Component Body Functions			
Chapter b1	**Mental functions**		
b126	Temperament and personality functions	59	55
b130	Energy and drive functions	64	X
b134	Sleep functions	50	X
b156	Perceptual functions	36	36
b160	Thought functions	46	X
b164	Higher-level cognitive functions	41	50
b180	Experience of self and time functions	50	46
Chapter b2	**Sensory functions and pain**		
b210	Seeing functions	X	59
b235	Vestibular functions	X	X
b250	Taste functions	46	X
b270	Sensory functions related to temperature and other stimuli	X	32
b280	Sensation of pain	55	X
Chapter b4	**Functions of the cardiovascular, haematological, immunological and respiratory systems**		
b410	Heart functions	46	X
b420	Blood pressure functions	27	X
b440	Respiration functions	32	36
b460	Sensations associated with cardiovascular and respiratory functions	27	41
Chapter b5	**Functions of the digestive, metabolic and endocrine systems**		
b525	Defecation functions	18	X
b530	Weight maintenance functions	50	X
b540	General metabolic functions	18	41
b545	Water, mineral and electrolyte balance functions	27	X
b550	Thermoregulatory functions	36	X
b555	Endocrine gland functions	46	X
Chapter b6	**Genitourinary and reproductive functions**		
b610	Urinary excretory functions	18	23
b620	Urination functions	X	50
Chapter b7	**Neuromusculosketal and movement-related functions**		
b730	Muscle power functions	46	X
b780	Sensations related to muscles and movement functions	32	X
Chapter b8	**Functions of the skin and related structures**		
b820	Repair functions of the skin	27	X
b840	Sensation related to the skin	59	55
b850	Functions of hair	50	X
b860	Functions of nails	18	X
Component Activities and Participation			
Chapter d2	**General tasks and demands**		
d210	Undertaking a single task	18	X

Chapter d3 Communication			
d330	Speaking	X	27
Chapter d4 Mobility			
d410	Changing basic body position	23	18
d415	Maintaining a body position	5	14
d450	Walking	9	27
Chapter d5 Self-care			
d550	Eating	32	23
d570	Looking after one's health	59	82
Component Environmental Factors			
Chapter e4 Attitudes			
e410	Individual attitudes of immediate family members	23	5

*Note: '*X': category did not reach the 'moderate consensus' level

Appendix D Categories with no consensus after the first Delphi round

ICF code	ICF category	Autologous (consensus in %)	Allogeneic (consensus in %)
Component Body Functions			
Chapter b1 Mental functions			
b110	Energy and drive functions	46	40
b114	Orientation functions	35	48
b117	Intellectual functions	31	44
Chapter b2 Sensory functions and pain			
b210	Seeing functions	23	X
b235	Vestibular functions	19	28
b240	Sensations associated with hearing and vestibular function	39	44
b265	Touch function	39	44
b270	Sensory functions related to temperature and other stimuli	39	X
Chapter b3 Voice and speech functions			
b310	Voice functions	15	20
Chapter b4 Functions of the cardiovascular, haematological, immunological and respiratory systems			
b450	Additional respiratory functions	X	32
b460	Sensations associated with cardiovascular and respiratory functions	46	X
Chapter b5 Functions of the digestive, metabolic and endocrine systems			
b540	General metabolic functions	42	X
Chapter b6 Genitourinary and reproductive functions			
b610	Urinary functions	46	X
b620	Urination functions	31	X
Chapter b7 Neuromusculoskeletal and movement-related functions			
b760	Control of voluntary movement functions	27	32
b770	Gait pattern functions	35	36
Chapter b8 Functions of the skin and related structures			
b830	Other functions of the skin	39	48
Component Activities and Participation			
Chapter d3 Communication			
d330	Speaking	39	X
Chapter d5 Self-care			
d560	Drinking	42	48
Component Environmental Factors			
Chapter e1 Products and technology			
e165	Assets	42	48

Appendix E Categories added by nurses and patients in the first Delphi round

ICF code	ICF category	Autologous (disagreement with inclusion in %)	Allogeneic (disagreement with inclusion in%)
Component Body Functions			
Chapter b1 Mental functions			
b140	Attention functions	18	9
b144	Memory functions	9	0
Component Activities and Participation			
Chapter d5 Self-care			
d510	Washing oneself	18	14
d520	Caring for body parts	18	14
d540	Dressing	27	23
Chapter d6 Domestic life			
d630	Preparing meals	27	23
d640	Doing housework	23	23
d650	Caring for household objects	36	36
Chapter d7 Interpersonal interactions and relationships			
d710	Basic interpersonal interactions	23	27
d720	Complex interpersonal interactions	23	14
d750	Informal social relationships	14	23
d760	Family relationships	9	18
Chapter d8 Major life areas			
d855	Remunerative employment	36	36
d870	Economic self-sufficiency	9	5
Chapter d9 Community, social and civic life			
d910	Community life	14	9
Component Environmental factors			
Chapter e3 Support and relationships			
e340	Personal care providers and personal assistants	18	23
Chapter e5 Services, systems and policies			
e555	Health professionals	27	14
e570	Social security services, systems and policies	18	0