

Cover Page



Universiteit Leiden



The handle <http://hdl.handle.net/1887/20218> holds various files of this Leiden University dissertation.

Author: Vries, Martine Charlotte de

Title: The moral landscape of pediatric oncology : an empirical study on best interests, parental authority and child participation in decision making

Issue Date: 2012-11-28

Addendum

REFERENCES
ABBREVIATIONS
SAMENVATTING
CURRICULUM VITAE
DANKWOORD
PUBLICATIONS

REFERENCES

- Ablett S, Doz F, Morland B, Vassal G, New Agents Group of the United Kingdom Children's Cancer Study Group (UKCCSG), Pharmacology Group of the French Society of Paediatric Oncology (SFOP). European collaboration in trials of new agents for children with cancer. *Eur J Cancer.* 2004;40:1886-1892.
- Ablett S, Pinkerton CR, United Kingdom Children's Cancer Study Group (UKCCSG). Recruiting children into cancer trials - role of the United Kingdom Children's Cancer Study Group (UKCCSG). *Br J Cancer.* 2003;88:1661-1665.
- Abrams AN, hazen EP, Penson RT. Psychosocial issues in adolescents with cancer. *Cancer Treat Rev.* 2007;33:622-630.
- Alderson P. In the genes or in the stars? Children's competence to consent. *J Med Ethics.* 1992;18(3):119-24.
- American Cancer Society [Internet]. Cancer facts and figures 2007. Atlanta: American Cancer Society; 2007. Available at: <http://www.cancer.org/acs/groups/content/@nho/documents/document/caff2007pwsecuredpdf.pdf>.
- American Federation of Clinical Oncology Societies. Access to quality cancer care: consensus statement. *J Clin Oncol.* 1998;16:1628-1630.
- American Academy of Pediatrics, Committee on Bioethics. Informed Consent, Parental Permission, and Assent in Pediatric Practice. *Pediatrics.* 1995;95(2):314-317.
- Anderson RA, Weddell A, Spoudeas HA, Douglas C, Shalet SM, Levitt G, et al. Do doctors discuss fertility issues before they treat young patients with cancer? *Hum Reprod.* 2008;23:2246-2251.
- Appelbaum PS. Clarifying the ethics of clinical research: a path toward avoiding the therapeutic misconception. *Am J Bioeth.* 2002;2:22-3.
- Appelbaum PS, Lidz CW, Grisso T. Therapeutic misconception in clinical research: frequency and risk factors. *IRB.* 2004;26:1-8.
- Appelbaum PS, Lidz CW, Klitzman R. Voluntariness of consent to research. A conceptual model. *Hastings Cent Rep.* 2009; 39(1):30-39.
- Appelbaum PS, Roth LH, Lidz CW. The therapeutic misconception: informed consent in psychiatric research. *Int J Law Psychiatry.* 1982;5:319-29.
- Appelbaum PS, Roth LH, Lidz CW, Benson P, Winslade W. False hopes and best data: consent to research and the therapeutic misconception. *Hastings Cent Rep.* 1987;17:20-24.
- Archard DW. Children, family and the state. Hampshire: Ashgate Publishing Limited; 2003.
- Audi R. The axiology of moral experience. *J Ethics.* 1998;2:355-375.
- Bahadur G, Ling KLE, Hart R, Ralph D, Riley V, Wafa R, et al. Semen production in adolescent cancer patients. *Hum Reprod.* 2002; 17(10):2654-2656.
- Bailes J. Managed care and oncology: the quality debate. *J Clin Oncol.* 2000;18:705-707.
- Baines P. Medical ethics for children: applying the four principles to paediatrics. *J Med Ethics.* 2008;34:141-145.
- Beauchamp TL, Childress JF. Principles of biomedical ethics. 6th Revised edition. Oxford: Oxford University Press; 2009.

- Bensing J. Bridging the gap. The separate worlds of evidence-based medicine and patient-centered medicine. *Patient Educ Couns.* 2000;39:17-25.
- Berger O, Grønberg BH, Sand K, Kaasa S, Loge JH. The length of consent documents in oncological trials is doubled in twenty years. *Ann Oncol.* 2009;20(2):379-385.
- Besselink MGH, Santvoort HC van, Buskens E, Boermeester MA, Goor H van, Timmerman HM, et al. Probiotic prophylaxis in predicted severe acute pancreatitis: a randomised, double-blind, placebo-controlled trial. *Lancet.* 2008a;371:651-9.
- Besselink MGH, Santvoort HC van, Buskens E, Boermeester MA, Goor H van, Timmerman HM, et al. Probioticcaprofylaxe bij voorspeld ernstige acute pancreatitis: een gerandomiseerde, dubbelblinde, placebogecontroleerde trial. *Ned Tijdschr Geneeskd.* 2008b;152:685-96.
- Blanchard CG, Labrecque MS, Ruckdeschel JC, Blanchard EB. Information and decision-making preferences of hospitalized adult cancer patients. *Soc Sci Med.* 1988;27:1139-45.
- Bleyer WA. The US pediatric cancer clinical trials programmes: international implications and the way forward. *Eur J Cancer.* 1997;33:1439-1447.
- Borry P, Dierickx K, Schotsmans P. The Birth of the Empirical Turn in Bioethics. *Bioethics.* 2005;19(1):49-71.
- Borry P, Schotsmans P, Dierickx K. Editorial: Empirical ethics: A challenge to bioethics. *Medicine, Health Care and Philosophy* 2004;7(1):1-3.
- Bredenoord AL. Ethics at the interface of reproductive medicine and genetic technology: the case of mitochondrial disorders [dissertation]. Ridderkerk: Ridderprint BV; 2010.
- Britten N. Qualitative interviews in medical research. *BMJ.* 1995;311:251-253.
- Brody JL, Annett RD, Scherer DG, Perryman ML, Cofrin KM. Comparisons of adolescent and parent willingness to participate in minimal and above minimal risk pediatric asthma research. *J Adolesc Health.* 2005;27:229-235.
- Broome ME, Richards DJ, Hall JM. Children in research: the experience of ill children and adolescents. *J Fam Nurs.* 2001;7:32-49.
- British Fertility Society [Internet]. A strategy for fertility services for survivors of childhood cancer. July 2003. Available at: <http://www.britishfertilitysociety.org.uk/practicepolicy/documents/fcc-paper.pdf>.
- British Royal College of Pediatrics. Guidelines for the ethical conduct of medical research involving children, *Arch Dis Child.* 2000;82,177-182.
- Buchanan A, Brock D. Deciding for Others: The Ethics of Surrogate Decision Making. New York: Cambridge University Press; 1989.
- Carroll KW, Mollen CJ, Aldridge S, Hexem KR, & Feudtner C. Influences on decision making identified by parents of children receiving pediatric palliative care. *AJOB Primary Research* 2012;3(1):1-7.
- Chappuy H, Baruchel A, Leverger G, Oudot C, Brethon B, Haouy S, et al. Parental comprehension and satisfaction in informed consent in paediatric clinical trials: a prospective study on childhood leukaemia. *Arch Dis Child.* 2010;95(10):800-804.
- Chappuy H, Doz F, Blanche S, Gentet JC, Tréluyer JM. Children's Views on Their Involvement in Clinical Research. *Pediatr Blood Cancer.* 2008;50(5):1043-1046.

- Charles C. Gafni A. Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med.* 1997;44:681-92.
- Code of Federal Regulations. 45 CFR 46:116–117. Federal Policy for the Protection of Human Subjects (Subpart A). Washington, DC: United States Department of Health and Human Services; 1991.
- Collins JA, Fauser BCJM. Balancing the strengths of systematic narrative reviews. *Hum Reprod Update.* 2005;11(2):103-104.
- Committee on Bioethics of the American Academy of Pediatrics. Informed consent, parental permission, and assent in pediatric practice. *Pediatrics.* 1995;95:314-317.
- Committee on Drugs, American Academy of Pediatrics. Guidelines for the ethical conduct of studies to evaluate drugs in pediatric populations. *Pediatrics.* 1995;95:286-294.
- Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Biomedical Research Involving Human Subjects. November 2002. Available at: http://www.cioms.ch/publications/layout_guide2002.pdf.
- Council of Europe. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine. European treaty series 164. Oviedo: Council of Europe, 4 April 1997. Available at: <http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm>.
- Coyne I. Disruption of parent participation: nurses' strategies to manage parents on children's wards. *J Clin Nurs.* 2007;17:3150-3158.
- Cramer K, Wiebe N, Moyer V, Hartling L, Williams K, Swingler G, et al. Children in reviews: methodological issues in child-relevant evidence syntheses. *BMC Pediatr.* 2005;5:38.
- Crawshaw MA, Glaser AW, Pacey AA. The use of pornographic materials by adolescent male cancer patients when banking sperm in the UK: Legal and ethical dilemmas. *Hum Fertil.* 2007;10(3):159-163.
- D'Aloja E, Floris L, Muller M, Birocchi F, Fanos V, Paribello F, et al. Shared decision-making in neonatology: an utopia or an attainable goal? *J Matern Fetal Neonatal Med.* 2010;23(S3):56-58.
- Daniels N. Wide Reflective Equilibrium and Theory Acceptance in Ethics. *J Philos.* 1979;76(5):256-282.
- Daniels N. Justice and Justification. Reflective Equilibrium in Theory and Practice. Cambridge: Cambridge University Press; 1996.
- Davis, DS. Genetic dilemmas and the child's right to an open future. *Hastings Cent Rep.* 1997;27(2):7-15.
- Davis D. Genetic Dilemmas: Reproductive Technology, Parental Choice, and Children's Futures. New York: Routledge; 2001.
- De Beaufort I, Van de Vathorst S, Hazebroek F, Van der Heiden B, Leeuwenburgh-Pronk W, Aartsen H, editors. Kwetsbare kinderen: een ethische zorg. Casus en commentaren. Den Haag: Uitgeverij LEMMA; 2008.
- Decker C, Phillips CR, Haase JE. Information needs of adolescents with cancer. *J Pediatr Oncol Nurs.* 2004;21:327-334.
- Denzin NK, Lincoln Y, editors. Handbook of qualitative research. Thousand Oaks: Sage Publications; 2000.

- DePaul MR. Balance and Refinement. Beyond Coherence Methods of Moral Inquiry. London/New York: Routledge; 1993.
- Dermatis H, Lesko LM. Psychological distress in parents consenting to child's bone marrow transplantation. *Bone Marrow transplant*. 1990;6:411-417.
- De Vries MC, Bresters D, Engberts DP, Wit JM, Van Leeuwen E. Attitudes of physicians and parents towards discussing infertility risks and semen cryopreservation with male adolescents diagnosed with cancer. *Pediatr Blood Cancer*. 2009;53(3):386-391.
- De Vries MC, Houtlosser M, Egeler RM. Informed consent en het persoonlijk perspectief. Het toestemmingsbeginsel in de Kinderoncologie (Informed consent and the personal view. The consent principle in paediatric oncology). *Tijdschrift voor Kindergeneeskunde*. 2005;73(5):161-165.
- De Vries MC, Van Leeuwen E. Reflective equilibrium and empirical data. Third person moral experiences in empirical medical ethics. *Bioethics*. 2010;24(9):490-498.
- De Vries MC, Wit JM, Engberts DP, Kaspers GJL, Van Leeuwen E. Norms versus Practice: Pediatric Oncologists' Attitudes towards Involving Adolescents in Decision Making concerning Research Participation. *Pediatr Blood Cancer*. 2010;55(1):123-128.
- De Vries R, Gordijn B. Empirical ethics and its alleged meta-ethical fallacies. *Bioethics*. 2009; 23(4): 193-201.
- Denzin NK, Lincoln Y, editors. Handbook of qualitative research. Thousand Oaks: Sage Publications; 2000.
- Dickens BM, Cook RJ. Adolescents and consent to treatment. *Int J Gynecol Obstet*. 2005;89:179-184.
- Diekema DS. Parental refusals of medical treatment: the harm principle as threshold for state intervention. *Theor Med Bioeth*. 2004;25:243-264.
- Directive 2001/20/EC of the European parliament and of the council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Official Journal of the European Communities 2001;L121:34-44. Available at: http://europa.eu.int/eur-lex/en/lif/dat/2001/en_301L0020.html.
- Dixon-Woods M, Fitzpatrick R, Roberts K. Including qualitative research in systematic reviews: opportunities and problems. *J Eval in Clin Pract*. 2001; 7(2):125-133.
- Dorn LD, Susman EJ, Fletcher JC. Informed consent in children and adolescents: age, maturation and psychological state. *J Adolesc Health*. 1995;16:185-190.
- Downie RS, Randall F. Parenting and the best interests of minors. *Journal Med Philos*. 1997;22(3):219-231.
- Dutch Childhood Oncology Group. Protocol DCOG ALL-10. Treatment study protocol of the Dutch Childhood Oncology Group for children with newly diagnosed acute lymphoblastic leukemia. Revised version 1.2 (08.08.2007).
- Dupuis HM. Verplichte diagnostiek en behandeling van pasgeborenen? In: De Wert GMWR, De Beaufort ID, editors. *Op de drempel van het leven*, Baarn: Ambo; 1991.
- Düwell M. Wofür braucht die Medizinethik empirische Methoden? Eine normativ-ethische Untersuchung. *Ethik Med*. 2009;21:201-211.

- Eder ML, Yamokoski AD, Wittmann PW, Kodish ED. Improving informed consent: suggestions from parents of children with leukemia. *Pediatrics*. 2007;119:e849-59.
- Eiser C, Davies H, Jenney M, Glaser A. Mothers' attitudes to the randomized controlled trial (RCT): the case of acute lymphoblastic leukaemia (ALL) in children. *Child Care Health Dev*. 2005; 31(5):517-523.
- Elliston S. The best interests of the child in healthcare. London: Routledge-Cavendish; 2007.
- Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *Br J Gen Pract*. 2000;50(460):892-899.
- Fallat ME, Hutter J, the Committee on Bioethics, Section on Hematology/Oncology, and Section on Surgery. Preservation of Fertility in Pediatric and Adolescent Patients With Cancer. *Pediatrics*. 2008;121:e1461-e1469.
- Feinberg J. The Child's Right to an Open Future. In: Feinberg J. Freedom & Fulfilment. Philosophical essays. Princeton: Princeton University Press; 1992. p. 76-97.
- Ferrari A, Bleyer A. participation of adolescents with cancer in clinical trials. *Cancer Treat Rev*. 2007;33:603-608.
- Freedman B. Equipoise and the ethics of clinical research. *New Engl J Med*. 1987;317(3):141-145.
- Fried TR, Bradley EH, Towle VR, Allore H. Understanding the treatment preferences of seriously ill patients. *New Engl J Med*. 2002;346:1061-1066.
- Gillon R. Philosophical medical ethics. Chichester: Wiley; 1985.
- Ginsberg JP, Ogle SK, Tuchman LK, Carlson CA, Reilly MM, Hobbie WL, et al. Sperm Banking for Adolescent and Young Adult Cancer Patients: Sperm Quality, Patient, and Parent Perspectives. *Pediatr Blood Cancer*. 2008;50(3):594-598.
- Goodwin T, Oosterhuis BE, Kiernan M, Hudson MM, Dahl GV. Attitudes and practices of pediatric oncology providers regarding fertility issues. *Pediatr Blood Cancer* 2007;48(1):80-85.
- Green D, Galvin H, Horne B. The psycho-social impact of infertility on young male cancer survivors: a qualitative investigation. *Psychooncology* 2003;12(2):141-152.
- Greenley RN, Drotar D, Zyzanski SJ, Kodish E. Stability of parental understanding of random assignment in childhood leukemia trials: an empirical examination of informed consent. *J Clin Oncol*. 2006;24:891-897.
- Grossman SA, Piantadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? *J Clin Oncol*. 1994;12:2211-2215.
- Guest G, Brunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods*. 2006;18:59-82.
- Hardart G. Including the family's interests in medical decision making in pediatrics. *J Clin Ethics*. 2000;11(2):164-168.
- Hegel GWF. Enzyklopädie der philosophischen Wissenschaften im Grundrisse. In: Gesammelte Werke Bd. 13. Hamburg: Meiner; 2000.
- Heneghan AM, Mercer M, DeLeone NL. Will mothers discuss parenting stress and depressive symptoms with their child's pediatrician? *Pediatrics*. 2004;113(3):460-467.

- Hilliard R. Categorising children in the clinic. *Sociology of Health and Illness*. 1981;3:317-336.
- Hinds PS, Drew D, Oakes LL, Fouladi M, Spunt SL, Church C, et al. End-of-life care preferences of pediatric patients with cancer. *J Clin Oncol*. 2005;23(36):9146-9154.
- Hinds PS, Oakes L, Furman W, Foppiano P, Olson MS, Quargnenti A, et al. Decision making by parents and healthcare professionals when considering continued care for pediatric patients with cancer. *Oncol Nurs Forum*. 1997;24(9):1523-1528.
- Hinds PS, Oakes L, Quargnenti A, Furman W, Bowman L, Gilger E, et al. An international feasibility study of parental decision making in pediatric oncology. *Oncol Nurs Forum*. 2000;27(8):1233-1243.
- Hope T. Empirical medical ethics. *J Med Ethics*. 1999;25:219-220.
- Hovav Y, Dan-Goor M, Yaffe H, Almagor M. Electroejaculation before chemotherapy in adolescents and young men with cancer. *Fertil Steril*. 2001;75(4):811-813.
- Iltis AS. Toward a coherent account of pediatric decision-making. *J Med Philos*. 2010;35:526-552.
- Instone SL, Mueller MR, Gilbert TL. Therapeutic discourse among nurses and physicians in controlled clinical trials. *Nurs Ethics*. 2008;5(6):803-812.
- Integraal KankerCentrum Nederland [Internet]. Cijfers over kanker 2011. Available at: www.cijfers-overkanker.nl. Accessed 26 June 2012.
- James A, Jenks C, Prout A. *Theorizing childhood*. Cambridge: Polity Press; 1998.
- James A, Prout A, editors. *Constructing and reconstructing childhood*. Basingstoke: Falmer Press; 1990.
- Jaspan HB, Cunningham CK, Tucker TJ, Wright PF, Self SG, Sheets RL, et al. Inclusion of Adolescents in Preventive HIV Vaccine Trials: Public Health Policy and Research Design at a Crossroads. *J Acquir Immune Defic Syndr*. 2008;47(1):86-93.
- Jemal A, Thomas A, Murray T, Thun M. Cancer statistics. *CA Cancer J Clin*. 2002;52:23-47.
- Jenks C. The postmodern child. In: Brannan J, O'Brien M, editors. *Children in families: research and policy*. London: Falmer press; 1996.
- Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet*. 2001;358:1772-1777.
- Joffe S, Fernandez CV, Pentz RD, Ungar DR, Mathew NA, Turner CW, et al. Involving children with cancer in decision-making about research participation. *J Pediatr*. 2006;149:862-868.
- Joffe S, Miller FG. Bench to Bedside. Mapping the Moral Terrain of Clinical Research. *Hastings Cent Rep*. 2008;38(2):30-42.
- Joffe S, Weeks JC. Views of American Oncologists About the Purposes of Clinical Trials. *J Natl Cancer Inst*. 2002;94:1847-1853.
- Jonas H. Philosophical reflections on experimenting with human subjects. *Daedalus*. 1969;98(2):219-247.
- Kai J. Parents' difficulties and information needs in coping with acute illness in preschool children: a qualitative study. *BMJ*. 1996;313:983-986.
- Kant I. *Werke in sechs Bänden*. Band VI. *Schriften zur Anthropologie, Geschichtsphilosophie, Politik und Pädagogik*. Darmstadt: Wissenschaftliche Buchgesellschaft; 2005.
- Kant I. *Das Elternrecht*. In: Kant I. *Die Metaphysik der Sitten*. Hamburg: Felix Meiner Verlag; 1986.

- Karjalainen S, Palva I. Do treatment protocols improve end results? A study of survival of patients with multiple myeloma in Finland. *BMJ.* 1989;299:1069-1072.
- Kars MC, Grypdonck MH, De Korte-Verhoef MC, Kamps WA, Meijer-van den Bergh EM, Verkerk MA, et al. Parental experience at the end-of-life in children with cancer: 'preservation' and 'letting go' in relation to loss. *Support Care Cancer.* 2011;19(1):27-35.
- Kearns GL, Abdel-Rahman SM, Alander SW, Blowey DL, Leeder JS, Kauffman RE. Developmental pharmacology. Drug disposition, action and therapy in infants and children. *N Engl J Med.* 2003;349:1157-1167.
- Kirschbaum MS. Life support decisions for children: What do parents value? *Adv Nurs Science.* 1996;19(1):51-71.
- Klassen TP, Hartling L, Craig JC, Offringa M. Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children. *PLoS Med.* 2008;5(8):e172.
- Kliegman RM, Stanton BMD, St. Gerne J, Schor N, Behrman RE, editors. *Nelson Textbook of Pediatrics*, 19th Edition. Philadelphia, PA: Elsevier Saunders; 2011.
- Kodish E, Eder M, Noll RB, Ruccione K, Lange B, Angiolillo A, et al. Communication of randomization in childhood leukemia trials. *JAMA.* 2004;291:470-475.
- Kon AA. The Role of Empirical Research in Bioethics. *Am J Bioethics.* 2009;9:59-65.
- Kopelman LM. The best-interests standard as threshold, ideal, and standard of reasonableness. *J Med Phil.* 1997;22(3):271-289.
- Kopelman LM. A new analysis of the best interests standard and its crucial role in pediatric practice. William G. Bartholome Award Address at the 2007 AAP National Conference and Exhibition Section on Bioethics Program, San Francisco, CA; 2007. Available at: www.aap.org/sections/bioethics/PDFs/KopelmanSpeech2007.pdf.
- Kopelman LM. Using the best-interests standard in treatment decisions for young children. In: Miller G, editor. *Pediatric Bioethics*. New York, NY: Cambridge University Press; 2010. p. 22-37.
- Kuhse H, Singer P. Should the baby live? The problem of handicapped infants. Oxford: Oxford University Press;1985.
- Kumar A, Soares H, Wells R, Clarke M, Hozo I, Bleyer A, et al. Are experimental treatments for cancer in children superior to established treatments? Observational study of randomised controlled trials by the Children's Oncology Group. *BMJ.* 2005;331(7528):1295. Epub 2005 Nov 18.
- Kupst MJ, Patenaude AF, Walco GA, Sterling C. Clinical trials in pediatric cancer: parental perspectives on informed consent. *J Pediatr Hematol Oncol.* 2003;25(10):787-790.
- Lee KJ, Havens PL, Sato TT, Hoffman GM, Leuthner SR. Assent for Treatment: Clinician Knowledge, Attitudes, and Practice. *Pediatrics.* 2006;118:723-730.
- Lee SJ, Schover LR, Partridge AH, Patrizio P, Wallace WH, Hagerty K, et al. American Society of Clinical Oncology Recommendations on Fertility Preservation in Cancer Patients. *J Clin Oncol.* 2006a;24:2917-2931.
- Leenen HJJ. *Handboek gezondheidsrecht. Deel 1: Rechten van mensen in de gezondheidszorg.* 5e druk. Houten: Bohn Stafleu Van Loghum; 2007.
- Leikin S. Minors' assent, consent, or dissent to medical research. *IRB.* 1993;15:1-7.

- Leuthner SR. Decisions regarding resuscitation of the extremely premature infant and models of best interest. *Journal of Perinatology.* 2001;21:193-198.
- Levetown M. The Committee on Bioethics. Communicating with children and families: From everyday interactions to skill in conveying distressing information. *Pediatrics.* 2008;121:e1441-e1460.
- Levi RB, Marsick R, Drotar D, Kodish ED. Diagnosis, disclosure, and informed consent: learning from parents of children with cancer. *J Pediatr Hematol Oncol.* 2000;22:3-12.
- Lindemann Nelson H, Lindemann Nelson J. *The patient in the Family. An Ethics of Medicine and Families.* New York: Routledge; 1995.
- London AJ. Clinical equipoise: foundational requirement or fundamental error? In: Steinbock B, editor. *The Oxford handbook of bioethics.* New York: Oxford University Press; 2007. p. 571-596.
- Lowe R, Bravery K, Gibson F. Navigating the maze: parents' views and influence on a paediatric haematology and oncology day care service. *J Clin Nurs.* 2008;17(23):3159-3167.
- MacIntyre A. *After Virtue.* Notre Dame: University of Notre Dame Press; 1984.
- Malterud K. Qualitative research: standards, challenges, and guidelines. *Lancet.* 2001;358:483-488.
- Marcoux S, Robaey P, Krajinovic M, Moghrabi A, Laverdière C. Predictive factors of internalized and externalized behavioral problems in children treated for acute lymphoblastic leukemia. *Pediatr Blood Cancer.* 2012;58(6):971-977.
- Mårtenson EK, Fägerskiöld AM. A review of children's decision-making competence in health care. *J Clin Nursing.* 2008;17:3131-3141.
- Masera G, Spinetta JJ, Janckovic M, Ablin AR, Buchwall I, Van Dongen-Melman J, et al. Guidelines for a therapeutic alliance between families and staff: a report of the SIOP working committee on psychosocial issues in pediatric oncology. *Med Pediatr Oncol.* 1998;30:183-186.
- McCullough LB. Contributions of ethical theory to pediatric ethics: pediatricians and parents as co-fiduciaries of pediatric patients. In: Miller G, editor. *Pediatric Bioethics.* New York, NY: Cambridge University Press; 2010.
- McKenna K, Collier J, Hewitt M, Blake H. Parental involvement in paediatric cancer treatment decisions. *Eur J Cancer Care.* 2010;19:621-630.
- M.D. Anderson Cancer Center [Internet]. Clinical Trials at the Children's Cancer Hospital. Houston, 2011. Available at: <http://www.mdanderson.org/patient-and-cancer-information/care-centers-and-clinics/childrens-cancer-hospital/clinical-trials/index.html>
- Miller FG, Brody H. A critique of clinical equipoise. Therapeutic misconception in the ethics of clinical trials. *Hastings Cent Rep.* 2003;33:19-28.
- Miller FG, Rosenstein DL. The Therapeutic Orientation to Clinical Trials. *N Engl J Med.* 2003;348(14):1383-1386.
- Miller RB. *Children, ethics, and modern medicine.* Bloomington, IN: Indiana University Press; 2003.
- Miller VA, Nelson RM. A developmental approach to child assent for nontherapeutic research. *J Pediatr.* 2006;149(1):S25-S30.
- Ministry of Health, Welfare and Sports. Dutch Medical Treatment Act (Wet op de Geneeskundige Behandelingsovereenkomst-WGBO, BW, boek 7). Stb. 1994, 838. Den Haag, The Netherlands: Sdu Uitgevers; 1995.

- Moody HR. Ethics in an aging society. Baltimore: Johns Hopkins University Press; 1992.
- Müller J, Sønksen J, Sommer P, Schmiegelow M, Petersen PM, Heilman C, et al. Cryopreservation of semen from pubertal boys with cancer. *Med Pediatr Oncol.* 2000;34:191-194.
- Nagel K, Wizowski L, Duckworth J, Cassano J, Hahn SA, Neal M. Using plain language skills to create an educational brochure about sperm banking for adolescent and young adult males with cancer. *J Pediatr Oncol Nurs.* 2008;25(4):220-226.
- Nagel T. The view from nowhere. New York: Oxford University Press; 1986.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: ethical principles and guidelines for the protection of human subjects of research. Washington: Department of Health, Education, and Welfare; 1979. Available at: <http://ohsr.od.nih.gov/guidelines/belmont.html>.
- Office for Human Research Protections. U.S. Department of Health and Human Services. International Compilation of Human Research Protections 2009 Edition. Available at: <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>.
- Olechnowicz JQ, Eder M, Simon C, Zyzanski S, Kodish E. Assent observed: children's involvement in leukemia treatment and research discussions. *Pediatrics.* 2002;109:806-814.
- Ondrusek N, Abrahamovitch R, Pencharz P, Koren G. Empirical examination of the ability of children to consent to clinical research. *J Med Ethics.* 1998;24:158-165.
- Ong LML, Haes JCJM de, Hoos AM, Lammes FB. Doctor-patient communication: a review of the literature. *Soc Sci Med.* 1995;40:903-18.
- Oosterhuis BE, Goodwin T, Kiernan M, Hudson MM, Dahl GV. Concerns about infertility risks among pediatric oncology patients and their parents. *Pediatr Blood Cancer.* 2008;50(1):85-89.
- Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med.* 2003;348:721-726.
- Paddeau P. Hogere machten en huisdieren worden niet bedankt. Valkenburg, The Netherlands: Uitgeverij Klimaat en de Gewone Baby Poes; 2012.
- Partridge BC. Adolescent psychological development, parenting styles, and pediatric decision-making. *J Med Phil.* 2010;35:518-525.
- Patiño-Fernández AM, Pai ALH, Alderfer M, Hwang WT, Reilly A, Kazak AE. Acute stress in parents of children newly diagnosed with cancer. *Pediatr Blood Cancer.* 2008;50(2):289-292.
- Patton M. Qualitative research and evaluation methods. Thousand Oaks, CA: Sage Publications; 2002.
- Pellegrino ED. The anatomy of clinical-ethical judgements in perinatology and neonatology: a substantive and procedural framework. *Semin Perinatol.* 1987;11:202-209.
- Pellegrino ED. The limitation of empirical research in ethics. *J Clin Ethics.* 1995;6:161-162.
- Peppercorn JM, Weeks JC, Cook EF, Joffe S. Comparison of outcomes in cancer patients treated within and outside clinical trials: conceptual framework and structured review. *Lancet.* 2004;363:263-270.
- Peters VAM. Users guide Kwalitan 5.0. Department of Research methodology, University of Nijmegen, The Netherlands; 2000. See: www.kwalitan.net.
- Piaget J. The Moral Judgment of the Child. New York: The Free Press; 1965.

- Placencia FX, McCullough LB. The history of ethical decision making in neonatal intensive care. *J Intensive Care Med.* 2011;26(6):368-84.
- Poder U, Ljungman G, Von Essen L. Posttraumatic stress disorder among parents of children on cancer treatment: A longitudinal study. *Psychooncology.* 2008;17:430-437.
- Polanyi M. *The tacit Dimension.* Garden City: New York; 1967.
- Popper K. *The Logic of Scientific Discovery.* London: Hutchinson; 1959.
- Quinn GP, Vadaparampil ST, Gwede CK, Miree C, King LM, Clayton HB, et al. Discussion of fertility preservation with newly diagnosed patients: oncologists views. *J Cancer Surviv.* 2007;1:146-155.
- Rawls J. *A Theory of Justice.* London: Oxford University Press; 1971.
- Reiter-Theil S. Does Empirical Research Make Bioethics More Relevant? 'The Embedded Researcher' as a Methodological Approach. *Med Health Care Philos.* 2004;7(1):17-29.
- Reynolds WW, Nelson RM. Risk perception and decision processes underlying informed consent to research participation. *Soc Sci Med.* 2007;65(10):2105-2115.
- Ries LAG, Melbert D, Krapcho M, Mariotto A, Miller BA, Feuer EJ, et al, editors. SEER Cancer Statistics Review, 1975-2004. National Cancer Institute. Bethesda, MD. [http://seer.cancer.gov/csr/1975_2004/], based on November 2006 SEER data submission, posted to the SEER web site, 2007.
- Ross LF. *Children, families, and health care decision making.* Oxford, New York: Clarendon Press; 1998.
- Ruddick W. Questions parents should resist. In: Kopelman LM, Moskow JC, editors. *Children and Health Care: Moral and Social Issues.* Dordrecht, The Netherlands: Kluwer Academic Publishers; 1989. p. 221-230.
- Ruddick W. Parenthood: Three Concepts and a Principle. In: Houlgate LD, editor. *Family Values: Issues in Ethics, Society and the Family.* Belmont, California: Wadsworth; 1988.
- Ruddick, W. Parents and Life Prospects. In: O'Neill O, Ruddick W, editors. *Having children. Philosophical and legal reflections on parenthood.* New York: Oxford University Press; 1979. p.124-137
- Saito K, Suzuki K, Iwasaki A, Yumura Y, Kubota Y. Sperm Cryopreservation before Cancer Chemotherapy Helps in the Emotional Battle against Cancer. *Cancer.* 2005;104:521-524.
- Salloch S, Schilmann J, Vollmann J. Empirical research in medical ethics: How conceptual accounts on normative-empirical collaboration may improve research practice. *BMC Medical Ethics.* 2012;13:5.
- Schapiro T. What is a child? *Ethics.* 1999;109:715-738.
- Schmiegelow ML, Sommer P, Carlsen E, Sørnsen JO, Schmiegelow K, Müller JR. Penile Vibratory Stimulation and Electroejaculation Before Anticancer Therapy in Two Pubertal Boys. *J Pediatr Hematol Oncol.* 1998;20:429-430.
- Schoeman F. Parental discretion and children's rights: background and implications for medical decision-making. *J Med Philos.* 1985 Feb;10(1):45-61.
- Schover LR. Psychosocial aspects of infertility and decisions about reproduction in young cancer survivors: a review. *Med Pediatr Oncol.* 1999;33:53-59.
- Schover LR, Rybicki LA, Martin BA, Bringelsen KA. Having children after cancer: A pilot survey of survivors' attitudes and experiences. *Cancer.* 1999;86:697-709

- Schover LR, Brey K, Lichtin A, Lipshultz LI, Jeha S. Knowledge and Experience Regarding Cancer, Infertility, and Sperm Banking in Younger Male Survivors. *J Clin Oncol* 2002a;20(7):1880-1889.
- Schover LR, Brey K, Lichtin A, Lipshultz LI, Jeha S. Oncologists' attitudes and practices regarding banking sperm before cancer treatment. *J Clin Oncol.* 2002b;20(7):1890-1897.
- Schover LR. Motivation for parenthood after cancer: a review. *J Natl Cancer Inst Monogr.* 2005;34:2-5.
- Schrader M, Müller M, Straub B, Miller K. The impact of chemotherapy on male fertility: a survey of the biologic basis and clinical aspects. *Reprod Toxicol.* 2001;15:611-617.
- Shilling V, Young B. How do parents experience being asked to enter a child in a randomised controlled trial? *BMC Med Ethics.* 2009;10:1.
- Sigman GS, O'Connor C. Exploration for physicians of the mature minor doctrine. *J Pediatr.* 1991;119:520-525.
- Simon CM, Kodish ED. "Step into my zapatos, doc." Understanding and reducing communication disparities in the multicultural informed consent setting. *Perspect Biol Med.* 2005;48(1 Suppl):S123-38.
- Singhal N, Oberle K, Burgess E, Huber-Okrainec J. Parents' perceptions of research with newborns. *J Perinatol.* 2002;22(1):57-63.
- SKION Later. Richtlijn follow-up na kinderkanker. Den Haag/Amsterdam; 2010. Available at: http://www.skion.nl/bestanden/richtlijn_follow-up_na_kinderkanker_deel_1_boekje_met_aanbevelingen_1.pdf. Accessed 25 June 2012.
- Snowdon C, Garcia J, Elbourne D. Making sense of randomization; responses of parents of critically ill babies to random allocation of treatment in a clinical trial. *Soc Sci Med.* 1997;45:1337-1355.
- Solomon MZ. Realizing bioethics' goals in practice: ten ways to 'is' can help 'ought'. *Hastings Cent Rep.* 2005;35:40-47.
- Spence K. The best interest principle as a standard for decision making in the care of neonates. *J Adv Nurs.* 2000;31(6):1286-1292.
- Spinetta JJ, Jankovic M, Masera G, Ablin AR, Barr RD, Ben Arush MW, et al. Optimal care for the child with cancer: A summary statement from the SIOP Working Committee on Psychosocial Issues in Pediatric Oncology. *Pediatr Blood Cancer.* 2009;52(7):904-907.
- Spinetta JJ, Masera G, Jankovic M, Oppenheim D, Martins AG, Ben Arush MW, et al. Valid informed consent and participative decision-making in children with cancer and their parents: a report of the SIOP Working Committee on psychosocial issues in pediatric oncology. *Med Pediatr Oncol.* 2003;40(4):244-246.
- Stanton B, Behrman RE. Overview of Pediatrics. In: Kliegman RM, Stanton BMD, St. Geme J, Schor N, Behrman RE, editors. *Nelson Textbook of Pediatrics*, 19th Edition. Philadelphia, PA: Elsevier Saunders; 2011.
- Stevens PE, Pletsch PK. Ethical issues of informed consent: mothers' experiences enrolling their children in bone marrow transplantation research. *Cancer Nurs.* 2002;25(2):81-87.
- Stiller CA. Centralised treatment, entry to trials and survival. *Br J Cancer.* 1994;70:352-362.
- Stiller CA, Eatock EM. Patterns of care and survival for children with acute lymphoblastic leukaemia diagnosed between 1980 and 1994. *Arch Dis Child.* 1999;81:202-208.

- Strauss AL, Corbin J. Basics of qualitative research: techniques and procedures for developing grounded theory. London: Sage Publications; 1998.
- Susman EJ, Dorn LD, Fletcher JC. Participation in biomedical research: The consent process as viewed by children, adolescents, young adults, and physicians. *J Pediatr.* 1992;121(4):547-552.
- Sutherland HJ, Llewellyn-Thomas HA, Lockwood GA, Tritchler DL, Till JE. Cancer patients: their desire for information and participation in treatment decisions. *J R Soc Med.* 1989;82:260-263.
- Tait AR, Voepel-Lewis T, Siewert M, Malviya S. Factors that influence parents' decisions to consent to their child's participation in clinical anesthesia research. *Anesth Analg.* 1998;86(1):50-53.
- Tan NHSS. Deconstructing paternalism - what serves the patient best? *Singapore Med J.* 2002;43(3):148-151.
- Tarnowski KJ, Allen DM, Mayhall C, Kelly PA. Readability of pediatric biomedical research informed consent forms. *Pediatrics.* 1990;85:58-62.
- Tates K, Meeuwesen L. Doctor-parent-child communication. A (re)view of the literature. *Soc Sci Med.* 2001;52:839-851.
- Tates K, Meeuwesen L. 'Let mum have her say': turn taking in doctor-parent-child communication. *Patient Educ Couns.* 2000;40:151-162.
- Taylor KM. Integrating conflicting professional roles: physician participation in randomized clinical trials. *Soc Sci Med.* 1992;35:217-24.
- Taylor KM, Feldstein ML, Skeel RT, Pandya KJ, Ng P, Carbone PP. Fundamental dilemmas of the randomized clinical trial process: results of a survey of the 1,737 Eastern Cooperative Oncology Group investigators. *J Clin Oncol.* 1994;12:1796-1805.
- The AM. Emotie en inzicht; eigen onderzoekservaringen als data. *Medische Antropologie* 1999a;11(2):323-334.
- The AM. Palliatieve behandeling en communicatie. Een onderzoek naar het optimisme op herstel van longkankerpatiënten. Houten / Diegem: Bohn Stafleu Van Loghum; 1999b.
- Tournaye H, Goossens E, Verheyen G, Frederickx V, De Block G, Devroey P, et al. Preserving the reproductive potential of men and boys with cancer: current concepts and future prospects. *Hum Reprod Update.* 2004;10:525-532.
- Tsai MH, Hsu JF, Chou WJ, Yang CP, Jaing TH, Hung IJ, et al. Psychosocial and emotional adjustment for children with pediatric cancer and their primary caregivers and the impact on their health-related quality of life during the first 6 months. *Qual Life Res.* 2012 Apr 22. (Epub ahead of print)
- Tuckett D, Boulton M, Olson C, Williams Al. Meeting between experts: an approach to sharing ideas in medical consultations. London: Tavistock Publications; 1985.
- UMC Utrecht [Internet]. Utrecht: UMC Utrecht; c2006-2012. Proefbehandeling bij ernstige acute alvleesklierontsteking geeft onverwacht hogere sterfte. Available from: <http://www.umcutrecht.nl/onderwijs/nieuws/2008/01/onverwacht-hogere-sterfte-in-onderzoek.html>.
- Ungar D, Joffe S, Kodish E. Children are not small adults: documentation of assent for research involving children. *J Pediatr.* 2006;149(1 Suppl):S31-33.
- Vadaparampil ST, Clayton H, Quinn GP, King LM, Nieder M, Wilson C. Pediatric oncology nurses' attitudes related to discussing fertility preservation with pediatric cancer patients and their families. *J Pediatr Oncol Nurs.* 2007;24(5):255-263.

- Van Delden H, van der Scheer L, Van Thiel G, Widdershoven G. *Ethiek en Empirie. Theorie en methodologie van empirisch ethisch onderzoek.* Maastricht: Océ Business Services, Universiteit Maastricht; 2005.
- Van Delden JJM. De herontdekking van de praktijk. K&M: *Tijdschrift voor Empirische Filosofie.* 1999;23:169-171.
- Van Delden JJM, Van Thiel GJMW. Reflective Equilibrium as a Normative-Empirical Model in Bioethics. In: Van der Burg W, Van Willigenburg T, editors. *Reflective Equilibrium. Essays in Honour of Robert Heeger.* Dordrecht: Kluwer Academic Publishers; 1998.
- Van Delden JJM. Beslissen om niet te reanimeren. Een medisch en ethisch vraagstuk [dissertation]. Assen: Van Gorcum; 1993.
- Van den Berg H, Langeveld NE. Parental knowledge of fertility in male childhood cancer survivors. *Psychooncology.* 2007;17:287-291.
- Van der Burg W, Van Willigenburg T, editors. *Reflective Equilibrium. Essays in Honour of Robert Heeger.* Dordrecht: Kluwer Academic Publishers; 1998.
- Van der Burg W. *Het democratisch perspectief.* Arnhem: Gouda Quint; 1991.
- Van Santen H. Patiënten probiotica waren al zieker. *NRC Handelsblad* january 25, 2008.
- Van Stuijvenberg M, Suur MH, De Vos S, Tjiang GC, Steyerberg EW, Derkxen-Lubsen G, et al. Informed consent, parental awareness, and reasons for participating in a randomised controlled study. *Arch Dis Child.* 1998;79:120-125.
- Van Willigenburg T. Inside the ethical expert. Kampen: Kok Pharos; 1991.
- Van Willigenburg T, Heeger FR. Justification of Moral Judgements: A Network Model. In: *Societas Ethica Jahresbericht.* Hannover: Societas Ethica; 1989. p. 53-61.
- Veatch RM. Indifference of subjects: an alternative to equipoise in randomized clinical trials. *Soc Philos Policy.* 2002;19(2):295-323.
- Veatch RM. Abandoning informed consent. *Hasting Cent Rep.* 1995;25(2):5-12.
- Vist GE, Bryant D, Somerville L, Birmingham T, Oxman AD. Outcomes of patients who participate in randomised controlled trials compared to similar patients receiving similar interventions who do not participate. *Cochrane Database Syst Rev.* 2008;16(3):MR000009.
- Wallace WH, Blacklay A, Eiser C, Davies H, Hawkins M, Levitt GA, et al. Developing strategies for long term follow up of survivors of childhood cancer. *BMJ.* 2001;323:271-274.
- Wang M, Lo P, Fan R. Medical Decision Making and the Family: An Examination of Controversies. *J Med Philos.* 2010;35(5):493-498.
- Wendler D. Can we ensure that all research subjects give valid consent? *Arch Intern Med.* 2004;164:2201-2204.
- Wendler D, Shah S. Should Children Decide Whether They Are Enrolled in Nonbeneficial Research? *Am J Bioethics.* 2003;3(4):1-7.
- Whitney SN, Ethier AM, Frugé E, Berg S, McCullough LB, Hockenberry M. Decision making in pediatric oncology: who should take the lead? The decisional priority in pediatric oncology model. *J Clin Oncol.* 2006;24(1):160-165.
- Wiley FM, Ruccione K, Moore IM, McGuire-Cullen P, Fergusson J, Waskerwitz MJ, et al. Parents' perceptions of randomization in pediatric clinical trials. *Cancer Pract.* 1999;7:248-256.

- Young B, Dixon-Woods M, Findlay M, Heney D. Parenting in a crisis: conceptualizing mothers of children with cancer. *Soc Sci Med.* 2002;55:1835-1847.
- Young B, Dixon-Woods M, Windridge KC, Heney D. Managing communication with young people who have a potentially life threatening chronic illness: qualitative study of patients and parents. *BMJ.* 2003;326:305-309.
- Zaner RM. Ethics and the Clinical Encounter. Englewood Cliffs: Prentice Hall; 1988.
- Zebrack BJ, Casillas J, Nohr L, Adams H, Zeltzer LK. Fertility issues for young adult survivors of childhood cancer. *Psychooncology.* 2004;13:689-699.
- Zwaanswijk M, Tates K, Van Dulmen S, Hoogerbrugge PM, Kamps WA, Bensing JM. Young patients', parents', and survivors' communication preferences in pediatric oncology: results of online focus groups. *BMC Pediatrics.* 2007;7:35.

LIST OF ABBREVIATIONS

ALL	Acute Lymphoblastic Leukemia
AML	Acute Myeloid Leukemia
CCMO	Centrale Commissie Mensgebonden Onderzoek (Central Committee on Research Involving Human Subjects)
CCT	Clinical Controlled Trial
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
HSCT	Haematopoietic Stem Cell Transplantation
MDS	Myelodysplastic Syndrome
NHL	Non-Hodgkin Lymphoma
IRB	Institutional Review Board
RCT	Randomized Controlled Trial
RE	Reflective Equilibrium
SKION	Stichting Kinderoncologie Nederland
WMO	Wet Medisch-wetenschappelijk Onderzoek met Mensen (Medical Research with Human Subjects Act)

