参考文献

序文

- 1. Lexchin J, Bero LA, Djulbegovic B, et al. Pharmaceutical industry sponsorship and research outcome and quality: systematic review.BMJ 2003;326:1167-70.
- 2. Schwitzer G, Ganapati M, Henry D, et al. What are the roles and responsibilities of the media in disseminating health information? PLoS Med 2(7):e215.
- Wilson PM, Booth AM, Eastwood A et al.Deconstructing media coverage of trastuzumab (Herceptin): an analysis of national newspaper coverage. Journal of the Royal Society of Medicine 2008:101:125-32
- 4. Shang A, Huwiler-Muntener K, Nartey L, et al.Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of homoeopathy and allopathy.Lancet 2005;366:726-32.
- Bjelakovic G, Nikolova D, Gluud LL, et al. Antioxidant supplements for prevention of mortality in healthy participants and patients with various diseases. Cochrane Database of Systematic Reviews 2008, Issue 2. Art. No.: CD007176

はじめに

- 1. Nolte E, McKee CM.Does health care save lives? Avoidable mortality revisited.London:Nuffield Trust, 2004.
- 2. Nolte E, McKee CM.Measuring the health of nations: updating an earlier analysis.Health Affairs 2008;27(1):58-77)
- 3. Gigerenzer G. Reckoning with risk.London: Penguin Books, 2003.Citing Franklin B. Letter to Jean Baptiste Le Roy, 13 November 1789.Writings, vol x.
- 4. Goldacre B. Bad Science:London:Fourth Estate, 2008, px.
- 5. Matthews A, Dowswell T, Haas DM, et al.Interventions for nausea and vomiting in early pregnancy.Cochrane Database of Systematic Reviews 2010, Issue 9.Art. No.:CD007575
- 6. Irwig L, Irwig J, Trevena L, et al.Smart health choices: making sense of health advice.London:Hammersmith Press, 2008. pdf freely available at: www.health.usyd.edu.au/shdg/resources/smart_health_choices.php and from www.jameslindlibrary.org.
- 7. Woloshin S, Schwartz LM, Welch HG.Know your chances: understanding health statistics.Berkeley:University of California Press, 2008. pdf freely available at <506>www.jameslindlibrary.org</506>.

第1章 新しいこと―それは良いことなのか?

- 1. Vandenbroucke JP.Thalidomide: an unanticipated adverse event.2003.Available from: www.jameslindlibrary.org.
- 2. Stephens T, Brynner R. Dark medicine: the impact of thalidomide and its revival as a vital medicine. Perseus Publishing, 2001.
- 3. Thomson D, Capstick T. How a risk management programme can ensure safety in thalidomide use. Pharmaceutical Journal 2004 Feb 14:194-5.
- 4. Krumholz HM, Ross JR, Presler AH, et al.What have we learnt from Vioxx?BMJ 2007;334:120-3.
- 5. Merck statements dated 7 December 2009, on Vioxx proceedings in Ontario, Canada, and 4 March 2010 on Vioxx judgment in Australia, available at www.merck.com.
- 6. Cohen D. Rosiglitazone what went wrong?BMJ 2010;341:c4848.
- 7. Lehman R, Yudkin JS, Krumholz HM.Licensing drugs for diabetes: surrogate end points are not enough, robust evidence of benefits and harms is needed.BMJ 2010;341:c4805.
- 8. Blackstone EH.Could it happen again? The Bjork-Shiley convexo-concave heart valve story. Circulation 2005;111:2717-19.
- Wilson PM, Booth AM, Eastwood A et al.Deconstructing media coverage of trastuzumab (Herceptin): an analysis of national newspaper coverage. Journal of the Royal Society of Medicine 2008:101:125-32
- 10. Timmins N. Drugs watchdog gets harsh treatment. Financial Times, 8 October 2005, p6.
- 11. Hawkes N. Wonder drug is "cure" for cancer, say doctors. The Times, 20 October 2005.
- 12. Press MF, Sauter G, Bernstein L, et al.Diagnostic evaluation of HER-2 as a molecular target: an assessment of accuracy and reproducibility of laboratory testing in large, prospective, randomized clinical trials.Clinical Cancer Research 2005;11(18):6598-607.
- 13. NICE draft guidance on trastuzumab (Herceptin) for early breast cancer (press release), 9 June 2006. www.nice.org.uk/page.aspx?o=328789.
- 14. Cumming J, Mays N, Daube J. How New Zealand has contained expenditure on drugs.BMJ 2010;340:1224-6.
- 15. NHS NICE Technology Appraisal TA34.Guidance on the use of trastuzumab for the treatment of advanced breast cancer.Issue date March 2002; review date April 2005. www.nice.org.uk/TA34.

第2章 期待される効果が達成されていない

- 1. Gilbert R, Salanti G, Harden M, et al.Infant sleeping position and the sudden infant death syndrome: systematic review of observational studies and historical review of clinicians' recommendations from 1940-2000.International Journal of Epidemiology 2005;34:74-87.
- Furberg CD.Effect of antiarrhythmic drugs on mortality after myocardial infarction. American Journal of Cardiology 1983;52:32C-36C.
- 3. Chalmers I. In the dark.Drug companies should be forced to publish all the results of clinical trials.How else can we know the truth about their products?New Scientist 2004, 6 March, p19.Citing Moore T, Deadly Medicine.New York:Simon and Schuster, 1995.
- 4. Cowley AJ, Skene A, Stainer K, et al. The effect of lorcainide on arrhythmias and survival in patients with acute myocardial infarction: an example of publication bias. International Journal of Cardiology 1993;40:161-6.
- Chalmers I. Evaluating the effects of care during pregnancy and childbirth.In:Chalmers I, Enkin M, Keirse MJNC, eds.Effective care in pregnancy and childbirth.Oxford:Oxford University Press, 1989:3-38.
- 6. Ulfelder H. The stilbestrol disorders in historical perspective. Cancer 1980;45:3008-11.
- 7. Office of Technology Assessment.Identifying health technologies that work: searching for evidence.Washington, DC:US Government Printing Office, 1994.
- 8. Hemminki E, McPherson K. Impact of postmenopausal hormone therapy on cardiovascular events and cancer: pooled data from clinical trials.BMJ 1997;315:149-53.
- 9. Anonymous.HRT: update on the risk of breast cancer and long-term safety.Current Problems in Pharmacovigilance 2003;29:1-3.Citing results of Women's Health Initiative randomized controlled trial (JAMA 2003;289:3243-53) and Million Women Study (Lancet 2003;362:419-27).
- 10. Roberts H. Hormone replacement therapy comes full circle.BMJ 2007;335:219-20.
- 11. Williams HC.Evening primrose oil for atopic dermatitis: time to say goodnight (editorial).BMJ 2003;327:1358-9.
- 12. Hoare C, Li Wan Po A, Williams H. Systematic review of treatment for atopic eczema. Health Technology Assessment 2000;4(37):1-191.
- 13. Takwale A, Tan E, Agarwal S, et al. Efficacy and tolerability of borage oil in adults and children with atopic eczema: randomised, double blind, placebo controlled, parallel group trial. BMJ 2003;327:1385-7.

第3章 多ければ良いと限らない

- 1. Crile G. A plea against blind fear of cancer.Life, 31 October 1955, pp128-32.
- 2. Baum M, Houghton J. Contribution of randomised controlled trials to understanding and management of early breast cancer.BMJ 1999;319:56871.
- 3. Veronesi U, Cascinelli N, Mariani L, et al.Twenty-year follow up of a randomized study comparing breast-conserving surgery with radical mastectomy for early breast cancer.New England Journal of Medicine 2002;347:1227-32.
- 4. Baum M. Breast beating: a personal odyssey in the quest for an understanding of breast cancer, the meaning of life and other easy questions.London:Anshan, 2010.
- 5. Japanese Breast Cancer Society.Results of questionnaires concerning breast cancer surgery in Japan 1980-2003.Breast Cancer 2005;12(1).
- Early Breast Cancer Trialists' Collaborative Group. Effects of adjuvant tamoxifen and of
 cytotoxic therapy on mortality in early breast cancer. An overview of 61 randomized trials
 among 28,896 women. New England Journal of Medicine 1988;319:1681-92.
- 7. Clinical Trial Service Unit website: www.ctsu.ox.ac.uk.
- 8. The Cochrane Collaboration website: www.cochrane.org.
- 9. Kolata G, Eichenwald K. Health business thrives on unproven treatment, leaving science behind. New York Times Special Report, 2 October 1999.
- Farquhar C, Marjoribanks J, Basser R, et al. High dose chemotherapy and autologous bone marrow or stem cell transplantation versus conventional chemotherapy for women with early poor prognosis breast cancer. Cochrane Database of Systematic Reviews 2005, Issue 3.Art. No.:CD003139
- 11. Farquhar C, Marjoribanks J, Basser R, et al. High dose chemotherapy and autologous bone marrow or stem cell transplantation versus conventional chemotherapy for women with metastatic breast cancer. Cochrane Database of Systematic Reviews 2005, Issue 3. Art. No.:CD003142
- 12. Piccart-Gebhart MJ, Procter M, Leyland-Jones B, et al.Trastuzumab after adjuvant chemotherapy in HER-2-positive breast cancer.New England Journal of Medicine 2005;353:1659-72.
- 13. Romond EH, Perez EA, Bryant J, et al.Trastuzumab plus adjuvant chemotherapy for operable HER-2-positive breast cancer. New England Journal of Medicine 2005;353:1673-84.
- 14. Carlson GW, Woods WC.Management of axillary lymph node metastasis in breast cancer: making progress.BMJ 2011;305:606-7.

第4章 早ければ良いとは限らない

- 1. Raffle A, Gray M. Screening: evidence and practice.Oxford:Oxford University Press, rev. repr., 2009.
- 2. Sense About Science.Making sense of screening.London:Sense About Science, 2009.Available from www.senseaboutscience.org.
- Goodman MT, Gurney JG, Smith MA, et al.Sympathetic nervous system tumors.In:Ries LAG, Smith MA, Gurney JG, et al (eds).Cancer incidence and survival among children and adolescents:United States SEER Program 1975-1995.National Cancer Institute, SEER Program.NIH Pub.No.99- 4649.Bethesda, MD, 1999.SEER Pediatric Monograph available at http:// seer.cancer.gov/publications/childhood.
- 4. Mullassery D, Dominici C, Jesudason EC, et al.Neuroblastoma: contemporary management.Archives of Disease in Childhood Education and Practice 2009;94:177-85.
- 5. Morris JK. Screening for neuroblastoma in children. Journal of Medical Screening 2002;9:56.
- 6. Raffle A, Gray M. op. cit., pp89-92.
- 7. Welch HG.Should I be tested for cancer? Maybe not and here's why. Berkeley and Los Angeles: University of California Press, 2004, p77.
- 8. Cosford PA, Leng GC, Thomas J. Screening for abdominal aortic aneurysm.Cochrane Database of Systematic Reviews, 2007, Issue 2, Art. No.:CD002945
- 9. Welch HG.Screening mammography a long run for a short slide? New England Journal of Medicine 2010; 363:1276-8.
- 10. Heath I. It is not wrong to say no. Why are women told only the benefits of breast screening and none of the possible harms?BMJ 2009;338:1534.
- 11. Gotzsche PC, Nielsen M. Screening for breast cancer with mammography.Cochrane Database of Systematic Reviews 2011, Issue 1.Art. No.:CD001877
- 12. Kosters JP, Gotzsche PC.Regular self-examination or clinical examination for early detection of breast cancer.Cochrane Database of Systematic Reviews 2003, Issue 2.Art. No.:CD003373(No change, Update, Issue 3, July 2008.)
- 13. McPherson K. Should we screen for breast cancer?BMJ 2010;340:c3106.
- 14. Cancer Research UK.Prostate cancer UK incidence statistics.Updated 23 December 2010. http://info.cancerresearchuk.org/cancerstats/types/ prostate/incidence.
- 15. Chapman S, Barratt A, Stockler M. Let sleeping dogs lie?What men should know before getting tested for prostate cancer.Sydney:Sydney University Press, 2010. pdf available from: http://ses.library.usyd.edu.au/bitstream/2123/6835/3/Let-sleeping-dogs-lie.pdf.
- 16. Holmstrom B, Johansson M, Bergh A, et al. Prostate specific antigen for early detection of prostate cancer: longitudinal study. BMJ 2009;339:b3537.

- 17. Djulbegovic M, Beyth RJ, Neuberger MM, et al.Screening for prostate cancer: systematic review and meta-analysis of randomised controlled trials.BMJ 2010;341:c4543.
- 18. Stark JR, Mucci L, Rothman KJ, et al. Prostate cancer screening: the controversy continues. BMJ 2009;339:b3601.
- 19. National Lung Screening Trial Research Team.Reduced lung-cancer mortality with low-dose computed tomographic screening.New England Journal of Medicine 2011;365:395-409.
- 20. Moynihan R. Beware the fortune tellers peddling genetic tests.BMJ 2010;341:c7233.
- 21. Thornton H. The screening debates: time for a broader approach? European Journal of Cancer 2003;39:1807-9.
- 22. Adapted from Wilson JMG, Jungner G. Principles and practice of screening for disease. Public health paper no 34. Geneva: World Health Organization, 1968.
- 23. COMARE 12th Report:The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals. Press release, 19 December 2007. www.comare.org. uk/12thReportPressRelease.htm.
- 24. Department of Health.Better protection for patients having 'MOT' scans: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/ MediaCentre/Pressreleasesarchive/DH 115243.
- 25. Food and Drug Administration.Radiation-emitting products:Computed tomography and full-body CT scans what you need to know: www.fda. gov/radiation-emittingProducts.

第5章 治療効果の不確実性にどう対処するか

- 1. Cabello JB, Burls A. Emparanza JI, et al.Oxygen therapy for acute myocardial infarction. Cochrane Database of Systematic Reviews 2010, Issue 6.Art No.:CD007160
- 2. Glasziou P, Chalmers I, Rawlins M, et al.When are randomised trials unnecessary?Picking signal from noise.BMJ 2007;334:349-51.
- 3. Goh CL.Flashlamp-pumped pulsed dye laser (585nm) for the treatment of portwine stains: a study of treatment outcome in 94 Asian patients in Singapore. Singapore Medical Journal 2000;41:24-28.
- 4. Druker BJ, Talpaz M, Resta DJ, et al.Efficacy and safety of a specific inhibitor of the BCR-ABL tyrosine kinase in chronic myeloid leukemia. New England Journal of Medicine 2001;344:1031-7.
- 5. Goldman J for the British Committee for Standards in Haematology.Recommendations for the management of BCR-ABL-positive chronic myeloid leukaemia.London:BSH, 2007.
- 6. Purohit N, Ray S, Wilson T, et al. The parent's kiss: an effective way to remove paediatric nasal foreign bodies. Annals of the Royal College of Surgeons of England 2008:90:420-2.

- 7. Sanghavi DM.How should we tell the stories of our medical miracles?Lancet 2010;375:2068-9.
- 8. Leaute-Labreze C, Dumas la Roque E, Hubische T, et al. Propranolol for severe hemangiomas of infancy. New England Journal of Medicine 2008;358:2649-51.
- 9. Huikeshoven M, Koster PHL, de Borgie CAJM, et al.Re-darkening of portwine stains 10 years after pulsed-dye-laser treatment. New England Journal of Medicine 2007;356:1235-40.
- 10. Waner M. Recent developments in lasers and the treatment of birthmarks. Archives of Disease in Childhood 2003;88:372-4.
- 11. Anti-Thrombotic Trialists' (ATT) Collaboration.Clinical Trial Service Unit website: www.ctsu.ox.ac.uk/projects/att.
- 12. Lin CWC, Moseley AM, Refshauge KM.Rehabilitation for ankle fractures in adults.Cochrane Database of Systematic Reviews 2008, Issue 3.Art. No.:CD005595
- 13. Lindley RI.Personal communication, 2005.
- 14. Wardlaw JM, Murray V, Berge E, et al.Thrombolysis for acute ischaemic stroke.Cochrane Database of Systematic Reviews 2009, Issue 4.Art. No.:CD000213
- 15. Schmidt B, Roberts RS, Davis P, et al; for the Caffeine for Apnea of Prematurity Trial Group.Long-term effects of caffeine therapy for apnea of prematurity.New England Journal of Medicine 2007;357:1893-902.
- 16. Caffeine citrate (Comment) in Neonatal Formulary 5.Available from: www.blackwellpublishing.com/medicine/bmj/nnf5/pdfs/comment/caffeine1.pdf.
- 17. Kenyon S, Pike, K, Jones DR, et al. Childhood outcomes after prescription of antibiotics to pregnant women with preterm rupture of the membranes:7-year follow-up of the ORACLE I trial. Lancet 2008;372:1310-18.
- 18. Kenyon S, Pike K, Jones DR, et al. Childhood outcomes after prescription of antibiotics to pregnant women with spontaneous preterm labour:7-year follow-up of the ORACLE II trial. Lancet 2008;372:1319-27.
- 19. Erythromycin (Comment) in:Neonatal Formulary 5.Available from: www.blackwellpublishing.com/medicine/bmj/nnf5/pdfs/commentary/ erythromycin.pdf.
- 20. Giuliano AE, Hunt KK, Ballman KV, et al. Axillary dissection vs no axillary dissection in women with invasive breast cancer and sentinel node metastasis: a randomized clinical trial. BMJ 2011;305:569-75.
- 21. General Medical Council.Good Medical Practice.London:GMC, 2006, p13.
- 22. Ashcroft R. Giving medicine a fair trial.BMJ 2000;320:1686.
- 23. Pritchard-Jones K, Dixon-Woods M, Naafs-Wilstra M, et al.Improving recruitment to clinical trials for cancer in childhood.Lancet Oncology 2008;9:392-9.

- 24. Equator network resource centre for good reporting of health research studies: www.equator-network.org.
- 25. Smithells RW.Iatrogenic hazards and their effects.Postgraduate Medical Journal 1975;15:39-52.

第6章 正しい治療の検査について

- 1. Hopkins WA.Patulin in the common cold.IV.Biological properties: extended trial in the common cold.Lancet 1943;ii:631-5.
- 2. Sanders TAB, Woolfe R, Rantzen E. Controlled evaluation of slimming diets: use of television for recruitment.Lancet 1990;336:918-20.
- 3. Glasziou P, Chalmers I, Rawlins M, et al.When are randomised trials unnecessary?Picking signal from noise.BMJ 2007;334:349-51) 。
- 4. Pocock SJ.Randomised clinical trials.BMJ 1977;1:1661.
- 5. Balfour TG.Quoted in West C (1854).Lectures on the Diseases of Infancy and Childhood.London:Longman, Brown, Green and Longmans, p600.
- 6. King G, Gakidou E, Imai K, et al. Public policy for the poor? A randomised assessment of the Mexican universal health insurance programme. Lancet 2009;373:1447-54.
- 7. Peto J, Eden OB, Lilleyman J, et al.Improvement in treatments for children with acute lymphoblastic leukaemia:The Medical Research Council UKALL Trials, 1972-84.Lancet 1986;i:408-11.
- 8. Noseworthy JH, Ebers GC, Vandervoort MK, et al. The impact of blinding on the results of a randomized, placebo-controlled multiple sclerosis clinical trial. Neurology 1994;44:16-20.
- 9. Moseley JB, O'Malley K, Petersen NJ, et al.A controlled trial of arthroscopic surgery for osteoarthritis of the knee.New England Journal of Medicine 2002;347:81-8.
- 10. Venning GR.Validity of anecdotal reports of suspected adverse drug reactions: the problem of false alarms.BMJ 1982;284:249-54.
- 11. McLernon DJ, Bond CM, Hannaford PC, et al on behalf of the Yellow Card Collaborative. Adverse drug reaction reporting in the UK: a retrospective observational comparison of Yellow Card reports submitted by patients and healthcare professionals. Drug Safety 2010;33:775-88.
- 12. Kocher T. Ueber Kropfexstirpation und ihre Folgen.Archiv für Klinische Chirurgie 1883;29:254-337.
- 13. Silverman WA, Andersen DH, Blanc WA, et al.A difference in mortality rate and incidence of kernicterus among premature infants allotted to two prophylactic regimens. Pediatrics 1956;18:614-25.

- 14. Zhang J, Ding E, Song Y. Adverse effects of cyclooxygenase 2 inhibitors on renal and arrhythmia events: meta-analysis of randomized trials.BMJ 2006;296:1619-21.
- 15. Vandenbroucke JP, Psaty BM.Benefits and risks of drug treatments: how to combine the best evidence on benefits with the best data about adverse effects.BMJ 2008;300:2417-9.
- 16. Whittington CJ, Kendall T, Fonagy P, et al.Selective serotonin reuptake inhibitors in childhood depression: systematic review of published versus unpublished data.Lancet 2004;363:1341-5.

第7章 偶然性を考慮する

- 1. Antithrombotic Trialists' (ATT) Collaboration. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials. Lancet 2009;373:1849. 60.
- 2. CRASH trial collaborators. Final results of MRC CRASH, a randomised placebo-controlled trial of intravenous corticosteroid in adults with head injury outcomes at 6 months. Lancet 2005;365:1957-9.
- CRASH-2 trial collaborators. Effects of transcamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. Lancet 2010;376:23-32.
- 4. Askie LM, Brocklehurst P, Darlow BA, et al and the NeOProM Collaborative Group.NeOProM:Neonatal Oxygenation Prospective Metaanalysis Collaboration study protocol.BMC Pediatrics 2011; 11:6.

第8章 信頼できる関連エビデンスをすべてレビューすること

- 1. ISIS-2 (Second International Study of Infarct Survival) Collaborative Group.Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17,187 cases of suspected acute myocardial infarction:ISIS- 2.Lancet 1988;332:349-60.
- 2. Reynolds LA, Tansey EM, eds.Prenatal corticosteroids for reducing morbidity and mortality after preterm birth.London:Wellcome Trust Centre for the History of Medicine, 2005.
- 3. Dickersin K, Chalmers I. Recognising, investigating and dealing with incomplete and biased reporting of clinical research: from Francis Bacon to the World Health Organisation. James Lind Library 2010 (www.jameslindlibrary.org).
- 4. Cowley AJ, Skene A, Stainer K, et al. The effect of lorcainide on arrhythmias and survival in patients with acute myocardial infarction: an example of publication bias. International Journal of Cardiology 1993;40:161-6.
- 5. Moore T. Deadly Medicine. New York: Simon and Schuster, 1995.
- 6. Stjernsward J. Decreased survival related to irradiation postoperatively in early operable breast cancer.Lancet 1974;ii:1285-6.

- 7. Stjernsward J. Meta-analysis as a manifestation of 'bondfornuft' ('peasant sense').JLL Bulletin:Commentaries on the history of treatment evaluation 2009 (www.jameslindlibrary.org).
- 8. Fugh-Berman AJ.The haunting of medical journals: how ghostwriting sold "HRT".PLoS Medicine 2010;7(9):e1000335.
- 9. Whittington CJ, Kendall T, Fonagy P, et al.Selective serotonin-reuptake inhibitors in childhood depression: systematic review of published versus unpublished data.Lancet 2004;363:1341-5.
- 10. Spielmans GI, Biehn TL, Sawrey DL.A case study of salami slicing: pooled analysis of duloxetine for depression. Psychotherapy and Psychosomatics 2010;79:97-106.
- 11. Antman EM, Lau J, Kupelnick B, et al.A comparison of results of metaanalysis of randomized control trials and recommendations of clinical experts.BMJ 1992;268:240-8.
- 12. Natanson C, Kern SJ, Lurie P, et al.Cell-free hemoglobin-based blood substitutes and risk of myocardial infarction and death: a meta-analysis. JAMA 2008;299(19):2304-12.
- 13. Chalmers I. TGN1412 and The Lancet's solicitation of reports of phase 1 trials.Lancet 2006;368:2206-7.
- 14. Jack A. Call to release human drug trial data. Financial Times, 8 August 2006.
- 15. Kenter MJH, Cohen AF.Establishing risk of human experimentation with drugs: lessons from TGN1412.Lancet 2006;368:1387-91.
- 16. McLellan F. 1966 and all that when is a literature search done?Lancet 2001;358:646.
- 17. Horn J, Limburg M. Calcium antagonists for acute ischemic stroke. Cochrane Database of Systematic Reviews 2000, Issue 1.Art. No.: CD001928
- 18. Horn J, de Haan RJ, Vermeulen M, et al. Nimodipine in animal model experiments of focal cerebral ischemia: a systematic review. Stroke2001;32:2433-8.
- 19. O'Collins VE, Macleod MR, Donnan GA, et al.1,026 experimental treatments in acute stroke. Annals of Neurology 2006;59:467-77.
- 20. CRASH trial collaborators. Final results of MRC CRASH, a randomised placebo-controlled trial of intravenous corticosteroid in adults with head injury outcomes at 6 months. Lancet 2005;365:1957-9.

第9章 臨床試験への規制はどこまで必要か

- 1. Emanuel EJ, Menikoff J. Reforming the regulations governing research with human subjects. New England Journal of Medicine 2011;10.1056/ NEJMsb1106942. NEJM.org
- 2. Chalmers I, Lindley R. Double standards on informed consent to treatment.In:Doyal L, Tobias JS, eds.Informed consent in medical research. London:BMJ Books 2001, pp266-75.

- 3. Fallowfield L, Jenkins V, Farewell V, et al. Efficacy of a Cancer Research UK communicating skills training model for oncologists: a randomised controlled trial. Lancet 2002;359:650-6.
- 4. Chalmers I. Regulation of therapeutic research is compromising the interests of patients.International Journal of Pharmaceutical Medicine 2007;21:395-404.
- 5. Roberts I, Prieto-Marino D, Shakur H, et al. Effect of consent rituals on mortality in emergency care research. Lancet 2011;377:1071-2.

第10章 良い研究、悪い研究、そして不要な研究

- 1. Equator network resource centre for good reporting of health research studies: www.equator-network.org.
- European Carotid Surgery Trialists' Collaborative Group. Randomised trial of endarterectomy
 for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery
 Trial (ECST). Lancet 1998;351:1379.87.
- 3. Cina CS, Clase CM, Haynes RB.Carotid endarterectomy for symptomatic carotid stenosis. The Cochrane Database of Systematic Reviews 1999, Issue 3. Art. No.:CD001081
- 4. The Magpie Trial Collaborative Group.Do women with pre-eclampsia, and their babies, benefit from magnesium sulphate?The Magpie Trial: a randomised, placebo-controlled trial.Lancet 2002;359:1877-90.
- Duley L, Gulmezoglu AM, Henderson-Smart DJ.Magnesium sulphate and other anticonvulsants for women with pre-eclampsia. Cochrane Database of Systematic Reviews 2003, Issue 2.Art. No.:CD000025
- 6. Global Report.UNAIDS report on the Global AIDS epidemic 2010: www.unaids.org/globalreport/Global report.htm.
- 7. Grimwade K, Swingler G. Cotrimoxazole prophylaxis for opportunistic infections in adults with HIV.Cochrane Database of Systematic Reviews 2003, Issue 3.Art. No.:CD003108
- 8. Chintu C, Bhat GJ, Walker AS, et al.Co-trimoxazole as prophylaxis against opportunistic infections in HIV-infected Zambian children (CHAP): a double blind randomised placebo-controlled trial.Lancet 2004;364:1865.71.
- 9. MRC News Release. Antibiotic drug almost halves AIDS-related death in children. London: MRC, 19 November 2004.
- World Health Organization and UNICEF.Co-trimoxazole prophylaxis for HIV-exposed and HIV-infected infants and children: practical approaches to implementation and scale up.WHO and UNICEF, 2009.
- 11. Soares K, McGrath J, Adams C. Evidence and tardive dyskinesia. Lancet 1996;347:1696-7.
- 12. Thornley B, Adams C. Content and quality of 2000 controlled trials in schizophrenia over 50 years.BMJ 1998;317:1181-4.

- 13. Howell CJ, Chalmers I. A review of prospectively controlled comparisons of epidural with non-epidural forms of pain relief during labour. International Journal of Obstetric Anesthesia 1992;1:93-110.
- 14. Horn J, Limburg M. Calcium antagonists for acute ischemic stroke. Cochrane Database of Systematic Reviews 2000, Issue 1.Art No.:CD001928
- 15. Horn J, de Haan RJ, Vermeulen RD, Luiten PGM, et al.Nimodipine in animal model experiments of focal cerebral ischemia: a systematic review. Stroke 2001;32:2433-8.
- 16. Fergusson D, Glass KC, Hutton B, et al.Randomized controlled trials of aprotinin in cardiac surgery: using clinical equipoise to stop the bleeding. Clinical Trials 2005;2:218-32.
- 17. Tallon D, Chard J, Dieppe <u>P.</u> Relation between agendas of the research community and the research consumer.Lancet 2000;355:2037-40.
- 18. Cream J, Cayton H. New drugs for Alzheimer's disease a consumer perspective.CPD Bulletin Old Age Psychiatry 2001;2:80-2.
- 19. Cohen CI, D'Onofrio A, Larkin L, et al.A comparison of consumer and provider preferences for research on homeless veterans. Community Mental Health Journal 1999;35:273-9.
- 20. Griffiths KM, Jorm AF, Christensen H, et al.Research priorities in mental health, Part 2: an evaluation of the current research effort against stakeholders' priorities. Australian and New Zealand Journal of Psychiatry 2002;36:327-39.
- 21. Oliver S, Gray J. A bibliography of research reports about patients', clinicians' and researchers' priorities for new research.London:James Lind Alliance, December, 2006.
- 22. Chalmers I. Current controlled trials: an opportunity to help improve the quality of clinical research. Current Controlled Trials in Cardiovascular Medicine 2000;1:3-8. Available from: http://cvm.controlled-trials.com/content/1/1/3.
- 23. Editorial.Safeguarding participants in controlled trials.Lancet 2000;355:1455-63.
- 24. Fugh-Berman A. The haunting of medical journals: how ghostwriting sold "HRT".PLoS Medicine 2010:7(9):e10000335.
- 25. Heimans L, van Hylckama V, Dekker FW.Are claims of advertisements in medical journals supported by RCTs?Netherlands Journal of Medicine2010;68:46-9.
- 26. Lexchin J, Bero LA, Djulbeovic B, et al. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. BMJ. 2003;326:1167-76.
- 27. Weatherall D. Academia and industry: increasingly uneasy bedfellows. Lancet 2000;355:1574.
- 28. Angell M. Is academic medicine for sale? New England Journal of Medicine 2000;342:1516-8.

- Grant J, Green L, Mason B. From bench to bedside:Comroe and Dripps revisited.HERG Research Report No. 30.Uxbridge, Middlesex:Brunel University Health Economics Research Group, 2003.
- 30. Pound P, Ebrahim S, Sandercock P, et al.Reviewing Animal Trials Systematically (RATS) Group. Where is the evidence that animal research benefits humans? BMJ 2004;328:514-7.
- 31. Weatherall D. The quiet art revisited.Lancet 2011;377:1912-13
- 32. Pirmohamed M. Cited in Mayor S. Fitting the drug to the patient.BMJ. 2007;334:452-3.
- 33. Editorial.The human genome at ten.Nature 2010;464:649-50.
- 34. Mackillop WJ, Palmer MJ, O'Sullivan B, et al. Clinical trials in cancer: the role of surrogate patients in defining what constitutes an ethically acceptable clinical experiment. British Journal of Cancer 1989;59:388-95.
- 35. The Psoriasis Association: www.psoriasis-association.org.uk.
- 36. National Psoriasis Association. Statistics about psoriasis: www.psoriasis. org/netcommunity/learn statistics.
- 37. Jobling R. Therapeutic research into psoriasis: patients' perspectives, priorities and interests.In:Rawlins M, Littlejohns P, ed. Delivering quality in the NHS 2005.Abingdon:Radcliffe Publishing Ltd, pp53-6.

第11章 公正な憲章の実施は皆の責任

- 1. Oliver S, Clarke-Jones L, Rees R, et al.Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. Health Technology Assessment Report 2004;8(15).
- 2. NIHR Guy's and St. Thomas' and King's College London's Biomedical Research Centre.Involving users in the research process: a 'how to' guide for researchers.Version 1, April 2010.Available from: www.biomedicalresearchcentre.org.
- 3. Cartwright J, Crowe S. Patient and public involvement toolkit.London: Wiley-Blackwell and BMJI Books, 2011.
- 4. European Science Foundation/EMRC.Implementation of medical research in clinical practice a growing challenge.Strasbourg:ESF, 2011.
- 5. Hanley B, Truesdale A, King A, et al.Involving consumers in designing, conducting, and interpreting randomised controlled trials: questionnaire survey.BMJ 2001;322:519-23.
- 6. Koops L, Lindley RI.Thrombolysis for acute ischaemic stroke: consumer involvement in design of new randomised controlled trial.BMJ. 2002;325:415-7.
- 7. Staley K. Exploring impact: public involvement in NHS, public health and social care research. Eastleigh: INVOLVE, 2009. Available from: www.invo.org.uk.

- 8. Petit-Zeman S, Firkins L, Scadding JW.The James Lind Alliance: tackling research mismatches.Lancet 2010;376:667-9.
- 9. Patient Partner Project.An EU programme 'Identifying the needs for patients partnering in clinical research': www.patientpartner-europe.eu.
- 10. Thornton H, Edwards A, Elwyn G. Evolving the multiple roles of 'patients' in health-care research: reflections after involvement in a trial of shared decision-making. Health Expectations 2003;6:189-97.
- 11. Dixon-Woods M, Agarwal S, Young B et al.Integrative approaches to qualitative and quantitative evidence.NHS Health Development Agency, 2004.
- 12. Kushner R. Breast cancer: a personal history and an investigative report. New York: Harcourt Brace Jovanovitch, 1975.
- 13. Lerner BH.The breast cancer wars: hope, fear, and the pursuit of a cure in twentieth-century America.New York:Oxford University Press, 2003.
- 14. Institute of Medical Ethics Working Party on the ethical implications of AIDS:AIDS, ethics, and clinical trials.BMJ 1992;305:699-701.
- 15. Thornton H. The patient's role in research. [Paper given at The Lancet 'Challenge of Breast Cancer' Conference, Brugge, April 1994.] In:Health Committee Third Report. Breast cancer services. Volume II. Minutes of evidence and appendices. London: HMSO, July 1995, 112-4.
- 16. Concorde Coordinating Committee.Concorde:MRC/ANRS randomised double-blind controlled trial of immediate and deferred zidovudine in symptom-free HIV infection.Lancet 1994;343:871-81.
- 17. Perehudoff K, Alves TL.Patient and consumer organisations at the European Medicines Agency: financial disclosure and transparency. Amsterdam: Health Action International, 2010. Available from www.haieurope.org.
- 18. Herxheimer A. Relationships between the pharmaceutical industry and patients' organisations.BMJ 2003;326:1208-10.
- 19. Consumers' Association. Who's injecting the cash? Which? 2003, April, pp24-25.
- 20. Koops L, Lindley RI.Thrombolysis for acute ischaemic stroke: consumerinvolvement in design of new randomised controlled trial.BMJ.2002;325:415-7.
- 21. Donovan J, Mills N, Smith M, et al for the ProtecT Study Group.Quality improvement report: improving design and conduct of randomised trials by embedding them in qualitative research:ProtecT (prostate testing for cancer and treatment) study.BMJ 2002;325:766-70.

第12章 何がより良い医療をつくるのか

1. Edwards A, Elwyn G, Atwell C, et al.Shared decision making and risk communication in general practice – a study incorporating systematic literature reviews, psychometric evaluation of outcome measures, and quantitative, qualitative and health economic analyses

- of a cluster randomised trial of professional skill development. Report to Health in Partnership programme, UK Department of Health. Cardiff: Department of General Practice. University of Wales College of Medicine, 2002.
- Farrell C, ed. Patient and public involvement in health: The evidence for policy implementation. A summary of the results of the Health in Partnership research programme. London: Department of Health Publications, April 2004. Available from: www.dh.gov.uk/en/Publicationsandstatistics/
 Publications/PublicationsPolicyAndGuidance/DH 4082332.
- 3. Adapted from Marshall T. Prevention of cardiovascular disease.Risk and benefit calculator.Available from: www.haps.bham.ac.uk/publichealth/ cardiovascular/index.shtml.
- 4. Evans I, Thornton H. Transparency in numbers: the dangers of statistical illiteracy. Journal of the Royal Society of Medicine 2009:102:354-6
- 5. Irwig L, Irwig J, Trevena L, et al.Smart health choices: making sense of health advice.London:Hammersmith Press, 2008.
- 6. Salzburg Global Seminar website: www.salzburgglobal.org.
- 7. Salzburg statement on shared decision making:Salzburg Global Seminar. BMJ 2011;342:d1745.Available from: www.bmj.com/content/342/bmj.d1745.full

第13章 正しい理由に基づく研究:より良い未来のための青写真

- 1. Chalmers 1, Glasziou P. Avoidable waste in the production and reporting of research evidence.Lancet 2009;374:86-89.
- 2. Roberts I, Yates D, Sandercock P, et al; CRASH trial collaborators. Effect of intravenous corticosteroids on death within 14 days in 10008 adults with clinically significant head injury (MRC CRASH trial): randomised placebocontrolled trial. Lancet 2004;364:1321-8.
- 3. Cochrane Injuries Group Albumin Reviewers. Human albumin administration in critically ill patients: systematic review of randomised controlled trials. BMJ 1998;317:235-40.
- 4. Finfer S, Bellomo R, Bryce N, et al (SAFE Study Investigators). A comparison of albumin and saline for fluid resuscitation in the intensive care unit. New England Journal of Medicine 2004;350:2247-56.
- 5. Edwards A, Elwyn G, Atwell C, et al.Shared decision making and risk communication in general practice a study incorporating systematic literature reviews, psychometric evaluation of outcome measures, and quantitative, qualitative and health economic analyses of a cluster randomised trial of professional skill development.Report to Health in Partnership programmme, UK Department of Health.Cardiff:Department of General Practice.University of Wales College of Medicine, 2002.
- Farrell C, ed. Patient and public involvement in health: The evidence for policy implementation. A summary of the results of the Health in Partnership research programme. London: Department of Health Publications, April 2004. Available from:

www.dh.gov.uk/en/Publicationsandstatistics/ Publications/PublicationsPolicyAndGuidance/DH 4082332.

- 7. Donovan J, Mills N, Smith M, et al for the ProtecT Study Group.Quality improvement report: improving design and conduct of randomised trials by embedding them in qualitative research:ProtecT (prostate testing for cancer and treatment) study.BMJ 2002;325:766-70.
- 8. Dickersin K, Chalmers I. Recognising, investigating and dealing with incomplete and biased reporting of clinical research: from Francis Bacon to the World Health Organization. James Lind Library, 2010 (www. jameslindlibrary.org).
- Chan A-W, Hróbjartsson A, Haahr MT, et al. Empirical evidence for selective reporting of outcomes in randomized trials: comparison of protocols to published articles. JAMA 2004;291:2457-65.
- 10. Chan AW, Altman DG.Epidemiology and reporting of randomised trials published in PubMed journals.Lancet 2005;365:1159-62.
- 11. Glasziou P, Meats E, Heneghan C, Shepperd S. What is missing from descriptions of treatment in trials and reviews?BMJ 2008;336:1472-4.
- 12. Clarke M, Hopewell S, Chalmers I. Clinical trials should begin and end with systematic reviews of relevant evidence:12 years and waiting.Lancet 2010;376:20-21.