

The Ethics of Personalised Medicine

Critical Perspectives

Edited by
Jochen Vollmann, Verena Sandow,
Sebastian Wäscher and Jan Schildmann

THE ETHICS OF PERSONALISED MEDICINE

This volume is a landmark for demythologising the buzzword 'personalised medicine', critically differentiating between hype and false hopes on the one hand and realistic approaches and outlooks on the other. By comprehensively comprising a wide range of excellent normative and empirical studies, it empowers anyone interested in better understanding the presuppositions and consequences of the term 'personalised medicine' to form a well-informed judgement on one of the most augured ideas in cutting-edge medicine.

Peter Dabrock, University of Erlangen, Germany, and Vice Chair
of the German Ethics Council and member of the European
Group on Ethics in Science and New Technologies (EGE)

The concept 'personalised medicine' has become a buzz word in contemporary medicine. However, it is not at all clear what the concept entails. The suggestion is that treatment will be adapted to the individual patient. Yet, the basis is not knowledge of the individual patient, but statistical analysis of characteristics of patient groups. Moreover, individual patient wishes and preferences may become less relevant, if treatment options are seen in terms of chances of patient groups. This book contains critical discussions of the concept of 'personalised medicine', both from an empirical and a normative perspective. It provides a timely and needed contribution to the debate.

Guy Widdershoven, VU University Medical Center, Netherlands

Gathering together a broad range of academics working in this important area, this book considers comprehensively the conceptual, ethical and practical issues associated with the ethics of personalised medicine. The editors are to be congratulated on this volume and for the way in which it carefully reflects on the issues involved in personalised medicine and its application in practice.

Mark Sheehan, University of Oxford, UK

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Jan Schildmann, MD MA, studied medicine at the Charité Medical School, Berlin, and received an MA in Medical Law and Ethics from King's College, University of London. He has qualified as a specialist in internal medicine and is currently head of the North Rhine-Westphalia Junior Research Group 'Medical Ethics at the End of Life: Norm and Empiricism' at the Institute of Medical Ethics and History of Medicine, Ruhr-University Bochum, Germany. His research focuses on clinical ethics (i.e. end-of-life decisions, ethics support services), research ethics (i.e. personalised medicine, conflict of interest) and methodological aspects of empirical medical ethics. His work has been published in more than 70 contributions in peer-reviewed journals and awarded with research prizes by the European Society for Philosophy of Medicine and Healthcare, and the German Society for Palliative Medicine.

Sebastian Schleidgen is a philosopher and ethicist. He works as Research Fellow at the National Center for Tumor Diseases (NCT), Ruprecht-Karls-University Heidelberg, Germany. He was trained in Philosophy and Sociology at the University of Constance, Germany (2000–7). He was a PhD student at the research training group 'Bioethics' at the International Centre for Ethics in the Sciences and Humanities (IZEW), Eberhard-Karls-University Tübingen, Germany (2007–10) and a Fellow in Philosophy at the Department of Philosophy, Harvard University, Cambridge, MA, USA (2009/10). He worked as Research Fellow at the Institute of Ethics, History and Theory of Medicine, Ludwig-Maximilians-University Munich, Germany (2011–14). His research interests are mainly in ethics, medical ethics, metaethics and political philosophy.

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für Biotechnologische Forschung, Braunschweig, Dept. Genetics, 1982, and Johns Hopkins University, Baltimore, 1995. He obtained a Professorship for Human Genetics at the Free University of Berlin in 1988 and was Director of the Institute of Human Genetics at Hannover Medical School from 1990 to 2014. He was Chairman of the German Board of Medical Genetics 1993–7, President of the German Society of Human Genetics 1998–2000, Member of the Ethics Council, Federal Ministry of Health, Germany, 1999–2002, coordinator of ORPHANET Germany, since 2002, appointed member and elected chair of the ‘Gendiagnostik-Kommission’ at the Robert-Koch-Institut, Berlin since 2009, and President of the European Society of Human Genetics 2011–12. He was honoured with Scientific Prizes of the German Society of Human Genetics and the German Cystic Fibrosis Society in 1987, habilitation and Heisenberg fellowships of the Deutsche Forschungsgemeinschaft. He is currently Editor-in-Chief of the *Journal of Community Genetics* and Clinical Utility Gene Cards Section Editor of the *European Journal of Human Genetics*. His current research interests include community genetics and translational medicine.

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Klaus Tanner (born 1953) has been the Professor of Systematic Theology and Ethics at the Faculty of Theology at the Ruprecht-Karls-University Heidelberg since 2008. He taught at the Martin Luther University Halle-Wittenberg (2000–8), at the Philosophical Faculty of the Technical University Dresden (1993–8) and at the Theological Faculty at Ludwig-Maximilians-University in Munich. He is an ordained pastor of the Lutheran Church in Bavaria. He was a member of the German Parliament’s Study Commission on ‘Law and Ethics in Modern Medicine’ (2000–2). He has been a member of the federal government’s ‘Central Ethics Committee for Stem Cell Research’ (ZES at the Robert-Koch-Institute) since 2002 and the German Research Foundation’s ‘Senate Commission on Genetic Research’. He is an elected member of the German Academy of Sciences Leopoldina (National Academy). He is on the board of directors of the Centre for Medicine- Ethics-Law (MER) at the Martin-Luther-Universität Halle-Wittenberg. He is on the Advisory Commission of the Evangelical Church

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Nicole Trachte, Dipl.-Kffr., is a consultant in the consulting agency CURATIS GmbH in Bremen, Germany. She is part of the working group which specialises in the secondary and tertiary facilities in the health-care system, primarily in hospitals. She finished her degree in business administration at the Faculty of Business and Economics at University of Duisburg-Essen, Campus Essen.

Jochen Vollmann is a physician and medical ethicist. He serves as Professor and Director of the Institute for Medical Ethics and History of Medicine and President of the Centre for Medical Ethics, Ruhr-University Bochum, Germany. Professor Vollmann was Visiting Fellow at the Kennedy Institute of Ethics, Georgetown University, Washington, DC (1994/5), Visiting Professor at the San Francisco School of Medicine, University of California and at the Mount Sinai School of Medicine, New York (1999/2000), at the Institute for the Medical Humanities UTMB, Texas (2001) and at the Centre for Values, Ethics and the Law in Medicine at the University of Sydney (2004, 2008, 2009, 2010, 2012, 2013 and 2014). He was honoured with the Prize for Brain Research in Geriatrics of the University of Witten/Herdecke, the Stehr-Boldt-Prize for Medical Ethics of the University of Zurich, the Research Award of the German Association of Palliative Medicine, as well as the University Teaching Award *lehrreich* of the Ruhr-University Bochum and the Gaudium docendi Teaching Award of the Society of Friends and Sponsors of the Ruhr-University Bochum. Professor Vollmann's research interests include informed consent and capacity assessment, mental health ethics, end-of-life decision-

making, advance directives, personalised medicine, medical professionalism, clinical ethics committees and clinical ethics consultation.

Christof von Kalle has been Director of the Department of Translational Oncology at NCT and DKFZ since July 2005, chairing the NCT Board of Directors. As a physician scientist, with a clinical background in haematology/oncology, Prof. von Kalle is an internationally renowned scientific leader in stem-cell research, mutation analysis and gene transfer, with >150 high-impact publications. He is an elected member of the European Academy of Cancer Sciences and serves as chair of the CCC Network of German Cancer Aid. Professor von Kalle co-ordinates overall NCT activities, with the primary goal of facilitating excellence in translational and clinical research. The department is home to internationally renowned research groups for stem-cell research, applied functional genomics, lymphoma research, molecular diagnostics and gene therapy. Physician scientists are involved in clinical activities, patient care and innovative clinical trials. The department oversees NCT POP, providing individual patient treatment based on in-depth molecular analysis.

Thomas Wabel is Professor of Protestant Theology (with a focus on Systematic Theology) at the University of Bamberg. Following his studies in Heidelberg, Bonn and Oxford, and after a research year at Harvard University in 1994, Wabel received his PhD in Systematic Theology from Heidelberg University in 1996. He has taught Systematic Theology at Frankfurt University, Humboldt University of Berlin, Justus-Liebig-University, Gießen, and Hamburg University, and he is a pastor in the Protestant Church of Hessen and Nassau (Germany). Professor Wabel held the Ernst Cassirer Fellowship at the Swedish Collegium for Advanced Study (SCAS) in Uppsala (Sweden) in 2008. He is author of *Sprache als Grenze in Luthers theologischer Hermeneutik und Wittgensteins Sprachphilosophie* (Berlin and New York: de Gruyter, 1998) and of *Die nahe ferne Kirche. Studien zu einer protestantischen Ekklesiologie in kulturhermeneutischer Perspektive* (Tübingen: Mohr Siebeck, 2010). Furthermore, his publications include books (both as editor and co-editor) on bioethics and medical ethics (2004, 2007), on neurophysiology, legal responsibility and free will (2005), and on commentary as a practice of liberal arts (2011). His articles in journals and books cover such topics as the role of intuition in moral reasoning (2005), religion and aesthetics (2006, 2007), the hiddenness of God (2010) and medical ethics (2012, 2013).

Anke Walendzik studied Economics at the Universities of Cologne and Warsaw and completed her doctorate at the University of Duisburg-Essen. She was working as a research associate from 2005 and has been working as head of the research unit 'Health Systems, Health Policy and Pharmaceutical Regulation' at the Institute for Health-Care Management and Research,

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Sebastian Wäscher, MA, is a researcher in Medical Ethics, with a focus on social science aspects. He has a background in Communication, Sociology and Philosophy. Sebastian has been a Research Assistant at the Institute for Medical Ethics and History of Medicine, Ruhr-University Bochum, Germany, and a member of the NRW-Junior Research Group ‘Medical Ethics at the End of Life: Norm and Empiricism’ since 2011. His research interests are questions at the end of life, empirical ethics, personalised medicine and qualitative research methodology.

Jürgen Wasem is an economist and public health researcher by training. He has served as a full Professor and Director of the Alfried Krupp von Bohlen und Halbach Endowed Chair for Health-Care Management and Research, University Duisburg-Essen, since 2003. Professor Wasem is a member of the medical faculty as well as of the faculty for Business and Economics at the University. Among former positions he was full Professor for Health-Care Management at the Department for Law and Economics of the Ernst Moritz Arndt University Greifswald, Professor for Health Economics in the School of Public Health of the Ludwig-Maximilians-University Munich, a senior researcher at the Max Planck Institute for the Study of Societies, Cologne, and consultant at the Department for Health Care and Health Insurance of the Federal Ministry of Labour and Social Policy. He is a member of the board of directors of the German Health Economics Association (dggoe), where he was chairman in 2013/14. He was the president of the German Association for Disease Management (DGDM), and is a member of the board of directors of the Federal Association for Managed Care (BMC). He is chairperson of the Academic Advisory Board on Risk Adjustment which is affiliated to the Federal Insurance Office.

Jürgen Windeler is a physician and the current Director of the Institute for Quality and Efficiency in Health Care (IQWiG) in Cologne, Germany. Between 1985 and 1993, Professor Windeler worked as an assistant physician, was a fellowship holder of the German Research Foundation, and worked as a research associate at various universities and hospitals, including the Department of Medical Informatics and Biomathematics at the Ruhr University of Bochum. Between 1993 and 1999, he was a university lecturer and Deputy Head of the Department of Medical Biometry at the Ruprecht Karls University of Heidelberg. He then joined the Medical Advisory Service of the German Social Health Insurance (MDS) in Essen, initially as the Head of the

Department of Evidence-based Medicine (1999–2004) and then as the Deputy Chief Executive and Chief Physician (2004–10). In September 2010 he took up the position of Director of IQWiG. Besides evidence-based medicine (EbM) in general, Professor Windeler's research interests include the application of EbM principles to medical devices, screening programmes, and personalised medicine. He has held an extraordinary professorship in Medical Biometry and Clinical Epidemiology at the Ruhr University of Bochum since 2001.

Eva C. Winkler is a physician ethicist at the National Centre for Tumour Diseases (NCT) in Heidelberg. She holds a PhD in cancer research from the University of Heidelberg as well as in Medical and Health-Care Ethics from the University of Basel (*summa cum laude*). Before she entered the PhD programme in Basel, she did research and training in Medical Ethics at the Harvard Medical School, Division of Medical Ethics (ethics fellowship) and as a Faculty Fellow at the Center for Ethics and the Professions, Harvard University, Kennedy School of Government. She is a board-certified internist who has been working in oncology both with in- and outpatient care for 15 years and as a consultant for many years. Dr Winkler works as a consultant at the Centre for Oncology at the NCT Heidelberg and is a group leader of the research programme Ethics and Patient-Oriented Care in Oncology (NCT-EPOC). She is co-directing the 'Ethics and Medicine' Working Group of the German Association for Haematology and Oncology. She is a fellow of the Marsilius Kolleg and project speaker for the interdisciplinary project 'Ethical and Legal Aspects of Whole Genome Sequencing (EURAT)' of the Marsilius Kolleg in Heidelberg.

Mathias Wirth is a theologian and ethicist who studied both Catholic and Protestant Theology with Philosophy. He holds the position of Lecturer and Research Associate at the Department of History and Ethics at the University Medical Centre Hamburg-Eppendorf, Germany. His research and teaching interests encompass Anthropology and Ethics, with a particular focus on Hebrew-Christian tradition in dialogue with current ethical debates on medicine, freedom and vulnerability. Examples of his work include *Can One Murder Out of Compassion? Ethics of Compassion according to Emmanuel Lévinas's Concept of Alteration* (2012), *The (In)Visible Human in Life Sciences: How Accurate is Karl Rahner's Enigmatic Human after Genome Sequencing and Brain Imaging?* (2012), and *Regula Tactus: The Actuality of an Ecclesiastical Norm as Prevention of and a Plea against Sexual Violence* (2013).

Sabine Wöhlke completed her studies in Cultural Anthropology and Gender Studies at the University of Göttingen, Germany. She has been a research assistant for Prof. S. Schicktanz at the Department of Medical Ethics and History of Medicine at the University Medical Centre, Göttingen, since 2006.

Her main interests include ethical aspects of genetic testing and predictive genetic testing, qualitative social-empirical research, and ethical and medical anthropological research on organ transplantation. She was scientific coordinator of the project 'Ethical aspects in individualized rectal cancer therapy: patients' expectations and attitudes toward prognostic tests using biomarkers – a socio-empirical and medical-ethical analysis' (funded by the DFG, KFO 179/2) from 2011 to 2014. She has been a member of the European working group 'Mind the risk' – ethical, psychological and social implications of provision of risk information from genetic and related technologies (funded by the Swedish Riksbankens Jubileumsfond), since 2014.

In 2014, Dr Wöhlke finalised her PhD with the title: 'Medical anthropological perspectives towards decisions and motivations of living kidney donations, with a special focus on gender differences'.

Introduction

Jochen Vollmann, Verena Sandow, Sebastian Wäscher and Jan Schildmann

‘Personalised medicine’ is commonly understood as the application of biological (for example, genomic) data to improve the diagnosis, therapy and prevention of diseases. Over the last few years, this phrase has become the symbol of medical progress and a label for better health care in the future. However, a controversial debate has developed whether these promises of better, more personal and more cost-efficient medicine are realistic. Therefore, the book assembles contributions of leading experts from normative and empirical disciplines with a focus on a critical reflection about ‘personalised medicine’ – a topic which is often dealt with in a rather uncritical way in current literature.

One important source for the research comprised in this volume is the four-year collaborative research project *Personalised Medicine in Oncology: An Interdisciplinary Study on Ethical, Medical, Economical and Legal Aspects* funded by the German Federal Ministry for Education and Research (Bundesministerium für Bildung und Forschung – BMBF). Experts from the fields of medical ethics, oncology, health-economics and law present findings from this joint research collaboration. The second source for contributions is a selection of presentations from the 2013 conference of the European Association of Centres of Medical Ethics (EACME) *‘Personalised Medicine’ – Medicine for the Person? Ethical Challenges for Medical Research and Practice*. The conference attracted leading researchers from Europe, North America and other continents which provided a forum for a multidisciplinary debate on the current state of research on the ethical, legal and social implications of personalised medicine.

The book is structured in three main parts which cover important topics in the field of personalised medicine beginning with the clarification of the vague concept of personalised medicine, through the presentation and reflection of clinical application, to a discussion on structural aspects of personalised medicine. A fourth part completes the book with recommendations for future development in personalised medicine.

Part I: Personalised Medicine – Medicine for the Person? Concepts and Contextual Aspects

The first part of the book reflects on the general concepts of personalised medicine. Therefore, questions on the meaning of the term ‘personalised medicine’ and related topics are discussed. The contributions stretch from definitions (Schleidgen and colleagues) and possible paradigm shifts (Fischer and colleagues; Browman) to the question of personhood (Wabel; Wirth; Heusser).

Sebastian Schleidgen and his colleagues argue that the lack of a clear definition of personalised medicine is problematic for both conceptual and empirical research. The aim of their chapter, ‘What is Personalised Medicine? Sharpening a Vague Term Based on a Systematic Literature Review’, is to develop a definition of personalised medicine to solve the problems arising from the vague use of the term. The authors conduct a systematic review in order to derive a definition of the term ‘personalised medicine’.

Tobias Fischer and his colleagues locate the discussion on personalised medicine between hypes, hopes and risks. The authors state that aspects of personalised medicine are situated in the realm of hypothetical ethics. With their chapter, ‘Alarming Symptoms of a Paradigm Shift? An Approach to Bridge the Gap between Hypothetical Ethics and the Current Status of Individualised Medicine Research’, they present an approach to bridge the gap between hypothetical ethics and the current status of research on personalised medicine.

Thinking of personalised medicine in terms of a paradigm shift, George P. Browman illuminates in his chapter, ‘Personalised Medicine: Getting Past the Controversies’, how new ways of thinking often begin with controversial discussions and then, slowly, arrive at more fruitful conversations. The aim of his chapter is to contribute to the discussion on personalised medicine in order to change the way of speaking from controversy to consensus. He sets up a framework for the future accessibility of personalised medicine and differentiates between two conceptual packages with unsolved and rising problems.

While these three chapters discuss very foundational questions of personalised medicine, the following three chapters focus on aspects of personhood and autonomy in personalised medicine.

Thomas Wabel argues in favour of a concept of ‘embodied autonomy’ in his chapter, ‘Patient as Person in Personalised Medicine: Autonomy, Responsibility and the Body’. This concept avoids a dualism of body and mind and is driven by the idea that ‘mind is essentially embodied’. To strengthen his argumentation, he uses empirical results from interview studies on personalised medicine as an example of how to conceptualise ‘embodied autonomy’.

Matthias Wirth analyses the term ‘personalised’ from a phenomenological theoretical perspective. In his chapter, ‘The Authority of Corporeality and Emotions: The New Phenomenology and its Relevance to the German Debate

on Personalised Medicine’, he shows how a concept of corporeality broadens our view of a personalised medical treatment. He argues that neither the immaterial nor the material aspect of human existence refers exclusively to the phrase ‘personalised’.

In line with Wabel and Wirth, Peter Heusser analyses the term ‘person’ in personalised medicine and agrees that a person is more than a mere genetic set-up. In his chapter, ‘Towards Integration of “Personalised” and “Person-centred” Medicine: The Concept of “Integrative and Personalised Health Care”’, he shows a friction between the scientific concept of personalised medicine as molecular medicine and the understanding of the term by lay people.

Part II: Personalised Medicine in Clinical and Practical Research

The second part of the book shifts from the theoretical perspective to the application of personalised medicine and draws a line from critical conceptual contributions on biobanking (Winkler and colleagues; Hirschberg and colleagues), through clinical research on new genetic biomarkers (Port and colleagues) to a general reflection from a social science perspective (Wöhlke and colleagues; Wäscher and colleagues; Prainsack).

The first two chapters discuss aspects of biobank research in the context of informed consent. Both chapters present various problems of biobank research and concentrate on informed consent procedures, but choose different ways of coping with the complex issue of consent in biobank research.

Eva C. Winkler and her colleagues argue from a clinical perspective and develop an ethical framework on this basis. They point out several ethical issues connected to genomic data use in medicine in their chapter, ‘Ethical Considerations for Developing a Best-Practice Guideline for Next Generation Sequencing in Oncology’. The main aim of the chapter is to give an overview of ethical and clinical questions concerned with the patient information process and consent in biobank-based genomic research.

Closely connected with Winkler, Irene Hirschberg and colleagues analyse guidelines on consent in biomedical research in order to develop a tool to distinguish relevant aspects of informed consent in biobank research in their chapter, ‘Practice Variation across Consent Templates for Biobank Research: A Survey of German Biobanks’.

On the basis of a meta-analysis of publications dealing with acute myeloid leukemia (AML), Matthias Port and his colleagues provide an account of the current evidence on the role of biomarkers for treatment and prognosis of this disease. In the chapter ‘Individualised Medicine in the Diagnosis and Prognosis of Patients Younger Than 65 Years with Normal Karyotype Acute Myeloid Leukemia: A Systematic Review and Meta-Analysis of the Impact of Fms-Related

Tyrosine Kinase 3 Internal Tandem Duplication (FLT3-ITD)', the authors identify the FLT3-ITD mutation as an important prognostic parameter in AML therapy and also discuss the challenges to critically appraise the relevance of biomarkers.

Three chapters take a social science perspective on clinical research in personalised medicine.

Sabine Wöhlke and colleagues analyse patients' perspectives on personalised medicine with a qualitative research design (observations and interviews). In their chapter, 'Taking it Personally: Patients' Perspectives on Personalised Medicine and its Ethical Relevance', they concentrate on ethical aspects of information and decision-making within the context of stratified treatment of rectal carcinoma.

Sebastian Wäscher and his colleagues give insights into the clinical social reality with their chapter, "Personalised Medicine" in Oncology: Physicians' Perspectives on Contributions to and Challenges for Clinical Practice'. They use qualitative interviews to illuminate the attitudes and values of oncologists who are confronted with the development of personalised medicine in their daily practice. The physicians draw a differentiated picture of personalised medicine in which they stress the advantages of stratifying therapies as well as the practical problems resulting from such a development.

Barbara Prainsack links the discussion on biobanking and the application of specific genomic data to a larger discussion on the clinical use of personalised medicine in her chapter, 'Through Thick and Big: Data-Rich Medicine in the Era of Personalisation'. She critically asks questions on the use of data and points out several challenges, such as the clinical utility of 'big data'.

Part III: Personalised Medicine in Health-Care Systems

The third part of the book assembles contributions on methodological and normative aspects relevant to the implementation of personalised medicine in health-care systems. This includes research on methodological characteristics of drug assessment (Windeler and Lange), aspects of reimbursement decision-making (Hessel; Noweski and colleagues), questions on the fair allocation of genetic testing (Rogowski and colleagues), legal aspects of orphanisation (Gottwald and Huster) and a critical analysis of priority setting and opportunity costs in European public health-care systems (Vollmann).

Jürgen Windeler and Stefan Lange argue in their chapter, 'Benefit Assessment of Personalised Interventions: Methodological Challenges and Approaches to a Solution', that, from a methodological point of view, no new concepts of quality assessment for personalised medicine are needed. Personalised medicine can be judged under the stance of evidence-based medicine, which usually means prospective controlled intervention trials.