proposals for completely decriminalising abortion ought to bear in mind that, at least so far as surgical interventions are concerned, the complete exclusion of the criminal law is impossible (given that *all* surgery depends upon a medical exception to the criminal law), and interference with the current statutory framework may, in fact, leave the practice more, rather than less, vulnerable. (p. 141)

Griffiths and Mullock consider how the medical exception applies to non-therapeutic cosmetic surgery. Drawing on a number of social and ethical concerns associated with commercial cosmetic surgery, they dispute whether the medical exception is appropriate in this context. Although I was not necessarily convinced by all of the conclusions in these two chapters, they both provide exemplary scholarship, formidable reasoning and welcome new perspectives on the respective issues under consideration.

Indeed, this collection is notable for the consistent high quality of the 13 chapters in it and the editors should be congratulated for compiling it. Space constraints, alas, prevent even a cursory description of all of the excellent contributions. But, given the food for thought contained here, it is doubtful that the medical exception will remain an under-researched topic for much longer.

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Jochen Vollman, Verena Sandow, Sebastian Wäscher, and Jan Schildmann (eds.),
The Ethics of Personalised Medicine: Critical Perspectives, Farnham, Ashgate, 2015,
 313 pp., Hardback and e-book, £70, ISBN 9781472447968

Personalised medicine has been much discussed as a means of great progress in medicine and health care. While it conjures up a vision of holistic medicine tailored to the unique individual and his/her environment, lifestyle and genes, personalised medicine has been commonly used in the medical literature to mean an approach that stratifies patients into groups using biological information. In the first chapter of this edited collection, Sebastian Schleidgen et al suggest a precise definition of personalised medicine following a systematic review of definitions found in relevant PubMed articles:

Personalised medicine seeks to improve tailoring and timing of preventative and therapeutic measures by utilising biological, information and biomarkers on the level of molecular disease pathways, genetics, proteomics as well as metabolomics. (p. 20)¹

1 S Schleidgen, C Klingler, T Bertram, WH Rogowski, and G Marckmann, 'What Is Personalised Medicine? Sharpening a Vague Term Based on a Systematic Literature Review'.

This edited collection has 19 chapters and 47 contributors from a range of disciplines including clinical genetics, oncology, philosophy, law, theology, public health, health economics and political science. The sources for the papers were research undertaken in a four year multidisciplinary project on personalised medicine in oncology, funded by the German Federal Ministry for Education and Research, and papers presented at the 2013 conference on personalised medicine organised by the European Association of Centres of Medical Ethics (EACME). The book is divided into four parts which, in turn, clarify the concept, consider clinical applications and structural aspects of personalised medicine. In the fourth and final part, Jan Schildmann et al make recommendations for the future development of personalised medicine.²

In Chapter 1 of Part I ('Personalised Medicine—Medicine for the Person? Concepts and Contextual Aspects'), and following their definition of personalised medicine above, Schleidgen et al conclude that the term 'stratifying medicine' would prevent the 'false hopes' that personalised medicine is individualised patient-centred medicine (p. 22). Rather, personalised medicine should be understood as an 'add-on' to standard medical care. Similarly, Tobias Fischer et al criticise the idea that 'individualised medicine' will bring about a paradigm shift in health care and give as an example the use of biomarkers to predict response to therapies for patients with testosterone decline and for patients with a specific type of heart failure.³ Their conclusion heralds themes that run throughout the book; progress is being made in limited areas of medical care but that progress is slow, and the prediction of diseases, particularly complex, multifactorial diseases, is proving even more difficult. The remaining chapters in Part I look critically at personalised medicine as technology rather than as person-centred health care. Mathias Wirth, for example, argues that medicine cannot be personalised in a clinical setting that ignores the need for respect, including attention to the emotions.⁴ Peter Heusser suggests that personalised medicine should learn from the more holistic approach of complementary or alternative medicine because 'otherwise personalisation can lead to depersonalisation' (p. 79).⁵

The second part of the book considers the application of personalised medicine, particularly in the treatment of cancer and leukaemia.⁶ Eva Winkler et al discuss the need for a code of conduct on handling data derived from patients' cancer tissue in a way that is ethically and legally sound.⁷ As Irene Hirschberg et al

2 J Schildmann, M Böttcher, M Gabriel, A Ganser, S Gottwald, F Hessel, S Huster, R Jahn, A Neumann, M Noweski, M Port, L Pouryamout, V Sandow, F Thol, S Wäscher, A Walendzik, J Wasem, and J Vollmann, "'Personalised Medicine": Multidisciplinary Perspectives and Interdisciplinary Recommendations on a Framework for Future Research and Practice', Ch. 19.

3 T Fischer, M Dörr, R Haring, and M Langanke, 'Alarming Symptoms of a Paradigm Shift? An Approach to Bridge the Gap Between Hypothetical Ethics and the Current Status of Individualised Medicine Research', Ch. 2.

4 M Wirth, 'The Authority of Corporeality and Emotions: The New Phenomenology and Its Relevance to the German Debate on Personalised Medicine', Ch. 5.

5 P Heusser, 'Towards Integration of "Personalised" and "Person-Centred" Medicine: The Concept of 'Integrative and Personalised Health Care', Ch. 6.

6 Part II 'Personalised Medicine in Clinical and Practical Research'.

7 EC Winkler, K Tanner, H Glimm, and C von Kalle, 'Ethical Considerations for Developing a Best-Practice Guideline for Next Generation Sequencing in Oncology', Ch. 7.

illustrate in their survey of German biobanks, consent forms currently vary greatly and none of the consent procedures cover the question of how data and material are dealt with once a participant dies or no longer has capacity.⁸ After a specific example of the significance of one biomarker in the prognosis and treatment of acute myeloid leukaemia,⁹ the focus of the chapters changes to the value of qualitative methods in understanding the values, opinions and experiences of those directly involved. In separate chapters on patient and physician perspectives, the research showed that both groups found the increase in complex information a challenge to understanding.¹⁰ Patients tended to leave informed consent forms unread and had 'pragmatic trust' in their physicians (p. 140), whereas physicians referred to the inevitable differentiation of expertise as the information flood could not be handled by one person. Barbara Prainsack examines 'data-rich medicine'—multi-layered datasets that consist of genomic information and personal information on lifestyle, diet and medical histories of relatives.¹¹ Patients may not be willing or able to contribute this information and, if they do, we do not yet know how to integrate datasets and have meaningful and accurate data available in the clinic.

Chapters in the third part of this collection discuss personalised medicine in healthcare systems and consider how personalised medicine can provide better health care and how national healthcare systems, including insurance-based systems, will cope with the new generation of 'personalised' drugs and the accompanying requirements for genetic tests.¹² Criteria for allocating resources are discussed, including identifying the greatest need and maximum benefit, promoting equity and avoiding inequality. The theme of this part is that there are no easy solutions given the resource constraints on healthcare budgets. Jochen Vollmann suggests that an increase in costs is likely, despite the promise that personalised medicine will result in reduced healthcare costs (p. 252).¹³ Sina Gottwald and Stefan Huster raise the possibility of personalised medicine products being designated as 'orphan drugs' for rare diseases, which would mean that, under German law, evidence of additional benefit to patients would not generally be required during early benefit assessment by the relevant government committee.¹⁴ They conclude that it might be necessary to reconsider this rule if pharmaceutical companies attempt to use it to gain access to markets.

8 I Hirschberg, H Kahrass, and D Strech, 'Practice Variation Across Consent Templates for Biobank Research: A Survey of German Biobanks', Ch. 8.

9 M Port, M Böttcher, F Thol, N Trachte, J Wasem, A Ganzer, L Pouryamout, and A Neumann, '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)', Ch. 9.

10 S Wöhlke, J Perry, and S Schicktanz, 'Taking It Personally: Patients' Perspectives on Personalised Medicine and its Ethical Relevance', Ch. 10; S Wäscher, J Schildmann, C Brall, and J Vollmann, "'Personalised Medicine" in Oncology: Physicians' Perspectives on Contributions to and Challenges for Clinical Practice', Ch. 11.

11 'Through Thick and Big: Data-Rich Medicine in the Era of Personalisation', Ch. 12.

12 Part III 'Personalised Medicine in Healthcare Systems'.

13 'Personalised Medicine: Priority Setting and Opportunity Costs in European Public Health-Care Systems', Ch. 13.

14 'Personalised Medicine as Orphan Drugs? Legal and Ethical Questions', Ch. 17.

In the final part,¹⁵ researchers who collaborated on the project 'Personalised Medicine in Oncology: An Interdisciplinary Study on Ethical, Medical, Economical and Legal Aspects' consider the future of personalised medicine.¹⁶ While there have been successes in oncology treatment for some groups, there are considerable challenges to its implementation more widely and, in general, the picture is one of 'evidentiary uncertainty' with a lack of agreement on what evidence is even necessary for personalised medicine interventions to be used.

As this summary of the contents indicates, the contributors to this collection approach personalised medicine from diverse disciplinary perspectives. The discussion moves through general concepts of personalised medicine, studies of clinical utility for one group of patients, to specific legal/ethical/economic issues and broader considerations of the necessary conditions for personalised medicine in public health-care systems. Work on making connections between chapters and differing or conflicting perspectives is largely left to the reader, as with most collections of this sort. However, given the diverse nature of the topics covered and the approaches used, this is probably a book readers will use to follow up their particular interests rather than read cover to cover.

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15 Part IV 'Personalised Medicine in Oncology: Recommendations for Future Developments'.

16 See n 2 above.