

Editorial

Personalised Medicine: the promise, the hype and the pitfalls

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Abstract: In engaging critically with personalised medicine and mapping pitfalls which mark its progress this project aims to stimulate conversations which deal intelligently with controversies for the sake of consensus. We aim to ask the ethical questions which will lead to the improvement of healthcare and we take an open-minded approach to finding answers to them over time. What is or should be meant by ‘personalised medicine’ is a major theme of this issue. It is a debate bound up with question of both values in the sense of ethical reflection and value in the sense of economic return. This editorial discusses and interrelates the articles of the issue under four headings: the promise and the hype of personalised medicine; the human person and the communication of risk; data sharing and participation; value, equity and power. A key intention throughout is to provoke discourse and debate, to identify aspirations which are more grounded in myth or hype than reality and to challenge them; and to identify focussed, practical questions which need further examination.

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Editorial

Personalised Medicine: the promise, the hype and the pitfalls

Therese Feiler, Kezia Gaitskell, Tim Maughan, Joshua Hordern

The articles which form this special issue of *The New Bioethics* have arisen from the project *Personalised Medicine: the promise, the hype and the pitfalls*, a collaboration between the University of Oxford Healthcare Values Partnership (www.healthcarevalues.ox.ac.uk) and the MRC stratified medicine consortium in Colorectal Cancer (S-CORT). The conference which formed the context in which many of the papers in the volume were initially presented was held in association with CASMI-Academic – the Centre for Advancement in Sustainable Medical Innovation – and the University of Oxford’s Centre for Personalised Medicine. As editors, we express our thanks to these partners and to the funders of the project, the Sir Halley Stewart Trust and the University of Oxford Wellcome Trust Institutional Strategic Support Fund (grant number 105605/Z/14/Z); and the funder of the next phase of the research, the Arts and Humanities Research Council (grant number: AH/N009770/1). We are also very grateful to the editors of *The New Bioethics* for granting us the opportunity to edit this special issue.

A critical approach to ‘personalised medicine’

In engaging critically with personalised medicine and mapping pitfalls which mark its progress this project aims to stimulate conversations which deal intelligently with controversies for the sake of consensus. We aim to ask the ethical questions which will lead to the improvement of healthcare and we take an open-minded approach to finding answers to them over time.

Nonetheless, a right desire for consensus must reckon with the controversial nature of the enterprise which has come to be known as ‘personalised medicine’. There is vigorous if polite

debate in journals such as the Lancet about whether the entire enterprise is ill-conceived and whether the focus of research spending should be shifted very substantially to public health: some say that the promises have not been delivered and are unlikely to be delivered (for debate see e.g. Dzau et al. 2015; Coote and Joyner 2015; Matuchansky 2015). Moreover, even in using the term ‘personalised medicine’ we are straight into critical work: what is meant by ‘personalised medicine’? Is not all medicine personalised, in some broad sense? In order to focus on medicine which operates at the molecular level, should we not really say ‘stratified medicine’? After all, it is arguable that no medicine should be promised that is truly tailored to an individual person, not only because that is generally scientifically and clinically implausible but also because it unkindly distorts the expectations of patients and the general public and may limit the understanding of the person to characteristics which are biomedically definable.

What is or should be meant by ‘personalised medicine’ is, therefore, a major theme of this issue. It is a debate bound up with questions of both *values* in the sense of ethical reflection and *value* in the sense of economic return. Indeed, an emphasis on how *values* shape decisions made about medical science’s role in society has become increasingly urgent. A UK House of Lords Science and Technology committee report in 2000 made the following observations on what it sees as a more generally troubled relation between science and society:

Some issues currently treated by decision-makers as scientific issues in fact involve many other factors besides science. Framing the problem wrongly by excluding moral, social, ethical and other concerns invites hostility...Underlying people’s *attitudes* to science are a variety of *values*. Bringing these into the debate and reconciling them are challenges for the policy-maker. (House of Lords Committee on Science and Technology, 2000.)

This suggests a rationale for why humanities disciplines such as theology and philosophy must be involved in the debates alongside social scientists, clinicians and medical researchers. Values lie at the heart of healthcare in general. Personalised medicine defined in the sense given above is no different. Humanities disciplines have both the competence and responsibility to explore and critique the values which are in play in any given activity. Everybody has values – scientists, physicians, patients, policy-makers, politicians. Everyone is invested in some way – whether professionally, as a patient, policy maker or member of the general public.

Humanities disciplines have the capacity to generate discussion about that investment and to press people towards asking important, sometimes challenging questions about values. Such modes of enquiry, embedded in and intertwined with the history of present society and modern medicine, are capable of illuminating implicit assumptions at work in enterprises such as personalised medicine. For example, in this specific project, theological reflection on values has played an important role in framing the questions. The desire to test out a critical juxtaposition of promise and hype was a theologically informed thought, seeking discernment of how truthfulness, personhood and promises about the future fare in precision medicine research.

The UK Government's Chief Scientific Adviser's report for 2014 emphasised the need for interdisciplinary engagement in scientific research:

in engagement — as in innovation itself — there are key roles for the creative arts, humanities and civil society. Some approaches are less formally structured than others, involving uninvited as well as invited engagement...diverse forms of public engagement can supplement, enrich and inform (rather than substitute) the conventional

procedures of representative democracy. (UK Government Office for Science, 2014: 61)

The report worries about a closed shop in public reasoning about science and argues instead for the ‘scope for dialogue to be extended to the workplace, the neighbourhood centre, the household and the church.’ (UK Government Office for Science, 2014: 67) On this view, public reasoning about the significance of genomic healthcare is underpowered unless it involves a critical awareness of key concepts and debates scrutinised in the humanities.

One interdisciplinary example of this critical literature is a 2015 volume edited by Joachim Vollman et al representing a major collaboration funded by the German government and reflecting a rich debate in German society drawing on many voices from oncologists to theologians to policy makers. It represents an important counterpoint to the widespread, largely uncritical acceptance of ‘personalised medicine’, especially in the Anglophone world (for an exception, Tannock and Hickman 2016). It also finds an echo in the recognition by political and social theorists of no religion such as Habermas and Zizek that their sources of interpretation of the world are intellectually shallow unless they pay attention to theological and religious traditions.

Vollman addresses the vagueness of the term ‘personalised medicine’, suggesting that three main positions can be identified: ‘(a) PM is not a new concept as medicine has always been individualised (b) PM is holistic health care centred on the needs of the individual patient (c) PM is treatment targeted at stratified subgroups.’ (Vollmann et al. 2015: 9). Later in the volume one definition in particular is argued for, after an extensive systematic literature review of 2,500 articles which contained 700 different definitions. This definition will be taken as the point of departure for this volume, if not the final destination for every author in it:

Personalised Medicine seeks to improve stratification and timing of health care by utilising biological information and biomarkers on the level of molecular disease pathways. (Vollmann et al. 2015: 21)

The promise and the hype of personalised medicine

This account is, however, not the first thing the general public might think when they hear of ‘personalised medicine’. Instead, the focus on the *personal* in personalised medicine may generate a mystique of unrealisable promises and expectations about medicines and treatments perfectly tailored to each individual person. The promissory nature of medicine in this field is the focus for the articles in the first section of this volume. The authors focus on how clinical, commercial and other sectors talk about personalised medicine – what promises are made; to whom are they made; can they be fulfilled; what drives the making of promises? How is the potential of personalised medicine to be distinguished from overstatement amounting to hype, if indeed the distinction between hype and promise can be accurately applied to the uncertainties which naturally attend the scientific enterprise? How are we to assess whether hype, if it exists, is good, bad; or just necessary in order to keep the show on the road?

These questions are posed in a context in which a significant gap has emerged between the promise of progress made by industry, researchers and politicians on the one hand and the reality of biomarker-based personalised medicine in research findings and clinical practice on the other. This raises issues of both historical and current clinical importance. How good are those involved in personalised medicine at distinguishing between optimism and over-promising (even intentional exaggeration or distortion)? How should the phenomena of hype and promise be best understood from historical, philosophical, sociological and theological perspectives? Have population health approaches suffered unduly because of personalised medicine hype? Are researchers and clinicians more susceptible to imprudent hype around

genomic medicine than patients? How might scientific, clinical and public expectations be best protected from the effects of unrealistic hype and unfulfilled promises while not extinguishing realistic hope and appropriate ambition?

In his article, Tim Maughan addresses many of these issues in relation to cancer, noting that with a few outstanding exceptions, progress has fallen below expectations because of the challenges of tumour heterogeneity and clonal evolution. While in both benign and malignant disease, diseases caused by single genetic alterations are more amenable to precision medicine approaches, most common diseases are caused by a complex interplay of multiple genetic and environmental factors making personalised medicine far more challenging. Drawing on his experience as both a clinician and researcher he observes that the current optimism for personalised medicine is distorting clinical consultations, resource allocation and research funding prioritisation. He concludes that a research active clinician must act both as an agent of change and development, and as a communicator of realism. Only a personalised medicine that includes a sober appreciation of what genomics can achieve, together with continued focus on the individual as a person not just as a genome, will contribute to further improvements in health and healthcare.

In a similar vein, Kezia Gaitskell details some of the ways in which ‘personalised medicine’ has had a positive impact on disease screening and prevention, by enabling more person-specific estimates of risk, and hence more personalised strategies for screening and risk reduction. But she also outlines potential difficulties and limitations of this approach and challenges the assumption that ‘personalised’ approaches are necessarily superior for prevention and screening. She argues especially for a renewed focus in research and practice on established and proven public health approaches, which typically lose out to high-tech, innovative research.

Steve Sturdy's contribution acknowledges these two lines of concern but takes its own approach. First, it queries the appropriateness of focussing analysis via a strong contrast between hype and promise. He argues that since the former is a necessary feature of any scientific enterprise, especially one which depends on private commercial backing, the proper critical focus should really be on how and why particular kinds of scientific promises are being articulated and circulated in the present. Charting the development of the biotechnology sector from the 1970s, when a focus on molecular biomarkers became prevalent, through to the present day, Sturdy offers a historical and sociological analysis of personalised medicine with attention to the way that promissory language linked together the concerns of government and commercial interests. He observes that personalised medicine has been much better at fulfilling its promise to reward private investment, whether in the pharmaceutical or biotechnology sector, than at delivering savings to health services and their funders. Applications that might secure economies in healthcare but undermine profitability have largely been ignored and the dominant direction of personalised medicine continues to be towards the production of new and expensive treatments for small populations of patients. While Sturdy thinks it unlikely that this trajectory can be sustained much longer, he also proposes, without much hope of success in light of the overall direction of health policy, that the problem of mounting costs for diminishing medical returns would be to decouple medical innovation -- at least insofar as it relies on public funding -- from the overriding expectation of commercial profit.

While each of these contributions represents a particular line of critique concerning the enterprise of personalised medicine, each is also in their own way constructive attempts to remedy problems rather than simply describe them. Maughan and Gaitskell take clinically contextualised approaches to addressing questions of hype and promise. Sturdy's approach, by contrast, suggests a very far-reaching policy approach which may, as he recognises, be impractical considering the intermeshed nature of commercial and public actors in the actual

research enterprise. If Sturdy is right about the unsustainability of the way that personalised medicine is developing, it would seem crucial that research and policy addresses the shaping force of the profit-motive in a way which informs the interaction of commercial and public interests. A suitable policy would have to be realistic about the sources of innovation, other-regard and selfishness which lie in *both* private and public sectors. This would have implications for fostering the kind a research environment which serves the public interest, in which temptations to neglect largescale public benefit may overwhelm even the best motivated private actors. Such an approach would connect well both with Maughan's vision of the clinician's mediating role amidst the factors which shape patient experience and of Gaitskell's emphasis on ensuring that population-level public health approaches are not forgotten in the search for ever more precise approaches to prevention.

Bearing these critical concerns in mind about hype and promise, the papers which follow explore various pitfalls which may mark the clinical and research trajectory as it heads down the road of applying stratification or personalisation in healthcare. These cluster under three main themes:

- The human person and the communication of risk
- Data sharing and participation
- Value, equity and power

The human person and the communication of risk

In this project, we have noted the importance of distinguishing between different possible meanings of 'personalised medicine' and of analysing the experience of personalised medicine by patients and healthcare workers within the disciplines of social sciences and humanities. On the one hand, notions of biological determinism might shape a certain biomedical, genomic

understanding of the person in ‘personalised medicine’. On the other, and preceding this narrow genomic usage but now re-emphasised as an overarching category, another sense of ‘personalised medicine’ has focussed on relational aspects of care, individual beliefs and values, shared decision-making, risk communication and strategies for individualised compliance. In a related but distinct way, typically emphasised in medical humanities disciplines such as theology and philosophy, patients are understood as persons whose self-knowledge and significance to others are not circumscribed by an understanding of their genetic profile and risks. Such knowledge and significance may nonetheless become submerged in healthcare systems as expectations of the predictive and therapeutic powers of genomic technologies come to dominate the hopes of patients and healthcare professionals alike. An important question sits alongside these issues. It concerns what social vision of human persons can underpin a political solidarity in suffering in which stratified medicine might play an integral part. But in order to realise such a vision in practice and ensure that scientific progress continues to command public support, it is important to understand public perceptions of risk and value – of what really matters to patients.

In this context, Rob Horne makes a fundamental claim about the shape of the field by arguing that 4P medicine should be reconceived as 5P medicine in order to incorporate the psycho-social dimensions of care. Building on his earlier work in the field, Horne argues that technological advances enabling us to personalise medical interventions at the biological level must be matched by parallel advances in how we support the informed choices essential to patient and public participation. Since we cannot take participation for granted, medicine must take account of the perceptions and capabilities that shape participation. Using analogies from dystopian literature and evidence from social sciences, he argues that we need a better understanding of how people perceive personalised medicine and how they judge its value and

risks. To realise the promise of personalised medicine, 4P medicine must be personalised at the psychosocial as well as biological dimension—putting the person into personalised medicine.

Alastair Kent takes a complementary end-user perspective and draws on Genetic Alliance UK's evidence from a Citizen Jury to highlight why what matters to patients should be factored into how personalised, or stratified, medicine develops its targeted therapies. While it is unlikely that these novel therapies will provide complete cures, they will address some but not all symptoms of a condition. The key issue, therefore, is that early engagement with patients and families will ensure that developments are targeted at those aspects of a condition which really matter, not just those that are easy to count. He argues that this will make the development process more efficient, and improve the likelihood that patients will be able to access therapies if the development process is successful. The question of what really matters to patients is therefore crucial to how research in this field and communication about risk and value proceeds.

Joshua Hordern's article takes a further step to consider how stratification and genetic risk shapes a person's self-knowledge and knowledge of others. His argument takes its keynote from theological interpretations of the human condition and the promises of God and challenges notions of personhood which are overly-dependent on characteristics which are biomedically definable. In particular, he considers why and how self-knowledge is important to understanding risk by arguing for four claims. First, he casts doubt on whether genetic knowledge should properly be called 'self-knowledge' when its ordinary effects on self-motivation and behaviour change seem so slight. Second, he identifies various temptations towards a reductionist, fatalist, construal of persons' futures through a 'molecular optic', temptations which ought to be resisted. Third, more constructively, he argues that any plausible effort to support behaviour change must engage with cultural self-knowledge, values and

beliefs, catalysed by the communication of genetic risk. For example, while a Judaeo-Christian notion of self-knowledge is distinctively theological, people's self-knowledge is plural in its insight and sources. Finally, he makes the case that self-knowledge is found in compassionate, if tense, communion which yields freedom from determinism even amidst suffering. Stratified medicine, he suggests, offers a newly precise kind of humanising health care through societal solidarity with the riskiest that can yield this kind of self-knowledge. However, he also notes, with reference to the parable of the lost sheep, that stratification may also mean that patients who do not fit into the sought after molecular subtypes experience accentuated suffering and disappointment. This may represent a forgotten downside of the core theological concern about hype and is a theme taken up at the end of this editorial and in future research.

The overriding emphasis for these three articles concerns how the subtle interplay between senses of 'personalised' are actually crucial to the progress of 'personalised medicine' understood in the molecular sense that Vollman et al. define above. The questions which require further analysis include the risks to care of persons attendant on a focus on biomedical cure, construed at a molecular level; whether it is possible and beneficial to stratify on the basis of psychological factors as well as biological ones; how healthcare professionals might be better trained to pay attention to the interaction of the communication of genomic information with the values and beliefs of patients, especially as regards their future happiness; and how the entire enterprise of personalised medicine might develop a wiser compassion for the patients as persons whom they seek to serve.

Data Sharing and Participation

In the previous section, issues of how the public perceive participation in personalised medicine were raised. But a distinct set of problems in relation to a participative, personalised medicine

are raised with respect to data sharing. On the level of practical policy, there are national and international databases which are not interacting sufficiently with each other to make as much progress as researchers and patients desire. The underlying dimension of this policy problem concerns the motivations for collaboration and participation. The combination of self-interest and compassion for present neighbours and future generations which inspires data sharing is liable to be undermined by fears of data loss and trust violation. This in turn may lead to the worry that the pearls of data shared by well-motivated and willing patients consent may be trampled underfoot in the pursuit of profit. The three articles in this section take distinct approaches to this set of concerns.

Mark Lawler focusses on the challenge of embedding a culture within the scientific, medical and patient communities that supports the appropriate sharing of genomic and clinical information in order to maximise its value. He describes the ethical, legal and regulatory challenges that arise in pursuing this aim. In particular, he notes the selfish silos which shape research agendas and researchers' behaviour. By way of practical solutions that will benefit patients, researchers and society, he details the work of the Global Alliance for Genomics and Health, a worldwide coalition of researchers, healthcare professionals, patients and industry partners, which is developing innovative solutions to support the responsible and effective sharing of genomic and clinical data.

Anna Middleton's contribution supports this Global Alliance for Genomics and Health policy agenda by charting the *personal* dimension of personalised medicine through social scientific work on the attitudes, values and beliefs of those affected by technology in the genomics arena. In short, the public are asked 'how is the technology working for you?' To this end, the rationale to an international attitude study, Your DNA, Your Say, is introduced together with an overview of the survey and film design. The project uses film to provide background

information and an online survey to gather public views on donating one's own personal DNA and medical data for use by others.

Jonathan Montgomery argues at an angle which acknowledges but cuts directly across the presuppositions of most thinking in this area including that which shapes the policy approaches of the previous two articles. He notes the use of ideas about ownership in discussions of data sharing in personalised medicine. Personal health data are thought by many to be 'theirs'. But paradoxically, personalised medicine (at least in the context of genomics) relies on the aggregation of private data into a dataset that is held as a form of knowledge commons. This leads him to explore notions of private and common property that lie behind discourse about data ownership. Having made these explicit, Montgomery is able to use justifications and jurisprudence of property both to clarify the persuasiveness and limits of such claims, and also how they differ from other principles that are at stake in the interplay between individual and collective goods in the delivery of personalised medicine. His provocative conclusion is that ownership might more plausibly lie with health professionals than patients. However, in a socialised medicine system, such as the NHS, such professionals are agents of the state and ownership would lie with the commons rather than any individual. This means that common rather than private ownership of genomic information may be more appropriate.

If Montgomery's line of analysis is correct, then the normal public language and legal situation regarding genomic data about persons is significantly less plausible than it might at first seem. Middleton's and Lawler's approaches deal with questions of attitudes and values and, for Lawler at least, the shaping power of the law on the environment for data sharing, especially on an international level. But following Montgomery's argument would have widespread implications for both Middleton's and Lawler's concerns not least by challenging the widespread public belief in 'my data' and, in due course, laws regarding data theft. On

Montgomery's view, it is plausible to say that the problem of public suspicion about sharing data might be overcome by a policy which downplayed the idea of data donation and recognised instead the co-produced nature of the data itself: that although it is still data 'about me' it is properly speaking 'our data'. This might inspire greater public participation in data sharing and engagement in its use which would in turn shape the way in which precision medicine can proceed.

Whatever one makes of Montgomery's provocative argument, this set of articles raises broader policy questions: does the idea of co-production really represent a plausible way of understanding the ownership of personal, genomic information; what can be done to enable participation in data sharing, clinical trials and research to be meaningful with respect to the values of participants; what moral arguments need to accompany legal provisions to enable relevant institutions and individual scientists to be sharing information better; and finally, what might need to happen in terms of legal reform to enable progress to be made towards a more plausible public approach to the ownership and deployment of genomic data?

Value, Equity and Power

In this final section, papers consider questions of value, equity and power in a time when pathways to personalised medicine are being forged both in the UK and abroad. 'Value' is used here primarily in the sense of financial values as distinct from the discussions of 'values' and beliefs which appears in papers in earlier sections. While there is an intuitive attractiveness to the idea that '4P' medicine will be more cost-effective, there remain questions about affordability, ensuring equality of access, the participatory role of patients, the (re-)alignment of commissioning strategy and duties of justice towards neighbours, particularly in low- and middle-income countries. A risk attendant on the development of personalised medicine is that of social stratification based on ability to pay which in certain circumstances may entrench or

encourage the corruption of power. What does the pursuit of value mean when both national and global questions of equity are in view?

Muir Gray, Tyra Lagerberg and Viktor Dombrádi note that while precision medicine through genomic technologies carries huge potential in the treatment of many diseases, particularly those with a high-penetrance monogenic underpinning, it also has ethical implications, particularly with regard to value and equity in healthcare. They define allocative, personal, and technical value ('triple value') in healthcare and how it relates to equity, before discussing key issues surrounding precision medicine from this perspective. Equity is taken to be implicit in the concept of triple value in countries that have publicly funded healthcare systems. They argue that precision medicine may risk concentrating resources on those who already experience greater access to healthcare and power both at the level of the national society as well as at the global level. This places particular responsibility in the hands of healthcare payers, who need to allocate healthcare resources appropriately based on case-by-case estimates of the value of different genomic technologies. However, clinicians and patients also need to be involved in optimising the undeniable potential of precision medicine in the healthcare system without reducing equity. Throughout, their discussion refers to the framework of the NHS RightCare Programme, which is a national initiative aiming to improve value and equity in the context of NHS England.

Richard Sullivan and Bishal Gyawali attend primarily to the international and global questions of equity and value. They argue that the value that new cancer drugs add is very debatable. Because of the skyrocketing cost of the new drugs, each new approval represents a multibillion market. However, unlike other branches of economics, cancer drugs are intricately associated with socio-political issues, emotional overlay, public pressure, industry manipulation and propaganda. They review the value added by new cancer drugs and examine the socio-political

agenda around them with highlights on the increasing gulf between high-income and low-middle income countries regarding the affordability of these drugs. Finally, they suggest a way forward to address this highly complex issue.

These articles together raise up the agenda hard questions on a national or international level for those who have committed their professional careers or personal hopes to personalised medicine. The threats of inequity and poor value healthcare for those least able to stand up for themselves attend the 'advance' of personalised medicine. This raises the question of what responsibility medical researchers actually have for national and global inequity when control typically lies in the hands of governments, commissioners and payers. To put matters starkly, is personalised medicine potentially a Trojan horse for a neoliberal research agenda which will only be available for the rich in many countries? Such a development might put at risk the socio-political ethos of risk-pooling which underpins the vision of solidarity in healthcare.

Conclusion: 'molecularly unstratified' patients

The aim of this issue of *The New Bioethics* has been to provoke discourse and debate, to identify aspirations which are more grounded in myth or hype than reality and to challenge them; and to identify focussed, practical questions which need further examination.

A key concern that emerges in this issue through the disciplines of theology, social science and medical science 'molecularly unstratified' patients, those who will not be assigned to receive novel, precision treatments. Paying attention to these patients is a next logical step in scrutinising the distinction between hype and reality. What moral, psycho-social and societal issues are important in relation to such patients and how might they be best addressed?

The clinical significance of being 'molecularly unstratified' is that hope-laden therapeutic options are closed down and allocation to non-targeted or standard therapeutic treatments, or

supportive care become the only path. For the unstratified patient, what remains is a speculative search for genetic or other disease drivers, a process much further back in the developmental pathway when compared to current therapeutic intervention, implying many years or decades of waiting before a therapeutic could emerge.

For such patients, the particular molecular nature of their cancer becomes the occasion of both feeling and being left out and left behind, bobbing untidily about in the wake of technological and scientific ‘advance’. The deflation of hope among and the difficulty of identifying next treatment steps for this group of persons may have the side-effect of a kind of psycho-social distinction between unclassified persons and those ‘lucky’ enough to be stratified in some way.

An issue such as this embodies why examining the promise, hype and pitfalls of personalised medicine is important. Left unexamined, the distinction between the stratified and the unstratified may become a factor in depressing expectations of personalised precision, hitherto powered by a heady mix of promise and hype. If this experience of being ‘molecularly unstratified’ is not carefully addressed, a dilution or at least pronounced heterogeneity in the public’s support for stratified approaches may develop.

This is but one example of why analysis of the promise, hype and pitfalls which surround ‘personalised medicine’ is needed. Our hope is that this issue of *The New Bioethics* lays the groundwork for addressing these and other challenges as they arise.

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