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Does science need bioethicists? Ethics and science collaboration in biomedical research

Angeliki Kerasidou and
University of Oxford, UK

Michael Parker
University of Oxford, UK

Abstract

Biomedical research is an increasingly multidisciplinary activity bringing together a range of different academic fields and forms of expertise to investigate diseases that are increasingly understood to be complex and multifactorial. Recently the discipline of ethics has been starting to find a place in large-scale biomedical collaborations. In this article we draw from our experience of working with the Malaria Genomic Epidemiology Network (MalariaGEN) and other research projects to reflect upon the integration of ethics into biomedical research. We examine the way in which ethics input may be valuable to research, the forms it tends to take, and also the problems and limitations of such collaborations.

Keywords

bioethicist; bioethics; biomedical research; ethics and science collaboration; ethics input

Introduction

Biomedical research is an increasingly multidisciplinary activity bringing together a range of different academic fields and forms of expertise to investigate diseases that are increasingly understood to be complex and multifactorial. The precise combinations vary. To take one example, genomic epidemiology research in malaria requires the contribution of, among others, clinicians, epidemiologists and geneticists to understand the various aspects and manifestations of the disease, parasitologists to understand the role of the malaria parasites, as well as statisticians to analyse the information gathered and computer scientists to build platforms of analysis.

Corresponding author: Angeliki Kerasidou, MalariaGEN Ethics Co-ordinator & Researcher in Ethics, The Ethox Centre, Nuffield Department of Population Health, University of Oxford, Old Road Campus, Headington, Oxford OX3 7LF, UK. angeliki.kerasidou@ethox.ox.ac.uk.

Declaration of conflicting interest
'In their capacity as ethicists, both AK and MP are and have been involved in collaborations with a number of scientific networks, including the Malaria Genomic Epidemiology Network

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Recently, another discipline has begun to find a place in large-scale biomedical collaborations. This discipline is not from the area of life sciences but from the humanities. This is the discipline of ethics – bioethics in particular.

In this article we consider the way in which ethics input may be valuable for biomedical research, and the different forms ethics support tends to take when working alongside scientific projects. We also examine the main challenges that can emerge from the close collaboration between ethics and biomedical science. We conclude that, despite the limitations, a close collaboration between biomedical sciences and ethics has the potential to greatly enrich both fields of enquiry and create opportunities for new research.

Ethics and biomedical sciences relationship: A brief history

The relationship between biomedical sciences and ethics is not new. Albert Jonsen places the beginning of bioethics in the 1960s, when discussions regarding the precarious aspects of biomedical sciences first started (Jonsen, 2004). In the 1970s it was philosophers and theologians, and later on lawyers and social scientists who began to explore the field of bioethics. Clinicians and other medical scientists were also actively present in bioethics discussions, through publications and on open forums. By the 1990s ethics in science had become so widespread that Joseph Coates called it ‘the new plague’ (Coates, 1994).

One of his main concerns was that ethics was carried out by amateurs with very little or no training (Coates, 1994). Since the 1990s numerous courses, diplomas and degrees on bioethics have been created, and are on offer at universities and colleges around the world. Many of these courses are specifically designed for biomedical practitioners and researchers, and do not require any previous training in moral philosophy or ethics. Special online courses are available to quickly bring scientists up to date with the ethical issues of their particular area of investigation. There is also an abundance of literature on bioethics into which scientists working in biomedicine could tap.

Inevitably, the nature of the relationship between ethics and biomedical research has changed with time. In the 1970s the first research ethics committees (RECs) and institutional review boards (IRBs) were established. The type of relationship between biomedical sciences and ethics they introduced was that of review and oversight, with researchers submitting their research protocols to the appropriate committee, and the committee reviewing it. Ethics review is now part of the standard procedure and a fundamental requirement for all biomedical research. Although some have questioned the actual impact of RECs and IRBs in promoting more ethical research (Coleman and Bouesseau, 2008), few would deny the importance of ethical oversight of research. However, the review model has its limitations in ensuring ethical research, as it only sees a project at the planning stage, and the interaction with scientists is brief.

In the 2000s, ethics consultation began to emerge as another, more enduring model of ethics and science interaction. The concept of research ethics consultation developed on the established model of clinical ethics consultation by aiming to provide ‘a forum in which scientists can engage with experts from other disciplines who can bring a broader set of perspectives for consideration’ (Cho et al., 2008). Unlike the review model, the role of

consultation is not only to evaluate a project, but also 'to educate the research community and to create institutional consensus about practices' (Cho et al., 2008: 7). The consultation model allows for more interaction and connection between researchers and the ethicists. As Cho et al. report, biomedical researchers seek ethics consultation not only at the planning stage of their project but during the project as well (Cho et al., 2008). An important characteristic of ethics consultation is that it tends to be situated within research institutions, and therefore in close proximity to research, but aims to retain its independence from particular research projects by being set up as a core facility, similar to other facilities such as biostatistics and bio-design (Cho et al., 2008).

Increasingly these forms of science–ethics interactions are being complemented by the emergence of an even more integrated model of science and ethics partnership, where ethicists not only offer ethics consultation to biomedical scientists, but also collaborate with them. Projects such as the International HapMap Project (http://hapmap.ncbi.nlm.nih.gov/), the Malaria Genomic Epidemiology Network (http://www.malariagen.net/), 1000 Genomes (http://www.1000genomes.org/), the ESRC Genomics Network (http://www.genomicsnetwork.ac.uk/) and the Human Genome Project (http://www.sanger.ac.uk/about/history/hgp/) have all had bioethicists working alongside others in the team. Notwithstanding the obvious benefits of such collaborations, some have argued that close collaboration between science and ethics has potential pitfalls (Cho et al., 2008). But before turning our attention to the challenges of such a relationship, it is worth considering its potential benefits.

Ways in which ethics input may be valuable

Providing support and advice with individual issues

The need for biomedical research is undeniable. However, it is important that research is never conducted at the expense of the life, health and well-being of other humans (WMA, 2008). The ethical notions of beneficence, justice, fairness and respect for persons – fundamental principles of medical practice – are also explicitly connected with biomedical research (NIH, 1979; WMA, 2008). *Good* biomedical research is not only research that uses high-quality scientific methods, but also research that maintains high ethical standards. It has been argued that ethical review and oversight does not, by itself, guarantee ethical research (Fost and Levine, 2007; Gunsalus et al., 2006), and that other measures should be put in place to ensure researchers' compliance with ethical guidelines and the maintenance of high ethical standards (Coleman and Bouesseau, 2008; Grady, 2010). The value of rethinking the role of RECs and IRBs notwithstanding, a closer integration of ethics and science in the form of collaboration could assist in achieving the goal of *good* research. A dedicated person or persons in a team with the appropriate expertise to think through ethical questions and guide scientific practice could offer greater assurance for ethical research.

Bioethicists have the training, expertise and methodological tools to provide answers to practical ethical questions within a specific context (Sheehan and Dunn, 2012). The addressing of bioethical issues can be an important part of the scientific design and methodology of a research project – consider, for example, the issues of recruiting participants, designing consent forms, or reporting results to participating communities –

and therefore, the sooner these issues are addressed the better for the scientific and ethical integrity of the project. One role of the ethicist in a collaborative project then can be to identify and map out ethical questions and to ensure that they are brought to the table for consideration alongside questions of a scientific or technological nature. Thus, a close collaboration between ethics and science could potentially lead to more ethical science. Furthermore, such collaboration could potentially help expedite the ethics review stage of the project, as close integration of ethics and science would result in an ethically and scientifically robust project.

The ethicist might also play an important role in collaborations with scientists by conducting ethical analysis of practical ethical issues that can potentially arise later in the life of the project. The ethicist can work with the scientific team to identify potential solutions and to develop models of good practice to ensure the appropriate and successful completion of the research. This is not to say that life scientists themselves are morally blind and need guidance from ethicists to be able to see the rights and wrongs of their practice, but '[it] is rather that the division of intellectual labour provides the benefit of input from persons devoted to the systematic study of the theoretical complexities embodied in ethical concepts applied in practical bioethical debate' (Lillehammer, 2004).

A good example that illustrates how ethics research can help resolve practical ethical issues is the research conducted by the MalariaGEN ethics team on consent in practice. There is an explicit requirement in national and international guidelines that consent processes should be tailored to the research population. However, many researchers will find themselves unprepared for the ethical dilemmas the recruitment and consenting process will reveal to them. MalariaGEN researchers were confronted with ethical issues relating to acquiring consent from mothers with critically ill children in resource-poor countries, and with explaining the need to collect samples from healthy children for genomic research. The ethics team helped resolve these issues with conducting further ethical empirical research at two sites and developing project-appropriate protocol and guidelines (de Vries et al., 2011).

Education and training of scientists and partners in ethics

The nature of the collaboration between ethics and science does not need to be one of delegation, but also one of mutual learning and development of moral craftsmanship (Parker, 2012). Scientists, in their great majority, are genuinely interested in the ethical aspect of their research, but navigating in the complicated area of bioethics is not as easy or as intuitive as one might think. As Benatar notes, there is a 'widespread but mistaken assumption (amongst scientists) that doing philosophy (well) does not really require any training or aptitude. Indeed, it is this attitude that underlies the common confidence to pronounce about moral and other philosophical matter without any sense of complexity of these matters' (Benatar, 2006). Ethical reasoning requires appropriate skills and training. Through the close relationship and collaboration with ethicists, scientists could sharpen their understanding of ethics in their area and further develop their skill of moral deliberation.

Cross-pollination between ethics and science

The benefits of collaboration between science and ethics can accrue in both directions. The field of bioethics has the potential to benefit greatly from being intimately involved in biomedical research projects. Bioethics is an area of applied ethics concerned with the normative analysis of biomedical practice and research. Namely, the focus of bioethics is bioscience and its application. Working alongside scientists allows bioethicists to closely observe their field of enquiry, but also to have a better sense of the ethical questions that are relevant and important to investigate, as well as uncover and discover the areas where ethical tensions and moral issues might lie. Some good examples of this in the MalariaGEN context are research projects that were conducted on the issue of genomic research and ethnic stigmatization (de Vries et al., 2012), and on the ethical issues arising in the collection, export and storage of blood samples from Africa (Tindana, 2013). In both cases, these interesting and important doctoral research projects in ethics arose out of recognition of the importance and relevance of these issues in the context of discussions between ethicists and scientists.

Helping to build trust and promote trustworthiness

Through the encouragement of discussion of difficult issues at the heart of research practice, the role of the ethicists can be that of promoting trust between partners and stakeholders (funders, researchers, research participants) and of enhancing the trustworthiness of a project. A person or group of people trained in moral thinking and reasoning, who can focus on aspects of a project other than the scientific ones, and can make it their role to encourage the shared exploration and practical resolution of these issues, has the potential to help promote and establish trust relationships. The suggestion here is that the presence of an ethics team may increase external trust and confidence because collaboration between ethicists and scientists may be seen as providing an ethical compass to the project. This could make existing and prospective collaborators and participants feel reassured that proper ethical standards would be employed and exercised throughout the life of the project. An example of this kind of approach is the United Kingdom's 100,000 Genomes Project, which has had from the outset the involvement of an ethics advisory group and an ethicist on its Board in recognition that '[a]n appropriate and rational approach to the ethical issues … will be essential to inspiriting public confidence in this programme, and to ensuring that participants have the assurances they need to allow them to take part' (http://www.genomicsengland.co.uk/).

What forms does ethics input tend to take?

In previous models of ethics and science collaboration where the focus was on review and oversight, or on consultation, ethics tended to be situated at the periphery of scientific work, and was only brought in to address specific issues at specific times, such as to review a project, or solve a particular problem that had emerged. In the new model of ethics and science collaboration ethics is present at all stages and in all parts of the biomedical research process.

Project design and preparation

Ethics is an integral part of biomedical research. Various principles have been developed in the area of bioethics to help researchers identify and deal with the ethical issues that might arise from their research, and a very large and diverse range of international, regional and national ethics guidelines exists. Indeed, the Office of Human Research Protections survey of 2012 found nearly 1000 different guidelines with the potential to affect the practice of international research collaborations (OHRP, 2012). Against this backdrop, the process of delineating areas that could potentially be ethically problematic, and of developing solutions to these problems, is not always easy. The guidelines that exist to guide researchers through the ethical analysis of their projects, although sometimes helpful, can only really serve as ethical signposts and indicators. They can turn the scientists' attention to widely recognized issues and indicate potentially problematic areas, but they cannot, except in a limited range of cases, supply specific answers to their specific problems. Interpretation and application of these guidelines to each specific scientific project is required.

The aforementioned example regarding the ethical research on consenting mothers of critically ill children for participation in malaria research clearly illustrates the point that guidelines can highlight ethical issues, but do not provide practical solutions. The MalariaGEN researchers were aware that consent was a basic ethical requirement for their research, but implementing it within the context their project was a challenge. Empirical research and ethical analysis was necessary in order to find a way to appropriately apply this fundamental ethical rule (de Vries et al., 2011).

Preparing for and obtaining ethics review

It is a requirement for all biomedical research projects to be approved by one or more independent RECs or IRBs. RECs and IRBs are tasked with examining whether researchers have identified the relevant ethical questions to their project, and whether they have found ways to adequately address them. Only when the REC or IRB is satisfied that all ethical issues have been appropriately addressed can the project commence. Not all researchers welcome this process. Some view it as a hurdle to overcome (Alberti, 2000) or as an unwelcome bureaucracy that delays research (Goldacre, 2011). Yet, the need for ethical oversight of biomedical research through independent ethics committees is generally recognized. It is reasonable to expect that a research project developed and designed with ethics in mind would have a much better chance of satisfying the REC's or IRB's criteria, and therefore, of acquiring ethics approval faster. Against this background, an ethics team can sometimes be an important resource to enable the research team to identify the ethical aspects of the research and put in place appropriate policies to address these. This is supported by MalariaGEN's experience with acquiring approvals from local RECs and IRBs to proceed with the release of genome-wide association and sequencing data. Releasing genetic and genomic information in the public domain is a sensitive issue raising important questions at an individual (Lunshof et al., 2008; McGuire and Gibbs, 2006), community (Haddow et al., 2007; Mudur, 1996) and population level (de Vries et al., 2012; Ellison and Jones, 2002). MalariaGEN's ethics team was involved in the consideration of the issues surrounding genomic data release and in the development of internal policies right from the beginning (Chokshi et al., 2006; Parker et al., 2009), and has retained an active role in the

continuing monitoring of this process. Being able to demonstrate an active and in-depth engagement with the ethical issues that surround genomic data release appears to have been reassuring for the majority of the ethics committees to which MalariaGEN applied, playing an important role in ensuring favourable decisions.

Research governance and policy development

Good governance is of paramount importance in achieving high-quality science and promoting good ethical practice. High ethical standards and ethical reflection need to be incorporated into rules and policies of management, oversight and audit. To take a small selection of examples, sample collection protocols, sample management and information management, data sharing, and access and publication policies are all governance issues with a scientific, project management and ethical dimension. In developing a policy on data access, answers to the ethical question of who should have access to the data and under what conditions will be key to the development and implementation of an effective and coherent policy. For example, MalariaGEN recognized at an early stage the possibility that releasing all human data generated by the consortium immediately and openly to the wider scientific community might put the local researchers based in developing countries, and who had contributed the samples, in a disadvantaged position in relation to other researchers based in well-organized and well-staffed laboratories in developed countries because they had less capacity in the analysis of these data. It was felt that an open-access policy might undermine the data contributors' academic and scientific prospects. In response to this ethical issue, the MalariaGEN ethics team collaborated closely with partners in both high- and low-income countries to develop a data access and data release policy that both promotes scientific research on this important disease and enables the consortium to meet its ethical and professional obligations towards its funders, partners, participants and wider scientific community (Chokshi et al., 2006; Parker et al., 2009).

Practical ethical problems requiring reflection and justification

Ethical issues are not always easy to foresee, even for ethics committees and those trained in ethics. Inevitably, therefore, unforeseen questions of an ethical nature will arise during the course of a project. Some such issues may be easily resolved, whereas others might require more in-depth research and analysis. Such an example is the research undertaken by the HapMap ethics team on the concerns raised by the communities that participated in the project, such as issues relating to fair opportunity to benefit from the research, reciprocity, and assessment of appropriate use of samples (Rotimi et al., 2007). One of the aims for the project was to 'help investigators better appreciate the view of the communities whose samples they seek to study', and guide informed consent, community engagement and sample collection plans within the HapMap project (Rotimi et al., 2007), and the involvement of an ethics team was crucial in meeting this project aim.

Challenges and limitations of close collaboration between ethics and science

Notwithstanding the potential benefits of close interaction between science and ethics, both for a more informed and engaged ethics and a more ethically enriched biomedical research, such collaborations also present a number of important challenges.

Loss of impartiality and critical distance

One of the potential advantages of a close collaboration between ethics and science is that it may provide the opportunity for embedded critical ethical reflection on the ethical aspects of the research project and greater insight into the important ethical issues that arise in practice. However, if ethics is too closely integrated into the project, there may be the potential for the critical distance upon which effective ethical reflection depends, to be threatened in ways that curtail the ethicist's ability to be critical.

Some have argued that close proximity to a project has the potential to fatally undermine the ethicist's ability to be impartial and objective (Elliott, 2001) or, even worse, that an ethicist may, perhaps unwittingly, give false credibility to an ethically dubious scientific project (Callahan, 2001). Others have suggested that team identification or alliance could, even unintentionally, compromise the ethicist's analytical expertise and objectivity (Sharpe, 2002). It has also been suggested that in cases where the ethicist's salary is funded by the same grant that funds the research project, this may negatively impact on the ethicist's ability to remain impartial (Cho et al., 2008).

Whilst the fear of conflict of interest needs to be taken seriously, this is unlikely, at least in the context of academic research, to lead to unethical research as all such research requires approval by an ethics committee both in the sponsor and host countries. Nonetheless, there is always the possibility that, regardless of the ethics review outcome of the research project, the quality of the ethics and, in particular, its critical dimension may be affected negatively by a too-close relationship between ethics and science. What this suggests, however, is not necessarily that ethics should keep its distance from science – given that in many cases proximity is necessary for a good understanding of the ethical dimensions of scientific practice – but rather suggest that 'reflexivity' should play an important role in bioethics as it does in social science, as advocated by Ives and Dunn (2010) and Parker (2007).

Disciplinary language

Anyone who has sat through a genetics presentation or tried to read a philosophy paper knows how difficult it can be to fully grasp what is being communicated when one is not trained in this area. It is true that each discipline has its own idiomatic language, but collaboration necessitates communication. It is crucial for bioethicists who are required to examine the ethics of a particular scientific method, medical practice or research protocol to be able to understand the science involved to the degree required for effective collaboration. Questions such as 'should the genetic information of individuals be freely available?' or 'should human cloning be allowed' cannot be fully addressed without some understanding of the science of genetic testing practices or cloning techniques. Equally, scientists need to

be able to understand something of ethics when discussing the ethical implications of their project with their ethicist collaborators. Learning a new academic language is not an easy task – it requires time and dedication, and most of all, willingness to understand and to be understood. Such considerations raise questions about the extent to which, even in the context of close proximity, genuine collaboration between science and ethics is in fact possible. To what extent are collaborations real? Clearly this is at least in part an empirical question.

Anecdotally, it is our view, based upon our experience of carrying out ethics research within large international scientific collaborations that, not underestimating the time and effort required, such communication and effective collaboration are both possible and rewarding in many cases. Experienced researchers are often, even perhaps usually, very interested in and concerned about the ethical dimensions of their work and enthusiastic about collaborating with ethics researchers to help identify and analyse such issues and to bring effective solutions to bear upon their day-to-day practice. But clearly there is a need for further research on the nature of scientific–ethics collaborations.

Appropriate recognition/respect

Understanding one another's role and recognizing their respective contributions to the project is as important to successful collaboration as understanding each other's disciplinary languages. In a group of scientists who are mainly concerned with the scientific integrity of their project, the role of the ethicist may sometimes be perceived as peripheral to the main enterprise. For some, the role of ethics in biomedical research begins and ends with the achievement of ethics approval. Once the project is approved by the appropriate REC it is assumed that the role of ethics has ended. There is some evidence to suggest that social sciences' and humanities' methodologies are not acknowledged as 'valid' research amongst biomedical researchers, leading to tensions and published examples of where this has led to bad feelings between collaborators (Prainsack et al., 2010). We have argued above that not only is the need to identify and address ethical issues an integral part of good scientific practice throughout research and that ethical questions can arise at all stages of a project, but it is also possible in our experience for such collaboration to be highly effective and conducive to excellent critical work in research ethics and also to offer a valuable contribution to successful science.

Accountability and responsibility

Who is ultimately responsible for the ethical conduct of research in scientific research collaborations with ethics partners? The issue of correctly attributing or sharing accountability in such collaborations could potentially be difficult. Clearly all parties involved in a collaboration bear some reasonable responsibility for the good conduct of research. In situations where poor practice is identified, should the scientific PI be held accountable, or should the responsibility fall upon the bioethicist? This is going to depend hugely upon the facts of the case. There will be many cases in which the ethics team bears no responsibility for the practice of their collaborators and others in which there may be a question of shared responsibility. There is the potential here for much complexity. For example, it is not immediately clear how the esponsibiity should be shared in situations

where, despite advice from the ethics team, the PI decides to pursuit a different course of action.

Conclusion

We have argued that closer collaboration between ethics and science can play an important role in supporting and ensuring ethical research through the promotion and encouragement of ethical reflection grounded in real world practice, and the development of models of good research conduct. Such collaborations offer a number of benefits and can generate real opportunities for high-quality critical ethical reflection and bioethics research. We have also highlighted the potential limitations of such collaborations. It is our view that suitably reflexive bioethics research can make an important contribution both to the promotion of ethical practice and policy in science, and also, to bioethics discourse and the academic bioethics literature. Clearly not all bioethics research into the ethics of biomedical research should take this form. Much – probably most – bioethics research will continue to be carried out away from the benchside, and it is clearly important that this continues to be the case. However, it is our view that bioethics research has the potential to be greatly enriched by collaborative research, by bringing together ethicists and scientific researchers – all research actors of different kinds. Science and humanities are sometimes thought of as the far opposites of the academic spectrum. However, we believe that both disciplines share a common quest for knowledge, for defining and addressing problems and for trying to solve them, and that much can be gained from the promotion of greater interaction between them.

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