



Mapping ethical and social aspects of cancer biomarkers

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ABSTRACT

Cancer biomarkers represent a revolutionary advance toward personalised cancer treatment, promising therapies that are tailored to subgroups of patients sharing similar generic traits. Notwithstanding the optimism driving this development, biomarkers also present an array of social and ethical questions, as witnessed in sporadic debates across different literatures. This review article seeks to consolidate these debates in a mapping of the complex terrain of ethical and social aspects of cancer biomarker research. This mapping was undertaken from the vantage point offered by a working cancer biomarker research centre called the Centre for Cancer Biomarkers (CCBIO) in Norway, according to a dialectic move between the literature and discussions with researchers and practitioners in the laboratory. Starting in the lab, we found that, with the exception of some classical bioethical dilemmas, researchers regarded many issues relative to the *ethos* of the biomarker community; how the complexity and uncertainty characterising biomarker research influence their scientific norms of quality. Such challenges to the *ethos* of cancer research remain largely implicit, outside the scope of formal bioethical enquiry, yet form the basis for other social and ethical issues. Indeed, looking out from the lab we see how questions of complexity, uncertainty and quality contribute to debates around social and global justice; undermining policies for the prioritisation of care, framing the stratification of those patients worthy of treatment, and limiting global access to this highly sophisticated research. We go on to discuss biomarker research within the culturally-constructed ‘war on cancer’ and highlight an important tension between the expectations of ‘magic bullets’ and the complexity and uncertainty faced in the lab. We conclude by arguing, with researchers in the CCBIO, for greater reflexivity and humility in cancer biomarker research and policy.

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1. Introduction

Cancer research has witnessed important developments over the last two decades towards personalised medicine, which aims to tailor cancer treatments to subgroups of patients sharing similar genetic traits. Biomarkers have been an important tool in this transition, and are often presented as a revolutionary new technology used for patient assessment to help determine predispositions to particular types of cancer, to screen and diagnose cancer types and stages, to estimate the disease prognosis, to predict the most effective course of treatment, and to monitor cancer recurrence [1]. There is a noticeable techno-optimism regarding cancer biomarkers, especially in policy reports where they are anticipated to facilitate a higher-quality, safer and

more efficient treatment of cancer while decreasing health care costs [2–4].

However, as for many revolutionary new technologies, biomarkers bring with them a host of ethical and social considerations. This has seen a small but growing body of literature addressing some of these particular issues, ranging across different disciplines including health economics and policy (see e.g. [5,6]), bioethics (see e.g. [7]), and philosophy of medicine (see e.g. [8,9]). Arguably, the cross-disciplinary nature of these issues has led to a fragmented literature, without an overview of this complex ethical and social terrain. We seek to contribute to the literature through a mapping of this terrain, and the interrelatedness of the ethical and social issues in it.

Another contribution of this paper is that it takes its point of departure in the ethical concerns and issues of scientific quality met in the cancer biomarker lab. This anchors the mapping of ethical and social aspects of cancer biomarkers in their laboratory context; while also providing practitioners and researchers working in the field a legitimate guide for their personal reflections on the ethical aspects and scientific norms of their everyday work.

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The mapping presenting in this paper therefore stems both from discussions within a working cancer biomarker research centre called the Centre for Cancer Biomarkers (CCBIO), in Bergen, Norway; and the cross-disciplinary literature. The author has been eliciting reflections among CCBIO researchers on the ethical and social aspects of their work, from the lab looking out; these reflections being triggered by some key themes in the literature. At the same time, the diverse considerations raised by CCBIO researchers have in turn framed the literature review. In this way, the review emerged from a dialectic move between literature and practice.

This paper explores the social and ethical issues that have been formulated through the practice-literature interaction, and highlights the interrelatedness of these issues. Here, we explore social issues both in terms of those faced in wider society, and more specifically those faced by the scientific community exploring biomarkers; what can be considered as the *ethos*, or norms, shaping that community. The exploration will be structured around three clusters. After elements of background and method in Section 2, Section 3 explores issues related to the ethos of science and ethical concerns met in the lab. Beginning from these issues of the ethics and ethos of science, Section 4 explores the ethical aspects of cancer biomarkers in a context of social and global justice, while Section 5 focuses on the social aspects of cancer biomarkers, in particular the cultural meanings of cancer. Finally, Section 6 concludes by arguing that the complexities, uncertainties and questions of scientific quality surrounding biomarker research demand humility and reflexivity, both in the lab and in policy-making.

2. Background and method

2.1. From blockbuster drugs to personalised medicine

In the last two decades, cancer research and care has been undergoing important changes as a result of an increased awareness of the complexity and heterogeneity of cancer (see e.g. Nature's special issue [10]). Traditional forms of cancer therapy associated with 'blockbuster' chemotherapy drugs have been increasingly criticised for leading to under- or over-treatment of patients, with a higher risk of adverse and sometimes lethal side-effects [11]. This 'one-size-fits-all' approach does not account for the heterogeneity within the primary tumour (intratumoural heterogeneity), between the primary tumour and metastases (intertumoural heterogeneity), or between cancer patients (intra-patient heterogeneity) [12]. In response, an expanding body of literature from the biomedical sciences (see e.g. [11,13]) has put forward 'personalised' or 'tailored' medicine as an alternative model for cancer research and care. Personalised medicine aims to adapt cancer treatments to sub-groups of patients who share similar genetic traits and tumour characteristics, and to provide patients with the right drug, at the right time and dose [11].

One clinical way of implementing personalised medicine is through cancer biomarkers. Biomarkers are substances or processes found in patients' tissues, blood or other body fluids, which indicate the presence of cancer in the body. According to Mishra and Verma [14], biomarkers can either be a molecule (like a protein or an antibody) secreted by a tumour, or a specific response of the body to the presence of cancer, such as biochemical changes like gene expressions and mutations. In a metaphorical way, cancer biomarkers are the 'fingerprints' of different tumours, and can help stratify patients according to their genetics and tumour characteristics. Research on cancer biomarkers is in its infancy, and so far only a few biomarkers have entered clinical practice. One successful cancer biomarker is the protein HER-2, which is overexpressed in about 20–25% of women with breast cancer,

indicating that they have higher chances to react well to the drug trastuzumab. Another example is the normal (non-mutated) KRAS gene, present in about 60% of patients with metastatic colorectal cancer, that indicates that only these patients are likely to respond to the drugs cetuximab and panitumumab.

Cancer biomarkers offer the promise of treatments that are both more efficient and safer for the patients, and cheaper than traditional cancer therapies in the long run, considering technological advances and reduced harmful side-effects in the patients. Biomarkers are thus a source of hope for cancer patients and medical practitioners alike, and have increasingly received both considerable political attention and public funding, including in Norway.

2.2. The Centre for Cancer Biomarkers (CCBIO) and integrated ELSA research

The Centre for Cancer Biomarkers (CCBIO) is a research centre based in Bergen, Norway. It aims to improve biological understanding, early diagnosis and treatment of cancer by using novel biomarkers. It was funded in 2013 by the Research Council of Norway for a period up to ten years, and received the status of Norwegian Centre of Excellence. Based at the University of Bergen, with most activities taking place at the Faculty of Medicine and Dentistry, the CCBIO consists of nine principal investigators and gather in total about 140 people including medical researchers, clinicians, bioinformatics researchers, economists and social scientists. Research activities are organised around three core programmes: pre-clinical studies, clinical studies and biomarkers. To integrate the three programmes, specific research projects have been initiated at CCBIO, that look for instance at the tumour-microenvironment interactions or at the discovery and validation of cancer biomarkers.

One particular characteristic of CCBIO is that it has integrated the study of the ethical, legal and social aspects of its research; also known as ELSA research. ELSA research looks at the ethical, legal and social aspects around emerging technologies in the various fields of biotechnology, nanotechnology or biomedicine. 'Integrated ELSA' in particular encourages a dialogue between the ELSA researchers and the researchers developing the new technology under scrutiny. The ethical, legal and social questions are identified in close cooperation, so that they can be reflexively discussed and integrated to the research process at an early stage, thus encouraging reflections about scientific responsibility [15]. Concretely for CCBIO, this means that alongside its three core research programmes, it also has an ELSA team, led by a Professor in philosophy of science, working with a post-doctoral researcher, myself as the author of the paper with a background in Science and Technology Studies, and a part-time research assistant. The ELSA team looks mainly at the ethical and social considerations around cancer biomarkers, and does so in an integrated way with the cancer biomarker researchers. This is why the mapping in this paper takes its point of departure in the ethical and social concerns met in the lab, to then look out to broader, ethical and social aspects of cancer biomarkers.

2.3. Method and purpose for the mapping

Mapping the terrain of the ethical and social aspects of cancer biomarkers was the starting point to the integrated ELSA research in CCBIO. The ELSA team first teased out key ethical and social considerations around cancer biomarkers from the cross-disciplinary literature, and presented these key themes to CCBIO researchers to help trigger their own reflections and discussions. Our interactions mainly took place during bimonthly junior scientist seminars, CCBIO's annual symposia and during a PhD

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