Data storms and fishing trips: bioinformatics in the engine-room of genomic global health policy

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Abstract: Bioinformatics comprises a diffuse, hybrid and unstable field of technologies (e.g. biochips, microarrays, supercomputers, 'the cloud'), skills, knowledges, databases and software tools, which are being brought together to transform biological materials into informatic forms useable for medical innovation purposes. These purposes include notably the development of new drugs under the framing of personalised or stratified medicine. The arrival of genetic and genomic analysis is producing unprecedented volumes of person-level information, which is one of the dynamics producing the current increasing and visionary movements around 'big data' in the life sciences. As national life science policies get ratcheted up governments' political agendas, it is clear that bioinformatics is becoming a clearer target of policymaking for example through investment schemes, infrastructure-building and skills development at both national and transnational levels. Alongside public and academic initiatives constituting the field, commercial ventures including big pharma companies are employing bioinformatics for pharmacogenomic R&D, and a range of companies are positioning themselves as providers of services for stakeholders inter-nationally who are outsourcing parts of their bioinformatics processing needs, such as gene annotation. While bioinformatics, or computational biology, is undoubtedly an essential engine for the development of genome-based global health objectives, it appears beset by a range of conflicts that commercial and governmental policies have to embrace. Drawing partly on political economy and recent theorisation of 'bio-objectification', this paper identifies the differential framings of bioinformatics in a range of policy discourses, focusing especially on *India*, *the UK,* and *transnational governance organisations* such as the WHO and Gates Foundation (drawing on initial exploratory research including document analysis and some initial interviews from a UK ESRC-supported 'Rising Powers' project). India was one of the first countries in the world to establish a national bioinformatics network, and the implementation of the UK's national life science strategy includes genome-related bioinformatics initiatives as part of its vision for the future health service. Innovation studies and STS research has begun to examine this field; the focus has been mainly on issues of standardisation, professional tensions, and public vs. private knowledge. The paper aims to demonstrate the growing policy recognition of the importance of bioinformatics, and traces tensions in the field relevant to global health politics and goals and their different manifestations in the states and transnational governance sites of interest, including: patenting vs. open source/open access; technonationalism vs. outsourcing; personal privacy vs. data linkage; data mining vs. disease targeting; bioinformatics connections to health informatics i.e. combination of genomic data with patient medical records; IT skills vs. biological skills; and communicable vs. noncommunicable disease targets.

Introduction

The unravelling of the human genome is said to have stimulated a 'gold rush' in the field of bioinformatics (Howard, 2000). Visions of the potential impact of genomics- based medicine on global public health objectives have consequently mushroomed. A Toronto research group study identifying the 'top 10' biotechnologies that would further the UN Millennium Development Goals of 2000 (aimed at alleviating conditions of the world's poorest people, three of which are directly health-focused) included:

- bioinformatics to identify drug targets and to examine pathogen-host interactions; and
- combinatorial chemistry for drug discovery. (Daar et al 2002)

Bioinformatics changes the way scientific research is undertaken: 'Laboratory life has changed to become more virtual, and the experiment has become redefined to rely increasingly on the construction, curation and mining of large scale databases, rather than using conventional 'wet' laboratories' (McNally and Glasner. 2006). In a celebration to dedicate the Gates Center for Computer Science at Carnegie Mellon University in the US in September 2009, Bill Gates stated the following in his speech:

> 'Today, we're in the midst of a remarkable transformation that will see computing revolutionize scientific discovery. Already, computing technology is the foundation for almost all scientific research. The ability to collect massive amounts of data in digital form and share it across the Internet has changed the way we drive progress in every field of science'... 'In healthcare, data-driven medicine and the ability to compute genomics and proteomics on a personal scale will fundamentally change how medicine is practiced. Medical data will be available in real time to be analyzed against each person's individual characteristics, ensuring that medical care is truly personal. Massive-scale data analytics will allow us to track disease so we can respond quickly to potential pandemics. All of these advances will help medicine scale to meet the needs of the more than 4 billion people who lack even basic care today'(http://www.gatesfoundation.org/Media-Center/Speeches/2009/09/Bill-Gates-Carnegie-Mellon-University)

In this paper, the Gates Foundation, now a massive charitable funder of global health-related research, is seen as an example of a transnational governance actor shaping the agenda of global health science and policy, in particular ways. The type of techno-utopian vision shown by Gates is a familiar vision (in Science & Technology Studies) , but the huge resources at the Foundation's disposal means that the direction and methods of its vision have to be taken seriously for their performative effects in the global health and bioscience research and policy arena. Given Bill Gates' own global biography it is of course unsurprising that digital computation and massive data form the backbone of his vision – and practice - of health and medical futures.

The bioinformatics field and its technologies

Unsurprisingly, commentators' versions of what bioinformatics consists of vary greatly. Essentially it refers to a combination of molecular biology and computer science, but can be seen as 'covering anything from epidemiology, the modeling of cell dynamics, to its now more common focus, the analysis of sequence data of various kinds (genomic, transcriptomic, proteomic, metabolomic)' (Harvey and McMeekin 2002, 10). More specifically the techniques involved include sequencing of DNA base pairs; gene expression (when and where genes are turned on), genetic differences among individuals (called single-nucleotide polymorphisms (SNPs)), the structures of various proteins, and maps of how proteins interact with each other. One basic operation involves searching for similarities, or homologies, between a newly sequenced piece of DNA and previously sequenced DNA segments from various organisms - near -matches allow researchers to predict the type of protein the new sequence encodes, producing leads for drug targets early in drug development and discounting associations unlikely to be significant. A massive area of research globally is that of genome-wide association studies (GWAS), which attempt the analysis of disease correlations by methods by genotyping of thousands of cases and controls at hundreds of thousands of genetic marker sites.

Technologically, the growth of the field in the 1990s and 2000s has been facilitated by the development of computer networking supporting possibilities of interconnectivity and of largescale data curation and storage. 'The key innovation in bioinformatics has been the invention of the microarray or 'gene chip'. A

microarray is a small glass slide which may be ordered as a series of slides, "...containing thousands of DNA sequences in an ordered array, which allows simultaneous analysis of thousands of genetic markers or sequences" (Oldham 2004).

Bioinformatics comprises a diffuse, hybrid and unstable field of technologies (e.g. biochips, microarrays, supercomputers, 'the cloud'), skills, knowledges, databases and software tools, which are being brought together to transform biological materials into informatic forms useable for medical innovation purposes (processes that can be summarised as 'bio-objectification', see below). These purposes include notably the development of new drugs under the framing of 'personalised' or 'stratified' medicine. The arrival of genetic and genomic analysis is producing unprecedented volumes of person-level information, which is one of the dynamics producing the current increasing and visionary movements around 'big data' in the life sciences. As national life science policies get ratcheted up governments' political agendas, it is clear that bioinformatics is becoming a clearer target of policymaking for example through investment schemes, infrastructure-building and skills development at both national and transnational levels. The field is developing rapidly and attracting major funding from public governments and the pharmaceutical industry. The development of this computational form of biology is increasing the scales of international collaborative activity and reconfiguring inter-disciplinary boundaries between biology, computer science, bio-engineering, and statistics. Clusters and centres in Europe, Japan, and the USA are seen as the major locations for genome and proteome projects (Harvey & McMeekin 2005). Both academic and commercial genomic researchers in the advanced industrial states outsource significant processing requirements overseas, including to China and India.

However, the national and transnational policy visions and actions driving this trend show wide geopolitical variation. Also, while techno-hype is fascinated with the downward spiral of the cost of sequencing a genome, less trumpeted is the cost of what has been called the 'interpretome' – the cost of making sense of genome data, requiring bioinformatics techniques - which can run into millions of pounds/dollars/euros.

Bioinformatics has so far attracted only a little attention from scholars in science policy/political economy/science & technology studies (STS)/sociology/anthropology. Most of the work to date can be described as focused on 'internalist' accounts, describing and interpreting the epistemology, knowledges, disciplines, field-shaping claims, data forms and processes internal to the field. For example Lewis and Bartlett (2013) emphasize the lack of 'disciplinary coherence' in the field, its service status in relation to biology within academia rather than as a primary innovative agenda-setting research area, and the disciplinary identities of practitioners of bioinformatics as either developers of tools or service providers; Mackenzie (2003) argues for what might be called a dis-embodiment perspective, which emphasizes the potential for private property ownership in the field; Harvey and McMeekin (2009), from a perspective of innovation pathway studies, similarly have discussed tensions between property issues and 'the commons' in the field.

The paper proceeds by outlining a conceptual approach to understanding the changing position of bioinformatics in health policy as a sector or technological zone (Faulkner, 2009). In this discussion I show how national state and transnational actors are framing, constructing and positioning bioinformatics in, and how it is being enrolled into and constitutes visions of national or global bioeconomies, public health and medical agendas. In analysing the developing position of innovative fields such as bioinformatics it is telling to examine the way in which state policies frame the field in terms of particular national and international ambitions, be they in health or other policy fields. I argue that the transformation of biological material into manipulable forms of digital data that bioinformatics accomplishes ('bio-objectification') is accompanied by

a range of tensions and opposing dynamics that currently shape and characterise the field. My (developing) case material currently concerns primarily the UK, India and some transnational actors.

Conceptual approach

I combine an analytic approach that aligns the political economy of the action and interaction of bioinformatics stakeholders, such as state agencies, academic centres, companies, with an approach that views bioinformatics work as engaged in a range of medico-political domains whose classificatory boundaries it may disturb or reinforce. The field of global health is a domain in which there is a conspicuous politics of disease categories such as infectious disease, rare disease, neglected disease, communicable disease and non-communicable disease, categories which become salient in the health policy debates of organisations such as WHO and national governments.

In studies of global political economy in which the governance strategies and respective positions of nation states are analysed, there is longstanding debate in terms of 'competition states' (the advanced industrial states) and 'developmental' or more lately 'adaptive' (there are many related terms) states which may attempt to 'catch up' and 'keep up' by governance strategies aimed at gaining market shares or through stimulating and steering indigenous innovation (Salter and Faulkner, 2011). Harvey and McMeekin (2005) have illustrated indigenous (and 'competitive') innovation in the case of Brazilian genomic innovation in the agriculture sector, showing how particular local national scientific interests (e.g. sugar cane based ethanol, and a plant pathogen that attacks grape vines amongst other crops) led to particular indigenous expertise that 'broke through' to global status, including on to the front page of *Nature,* and in the case of the plant pathogen development of genome annotation capacity which was then sought by commercial interests in the US.

Alongside this conceptual lens, I bring in a focus on informatics as a mobiliser and enactor of health goals. The digital age brings a broad and deep process of informaticisation of society, the economy and medicine (Brown and Webster, 2004). Bowker and Star's well known work (1999) has emphasized the importance of information infrastructures in structuring the 'built moral environment,' in which we can include societies' orientations to health and medicine. It is now commonplace to understand that 'technical' issues like how to name things and how to store data constitute the taken-for-granted world. In the same vein: 'bioinformatics, far from being neutral, entails values and specific enactments of specific human identities.' (Baren-Nawrocka 2013). In bioscience and biotechnology, biological material is variously turned into 'objects', through 'bio-objectification' processes wherein life-forms or living entities are first made into objects through scientific labor and its associated technologies, and then come to be attributed with specific identities, often through contested processes (Holmberg et al 2011; Vermeulen et al 2011). As Mackenzie (2003) has noted: 'we should read the tools, interfaces and portals built around the sequence database as artefacts that reflect (those) imagined bodies.' Disruption of existing medical scientific and healthcare boundaries is a key feature. Applying this concept to bioinformatics, we can propose that the boundaries between the biological and the digital, the in-vivo and the in-silico, and the boundary between biomedical research, health goals and healthcare systems will be challenged, possibly engendering new social, medical and economic directions, and typically attracting the attention of governance actors (Hansen & Metzler 2012). We shall see clearly that national and global policy actors are engaged currently in efforts to mobilise this set of knowledges and activity toward a range of health and medical goals, and that significant differences in national orientations to valuing bioinformatics can be discerned. Bioinformatics heightens the importance of classificatory issues in its implications for how it might shape the agendas of health

policymakers and health entrepreneurs or be mobilised by them, as well as resulting in a wide range of 'objects', some of which are commercialisable products in the health sector.

A note on method

This draft working paper is based on early-stage research being conducted as part of a UK Economic and Research Council (ESRC) funded team research project, conducted at King's College London and the University of Sussex: ' State strategies of governance of biomedical innovation: the impact of China and India' (Salter et al, 2012; support of ESRC gratefully acknowledged). The project focuses on regenerative medicine and 'personalised' medicine. A wide range of documents have been assembled including government policies, stakeholders' position papers, scientific articles, media reports and commentary, market analysis, and so on. Fieldwork consists of interviews and conference/meeting observations and 'policy workshops'. Apart from documentary data, this paper draws on an initial 6 interviews on bioinformatics/pharmacogenomics, conducted mainly in academic science centres, 4 in the UK, one in the US, and one in New Delhi.

Tensions in bioinformatics

The bioinformatics field can reasonably be divided into the different domains of drug discovery research, provision of content and data integration in database form, provision of informatics processing tools including those for 'data mining', and the production and use of microarray technology itself.

Bioinformatics presents economic business opportunities as well as the promise of eventual health benefits, and this is one of the most controversial tensions in the field, encapsulated in the tension between open access/open source principles and law and practices of intellectual property (IP) and patenting (cf. Gopalan, 2009). It is now conventional for academic journals to require researchers to deposit raw data online, a position supported by powerful global funding organisation such as the Wellcome Trust. A commonly cited convention here is that a 'pre-competitive' space should be based on these open source principles in order to encourage data sharing and early-stage innovation, to be followed by a commercial, competitive phase where IP can be claimed (US interview; the current extent and preservation of this open access convention is a matter of debate and need for empirical research). A related argument is to distinguish between primary (e.g. DNA sequence) and secondary databases, arguing that the former should be public domain and suitably supported by government subsidy, and the latter open to patenting (Chang J, Zhu X., 2010). In terms of technology, DNA microarray biochips are crucial to gene sequencing and other informatics operations and this has been the subject of various patent disputes in the late 1990s and early 2000s between companies seeking dominance in the field such as Affymetrix and Incyte (Abhilash, 2010). The lack of standardization in arrays presents an interoperability problem that hinders the exchange of array data. Various grass-roots open-source projects are attempting to facilitate the exchange and analysis of data produced with non-proprietary chips.

In order to illustrate the different approaches to the framing and policy development of bioinformatics in the UK and India, and the different emphases they therefore place on different disease areas, I now present brief outlines of key features of the recent policy developments in each.

UK shaping of bioinformatics: genomic medicine

In the UK, ownership and intellectual property issues related to bioinformatics have been dominated by the Cambridge-based and Wellcome Trust supported insistence on open source and open access public domain principles. The early-mover power and standardising influence on microarray technology of this model, associated with the European Bioinformatics Institute (EBI) also based in Cambridge, has been described by Rogers and Cambrosio (2011).

In the early 2000s, it was suggested, interestingly, in a Department of Trade & Industry report, that the main strength of UK bioinformatics at that time lay in agrifood applications rather than health and medicine (Harvey & McMeekin 2002). Be that as it may, medical and health applications have now been brought to the fore in recent government policy development. Much of the policy development in UK bioinformatics is now framed in terms of 'genomic medicine'. The UK's House of Lords conducted an inquiry into this topic in the late 2000s, to which the government responded (Secretary of State for Health, 2009). Their response included noting recent investments and a range of measures specific to bioinformatics, notably:

> 'In 2009 more than £9 million… awarded by the MRC (Medical Research Council) to support the UK research community's access to high quality equipment for DNA sequencing via substantial investment in the latest technology. Four regional hubs located across England and Scotland will provide technical support and bioinformatics expertise'
>
> 'We recommend that the Government show leadership on leveraging sustainable funding to the European Bioinformatics Institute (EBI), through the European Research Infrastructure (ESFRI) instrument and through the UK Research Councils. This would reduce the dependence of the EBI on charitable and cyclical funding and allow further growth of the Institute commensurate with the recent growth in genomic databases and the value of the EBI to the UK science base… The UK is leading discussions at a pan-European level to help develop a more secure funding structure for the EBI. Since 2008, Research Councils UK (RCUK) has made it a priority to provide capital expenditure to renew computing facilities at the European Molecular Biology Laboratory – European Bioinformatics Institute (EMBL-EBI)'.'This forms a key part of the emerging pan‐European science project, the European Life Science Infrastructure for Biological Information (ELIXIR), an initiative involving 32 partners from 13 countries aimed at establishing an infrastructure for biological information in Europe that attracts sustainable funding. The expansion in EMBL-EBI I data management capacity is vital…'

Note the importance of 'Europe' as a strategic platform of collaboration in the above.

> 'We recommend the establishment of a new (i.e. national) Institute of Biomedical Informatics to address the challenges of handling the linking of medical and genetic information in order to maximize the value of these two unique sources of information. Such an institute would bridge the knowledge, culture and communications gap that currently exists between the expertise in NHS (National Health Service) IT systems and bioinformaticians working on genome research. The Institute would guide the NHS in the creation of NHS informatics platforms that will interface with databases containing personal genetic data and with publicly available genome databases (Paragraph 8.23). We recommend that the Department of Health should establish a centre for national training in biomedical informatics (within the Institute of Biomedical Informatics) with the aim of providing training that bridges the gap between health records information technology and genome informatics, and ensuring the delivery of an expert workforce for the NHS (8.24). '

And in the above we see how bioinformatics is being brought under the umbrella of genomic medicine, and also strongly linked the public healthcare system of the NHS. The latter is a development more advanced in certain research centres in the US.

The UK government produced a national Life Sciences Strategy (having earlier created an Office for Life Sciences within its Department for Business, Innovation Skills (BIS)), which was launched by the Prime Minister in November 2011. The terminology of this policy repays some attention, for example with the extensive use of the notion of 'bioresources', which means not only biological material such as that stored in biobanks, but also the population of the country and patients encountering the national healthcare system. The policy makes some specific provisions for increasing bioinformatics capability in the UK, notably:

> 'Informatics – ELIXIR: We are moving at pace to deliver a robust informatics infrastructure via ELIXIR. ELIXIR is a programme to assemble and manage biological and genetic information generated by research. UK-funded research breakthroughs have recently led to a revolution in commercially available high-throughput gene sequencing technology. This revolution has created challenges in storing and analysing the huge volume of data generated. It is vital that this data is collected, stored and curated in user-friendly ways that allow its efficient retrieval and rapid exploitation. ELIXIR will allow us to do just this. ACTION: We will invest £75 million to: - expand the existing European Bioinformatics Institute in Cambridge to provide a new facility for biological data-storage to support life sciences research and its translation; and - deliver a new technical hub (Hinxton, Cambridge) which will house 200 staff and will coordinate the network.

In 2012, Sir Mark Walport, director of the Wellcome Trust, which spends more than £100 million a year on genomic research, endorsed the recommendations of the (Bell) report on genomic medicine:

> "Our advancing ability to read and understand the genetic code is already beginning to spark transformative improvements in healthcare, by refining diagnosis and revealing the processes of disease…We particularly support the proposal to link genomic data to patients' anonymised medical records through a secure national centre, which would create an unparalleled resource for research and diagnosis without compromising confidentiality or privacy. It is also important to develop medical informatics services that can make sense of complex genomic data, and to update professional training to meet the challenges of the genomic age…We are committed to working with the Government to address these challenges, building on the world-class genomics and bioinformatics expertise available in the UK at the Wellcome Trust Sanger Institute and the European Bioinformatics Institute."

Tensions in the innovation model to take forward this vision are conspicuous in UK debates currently. For example a representative of the Medical Research Council (MRC) asserts that for the true potential of life sciences in the UK to be realised, 'industry and academia will have to engage in much more complicated partnerships that in the past…The science must remain at the forefront, but each company will see the science question in a different way, so a shared and very well-developed science agenda will be critical' (Dr (Declan Mulkeen, conference report at http://www.pharmatimes.com/Article/13-03-26/UK_life_sciences_let_down_by_poor_informatics_skills_experts_warn.aspx).

Similarly, medical media headlines have included such as:

> UK life sciences let down by poor informatics skills, experts warn: 'Health informatics is set to be a major driver of success for UK life sciences, but the sector - and industry in particular - does not yet have the necessary analytical skills, according to leading experts…"We need to build up a cadre of people who can do this," (government life sciences champion) Professor Sir John Bell, and AMS president Professor Sir John Tooke agreed that medical training should move towards including the provision of skills in informatics and bioinformatics..' (meeting at the Academy of Medical Sciences)… Speakers agreed that the existing pattern of collaboration between the pharmaceutical industry and academia has to change. Sir John Bell called for the whole process to begin again "with a clean sheet," and to focus on 'open and adjacent' innovation. (UK News | March 26, 2013. Lynne Taylor . Pharma Times)

Such opinions are supported by our research team's interviews to date, with some skill gaps especially mentioned such as in computational chemistry.

In 2012-2013 the UK government announced the formation of 'Genome England'. Genome England will be a company owned by the Department of Health that 'will introduce high-tech DNA mapping for cancer patients and those with rare or infectious diseases and link that new data to the patient's medical records'. It is the organisational form devised to implement the '100,000 genomes' project announced in 2012. The £100 million funding will also be used to train healthcare professionals in the clinical application of genomic data, and new genetic scientists to develop novel treatments. Genome England will manage the contracts for specialist UK-based companies, universities and hospitals to supply sequencing, data linkage and analysis services. It will have responsibility for regulating issues of data storage and security and patient consent to participation.

Thus overall we can see bioinformatics being strongly drawn into the agenda of a future vision for healthcare and medical innovation based on the genomic revolution. The embedding of bioinformatics in healthcare delivery organisations through integration of electronic patient record data is notable. Cancer and rare diseases are high on the medicopolitical agenda, with strong emphasis on genomics-based drug development and identification of new biomarkers and diagnostics, in other words 'pharmacogenomics'. However, much of the developmental trend appears aimed at developing 'platform' technology that can have multiple disease-related applications. These features provide a striking contrast with developments in India, to which I now turn.

India shaping bioinformatics: techno-nationalism, outsourcing and national disease

India's well-acknowledged expertise in IT and its huge generics drug industry certainly shape the landscape in which bioinformatics is developing in the nation.

India was one of first countries in the world to establish a nationwide bioinformatics network, which comprised 57 connected informatics centres set up in 1987. This was initially at least a technological network allowing electronic network communications. The government Department of Biotechnology (DBT) is the main responsible government department. DST (Science & Technology) is involved especially for supporting biochip technology aspects. The Bioinformatics Institute of India (BII) was formed in 2002 registered as a professional society under Indian rules, for 'academicians, scientists and engineers'. The Indian Department for Biotechnology published a national bioinformatics policy in 2004, with an explicit aim of making India a significant presence on the global stage. The Indian Council of Medical Research (ICMR) has initiatives in the bioinformatics field, outlined below. Developments in India strikingly combine attention to the field as a business sector and as a vehicle of (some) national health goals.

The worldwide market for bioinformatics tools and services is estimated by Indian sources to exceed US$40 billion within the next five years. An ABLE/Biospectrum Biotech Survey 2013 reported: 'Bioinformatics is growing as an independent discipline and is fundamental to the growth of biotechnology. India has achieved remarkable success in the software industry. BioInformatics sector grew by 11% (2003-13)... The fragmented bioinformatics market will see a growth in the coming years because of government's spending on R&D in addition to increase in private fundings.' It is claimed that over 200 companies have some involvement in bioinformatics in India, divided amongst three types of companies – pure research bioinformatics, IT companies, and CRAMS (contract research and manufacturing services). A 'huge proportion' of the sector is said to be focused on outsourced work (RNCOS, 2012). It is claimed that the emergence of genomics is challenging the long-established devotion of multinational company business models to protection of IP through patents, with a move toward forming alliances to 'keep genomic data free of any protection' (Desai, personal communication).

The Indian Council for Medical Research (ICMR) has its own Biomedical Informatics Centre, formed in 1999 with support from WHO's tropical diseases research fund. A number of disease targets can be identified in their mission - nine centres were initially created. One of the original nine centres (now comprising seventeen 'projects') is the Biomedical Informatics Centre (BMIC) at the Tuberculosis Research Centre (Chennai). The aim of this centre, typical of the model, includes: 'to enhance understanding of TB and HIV/AIDS using computational approaches; to provide bioinformatics support for biomedical research; to impart skills in bioinformatics through training programmes / workshops' (http://bmi.icmr.org.in/DDTRP/bic@trc.php). The other BMIC centres include those with a focus on or being part of: the National Institute of Cholera and Enteric Diseases, Kolkata, established 2006; National Institute of Nutrition, Hyderabad; National Institute for Research in Reproductive Health, Mumbai; Rajendra Memorial Research Institute of Medical Sciences, Patna (nano-informatics); All India Institute of Medical Sciences (AIIMS), New Delhi (drug design, protein modelling); Institute of Cytology and Preventive Oncology, Noida; Regional Medical Research Centre, Dibrugarh (malaria and mosquito-borne disease); Regional Medical Research Centre, Bhubneshwar (filarial and dengue disease). Some of the centres undertake unspecified generic work, eg. genotyping and genome-wide association studies (GWAS).

Also focused on a disease of major national importance, DBT sponsors TBNet India, a network of 13 centres whose aims include attempting to understand different strains of drug-resistant TB and gathering and curating published protein sequences, unpublished submitted sequences and cellular, molecular and biochemical data publications on mycobacterial proteins in a Tuberculosis Reference Database.

The National Institute of Biomedical Genomics (NIBMG) was established near Kolkata as an autonomous institution by the Government of India in 2010, under the aegis of the Department of Biotechnology. This is said to be the first institution in India explicitly devoted to research, training, translation & service and capacity-building in biomedical genomics. The main objective of the institute is to 'promote better public health in India by conducting large genetic epidemiological studies on Indian populations on diseases of importance in India, including susceptibilities to infectious diseases and responses to vaccines against infections' (website). IGIB (the Institute of Genomics and Integrative Biology was established under the central Council of Scientific and Industrial Research (CSIR), part of the Department for Biotechnology, 'engaged in research of national importance in the areas of genomics, molecular medicine, bioinformatics, proteomics and environmental biotechnology' (website). IGIB has a basic mission of translating genomics into commercialisable healthcare products . At the time of writing its website lists 148 patents held across all fields of its activity. Founded in 2002, main research areas at IGIB include: major disease-related Indian genomic variation, personal genome sequencing, Ayurgenomics, and genetic and epigenetic factors in

obesity and metabolic disorder. The University of Columbia is partner in some of IGIB's sequencing work. Associated companies include Vyome Biosciences, specialising in dermatological products.

Thus we observe a range of different activity in the bioinformatics field in India, divided between commercial outsourcing enterprise and public government supported informatics activity some of which is targeted to 'Indian' disease issues, some of which not (the extent of which is yet to be assessed by the present author). The arrival of biomedical *genomics* per se is clearly a very recent development.

Perhaps reflecting the diversity of activity in the bioinformatics field, there is notable criticism of the innovation pathway of bioinformatics within the country:

> 'The present Bioinformatics Policy lacks vision and fails to address the pertinent issues related to research and development in this arena. Hence, to realise this vision, it is essential to form of a stringent and functionary regulatory body, to systematise, control and facilitate projects related to bioinformatics and synthetic biology research. ' (interview professor of bioinformatics, New Delhi, 2013)

So (compared to the UK for example), the extent of bioinformatics enrolment into the emergence of a national policy discourse on pharmacogenomics in India is very recent. The Indian government has only in the last three years started addressing the translational issue of pharmacogenomics as part of national health strategy. The main action is to have issued guidance on the design of pharmacogenomics clinical trials, which states that trial populations and the aims of trials must have relevance to diseases relevant to the Indian population. Likewise, the ICMR has just set up a task force on pharmocogenomics to focus on specific research topics in the field. The task force will focus on topics including identification of genes and pathways involved in 'pharmacokinetics and pharmacodynamics of common drugs, and validation of human single nucleotide polymorphisms (SNP) haplotypes of short-listed genes in Indian population'. The task force is also intending to conduct research on the development of an 'Indian pharmacogenomics chip' (which I believe is being developed at least partly by Indian researchers based in US academia (this requires confirmation).

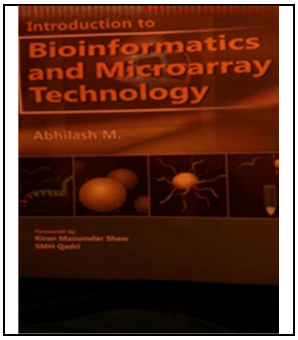
Survey of commercial activity in the field shows a number of life science companies moving to work in the pharmacogenomics field (Parveen 2010). However, there is strong perception that India, in competitive/developmental state terms, is a latecomer to this field:

> 'India's pharmaceutical market, mostly deals with generic drugs, therefore, it further strengthens the view that drug response monitoring program based on pharmacogenomic profiling of Indian populations is ideal for having a safer response to medications' India is far behind in addressing the foreseeable challenge of drug response monitoring or even on biomarker discovery. It is indeed high time that we realizes the potential of pharmacogenomic technologies or we end up paying SNP Consortium Ltd. or Pfizer or AstraZeneca for accessing our own databases, as these companies are already in the process of screening the Asian-Indian subgroups living in the United States…Scientific journal, *Nature*, in 2010 indicated that India is way behind in the global map of genomic technology landscape. It is an opportunity for India to tap its intellectual resources to initiate a mission mode program in addressing the concerns of human health (Banerjee 2011).

Trade organisations such as an Indian Pharma Industry representative organisation likewise compares India's position to other 'Rising Powers': 'India at this point is ahead of China in chemistry but the impression in many countries is that India is weak on biology front. It is found that India's strength in biology

sector is very limited especially in genetically modified animals, biochips and basic molecular biology. The biology capabilities are mainly in government institutes with a handful of companies having skills in molecular biology and protein expression'. Commentary on this position also alludes to a need to 'bridge the gap between bioinformaticians and experimental biologists' (DBT, 2011).

Nevertheless, significant for the Indian genomics-based drug discovery/drug development sector, is a remarkable initiative with symbolic significance for the Indian innovation pathway, namely the Open Source Drug Discovery (OSDD) program, supported by the CSIR. OSDD is claimed as one of the world's first attempts to apply an open source/participative innovation model drawn from the IT world to pharmaceutical innovation for *soi-disant* 'neglected' diseases. CSIR OSDD aims to discover novel therapies for tuberculosis and other neglected tropical diseases. Its activities are stated to 'spread throughout every stage of the discovery process (from 'drug target identification to lead optimization'). It has 'initiated discussions with pharmaceutical companies regarding pre-clinical and clinical trials'. Its main achievements to date are: the re-annotation of the *Mycobacterium tuberculosis* genome and the generation of 11 models for prediction of anti-tuberculosis activity' (Årdal and Røttingen, 2012). The author of the book below has won awards for his work at OSDD on *M.tuberculosis* :



The Director of CSIR is 'mentor' of OSDD.[1] An independent Europe-based evaluation of OSDD states that volunteers are attracted to the project by publicity in academic journals and utilizing social media and networks. CSIR OSDD has also 'effectively paired up with' Indian universities and colleges, incentivizing students to volunteer as parts of classroom assignments or positioning participation as valuable hands-on experience. They have also 'built in an element of patriotism' linking finding cures for tuberculosis as an Indian responsibility due to the high prevalence of the disease in India. This effect is reinforced through project marketing efforts, like the project's own music video and offer of prizes such as free holiday lets of property 'close to a bird sanctuary'. 'Large number of students can participate and benefit from this activity.

[1] Samir K. Brahmachari – Director of CSIR. **'**His current focus is on leveraging the angle of personalised medicine towards pharmacogenomics with focus on affordable healthcare. He conceptualized and led the Indian Genome Variation Consortium Project to provide the first comprehensive genetic map of the extremely diverse Indian population and identify predictive markers for complex diseases and pharmacogenomics studies.He has also conceptualized the Ayurgenomics project that aims to integrate the principles of personalized medicine from Ayurveda, an ancient Indian medical system with modern genomics to bridge the gap from genotype to phentoype. Prof. Brahmachari is the Chief Mentor of CSIR-Open Source Drug Discovery (OSDD) project, a CSIR-led Team India Consortium with global partnership. Emerging as India's first crowd sourcing initiative, OSDD is today a global translational research platform with more than 7500 participants from 130 countries. He has championed Private-Public Partnership conceptualizing 'Genomed', the first-of-its-kind knowledge alliance in India between a government Institute and a private pharmaceutical company. He has also established The Centre for Genomic Application (TCGA)'. http://en.wikipedia.org/wiki/Samir_K._Brahmachari . Accessed November 2013.

OSDD's focus is in Drug discovery and Development in TB, Malaria and other neglected diseases. Chemistry, Medicinal Chemistry, Biology and Informatic discipline plays a vital role in the early drug discovery.' Actually the innovation model is not open source *per se* because they use a protective license system and in effect a 'gated community' mode of access to the scheme. OSDD also aligns itself with the Indian generics drug industry business model: 'The drugs that come out of OSDD will be made available like a generic drug without any IP encumbrances so that the generic drug industry can manufacture and sell it through their channels anywhere'.. '(this) creates the environment of affordability' (website). Independent assessment concludes that 'OSDD brings in the concept of open source, crowd source, open science, open innovation and product development partnership concepts on the same platform and leaves delivery of drugs to market forces' (Årdal and Røttingen 2012). OSDD itself claims that the 'OSDD community comprises over 7900 participants from more than 130 countries' (OSDD website, December 2013).

In relation to non-communicable diseases, now endemic in developing states including India, India takes part in the global International Cancer Genome Consortium. Its director, (Mike Stratton, based in the Sanger Centre, Cambridge, UK) referring to the ambition to identify all the genes critical in the development of cancer, has 'hailed the role of the Kalyani-based Institute of Biomedical Genomics'…"It is playing an important role in focusing on oral cancer which is quite prevalent in India. There are 17 countries in this project who will eventually analyse over 25,000 cancer genomes. China is studying stomach cancer, and Japan's looking at liver cancer," said Stratton' (The Telegraph, Calcutta, 2011).

In summary, these somewhat patchy examples of bioinformatics developments in India show an emerging sector of very diverse activity and visions. On the one hand we see the well-known pattern of outsourcing of clinical trials from the advanced states being reproduced in a developing bioinformatics service sector, and on the other we see a more steered biomedical economy being shaped by government initiatives and infrastructures, with some unique national elements and some notable international collaborations. The noninvasive nature of genomics and massive human population resource may also bolster Indian achievement in this sector (Desai, personal communication). In terms of disease target strategies, it seems clear that infectious and neglected diseases are being addressed to some extent, and that the growing incidence of noncommunicable diseases such as cancer is also impacting on the shaping of the bioinformatics agenda. The published critiques by some commentators evidences a strong perception perception of India's current competitive lag on the global bioinformatics stage especially in aspects of expertise in biology, even though this has long been one of the most supported sciences in India. However, the latter is a conspicuous perception in the UK as well.

<u>Transnational biomedical informatics actors: some examples</u>

Transnational health policy has galvanised bioinformatics since the late 1990s unravelling of the human genome.

In 1998, World Health Organization-Tropical Diseases Research convened a scientific working group on "The utilization of genomic information for tropical disease drug and vaccine discovery". This group recommended that bioinformatics be considered a top priority, in light of opportunities this new field provides for disease-endemic country researchers and institutions. The WHO-based Special Program on Tropical Diseases Research and Training began running training programmes on bioinformatics for scientists in the developing world' (Hardy et al 2008). In 2001 WHO appointed four Regional Centers for Training in Bioinformatics and Applied Genomics, establishing programs in Africa, Asia and Latin America (www.who.int/tdr/grants/awards/bioinformatics-10-01.htm). The institutions

Selected were: the South African National Bioinformatics Institute; the Departments of Parasitology and Computing Sciences, Univ. São Paulo, Brazil, Mahidol University in Bangkok, Thailand; and the International Center for Genetic Engineering and Biotechnology in Delhi (ICGEB).

In 2004, a UNICEF/UNDP/World Bank/WHO Special Programme for Research & Training in Tropical Diseases was established (WHO website). A 'Working Group on Applied Genomics to Drugs and Diagnostics' led to support being provided to identify drug targets for parasites and vectors of a range of tropical diseases including Chagas disease, leishmaniasis, malaria, and tuberculosis. It was noted that the availability of the genome sequences of these produced 'an unprecedented opportunity to use whole genome … methodologies, computational biology, and functional genomics to identify new drug/insecticide targets and diagnostic reagents'. Examples of invited proposals included 'Use of computational bioinformatics approaches to identify novel pathogenic mechanisms and potential insecticide targets'.

The Gates Foundation, as implied in the introduction to this paper, is also now active in sponsoring research that mobilises bioinformatics. For example, the 'Gates Grand Challenges - Explorations in Global Health' includes 'New Approaches for the Interrogation of Anti-malarial Compounds' (February 2012). The initiative notes that 'The Medicines for Malaria Venture (MMV) has recently selected 400 compounds from the chemical libraries of St. Jude Children's Research Hospital, Novartis and GlaxoSmithKline to form a "Malaria Box" that is available for further study'. The ambition is to stimulate

> 'the development of next generation malaria drugs. We wish to encourage researchers to develop and apply innovative biological, chemical, **computational**, and systems-based approaches for the interrogation of anti-malarial compounds to maximize knowledge gained from the publicly-available anti-malarial compound set…' (Gates Foundation Grand Challenges website).

(These brief examples will be expanded in later version of this paper).

Discussion

This working paper is based on early, partial data. Conspicuously absent, for example, are significant data about the international pharmaceutical industry activity, further attention to civil society issues such as privacy concerns and access to medicines, and further evidence of international collaborative activity. I have also avoided at this stage reference to the other 'omics apart from genomics.

With that caveat, in this discussion, I compare the picture assembled to date in the cases of India, UK and transnational actors. I point to the various tensions in the dynamics of the bioinformatics sector that are apparent (or hinted at), and conceptualise these in terms of the concepts introduced at the beginning of the paper. I speculate about the significance of these developments for global health as a field and for specific population health and disease agendas.

So how can we understand the emerging significance of bioinformatics for global health? First, is there evidence that the genomic-related research agendas in India and the UK show evidence of having a national character geared toward the perceived health needs of the respective populations? The answer is yes, to varying extents and in different ways. The recent initiatives in the UK of Genome England are most obviously geared toward introducing more personalised genetic/genomic testing directly into the healthcare system, notably in the field of cancer drug therapies. It is also notable that the governance frame into which bioinformatics is being drawn is that of 'genomic medicine'. In India, the genomic medicine

framing is largely absent, as is the ambition to embed genomics and thus bioinformatics into the fabric of healthcare delivery systems and clinical trialling.

The account focused primarily on India and the UK provides evidence in terms of national policy of both inward and outward facing policies and actions. Technoscientific 'nationalism' can be seen in both cases. In terms of the sectorisation of bioinformatics as a technological zone, India appears to have currently a mixed bioinformatics economy model with a strong service element serving academic and commercial researchers globally, while the UK appears to have a more public sector-based bioinformatics economy with strong outsourcing and a globally important node in Cambridge, with new nodes being built currently with the new investments being made.. There is clearly a very dynamic market for outsourced services where price is key – for example a US interviewee suggested that companies in the Philippines are currently under-cutting Indian companies in this field.

There are some commonalities in India and the UK in the problems perceived for bioinformatics as a sector, notably the perceived need for more, and more advanced skill-building at the interface of biology and computation. The policy discourse in both states has highlighted this issue. Likewise, both states appear to identify issues in the sector that require regulatory policymaking. In the UK we see an attempt to how that the NHS is 'open for business' (to use a phrase current amongst UK government politicians) – the business of clinical trials. In India we see, in competition terms at least, a 'late' emergence of pharmacogenomics discourse compared to UK, and relative lack of an attempt to engineer an integration of national healthcare system, clinical trials and health informatics and bioinformatics in a genomics-driven vision of scientific advance. Is India 'less advanced' than the UK or the European collaborations noted in this paper? Or, are there signs of indigenous innovation like those mentioned for Brazilian genomics in the introduction here? The self-perception by some critical commentators is indeed that India is 'lagging'; however, this perception may be one shaped by ideals of Indian genomic health ambitions that are not shared by those non-elite actors active in providing bioinformatics services to customers in the global bioeconomic marketplace. It is thus not easy to define it in simple terms as a competitive or adaptive state without considering the different dimensions of its bioinformatics project in more detail.

The structure of the policy centres attempting to shape and guide bioinformatics in these nation states also appears very different. While India's initiatives appear strongly driven by the government Department of Biotechnology, the UK's governance ecology appears much more diverse with key actors including the government itself (Office of Life Sciences), but also notably the research councils, and specially configured Technology Strategy Board, and the charitable Wellcome Trust. With the advent of Genome England, ethics actors and industry actors will also play significant steering roles.

The relative lack of reference to disease targets, drug development and other translational issues in the national bioinformatics policy discourse, especially in the UK, is notable. One can only speculate as to the extent to which this is due to the 'social distance', or perhaps sociotechnical distance, between informatics work and health goals, or whether this can be explained more by the 'platform' status of bioinformatics – as a director of a major academic biomedical informatics centre in the US told me, 'we are agnostic regarding different diseases'. This appears particularly strong in the case of the UK/EU developments, and is perhaps characteristic of genomic research effort focused more on a 'basic science' model of developing platform technologies. Nevertheless, as has been shown above, there are policy priorities and disease target agendas to be discerned in the health visions and bioinformatics shaping activity described above. In the UK, the clear primary focus is on cancers, and the aim of developing of cancer biomarkers with the ability to better target drug therapies for different types of cancer at different disease stages. In India by contrast, and in the

transnational domain, there is some, though not exclusive, focus on communicable and 'neglected' tropical diseases.

The example of OSDD from India, though it is only one developing initiative, is symbolically resonant. It shows an alignment of emerging, novel genomic-based and disease-targeted science with the existing economic interest and market strength of India in generic drug manufacture. The discursive, ideological link forged between a commitment to crowdsourcing participatory science involving bioinformatics, the generics industry, and the infectious disease targets is particularly striking as an example of communitarian *medico*-technonationalism. In contrast, the UK, which has historically prided itself on the socialist roots of the publicy-funded National Health Service, continues to court controversy by embarking on the Genome England project which will inevitably require major commercial investments in operations that will require the intimate genomic and clinical healthcare data of tens of thousands of citizens[2].

Bio-objectification has been an implicit concept in much of this paper. Bioinformatics work can be regarded as a bio-objectification process *par excellence*. Biomedical research that aims at impacting medical practice is often dubbed 'translational' research, a metaphor that highlight the objectification process while at the same time skating over the computational work involved, e.g. in centres for 'translational genomics'. Bio-objectification here can be regarded as a sociotechnical process of transformation of genomic biology into biodata; and it can also be regarded as a more diffuse process of transformation of genomic matter into 'value' in a variety of forms, which may achieve an acknowledged status of a bioeconomic sector. This paper has shown some of the different stakeholders involved in attempting to create new drug objects by supporting bioinformatics work, and those involved in providing and capitalising on bioinformatics objects such as complex multi-dimensional databases. I have touched on trends and controversies in intellectual property aspects of these various value-building objectifications, and pointed out the global marketplace for outsourcing technical bioinformatics work.

What might be called the 'bio-objectification thesis' implies a challenging of sociomedically important boundaries, and entails Baren-Nawrocka 's (2013) claim, noted above, that bioinformatics is value-laden and not 'neutral'. Are these characteristics evident in the accounts that I have assembled in this paper? It is difficult to be clear about this. Bioinformatics is treated as a functional black box in (especially UK) policy discourse, at the service of genomic health goals. In this sense, it does serve as a vehicle 'disrupting' established medical science and healthcare practice, arguably in a depoliticised form. However, the US bioinformatics director's comment that they are 'agnostic' regarding disease is a scientific position (the centre in question undertakes work on breast and colorectal cancer, for example), because clearly bioinformatics work is enrolled into a variety of different stakeholders' health agendas and priorities. Thus, at this point and in this research, it remains an open question as to whether bioinformatics tools and databases themselves encode and embed *particular* health or social values, beyond a general conveyance of a genomic style of medical futures.

Finally, regarding matters that are commonly framed as 'ethical issues', I note that the media reporting of genomic medicine (in the UK at least) is preoccupied with civil liberty issues of privacy, almost to the exclusion of what might be considered by some the far more worrying issue of the asymptomatic genetic/genomic risk profiling of millions of non-patient citizens. Where is the public discussion of this in India, the UK or elsewhere? Is there a genomic imperative that is irresistible? In India, there is a vocal

[2] The November 2013 recent announcement of a parallel or competitor, commercial, US-based 100,000 genome initiative in the UK is even more controversial: http://www.personalgenomes.org/network

protest movement targeting the government aimed at extending affordability and access to *Herceptin* drawing on India's generic drug innovation industry model. Herceptin is a monoclonal antibody drug that acts genetically, produced by multinational Roche for treatment of advanced breast cancer. It is notable that Roche relinquished its patent on Herceptin in India in August 2013, responding to the strong current social and political movements on pharmaceutical innovation and access in India. Bioinformatics is likely to become implicated in similar sociomedical, ethically important and complex movements around genetic and genomic medicine, which bioinformatics governance will have to take into account.

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