ICTs and the Health Sector

TOWARDS SMARTER HEALTH AND WELLNESS MODELS

OECD

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Foreword

This report examines the challenges facing health care systems and the strategic directions for a smarter health and wellness future, from both technological and policy viewpoints. It looks at the role of information and communication technologies (ICTs) and discusses the research and policy options that could further the development of smarter health and wellness systems.

The report draws on the OECD-National Science Foundation (NSF) workshop entitled "Building a Smarter Health and Wellness Future", which was held in Washington DC, United States, on 15-16 February 2011. It comprises an overview of the key messages from experts' presentations and debates at this workshop, combined with enhanced evidence and discussion based on six authored papers (see Part II). The themes of these six papers reflect a selection of priority policy and research areas identified at the workshop:

- the need for integrated health and social care;
- participatory care and personally controlled health records;
- the challenges of personalised medicine;
- convergence of technologies and health innovation;
- the new privacy and security risks;
- big data and health.

An initial document summarising main points raised at the workshop has already been published online. A more scientifically detailed output from the event has been produced in a special issue of the *International Journal of Medical Informatics* (Vol. 82, Issue 4, pp. 209-219).

Recognising the importance of the issues addressed in the present publication, the OECD's Committee for Information, Computer and Communications Policy (ICCP) decided in 2012 to embark on further work, which has also involved case studies in six OECD countries.

The project was generously supported by a grant of the United States National Science Foundation. As it developed, the report benefitted from comments and input from speakers and OECD member country experts. Special acknowledgments go to Prof. Michael Rigby, the workshop rapporteur, for his review and comments; Dr. Suzi Iacono for guidance in identifying priority areas for this project; and Dr. William Barkis for his input and assistance in organising the workshop. In the OECD Secretariat, Elettra Ronchi was responsible for the project and drafted the report. Elodie Pierre, Jane Warren-Peachey, Joseph Loux and Julia Gregory provided critical administrative and editorial support. The Secretariat also recognises the contribution of members of the OECD's Business Industry Advisory Committee (BIAC) who participated in the workshop and commented on the report.

The report is published on the responsibility of the Secretary-General of the OECD. The views expressed are those reported at the workshop and do not necessarily reflect the views of the NSF, of the OECD or of its member governments. Mention of industrial companies, trade names or commercial products or processes in this report does not constitute an endorsement or recommendation by the OECD or the various bodies mentioned above.

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Executive summary

Health and wellness are an increasingly important topic of discussion in all OECD countries because of social and demographic changes, the rise in chronic diseases, and the need to improve the efficiency and quality of health-care delivery.

There is broad and growing consensus that any systematic effort to address these challenges requires the intensive use of information technology to support new and "smarter" models of care. Such models aim to keep the elderly and the disabled in their own homes rather than in the considerably more expensive hospital or nursing home systems, enable longer-term independent living and encourage personal responsibility for healthier lifestyle choices.

Alongside these new models of care, a vision for a "learning health system" is taking shape, one in which "progress in science, informatics and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly refine and deliver best practices for continuous improvement in health and health care" (Grossman et al., 2011).

Achieving this vision will require enhanced capacity to share process and analyse large streams of data from different and heterogeneous sources and a major change from traditional practices. Today's health care is reactive, episodic and focused on disease. The new health care will need to be pro-active, preventive and focused on quality of life and well-being. Current health care is hospital- and doctor-centred. The new smart models will need to be patient-centred and much care will be provided at home and include the broader social network (with family and community contributing significantly to individual health and well-being). The current approach to diagnosis and treatment is based on the training and experience of the clinicians. Smarter models will deliver more evidence-based approaches and personalised care.

This report examines the strategic directions that OECD countries are considering to achieve this health and wellness vision from both the technology and policy viewpoints. It looks at the role of information and communication technologies (ICTs) and discusses research and policy options to further the development of smarter health and wellness systems.

A better understanding of barriers and enabling conditions can help inform a research agenda and policy action to ensure that the new and emerging smart health models are accepted and used in a timely manner and with maximum benefit for all stakeholders. The widespread adoption and use of ICTs to deliver better models of care will not happen solely on the basis of scientific and technological advances. They will require the right set of policies to be in place for both developers and users (patients, doctors and reimbursement systems) in order to achieve a clear health benefit.

This report draws on a workshop co-organised by the OECD and the US National Science Foundation (NSF) entitled "Building a Smarter Health and Wellness Future", which was held in Washington, DC, on 15-16 February 2011. It gives an overview of the experts' presentations and debates, combined with evidence and discussion based on six authored papers (see Part II). The themes of these papers reflect a selection of priority areas identified at the OECD-NSF workshop: the need for integrated health and social care; participatory care and personally controlled health records; the challenges of personalised medicine; convergence of technologies and health innovation; the new privacy and security risks; and big data and health.

The workshop was also an opportunity to discuss where the OECD can provide further policy insight and expertise. Experts made a number of recommendations for international action in four areas in which the OECD may decide to do follow-on work: *i)* address the big data challenges; *ii)* foster meaningful innovation; *iii)* understand and address the potential new risks; and *iv)* support concerted effort to un-silo communities for a virtual care future. Main points for further actions on these areas are summarised below.

Address the big data challenges

It is predicted that more health and wellness data will be generated in the next few years than ever before – all of which must be stored securely and accurately, and converted to meaningful information at the point of care. Large-scale aggregations of computer-based clinical and administrative records, advances in genomics, new diagnostics and medical imaging, sensor and mobile technologies, and geospatial location tools, are contributing to this growth.

In aggregate, capturing and delving into these large, heterogeneous streams of data will contribute to improving population health, prevention of disease, quality and safety of health care, and to generating greater system-wide efficiencies, including for health care research and innovation. Database and decision-support tools, interfacing with electronic patient records, will increasingly become the principal mechanism by which research results are fed back into clinical choices.

There are, however, challenges in getting data out of the different clinical information systems, monitoring and mobile devices. Conventional technology and analytical tools today cannot effectively manage or even capture the many health data streams, and ensure that they will be turned into useful and actionable health information. Large streams of health data are of no intrinsic value, and are costly and may create a false sense of security. Data integrity is one of the most challenging problems in sensor networks generally and there is much research to be done to develop robust procedures for aggregation and analysis.

Of vital importance is the development of new powerful data-mining, analytical and computational tools to draw meaning from the data and of responsive services to act on that data.

Foster meaningful innovation

Progress requires moving from silos of technology toward an integrated ecosystem of smart solutions. Research and development and the new smart models of care are increasingly being shaped by convergent technologies. "Stovepipe" or "siloed" approaches will limit the potential to develop new, smarter models of care. This also means that devices will have to function seamlessly and adapt to multiple user needs in the health sector and partner sectors.

Innovation needs to be far more than technological innovation, however. Health-care responses, and means of delivering smart services, need radical organisational and social innovation in view of the multiplicity of actors with different cultures and roles. They must include the points of view of both public- and private-sector stakeholders.

Innovation must also consider how the patient/citizen is affected by and deals with the new models of care. It should consider the needs of the person and his/her context and capacity to operate innovative solutions.

Understand and address potential new risks

With any new technology or other innovation come new risks, and unanticipated outcomes. While it is right to pursue and promote new opportunities rigorously in the interests of citizens and society, equal thoroughness must be given to the development of quality assurance, monitoring of use, identification of potential adverse outcomes or intentional abuses, constructive reporting and analysis of incidents and events, and creation of appropriate controls, mechanisms and regulation.

There are strong pressures to undertake health and wellness research and deploy it rapidly. For innovation in pharmaceuticals, strong mechanisms have been built up to promote sound research and development practices, including testing effects and linking the clinical outcomes to guidance and controls.

The adoption and use of health information technologies and the design and redesign of health care delivery systems have not been so rigorously served. Risks from expanded use of electronic health records, for example, remain largely unknown.

Greater electronic data availability, mobile devices including intelligent medical implants, cell phones that sense and process health data, and a variety of new types of sensors and actuators that can be worn on the body, are creating a changing landscape raising new security and privacy concerns. These range from modest risks to the privacy of activity data (like data collected by a pedometer) to safety-critical risks (like the integrity of software in an insulin pump).

Measures are needed to better determine and mitigate these threats and ensure that residual risks are acceptable. This must be part of the ethical development of smarter health and wellness systems in the new data-driven economy.

A number of areas specific to ICTs require more research in order to support better practices: access controls and audit; encryption and trusted base; automated policy; mobile health (m-health); identification and authentication; and data segmentation and de-identification.

Promote organisational and social innovation for an integrated care future

Efforts must be co-ordinated and integrated, and avoid overlap or duplication. However, the two steps of "demolishing" professional or sector-specific silos and of moving from fixed and institution-based provision of care towards ubiquitous care based on remote monitoring are challenging in themselves and also require disruptive innovation. Such radical change is vital but must be managed sensitively and constructively. Establishing and sustaining the engagement of participants is critical to the success of these initiatives.

Existing processes have developed for good reasons and they ensure comfort and stability, certainty and accountability, development and satisfaction. In the new order, new processes will be needed that fulfil the same needs but also support the new integrated way of working and do not constrain innovation.

Communities are not homogenous and citizens are not identical. Individuals and families vary in many ways, and areas of particular relevance for the health and wellness agenda are education, income and financial resources, lifestyle and family size and structure. Belief systems, cultural and ethnic backgrounds, and employment or vocational history are also influential. A challenge for the structure and modalities of future smart care is to ensure that it is equally available and accessible to all, within the context of the national patterns of care provision.

Next steps: Developing an agenda for international policy action

The OECD-NSF workshop outcomes point to the need for a multi-stakeholder, international policy agenda to create the conditions for accelerating innovation and for promoting sustainable and scalable care solutions. Participants at the workshop identified mobile-health as a rapidly evolving field where international guidance would be particularly useful and would provide a good starting point for exploring how best to address the issues outlined below:

- **Data challenges and the need for trusted services.** Systems need to be designed to deal with personal health (and other relevant) data. Widely accepted privacy and security standards for personal data collection, analysis and use are needed.

- **Integration and interoperability.** A "siloed" approach will limit the potential of the new smart care models. The new range of mobile devices in the health sector has to function seamlessly and adapt to multiple user needs. Government action is needed to accelerate innovation and greater system-wide integration and scaling.
- **Financing and the new business models.** It is necessary to understand the regulatory structures that provide incentives at different levels of the health delivery system to encourage investment in, and use of new models of care.
- **Evidence-based implementation.** Metrics will have to be developed to monitor and evaluate the use of the new devices and platforms, their costs and benefits, to identify best practices, and to generate economic models for planning and analysis. There is also a need to develop performance measurements to understand health outcomes and/or health-care system outcomes.
- **Capacity building and training.** There is huge demand for training health providers and community health workers in the use of the new technology platforms and improve patients' understanding and use of these new tools. Case studies could help to identify best practices.

Reference

Grossmann, C.W., A. Goolsby, L. Olsen and J.M. McGinnis (2011), *Engineering a Learning Health care System: A Look at the Future: Workshop Summary*, The Learning Health System Series Roundtable on Value & Science-driven Health Care, The National Academies Press.

Part I

Emerging smarter models of care

Chapter 1

Health and wellness needs

Smarter health and wellness systems are needed to support better and more efficient care, encourage greater system-wide accountability and facilitate the promotion of healthy lifestyles and independent living. "Smart" technologies can help governments to tackle the current weaknesses in six key components of health systems: service delivery, finance, governance, quality of care, workforce and information. Effective integration of health and social care represents a key barrier to progress.

The statistical data for Israel are supplied by and under the responsibility of the relevant Israeli authorities. The use of such data by the OECD is without prejudice to the status of the Golan Heights, East Jerusalem and Israeli settlements in the West Bank under the terms of international law.

OECD health-care systems are in need of repair. Health-care costs are rising much faster than most other costs and consume an ever increasing proportion of nations' gross domestic product (GDP). However, increased health care spending does not always lead to better health outcomes. Too many patients suffer harm from preventable medical errors, and only about half of chronic care patients receive all recommended health care.

As spending rises, there is pressure to ensure that resources are well spent and help people live healthier lives. Finding ways to achieve smarter, more efficient delivery of health care has therefore become a key preoccupation of OECD governments, especially in the present economic and financial context.

In considering future health and wellness needs, six main areas require smarter solutions. These are discussed below.

Rising health costs and the need for greater efficiency

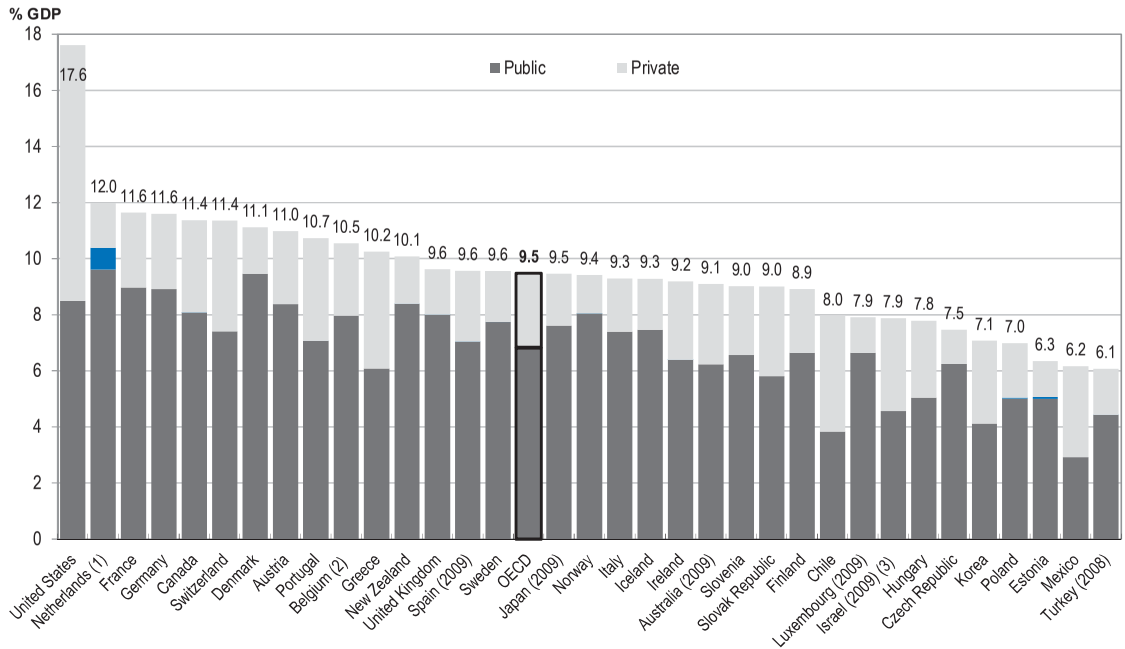
Health is one of the principal areas of public expenditure in OECD countries and forecasts show health spending continuing to climb for the foreseeable future (OECD, 2012). From 1990 through 2010, an increasing share of GDP in OECD countries has gone to health care. On average, total spending on health care represented about 9.5 % of GDP in 2010 (Figure 1.1), up from just over 5% in 1970 and around 7% in 1990. In Japan, the share of spending allocated to health has increased substantially in recent years to 9.5%, up from 7.6% in 2000, and is now equal to the OECD average.

While the rate of increase slowed from 2003 to 2008, the rise in health expenditure has nonetheless exceeded economic growth in almost all OECD countries in the past 15 years.

To maintain this rate of growth would require OECD governments to devote an ever larger share of national income to health and an ever smaller amount to other expenditure areas. This is unlikely.

For some years, governments have experimented with a range of policy tools to control the escalation of costs. Short-term "command and control" policies can hold expenditures down in the short term but often have unfortunate consequences in the long term. In addition, they do little or nothing to moderate the underlying pressures that push health spending up over the medium term (OECD, 2010a).

Figure 1.1. Health expenditure as a share of GDP, OECD countries, 2010



1. In the Netherlands, it is not possible to distinguish clearly the public and private share for the part of health expenditures 2. Total expenditure excluding investments. 3. Information on data for Israel: http://dx.doi.org/10.1787/888932315602.

Source: OECD Health Data 2012.

Promising avenues for controlling health spending in the longer term include improving value for money, particularly by improving the quality and efficiency of health-care delivery and co-ordination of care (OECD, 2010a). The care supply structures are still unduly fragmented in many OECD countries. The result is major inefficiencies and excess costs: hospital facilities are often oversized and absorb a disproportional share of resources. Reducing the need for high-cost care through a shift towards more effective person-centred, primary/community care and prevention also has great potential, owing to the increasing prevalence of chronic diseases (often multiple chronic diseases) as populations age. Such a shift faces, however, structural obstacles in several countries.

Gaps in effective and preventive care

There are significant gaps between the health care that people should receive and the care they actually receive. Medical practice varies both across and within countries, and the variation often seems unrelated to differences in needs. The variations in medical practice include possibilities of overuse and underuse of certain health services and thus have important policy implications regarding the quality, efficiency and equity of health service delivery.

Overuse occurs when a drug or treatment is given without medical justification. This includes, for example, treating people with antibiotics for simple infections or failing to use effective options that cost less or cause fewer side effects. Underuse occurs when doctors or hospitals neglect to give patients medically necessary care or to follow proven health-care practices.

A study conducted by the Rand Corporation in 1998-2000 in the United States showed that patients received only 54.9% of recommended care for a set of 439 quality indicators defined for 30 acute and chronic conditions. Quality care indicators were based on recommendations pertaining to screening, diagnosis, treatment and follow-up for each condition. While more than 75% of recommended care was provided for senile cataract or breast cancer, this percentage did not exceed 50% for ten of the conditions. Only 22.8% of recommended care was provided for hip fracture and 10.5% for alcohol dependency. In many but not all cases, non-adherence to recommended care corresponded to an underuse of health-care services (McGlynn et al., 2003).

Other studies have produced similar evidence of non-adherence to recommended care in medical practice. For instance, a study of 20 000 patients with diabetes at Fraser Health Authority, in British Columbia (Canada), between 1996 and 2001 showed that no more than 50% received all of the services and tests recommended in clinical practice guidelines no matter how often they saw their doctor (Krueger, 2006; OECD, 2010b).

Medication errors

Errors of medication account for a significant number of hospital admissions and primary-care consultations. Three types of errors are common: errors due to forgetfulness or inattention, errors of judgement or planning (rule-based errors), and errors resulting from a lack of knowledge, for example of patients' prior history of allergies.

A number of established medicines, now well beyond patent protection, may cause significant adverse reactions in some patients. These include medicines such as aspirin, ibuprofen and other common drugs such as anti-depressants, β-blockers and opiates (Pirmohamed *et al.,* 2004). Adverse drug reactions have been estimated to be one of the leading causes of death in the United States (estimated at between the fourth and sixth leading cause).

Improvements are needed. The ability to predict – more accurately and more quickly – patient response to a given medicine or treatment will be important to achieve better patient safety, health outcomes and more efficient health expenditures.

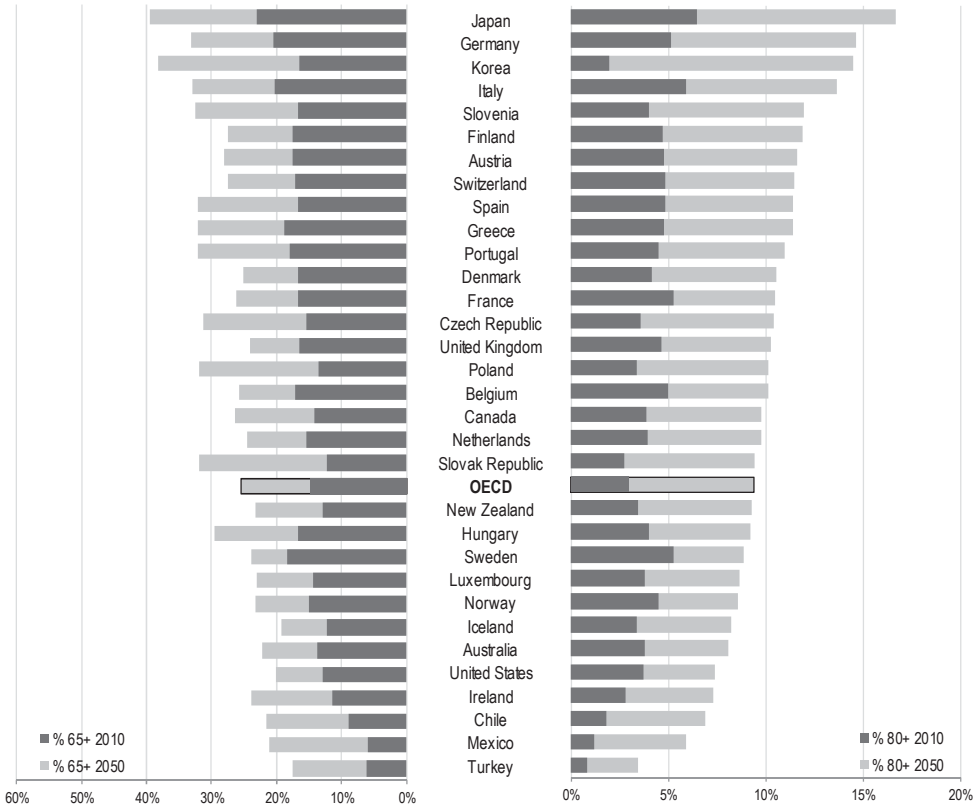
Demographic changes and increasing prevalence of chronic diseases

OECD countries have all enjoyed extraordinary gains in longevity, with average life expectancy at birth rising from 66 years in 1950 to just over 76 years in 2007. Life expectancy of over 80 years of age, in particular, is expected to increase by 2.5 times between 2008 and 2050. The front runners among the OECD countries are Japan and Korea in Asia, and Italy, Norway and Sweden in Europe. Norway and Sweden have the highest share of persons aged 80 and over in the OECD area (Figure 1.2).

In Japan, the proportion of the population over 80 years of age is expected to rise from a current 7% to 17% by 2050, while that in the EU27 is expected to rise from 5% to 11.5%, in both cases more than doubling in 40 years.

While by no means all of the elderly have chronic health problems, the rapidly expanding cohorts of elderly and older elderly individuals will mean a significant proportion with chronic diseases. Moreover, the last three years of life, regardless of age, are on average the most expensive.

Figure 1.2. Shares of the OECD population aged over 65 and 80 years, 2010 and 2050



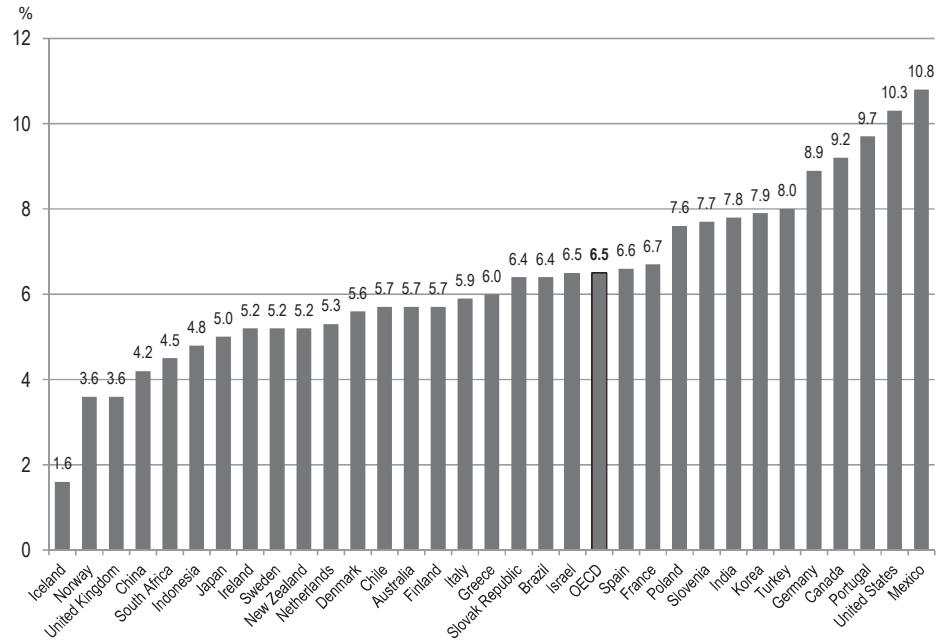
Source: OECD Labour Force and Demographic Database, 2010; OECD (2011), *Help Wanted? Providing and Paying for Long-term Care*, OECD Publishing, doi: 10.1787/9789264097759-en.

In the United States most 70-year-olds are affected by at least one chronic condition. Cardiovascular diseases alone affect 40% of men (Adams *et al*., 1999). OECD research has also recently shown a generalised increase in the prevalence of diabetes among the elderly. Alarming trends are observed even in countries that are traditionally minimally affected by such diseases. For instance, Japan has had a 5.3% average annual increase in the prevalence of diabetes during 1989-2004 (LaFortune and Balestat, 2007). Co-morbidities also increase with age. At least 35% of men over 60 years of age have two or more chronic conditions (WHO Europe, 2006), and of the 17 million people living with long-term chronic diseases in the United Kingdom, up to 70-80%

would need support for self-care (Watkins, 2004). Unhealthy diets, sedentary lifestyles and obesity are also responsible for a considerable share of the burden of ill health and morbidity described above.

The economic impact of diabetes is substantial. Health expenditure in OECD countries in 2010 to treat and prevent diabetes and its complications was estimated at USD 345 billion (IDF, 2009). In the United States alone, some USD 116 billion was spent on diabetes-related care in 2007 (ADA, 2008). In Australia, direct health-care expenditure on diabetes in 2004-05 accounted for nearly 2% of recurrent health expenditures (AIHW, 2008). Diabetes was the principal cause of death of almost 300 000 persons in OECD countries in 2009, and is the fourth or fifth leading cause of death in most developed countries. If left unchecked, the number of people with diabetes in OECD countries (Figure 1.3) will reach almost 100 million in less than 20 years.

Figure 1.3. Estimates of the prevalence of diabetes, adults aged 20-79 years, 2010



Source: OECD (2011), *Health at a Glance 2011: OECD Indicators*, OECD Publishing, doi: 10.1787/health_glance-2011-en.

The future sustainability of OECD health-care systems will depend upon their ability to improve the quality and efficiency of care for older populations and the chronically ill. This will require a major transformation or redesign of practice that combines delivery system redesign, enhanced use of technology for real-time decision making, and patient self-management support to ensure more productive interactions and thus better outcomes (Table 1.1).

Table 1.1. Implications of demographic change and the increasing burden of chronic conditions

Pressures for change	Needs
An ageing population	The likely impact on overall demand will depend on disability trends, but the nature of the required care will shift towards an emphasis on long-term conditions, patient-centred and home-based associated support services.
Significant rise in the number of patients with chronic conditions	New care models are needed to manage conditions and prevent exacerbations through the use of more proactively planned care in a primary/community-based setting and the promotion of patient self-management.
Increased incidence of multiple complex symptoms and co-morbidities	Care is likely to require more co-ordination of services across the continuum of care.
Workforce availability	Ageing of the workforce and increased demand will affect workforce availability, effective use of health practitioner skill sets, and investment in information technology and primary/community-based infrastructures.
Greater prevalence of chronic conditions and lifestyle choices	It will be necessary to make greater use of patients' personal resources and self-management potential.

The growing fragmentation of care and the need for more responsive, patient-centred services

With more patients receiving care for chronic conditions from multiple providers, health systems are increasingly fragmented. This results in poor patient experience and ineffective and unsafe care. Patients with chronic diseases receive a wide range of clinical inputs from different specialities, including allied health professionals. This leads to a problem of co-ordination of health-care settings that are generally organised and paid differently and often operate under incentive structures (relative to cost control and quality) that are not aligned, or even at odds with each other.

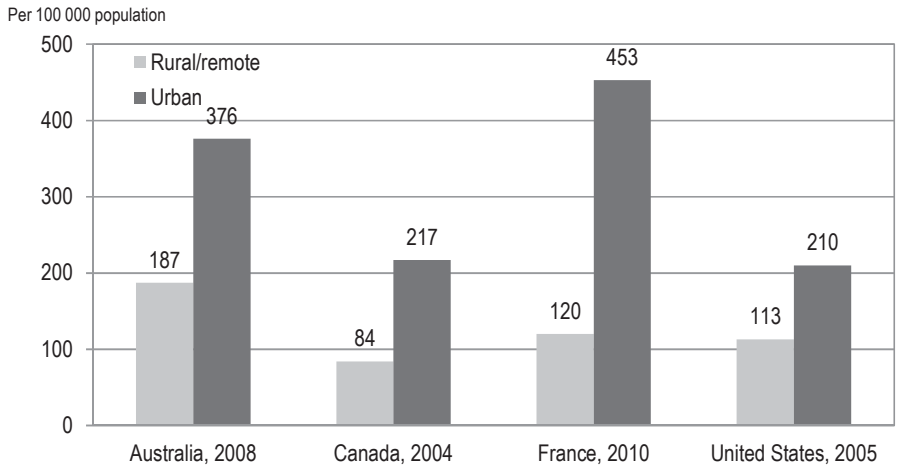
Beyond the health system, there is also the difficulty of co-ordinating health care and social care, which are usually organised and financed in dramatically different ways. Though they serve the same citizens, and each depends for its efficiency on the other, there is seldom a shared management structure and thus no vehicle for integrating governance, funding and informatics. In order to address patients' expectations for seamless care regardless of the system, it will be increasingly important to consider co-ordination and integration of care in a perspective that goes beyond health care.

The role of patients in the care process has also taken on much greater importance in recent years. There is growing recognition that patients play a critical and under-utilised role in managing their own health.

Declining availability of a health workforce

Access to medical care requires an adequate number and proper distribution of physicians and nursing care. Shortages of health professionals in a geographic region can lead to increased travel times for patients and higher caseloads for doctors and allied care givers. The shortage and/or uneven distribution of physicians is a challenge in a number of OECD countries, especially in territories with remote and sparsely populated areas, with long travel times to the nearest urban region (Figure 1.4).

Figure 1.4. Physician density in rural and urban regions, four OECD countries, latest available year



Source: OECD (2011), *Health at a Glance 2011: OECD Indicators*, OECD Publishing, doi: 10.1787/health_glance-2011-en.

Physician density is greater in regions with a large urban population, owing to the concentration of services such as surgery and specialised practitioners. In Canada, just under 16% of "family physicians" (mostly general practitioners) and only 2% of specialists were located in rural areas and small towns in 2006, whereas 24% of the population resided in these areas (Dumont et al., 2008). Similarly, in the United States, 17% of the population lived in non-metropolitan areas in 2004, but only 9% of practising patient care physicians, and almost 50% of US counties had no obstetricians or gynaecologists providing direct patient care (NCHS, 2007). In 2010 in France, 22% of general practitioners and 4% of specialists practised in towns of up to 10 000 population, which accounted for 36% of the population (DREES, 2010).

Workforce shortages, particularly in rural areas, threaten the health system's ability to provide the full range of high-quality health services and can create important equity issues.

Increasing demand for home care

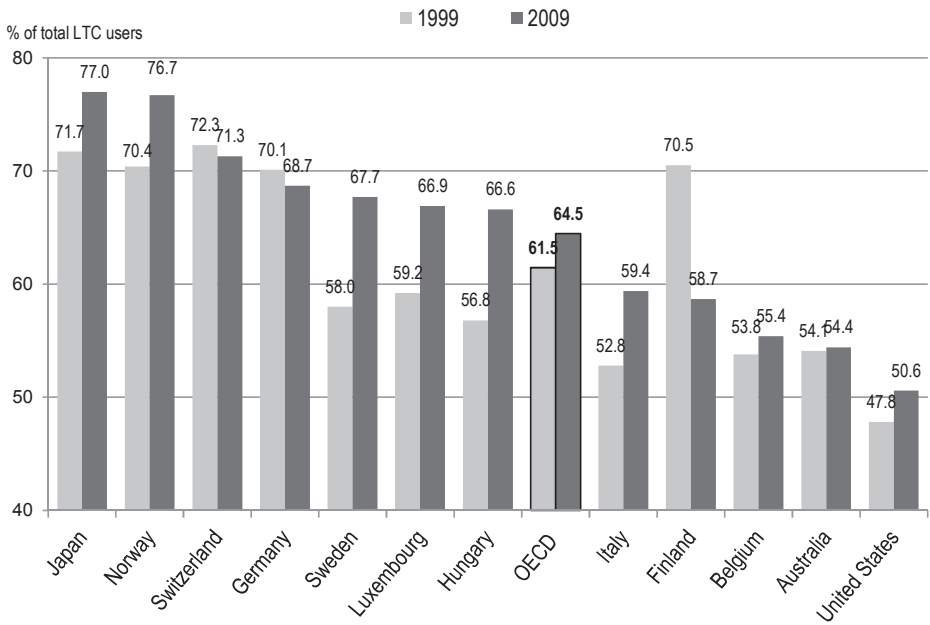
There are also expectations of an increasing amount of home care in place of hospitalisation or institutionalisation. Home-care arrangements account today for more than 30% of public resources spent on long-term care in many OECD countries.

Enabling dependent older people to stay in their own homes is not simply a response to the need to reduce public spending. Today's pensioners have higher incomes than in the past and can afford to pay more for their own care. Housing standards have also risen. Over the past decade, many OECD countries have introduced programmes to deliver long-term care at home. Several countries have expanded community-based services and home-care coverage and support (e.g. Canada, Ireland and Sweden). Others have introduced financial support for users, for instance in the form of cash benefits for long-term care (LTC) recipients at home in Austria and the Netherlands.

In most countries for which data on trends are available, the number of people receiving long-term care at home (as a share of the total number of LTC recipients) has increased over the past ten years (Figure 1.5). The proportion of LTC recipients at home is highest in Japan and Norway. In both countries, the proportion has gone up over the past decade, so that now more than three-quarters of LTC recipients receive care at home.

This will produce more demand for home support workers, an already stretched workforce. Demand is likely to be reinforced by other societal changes such as rising rates of female participation in the labour market, declining family size, childlessness, divorce and the continuing rise in the "step-kin" or "patchwork" family (OECD, 2011).

Figure 1.5. Share of long-term care recipients receiving care at home, 1999 and 2009 (or nearest year)



Source: OECD (2011), *Health at a Glance 2011: OECD Indicators*, OECD Publishing, doi: 10.1787/health_glance-2011-en.

Conclusions

This overview of the main pressures on health systems shows that the future sustainability of health systems will depend on how well governments are able to anticipate and respond to these pressures. There is broad and growing consensus that these challenges will not be solved by doing more of the same. Bold action is required, as well as willingness to test innovative care delivery approaches.

Any systematic effort will require the intensive use of information technology to support new and "smarter" models of care that take account of the need to keep the elderly and the disabled in their own homes rather than in considerably more expensive hospital or nursing home systems, to enable longer-term independent living and to encourage personal responsibility for healthier lifestyle choices. It will require enhanced capacity to transfer, process and analyse health and behavioural data to support patient-centred

care, and a more efficient clinical research effort for improved prevention and better disease management.

As discussed in subsequent sections, "smart" initiatives are under way in many OECD countries. Information technology is rapidly advancing, is more widely available, and is becoming more affordable. The availability of tele-medicine, of sensors that can seamlessly detect and report vital signs, of mobile applications and care management systems that can improve adherence to diet and guidance on medication, all promise to enable the transformation of care delivery.

However, the need for co-ordinated and systemic action rather than separate responses is also increasingly recognised. Efforts must be integrated and co-ordinated and avoid overlap or duplication; but the two steps of "demolishing" professional or sector-specific silos and of moving from fixed and institution-based provision of care towards ubiquitous care provision are challenging and require disruptive innovation in many processes.

This radical change is vital and must be managed sensitively and constructively. As noted in Chapter 5, the effects of decades of isolated development will not be eliminated solely by the provision of ICT-based smartness. It is necessary to confront the related human and cultural and organisational factors in order to seek a holistic approach to health and social care provision that is commensurate with the values of a caring global society fit for the 21st century.

References

Adams, P.F., G.E. Hendershot and M.A. Marano (1999), "Current estimates from the national health interview survey 1996", *Vital Health Statistics*, Vol. 200, pp. 1-203.

ADA – American Diabetes Association (2008), "Economic costs of diabetes in the US in 2007", *Diabetes Care*, Vol. 31, No. 3, pp. 596-615.

Australian Institute of Health and Welfare (AIHW) (2008*), Diabetes: Australian Facts 2008*, www.aihw.gov.au/publication-detail/?id=6442468075.

DREES (2010), *"Les médecins – au 1er janvier 2010"*, Document de travail, No. 152, DREES, Paris.

Dumont, J.C., P. Zurn, J. Church and C. Le Thi (2008), "International Mobility of Health Professionals and Health Workforce Management in Canada: Myths and Realities", *OECD Health Working Papers*, No. 40, OECD Publishing, doi: 10.1787/228478636331.

Krueger, H. (2006), "The Relationship Between Long-Term Adherence to Recommended Clinical Procedures and Health Care Utilization for Adults with Diagnosed Type 2 Diabetes", PhD dissertation, University of British Columbia, Department of Health Care and Epidemiology.

International Diabetes Foundation (IDF) (2009), *Diabetes Atlas*, 4th edition, IDF, Brussels.

Lafortune, G. and G. Balestat (2007)," Trends in Severe Disability among Elderly People: Assessing the Evidence in 12 OECD Countries and the Future Implications", *OECD Health Working Papers*, No. 26, OECD Publishing, doi: 10.1787/217072070078.

McGlynn, E.A. et al. (2003), "The quality of health care delivered to adults in the United States", *New England Journal of Medicine*, 348 (26): 2635-2645

National Centre for Health Statistics (NCHS) (2007), *Health, United States, 2007*, NCHS, Hyattsville, MD.

OECD (2012), OECD Health Data 2012, www.oecd.org/health.

OECD (2011*), Help Wanted? Providing and Paying for Long-Term Care*, OECD Publishing, doi: 10.1787/9789264097759-en.

OECD (2010a), *Value for Money in Health Spending*, OECD Health Policy Studies, OECD Publishing, doi: 10.1787/9789264088818-en.

OECD (2010b), *Improving Health Sector Efficiency: The Role of Information and Communication Technologies*, OECD Health Policy Studies, OECD Publishing, doi: 10.1787/9789264084612-en.

Pirmohamed, M., S. James, S. Meakin, C. Green, A.K. Scott, T.J. Walley, K. Farrar, B.K. Park and A.M. Breckenridge (2004), "Adverse drug reactions as cause of admission to hospital: Prospective analysis of 18 820 patients", *British Medical Journal* 329 15-19.

Watkins, P. (2004), "Chronic disease", *Clinical Medicine*, Vol. 4, No. 4, pp. 297-298

WHO Europe (2006), *Gaining Health. The European Strategy for the Prevention and Control of Non-communicable Diseases*, World Health Organization, Regional Office for Europe, Copenhagen.

Chapter 2

From personalised to ubiquitous care

The opportunities held out by mobile platforms, the storage capabilities through cloud computing, transmission and processing technologies, new sensing technologies, and computing power are such that it is now possible to deliver care in wholly new ways. The health and social care sectors have been slow to make radical changes. The depth of investment in current structures, innate professional conservatism, regulatory uncertainty, and above all the asymmetry of information and problems related to patient empowerment and accountability have, until recently, held back change.

In 2010, the President's Council of Advisors on Science and Technology of the United States, in forecasting the digital future, named health care as a prominent area for research and development. It noted that effective technology-based solutions must deal with a multitude of constraints arising from clinical needs, social interactions, cognitive limitations, barriers to behavioural changes, heterogeneity of data, semantic mismatch, and the limitations of current cyber-physical systems.

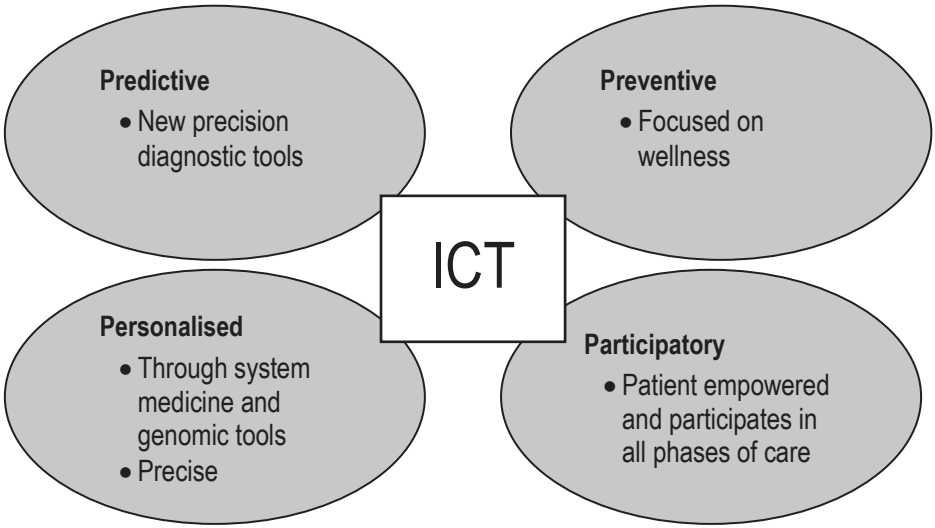
The complexity and broad range of these issues require multidisciplinary teams of scientists and engineers to identify and address limitations on the quality of life, the independence of chronically ill and elder individuals, and other aspects of well-being. Fundamental technological advances are also needed to understand what prevents people from engaging in health-promoting life styles, including diet and exercise, and from participating in their health-care decisions.

It is increasingly clear that radical innovation is needed and that the application of technology can help achieve these changes. Today's health care is reactive, episodic and is focused on disease. The new health care will need to be proactive, preventive and focused on quality of life and well-being. Current health care is hospital and doctor-centred. This model needs to be replaced by a patient-centred approach and much care will have to provided at home and include the broader social network (family and community as significant contributors to individuals' health and well-being). Care should account for differences in individual conditions, needs and circumstances, and engage the patient as a partner in addressing all the factors that shape wellness, illness and restoration of health. Care should be a team activity with the patient as the central member, and there should be seamless integration across caregivers and institutions to achieve and maintain optimal health throughout the patient's life.

The current approach to diagnosis and treatment is based on the training and experience of clinicians, and treatment decisions are often influenced by anecdotal rather than statistical information. This will need to change to deliver more evidence-based treatment and personalised care.

Achieving this goal will require a paradigm shift towards a model of care that is participatory, predictive, personalised and preventive (the P4 model; Figure 2.1). This model, developed by Hood and Friend (2011) shows, first, that medicine is an information science; second, the need for systems or holistic approaches to address the enormous complexities of disease; third, the emergence of new knowledge and technologies for personalisation of care; and fourth, the need for powerful new analytical technologies, both mathematical and computational, to decipher the billions of data points associated with each individual.

Figure 2.1. P4 medicine



Source: Based on L. Hood and S.H. Friend (2011), "Predictive, personalized, preventive, participatory (P4) cancer medicine", *Nature Reviews Clinical Oncology* 8:184-187.

In this context, advances in information technology offer a number of opportunities. Most efforts in recent years have focused on the adoption of electronic health records (EHRs) by general practitioners and in hospitals. Care providers are struggling to convert to EHRs and are slowly doing so in most OECD countries. It is not an easy process but it is paving the way for greater evidence-based and personalised medicine.

Applications that move beyond EHRs and encourage new, ubiquitous information sharing platforms hold the most promise for transformational change, as will be seen in the following section and in Chapters 6 and 10.

Personalised medicine

The power of health information processing is such that it is possible today to personalise therapy in wholly new ways. First, the ability to search and process an individual's electronically recorded medical history enables rapid identification not just of personal biological responses such as allergies, but a much richer pattern of personal information such as results of diagnostic tests and outcomes of particular therapies. Second, genomic information can help identify variations in population groups that influence response to care, while personal genetic profiles can inform not only individual therapy but also selective targeted prevention.

Advances in DNA sequencing and whole genome analysis have made it possible to gain better understanding of response to treatment. In oncology, for example, pathologists measure oestrogen receptor expression to determine eligibility for tamoxifen hormone therapy for breast cancer. Its effectiveness has been found to be contingent on an enzyme (cytochrome enzyme P450 2D6) that is needed to metabolise the drug, although the results of studies have not always been consistent (Roederer, 2009). Commercial tests are now available for the genotyping of this enzyme with the aim of individualisation of therapy.

With the declining cost of whole genome sequencing, genomic information is expected to be streamlined into medical practice. Effective translation to the clinic will, however, require addressing a range of technical and policy issues that are discussed in greater depth in Chapter 6. Among the technical issues to be resolved is the need for new data management and processing methods to realise the potential of personalised medicine. These include: *i)* processing large-scale robust genomic data; *ii)* interpreting the functional effect and impact of genomic variation; *iii)* integrating systems data to relate complex genetic interactions with phenotypes; and *iv)* making the data available at point of care in ways that do not impair the clinician's ability to prescribe accurately and rapidly drugs that are safe and effective for a specific patient (Fernald et al., 2011).

In addition, the full extent of patient data will need to be accessible so that questions that concern multiple data sources can be raised and answered. This flood of data introduces significant challenges which the bioinformatics community will need to address. For example, a physician in clinical practice may need to ask about the criteria for diagnosing a disease and the recommendations for personalised medicines. Consistency and completeness of patient EHRs will be increasingly important.

While simple questions may be answered by queries to a single data set, others may be addressed only by integrating knowledge across data repositories developed for diverse uses. Such data repositories often do not adhere to a unified schema or standard and semantic inconsistencies make it difficult at present to carry out the necessary linkage analysis. "Patterns" can only be accurately detected if the form and consistency of data are assured.

Ontologies, which formalise the meaning of the terms used, are expected to play a major role in the automated integration of patient data with information relevant to personalised medicine. Ontologies have already been developed to support drug, pharmacogenomics and clinical trials and provide a mechanism for integrating and exchanging biological pathways. They are increasingly used in health care and life sciences applications (Shah et al., 2009).

In addition, privacy issues arise in linkage analysis involving genotype-phenotype information. Some experts have suggested that certain molecular genotypes are rare enough to make it possible to identify a specific individual (Gymrek et al., 2013). Successful exploitation of personalised medicine will require a comprehensive system that maintains individual privacy but provides a platform for the analysis of the full extent of patient data.

Security issues are also of critical importance. The sheer volume of data and the potentially broad number of end users in a clinical setting call for highly secure systems that incorporate sophisticated tools to authenticate authorised users and effective measures to monitor access to patient data. The challenge is to build systems that have the flexibility to accommodate many new data inputs and are capable of providing output to specialised tools to support clinical decisions.

While these efforts are difficult, disruptive and time-consuming, they are necessary to catalyse the adoption and widespread implementation of personalised medicine.

Ubiquitous and pervasive patient care

The ubiquitous care model is based on the utilisation of smart sensing and biometric devices for real-time monitoring, analysis and transmission of health data. The information can then be accessed by health-care providers for informed diagnosis, clinical decisions on treatments, and evaluation of outcomes. It can also be viewed and acted upon by patients for education and prevention.

The technology to support ubiquitous sensing already exists and an increasing amount of physiological monitoring data streams are now displayed on medical devices around the world every day. The challenge is to combine these technologies with network infrastructure to create an integrated architecture and extend care beyond the hospital to the home and mobile patients.

For example, to manage patients with acute diabetes, the blood glucose level can be monitored continuously in vivo and control insulin delivery from an implanted reservoir. In cardiology, the value of implantable sensors for continuous monitoring of the most important physiological parameters for identifying precursors of major adverse cardiac events, including sudden death, is increasingly recognised. The data streams provide enormous potential for improved diagnostics, prevention, support of evidence-based practices and remote health care. These data can yield answers to clinical questions or raise new questions that can influence care responses.

Body area networks (BAN) are another source of rapid progress. Medical applications of BAN cover continuous waveform sampling of biomedical signals, monitoring of vital signs, and low-rate remote control of medical devices. They can be broadly classified into two categories depending on their operating environments.

One is the so-called wearable BAN, which mainly operates on the surface or in the vicinity of the body, such as medical monitoring. Another is the so-called implantable BAN, which operates inside the human body, e.g. a capsule endoscope or pacemaker. The former systems typically consist of several devices that include tiny sensors; these are wearable and placed on or in close proximity to the body to monitor the patient. They provide long-term health monitoring of patients under natural physiological states without constraining their normal activities. The latter, (in-body sensor networks) allow communication between implanted devices and remote monitoring. One example of these smart applications is the "virtual ward"- where patients are monitored at home and visited by mobile medical teams when the data show the need for it. This is generally better for patients and cheaper for the community that pays for it.

Unobtrusive monitoring based on statistical pattern recognition and machine learning will revolutionise early diagnosis and prevention. For individuals with chronic conditions, this unobtrusive monitoring could result in better patient outcomes by allowing the physician to monitor compliance with pharmaceutical regimens and activity level guidelines. It would also help to better understand the variations in patient outcomes.

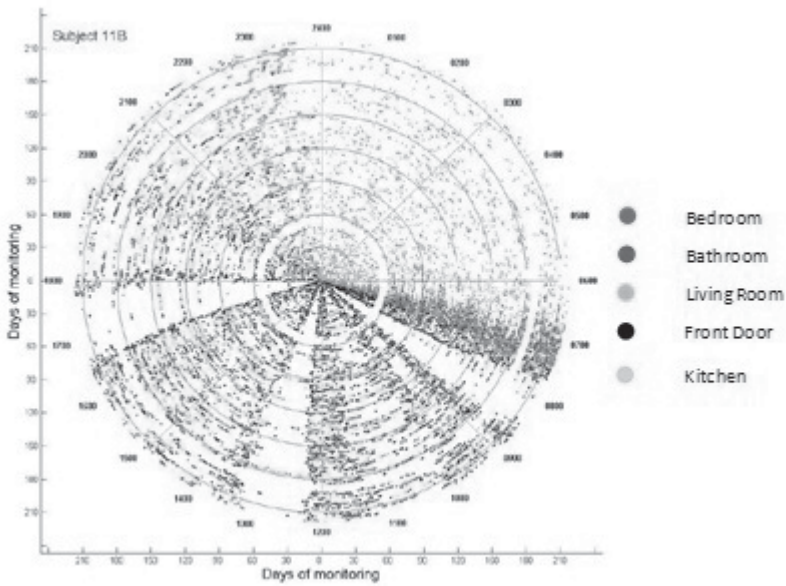
For older patients these devices could be utilised to monitor not only the pharmaceutical regimen and measures similar to those mentioned above, but also falls and near-falls, physical activity, socialisation, or overall mobility. For example, wearable detectors of falls that include accelerometers are a good example of information technology for assisted living at home (Brown, 2005). In most of these systems, a periodic report from the sensors is sent via wireless communication to a local base station. The business potential of applications that target older persons living in their homes is huge.

Ubiquitous computing can also be used to provide context and location-aware cues for health action. The power of such techniques comes from the capacity to cross-link information from multiple sensor systems and other information sources. For example, global positioning system (GPS) data can be cross-linked with accelerometer-based estimates of physical activity and geographic information systems (GIS). Bluetooth can be used to determine individuals' relative proximity to each other or to fixed locations in the study of infectious disease.

Examples of the use of cross-linked sensor-based information include encouraging people to take the stairs instead of the elevator in order to increase physical activity levels, or using text messages on a mobile phone to remind individuals to measure their blood glucose. Specific strategies to deliver cues that persuade individuals to behave in a healthy way are another promising area for ubiquitous computing. Ubiquitous sensors can play a strong role in integrating health care by providing clinicians a novel and less biased window on their patients' habits and behaviours. As this comes at a cost in terms of privacy they must be used on a freely consented basis.

The ever-decreasing cost of sensor-based smart devices, and the medical need for better information regarding a patient's habits outside the clinical environment, make widespread adoption of these systems feasible and plausible. Properly validated, these sensors have the potential to transform both personal and institutional care by providing high-fidelity contextual information to individuals and practitioners (Figure 2.2).

Figure 2.2. Sensor events in a residential facility



Source: M. Pavel (2011), "Predicting future data game changing challenges", presentation at the OECD-NSF Workshop on Building a Smarter Health and Wellness Future, Washington, DC, 15-16 February, www.oecd.org/sti/biotech/oecd-nsfworkshopagendabuildingasmarterhealthandwellnessfuture.htm.

The biggest hurdle is the ability to configure and deploy these systems at point of care and collect and derive insight from data without the need for a deep understanding of the underlying hardware or software. Context awareness imposes significant demands on the knowledge maintained by these systems and the inferencing algorithms that use that knowledge. In order to be context-aware, a system must maintain an internal representation of users, needs, roles and preferences. Although a myriad of signal analysis, pattern recognition, clustering and data-mining algorithms exist to manipulate and draw meaning from sensor-based information, physicians have neither the time nor the expertise to apply them.

Efficient and user-friendly data-flow processing will therefore play a key role in ubiquitous computing. The challenge is to bring human knowledge and expertise together with device-generated data to produce a better health outcome. The inclusion of the human element in developing these new approaches is critical because good patient care cannot be reduced to mere data points.

A second crucial requirement for the implementation of such systems is robust privacy and security. The security and protection of the privacy of data collected from a wearable BAN (WBAN), either while stored in the WBAN or during transmission from the WBAN, is an unresolved concern, with challenges in terms of data confidentiality, data integrity and data authentication.

Conclusion

Discussion at the OECD-NSF workshop indicated that the two major challenges facing progress towards these smart models of care are technical and social barriers. A key technical hurdle, for both personalised and ubiquitous care, is to deal with the exponentially accelerating accumulation of patient data. These are likely to generate, within a decade, a "virtual cloud" of billions of data points that define the health situation of each individual. Information technology systems for health care must reduce this enormous quantity of data to simple actionable hypotheses about wellness and disease for the individual at point of care.

By and large the process of ubiquitous real-time monitoring of patients is information-intensive; the information generated is often fragmented and spans a range of processes, parameters and decision criteria. This can lead to an information overload for health-care professionals and significant network traffic. In addition, the vast majority of data streams are lost once they pass off the monitoring screens. Effective conversion of information into clinically actionable knowledge will depend on the development of robust algorithms and computational models that can fuse and derive meaning from the diverse sets of information. Key factors influencing scalability include: *i)* seamless

integration and interoperability of the technology; *ii)* reliability of message capture, transmission and delivery to health-care professionals and the amount of information transmitted per patient; *iii)* frequency of monitoring and transmission and context awareness.

To exploit fully the new smart approaches to care, acceptance and usability issues will have to be carefully considered. Ubiquity means that the patient enjoys an integrated service and does not have to arbitrate among service components. However, it brings new issues of team working, negotiation and concordance, not least when one agent's action affects the demand upon another's resources.

New privacy and liability issues will arise with both personalised and ubiquitous care. How should patients, physicians and the health-care community be educated about the power and implications of these new approaches? Patients may not perceive personalised medicine or sensor-based care as different from other medicines and techniques used to care for them. However, they accord great importance to privacy and confidentiality. Patient concerns relate to the process of obtaining personal data, to the use of the data extracted, and particularly to the potential release of the data to third parties (e.g. employers, health insurers, etc.).

Some of these concerns can be addressed through legislation and other policy instruments. Others will necessitate new approaches to anonymising data sets and providing secure computational environments. They will also require active engagement of patients and their families.

The lack of recognition of the value of these new models of care by current pricing and reimbursement mechanisms is a disincentive for further development. It will be necessary to show evidence of the cost and benefits of these new models.

As experience with these models is in the early stages, there is value in learning from international initiatives and strategies to support these new developments across OECD countries.

References

Brown, G. (2005), "An Accelerometer-Based Fall Detector: Development, Experimentation, and Analysis", internal report, University of California at Berkeley, July.

Fernald, G.H., E. Capriotti et al. (2011), "Bioinformatics challenges for personalized medicine", *Bioinformatics*, 27(13):1741-1748

Gymrek, M., A.L. McGuire, D. Golan, E. Halperin and Y. Erlich (2013), "Identifying personal genomes by surname inference", *Science*, 339:321-324.

Hood, L. and S.H. Friend (2011), "Predictive, personalized, preventive, participatory (P4) cancer medicine", *Nature Reviews Clinical Oncology* 8:184-187.

Pavel, M. (2011), "Predicting future data game changing challenges", presentation at the OECD-NSF Workshop on Building a Smarter Health and Wellness Future, Washington, DC, 15-16 February, www.oecd.org/sti/biotech/oecd-nsfworkshopagendabuildingasmarterhealthandwellnessfuture.htm

Roederer, M.W. (2009), "Cytochrome P450 enzymes and genotype-guided drug therapy", *Current Opinion in Molecular Therapeutics*, 11(6):632-40.

Shah, N., C. Jonquet, A. Chiang, A. Butte, R. Che and M. Musen (2009), "Ontology-driven indexing of public datasets for translational bioinformatics", *BMC Bioinformatics 2009*, 10(Suppl 2):S1.

Chapter 3

Smart participatory care models

Better health outcomes require greater patient empowerment. Personally controlled health records, participatory mobile health and health apps, and social networks today provide an environment conducive to more "co-ownership and co-production" of health and wellness. They represent a new participatory care paradigm and are transforming the ways in which patients connect and communicate, share personal health information, discover and access new care options. The effectiveness, safety and utility of these innovations for accelerating the diffusion of information on healthy lifestyles, fostering behavioural modification and health innovations, including clinical research, require further exploration.

Achieving smarter health and wellness requires changes not only in health-care delivery but also in how patients are engaged and informed so that they have better health outcomes.

Advocates of patient-centred health have long argued that individuals should take responsibility for their own health. Awareness of the difficulties of self-management - including poor rates of adherence to treatment guidelines, reduced quality of life and poor psychological well-being - point to the need for improved self-management strategies. The argument for self-management clearly applies to chronic diseases such as diabetes and obesity, and health systems increasingly see their roles in terms of support. To the extent that individuals are the best judges of their own welfare, the chances of success of any care or prevention programme will depend on patient engagement and meaningful co-ownership and co-production of healthy behaviours. A growing body of literature shows in fact that when patients assume responsibility for their health care, they may achieve measurable improvements in safety and quality.

By putting the patient at the centre of health-care transactions, health-care providers can also begin to break down the silos of specialty-based medical care and of the various disciplines involved in alternative care. In a patient-centred data system, every patient is a data point from which much can be learned.

At Kaiser Permanente, an integrated managed care consortium, for example, electronic health records (EHRs) incorporate algorithms that analyse patients' data to create individualised support tools. The tools are used by teams of caregivers as they work with and advise individual patients. Personalised information is used to select treatment but may also be used to suggest changes in behaviour, best weight and activity levels, and other health-promotion opportunities. In Colorado, using intensified team care that is guided by patients' data, Kaiser has experienced a 72% reduction in deaths from heart disease (A. Silvestre, 2011).

With the explosion of mobile health and social media, ICTs are uniquely positioned to deliver prevention and wellness messages to help people change their lifestyle and behaviours to prevent disease and maximise well-being.

In particular, personal health records (PHRs), participatory m-health, and social networks represent a new care paradigm and are transforming the ways in which patients connect and communicate, share personal health information, discover and access new care options. This section reviews developments in these areas; Chapter 7 provides a focused perspective on Australia.

Personal health records

A personal health record (PHR) is a web-based medical history in which copies of medical records, reports about diagnosed medical conditions, medications, vital signs, immunisations, laboratory results, and personal characteristics such as age and weight are stored. Implementations to date have ranged from web pages for patients to enter their own data, to physician-hosted patient portals that give patients access to their EHRs, to employer/payer portals that give patients access to claims data.

PHRs have been much discussed over the past few years, and there is much interest in this area in health information technology, policy and market sectors. Personally controlled electronic health records (PCEHRs) are a special class of PHRs, which are distinguished by the extent to which users control access to their records.

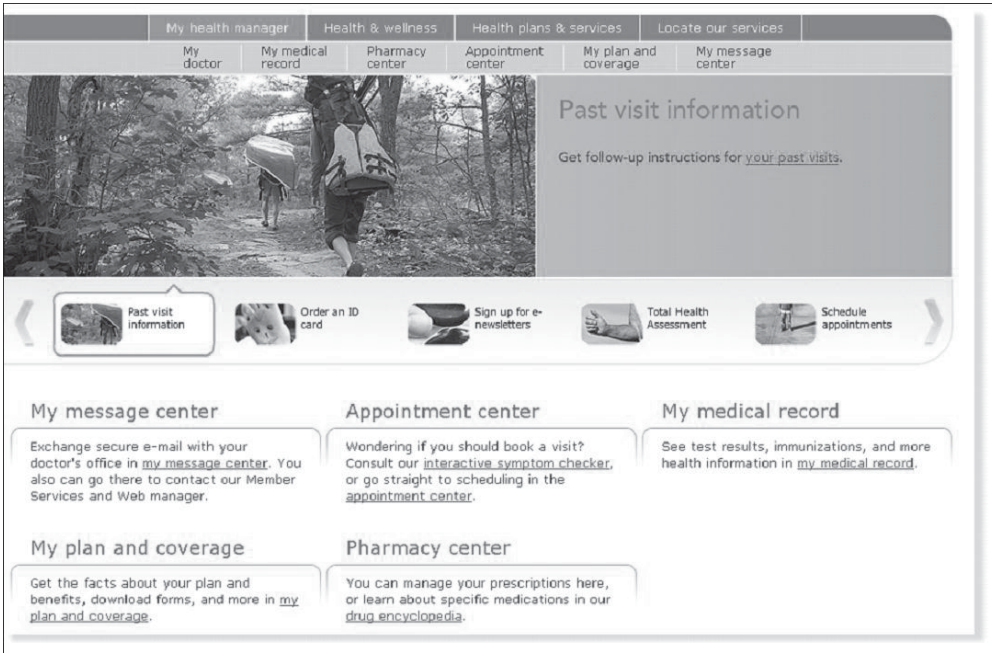
PHRs, as discussed in Chapter 7, offer a major opportunity to improve the quality and safety of health care, reduce waste and inefficiency, and improve continuity and health outcomes for patients.

In the United States, the Palo Alto Medical Foundation (PAMF) and Kaiser Permanente were among the early adopters of PHRs. In 1999, Epic Systems (Madison, WI), an established vendor of ambulatory care EHR systems, decided to develop a patient portal to their EHR product, which they called MyChart. The PAMF worked with Epic to develop the functionality requirements for a PHR that was integrated with their EHR.

PAMF became the first customer of MyChart, which was implemented at the end of 2000. Since then, over 90 000 patients have used PAMFOnline (www.pamfonline.org, the PAMF version of MyChart); they represent approximately 45% of the primary care base of the Palo Alto division of PAMF. Across the United States, 2.4 million patients use MyChart. As of September 2007, 26 000 patients logged in to PAMF's MyChart each month and sent 20 000 secure messages.

Kaiser Permanente introduced its PHR system, My Health Manager, in 2000 to allow patients to view their information on line and to provide them with health management tools (Figure 3.1). My Health Manager gives members access to their clinical records and to time-saving tools which allow them to interact with their providers and health plan. More than 3.3 million Kaiser Permanente members had activated their PHR on kp.org by 2011, making it one of the most actively used PHRs in the world. Over 890 000 secure e-mail messages are sent each month to Kaiser Permanente doctors and clinicians, proof of growing consumer interest in e-visits. More than 25.8 million lab test results have been viewed online by Kaiser Permanente members (A. Silvestre, 2011).

Figure 3.1. Kaiser Permanente's My Health Manager



Source: https://healthy.kaiserpermanente.org/health/care/consumer/my-health-manager.

A number of large consumer-focused technology infrastructure companies, most notably Microsoft and Google, have also launched PHR software platforms. These services, intended as Internet-accessible health-care data repositories for individual patient records, aim to facilitate the importing of a wide variety of personal health data, such as prescription history and treatment records.

Microsoft's HealthVault, launched in 2007, now includes a component called Community Connect, which provides point-of-care access to PHRs for practitioners via an institutional portal. Community Connect was launched in 2010, and has been adopted by several small regional hospitals and health-care networks across the United States (McGee, 2010).

Google Health, released by Google in 2008, was discontinued in 2011. The platform was very similar to HealthVault; it offered a centralised health data repository that gave physician and institutional point of care access to data, subject to patient discretion. The service initially announced partnership plans with several well-known American hospitals, pharmacies and health diagnostics companies. When it closed the service, Google announced that the service had failed to find sufficient interest among its intended audience – patients and health-care providers (Lohr, 2011).

PHRs are developing rapidly and are being introduced as part of national e-health agendas in a number of OECD countries. Early experience in the United Kingdom suggests that patients have, on the whole, responded positively. While some express concerns over security and confidentiality, few problems have been reported and it would appear that potential risks are being traded off against the utility gains afforded by PHRs (Pagliari et al., 2007).

In order for PHRs to be beneficial, as discussed in Chapter 7, they need to be appropriately integrated into the care process. Early online PHRs only included patient data with no integration with health-care providers, but these failed to deliver significant value. PHRs have since become increasingly complex and interactive, by incorporating electronic communications and education and increasing the portability of records.

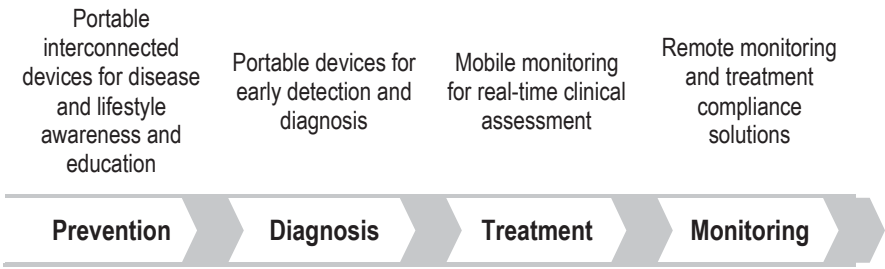
Such an architecture requires agreed standards for transmitting clinical data, terminology and security to ensure interoperability. Changes in patient-clinician relationships must also be anticipated and effectively managed. This is likely to require changes in professional practice and culture.

Over the next several years, a range of products are likely to be introduced that will enable the patient to connect to numerous data sources and consolidate data from pharmacies, clinics and hospitals. Patients will be able to view consolidated data and add entries such as over-the-counter medications, quantitative measurements (e.g. glucometer readings), and qualitative observations (e.g. report of subjective symptoms or notes).

Participatory mobile health and health apps

M-health is by far the fastest growing segment of IT-based health-care delivery systems. It offers a wide range of smart modalities that allow patients to interact with health professionals or with systems that can provide helpful real-time feedback along the care continuum from prevention to diagnosis, treatment and monitoring (Figure 3.2). M-health is of particular value for the management of health conditions for which continuous interaction is important, such as diabetes and cardiac disease. A wide range of devices are utilised for m-health today, including mobile phones tablets, global positioning system (GPS) devices, mobile tele-care devices, mobile patient monitoring devices.

Figure 3.2. Smart m-health applications



Source: OECD adapted from PricewaterhouseCoopers (2012), "Touching Lives through Mobile Health: Assessment of the Global Market Opportunity", GSMA, February, www.gsma.com/connectedliving/wp-content/uploads/2012/03/gsmapwctouchinglivesthroughmobilehealthreport.pdf.

Among these devices, mobile phones in particular offer the potential to diffuse, broadly and cheaply, more intensive self-monitoring, feedback, self-management and clinical support than was previously possible. Smart phones in particular support a diverse set of data streams and monitoring activities: automated traces of actigraphy, location and other data that can infer physical activities, sleep, and environment; automated and manually entered physiological measures (e.g. readings from a glucose meter); and prompted or user-initiated self-reports of the user's symptoms or behaviour. This information, appropriately managed, can be leveraged to trigger highly personalised interventions, and thus significantly improve an individual's ability to understand and manage his or her behaviour.

Four areas are important to successful widespread adoption of participatory m-health: *i)* establishing and sustaining the engagement of participants; *ii)* widely accepted privacy and security standards for personal data collection, analysis and use; *iii)* integration and interoperability (the mobile devices have to function seamlessly and adapt to users' multiple health needs); *iv)* financing and new business models: there is a need to adapt regulatory structures and align incentives at different levels of the health delivery system to encourage investment in, and use of, m-health.

To achieve widespread use, mobile and health-care industries will need to work towards interoperable solutions that enable economies of scale. Without agreed standards and connectivity for information exchange across the ecosystem of personal mobile devices and care services (Table 3.1), there will be wide variation in the granularity and quality of the information that is collected and analysed. This would limit clinical utility and payers would be reluctant to invest.

Table 3.1. A typical personal m-health ecosystem

Sensors		Connectivity	Aggregation and computation	Network (plain old telephone service, cellular, broadband)	Services
Home sensing and control	Weight scale	Zigbee	PC		Health-care provider service
Bed/chair sensors	Blood pressure	Bluetooth	Personal health system		Disease management service
Implant monitors	Glucose meter	Z Wave	Cell phone		Diet or fitness service
Baby monitors	Pulse oximeter	USB	Set-top box		Personal health record service
Personal emergency response system	Spirometer	Medical implant communications service/medical electronic data service	Aggregator		Implant monitoring service
Consumer electronics	Medication tracking	Ethernet			
	Pedometer	Wifi			
	Fitness equipment	Homeplug			

Source: Carroll et al. (2007), "Continua: an interoperable personal health ecosystem", *IEEE*.

The current mobile technology ecosystem is overly reliant on siloed proprietary systems. Tools and technologies that catalyse open innovation are needed to enable a health-care system that is responsive to continuing discovery, invention, evolution and use. Many of the barriers to deploying open systems are non-technical, but they can only be broken down if the technological foundations of open systems are in place (Estrin, D. OECD-NSF Workshop, 2011). Open platforms encourage sharing and standardisation of software, methodologies, data and analytics. They can create infrastructure that can be tested in a specific context and adapted to others. They can also include reference implementations of modular system components and can be used to support novel workflow elements, explore alternate cost models, evaluate new techniques and tools, and compare approaches to the same problem.

The business potential of participatory m-health solutions is tremendous. Mobile monitoring services and applications are expected to drive the m-health market and are expected to account for about 65% of the market, corresponding to USD 15 billion, in 2017. Chronic disease management and post-acute-care monitoring services will be a large share, with a projected USD10.7 billion in revenue in 2017, with a majority of revenues contributed by the former.

Independent ageing solutions also offer significant opportunities with potential revenue of USD 4.3 billion in 2017 (PwC, 2012).

Health system reimbursement regimes do not currently cover this type of product. Very few mobile solutions are reimbursed by payers today, and most are still in the pilot stage. In addition, to be reimbursed, mobile health solutions need to prove value for money or evidence that their use can generate greater efficiencies and quality of care.

Mobile health apps

As mobile platforms become more user friendly, computationally powerful, and readily available, innovators have begun to develop increasingly complex mobile apps to leverage the portability mobile platforms offer. Some of these apps aim specifically to help individuals manage their own health and wellness. Other mobile apps target health-care providers as tools to improve and facilitate the delivery of patient care, e.g. for wound measurement or ultrasound imaging (Franko, 2011; Freshwater, 2011). This section focuses on apps marketed to consumers.

The variety and availability of consumer health apps has exploded in recent years (Table 3.2). According to Research2Guidance and MobiHealthNews, in 2012 there were between 10 000 and 13 600 health apps in the Apple iTunes store, making them one of the fastest-growing categories. Research2Guidance estimates that the world market for m-health apps will reach over USD 1.2 billion in 2012.

Health apps range from exercise and fitness apps, dieting, heart rate monitors, sleep trackers and mood trackers to a host of peripherals that attach to a smartphone to provide everything from aid to monitoring diseases to EKGs and eye exams (Handel, 2011). Some m-health apps use game dynamics to motivate collective action. Others combine patient data with passive data to provide insights on how individuals are using the device and better understand social and psychological factors that can determine outcomes.

Table 3.2. Apps for health and wellness

Cardio	16.2%	Mental health	5.4%	Smoking cessation	2.0%
Diet	14.1%	Chronic conditions	5.3%	Medication adherence	1.7%
Stress and relaxation	10.4%	Calculator	4.9%	PHR	0.9%
Strength training	8.1%	Sleep	3.6%		
Women's health	7.1%	Emergency	2.5%	Other	17.9%

Source: MobilHealthNews (2012), "An analysis of consumer health apps for Apple iPhone 2012".

PatientView's European Directory of Health Apps 2012 reports mobile apps for 62 health specialties and features apps in 32 European languages. The most commonly featured health apps are for dietary control, diabetes management and medication reminders.

This ranking reflects market priorities and possible medical utility. People with diabetes have a heavy data tracking burden. The regular use of a dedicated app and "automatic journaling" can provide critical insights on disease management. Glucose-level data coupled with information on insulin administration, dietary intake and physical activity can give a personalised view of overall blood glucose management that allows for a degree of troubleshooting and prevention. Estimating the carbohydrate content of meals is another challenge for those with insulin-dependent diabetes. For these individuals, miscalculating the carbohydrate content can lead to dangerously low or high blood glucose values. Mobile apps can be used to consult the carbohydrate content of many foods to improve estimates of carbohydrate or calorie content.

Governments are also gradually using mobile health apps to deliver medical information to consumers, promote healthy life styles and behavioural changes to manage specific health conditions in vulnerable populations. The US National Institutes of Health's LactMed app, for example, gives nursing mothers information about the effects of medicines on breast milk and nursing infants.

In the United Kingdom, the National Health Services launched in 2011 a mobile app that provides health-care advice. It gives access to information on health and symptoms for problems including dental pain, diarrhoea and vomiting, abdominal pain, rashes, back pain and burns. The apps are linked to NHS Direct's telephone service. If further assessment is recommended, patients can submit their contact details and request advice from the NHS Direct nurse.

Supply chain and business models

The supply chain for health apps is very complex. Four types of companies are mainly responsible for smartphone-based app products and services: mobile carriers (which provide smartphone users with access to wireless networks for voice and data uses); operating systems (the main operating systems are Apple's iPhone iOS, Google's Android, and Research in Motion's BlackBerry); manufacturers (smartphones are made by a variety of electronics companies); and application developers.

The products and services developed by these companies allow users to take advantage of the various functions smartphones provide. Big pharmaceutical companies are also entering this market and generally sponsor m-health apps that go far beyond a simple allergy tracker or pill reminder (e.g. Sanofi Aventis' sensor-based iBGStar Diabetes monitoring app) and sensors are a growing part of this landscape.

From a business perspective, the use and sharing of behavioural, health, wellness and mobile location data offer potentially significant returns to the mobile industry and pharmaceutical companies, by providing and improving goods and services and increasing advertising revenue.

Pharmaceutical companies are very interested in solutions that increase the value of their medicines and diagnostics. Solutions may be provided free of charge or may be added to "service packages" with the medicine.

A scan of iPhone apps of a few of the largest pharmaceutical companies (GSK, Novartis, Sanofi-Aventis, Roche, Johnson&Johnson), illustrates the interest in this space (Table 3.3). The 2011 pharmaceutical industry report by Ernst & Young reveals that in 2010, new initiatives in health technology by pharmaceutical companies increased by 78%. A staggering 41% of these were smartphone apps.

The benefits for the consumer and health systems are potentially very significant as well. One of the challenges for promoting healthier behaviours is to raise awareness of how small changes build over time to achieve a specific health outcome. For example, relatively small changes in activity level or dietary intake can create a 500 calorie deficit each day and produce a modest one pound a week weight loss. The impact of such small changes often requires extensive tracking of a particular behaviour. Mobile apps can facilitate this process.

The learning that occurs may also correct commonly held misconceptions. Apps that offer personalised online services, with information for a particular individual, can also help to cope emotionally by providing strategies and tactics for disease management and stressful or emotionally charged life events. Social network features of many apps can also help to cope, for example through possibilities of both online and live exchange with a health care provider. Tracking data electronically also allows for automatic virtual rewards or reinforcement when individuals reach particular goals. A common example is devices that track physical activity such as walking and running. Data are uploaded from the device to an interactive website that gives virtual or actual rewards on the basis of the level of activity.

Table 3.3. Functionalities of iPhone apps offered by large pharmaceutical companies

Target customer	Disease-specific	Product-specific
Health care professional	Prognosis calculator Risk calculator Information Education EKG readings Decision-making tools	Product-dosage calculator Prescribing information Risk calculator Disease progression calculator
Patients	Disease awareness Education Patient diary Treatment tracking Symptom tracker Clinical trial locators Specialist search engines Reminder	Medication tracker, reminders
General public	Educational games Specialist locator Disease awareness News and information Message boards Vaccination tracker Pharmacy locator	

Source: Adapted from A.T. Kearney (2010), "Mobile health, who pays?", www.atkearney.com/documents/10192/178350/mobile_health.pdf.

Although health and wellness apps are evolving rapidly, various regulatory and economic challenges need to be addressed if they are to be taken up more widely by health-care systems.

First, while these apps appear to offer many potential benefits, they can also present risks. Major concerns relate to the quality of the information and services provided, to privacy (e.g. the risk of disclosure of data to unauthorised third parties for unspecified uses), to consumer tracking, to identity theft, threats to personal safety, and to surveillance. Mobile industry associations and privacy advocacy organisations have recommended practices to better protect consumers'

privacy when use is made of customers' personal information. These practices, however, are often not mandatory (GAO, 2012). In the absence of clear disclosure to consumers about how their data are used and shared, consumers lack the information they need to give informed consent about the use of these data.

Second, a range of new partnerships are emerging around the health apps sector. There is a need to better understand this rapidly evolving ecosystem, the business models, the market potential and the related governance frameworks.

Finally, more robust evidence is needed on the efficacy of these apps as a way to condition individuals' health attitudes and practices and as tools to foster their adherence to medication or therapy routines.

Social networks and virtual communities

Social networks provide patients with life-changing illnesses a platform to find other patients with similar demographic and clinical characteristics and to learn from their experience. They also provide patients with unparalleled access to information and to choices in terms of prevention, treatment and providers. In the past few years, in countries across the globe, the power of social networks has shown that health providers and regulators need to respect and work in tandem with these expressions of unconstrained citizen communication.

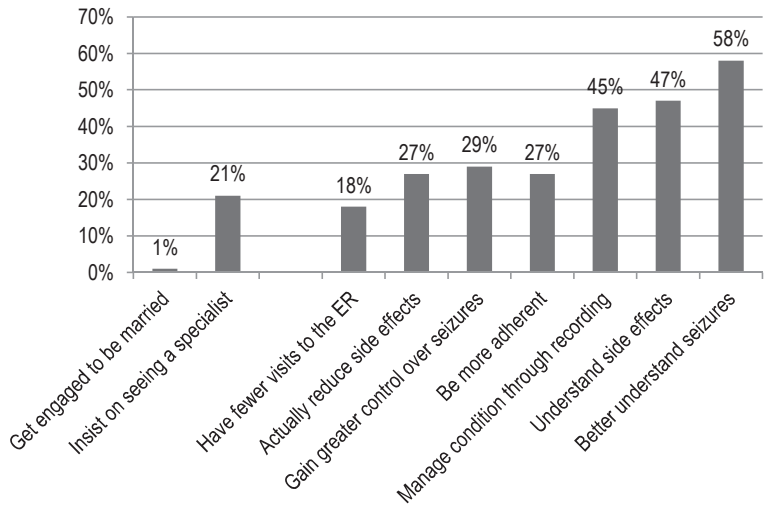
These networks seem particularly well suited to empower patients through coaching and to support changes of behaviour. Social interactions can have a high "persuasive potential" and can intervene at the right time, in the right context and in a convenient way. This is important because one of the prerequisites for a patient to become an active participant in his or her care is self-confidence and motivation.

Online social communities provide a vehicle for individuals with chronic diseases such as diabetes to share information. Participants contribute personal stories and experiences that provide learning opportunities for other participants with similar problems (Figure 3.3). Observing other patients' disease management techniques gives individuals a means of evaluating their own behaviour. Some online communities are moderated by health-care professionals who can offer expert advice via message board posts or synchronous chat sessions.

As these online communities grow in numbers and in scope, there is a need for studies on their quality, safety and effectiveness. Users' behaviour in health networks suggests, for example, different attitudes regarding privacy from what might be expected in face-to-face interactions. In a social network, members may share personal information that could be used to identify them,

such as their name, a photograph or an email address. Sensitive information that members provide about themselves and that is widely shared with the social network community may include prescriptions, genetic disease, sexual dysfunctions, and surgical or other treatment complications that would be considered imprudent to share in public and would certainly violate most privacy legislation if released by health-care providers. It is possible that many users do not grasp the longer-term privacy implications of their actions.

Figure 3.3. User-reported benefits (PatientsLikeMe, 2011)



Source: PatientsLikeMe, www.patientslikeme.com.

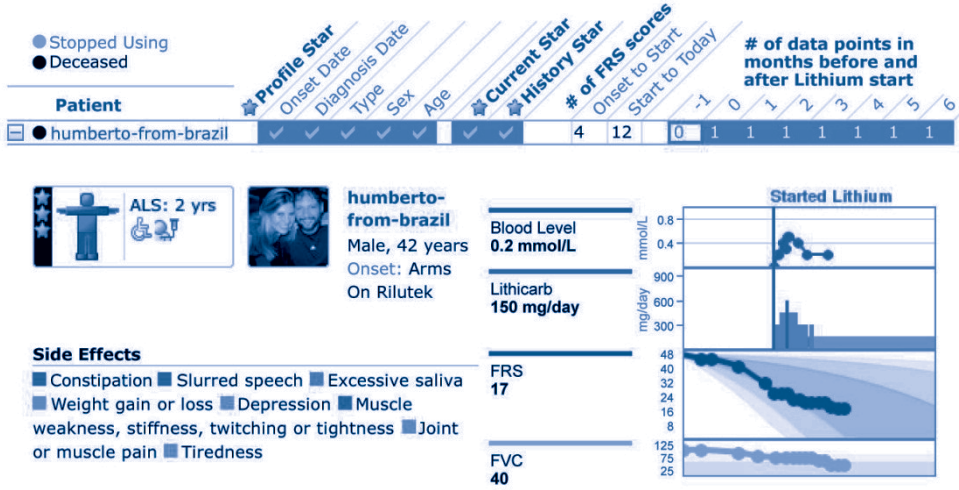
The broader social returns

There is growing recognition that online communities not only provide a place for members to support each other but also generate information that can be mined for public health research, monitoring, and other health-related activities.

Hospitals increasingly use social networks for promotional purposes and to gauge consumer experiences with their organisations. More than 700 of the United States' 5 000 hospitals have a social media and social networking presence to enhance their ability to market services and communicate with stakeholders (Bennett, 2010). Medical centres are also developing communities to understand how their patients view their care experiences. For their part, government agencies are using social networks to engage the public (for example, during product recalls and in preparations for the H1N1 flu pandemic) (CDC, 2009).

Although such studies cannot meet the standards of randomised clinical trials, social networks are increasingly viewed as an opportunity to collect possibly useful early-phase data by capturing patients' self-experimentation. For example, the social network PatientsLikeMe recently developed a lithium-specific data collection process to capture information about 348 individuals suffering from amyotrophic lateral sclerosis (ALS) who were registered with the network and who began taking the drug off-label via their physician (Wicks, 2010) (Figure 3.4). Neither randomised trials nor non-randomised clinical studies have yet to provide an effective therapy for ALS. It is a neurodegenerative disease that causes progressive weakness and muscle atrophy and is rapidly fatal; median survival from symptom onset is 2–5 years.

Figure 3.4. Lithium tracking tool, individual patient view



Source: PatientsLikeMe, www.patientslikeme.com.

Increased sharing of health information creates a useful resource on disease treatments and patient self-reported outcomes, an advantage that PatientsLikeMe explicitly embraces in its "openness philosophy". The observation that patients are "ready and willing to share with each other so that other people can benefit from their experiences suggests the need to look beyond a purely information-seeking behaviour. Patients may surrender privacy not simply to obtain information or to gain emotional support for themselves but to provide such support to other members of their online community. Indeed, some users of health social networks report finding information that they otherwise may not find among their regular health providers.

Conclusions

The most significant health and wellness challenges in most OECD countries involve chronic illnesses from diabetes, hypertension and asthma to depression and poor lifestyle behaviours (poor diet, lack of exercise and smoking). Giving people access to their own health information is essential to promote healthier lifestyles, support self-management and make informed decisions.

The increasing 3G and 4G rollouts and fibre have opened up a whole new world of possibilities for using mobile devices and the Internet to address health-care challenges. The potential of mobile devices, services and applications to support self-management, behavioural modification and participatory health care is greater than ever before.

The platforms reviewed in this section have the potential to increase patients' access to health services and information and their empowerment and self-care. They can influence a person's subjective assessment of the effectiveness and feasibility of specific behaviours and health actions.

PHRs, participatory m-health and mobile apps use the power of ICTs to assist individuals and their doctors to monitor and manage symptoms, side effects and treatment of chronic illnesses outside the clinical setting, and to address the lifestyle factors that can bring on or exacerbate these conditions. By empowering individuals to track and manage their health-related behaviours and outcomes, these approaches, particularly if combined in an integrated ecosystem, have the potential to greatly improve people's health and quality of life, while reducing societies' overall health-care costs. They hold the promise to become an integral part of the health-care landscape.

Through social networks patients increasingly have the ability to evaluate what works and what does not work, seek support and feedback in closely matched cohorts and bring that information back to their care providers. In addition, through rich, longitudinal observation of patient outcomes, public health actors can begin to make decisions based on higher-value samples of patient populations that provide feedback in close to real time. Adverse events due to pharmaceuticals can more easily be monitored and modelled.

The implementation of these platforms and the new participatory health models nonetheless raises a number of research and policy questions.

First, establishing and maintaining participants' engagement is essential to the success of any participatory health initiative. It will be important to examine carefully how the introduction of these various platforms and technologies affect the lives of those they are intended to help and to ensure that their use improves individual care experiences directly.

Second, it is important to balance benefits, sharing, collaboration and ease of use against the potential risks of these technologies. Social networks and mobile platforms may accelerate the exchange of health-care information, but careful attention must be given to policy related to privacy, security, data stewardship and personal control.

The rapid advances in technology in this area have outpaced regulatory frameworks. This raises concerns that range from the potentially modest risks to the privacy of data on activity (e.g. data collected by a pedometer) to safety-critical risks and quality assurance (e.g. the integrity of the software in a sensor used in combination with a health app to manage diabetes). These technological advances have also blurred the distinction between areas such as medical devices and medical apps and raise concerns for government regulatory agencies.

Research is needed to determine threats and requirements and "safe rules of the road" such as proper procedures for securing device software and for the handling of data by intermediaries that stand between these platforms and users. For example, it will be important for participants to be able to specify what information is shared, with whom and for how long. It is also necessary to protect consumers from misinformation that might lead to potentially harmful consequences.

Third, a range of new partnerships are emerging around these applications. There is a need to better understand this rapidly evolving ecosystem, the business models, the market potential and the related governance frameworks. This should be combined with the development of robust metrics for measurement and evaluation.

References

A.T. Kearney (2010), "Mobile Health, Who Pays?", www.atkearney.com/documents/10192/178350/mobile_health.pdf

Bennet, E. (2010), Hospital social network data and charts, http://ebennett.org/hsnl/data, 22 May, in Deloitte (2010) Issue Brief: "Social Networks in Health Care: Communication ,Collaboration and Insights", http://www.ucsf.edu/sites/default/files/legacy_files/US_CHS_2010SocialNetworks_070710.pdf

Carroll, R. et al. (2007) "Continua: an interoperable personal health ecosystem", *IEEE*.

Centers for Disease Control and Prevention (CDC) (2009), "H1N1 Web and Social Media Metrics Cumulative Data Report April 22, 2009 – December 31, 2009", Division of eHealth Marketing (DeHM), National Center for Health Marketing (NCHM).

GAO (2012) Mobile device location data, United States Government Accountablity Office.

Handel, M.J., "mHealth (mobile health): Using apps for health and wellness", *Explore (NY) 2011*, 7:256-261.

Lohr, S. (2011), "Google to end health records service after it fails to attract users", *The New York Times*, 24 June.

McGee, M. (2010), "Microsoft HealthVault extends access to hospital data", *InformationWeek Healthcare*, 3 March.

MobilHealthNews (2012), "An analysis of consumer health apps for Apple iPhone 2012", http://mobihealthnews.com/research/an-analysis-of-consumer-health-apps-for-apples-iphone-2012/

Pagliari, C., D. Detmer and P. Singleton (2007), "Electronic Personal Health Records, Emergence and Implications for the UK", The Nuffield Trust, http://nuffield.dh.bytemark.co.uk/sites/files/nuffield/publication/elec-personal-health-records-web-final-mar07.pdf.

PriceWaterCoopers (2012), "Touching Lives through Mobile Health: Assessment of the Global Market Opportunity", GSMA, February, www.gsma.com/connectedliving/wp-

content/uploads/2012/03/gsmapwctouchinglivesthroughmobilehealthreport.pdf

Silvestre, A. (2011) "Incentives, business models, and the economics of the new models of care: Shaping the innovation ecosystem", presentation at the OECD-NSF Workshop on Building a Smarter Health and Wellness Future, Washington, DC, 15-16 February, www.oecd.org/sti/biotech/oecd-nsfworkshopagendabuildingasmarterhealthandwellnessfuture.htm.

Wicks, P., T.E. Vaughan, M.P. Massagli and J. Heywood (2011), "Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm", *Nature Biotechnolgy,* 29(5), 411-414

Wicks, P., M. Massagli, J. Frost, C. Brownstein, S. Okun, T. Vaughan, R. Bradley and J. Heywood (2010), "Sharing health data for better outcomes on PatientsLikeMe", *Journal of Medical Internet Research,* 12(2): e19

Chapter 4

Actions to build a smarter health and wellness future

The OECD-NSF workshop offered an opportunity to discuss and determine areas in which the OECD can provide further policy insight and expertise. Participants focused their discussion on four important cross-cutting dimensions for building a smarter health and wellness future: big data challenges, knowledge generation and use; meaningful innovation; the potential new risks; organisational and social innovation for an integrated care future. This chapter and Chapters 8, 9 and 10 map the current situation in these areas and the ways in which the new smart models of care present challenges and opportunities in each.

Address the big data challenges, knowledge generation and use

Advances in cyber-infrastructure have created a virtual deluge of new types of data, from new data on human interactions through digital imaging, sensors, and analytical instrumentation to new ways of collecting biological and geospatial information, to combining data from different sources, such as clinical and administrative records.

It is predicted that more medical information and health data will be generated in the next few years than ever before. All of it will have to be mined, stored securely and accurately, and converted to meaningful information at the point of care. Sequencing one human sample can result in 4 million gene variations or tens of megabytes of processed data. There are significant technical problems for mining, comparing and analysing data sets of this magnitude.

Additional data challenges are arising with the growth of a ubiquitous, sensor-based health data environment that will allow real time monitoring of vital signs and other clinical events, for instance of complications in pregnancy or of specific clinical conditions of a chronic illness, or of daily living to identify quickly when a frail person has an adverse incident and needs help. Ubiquitous computing is a compelling vision for the smart and wellness future that is rapidly approaching realisation. But these applications require real-time continuous archiving of multi-modal datasets and multi-domain collaborative annotations and post-therapeutic visualisation of the archived data. Organisations will need to manage and retain large volumes of data over the long term. Achieving this in a cost-efficient, scalable manner to meet future growth represents what some call "the big-data retention challenge."

Getting data out of the different clinical information systems and monitoring devices and extracting knowledge from them is also a challenging task. Today, where electronic data does exist, it is tied to specific applications or databases. These are often not interoperable and it may be hard, if not impossible, to link, merge and process these data meaningfully. In addition, incentives to share data are limited. Privacy regulations often restrict access to health-care data for purposes of aggregation and analysis outside of the providing agency. Further complicating the process of data aggregation across sources, most data repositories have evolved as silos of information in the laboratories or institutions that created them.

Drawing value from unstructured data

As EHRs and other health informatics devices become increasingly widespread, harnessing unstructured/fuzzy data may also yield valuable information. Unstructured information includes handwritten physicians' case notes, discharge summaries, surveillance reports or health records as well as audio recordings, and text records from electronic mediums such as email messages. More than 80% of a health institution's data today is unstructured. This content contains valuable information, but there's historically been no easy way to analyse it.

Analysis of unstructured data is inherently more complex than analysis of structured data, owing to the former's lack of empirical markers in reports, observations or written records. However, specific technical solutions can be used to analyse unstructured data. The development of automated approaches, such as natural language processing (NLP), that extract specific medical concepts from textual medical documents that do not rely on discharge codes, offers a powerful alternative to either unreliable administrative data or labor-intensive, expensive manual chart reviews.

Using NLP with an electronic medical record can, for example, greatly improve postoperative complication identification compared with the traditional patient safety indicators, or an administrative-code based algorithm. In addition, a NLP–based search strategy is far more scalable than manual abstraction, potentially allowing surveillance on an entire health care system population rather than a subsample (Nadkarni et al., 2011). The application of NLP in health care remains, however, extremely challenging, based on the sheer volume of specialised medical terminology and clinical care procedures.

Towards a learning health system

A significant knowledge gap affects today's health-care systems: the gap in knowledge about what approaches work best, the quality of the care delivered, under what circumstances, and for whom.

Deep mining of data from electronic health records (EHRs) and other distributed ICT systems creates an enormous potential for filling this gap and better understanding of the performance of health systems, the determinants of health and outcomes, and for conducting clinical and translational research at speeds approaching real time. What is now regarded as clinical data could be transformed into statistical data at both individual and population levels. Data derived from distributed ICT systems could, for example, be processed against societal and other data to uncover patterns of behaviour and causality as well as trends in the incidence and prevalence of health problems, thereby radically changing the nature of public health, health promotion and clinical research.

When this process can happen routinely, with mechanisms in place to establish and maintain public trust that the process is secure and private, a country will have substantially progressed towards establishing a so-called "rapid learning health system".

It has been stressed that there is great potential for shared EHRs to lead to real-time decision support systems and feedback loop systems for clinicians, public health practitioners and policy makers. Examples of what can be achieved at relatively small scale include Kaiser Permanente and academic medical centres such as the Mayo Clinic or that of Duke University.

In many countries, population health monitoring and health statistics are, however, still explicitly secondary to the primary uses of EHRs. Consequently, the conceptualisation and implementation of EHR systems do not typically include their use in population health and health statistics or clinical research. The degree to which EHR systems can facilitate collection of health data is constrained by limitations such as the prevalence of data recorded as unstructured narrative or text, lack of standardisation of data content, and data privacy and access issues due to silos created by legacy systems and organisational boundaries.

Taking the learning system from an idea to a working reality will require mutually reinforcing and interoperable technologies, standards and policies created specifically in view of the secondary use of data stored in EHRs and other devices.

Key issues for further policy action and research are:

- The benefits and risks of "big data" collection, including in relation to privacy, need to be carefully considered prior to collection as it is important to ensure that data can become useful and actionable health information.
- Interoperability of devices, applications and services is important and requires the use of common standards.
- Need for better linkages of health and wellness data with social, and environmental data
- More effective approaches for extracting knowledge and meaning from large, heterogeneous and "fuzzy" data sources to inform health and care systems.
- Research on integrated sensing, clinical and service design to find ways to turn sensor data into actionable data, e.g. how to combine multiple signals to identify key events, minimise false alarms, and ensure appropriate response.

- Development of efficient databases, analysis and visualisation tools and user-friendly interfaces to allow access to appropriate data at the point of care.

Understand and address the potential new risks

Fundamental to achieving widespread adoption of the new smarter health and wellness is addressing security and privacy. How ICT systems will deal with privacy and security must be very visible to users and must be first on the list of items to communicate to patients.

The collection and use of personal health data presents a number of important risks to the privacy of individuals. Some types of health data are especially sensitive. Examples include records related to mental health, drug abuse, genetics, sexually transmitted diseases, and more. Significant harm can result to individuals from the misuse of their personal health information. Losses to individuals can be severe and can include financial and psychosocial harms. Financial harms can result from discrimination in health insurance or employment. Psychosocial harms could include embarrassment, stigma and loss of reputation, resulting in isolation and stress. Disclosures of personal data can also increase individual's risk of experiencing identity theft. Less discussed, but of social relevance, is also the risk of loss of public confidence in government and its institutions that could result from misuses of individuals' personal health records, including a loss of confidence in the health care system.

On the other hand, there are significant risks to individuals and to societies when health information assets are not developed, or are unused or are very difficult to use. Societies lose the opportunity to monitor and report on their population's health and the quality and safety of health care services. This elevates the risk of individuals experiencing inefficient, ineffective and even harmful health care. Societies also lose the opportunity for research and innovation to improve health and health care outcomes, which can improve well-being, productivity and the efficient use of public resources.

Public and private health care organisations are, however, struggling with the rapid changes in the systems they need to secure. In particular, mobile devices, including intelligent medical implants, cell phones that sense and process health data, medical apps and a variety of new types of sensors and actuators that can be worn on the body, are creating a changing landscape for managing health information. Data are collected everywhere, not just in a medical facility, and can be collected by just about everyone. While there is tremendous public good in driving adoption of these new smart models of care, the emerging digital platforms will be so personally and intimately placed that it just is not an option to leave privacy and security issues addressed at a later date.

There is urgent need for coherent and consistent policies around the storage, exchange, and access to patient health data, and on patient consent. Interpretation of privacy and security requirements are still often determined locally within countries and vary significantly between countries. If privacy policies are not consistent, sharing data becomes more difficult because stakeholders may have differing views of what can be shared and with whom. In addition, while considerable progress can be made by applying current best practices to the management of data, a number of areas require more research in order to support better practices. These include: access controls and audit; encryption and trusted base; automated policy; mobile health (m-health); identification and authentication; and data segmentation and de-identification. These areas are discussed in Chapter 9.

Key issues for further policy action and research are:

- As teamwork and integrated care develop, data are shared more widely. This will require new paradigms and regulations on access to data, how much data should/can be collected and shared, and with whom. Widely accepted privacy and security standards are needed for health data collection, analysis and use.
- Identify critical lessons and guiding principles to ensure that privacy and data protection are embedded throughout the entire life cycle of the new smart technologies, from the early design stage (privacy by design) , including in remote and mobile systems.
- Explore broader policy implications of mining, storage and use of information collected by social networks about individual health profiles, including the benefits and risks of open sharing of personal details on social sites (including health-based ones).
- Support further research on the impacts of "disintermediation" ("taking the doctor out of the picture") and behavioural modification platforms (e.g. to increase patients' adherence to prescribed drug therapy and wellness initiatives), including the new and evolving balance between personal and social responsibility.
- Explore the risks and opportunities of "fuzzy" and semi-structured data. Better inferential tools and automation are needed so that large volumes of records can be examined and results validated.
- Identify the risks to quality (and to sound ethical practice) of remote monitoring, distributed care delivery, virtual teams, and informal care provider co-production. Create and validate in practice new paradigms of quality assurance and quality control, including dimensions of a

"learning service". Such paradigms must be able both to cross traditional organisational and professional boundaries and work within them, and citizen viewpoint and choice must be appropriately accommodated.

- Undertake sociological and behavioural research with citizens and practitioners to ensure that the increasing use of technology and standard responses does not take the "caring" out of health and social care, while ensuring that support is efficient, effective and accessible.

Foster meaningful innovation

While health care organisations have access to an ever-increasing number of information technology products, many of these systems cannot talk to each other, and health information exchange remains a serious problem. "Stovepipe" or "siloed" approaches to innovation, which replicate the current, fragmented health care ecosystem, limit the potential to develop new, smarter models of care. Progress will require an open, shared architecture that moves from silos of technology toward an integrated ecosystem of interoperable smart solutions.

M-health apps, for example, can contribute to a rapid learning health system, but this will be difficult if each app is built as a closed application with a proprietary data format, management and analysis. Estrin and Sim (2010) note that an open architecture built around shared data standards and the global communication network can promote the scaling, coherence and power of M-health. Just as the decision to build the Internet on a common IP protocol with open interfaces was critical to its success, and just as more recently the Android market and Firefox browser have made it easy for third-party developers to innovate and proliferate, an open architecture can pave the way for rapid exploration and innovation in the health sector, as well as iterative improvement.

Such an architecture can encourage innovation in health practices by easing the development of applications. Shared standards and reusable components can enable rapid authoring, integration and evaluation of personal data for clinical care and research. Hospitals, accountable care organisations and public-health practitioners could mix and match from a rich, flexible body of data acquisition and analytical components to configure custom apps to complement ongoing developments in scalable and sustainable health information systems.

As discussed in Chapter 10, similar issues arise with developments in converging technologies such as bio-informatics, genomics, nanotechnology and synthetic biology.

The question is the paradigm that will allow the field and industry to grow: patents, copyright or open source; a combination of these; or an entirely new strategy that enables the free flow of information but also protects ownership and encourages innovation in the field?

Key issues for further policy action and research are:

- Exploration and exploitation of the potential of open platforms, open innovation, products and processes to help foster and accelerate innovation.
- Development of frameworks and incentives to support the move from silos of technology to an integrated ecosystem of smart solutions – including multidisciplinary approaches (integrating a range of technologies, health and care systems, and societal systems). In particular, research funding systems need to be able to support cross-disciplinary research, including scaled evaluation, while professional, legal and other constraints need to be adjusted to enable this work.
- Identification of means to support iterative research and effective international co-ordination and collaboration; use of existing and new techniques to lay the groundwork for more fundamental research.
- Examination of the range of incentives or mechanisms used to influence adoption of innovation –implementation of applications, and use by practitioners and citizens – by identifying drivers of innovation but also barriers (many of which may be based on sound but potentially outmoded principles and concerns).
- Develop and share understanding of the roles of social and community contextualised innovation.

Promote organisational and social innovation for an integrated care future

Smart innovation is far more than technological innovation. Health-care responses, and means of delivering smart services, call for radical organisational and social innovation given the multiplicity of actors with different cultures and roles and both public- and private-sector points of view.

Efforts must be integrated and co-ordinated and avoid overlap or duplication. However, breaking down professional or sector-specific silos and moving from fixed and institution-based provision of care towards ubiquitous care based on remote monitoring raises challenges and requires disruptive innovation that will affect many existing processes. This radical change is vital, but must be managed sensitively and constructively. Establishing and sustaining the engagement of participants is critical to the success of these initiatives.

Existing processes have developed for good reasons. They ensure comfort and stability, certainty and accountability, development and satisfaction. The new order will require processes that fulfil the same important needs but also support the new integrated way of working and do not constrain innovation.

Involving users

Communities are not homogenous and citizens are not all the same. Individuals and families vary in many ways. Of particular relevance for the health and wellness agenda are education, income and financial resources, lifestyle, and family size and structure. Influential for many are belief systems, cultural and ethnic backgrounds, and employment or vocational history. The structure and modalities of future smart care must ensure that it is equally available and accessible to all, within the context of national patterns of care provision.

Innovation must also address health and wellness support focused on the patient/citizen, with co-ownership and co-production by the individual and his/her trusted carers. Account must be taken of the fact that each individual will have vastly different informal support in terms both of quantity and competence. Such innovation will require changes to concepts, professional roles, inter-professional collaboration, funding, legislation and regulation, and quality monitoring.

Firms need to open up their innovation process and include users in order to ensure that their product is acceptable and is adopted. By tapping users' tacit knowledge and understanding their needs and challenges, companies can gain valuable insights early in the innovation process. But while user-driven innovation can help companies to innovate successfully, it cannot be used alone, isolated from other forms of innovation.

User-driven innovation is a popular term at the moment. Many different ways of working with users are being called user-driven innovation, some of them more justifiably than others. According to the Danish Business Authority (www.ebst.dk/brugerdreveninnovation.dk/about) "user-driven innovation" can be described as: "the process whereby knowledge is obtained from users with a view to developing new products, services and concepts. A user-driven innovation process is based on an understanding of user needs and a systematic involvement of users." This includes both conscious and unrecognised user needs.

Without early and ongoing user involvement in the innovation process for products and new care services it is difficult to ensure usability. Usability is achieved, among other things, by prioritising the most important functions for users in order to reduce complexity and make operation simpler.

As well as building forward views about how technology can be used to change current practice, simulations should also seek to build back from how citizens' health and wellness might best be supported in 10 to 20 years from now and identify the necessary paths to reach that goal.

Key issues for further policy action and research are:

- Research on the risks and opportunities of the paradigm of a mixed economy of care, on how to measure "quality", and how to link individual and team responsibility.
- Encourage research on incentives for new patterns of virtual care involving professional services, family and informal care providers, including new business models, the implications of changing roles, potential liability issues, and the roles, needs and rights of informal care providers.
- Address issues of equity of access, acceptability and appropriateness, and risks of a new e-health divide and service disempowerment resulting from the smart e-enabled paradigms and potentially intrusive and impersonal technologies.

Reference

Nadkarni, M.P., L. Ohno-Machado and W.W. Chapman (2011), "Natural language processing: An introduction", *Journal of the American Medical Informatics Association*, 18:544-551.

Part II

Key challenges and opportunities for a smarter health and wellness future: Expert contributions

The themes of the six papers in this section reflect a selection of priority policy and research areas identified at the OECD-NSF workshop: the need for integrated health and social care; participatory care and personally controlled health records; the challenges of personalised medicine; convergence of technologies and health innovation; the new privacy and security risks; big data and health.

Chapter 5

Objectives and issues in integrating social care and health care delivery

Michael Rigby

Sharing patient information, medical or care plans with care-givers across the social and health care sectors requires significant changes of mind-set, as well as new and clear governance and accountability models. This chapter outlines the key issues needing deeper policy discussion and concordance at societal and organisational level.

Health and social care are both vital towards the common goal of maintaining health. As the World Health Organisation states (2006), health is "A state of physical, mental, and social well-being, and not merely the absence of disease". This is far more than the product of health care services – it is a state personal to the individual, in their own circumstances, and a range of activities and enabling factors are essential for its maintenance. Such activities of normal living include cooking and eating, exercise, and socialisation. Enabling factors include safe housing and adequate income or sources of essential supplies. When any of these functions is compromised, such as by illness, disability or frailty, overall health is compromised, and therefore support is needed. In almost all countries, however, social care provision is separate from health care not just in delivery, but in legislation, funding and organisation, and housing support is separate again.

Such isolated elements of service delivery are often referred to as 'silos' of care. The greatest divide is between health care and social care, even though each is vital towards the common goal of maintaining health. Thus when a person has a health-related condition which requires a range of support services this, in turn, requires efforts of co-ordination across all these services, which is often left to the vulnerable citizen to negotiate. Furthermore, the citizen is left poorly served – confused when individual services work to different aims and priorities, and frustrated when service delivery clashes and they have to negotiate with schedule-driven providers.

The need for greater co-ordination points strongly to the need to use modern information and communication technologies (ICTs) since these are the technological means of facilitating integration and smartness. New ICTs are enabling more care to be delivered at home, but as applications are often disease specific, such as for cardiac monitoring, there is the strong risk that the new technologies will enable more home care but at the expense of creating the new generation of even deeper "silos of care". But this is an organisational and technical view.

The consumer view – both of the person requiring care and of their family and neighbourhood informal carers – is somewhat different. The citizen seeks a cohesive pattern of harmonised care delivery which recognises them as an autonomous individual with specific physical, mental and contextual needs, and a right to choice and preference – albeit within reasonable resource constraints.

The professional and provider view is relevant, too. Within both health and social care delivery professionalism, accountability, and confidentiality have always been important. But the move from knowledge asymmetry – where the doctor has far more information than the patient – to greater information availability, coupled with health co-production, are changing the nature of relationships. Sharing patient information (with subject consent) and medical or care plans with co-providers from other disciplines and agencies also requires significant changes of mind-set, as well as new and clear governance and accountability models. This chapter will outline the key issues needing deeper discussion and concordance at societal and organisational level. In so doing, it will draw on specific studies.

The need for greater smartness

Even when supported by modern technology, fragmented services cannot be considered as "smart" in the true meaning of the word. If society is to be meaningful in its care for older and other person requiring care, true smartness is needed to ensure a holistic and co-ordinated pattern of support. Many countries are now acknowledging this at policy level, but it will need more than goodwill and aspiration for effective co-ordination to take effect, as the service structures and approaches necessarily are so different. It is necessary to understand fully the differences of function and approach in order to ensure greater harmony and smartness, yet without losing each special set of skills and services.

Social care

Despite the variation between countries in social care provision, two common characteristics prevail. The first is that **the criteria, values, and means of assessing the need for formal support are very different**. Though individuals are encouraged to take personal responsibility for their health, once a health problem arises **the provision of health care is by a professional body**. By contrast, daily living is the responsibility of the individual whenever possible, supported as necessary by their family as part of normal family life. Thus in social care the degree of need for support from outside the extended family varies according to personal, family and social circumstances, so that for any level of dependence **the degree of need for external social care support varies according to social context** and this requires provider-based assessment. And this process itself is fraught with moral (and doctrinal) dilemmas – in particular, should society or other external funders compensate for low motivation of family? Few would disagree that a dependent person with no family should not be penalised for that situation, but the position is more contentious if there are potential family

contributors but they expect instead that external services carry the load. This is very different to health care, where in almost any country whatever the local model of service provision, equity and equality of availability to any individual with similar need are core principles. Thus health care service need is assessed on primarily on objective clinical criteria and supplied equally to all, while social care service need is based on bridging the gap between what is available within the household context and what is needed by an individual to achieve a level of daily functioning (the main exception to this distinction being that with home health care the patient or family members may be asked to undertake some specific procedures if assessed as able).

Secondly, social care provision is generally provided from a **truly mixed market** of public services, private commercial services, unpaid volunteers, and not-for-profit bodies of various kinds which themselves may require full cost reimbursement, voluntary reimbursement, or no reimbursement (Hill et al., 2008). So the processes of governance, registration and regulation are important to provide protection, while secondly the processes of maximising support and minimising cost, and balancing equity in public or insurance reimbursement with client or family financial contributions also is a potentially difficult area. By contrast, even where there are different suppliers of a health package of support, it is the health care funder which ensures integration, budgeting and reimbursement.

Barriers to co-ordination

In most developed countries the whole set of **political, regulatory, and funding structures are different between health care and social care**, with each country having its own pattern. Not only is care provision and delivery fragmented, the very governance structures are set against facilitating co-ordination. Though they serve the same citizen, and each depends for its efficiency on the other, there is seldom a formal shared management structure, and thus there is no vehicle to initiate the harmonisations, not least of governance, funding, or informatics.

Additionally, at the time when the benefits of harmonisation between health care and social care delivery are increasingly clear ethically and increasingly urgent economically, four other tendencies are reinforcing the differences.

Specialism-driven fragmentation

The first is the increasing specialism within both health services and social care services, as well as between one another. In each sector, not only is increasing specialism seen as key to quality of service, but emergent

regulations and qualifications support this. Intrinsically and inherently each may be good, such as special medical and nursing qualifications for specific care groups and clinical procedures, and social care skills such as nutrition and food hygiene competence for those handling meals, lifting procedures when moving patients, and training for those allowed to offer counsel or advice, but this general trend reinforces a tendency towards fragmentation of provision, and creation of more silos of specialist knowledge and detailed records. This specialism may have intrinsic justification, but acts directly counter to the citizen-based aims of holism and of service co-ordination and integration.

Sector-specific ICTs

While there is increasing investment in ICT applications in health care and (though to a lesser extent) in social care, it is almost always sector-specific. This grows out of the separate organisational and funding structures, with lack of umbrella co-ordinating mechanisms or cross-sector investment or standards mechanisms. The most encouraging exception to this is Finland, which is seeking to harmonise the two e-government strands of e-health and e-social care strategies.

Record-keeping differences

Important and challenging also is the fact that there are major differences in record keeping between health care and social care, whether paper-based or electronic (Rigby et al., 2008). Health records are focused on one patient, with often considerable technical detail and depth, and the confidentiality to the individual is strongly protected. Social care records by contrast place the citizen in their home context of family and carers, including attitudes and effects on each so as to ensure mutual support and understanding, as well as most suitable forms of targeted support. At the same time, social care records contain far less technical information. Health records have a high proportion of physical and biological data such as blood pressure, laboratory results and digital radiology, and other defined facts such as diagnoses and prescriptions, and comparatively little narrative or subjective material. The opposite is true for social care records, which comprise largely of observations and of assessments of attitude and functioning. Each uses their own vocabulary of technical terms; indeed, each sector might profitably learn from the other about the merits of subjective contexts and objective measures respectively. But given these fundamental functional and structural differences, the sharing of elements of one set of records, within the culture of use of the other, has the potential to raise several kinds of problems unless addressed systematically.

Independent reform rather than cohesion

A final challenge in most countries and systems is the lack of a level of co-ordination and ownership between health and social care. Though there are some important exceptions, in most countries not only are the management and funding of health care quite distinct from the management and funding of social care, but each is in many cases going through processes of reform, often ideologically driven. While reform is in principle neither good nor bad, that depending on the content and the implementation, often it is too frequent and thus destabilising – for instance, the English NHS has undergone fundamental reforms at approximately three year intervals; in the Netherlands the electronic health record programme has been revised before being fully implemented; and in Finland agreed integration of health and care e-strategies will be held back by planned reform of local government structures as the care delivery agents. Also it is the lack of co-ordination of these reforms which further acts against increasing holistic support. This is particularly true when reform involves new governance and funding mechanisms, and when it increases market mix (both often being the case), as this results in lack of counterparts being available with whom to enter into meaningful discussion. It is also a major impediment to informed and effective ICT innovation and investment, as the priority has to be change to existing systems to match new frameworks and organisations, and ensure the supply of revised management data, at the very time when ICT development should be concentrating on enabling smartness of delivery.

The citizen need: Ensuring a care continuum

The result of this often fragmenting patchwork of service remits and responsibilities as well as delivery patterns is that it is the vulnerable citizen, or their over-stretched carers, who have to navigate the systems and negotiate solutions. This is not equitable in caring societies, which are the aim of OECD member states. But the effects of decades of separate development will not be eliminated solely by the provision of ICT-based smartness – indeed, despite policy aspirations, discordances in support are likely to widen if ICT systems develop according to their parent organisations' mutual independence, starting with the simplest things such as difference of client identification and of descriptions of care need.

Given these complexities, it necessary to confront decades of service evolution in order to seek a holistic approach to health and social care provision to citizens, commensurate with a caring modern society fit for the 21st century. The motivating rationale is five-fold: expectation, ease, equity, efficiency and e-enablement.

Expectations of good service delivery, and of harmonisation of provision, are rightly becoming the norm in modern society. Supermarkets can keep full ranges of provisions stocked on shelves to match demand fluctuations, civil aviation can run complex services but with simple passenger interfaces, and in many other areas of commerce good service standards are offered and indeed expected. So it is a stark contrast when the support for a person such as an elderly lady with arthritis and diabetes is fragmented, unco-ordinated in delivery, and possibly conflicting in objectives or methods. Despite health being a very high personal attribute and value, delivery agencies still too often focus on technical standards and organisational efficiency at the expense of the dependent recipient.

Ease applies to both client and care providers. With the current dis-co-ordination of provision of health-related support, there can be many conflicts, from the simple ones such as clashes of appointments, to the more central such as different expectations of the person's ability, prognosis, and potential future life pattern. Given these conflicts, it is the person themselves who has to resolve these. It is quite unreasonable to expect an older or ill person, possibly with some of the mild confusion or most common disabilities of old age, quite likely including hearing difficulties, to navigate round menu-driven telephone systems, let alone professional assessments and future plans, unaided – requiring the most vulnerable citizens having to rationalise the most complex organisations. And at the care delivery level, many professionals from different organisations have to make best use of their time and at the same time seek to reassure their clients and make life as easy as possible for them. They too can see the difficulties outlined, but are often unable to operate outside their own lines of delegated duty.

Equity is a core societal value. Given that each individual's circumstances are varied, a blanket pattern of provision by each agency does not fit well. More tailoring to the individual is necessary to match different unmet support needs, and the required solutions are based on the interaction of health and social care needs for a particular condition of health impairment.

Efficiency is the organisational and societal goal potentially to be achieved over and above the better service achieved by harmonisation. If one worker can act as the observer for other services; if delivery schedules can be co-ordinated, and if any professional can (with client consent) see parts of other agencies' records, then greater efficiency will result. And given the increasing pressure on services with demographic change, then this is a societal gain, not simplistic cost-cutting.

E-enablement is the new means by which such harmonisation can be achieved. Within the scope of existing information and communication technologies, but with new attitudes, models and governance, much can be

achieved – such as shared record components; shared triggers and alerts, electronic messaging, common delivery diaries (Rigby, 2008), information-seeking brokers (Budgen, 2007), and the rich range of remote ambient living and condition-specific vital sign monitoring. What a decade ago was an impossible challenge to paper systems and visit-based observation now could be easily accomplished if only the health and care sectors, and their regulatory and political overseeing bodies, could create and apply the same freshness of innovation that has transformed civil aviation, or enables search engine providers to link a map, a mapped bus stop, a street view picture of the bus stop, the bus timetable, a route map, journey planning functions, and real running time information of current delays to be viewed with no prior knowledge through single mouse clicks, as for example with Google maps (with the symbols being standard, but the data supplied being that available in any specific location).

Overcoming the challenges: A developmental agenda to enable integration

A number of bodies have created an environment to move towards addressing the core issues, both at a high level and at application level. In 2010 the European Science Foundation funded an exploratory workshop to explore "The Challenges of Developing Social Care Informatics as an Essential Part of Holistic Health Care", from which a report is available on the ESF website (Rigby, 2010) and is summarised in Rigby et al. (2011). This has now resulted in publication of a science position paper on the social science research issues which need to be addressed if the objective of applying ICTs to support delivery of integrated person-centric care is to be achieved successfully (Rigby et al., 2013). The joint OECD-NSF Workshop in Washington, DC in 2011 drew these issues into the wider enveloping context of smarter health systems to enable the facing of the demographic and other challenges, particularly utilising modern information and communication technology. Most recently the European Commission has created the European Innovation Partnership on Active and Healthy Ageing to address the health and related response to Europe's ageing demography, and elements of the issues needing to be addressed are envisaged in its future calls for research and for innovation. All of these supra-national bodies are expected to pursue elements of this agenda within future actions.

At national level, and locally, initiatives are under way. However, except where (as in Finland) there is a single agency responsible for both health and social care, the steps are modest and tentative, though this is not necessarily inappropriate as neither trust nor understanding can be built instantly nor by directive. But it will be important for these initial innovations to be examined

and evaluated, so lessons can be learned and shared. Other countries such as England have declared strongly the principle of co-ordinating health and social care, but at national level have not yet made any radical changes to organisations, funding, or governance, preferring to seek collaboration and compromise within existing systems – and the effectiveness or otherwise of this approach too will only be proven or disproven with experience.

The issues to be addressed

The ESF workshop led to a unanimous cross-professional declaration of the issues to be addressed. This has been acknowledged both by the OECD and the ESF in their publication of it as an addendum to their reports (Rigby et al., 2011, 2013). Some of these key issues require societal and political discussion, others relate to new organisational and delivery concepts harnessing existing communications and information management technologies for greater co-ordination.

Whilst change will need to fit into national contexts, in many cases the identification of good practice and research and development could be undertaken collaboratively at a supra-national level, and informed societal debate initiated. Indeed, the setting of principles at this level may have distinct advantages in raising them above national combative political processes, and making it easier for the underlying issues to be considered in the context of societal need – as happened effectively, for instance, with data protection legislation in Europe, or various OECD guidelines and recommendations such as for enhanced access and more effective use of public sector information or for the security of information systems and networks.

The issues to be addressed to make effective integrated support feasible can be summarised as follows:

1. Using planned research to elicit and **define the range of user needs (personal, professional, and organisational)** for an ICT-enabled supporting framework. These will range from finding trusted information sources about services and their providers, through to management of personal budgets of resources contributed by public or insurance bodies for the care of individuals.

2. Establishing the basis for a charter of subject rights for electronic record and care delivery systems containing social care data, recognising the various constituent rights including subject access; subject recording; subject-selected rules for information sharing to formal and informal third parties, and explicitly qualified rights of defined appointed representatives and agents.

3. Developing suitable robust models of information system custodianship, as well as models of rights to data access, clear and citizen-oriented rules for urgent sharing of information and wider rights of access for specific purposes including quality assurance and training. This would mean that there were clear rules as to who could share what within and between agencies and individuals, with the citizen having informed choice in the matter. Linked rules would allow for deeper sharing in an emergency, but such special use would immediately be logged and reported so as to preclude abuse.

4. Sponsoring research and development of leading-edge ICT innovation and appropriate applications, including (but by no means restricted to) controlled forms of information brokerage, cross-viewing, or record sharing between agencies and providers, as well as by citizens and their supporters, using systems as a means of protecting privacy and controlling agreed disclosure. These solutions are perfectly feasible within modern hardware and software capabilities, but need demonstration in use to be convincing on a wide scale. Such initial developments will be comparatively expensive if undertaken in a careful and scientific way, but such investment would provide learning for application on a much wider scale.

5. Developing a shared ontology for social care linked also to health care – this is a structured vocabulary and terms so that information can (within ethical rules) be shared between professional support staff without ambiguity or misunderstanding.

6. Facilitating research into planning- and delivery-enabling technologies in social care linked to health care, such as technology assisted scheduling, resource management, request handling and negotiation, near real time delivery monitoring, planning tools to enable citizens as well as formal carers to build packages of care within personal need, resource and policy constraints, and assessment and decision support tools that assist both citizens and professionals when profiling needs or identifying risks. These technologies largely exist in commerce, but have not adequately been developed (based on research) to be applied in health and social care.

7. Assessing means of making such informatics support acceptable and non-threatening for citizens, recognising that many of the most needy and vulnerable will not be informatics literate. This must be trusted and enabling technology, not disempowering. A mix of both innovative design, use of multiple technologies, and other solutions such as designated trusted agents, will be necessary and must be research based.

8. Thorough and systematic consideration of the ethical, legal, governance and regulatory issues. Concepts and solutions should be tested in different settings, cultures, and populations to ensure applicability and acceptability. There are many aspects ranging from professional and organisational accountability to means of quality measurement and quality assurance, including those which look at the totality of inter-agency care, as well as cross-agency leadership and co-ordination.
9. Developing new methods and paradigms of costing, charging, and budget and resource management, not least recognising that in many cases the individual citizen will be operating in a mixed economy. Personal, organisational, and social costs need to be accommodated, as well as budgeting and cross-charging, and management of user co-payment where this is in operation.
10. Developing and applying education programmes for citizens, professionals, informaticians in both social care and health, and policy makers to enable achievement of this vision of caring. Success will be very dependent on understanding and informed use, and this will need public awareness, education on overall principles and policies, and training in individual applications.

In general, these are not issues about new technology, and should not in any way depersonalise care. Instead, they are focussed on personalising and integrating care, and achieving the goals of expectation, ease, equity and efficiency though appropriate modern e-enablement to the standard of other services in society. Encouragingly, the European Commission is intent on seeking a number of initiatives for funding as research projects, pilots, or learning networks, while the European Science Foundation intends to publish a position paper on the research issues, linking the need for social science research to the ICT issues and societal needs, these being additional to this initiative of OECD (Rigby et al., 2013).

The citizen-based goal

The focus is on the citizen being able to maintain independent living, though this may be facilitated by family, friends, or formal services. In the early stages of life, and often in the very later years, persons need assistance in order to maintain well-being and health; this is also the case for anyone with an illness or disability which compromises their self-maintenance ability. These are not traditional health services. Without this support the health of the individual with particular needs would be compromised and then fail, but the new demographics of illness survival, ageing and family dispersal mean that external support is increasingly going to be necessary. But given the balance of needs and complexities of the life of a person with illness- or impairment-

based needs, the services providing social care support must work in harmony with those providing health care. At the same time it is important to maximise the dignity, autonomy, choices, and empowerment of the individual, and to optimise the contribution of informal carers while giving them due recognition and support as valued members of the support team.

Conclusion

Pressures for social services to act effectively in support of health are growing. There are demographic pressures of increased longevity, coupled with more people surviving serious illness, but often with increased dependency. This is compounded by societal pressures for more and better services for needy members of society. Also, there are on occasion, cases of persons having to remain in hospital or institutional care longer than necessary due to lack of truly co-ordinated home-based support, which is unfair to the individual while also wasting health resources. Coupled with this there are increased consumer expectations of service availability and quality based on more widespread consumer-orientated attitudes of commerce and society, and increased awareness from what is often referred to as the Information Society. In turn the electronic services endemic in this Information Society raise expectations that such technologies will be harnessed in the provision of consumer-focussed care services.

Continuation of the existing fragmented and discordant approach, with each organisation, profession and discipline arguing its own autonomy at the expense of designing and delivering holistic care to the individual, cannot be supported. Those with health-related needs, which will include the most vulnerable dependent in society, and others on a trajectory to a similar state if not optimally supported, deserve provision of carefully planned and integrated support, at the same time efficiently delivered and without duplicating or replacing the natural caring capacity of families and communities when available. It is a paradox that while large resources are devoted to researching new drugs and other health care interventions, so little effort or investment is put into research on the conditions to enable and drive innovation in delivering integrated support to health of individuals with clear social care needs. In a caring society, this needs to be redressed, and attention paid first and foremost to care in support of health.

References

Budgen, D., M.J. Rigby, O. Brereton and M. Turner (2007), "A data integration broker for health care systems", *IEEE Computer* 40(4), 34-41.

Hill, P., A. Allman, M. Rigby and R. Wilson (2008), "Social care informatics: Beginning to face up to the reality of the mixed services economy?" in P. Cunningham and M. Cunningham (eds), *Collaboration and the Knowledge Economy: Issues, Applications, Case Studies*, IOS Press, Amsterdam, 14-21.

Rigby, M. (ed.) (2010), "The challenges of developing social care informatics as an essential part of holistic health care", report of an ESF exploratory workshop, Keele University, 21-23 July. (Available at www.esf.org/activities/exploratory-workshops/workshops-list.html?year=2010)

Rigby, M (2008), "A patient care electronic diary to empower the patient and their virtual care team" in P. Cunningham and M. Cunningham (eds), *Collaboration and the Knowledge Economy: Issues, Applications, Case Studies*, IOS Press, Amsterdam, 57-63.

Rigby, M., S. Koch, D. Keeling and P. Hill (2013), *Developing a New Understanding of Enabling Health and Well-being in Europe – Harmonising Health and Social Care Delivery and Informatics Support to Ensure Holistic Care*, European Science Foundation, Strasbourg, ISBN: 978-2-918428-92-3.'

Rigby, M, P. Hill, S. Koch and D. Keeling (2011), "Social care informatics as an essential part of holistic health care: A call for action", *International Journal of Medical Informatics* 80, 544-554.

Rigby, M, P. Hill and A. Allman (2008), "Ensuring trust and governance in e-social care" in P. Cunningham and M. Cunningham (eds.), *Collaboration and the Knowledge Economy: Issues, Applications, Case Studies*, IOS Press, Amsterdam, 22-28.

World Health Organisation (2006). "Constitution of the World Health Organization" in *Basic Documents*, 45th edition, supplement, WHO, Geneva, October.

Chapter 6

Integrating personalised medicine into health care: Opportunities and challenges

Jennifer Leib and Kathryn Schubert

Personalised medicine as a new concept entails a paradigm shift in medical practice and faces a range of challenges: the science is emerging and complex, regulatory pathways are not optimal, and health care financing and delivery create barriers to adoption. This chapter discusses the opportunities that the successful implementation of health information technology could bring to further personalised medicine.

The burgeoning field of medicine stemming from advances in genomic research is often referred to as personalised medicine or stratified medicine. The United States President's Council of Advisors on Science and Technology (PCAST) defines personalised medicine as the tailoring of medical treatment to the individual characteristics of each patient (September 2008). Improved understanding of disease pathogenesis and risk enables patients to be sub-divided into groups based on genetic or other biological markers. By stratifying patients, preventative and therapeutic interventions can be tailored to be more effective and have fewer undesirable side effects. Since the completion of the Human Genome Project, there have been many advances in personalised medicine. In 2011, 72 new personalised medicine drugs, treatments and diagnostics were introduced into the market, and it is estimated that 60% of all treatments in preclinical development today rely on biomarker data (Personalised Medicine Coalition, October 2008). According to the US Food and Drug Administration (FDA), 10% of marketed drugs inform or recommend genetic testing for optimal treatment and 33 pharmacogenomic biomarkers are included on FDA-approved drug labels (Table of Pharmacogenomic Biomarkers in Drug Labels).

Box 6.1. What governments will need to do to address challenges to foster personalised medicine

To address challenges to foster personalised medicine, governments will need to:

- Support public and private investment in biomedical and translational research.
- Collaborate to develop clear, consistent and predictable regulatory and reimbursement decision pathways.
- Educate the public on genetic privacy protections.
- Integrate genomics into medical school and continuing education curricula.
- Expand bioinformatics infrastructure to accommodate large genomic datasets and establish policies for storing and accessing genomic data.

Personalised medicine as a new concept entails, however, a paradigm shift that must be understood and accepted by all health care professionals. The field faces numerous hurdles to its adoption into clinical practice and needs additional incentives to further build upon the current state of the science and technology. The opportunities to improve our understanding of disease and identify new interventions are tremendous after the mapping of the human genome, but much work still needs to be done to benefit from these scientific discoveries. This chapter describes the challenges awaiting personalised medicine and the opportunities to push the field forward as it relates to the regulation of personalised medicine products, reimbursement or payment for services, and integration of information technology into health care systems.

Whole genome sequencing: Rapid advances in technology

The Human Genome Project, an international collaborative research project, spearheaded by the National Institutes of Health (NIH) and the US Department of Energy (DOE) to sequence an entire human genome, took approximately 13 years to complete and USD 3.8 billion in funding from the US government (Human Genome Project, July 2012). Unravelling the genetic code led to countless scientific discoveries that advance our understanding of inherited, acquired, and complex common diseases. This international effort to decode the human genome also led to downstream applications, including the improved diagnosis of disease, assessment of disease risk, prognosis, and opportunities for targeted prevention, genomic driven drug discovery, combination drug/diagnostic products, gene therapy and population screening among others.

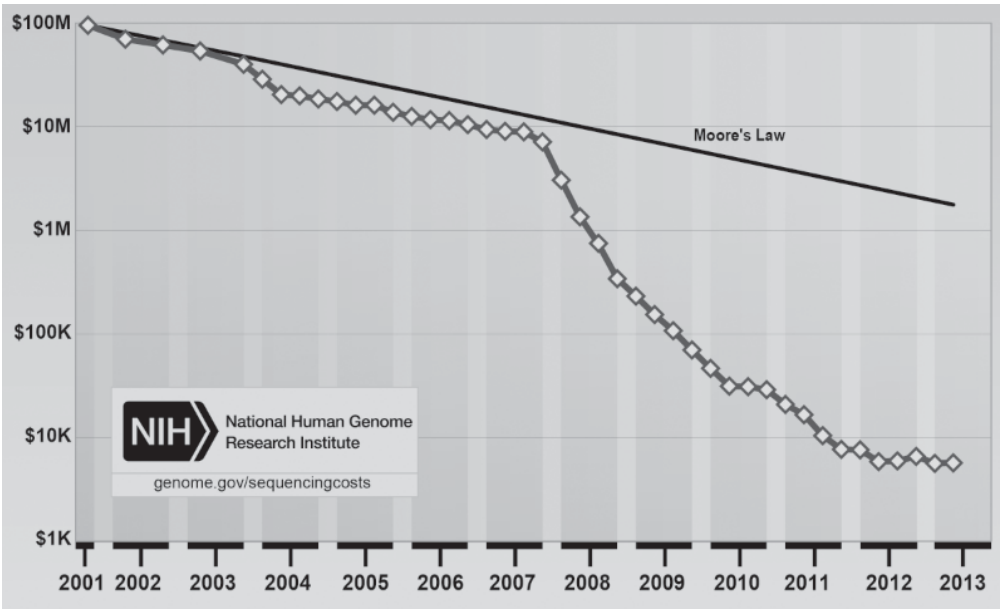
Not only has the USD 3.8 billion investment in decoding the human genome resulted in tremendous new insights into our understanding of human disease and the prevention and treatment of disease, but it also found an economic return on its investment. The Batelle Technology Partnership Practice (2011) prepared a report titled, *Economic Impact of the Human Genome Project,* and determined that the investment in the Human Genome Project created 310 000 jobs, a USD 796 billion economic impact, and launched a genomics revolution. For every dollar spent on the Human Genome Project, the return on investment to the US economy was USD 141, leading the authors of the report to argue that the Human Genome Project is the "single most influential investment to have been made in modern science and a foundation for progress in the biological sciences moving forward" (page ES-2).

Much of the technological innovation resulting from this investment has been in improving the speed, quality, and accuracy of whole genome sequencing. For genomics and personalised medicine to have utility in health care the costs of obtaining a whole genome sequence on a patient must reduce dramatically. Only six years after the formal completion of the Human Genome Project, Complete Genomics announced the ability to sequence an entire genome for USD 5 000 (Waters, 2009). For the first time, this per sample price made it possible for researchers and industry to incorporate whole genome analysis into their practices. Clinicians now have the option of assessing the sequence of a patient's DNA to provide insight into their diagnosis. And, pharmaceutical companies have a more affordable option of incorporating genomics into their drug development and clinical trial design.

To truly integrate whole genome analysis into health care, the cost must be even lower. In January 2012, Life Technologies, Inc. and Illumina, Inc. announced new products that offer full genome sequencing with a sample turnaround time of less than one day for only USD 1 000 per sample. The main difference between the two platforms will be the upfront costs - Life Technologies' machine costs USD 150 000 and Illumina's sequencer costs USD 740 000.

Figure 6.1. Declining costs of genome sequencing

Cost per genome



Source: www.genome.gov/sequencingcosts/

These market efforts are occurring alongside the Archon Genomic X prize contest that will award USD 10 million to the first team to rapidly, accurately and economically sequence 100 whole human genomes to an unprecedented level of accuracy. The contest is currently underway and the prize will be announced in February 2013. With incentives like the X Prize, the desire to be first to market with the latest sequencing technology, and the already rapidly decreasing costs of whole genome sequencing, it is not unreasonable to believe a USD 100 genome will be possible within the next decade.

Challenges to the adoption of personalised medicine technologies

The exceptionalism of genetic information: When fear limits uptake of new technologies

Since the Human Genome Project began, researchers and Policy makers have considered the ethical, legal and social implications of decoding the human genome. In particular, many theorised and extensively studied how fear of discrimination based on one's genetic makeup would deter people from obtaining life-saving genetic tests (Apse, 2004; Hadley, 2003). Although there have been few documented cases of genetic discrimination, the public's fear of genetic discrimination in the United States is pervasive. In 2007, a survey of more than 1 000 Americans found 93% of respondents felt that employers and health insurers should not have access to their genetic test results (Baruch, 2007).

In 2008, the US Congress overwhelmingly passed the Genetic Information Nondiscrimination Act (GINA) into law, which prohibited discrimination based on one's predictive genetic information in employment and health insurance. GINA provides a baseline level of protection against genetic discrimination for all Americans, making this type of health information more protected than any other type (Leib, 2008). Employers are prohibited from using predictive genetic information in any hiring, firing, promotion, or other employment-related decisions. With very few exceptions, employers are also barred from asking or requiring an employee from taking a genetic test. The law prohibits health insurers from requesting or requiring a genetic test and from using genetic information in underwriting of plans for both the group and individual insurance markets, including coverage decisions. Currently, insurers cannot use genetic information as a preexisting condition. GINA does not, however, explicitly prohibit discrimination in life insurance, disability insurance, and long-term care insurance. In the European Union, many Policy makers would like to have protections from genetic discrimination in mortgages and other commercial transactions.

The high level of protection afforded by GINA to genetic information will be extended to all types of health information in 2014 with the implementation of the Patient Protection and Affordable Care Act, commonly referred to as the health reform legislation. But today, genetic information remains the most protected form of health information in the United States.

Despite dozens of claims having been filed under GINA, advocates fear that many more cases are actually occurring and that the underreporting is a reflection of the public's lack of awareness of these new privacy protections. Each year, Cogent conducts a national survey called the Genomics, Attitudes & Trends Study. In 2011, Cogent reported that approximately 71% of respondents cited concerns that health insurance companies would access their information without permission, and more than half are extremely concerned about this privacy violation . Even more concerning is that 81% of physicians surveyed said they were not familiar with the GINA, and, only 16% of Americans are aware of laws that protect the privacy of their genetic information (Cogent). In his floor remarks on the Senate's final passage of the GINA in 2008, Senator Edward Kennedy from Massachusetts referred to the legislation as the first new civil rights bill of the 21st century (Kennedy). However, until awareness and understanding of these protections improve, the public will continue to fear genetic discrimination and limit their willingness to include genetic information in their medical records, including electronic medical records.

In 2011, the US Department of Health and Human Services (HHS) announced its intention to update the rule governing human subjects research protections, known as "the common rule." In July 2011, the Department published an Advanced Notice of Proposed Rulemaking (ANPRM), which details the anticipated changes. The proposed amendments would require written general consent for research using pre-existing data or biospecimens, even when all identifiers have been removed. Participants would need to sign a standard, brief general consent form allowing for broad, future research. The ANPRM states the reason for this change to be that regardless of what information is removed from the sample, extracted DNA from a biospecimen can potentially identify individuals" (Revision to Common Rule 2011).

Many advocates consider this concern as disproportionate and their conclusion that bio-specimens cannot be de-identified to be far reaching (Lyon, 2011). With patients, physicians, government officials and the general American public expressing great caution in sharing genetic information and apprehension about the privacy of this type of health information, integrating personalised medicine technologies into the clinic has a unique set of challenges. Addressing the fears and misperceptions will be necessary to facilitate the utilisation of genetic testing, otherwise despite these major policy initiatives, concerns about privacy will remain a significant hurdle for personalised medicine.

Escalating need to support provider training and education

Currently, personalised medicine is highly utilised in some medical specialties, such as oncology, where genetic testing and genomic sequencing is part of routine efforts to diagnose, stage and treat disease. As genetic testing is integrated into primary care settings, personalised medicine will become a more routine part of medical practice. To anticipate the adoption of these new technologies, physicians and provider education and training must include genomics. Ideally, this education will start early in medical school, but continuing medical education programmes will play a crucial role in keeping health professionals abreast of the latest discoveries and applications. A 2011 report by the US Secretary's Advisory Committee on Genetics, Health and Society found that "genetics education and training are critical to realising the benefits of genetic technologies and guarding against the potential for harm" (Secretary's Advisory Committee on Genetics, Health and Society, 2011). Recognising the growing adoption of electronic health records (EHR), the Committee also recommended that a task force be convened to help professionals prepare for the genomic age including the incorporation of genetic content into electronic medical records.

Similar recommendations were made in 2006 by the European Society of Human Genetics. But because of differences in professional education and regulation between European countries, setting curricula was not deemed a feasible option. Core competences are instead used as a basis to unify the existing genetic services across national boundaries. These core competences provide a basis for education, but much work is ahead to ensure that curricula, courses and educational opportunities are available to support health professionals in achieving competence (Skirton, 2010; Clark, 2008). Innovative, forward-thinking educational programmes are needed to lead to a new generation of health professionals prepared to take full advantage of personalised medicine.

Without a solid understand of the utility of genetic information, health professionals will be unable to appropriately and accurately integrate new personalised medicine technologies into their practices. Even more concerning, their lack of understanding of genomics could discourage them to even order new tests or prescribe tailored treatments as they feel insecure about their ability to interpret and apply this information. Without proper education and training of health professionals, the adoption of new genomic-based technologies will be delayed.

Uncertainty in regulatory requirements hinders development

The lack of a clear, consistent, and predictable regulatory pathway creates numerous challenges for diagnostic developers and the field of personalised medicine. By their nature, diagnostic tests play the central role in the personalisation of medicine: one can only better characterise a disease process or predict who might respond well or poorly to a treatment by measuring some biological characteristic of the patient. In fact, the explosion of human genetic information and advances in diagnostic technology platforms over the past decade have permitted real progress in personalised medicine.

Successive policy reports in the United States, Canada, Europe and Australia have highlighted the need for enhanced regulation of genetic tests, in particular the need for more rigorous and systematic evaluation of new tests. This and the next sections will map recent developments in the regulatory space.

In the United States, the Food and Drug Administration (FDA) evaluates the safety and effectiveness of drugs and medical devices, and considers both laboratory developed tests (LDTs) and in vitro diagnostic test kits (IVDs) to fall within its oversight jurisdiction.

Box 6.2. US FDA definitions of a laboratory developed test and of in vitro diagnostic test kit

Laboratory Developed Test: a class of in vitro diagnostics (IVDs) that are manufactured, including being developed and validated, and offered, within a single laboratory.

Source: www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm.

In Vitro Diagnostic (IVD) Test Kit: IVDs are medical devices that analyse human body fluids, such as blood or urine, to provide information for the diagnosis, prevention, or treatment of a disease.

Source: www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/default.htm.

LDTs encompass a wide range of tests, both by technology platforms and their intended use. LDTs can be as simple as spectrometry-based tests or use sophisticated molecular-basedtechniques such as microarray analysis or whole genome sequencing. LDTs are used for population screening, confirmation of a clinical diagnosis, pharmacogenomic analysis, tumor typing, disease prognosis, risk stratification, and more. LDTs are an essential element in the advancement of personalised medicine.

While having the authority to evaluate the safety and efficacy of LDTs, historically, the FDA has practiced enforcement discretion leaving the bulk of the oversight activities within individual laboratories. The Centers for Medicare and Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) programme monitors and establishes laboratory practices and standards, and many labs also see accreditation from organisations such as the College of American Pathologists.

Changes in the way diagnostics are developed and marketed including new tests for complex traits, the growing number of sole source laboratories, and the development of tests for disease progression, risk information, and treatment response led the FDA to question its previous position of enforcement discretion on LDTs. The FDA acknowledges that accrediting agencies assess a test's analytical validity, but believe there is a gap in the oversight of the clinical validity of the tests. Stakeholders began recognising the real possibility of a significant shift in the FDA's position on enforcement discretion in 2007 with the publication of FDA draft guidance documents calling for increased oversight of a subset of complex tests called In-Vitro Diagnostics Multi-Variate Index Assays (IVDMIAs).

The guidance proved controversial with many industry stakeholders raising concerns about the potentially harmful effects of FDA regulation on innovation in this field while others expressed that FDA had not gone far enough.

In 2010, the FDA announced its intention to change its policy for all LDTs and convened a two-day public meeting to solicit comments and recommendations on how best to proceed. The following year, the FDA published a list of titles of guidance documents they plan to release in 2012 that included the *Framework for Regulatory Oversight of Laboratory Developed Tests, FDA Notification and Medical Device Reporting for Laboratory Developed Tests, and Quality System Requirements Guide for Laboratory Developed Tests*.

Without knowing the fate of the regulatory requirements, investors increasingly hesitate to fund emerging businesses in the area of personalised DNA testing, where laboratory-developed tests play an important role (Olsen, 2012).

The lack of a clear regulatory pathway is a concern outside of the United States as well. In the European Union, similar to the United States, diagnostics can be marketed as a LDT or a test kit. For kits, manufacturers must first obtain a European Conformity (CE) mark, which confirms that the products have met all legislative requirements and good manufacturing practices. With the CE mark affixed to their kit, manufacturers can distribute their product freely. The European Medicines Agency (EMA) also reviews all medical products including LDTs. Obtaining a CE mark is much simpler than

achieving FDA clearance or approval. For this reason, many American test developers launch their products in Europe prior to distributing them in the United States.

The lack of uniform regulatory requirements across countries creates additional burdens and costs for test developers, and may lead to inconsistent quality of products across the world and limited access to them depending on where patients reside.

Lack of transparency and inconsistent reimbursement and coverage decisions slows uptake and utilisation

Once test developers meet the regulatory requirements and are able to bring a test to market, they then face the daunting and equally unpredictable pathway of securing coverage and payment for their diagnostic.

Reimbursement policy differs greatly in the United States and Europe due to the vast differences in the health care systems. In the United States, much has been said for the state of reimbursement of new complex diagnostic tests, often used in personalised medicine.

Similar to other medical services, laboratory diagnostic tests are described by Current Procedural Terminology (CPT) codes for the purposes of billing, claims adjudication and health services research. The American Medical Association develops the codes to serve as a uniform language to describe medical, surgical, and diagnostic procedures. The codes facilitate billing and reimbursement in the United States.

"The Adverse Impact of the US Reimbursement System on the Development and Adoption of Personalised Medicine Diagnostics (PMD)", a paper commissioned by the Personalised Medicine Coalition in 2010, described various aspects of the CPT coding system which pose significant challenges for PMDs. Of particular relevance is the fact that the CPT system lacks the flexibility to accurately code for tests that could provide one or many analytical and clinical results from the same procedure (e.g. multiplex analyses or whole genome sequencing), or which might provide varying clinical value depending on the disease being tested (e.g. the same multi-gene panel for different cancers). The author, Dr. David Parker, notes that not having an appropriate CPT code for a diagnostic test limits the ability to get reimbursed and at a minimum, it takes 14 months for a CPT code to be created (p. 6).

Recognising that many challenges stem from inadequate coding, the American Medical Association facilitated a molecular diagnostics working group of the CPT Editorial Panel that developed more than 100 new CPT codes for molecular diagnostics which will be implemented for use in January 2013.

Coverage decisions, however, not only require an understanding of what specifically would be paid for but also the clinical circumstances under which payment would be justified, i.e. the clinical utility of the procedure. Even in instances where adequate CPT codes exist, payers will not reimburse unless there is demonstrated evidence of clinical validity and utility.

Today most genetic tests are validated using retrospective data and archived samples. It would be economically and practically challenging to assess the validity and utility of genetic tests through prospective randomised studies (West, 2011, pp. 13-14). Such studies could cost tens of millions of dollars, which would make for a poor return on investment for tests priced in the low hundreds of dollars. Many stakeholders, therefore, advocate that the United States move toward a value-based pricing model where the research and development investments are incorporated into the coverage decisions and that payment for the tests reflect these upstream costs. Some payers choose to conduct their own studies. For instance in the United States, Medco funded a study to examine the benefits of pharmacogenetic testing for Warfarin dosing and Kaiser Permanente completed a study on its beneficiaries to examine the benefits of the Oncotype Dx test.

As Parker concludes, "the path to coverage must be apparent, and the standards of evidence clear and appropriately set to be feasible both scientifically and economically. Payment must be sufficient, rationally determined, and grounded in the utility or value of the service being provided" (p. 15). Fixing the current reimbursement system in the United States is a necessary step to advance personalised medicine.

While regulatory decisions are largely made for the entire European Union, payment determinations are made at the country level. In her analysis of reimbursement policy in the European Union, Susan Garfield found that many European countries are limited in their ability to adequately assess and consequently, rapidly provide access to personalised medicine technologies (2011).

Furthermore, none of the ten countries surveyed use a value-based pricing pathway. Test developers are working with individual payers on a country by country basis, and at times, on a hospital by hospital basis, to secure coverage for their diagnostics. Similarly to the US, this fragmented approach creates a patchwork quilt of coverage for a product, resulting in challenges for businesses as well as for patient access to advanced diagnostics.

Germany was found to have the most supportive reimbursement policies for personalised medicine technologies followed by the United Kingdom and France. In descending order, the remaining countries were Italy, Sweden, Switzerland, Spain, Norway, Finland and the Netherlands. The lack of uniform reimbursement policy in the United States and Europe will continue to create challenges for the adoption of personalised medicine.

Public-private partnerships and pre-competitive collaborations

There is considerable evidence that public investment in biomedical research has been declining across the OECD area over the last decade. In light of this decline there has been increasing support for public-private partnerships, many of which – at least in the United States, have been facilitated through the creation of foundations for federal agencies such as the Foundation for the National Institutes of Health and the Critical Path Institute. As economic realities reduce government funding for research across the world, the importance of these partnerships for scientific and technological innovation will continue to grow.

For instance, in 2004, to accelerate scientific discovery, the National Cancer Institute's Center for Bioinformatics and Information Technology launched the cancer Biomedical Informatics Grid (caBIG) to mobilise digital capabilities for researchers. With caBIG software and standards, cancer centers can share data resources with the larger cancer care and research community and use resources contributed by others. According to the programme's website, "On the grid, these resources can be aggregated from multiple sites to appear as an integrated research dataset, while the individual resources remain under the control of the local organisations" (cancer Biomedical Informatics Grid).

Under the leadership of the Foundation for the National Institutes of Health, members of the Biomarkers Consortium collaborate to develop and qualify promising biomarkers to accelerate the development of new technologies and therapies for the early detection, diagnosis, and treatment of disease. With a financial contribution, both non-profit and for-profit institutions can join in either a scientific or supporting membership role to help lead the Consortium and promote the focus of projects (Biomarkers Consortium).

Looking forward, a promising partnership still in formation is a collaboration to develop tools to advance whole genome sequencing from the research lab to the clinic. At the 2011 American Society of Human Genetics annual meeting, the National Institute of Standards and Technology convened officials from the US FDA, the Centers for Disease Control and Prevention, and the National Institutes of Health to meet with private-sector stakeholders to consider the tools needed to integrate whole genome sequencing into the clinic.

In April 2012, the White House published a *National Bioeconomy Blueprint* as part of the Administration's commitment to supporting scientific discovery and technological breakthroughs to ensure sustainable economic growth while improving the health of the American public. The Blueprint identified five strategic objectives including "Identify and support opportunities for the development of public-private partnerships and precompetitive collaborations – where competitors pool resources, knowledge, and expertise to learn from successes and failures." To catalyse these partnerships, the White House asks federal agencies to provide incentives.

Challenges of integrating personalised medicine into health information technology in the United States

The effort to incorporate Health Information Technology (HIT) into the everyday practice of medicine in the United States – not just for personalised medicine – is a long-term project with the most important phases and details still in process. There are significant challenges and opportunities that HIT could bring to further personalised medicine. The Health Information Technology for Economic and Clinical Health (HITECH) Act codified into law the Office of the National Co-ordinator and created incentive payments for those physicians and hospitals providing care to Medicare and Medicaid patients who met a specific set of criteria and could prove themselves to be meaningful users of HIT. With its enactment in 2009, HITECH gave the federal government the tools it needed to move HIT forward, including funding, programmatic support, and improved co-ordination of the federal effort to implement HIT. HITECH also provided grants to those who are eligible to receive incentive payments and to start building the necessary IT infrastructure.

In 2011, just 57% of office-based physicians used EMR/EHR systems. Even more striking is that only one-third of physicians have a system in place that meets the HHS criteria for a "basic system" (Hasiao, 2012). HHS has been working to implement "meaningful use" regulations to ensure that EMRs will be held to certain standards, be interoperable, and provide the appropriate privacy standards for patients. Unfortunately, these regulations are too basic to support the advancement of personalised medicine as they include measures such as computerised provider order entry for medications, being able to generate and transmit electronic prescriptions, maintain active medication and allergy list, vital signs, clinical summaries and privacy/security standards (Hsiao, 2011). In the future, the regulations will be expanded to simplify the reporting of clinical quality measures, allow for the use of large amounts of data by hospitals to "drive efficiency, as hospitals can use it to improve predictive modeling, deliver more personalised treatments for patients and better manage population health" (Caramenico, 2012). Additional stages

will focus more on safety, quality and efficiency, although it is unclear just how much broader final regulations will be.

Beyond the most basic technology issues, there are bigger challenges about how personalised medicine might fit into the current HIT framework that need to be addressed either before or in parallel to implementation of HIT. The measures to document meaningful use of EHRs are the most basic of data points, such as documenting a patient's smoking history and blood pressure. While such measures will certainly improve the efficiency of a physician's office or hospital, it still remains questionable as to whether the records will provide the ability to tailor treatments or make diagnoses easier for physicians. Just the ability to store health information electronically is not the same as using the technology to diagnose, analyse or make medicine more personalised. These early measures only ascertain the completeness of the electronic medical record and fail to address the usefulness of the EMR. To reach their full potential, meaningful use standards and regulations need to be flexible enough to expand in the future to include the use of personalised medicine.

To ensure the inclusion of robust and useful data in health records, HITECH included provisions that provide incentives for compliance to meaningful use requirements and penalties for hospitals, physicians, etc. that fail to meet the criteria.

EMRs are not new to pathologists, who have been using software to store, share and report laboratory results for decades. For this reason, pathologists are prime to be early adopters of HIT. However, the meaningful use regulations create challenges for this specialty. Pathologists rarely see patients in clinic and most often, interact only with the test-ordering physician. As such, it is impossible for them to meet the stage 1 meaningful use requirements that call for the inclusion of data obtained from examining a patient. Despite being the medical specialty leading the way for the adoption of HIT, they face future penalties for not meeting the requirements of meaningful use. Addressing this unintended consequence will be important to integrating personalised medicine into HIT.

Interoperability is the ability of diverse systems and organisations to work together and was a major challenge pre-HITECH. The law ensures that for eligible professionals and institutions to receive the incentivise payment, they must use technology that meets certain standards to create interoperability with other providers, between pharmacies and offices, office and hospitals, offices and labs, labs and researchers, etc. Without the ability for systems to "talk" to each other, HIT will not meet its potential. Ensuring that electronic records can be transferred or shared among a patient's primary care physician and specialists is an issue that must still be addressed. Additionally, a major concern highlighted by a recent study in *Health Affairs* is that those providers

who are ineligible for HITECH incentives are not implementing EMRs. The authors explain, "if large segments of the health care system remain paper based, then investments to support EHR adoption and use by eligible hospitals and physicians might not produce the expected quality and efficiency gains" (Wolf, 2012, p. 509). In fact, this study found low adoption rates for EHR systems in ineligible hospitals as low as 2-6%. Good incentives are integral to the adoption of HIT.

HHS is working through the Center for Medicare and Medicaid Innovation (CMMI) to pilot patient-centered medical homes and accountable care organisations that co-ordinate the care of patients among all providers and ensure that each health professional has adequate access to a patient's medical records. HIT is an integral part to these demonstration programmes, which are currently underway in select regions of the country.

In the short term, "by leaving out ineligible providers, the nation risks building a new digital divide in which key providers, which already have low levels of electronic clinical data, may fall further behind" (Wolf, 2012, p. 512). This is especially important for personalised medicine, as the whole picture of a person's health must be examined to appropriately diagnose disease and tailor treatment. To enable progress, first and foremost there is the need to develop a bioinformatics infrastructure not only capable of maximising the utility of electronic medical records, but one that can accommodate large scale data sets resulting from whole genome sequencing. Without such infrastructure, the potential of personalised medicine to improve the ability to prevent, preempt and individually tailor treatments for disease will be limited.

The promise of personalised medicine looms large, and the adoption of health information technology will help foster this field. In its annual report, *The Case for Personalised Medicine*, the Personalised Medicine Coalition believes that personalised medicine will not reach its full potential or widespread adoption until the health care system incorporates health information technology into practice (2011). The President's Council of Advisors on Science and Technology also share this belief in its report on personalised medicine from 2008, "health care information technology tools, including electronic medical records, personal medical records, and clinical decision support systems will be essential enablers for the development and widespread use of genomics-based molecular diagnostics" (p. 20).

Data storage and management challenges

The challenge of incorporating genomics into electronic medical records largely has to do with the massive volumes of data obtained from analyzing the genome, the transcriptome, proteins, and other molecular entities. Sequencing one sample can result in 4 million variations from a reference genome or tens of megabytes of processed data (Baker, 2010). Running multiple samples is quickly straining the ability to store, transmit and analyse the data, and to fully integrate whole genome sequencing into the clinic to the point of enabling clinical decision-making, new user-friendly bioinformatics tools are needed (Pollack, 2011).

Researchers remain undecided on how much data to store. Some hold onto everything including the raw, unanalysed sequence data, while others only store data after the sequencing reads are reassembled (Baker, 2010). Policy makers will face a similar dilemma in deciding which genomic information to include in an EMR, i.e. should the raw data be archived separately from the EMR and if so, then for how long? Considering most clinicians lack the training to interpret sequencing data, having easy access to the data in an EMR seems unnecessary and unlikely to affect patient care. Further, considering the expense of storing such a large dataset in a functional and accessible system coupled with the decreasing cost of sequencing, it may be more economical and practical to only store the clinical reports and re-sequence a patient's sample in the future if further assessments are indicated. In the future, if the promise of a USD 100 whole genome sequencing with a rapid turnaround time holds up, this would definitely be a cheaper, easier, and more practical solution than storing billions of data points.

The Association for Molecular Pathology created a Whole Genome Analysis Working Group to explore the challenges of incorporating next-generation sequencing into the clinic. Dr. Jane Gibson, Chair of the working group, presented its work at a NIH-sponsored conference in May 2012 (Gibson, 2012). In addition to the storage and data management challenges, the Working Group identified the lack of databases curated to acceptable standards for use in clinical settings to likely be the most significant challenge in managing and reporting genome sequencing data. As the ability to interpret and understand genomic data advances, it may be reasonable to reanalyse a patient's results. However, updating the EMR after the reinterpretation of the data raises significant technical and policy issues. Policy makers will need to determine the appropriate way to update a record after the formal inter-pretative report is completed. Addressing these bioinformatics needs and the related policy issues will be crucial to facilitating the inclusion of genomic information into electronic medical records, and play a major role in integrating personalised medicine into practice.

Role for the international community to address challenges

There are numerous opportunities for the international community to collaborate to address the challenges and barriers to the advancement and widespread adoption of personalised medicine discussed in this chapter. Continued public and private investment in biomedical research and innovation will further drive the cost of sequencing technology lower as our scientific understanding of genomics grows. Governments need to continue to fund biomedical research and pursue alternative strategies such as public-private partnerships in light of the economic realities of the present time. These collaborations should not be limited to one country and governments should encourage partnerships with foreign institutions that share common goals.

Even if this investment is maintained, translation of the products into the clinic will face delays due to the lack of clarity and predictability in both the regulatory and reimbursement pathways. Additionally, the lack of consistency in reviews across countries will result in disparities in patient access. Hence, an opportunity exists to convene an international group of stakeholders to define and establish uniform standards for assessing the safety, effectiveness, and clinical utility of diagnostics. These guidelines can assist regulatory bodies and payers as they develop their own policies and guide industry as they develop business plans for bringing new products to the market.

To foster the post-market adoption of personalised medicine products and increase utilisation of innovative diagnostics, governments with policies in place prohibiting discrimination based on genetic information must educate its public on these protections. Patients will remain unnecessarily hesitant and discouraged from participating in genetic testing without efforts to increase awareness and understanding. Likewise, health care providers need to understand genomic medicine in order to appropriately offer and advise patients on genetic testing options. Without these education efforts, patients and providers will remain timid with personalised medicine, which will further delay the uptake of these advances that can improve the quality of their care.

Last, HIT and electronic health records have the potential to improve the administration of health care systems. New technologies and bioinformatics infrastructure are necessary to integrate genomic data into records. Additionally, governments need to decide what types of information should be stored, the best way to access the information, and the standards for protecting privacy of sensitive genomic health information. The Organisation for Economic Co-operation and Development is uniquely positioned to spearhead these efforts, develop consensus guidelines, implement education campaigns, and support investments in personalised medicine. Hopefully, this international body or another entity will champion these initiatives, build upon the current advances in personalised medicine and collaborate to usher in the next generation of technologies, diagnostics, and treatments in this burgeoning field.

References

Apse, K.A. et al. (2004), "Perceptions of genetic discrimination among at-risk relatives of colorectal cancer patients", *Genetics in Medecine,* 6, 510-516.

Baker, M. (2010), "Next-generation sequencing: adjusting to data overload", *Nature Methods,* 7, 495-499.

Baruch, S. et al. (2007), "US public opinion on uses of genetic information and genetic discrimination: *Genetics & Public Policy Center*, 24 April, www.dnapolicy.org/resources/GUNA-public_opionion_genetic_information_nondiscrimination.pdf (accessed 18 June 2012).

Battelle Technology Partnership Practice (2011), "Economic Impact of the Human Genome Project", May, www.unitedformedicalresearch.com/wp-content/uploads/2012/08/Economic-Impact-of-the-Human-Genome-Project.pdf (accessed 14 June 2012).

Biomarkers Consortium (website), www.biomarkersconsortium.org/about.php (accessed 14 June 2012).

Caramenico, A. (2012), "Stage 2 meaningful use will relieve reporting burdens, boost big data", *Fierce Health Care.* 16 March, http://www.fiercehealth care.com/story/stage-2-meaningful-use-will-relieve-reporting-burdens-boost-big-data/2012-03-16 (accessed 16 March 2012).

Clark, C. (2008), "Scripps plans to start new medical school," *San Diego Union-Tribune,* 25 March, available at: http://legacy.utsandiego.com/news/metro/20080325-9999-1n25school.html (accessed 6 July 2012).

Enhanced Online News (2011), "Americans' concern about the privacy of their genetic information reaches new high", 10 January, http://eon.businesswire.com/news/eon/20110110006276/en/CGAT/Genomics/Cogent-Research (accessed 5 July 2012).

Garfield, S. (2011), "Advancing access to personalized medicine: A comparative assessment of European reimbursement systems", *Personalized Medicine Coalition,* October.

Gibson, J. (2012), "Next generation sequencing in the clinic- considerations for molecular pathologist", presented at the National Cancer Institute, May, www.blsmeetings.net/NCINextGenSequencing/index.cfm (accessed 15 July 2012)

Hadley, D.W. et al. (2003), "Genetic counseling and testing in families with hereditary nonpolyposis colorectal cancer", *Archives of Internal Medicine* 163:573-582.

Human Genome Project Information Archive (website), www.ornl.gov/sci/techresources/Human_Genome/home.shtml (accessed 18 June 2012).

Hsiao, C.J. et al. (2012), "Most physicians were eligible for federal incentives in 2011, but few had EHR systems that met meaningful-use criteria", *Health Affairs*, No. 5, May.

Hsiao, Chun-Ju et al. (2011), "Electronic Health Record Systems and Intent to Apply for Meaningful Use Incentives Among Office-based Physician Practices: United States, 2001–2011" *NCHS Data Brief.* No. 79, November, www.cdc.gov/nchs/data/databriefs/DB79.pdf (accessed 3 June 2012).

Kennedy, E. (2008), "Genetic Information Nondiscrimination Act of 2007", *Congressional Record,* National Library of Congress, S3363-S3365.

Leib, J.R. et al. (2008), "The new genetic privacy law: how GINA will affect patients seeking counseling and testing for inherited cancer risk", *Community Oncology* 5(6), June, 351-354.

Lyon, E. (2011*),* "Letter to FDA", 24 October, www.amp.org/advocacy/documents/ANPRM_ResearchProtections_Oct2011.pdf (accessed 15 July 2012).

National Cancer Institute, "Cancer biomedicale informatics grid", http://cabig.cancer.gov/about/ (accessed 16 July 2012).

Olsen, S. and A. Berger (2012), "Genome-based diagnostics clarify pathways to clinical use, workshop summary." *The National Academies Press.*

Parker, D. (2010), "The adverse impact of the US reimbursement system on the development and adoption of personalized medicine diagnostics, *The Personalized Medicine Coalition,* www.personalizedmedicinecoalition.org/sites/default/files/files/Reimbursement%20Issue%20Brief(1).pdf (accessed 5 July 2012).

Personalized Medicine Coalition (2011), "The Case for Personalized Medicine," 3rd Edition, November, www.personalizedmedicinecoalition.org/sites/default/files/files/Case_for_PM_3rd_edition.pdf (accessed 3 July 2012).

Pollack, A. (2011), "DNA Sequencing Caught in Deluge of Data", *The New York Times,* 30 November, www.nytimes.com/2011/12/01/business/dna-sequencing-caught-in-deluge-of-data.html?pagewanted=all (accessed 22 June 2012).

President's Counsel of Advisors on Science and Technology (2008), "Priorities for Personalized Medicine," September, available at: www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v3.pdf.

Skirton, H., C. Lewis, A. Kent and D. Coviello (2010), "Genetic education and the challenge of genomic medicine: development of core competences to support preparation of health professionals in Europe," *European Journal of Human Genetics* 18(9): 972-977.

US Department of Health and Human Services (2011), "ANPRM for Revision to Common Rule", 22 July, www.hhs.gov/ohrp/humansubjects/anprm2011page.html, (accessed 15 July 2012).

US Department of Health and Human Services (2011), "Genetics Education and Training," Secretary's Advisory Committee on Genetics, Health and Society", February, http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_education_report_2011.pdf (accessed 30 June 2012).

US Food and Drug Administration (2012), "Table of Pharmacogenomic Biomarkers in Drug Labels", October, www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm (accessed 20 June 2012).

US Food and Drug Administration (2012), "Medical Device User Fee and Modernization Act", August, www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm (accessed 28 June 2012).

US Food and Drug Administration (2007), "Draft guidance for industry, clinical laboratories, and FDA staff – In vitro diagnostic multivariate index assays", 26 July, www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079148.htm (accessed 6 July 2012).

Waters, R. (2009), "Complete genomics gets genomic sequencing under $5,000 (Update 1)," *Bloomberg*, 5 November, www.bloomberg.com/apps/news?pid=newsarchive&sid=aWutnyE4SoWw (accessed 14 June 2012).

West, D.M. (2011), "Enabling personalized medicine through health information technology: Advancing the integration of personalized medicine," *Brookings Institution*, January.

White House, The (2012), "National Bioeconomy Blueprint" April, www.whitehouse.gov/blog/2012/04/26/national-bioeconomy-blueprint-released (accessed 15 May 2012).

Wolf, L. (2012), "Hospitals ineligible for federal meaningful-use incentives have dismally low rates of adoption of electronic health records", *Health Affairs,* March, p. 506.

Chapter 7

Managing our own health and well-being: Australia's personally controlled electronic health record

Bettina McMahon

This chapter outlines the work Australia has done to achieve the vision of an open, shared architecture in health care. It reviews the key milestones of the national eHealth agenda: from the formation of an integrated infrastructure and development of common standards, to the development of the Personally Controlled Electronic Health Record to increase consumers' engagement and control over their medical information.

A personal health record (PHR) is a digital web-based collection of a patient's medical history in which copies of medical records, reports about diagnosed medical conditions, medications, vital signs, immunisations, laboratory results, and personal characteristics like age and weight are stored (see Weitzman et al., 2009).

PHRs have been much discussed over the past few years, and considerable activity concerning them is occurring in health information technology, policy, and market sectors. Personally Controlled Electronic Health Records (PCEHRs) are a special class of PHRs distinguished by the extent to which users control record access and contents. User control over these functions is governed by subscription and access control mechanisms and annotation capabilities within the record system. It is generally assumed that increasing individuals' abilities to view and share their medical histories or clinical decision support messages, including from distributed information sources, multiple care sites, and time periods, will result in better self-care preparation and motivation, reductions in treatment and medication errors, and improved health.

While anticipated benefits of PCEHRs may eventually drive their diffusion, the overall approach of a citizen- or patient-centered health record system that interoperates with, but is not tethered to, a provider system represents a fundamental change from current approaches to health information management.

The introduction of a PCEHR for each Australian is one of the most important systemic opportunities to improve the quality and safety of health care, reduce waste and inefficiency, and improve continuity and health outcomes for patients. Giving people better access to their own health information through a PCEHR is also essential to promoting consumer participation, and supporting self-management and informed decision-making.

To provide people with a PCEHR, standards for open architecture to ensure interoperability on a national scale are a necessary pre-requirement. Australia has been progressing the open architecture agenda since the formation of the National eHealth Transition Authority (NEHTA) in 2005, and the goal is to deliver a national PCEHR by mid-2012.

This work has been driven by the need to reform health care provision in Australia. Australia's universal health care system is one of the best in the world, but the rapidly growing ageing population and the increasing frequency (prevalence-incidence) of chronic conditions are increasing the cost of health care as a proportion of gross domestic product. Transforming standard practice, however, requires more individual responsibility and a system where the consumers have greater choice and control in managing their own health, with the support from medical professionals when needed.

Achieving greater access to care, improved outcomes, and reduced costs depend on new care delivery models, including self-monitoring and corrective action in partnership with health care providers. To enable health care consumers to play a more active role in their care management, new tools and information are required to help them understand what is going on with their health, make the right decisions, and recruit the right professionals into their medical care teams. The ability to connect data, systems and people across the care continuum is critical to the success of these new models.

This chapter outlines the work Australia has done to achieve the vision of an open, shared architecture in health care. From the formation of NEHTA to develop integration infrastructure and standards, to the development of the PCEHR to increase consumer engagement and control over their information, the objective of greater co-ordination across the care continuum and better health care through interoperability has guided national eHealth policy and investment.

The need for reform

In 2008, the Australian Government established the National Health and Hospitals Reform Commission to develop a long-term health reform plan for Australia. In its final report released in 2009, the Commission noted that despite its many strengths, the Australian health system was under growing pressure (National Health and Hospitals Reform Commission, 2009). Significant challenges existed in meeting increasing demand and expenditure in health care, unacceptable inequalities in access and outcomes, meeting people's expectations of safety and quality, and dealing with workforce shortages (National Health and Hospitals Reform Commission, 2009, p. 45).

Australia is not alone in facing these challenges. The OECD-NSF Workshop highlighted common challenges faced by participating nations including rising health costs, demographic changes in populations and associated changes in demand for health care, workforce availability, and a greater demand for responsive health care.

Another challenge faced by Australia was identified by the National Health and Hospitals Reform Commission. The Commission observed that Australia's health care was fragmented by different funding and performance accountability and responsibilities between levels of government, which hampered a co-ordinated response to the challenges facing the system (National Health and Hospitals Reform Commission, 2009, p. 56).

This situation reflects the health care funding arrangements and responsibilities specific to Australia. The Australian Government funds universal medical services and pharmaceuticals and gives financial assistance to public hospitals, residential aged care facilities and home and community care for the aged. It is also the major source of funds for health research and provides support for training health professionals and financial assistance to tertiary students.

State and territory governments provide a variety of direct health services, including most acute and psychiatric hospital services. State and territory governments also provide community and public health services, including school health, dental health, maternal and child health, occupational health, disease control activities and a variety of health inspection functions.

Local governments provide home care and personal preventive services, such as immunisation. In addition to the provision of these various health care services, over 50% of Australians also hold private health insurance (Private Health Insurance Administration Council, 2011). Around one-third of hospital days are funded through private health insurance, the majority of surgery (59%) and services that are not publicly funded for many Australians, such as dental, physiotherapy and chiropractic treatments.

Table 7.1. Private health care insurance in Australia

Percentage of Australians holding private hospital insurance in 2011	45.7%
Percentage of Australians holding private general health care insurance in 2011	53.0%

Source: Private Health Insurance Administration Council (2011), *Quarterly Statistics: December 2011*, pp. 4-5.

Discussion at the OECD-NSF 2011 workshop indicates that similar fragmentation exists in other OECD countries. The relevance of this fragmentation may not be immediately apparent to a discussion of technology and smarter use of information in health, but has been an important consideration in Australia's eHealth strategy for two reasons:

- Improved information flows across organisational boundaries have the potential to improve health outcomes within the complex structure of health care provision in Australia.
- The information architecture to share information across these boundaries would need to operate within this dynamic.

While a system that is cognisant of the structure of health care provision presents opportunities to improve health outcomes, a system that neglected this would face significant barriers in the implementation phase as it would be out of step with health care workflows and funding.

The next section of this chapter expands on the reform goals proposed by the National Health and Hospitals Reform Commission, and the role eHealth could play in the reform. It will then go on to discuss the information architecture for the PCEHR, which is designed to work within the Australian health care context.

Reform goals

The National Health and Hospitals Reform Commission (2009, p. 3) identified three reform goals to set up Australia's health care system:

- Tackle major access and equity issues that affect health outcomes for people now.
- Redesign our health system so that it is better positioned to respond to emerging challenges.
- Create an agile and self-improving health system for long-term sustainability.

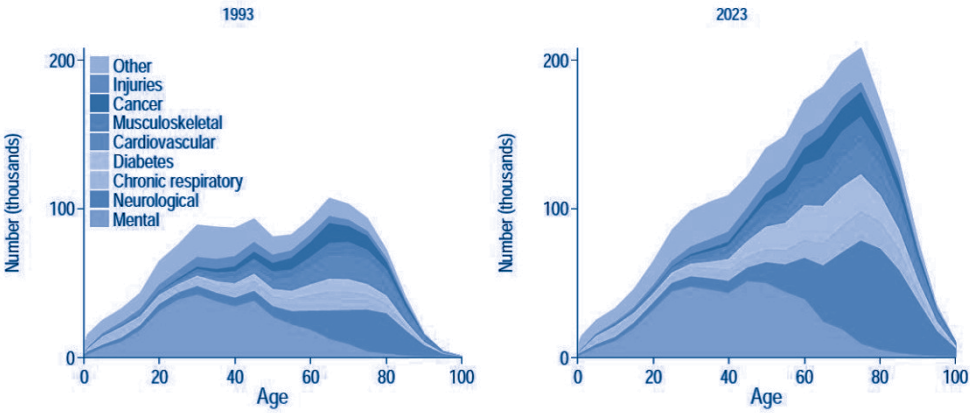
The report outlined policies and strategies to achieve these reform goals, including regulatory, funding and governance initiatives. It also identified the role of technology, and in particular, an electronic health record controlled by consumers:

Making the patient the locus around which health information flows is critical and will require a major investment in the broader e-health environment. Electronic health information and health care advice will increasingly be delivered over the internet. Broadband and telecommunication networks must be available for all Australians if we are to fulfil the real promise of e-health (National Health and Hospitals Reform Commission, p. 8).

Greater consumer engagement and empowerment are necessary to improve Australia's health system. Improving consumer engagement and access to information would empower consumers to make more informed decisions about their health and wellness. Strengthening the consumer voice in the provision of care would increase their involvement in decisions about their health care and move towards a future where consumers are able to accept more responsibility for their health outcomes. Co-ownership and co-production of health information by both the consumer and their trusted providers is a critical step in this journey.

The Australian Government response to the Commission's report was released in 2010 (Commonwealth of Australia, 2010), and included AUD 467 million to deliver a personally controlled electronic health record (PCEHR). The PCEHR would enable Australians to access their own health care information and permit authorised health care providers to use the information in providing better co-ordinated and effective care for the consumer. Implementation was to focus initially on people who have the most contact with the health care system, specifically, people with chronic and complex conditions, older Australians, Aboriginal and Torres Strait Islander peoples, and mothers and their newborn children (National Health and Hospitals Reform Commission, 2009). Considering chronic conditions as an example, in 2004-05, 77% of Australians had at least one long-term condition, with chronic conditions estimated to consume about 70% of the health care budget (Australian Institute of Health and Welfare, 2008). Importantly, the emergence of many chronic conditions is influenced by potentially modifiable determinants of health/risk factors (Australian Institute of Health and Welfare, 2006).

Figure 7.1. Prevalence of disability in Australians (prevalent years lived with disability) due to selected broad cause groups. 1993 and projections for 2023



Source: Australian Institute of Health and Welfare (2007), "The burden of disease and injury in Australia 2003", available at: www.aihw.gov.au/publication-detail/?id=6442467990&libID=6442467988 (cited 11 March 2012).

The Personally Controlled Electronic Health Record

A description of the scope and functions within the PCEHR is set out below. The PCEHR will enable better access to important health information currently held in dispersed records around the country by displaying clinical information such as a person's:

- medical history
- medicines
- allergies and adverse reactions
- immunisations
- records in the Australian Organ Donor Register
- records in the Australian Childhood Immunisation Register.

A consumer will also be able to enter information on:

- over-the-counter medications
- allergies and adverse reactions
- the location and custodian of an advance care directive (if they have one).

In addition, information relating to specific medical events will also be available through the PCEHR, including:

- hospital discharge summaries
- referrals
- specialist letters
- summaries of medical events.

In the future, other information will be available such as pathology and diagnostic test results. Consumers who would like to participate in the PCEHR will be able to register from July 2012. Only those consumers who actively choose to register for a PCEHR will have one created. Consumers who choose to participate will be able to:

- access all the health information stored in their PCEHR
- control who has access to their PCEHR and view an audit trail to see who else has accessed their PCEHR

- share information with their health care providers, such as allergies and over the counter medications
- improve the quality of their health information by highlighting potential errors in their records and requesting the potential error be reviewed.

Authorised health care providers will be able to view information in the PCEHR in line with the access controls the consumer has set. For example, if a consumer marks some information as being available in a medical emergency only, this will not be visible to health care providers outside an emergency. The PCEHR will clearly notify providers that it may not represent a complete set of health information about a consumer. Privacy protections through technical, legal and regulatory mechanisms are discussed later in this chapter.

The data challenges

Creating a workable architecture

As discussed earlier, the Australian health system comprises a mix of funders and service providers. The information architecture must work within this mix and support improved information sharing amongst participants. When considering an appropriate information architecture, Australia looked at international eHealth implementations and the cultural and commercial contexts in which they operated.

The UK National Programme for IT was built within a nation-scale, single-payer health systems. The Programme has nation-scale management and governance structures to support this, which involve a top-down system architecture and standards compliance.

In contrast, the United States has embarked on a different approach to its information architecture, building more from the bottom-up. Service providers have formed regional coalitions to interconnect their systems into health information exchanges, with an expectation that regional health information exchanges will eventually aggregate into a nation-scale system.

In a 2009 analysis of these implementations, Australian eHealth researcher Dr. Enrico Coiera considers the advantages and disadvantages of taking a top-down and bottom-up approach (Coiera, 2009). He notes that top down approaches tend not to integrate existing systems within the architecture particularly well, with many of those systems being replaced. However, the new national system may not meet the local needs of users as well as the systems they replaced, and may be less responsive to emerging changes in information needs. On the other hand, bottom-up approaches can result in

particularly complex architectures that tend not to be aligned with national policy goals (without significant financial incentives to move the market).

Australia has taken an approach more aligned to the one described by Dr. Coiera as a 'middle-out' approach. This approach focuses on inter-operability standards which can be applied in existing and new systems to support interoperability nationally. This approach recognises the significant investment made by governments and private health care organisations in health IT systems over the past 20 years by allowing these systems to continue to support the specific health care function for which they were designed, but to be able to interoperate with a broader health IT network.

NEHTA, integration infrastructure and national standards

This 'middle-out' approach to managing and sharing data is reflected in the purpose of the National eHealth Transition Authority (NEHTA) to accelerate the adoption of eHealth by delivering integration infrastructure and standards for health information.

NEHTA was formed in 2005 by the federal and state/territory governments of Australia to lead the uptake of eHealth systems of national significance. The first priority for NEHTA was to establish the essential foundations required to enable eHealth (NEHTA, 2009). These include:

- national health care identifiers to uniquely identify individuals, health care providers and health care organisations.
- clinical terminology and information; the distribution of the Australian extension of SNOMED CT, the Australian Medicines Terminology to uniquely identify medicines, and information models that specify how clinical information should be consistently structured.
- a national product catalogue and messaging specifications to enable eProcurement and improved supply chain management.
- standards for secure messaging and system security and authentication.

These foundations form, in turn, the foundations for the PCEHR. For example, health care identifiers will be used to uniquely identify consumers and health care organisations accessing the PCEHR. SNOMED CT and the detailed clinical information models defined by NEHTA will be used by systems connecting to the PCEHR. National authentication will be used to verify the identity of health care providers accessing the system.

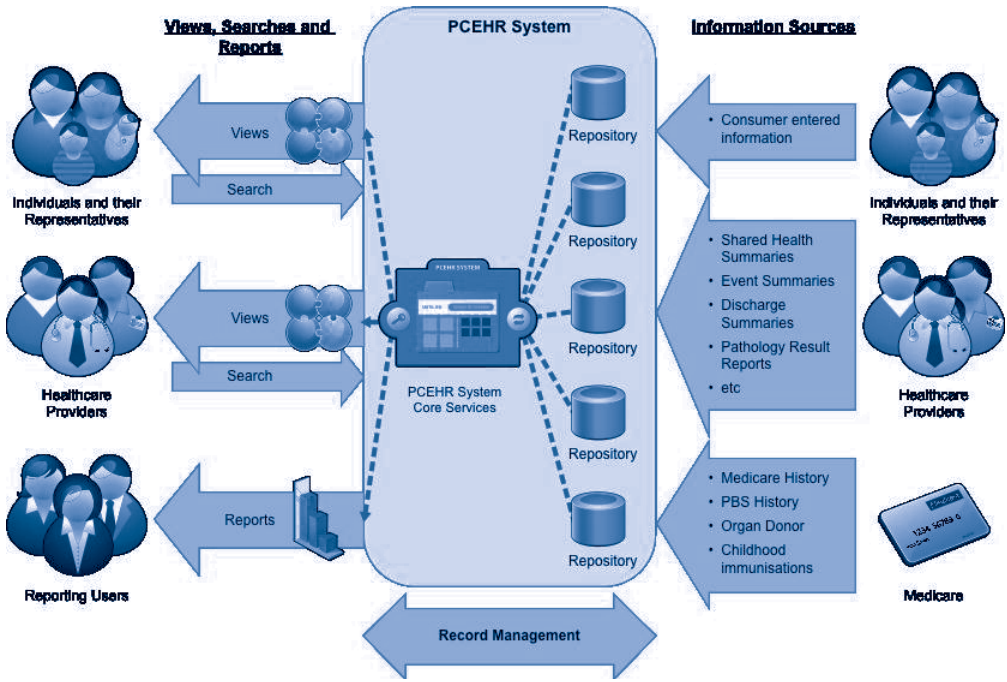
Another priority for NEHTA was to develop national standards for clinical documents such as referrals, specialist letters, hospital discharge letters and electronic prescriptions. These specifications will be used to define how these types of documents should be structured when sending them outside organisational boundaries and to the PCEHR.

Creating a scalable architecture

The architecture of the PCEHR itself involves some national infrastructure, but the focus is on the specifications and standards that defined how other systems will be able to connect with the national infrastructure.

The diagram below shows how existing and future repositories of data will be able to connect with the PCEHR.

Figure 7.2. The PCEHR system



Source: Australian Government (2011), "Concept of operations relating to the introduction of a personally controlled electronic health record system", www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/PCEHRS-Intro-toc (cited 2 January 2012).

This architecture is intended to create national infrastructure such as security management and shared health summaries to allow existing information sources to connect into the system and to enable future innovation to occur and connect into the system as the need arises. It is anticipated that much of the innovation is likely to occur in the consumer area in the medium term, which is reflected in the strength of the consumer application market[1] (Mobihealthnews, 2011). As one of 12 lead eHealth sites implementing the PCEHR[2], NEHTA is supporting private health insurer Medibank Private to develop a consumer health diary for consumers.

Addressing potential new risks

With improved access to health information comes the increased risk of unauthorised access. The ability for a person's private health information to be accessed without that person's consent has been a concern for many Australians.

This risk is being addressed by allowing consumers to have choices over how their health information in the PCEHR is accessed. The PCEHR system is an "opt-in" system in that consumers need to actively register to have one[3]. Beyond that, many other consumer controls are in place.

The approach to privacy in the PCEHR is based on the concept of having many complementary layers of protection. This includes technical controls, effective and transparent governance arrangements including enquiry and complaint processes, legal protections and penalties, and regulatory oversight.

Technical access controls

Technical access controls in the PCEHR include:

- Controlling who has access. A consumer can control how an organisation is added (or removed) from the list of organisations that are permitted to access a consumer's PCEHR.
- Setting basic access controls. These controls enable all health care organisations involved in providing health care to the consumer to access the consumer's PCEHR.A consumer can choose to be notified when a new organisation has accessed their PCEHR.
- Setting advanced access controls. These controls include setting up a Provider Access Consent Code (PACC) without which access to the consumer's PCEHR is not possible, except in an emergency, restricting organisations from being on the access list and managing document level access.

- Emergency access. Access controls may also be overridden in situations where the consumer requires emergency care, in line with current laws and practices.

Access controls can allow those documents considered sensitive by the consumer to only be seen by a limited group of health care providers chosen by that consumer. If a consumer does not wish to restrict their PCEHR in any way, access will be open to any health care providers legitimately involved in their care. In addition to these controls, a consumer may ask their health care provider to not upload a specific document into their PCEHR.

Some medical professionals have raised concerns that if consumers are able to restrict access to information in their PCEHR, this will create clinical risk because health care providers will be basing their decisions on only part of the story. In developing the specifications for the PCEHR, NEHTA acknowledged the importance of access to accurate clinical information for good clinical decision making. However, NEHTA also noted the reality where consumers currently exercise choice in the information they provide to different health care providers. The PCEHR is intended to increase the control that consumers have over their information, not reduce it. Therefore, the option for consumers to withhold information in some circumstances remained in the design. It is important to note that the PCEHR will not change the current processes by which health care providers communicate directly with each other about a consumer's health care.

Governance arrangements

Governance arrangements are set out in draft legislation that was before the Parliament of Australia at the time of writing. They include:

- The system operator defined in legislation. This will initially be the Secretary of the Department of Health and Ageing or another body established by the regulations.
- Establishing a jurisdictional advisory committee to advise the System Operator on matters relating to the interests of the Commonwealth, States and Territories. The jurisdictional advisory committee will ensure State and Territory involvement in the operation of the PCEHR system.
- Establishing an independent advisory council to advise the System Operator on matters relating to the operation of the system, and in particular consumer security, privacy and clinical matters relating to its operation. It will ensure the involvement of key stakeholders, including consumers and health care providers.

- The role of the Ministerial Council[4] defined in legislation – the Minister must consult with the Ministerial Council on various matters, such as making regulations, providing reports on system operations and privacy management, and appointing a person to review the operation of the Act.
- Operating enquiry and complaint processes – the System Operator will provide a call centre to allow consumers to register or withdraw from the PCEHR system, manage their access controls, or make an enquiry or complaint.

Legal protections

Legal protections are set out in draft legislation that was before the Parliament of Australia at the time of writing. They include:

- Civil penalties for any unauthorised collection, use and disclosure of health information contained in a person's PCEHR. These civil penalties will apply to consumers as well as other entities, including corporations.
- Some penalties incorporate fault elements. For example, the fault element in section 51 is designed to ensure that liability does not arise where there is inadvertent or mistaken access to a person's PCEHR, but does arise with intentional unauthorised or inappropriate access. The Draft Bill does not affect any existing criminal laws.
- In addition, an act or practice that contravenes the Draft Bill in connection with a consumer's health information included in a consumer's PCEHR would be taken to be an interference with privacy for the purposes of the *Privacy Act 1988*. This would enable complaints to be made to the Office of the Australian Information Commissioner and penalties applied.

Regulatory oversight

Regulatory oversight are also set out in draft legislation that was before the Parliament of Australia at the time of writing. It includes:

- The Information Commissioner is given enforcement powers in the legislation, in addition to power within the *Privacy Act 1998*. The PCEHR System Operator will routinely report to the Information Commissioner, and the Office has an ongoing role in the review of the legislation.
- A range of regulatory responses are provided, including penalty regimes, enforceable undertakings and injunctions.

- Mandatory breach reporting to the System Operator and Information Commissioner.

Overarching all these protections is the ultimate choice for consumers – whether to have a PCEHR or not. If a consumer does not want to share their information with health care providers through the PCEHR then they have the choice to abstain. The legislation provides that a consumer not be discriminated against or refused health care if they do not have a PCEHR.

How security will be managed

The PCEHR system will not replace or hold all the information contained in health care providers' records. Instead, the PCEHR system will draw upon information held in registered repositories (held in Australia only) to provide a summary view of a consumer's key health information, available to any health care provider in Australia that has registered for the PCEHR, including general practitioners, hospital emergency departments, specialist providers, nurses, dentists, physiotherapists etc.

This architecture avoids consolidating health records wherever possible, addressing increased security risks in merging databases (the 'honeypot' effect). Interoperability is achieved through NEHTA's publication of structured content specifications and CDA Implementation Guides which specify the way in which information will be structured in clinical messages. Software must pass conformance testing against the specifications in order to connect as a repository to the PCEHR.

An organisation which operates a repository will be required to apply to the PCEHR system operator to register as a repository operator and will be subject to security requirements to be set out in regulation. The system operator, repository operators or portal operators have mandatory notification obligations in the event of:

- unauthorised collection, use or disclosure of health information included in a consumer's PCEHR
- an event that compromised, or may compromise, the security or integrity of the PCEHR system
- any change to their conditions of registration, including whether the organisation changes such that it is no longer mostly owned and managed in Australia.

This level of mandatory breach reporting is over and above reporting obligations in existing privacy legislation in Australia and will commence on 1 July 2012, subject to passage of legislation through the Australian Parliament.

Fostering meaningful use

As discussed earlier, the Australian Government expects the PCEHR to progress its health reform goals. However, this technology is not being developed in isolation of broader reform initiatives, but as part of a co-ordinated programme to address the barriers of system fragmentation. The Government's health reform strategy *A national health and hospitals network for Australia's future: Delivering the reforms* (Commonwealth of Australia, 2010) outlines new governance and funding arrangements to support eight streams of implementations (including an eHealth stream). There is no expectation that a technical system will reform health care if it is implemented in isolation.

In a 2010 report, Booz & Company note that a reason many eHealth initiatives fail is because the costs and benefits are often misaligned in health care; those who are required to make the highest investment often reap minimal benefits, whereas those who stand to gain most incur fewer costs (Booz & Company, 2010). The authors note that governments are best placed to intervene in this distorted market, but caution that policy makers must fully understand the business case and system they aim to change.

In addition to the technical work to develop a PCEHR, Australia is progressing two complementary streams of work:

- Change and adoption: implementing a strategy to encourage uptake of the system across the health care sector and community. This will include a range of elements including working with software vendors to ensure desktop software is available in the acute and community sectors, supporting medical colleges to lead reform in their professions through more effective use of ICT, and providing support and incentives to parts of the sector that require investment in technology or significant changes to business processes
- Benefits realisation: developing measures to baseline health care outcomes and track changes related to the implementation of the PCER over time

These initiatives will not only measure and monitor progress, but will inform changes required to revise take up strategies based on the experience of implementation. For example, since July 2010, incentives have been in place to pay pharmacists 15 cents for every prescription they dispense electronically; however, there have been very low levels of take-up in the pharmacy sector. This is partly due to a lack of incentives to prescribers (the other side of the transaction) and a lack of pharmacy software available in the market that implements the NEHTA electronic prescription specifications. Australia is now considering options to accelerate implementation of

electronic prescriptions in pharmacy and GP software, and strategies to increase the number of electronic prescriptions written by prescribers. An end to end strategy that addresses behaviour chain of all participants is more likely to achieve the desired adoption outcome, but can be a challenge where incentive programmes are tied into national agreements with parts of the medical sector, which are often refreshed every 2-3 years.

Conclusion

Since 2005, Australia has progressed health care reform through the agenda of an open information architecture for health through the development of eHealth foundations and infrastructure. These foundations will be applied in the PCEHR which will be available from July 2012.

Over recent years, many of the eHealth foundations were delivered, including health care identifiers, consistent clinical terminology and standards for secure messaging. Since that time, there has been an increasing expectation on NEHTA to support implementation and demonstrate return on investment on eHealth expenditure. Despite many studies on expected benefits of investment in eHealth, there are few studies on the impact of large scale information technology investments on health care outcomes at a population level. This is perhaps because there have been few implementations beyond local pilots, although this is changing with large scale implementations in the United Kingdom, the Scandinavian countries, Singapore and North America. It could also be because eHealth tends to provide infrastructure that enables health care to be delivered in a more effective and efficient way, but does not in and of itself provide the benefits, so proving a causal link could be problematic.

Australia is currently developing measures to monitor the benefits of the PCEHR. However, there would be benefit in further research on methodologies to measure improved health care outcomes as a result of eHealth implementations, aside from studies of eHealth pilots.

The PCEHR and an open information architecture is an important step for Australia to provide consumers with access to information and empower them to play a more active role in managing their health care. While it will contain basic information in the initial implementation, the architecture will allow innovation and other connections into the future as the community demands this and the commercial sector and governments respond.

Notes

1. Over 9 000 iPhone health apps were available for consumers in September 2011.
2. Information about the lead sites is available on the NEHTA website: www.nehta.gov.au/ehealth-implementation/pcehr-lead-sites.
3. Strategies to stimulate consumer uptake are currently being finalised, but are likely to include direct communication to targeted cohorts such as people with chronic conditions, and mothers with babies, through targeted campaigns and engagement with consumer groups.
4. The Ministerial Council includes membership of Ministers of health departments in each Australian State and Territory.

References

Australian Institute of Health and Welfare (2008), *Australia's Health 2008*, Cat. no. AUS 99, AIHW: Canberra.

Australian Institute of Health and Welfare (2006), *Chronic Diseases and Associated Risk Factors in Australia*, AIHW: Canberra.

Booz & Company (2010), "Optimising eHealth value: Using an investment model to build a foundation for program success", pp. 2-3, www.booz.com/anzsea/home/40212171/40212709/40213345/eHealth (cited 16 December 2011).

Coiera, E. (2009), "Building a national health IT system from the middle out", *Journal of the American Medical Informatics Association*, 16:271-273.

Commonwealth of Australia (2010), *A National Health and Hospitals Network for Australia's Future: Delivering the Reforms*, www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/DeliveringTheReforms (cited 31 December 2011).

National eHealth Transition Authority (2009), *NEHTA Strategic Plan 2009-2012*, www.nehta.gov.au/about-us/strategy (cited 2 January 2012).

National Health and Hospitals Reform Commission (2009), *A Healthier Future for All Australians. Final Report of the National Health and Hospitals Reform Commission,*

www.health.gov.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report (cited 31 December 2011).

Private Health Insurance Administration Council (2011), Quarterly statistics: December 2011, www.phiac.gov.au/resources/file/quarterlystatistics/Qtr%20Stats%20Dec11.pdf (cited 11 March 2012).

Weitzman, E.R., L. Kaci and K.D. Mandl (2009), "Acceptability of a personally controlled health record in a community-based setting: implications for policy and design", *Journal of Medical Internet Research*, www.jmir.org/2009/2/e14/#ref1.

Chapter 8

Strengthening our capability to analyse big data streams in health systems: The challenges

Sharon-Lise Normand

In a broad range of health areas, data is being collected at unprecedented scale, and the quantity and quality of personal health data has grown exponentially and will continue to grow in the future. As technology pushes forward, the diversity of personal information, such as genomic data, laboratory data, diagnostic data, and image data, will also continue to rise. This chapter examines how the opportunities to learn and generate value from big data systems will depend on the statistically valid use of this information.

The excitement of big data systems rests on the hope that use of timely, comprehensive, and high quality data will strengthen all aspects of health care – from disease prevention to improvement in health and in quality of life. There is little doubt that in a broad range of health areas, data is being collected at unprecedented scale, and the quantity and quality of personal health data has grown exponentially and will continue to grow in the future. As technology pushes forward, the diversity of personal information, such as genomic data, laboratory data, diagnostic data, and image data, will also continue to rise.

The opportunities to learn and generate value from big data systems will depend on the statistically valid use of the information. The sheer size and heterogeneity of the data being collected is a major challenge. Unfortunately, the majority of statistical approaches to inference were developed in an era when "sample sizes" were relatively small, and when data acquisition technologies and computing power were limited.

This chapter focuses on the practical and theoretical statistical challenges introduced by big health data systems for assessing causal relations. For ease of exposition, issues are discussed in the context of structured electronic ambulatory, inpatient, registry, and billing medical data collected during routine care (Box 8.1) where the objective is to identify effective therapies. Focusing on these data types presents a sufficiently rich context to highlight key statistical challenges and to provide meaningful perspectives. Broadening the data types will, of course, raise additional analytical issues. Throughout, big data and high dimensional data are used interchangeably.

Box 8.1. What is routine care?

Routine care is a term used to describe the full spectrum of patient care practices in which health care practitioners (physicians, nurses, etc.) have the opportunity to provide care. Sometimes referred to as (1) usual care, (2) usual circumstances of routine practice, or (3) typical patients under normal practice circumstances. Routine care contrasts with patient and health care provider characteristics delivered in randomised clinical trial settings where, by design, (a) specific and often narrow patient inclusion criteria and (b) centers of excellence are utilised in randomised settings.

Some statistical challenges with big health data

While many statistical considerations arise with big health data, the focus here is on problems that appear when estimating causal relations using observational data that are high dimensional. The dimensionality issue poses many estimation, classification, and visualisation problems in of itself. Similarly, the observational nature of the data threatens the validity and the certainty of causal associations. Taken together, however, unique statistical issues surface – paradoxically, with big health data, the number of experimental units is much *smaller* than the number of parameters (Box 8.2) – how to measure the strength of evidence of a causal relation in such context, how to produce evidence of a causal relation, and how to combine evidence to learn about a causal relation. For example, is the use of statistical significance testing as a measure of evidence wise? If big health data contain virtually everything that explains who gets a particular treatment and how that treatment causes changes in an outcome, is there really a need to use randomisation? Should information obtained from different health care systems from different countries be combined in order to determine the effectiveness of particular treatments?

Box 8.2. With big health data, the number of experimental units is often much smaller than the number of parameters

What is big? One measure of big is defined by the ratio of the number of experimental units, n, divided by the number of unknown parameters, p, which, loosely, measures how much information is available to estimate each unknown parameter. The experimental units could be patients, physicians, hospitals, or ambulatory practices. This ratio is important because virtually all introductory statistical texts recommend that the number of experimental units should be much larger than the number of parameters when making inference. The reason for the recommendation is that the theoretical justification for the use of the majority of statistical tools is based on what happens as n gets large when p is fixed. Consider use of linear regression to estimate the relationship of age on the patient satisfaction after undergoing surgery in a cohort of 100 patients. Here the experimental unit is the individual, the number of unknown parameters is two (an intercept and an age coefficient), and the number of experimental units is 100, yielding a ratio of 50. Thus, there is approximately 50 independent pieces of information to estimate each unknown parameter. With big health data, the number of experimental units is much *smaller* than the number of parameters. In genomics, for example, expression levels for thousands of genes in a (relatively) small number of individuals may be collected yielding a ratio much smaller than 1 – a small amount of information to estimate each parameter. New theory and new tools, beyond those that expedite the mechanics of searching and accessing information, will therefore be required to efficiently produce statistically valid information in this new environment.

Measures of evidence

The use of big health data systems for learning what works will need to change at least two widely held beliefs. The first is that evidence for determining whether a therapy is effective should be based on statistical significance-testing. This approach involves specifying two competing hypotheses, the null hypothesis that assumes that there is no difference in efficacy between two treatments and an alternative hypothesis that assumes there is a difference between the two treatments. A statistic is calculated using what was observed, such as the average survival difference between two groups of patients exposed to the two treatments. Then the probability of "obtaining an average survival difference equal to or more extreme than what was actually observed (assuming there *really is no difference between the two treatments)"* is calculated.

This probability, denoted the p-value, reflects a measure of discrepancy between the observed data and the null hypothesis – small p-values (in medicine, almost universally those < 0.05) indicate that a discrepancy exists. Understanding what this discrepancy means (see Westover et al., 2011 and references therein) and how to translate the results into clinical practice has generated much confusion, leading to numerous misinterpretations (Box 8.3). By construction the p-value assumes the null hypothesis is true so clearly it cannot provide a measure of evidence for the null hypothesis. Similarly the p-value is not a measure of evidence for the alternative hypothesis. This limitation exists for both big and small data.

Box 8.3. Common misinterpretations of p-value < 0.05

- There is a less than 5% likelihood that the results are due to chance.
- The probability that the two treatments are no different is less than 5%.
- The probability that treatment A is different from treatment B is greater than 95%.

P-values pose additional problems for big data, however, because of their dependence on sample size. Studies based on extremely large databases are more likely to find a statistically significant treatment effect that is not meaningfully different from the null value (Ioannidis, 2005). Various "fixes" have been suggested, such as requiring a more extreme p-value, for example requiring the p-value to be less than 0.001, to declare statistical significance and conclude a causal relation, but these strategies aim to reduce the overall error rate rather than produce a measure of *evidence* for a

hypothesis. More training will be required to have investigators focus on the substantive significance of study results, or on measures of evidence beyond p-values.

The second widely held principle relates to the existence of a *fixed hierarchy* of the strength of the evidence provided by a study (Table 8.1; Harbour and Miller, 2001). The strength the study design depends on its ability to minimise the possibility of bias and to maximise generalizability with preference given to tightly controlled randomised trials, followed by generalizability, blinding of study participants, control of reporting outcomes, etc. Undoubtedly some types of information are better than other types to answer particular questions. The hierarchy of evidence *changes* with the decision to be made. For example, determining whether a "first in human" medical technology is clinically efficacious may require randomised controlled testing (i.e. information derived from random allocation and testing of the specific treatment or technology in the populations meant to receive the new technology). On the other hand, if a health insurer wishes to determine whether to cover the costs of a new surgical procedure for its beneficiaries, then a cohort study including patients, health care providers, and delivery systems encountered in routine care would be strongly preferable. Big health data systems can provide valuable information for these types of questions.

Table 8.1. Levels of evidence

High-quality meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials with a very low risk of bias
Well conducted meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials with a low risk of bias
Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials with a high risk of bias
High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
Well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
Non-analytic studies (such as case reports, case series)
Expert opinion

Source: Adapted from Harbour and Miller (2001), "A new system for grading recommendations in evidence-based guidelines", *BMJ*, 323: 334-36.

In addition to the fixed hierarchy of evidence, the inclination to select *one* level in the hierarchy, such as information based on a well conducted randomised controlled trial or on many trials, at any particular point in time is surprisingly limiting and unrealistic. With the emergence of big data, the technical ability to assemble *all* available data will increase. Statistical tools to combine data across all levels of the hierarchy require further development and study.

Producing evidence

The growing interest in estimation of causal relations has been driven by numerous factors: the evolution of data acquisition and storage technologies, the escalation in the processing power of computers, the broadening of research teams and questions, and the global proliferation of information. While many of the research domains are new, the basic statistical problem is old – how to determine cause and effect. There are three main concerns in estimation of a casual relation using big data. These are further described below.

Confounding

The main concern in estimation of a casual relation using observational data is confounding – variables (denoted confounders) that influence both the treatment and the outcome exist. Ignoring such variables when assessing the association between a treatment and an outcome can lead to wrong conclusions. For instance, suppose there is interest in determining whether patients implanted with metal artificial hips require hip revision surgery sooner than patients implanted with ceramic hips. If patients implanted with metal hips are older than those implanted with ceramic hips, the difference in time to revision surgery between the two groups of patients may be due to the differences in age between the two patient groups rather than to the different hips. Randomisation ensures that, on average, individuals randomised to different treatments are similar with the exception of the treatment assigned. In the absence of randomisation, adjusting for observed baseline health and age differences in patients who receive different treatments is critical in order to attribute differences in the outcomes to the treatment. The availability of big health data systems facilitates the estimation of causal relations, because, by construction, they contain information on a large number of potential confounders, e.g. large p, to improve adjustment of baseline health differences between groups of patients who receive different treatments. Ideally, if all variables that influenced which patients received which treatments were available,[1] randomisation would be unnecessary. However, large data systems with many variables or "high dimensional data" introduce other challenges and require new and innovative methods for analysis.

High-dimensional data

Fields such as genetics rely on high-dimensional data, and – thanks to recent advances in technology – high-dimensional data are becoming increasingly common in health, behavioral, and social sciences. Examples of high-dimensional data include gene and protein expression data where tens of thousands genes may be available for a thousand subjects, imagery data where new optical sensors produce imagery in a full spectrum with thousands of frequency bands measured, and sensor array information in neuroscience where sensors attached to scalp will produce thousands of samples per second. The problem is how to extract meaningful statistical and biological information. High dimensional data are difficult to work with for a number of reasons. First, the "large p, small n" problem described earlier in this chapter requires novel dimension reduction strategies and corresponding theoretical justifications. Suppose in assessing the survival advantage of a new drug, 1 000 potential confounders are available and each are binary valued, e.g. symptom is present or absent. This many variables lead to 21 000 (a big number) possible regression models that could describe the relationship of confounders and of treatment to survival. Surely only a relatively few of the 1 000 variables are true confounders and so the goal involves seeking a solution to find those variables that are "important" for understanding the underlying phenomena of interest, getting rid of those for which there is no relationship (i.e. the regression coefficients are zero). Several "dimension reduction" methods have recently been developed which rely upon this notion of sparsity – the idea that only a relatively small number of variables are needed to parsimoniously represent the underlying structure of the data. Some methods assume that many of the model parameters are zero by imposing a penalty on including too many variables. The approaches can be used to identify the true confounders and reliably estimate their values[2] but much more experience and new tools are required. Practical issues, including how to visualise data with so many dimensions and what are the appropriate diagnostics to assess the validity of the models, are largely unsolved.

Perhaps the most common dimension reduction approach involves limiting the number of confounders based on perceived clinical relevance and then estimating a single model that includes only the clinically relevant confounders. In reality, many models may fit the data well and in practice many models will be estimated although only one will be reported. This leads to a second problem with big data – selective inference – i.e. drawing inference on a selected subset of the parameters, a subset that is selected because the parameters within seem interesting after viewing the data. The inference can be in the form of hypotheses testing, point estimation or interval estimation.

Selective inference is both common and unavoidable with big data, yet it is an acute problem that if unattended hampers the replicability of discoveries.

One solution to selective inference requires publication of protocols and computer code, or report of a false discovery rate.[3] However, this basically is a reporting solution and does not address the uncertainty inherent in the final results nor does it address the fundamental fact that several models are typically sufficient to describe data. For example, introductory regression text books recommend a number of different statistics for determining the "best" model. Yet, historically, we know that the different statistics can lead to selection of different models. Basing results on a single model is somewhat arbitrary. Averaging findings across candidate models should provide more robust conclusions (Raftery et al., 1997) but this strategy requires quite a paradigm shift.

Increasing numbers of possible comparisons

The expansion of health information not only increases the number of available confounders, but also the number of different treatments and different outcomes to compare. Suppose interest centers on comparing the effectiveness of treatments for schizophrenia that are available in route care. The number of different treatments can be surprisingly large – there are pharmacological treatments, psychosocial treatments, and combinations of these. Even within pharmacological treatments, there are many atypical antipsychotics and many different conventional antipsychotics. Thus, a third challenge with big data is the large number of possible comparisons. Accompanying the numerous causal comparisons is the identification of confounders. While methodology exists to estimate causal relations when there are many treatments (Tchernis et al., 2005), there is little practical experience when the numbers of treatments are greater than four or five.

Lastly, big data will likely include many diverse types of outcomes. While these will provide a comprehensive assessment of the effectiveness of treatments, the multivariate nature of the outcomes introduces other challenges – how to model the collection of outcomes simultaneously. The two most common strategies used to deal with the problem of many outcomes are to *(1)* pool the outcomes through the creation of a composite endpoint or *(2)* analyse each outcome separately. Pooling approaches are simple to describe and to implement, but have several undesirable properties. Separate analysis of each outcome may be based on different subsets of individuals when outcomes are missing for some of the outcomes, and this leads to interpretation problems. Simultaneously modeling the outcomes seems ideal but multivariate distributions that appropriately characterise the multiple outcomes are not practical because, often the multiple outcomes will be

measured on different scales (e.g., body weight, presence of an infection, time to recurrence), and finding multivariate distributions to accommodate this feature is tough. There are several statistical approaches now available to researchers to analyse multiple outcomes simultaneously that overcome these issues but have not been widely embraced[4]. Moreover, the statistical properties of these procedures in large databases are unknown.

Pooling related but distinct information

One of the basic premises in data analysis is that information can be combined in order to learn something – averages of infection rates are computed and compared to prior years, or regression models are used to pool information across individuals to characterise the relationship between the risk of infection and age. The justification for combining data depends on several factors, not the least of which is context, e.g. the desire to combine apples with apples. The size and diversity of big health data and its potential global availability affords many pooling opportunities. For instance, to determine if the occurrence of a rare but lethal adverse event is caused by a particular therapy, pooling information on adverse events across many countries or regions will bolster the probability of finding a real causal relation because more data will be utilised.

Is it reasonable to combine all the data? How the data should be pooled depends on what level of information is available, and the number and size of factors that may impact variation in the information. For instance, pooling adverse events that have been patient-reported with those that have been physician-reported may raise some concerns. Other key data features include data completeness (extent of missingness), data quality (invalid data entries), the units of measurements (whether averages or the constituent components are collected), and the design (blinded reporting of outcomes, retrospectively collected, prospectively collected, randomised).

With powerful data acquisition technologies, why not pool more and different types of data if there are key areas where uncertainty exists? Suppose there is interest in determining whether metal artificial hips cause hip revision surgery sooner than other types of artificial hips for diabetic octogenarians living in rural areas. Using big health data, information for this likely small subgroup could be queried within and across big health data systems. The assumptions underpinning this approach are that subgroups of patients implanted with artificial hips are similar across geographic regions, that hip revision rates following implantation with artificial hips – regardless of the material from which they are constructed – are related, and that the engineering performance characteristics of the artificial hips are related (again regardless of the material). The particular relationships are assumed to exist, they may be strong or weak, but assembling all the available information may

reduce uncertainty where there is little information (Normand, Marinac-Dabic, et al., 2010; Normand and McNeil, 2010). Using the rules of probability, statistical models can be posited to combine the data. There is very little practical experience in combining information of this sort and few inferential tools to do so.

Concluding remarks

This chapter summarised a few key statistical issues in the use of big data , specifically those that result from the intersection of high dimensional data and observational data for estimating causal relations. Undoubtedly, there are many other important challenges, such as issues of data security and protection of personal health information, methodology to validate or assess the quality of big health data, and data documentation. However, even in the context of the few issues considered here, substantial research is required to take advantage of the benefits that big data presents:

- A better understanding of the theoretical basis, for the tools utilised in the analysis of big health data systems (e.g. the asymptotic properties of estimators in the "big p, small n" setting).
- More training to focus on the substantive significance of study results and more practical experience with measures of evidence beyond p-values.
- A better understanding and enhanced experience with tools that exploit the sparsity of unknown parameter spaces, including the development of data visualisation techniques to support the modeling tools.
- Theoretical development of model averaging principles when estimating causal relations and corresponding practical applications.
- Initiation of educational programmes to shift evidence paradigm away from findings based on a single model to model averaging to accommodate the increased uncertainty and the validity of findings.
- A better understanding of the operating characteristics associated with causal estimation methodology in the presence of many treatments and many outcomes.
- Development of inferential tools that will enable pooling data related but distinct sources of information and accompanying methodology to validate results.

Notes

1. We would also need to know the specific form of the relationship of each confounder with the choice of treatment and with the outcome.
2. Penalised least squares, least absolute shrinkage and selection (Lasso) methods, and sparse additive models are some examples.
3. A false discovery rate is a procedure that controls the expected proportion of incorrectly rejected null hypotheses.
4. See http://www.math.smith.edu/multinform/index.php.

References

Goodman, S.N. (1999), "Towards evidence-based medical statistics. 1. The p-value fallacy", *Annals of Internal Medicine*, 130, 995-1004.

Harbour, R. and J. Miller (2001), "A new system for grading recommendations in evidence-based guidelines", *BMJ*, 323: 334-36.

Ioannidis, J.P. (2005), "Why most published research findings are false", *PLOS Medicine*, 2(8):e124.

Normand, S.-L.T., D. Marinac-Dabic, A. Sedrakyan and R. Kaczmarek (2010), "Rethinking analytical strategies for surveillance of medical devices: the case of hip arthroplasty", *Medical Care*, 48:S58-S67.

Normand, S.-L.T and B.J.McNeil (2010), "What is evidence?", *Statistics in Medicine*, 29(19), 1985-1988.

Raftery, A, D. Madigan and J. Hoeting (1997), "Bayesian model averaging for linear regression models", *Journal of the American Statistical Association*, 42(437), 179-191

Rawlins, M. (2008), "De testimonio: On the evidence for decisions about the use of therapeutic interventions", *Lancet*, 372, 2152-2161.

Rubin, D.B. (2010), "On the limitations of comparative effectiveness research", *Statistics in Medicine*, 29(19), 1991-1995.

Tchernis, R., M. Horvitz-Lennon and S.-L.T. Normand (2005), "On the use of discrete choice models for causal inference", *Statistics in Medicine*, 24, 2197-2217.

Tunis, S.R., B. Jenner and M. McClellan (2010), "Comparative Effectiveness Research: Method development, policy context & research infrastructure (with discussion)", *Statistics in Medicine*, 29(19), 1963-1997.

Westover, M.B., K.D. Westover and M.T. Bianchi (2011), "Significance testing as perverse probabilistic reasoning", *BMC Medicine*, February, 9:20.

Chapter 9

Building a smarter health and wellness future: Privacy and security challenges

Carl A. Gunter

This chapter explores emerging privacy and security challenges for health information technology (HIT) that call for new ideas. Six key challenges are identified and discussed: access controls and audit, trusted base, automated policy, mobile health, identification and authentication, and data segmentation and de-identification.

Advances in information technology (IT) promise to improve health and wellness by holding and managing detailed and precise records related to diagnoses and treatments and encouraging good lifestyle choices through applications like fitness monitoring. These benefits will come through improved abilities to collect, manage, share, and act upon digital information using computers and digital network links. Many of these technologies will use broadcast wireless communications, global network connectivity provided by the Internet, and shared hosting of data and computations based on cloud computing. Each of these technologies, and many others likely to be used, raise essential questions about the privacy and security of the data they store or transmit.

For example broadcast wireless data is easily "sniffed" so that even encrypted links can leak information through traffic analysis. The Internet suffers notorious problems with skilled and ethically challenged hackers who have access to systems across the world, and cloud computing is in its early days and displays shifting conventions about how personal data will be mined for the commercial beneft of the cloud provider.

This chapter explores emerging privacy and security challenges for health information technology (HIT) that call for new ideas. While there is much to be gained in security of HIT by simply applying procedures and protocols that have worked in other areas like the financial services sector, there are many special characteristics of HIT and trends in HIT that call for innovation. This may be either in the way existing techniques are applied or in the need for new techniques.

To see this in an example, consider the analogy between personal health records (PHRs) and personal online banking. PHRs make health care provider data about a patient available to the patient, just as personal banking makes bank data about a customer available to the bank customer. Online personal banking and PHRs thus have many privacy and security issues in common. There is a need for good authentication protocols (keys and passwords) and support for an encrypted communication channel. Patients, like banking customers, may want to merge information from multiple sources to get a unified view, as some financial services packages (like tax preparation software) enable. There is common need to share data with third parties: just as a patient needs to show medical records to a new doctor (like a specialist), a banking customer may need to show data to a financial entity (like a mortgage lender). However, beyond these similarities there are also critical differences. For instance, consumer financial data are relatively simple compared to medical data, which use a large and changing vocabulary of terms and codes for medical conditions and treatments that can be difficult for doctors to

understand, let alone patients. This has consequences for privacy because patients need help understanding how to share their medical data with parties that could benefit from having it. This includes sharing with members of the medical profession of course, but also sharing with third parties like online vendors who offer to host medical data and provide analytic services. Even in circumstances where financial data is as complex as health data, the means and motivations for sharing are quite different. In addition, it is not the case that the financial services sector has solved its own security problems fully. Problems like identity theft remain a major challenge for financial services even as they are also becoming one for health care.

We consider six key areas where research is needed to improve techniques for privacy and security of HIT. Before attending to these key areas, it will first be worthwhile to provide some background on HIT policy developments that raise privacy and security issues, and to make some introductory remarks about the concepts of privacy and security. Then, we will concentrate on the following key areas: access controls and audit, trusted base, automated policy, mobile health, identification and authentication, and data segmentation and de-identification. We conclude with discussion of some cross-cutting concerns.

HIT directions driving privacy and security issues

There are a variety of important trends in HIT that drive issues with privacy and security. We begin by discussing a few of these. The concept of the learning health care system, which we describe in a moment, provides a framework for thinking about trends in health data use. Two specific areas illustrate the opportunity for learning based on HIT. First, health information exchange between providers, patients, researchers, and public health make provider data available for learning and, second, mobile health enables new types of data to be collected from individuals by monitoring information about their lifestyles.

Learning Health System (LHS) is an agenda developed by the Institute of Medicine (IOM) Roundtable on Value & Science-Driven Health Care (Grossmann et al., 2011): "Our vision is for a health care system that draws on the best evidence to provide the care most appropriate to each patient, emphasises prevention and health promotion, delivers the most value, adds to learning throughout the delivery of care, and leads to improvements in the nation's health."

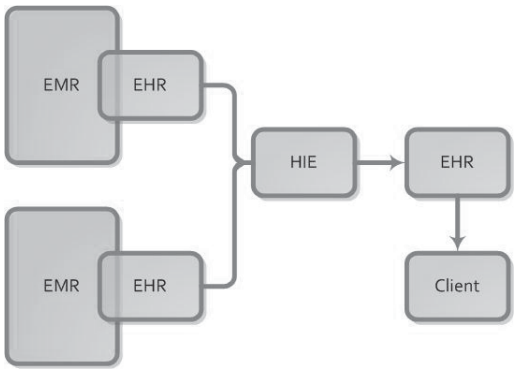
Although this IOM statement is aimed at action in the United States, international efforts have similar goals. The stated goal for LHS is to reach a point at which clinical decisions are supported by accurate, timely, up-to-date information that reflects the best available evidence.

The connection of this agenda to HIT is the enabling capability of computers and digital networks to collect and transmit data that can be used to develop evidence and assure that the right information based on this evidence is in the hands of the provider or individual at the point a health decision is required.

In particular, HIT is a critical enabler of Health Information Exchange (HIE), a phrase that typically refers to the exchange of health data between diverse parties for the better care of individual patients. A paradigmatic example is enabling the primary care giver for a patient to send the patient's record to another provider where the patient needs specialised or emergency care. Such exchanges save money by avoiding unnecessary tests and can save lives by reporting safety critical information like medications and allergies.

Used as a noun, "HIE" is a system that facilitates exchange, often by setting up secure and standardised communications between providers to serve as an infrastructure for exchange. One key issue addressed by HIEs is inter-operability. A typical architecture for such an HIE appears in Figure 9.1. The Electronic Medical Record (EMR) of a provider is (typically) a proprietary system that holds health records in a computer. A portal allows records from the EMR to be converted to a standard EHR format such as a Continuing Care Document (CCD). When a provider seeks a record for a patient from the HIE, the system returns a consolidation of such records obtained from the participating providers that have records on the patient. This consolidated record is then made available to a client user like a doctor in an emergency room that is treating the patient.

Figure 9.1. HIE architectures

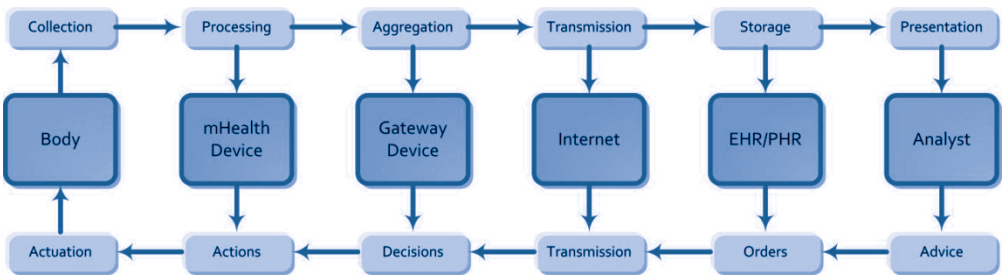


There are many variations on this theme. For instance, the records can be pushed to the HIE central repository and stored there for quick recall, or they can be retrieved only on demand, so that records not requested are never seen by the HIE. These and similar choices affect a second key issue addressed by HIEs, namely privacy and security. We discuss these issues in some of the challenges below.

Mobile health (mHealth) concerns the increasing use of mobile sensors to monitor health and wellness conditions and, for certain types of devices, carry out actions to improve health (actuators). On the one hand mHealth devices like pedometers in cell phones assist with measurements that encourage healthy lifestyles. On the other hand, mobile implants, which can be broadly classified as mHealth devices, collect health vitals and can intervene with actuation in an emergency. For example, an implanted defibrillator intervenes with an electric shock when it detects a cardiac emergency.

Risks are quite different for these two extremes, but there are an increasingly large number of devices that fall between these extremes. There is interest in having insulin pumps that communicate with cell phones to facilitate viewing and sharing of data. Figure 9.2 illustrates a common pipeline of communications for mHealth devices. A sensor on (or within) the body collects data that flows to an mHealth device. This device talks, for instance, to a cell phone or wireless station (gateway device), which, in turn, sends the data over the Internet to an EHR, PHR, or EMR where it is available for viewing by an analyst (a doctor for instance). The pipeline can then be used in reverse for configuration or actuation. The overall pipeline can also be"short circuited"at various stages. For instance, the individual wearing the device might process and view the data on his or her device without sending it over the Internet.

Figure 9.2. mHealth pipeline



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Privacy and security

A few background comments on privacy and security will be useful for this discussion. First of all, it is helpful to distinguish between these two concepts. Privacy is notoriously difficult to define precisely (Nissenbaum, 2011), but it commonly refers to the desires and expectations of individuals about how, when, what, and to whom information about themselves is revealed to others. Privacy violations are violations of these desires and expectations. If Alice tells her friend Bob a personal fact about herself in confidence, like, say, that she has been diagnosed with cancer, and then Bob mentions this in a Facebook comment, Alice may well consider this a violation of her privacy. As recognised as far back as the Hippocratic Oath, it is essential to assure that patient privacy is respected during the provision of health care and treatment services. Without this assurance many individuals will not seek the health services they need.

By contrast, security typically refers to instances in which information is deliberately accessed and used for unauthorised or illegal purposes. For instance, if Alice responds to a phishing email and reveals her personal banking password to a hacker who accesses her bank account, then Alice is a victim of a security breach. Privacy and security are closely related. For instance, the attacker who accessed Alice's bank account will probably learn how much money she has, a fact she would not have revealed to a stranger.

The improper use of HIT can increase the danger of compromising the security and privacy of individuals. HIT allows health information to flow easily from one place to another, a property sometimes called "liquidity". Providers exploit liquidity to share data with payers, researchers, public health, and other providers. These flows may well violate expectations of subjects. For instance, fitness data may be mined by an online provider to target advertisement to an individual based on readings collected by the individual's cell phone and stored by the provider.

Patients may feel that the data providers share with payers is more revealing of details than it needs to be. A common approach to addressing these problems is to subject information flows to the consent of the subject whose information is being shared. Consent is a cornerstone concept of medical privacy and provides a ready baseline for judging privacy protections in a given context. However, it does have important limitations.

First of all, rules for the protection of the public sometimes over-ride consent, such as laws for reporting gunshot wounds to law enforcement. There are also rules to demand or allow reporting personal data for purposes of medical research or public health. Second, patients are not always in a good position to judge whether a detailed instance of information sharing is too

much or too little. Hence consent could decrease privacy by leading patients to make decisions to share data where they do not understand consequences that may be clear to persons with professional knowledge of the risks and benefits. In short, medical privacy and consent are deeply connected, but they are not equivalent.

Security threats in health care are an evolving concern. While in the financial sector the motives of an attacker are often clear, this is often not the case in health care. For instance, a phishing attacker wants to get types of private information that can be monetised in the online black markets, information like bank account passwords and credit card numbers. In the health care sector, where the data is usually not so clearly connected to a financial instrument, the motives are less clear.

Three factors need to be taken into account in predicting attacker motives and assessing security risks. First, health data often has associated administrative and financial data. For instance, patient demographics may well include enough information to get a credit card in the patient's name. Moreover, personal information can be used to file fraudulent claims. In countries where health care insurance is not available to everyone, there is an incentive for medical identity theft, in which an attacker gains the health care insurance benefits of another by impersonation. This obviously carries large risks for victims whose medical record is corrupted. Large-scale insurance fraud in the form of false billings is another common incentive.

Second, health data may become collateral damage in an attack. A computer virus is probably indifferent to whether it is infecting a home PC used for entertaining children versus a PC that runs a safety-critical process in a hospital. This threat is exacerbated by the regulatory review process for hospital equipment, which may slow the updating of software, hence preventing the rapid application of security patches. This could lead, paradoxically, to a situation where a home PC for children is more secure than the hospital PC. Detection of an intrusion in a hospital would result in the system being taken out of service until recovery is carried out.

Third, even if health data may motivate fewer attackers than in other sectors of the economy, it is often exceptionally critical to the safety of an individual and its corruption can be life-threatening. It may seem unthinkable that someone could deliberately consider corrupting health data, until it is done. We can look to instances like the 1982 poison Tylenol murders in Chicago as an unthinkable attack on the integrity of a health product to see that HIT systems are at risk to such extreme attackers. This sort of problem is likely to apply to IT contexts; for example, there was an incident in which the Epilepsy Foundation web site was used to upload images that cause seizures and migraines when viewed by some epileptics.

Access controls and audit

A key challenge for providers implementing HIT is to regulate access to patient information. The obvious step of establishing access controls to limit personnel access to a "by need" minimum is challenged by the complexity of clinical workflows and the high risk of denying access to key information, like drug allergies and so on, to personnel who might be involved in reacting to an emergency.

On the bright side, unlike rooms full of paper records, it is possible to trace, through electronic logs, which users look at which records so an auditor can use this information to detect abuses. There have been many examples of abuses that were caught in this way. Some involve access to the records of celebrities like athletes and actors; others involve incidents where, for instance, an employee of a provider accesses the record of a former spouse. These and other types of abuses are often addressed by investigations carried out after a complaint.

For instance, if an employee uses patient records to get credit card information, auditors can trace and identify the employee by carefully analyzing log data. This reactive procedure is increasingly inadequate because it does not scale up to new threats like large scale identity theft or to the increasing magnitude of the problem posed by the growth of providers and their connections through HIE. Research is needed to provide better automation so that large volumes of records can be examined by computer algorithms that are thorough and flexible enough to learn and infer threats quickly and feed experience from operational behavior back into preventative measures.

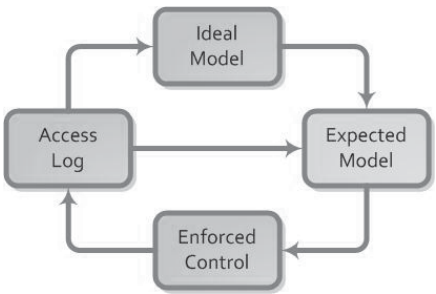
Two common strategies for addressing this problem provide steps in the right direction. One is to establish heuristics for common types of abuses, such as an employee inspecting the record of a patient with the same last name as themselves. A second is to set up rules which can be over-ridden in an emergency, a strategy sometimes called "break-the-glass" security. Heuristics suffer the problem that they cover only the types of abuses for which rules have been well-recognised and hence still have a reactive character. Break-the-glass has the problem that an overly restrictive set of rules may lead to so many instances of glass breaking that they cannot be meaningfully reviewed (Røstad and Øystein, 2007).

However, both strategies can be seen as contributing to a process that has developed more fully in other areas such as the financial services sector (credit card fraud detection) and messaging (spam detection). Adaptation to health care requires addressing issues specific to health care, such as the potentially high risks of a mistaken denial of access. The general idea is to develop

systematic ways to learn quickly from experience and use this learning process to manage access rights in a kind of continuous quality control. Figure 9.3 illustrates the approach known as Experience Based Access Management (EBAM) (Gunter, *et. al.,* 2011), which can be applied to reconcile differences between an ideal access model and the enforced access control.

Access logs are used to measure differences between existing enforced controls and an ideal model for access rights. The ideal model represents the rules that should be applied. For many reasons these rules are only partially reflected in the enforced controls implemented by the electronic records system. However, information from the access log can be compared to the ideal model. This comparison can itself inform an engineered system, here called the expected model, which is used to learn and model legitimate accesses for purposes of improving enforced control and generating action items for organisational enforcement. Technologies that aid the development of an effective expected model have been accelerating in recent years (Boxwalla, *et. al.*, 2011; Chen, *et. al.*, 2012) and will soon be funding their way into practice.

Figure 9.3. Experienced-based access management (EBAM)



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Trusted base

Providers are struggling with rapid changes in the systems they need to secure. Early hospital computing systems used mainframe computers that could be accessed from terminals located in a hospital facility. This trusted base was relatively easy to secure until the Internet offered remote access, but standard enterprise protections such as firewalls and virtual private networks (VPNs) were accepted as being sufficiently effective. Now the situation is increasingly complicated by a range of technology changes.

Consider, for example, bring your own device (BYOD) arrangements in which employees put sensitive data on their own cell phones and tablets, the use of cloud services in which patient records are held by third parties, participation in HIE systems that move data between a changing collection of institutions, and the deployment of patient portals, which provide a new attack surface that can be assailed by unauthorised users for access to provider information systems. All of these changes redefine the nature of the trusted base.

Another area of concern is the rise of Advanced Persistent Threats (APTs), which entail sophisticated attacks, possibly supported by capable attackers like intelligence agencies. While there is currently no evidence that these attacks target health records, they are creating significant levels of collateral damage to EMR systems, especially when such systems are attached to certain types of targets like government and university networks. Such threats spur the need for greater attention to defining and maintaining the trusted base of health care systems.

Dealing with changes in trusted base requires careful risk analysis shows to determine which systems most need protection; proportionate measures can be taken for these systems. For example, a university hospital system that prepares records for certain types of research can de-identify records before they are shared with researchers; this provides risk mitigation in cases where the systems used by the university researchers operate at a lower security level than the trusted base of the hospital EMR.

Protection mechanisms established for the NIH-funded National Center for Biomedical Computing (NCBC) aiming to integrate Biology and the Bedside (i2b2) provides a case study (Murphy, *et. al.,* 2011). The system aims at a balance in which data that is subjected to more risk, such as data released to the public, is given proportionately more protection using techniques like de-identification. Encryption is a powerful tool for addressing challenges with trusted base. This is well-illustrated by secure transport protocols that allow data to be transmitted "in flight" over the Internet even when Internet routers are not trusted. This technique is used broadly for health care data, but less progress has been made on protecting data "at rest" in storage systems. Many examples of breaches of health care data have been of this kind. In particular, if the data stored on a laptop, removable media, or backup media is encrypted, then its physical theft is less of a loss. Similarly, if the data maintained by a compromised cloud service is encrypted, the threat of a privacy compromise is greatly reduced.

Research is needed to make such strategies efficient and convenient enough to enable their universal deployment, particularly to protect data at rest. General techniques can be applied to health records to achieve many goals, but there are also good ideas specific to health care (Benaloh et al., 2009).

Automated policy

A key challenge faced by many health care organisations (HCOs) is the need to share EHRs and exchange health data securely through HIEs such as those being set up by many states and regions in the United States, and through rapidly evolving partnerships with various business associates. Most HCOs must comply with a diverse set of policies, both internal and external, to exchange health data. The cost of ensuring compliance with these policies can sometimes be quite high due to the need for human policy experts and analysts to evaluate whether the organisation is in compliance.

Current techniques to support health information exchange are too informal and manual to provide the desired efficiency and speed. For instance, if it is necessary to get an attorney to review and authorise each interstate data exchange by a provider in the United States, then a high level of exchange of EHR data will lead to a high level of expense (and delayed access). Enabling computers to settle policy decisions such as privacy compliance automatically can lead to reduced costs, improved care (though timely information exchange), and better support for secondary use of data.

Research is needed to determine reliable ways to formally express policies to enable fully automatic solutions. A benchmark that has been addressed by a number of studies (Breaux and Anton, 2008; DeYoung et al., 2010) is the formal specification of the US Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. We also require strategies to integrate and enforce formally expressed policies in common health care information architectures. Such advances will touch on other important areas like legal and medical ontologies and will inform the development of legal codes and consent management in the future.

Mobile health

A first concern for mHealth devices is how to secure the entire mHealth pipeline depicted in Figure 9.2. Some of the steps are familiar from current systems. For instance an enterprise laptop operating remotely will typically need to deal with a gateway device (like a wireless base station), the Internet, and an enterprise server. Typical solutions include security tunneling protocols like Transport Layer Security (TLS), IPsec virtual private networking, and

wireless WiFi protected access (WPA). These techniques apply to mHealth devices as well, up to a point. For instance, a pedometer integrated into a cell phone can use whatever security is used by the cell phone to communicate its readings to a server. A more interesting problem arises when the pedometer is independent of the cell phone and needs a secure communication link of its own. Bluetooth seems like a logical choice for this sort of application and many of the first generation of mHealth sensors do indeed use a cell phone as a gateway device and Bluetooth security to protect the communications out of the mHealth device. This approach is challenged by problems related to secure pairing (because many medical devices will not have displays), privacy concerns about discovery mode, interference with other Bluetooth devices, and the scalability of Bluetooth to larger numbers of devices (Mare and Kotz, 2010). The growth of wearable computing devices has spawned the new subject of body area networking (BAN) and security mechanisms appropriate to BAN will need to be developed.

Another area of concern is protecting the integrity and privacy of mHealth applications at nodes of the mHealth pipeline. For instance, a mobile application on a cell phone may share the platform with applications like video games downloaded from an application store. This type of sharing may expose significant safety risks particularly for actuator devices like insulin pumps. Yet another concern is the nature and motives of parties like EHR/PHR and analysts on the right side of the mHealth pipeline, many of whom will have business models that envision monetising health data through data mining. For instance, a health device may offer a "premium plan" for people to share their data in a pool for comparison. This is not a bad thing by itself, but such intermediaries are likely to use personal data more freely than, for example, HIPAA entities are allowed to do in the United States and this could violate expectations for many mHealth clients.

One of the primary areas of current concern for mHealth is to identify requirements for privacy and security that are special to the space (Avancha et al., 2013). Rules of the road for intermediaries need attention, but many of these can follow precedents like fair information practices. Other aspects seem newer. For example, there is an exceptional need to develop good isolation for applications on cell phones if mHealth applications are to run securely there. This problem is very similar to the trusted base issue of BYOD for cell phones in enterprise applications and it may be that the same security solutions can be used for both. However, there are instances where there is no clear analogy. For instance, the vulnerability of remote-controlled medical devices remains a concern since it has been shown (Halpern et. al., 2008) that current wireless links are vulnerable to attacks on the integrity of widely used types of implants. One interesting direction is the use of "amulet" like auxiliary devices that provide security with good tradeoffs for

these requirements (Gollakota et al., 2011; Sorber, et al., 2012) achieved, for example, by jamming unauthorised wireless communications with the medical device. In some cases there will be a desire to keep the existence of an mHealth device private. Potential examples include fetal heart monitors and devices associated with controlling addictions.

Identification and authentication

A long-standing problem in health care delivery is the risk of mis-identifying a patient. Misidentifications cost lives, but procedures to reduce this risk are often cumbersome and may impede effective sharing of data between institutions. In addition to the problem of identification there is an emerging problem with authentication, that is, in proving identity. Inadequate authentication procedures are exploited by attacks like medical identity theft.

Increasing use of computer-based access diminishes traditional mechanisms of authentication like face-to-face meetings between individuals who know each other personally. This problem will become worse with the deployment of HIEs, which greatly increase the pool of people for whom identification and authentication are required within a single system.

While some of the problems in this area are non-technical policy concerns (like whether a national identity number system can be imposed) and many issues will be sufficiently addressed by broader Public Key Infrastructure (PKI), there is also a need for novel contributions. What is especially needed is a "science of identifcation and authentication" in which studies that involve the full gamut of regulatory, human factor, cryptographic, computer system, and other relevant considerations are subjected to analysis so that meaningful progress can be made and measured (Bonneau et al., 2011). Current research in this area needs to be expanded and integrated with operational approaches that can scale. For example, one of the earliest studies on PHRs in the UNITED STATES used triple-factor authentication for both patients and health care professionals (Masys et al., 2002), an approach that is very secure but unlikely to be scalable for usability and maintenance reasons. By contrast, in the German Nationwide Health Information Technology Infrastructure (HTI) (Dehling and Sunyaev, 2012), medical professionals are given Health Professional Cards (HPCs) while a distinct class of Secure Mobile Cards (SMCs) are associated with institutions like hospitals and pharmacies. This division allows larger institutions to operate by delegation using SMCs so that the HTI authorities do not need to maintain authentication information for all employees.

Data segmentation and de-identification

It is widely recognised by both HCOs and government regulators that patients feel that some types of health data are especially sensitive. Examples include records related to mental health, drug abuse, genetics, sexually transmitted infections, and more. When health data is shared, there is a desire to transmit this information only when it is necessary. For example, a provider who needs immunisation records may not need to see mental health notes. Interest in how to perform this kind of data segmentation has intensified with the growth of HCOs and the introduction of HIEs. However, there is little understanding of exactly how this type of segmentation can deliver meaningful privacy with acceptable impact on the safety and quality of care. Vendor products that claim to segment data may mislead patients and providers if they are poorly designed. De-identification can be viewed as a special instance of data segmentation in which information that personally identifies the patient is redacted or abstracted. The data segmentation problem needs some of the rigor that has been applied to the de-identification problem. In particular, we require ways to measure the tradeoffs between privacy, safety, and quality. These measures should be used to determine tradeoffs for specific segmentation technologies. For example, with de-identification there are measures of "diversity" that aim to quantify the level of privacy afforded by the identity-protecting transformations. There is a lively debate around the value of these measures and their practical application. By contrast we do not yet have any comparable measure that can be used to quantify the goal and effectiveness of removing, say, an item from a list of medications, as a protection against revealing a stigmatising medical condition. It would be especially welcome to have some way to measure the impact that hiding information may have on care.

The de-identification problem itself also faces new challenges such as how to protect privacy of genomic data. Is genomic data like a lab result that can be treated like any other lab result or is it *intrinsically* identifying and therefore needs its own means of de-identification? New techniques are emerging in this area, for example, applications of cryptographic techniques that can be used to answer specific questions without revealing additional information. New research is required to determine information flows and privacy risks and to design sufficiently efficient protective measures.

Conclusions

The six privacy and security challenges described in this chapter are not the only ones that face the area and they are overlapping in many instances. In particular, there are cross-cutting considerations that have not been listed explicitly. This concluding section will focus on two of these, namely the question of balancing benefits with costs and the impact of public policy and regulatory frameworks.

Balancing benefits with costs for security precautions is a long-standing challenge to justify expenditures for security protections.

In some instances there are clear quantifications that can be made. For example, at one time there were waves of virus attacks that had an impact on system integrity and availability; costs for these attacks could be calculated in terms of lost employee productivity and the need to assign IT staff to recovery and counter-measures. Security precautions are often developed with a "pierce and patch" philosophy where vulnerabilities are patched after they have been exploited by attackers.

One can reasonably expect to see this strategy being used for HIT just as it is in other areas, but the different circumstances and risks of HIT will often require special consideration. Implanted devices offer a good illustration. There is no evidence currently that there have been attacks on such devices, and basic security counter-measures like cryptographic authentication have costs. Since implants are limited by battery life and must be serviced surgically when the battery runs low, any cost of power must be strongly justified. Searching for the right balance is essential, but this balance is not something that can currently be plugged into a set of cost/benefit equations to get a solution. Aside from this general problem with security, the health and wellness space also faces challenges with balancing privacy costs and benefits. For instance, a patient may feel his privacy is protected by hiding a fact from a provider, but this hiding may lead to a misdiagnosis that wastes resources or harms the patient. On the other hand, if all information is routinely revealed then there are individuals who may decide to not seek care in a timely way from fear of disclosure, which may again lead to waste or harm.

In many countries health and wellness is deeply influenced by public policy and the incentives provided to private parties. Key stakeholders commonly include patients, payers (including tax payers), providers, vendors, and regulators. The kinds of research challenges that look important often depend on the interactions between these stakeholders. For instance, the particulars of research on how to model HIPAA make sense for the United States, which is governed by HIPAA, but not for the European Union, which

has a different framework for privacy regulation that is not sector specific. However, there is common ground in some areas like the need for European vendors to comply to regulations for their US product sales, and the need for techniques to demonstrate compliance to regulations regardless of their local variations.

One thorny issue that will affect most health care regulatory systems is the scope of regulation for safety and security for devices. There are at least two driving issues. One is the growth in the types of devices that can satisfy a medical purpose previously dedicated to regulated medical devices. For instance, if a cell phone is being used as a stethoscope and stethoscopes are regulated, should cell phones also be regulated? Or should there be regulations only on the medical applications on cell phones that provide stethoscope functionality? Should this regulation also cover the relevant hardware on or associated with the cell phone that is involved in the stethoscope functions? Safety will undoubtedly be a leading consideration in these considerations, but security and privacy issues will have their own place. For instance, many of these medical capabilities will draw information into cloud services, and there is a question of their regulation. Also, the hosts for these types of information will begin to share it with regulated providers for the benefit of patients and perhaps for other reasons. How should this sharing be regulated?

Another interesting question that relates to cost/benefit assessment and regulation is the extent to which privacy and security should be considered an externality in the economic sense. That is, are privacy and security violations similar to pollution, where the true costs must be placed on responsible parties through regulatory controls? This is a common view for health care at providers where the economic incentives for privacy protections are often calculated in terms of fines to be avoided. Progress on cost/benefit analysis, regulatory incentives, and their combination will drive many aspects of privacy and security for health and wellness in the future.

References

Avancha, S., A. Baxi and D. Kotz (2013), "Privacy in mobile technology for personal health care", *ACM Computing Surveys*, 45.

Benaloh, J., M. Chase, E. Horvitz and K. Lauter (2009), "Patient controlled encryption: ensuring privacy of electronic medical records", in R. Sion and D. Song (eds.), *CCSW*, pp. 103-114, ACM.

Bonneau, J., C. Herley, P.C. van Oorschot and F. Stajano (2012), "The quest to replace passwords: A framework for comparative evaluation of web authentication schemes", in *IEEE Symposium on Security and Privacy*, pp. 553-567, IEEE Computer Society.

Boxwala, A.A., J. Kim, J.M. Grillo and L. Ohno-Machado (2011), "Using statistical and machine learning to help institutions detect suspicious access to electronic health records", *JAMIA*, 18(4):498-505.

Breaux, T.D. and A.I. Anton (2008), "Analyzing regulatory rules for privacy and security requirements", *IEEE Transactions on Software Engineering*, 34(1):5-20.

Chen, Y., S. Nyemba and B. Malin (2012), "Detecting anomalous insiders in collaborative information systems", *IEEE Transactions on Dependable and Secure Computing,* 9(3):332-344.

Dehling, T. and A. Sunyaev (2012), "Information security of patient-centred services utilising the German nationwide health information technology infrastructure", in *USENIX Workshop on Health Security and Privacy*, Bellevue, WA, August.

DeYoung, H., D. Garg, L. Jia, D.K. Kaynar and A. Datta, "Experiences in the logical specification of the HIPAA and GLBA privacy laws", in E. Al-Shaer and K.B. Frikken (eds), *WPES*, pp. 73-82.

Gollakota, S., H. Hassanieh, B. Ransford, D. Katabi and K. Fu (2011), "They can hear your heartbeats: non-invasive security for implantable medical devices", in S. Keshav, J. Liebeherr, J.W. Byers, and J.C. Mogul (eds.), *SIGCOMM*, pp. 2-13, ACM.

Grossmann, C.W., A. Goolsby, L. Olsen and J.M. McGinnis (2011), *Engineering a Learning Health care System: A Look at the Future: Workshop Summary*, The Learning Health System Series Roundtable on Value & Science-driven Health Care, The National Academies Press.

Gunter, C.A., D.M. Liebovitz and B. Malin (2011), "Experience-based access management: A life-cycle framework for identity and access management systems", *IEEE Security & Privacy Magazine*, 9(5), September/October, pp. 48-55.

Halperin, D., T.S. Heydt-Benjamin, B. Ransford, S.S. Clark, B. Defend, W. Morgan, K. Fu, T. Kohno and W.H. Maisel (2008), "Pacemakers and implantable cardiac defibrillators: Software radio attacks and zero-power defenses", in *IEEE Symposium on Security and Privacy*, pp. 129-142, IEEE Computer Society.

Mare, S. and D. Kotz (2010), "Is Bluetooth the right technology for mHealth?", position paper in *USENIX Workshop on Health Security (HealthSec*), August.

Masys, D.R., D. Baker, A. Butros and K. E. Cowles (2002), "Giving patients access to their medical records via the internet: The PCASSO experience", research paper, *JAMIA*, 9(2):181-191.

Murphy, Shawn N., Vivian Gainer, Michael Mendis, Susanne Churchill, and Isaac Kohane. Strategies for maintaining patient privacy in i2b2. *JAMIA*, 18:10-108, 2011.

Nissenbaum, H., (2011), "A Contextual Approach to Privacy Online", *Dædalus*, vol. 140, issue 4, September, American Academy of Arts & Sciences.

Røstad, L. and N. Øystein (2007), "Access Control and Integration of Health Care Systems: An Experience Report and Future Challenges", in *Proceedings of the 2nd International Conference on Availability, Reliability and Security (ARES 07)*, IEEE CS Press, pp. 871–878.

Sorber, J., M. Shin, R.A. Peterson, C. Cornelius, S. Mare, A. Prasad, Z. Marois, E. Smithayer and D. Kotz (2012), "An amulet for trustworthy wearable m-health", in G. Borriello and R.K. Balan (eds.), *HotMobile*, p. 7, ACM.

Chapter 10

Converging technologies for a smarter health and wellness future

Todd Kuiken

Many of today's technological and scientific developments are breaking the boundaries between nanotechnology, biotechnology, information technology and cognitive sciences. This chapter discusses the scope and impact of this change and how the many different data challenges that are emerging suggest the need for a new informatics era. It analyses the governance issues and considers possibilities for international action to help further the use of converging technologies for a new data-driven, smarter health future.

"Converging technologies" refers to the synergistic combination of nano-technology, biotechnology, information technology and cognitive sciences (NBIC), each of which is currently progressing at a rapid rate, experiencing qualitative advancements, and interacting with more established fields such as mathematics and environmental technologies (Roco, 2003).

Research based on converging technologies is expected to have a direct influence on health care, ageing population and well-being.

The potential benefits are large – but so are the perceived risks to environment, health and safety. These risks must be addressed early.

Technology moves at a rapid pace, yet the governance structures that should enable technology development, prevent unintended risks, and provide economic development are struggling to keep pace. Despite the recent progress and promises for significant benefits, the policy implications of converging technologies is not well understood.

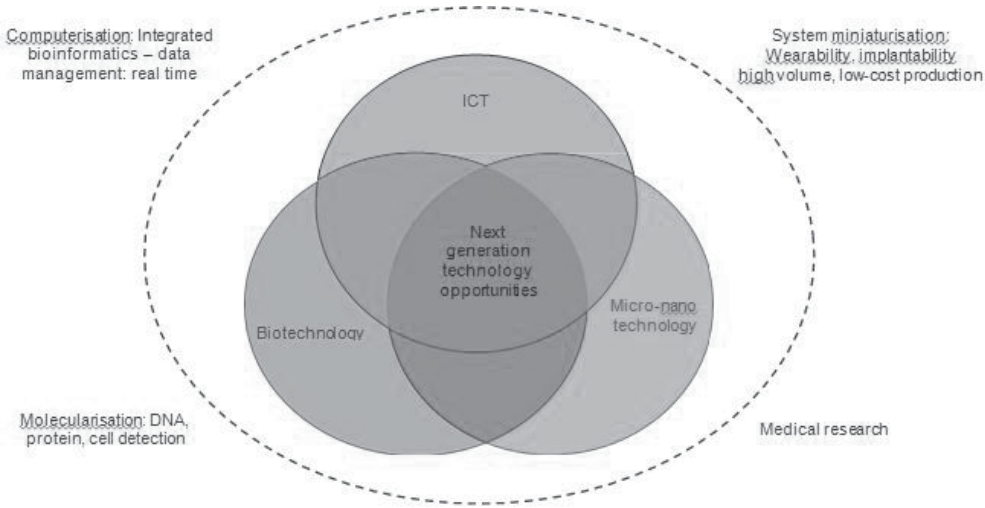
This chapter reviews these developments, their relevance to health and wellness research, focuses on the progress made in the governance of such converging technologies and suggests possibilities for international action. Specifically, this chapter suggests that supporting the transformative impact of converging technologies will help create the foundation for a new data-driven, smarter health future.

Converging technologies

Convergence can create intelligent systems and environments as a means for improving everyone's quality of life and creating access for people with special needs. For example, a combination of wireless technology and nanoscale sensors could allow blind people to walk alone and eventually drive.

New developments in science and technology are breaking the boundaries between information and communication technology (ICTs), micro-nano systems and biology through miniaturisation and the ability to manipulate matter at the atomic scale and to interface those with biological systems (Lymberis, 2010; Gonzales-Nilo, 2011). Chow-White and Garcia-Sancho suggest that biology and computing have been converging over time, are intimately linked and the lines between the two are now indivisible, producing new data practices and a new scientific approach to understanding genetic code and the human body. They conclude that "biology, computing, and social orders interact and are reciprocally shaped around spaces of convergence, but none of them fully determines the sequencer, the database, or other genomic technologies"(Chow-White and Garcia-Sancho, 2012, p. 30); however, they all need each other in order to exist (Figure 10.1).

Figure 10.1. Next generation technology opportunities are emerging from spaces of convergence



Source: Adapted from Lymberis (2010), "Micro-nano-biosystems: An overview of European research", *Minimally Invasive Therapy,* Vol. 19, 136-143.

The integration and synergy of the four technologies (nano-bio-info-cogno) originate from the nanoscale, where the building blocks of matter are established.

Advances in nanotechnology and synthetic biology are, therefore, a vital and critical part of convergence. These two sectors, which are strongly related, are briefly described below.

Nanotechnology is the study and manipulation of matter at the atomic, molecular and macromolecular scales, typically referred to as having one dimension between 1-100 nanometers. One subset of nanotechnology, which utilises biomolecular self-assembly to construct artificial structures and devices based on the properties of DNA or proteins, is referred to as bio-nanotechnology and DNA nanotechnology in particular. Advances in nanotechnology are providing new tools and materials creating the ability to match the scale of biological systems components in addition to exhibiting electrical, magnetic, optical, thermal, and chemical properties aiding in the construction of complex networks of functional parts (Doktycs and Simpson, 2007). This was envisioned in the early developments of nanotechnology research programmes (Roco, 2003).

Synthetic biology's aim is the rational design and construction of new biological parts, devices and systems with predictable and reliable functional behavior that do not exist in nature, and the re-design of existing, natural biological systems for basic research and useful purposes.

Synthetic biology involves the combination of different scientific disciplines that go beyond biology, including engineering, chemistry, physics, computer sciences and bioinformatics. It builds on genetic engineering technologies and the ease with which it is now possible to synthesise genes and large DNA fragments.

The relationship between synthetic biology and nanotechnology is a mutual one (Ball, 2005), with nanotechnology offering components and concepts for synthetic biology and if successful, synthetic biology could become the ultimate bionanotechnology (Marko, 2007; Jungmann, 2008).

According to Jungmann, DNA nanotechnology "can be regarded as one aspect of in vitro synthetic biology" (Jungmann, 2008, p. 99).

Harnessing the power of informatics

Informatics is a method of using information and computer science for collecting, analyzing and applying information. It is part of the infrastructure that supports biological investigations, and without which big biology cannot be done. Over the past 20 years we have seen the rise of e-science (IDC, 2007) which utilises massive computer networks, information science tools and social networking technologies to combine and analyse large-scale data sets. The success of the Human Genome Project exemplifies the importance of informatics to big science projects.

"X-informatics" has been used as a general descriptor for the applications informatics within a specific field, discipline or science, i.e. nanoinformatics for nanotechnology, bioinformatics for biology and ecoinformatics for ecology (IDC, 2007).

Nanoinformatics "is necessary for intelligent development and comparative characterisation of nanomaterials, for the design and use of optimised nanodevices and nanosystems, for development of advanced instrumentation and manufacturing processes, and for assurance of occupational and environmental safety and health". The difficulty with successfully utilising large scale informatics tools is being able to verify the accuracy of the data, setting up metrics for inputting data into a database, determining who controls such a database, and who "owns" the data.

Information processing is a key issue in enabling the convergence of NBIC technologies. Current and future converging technologies will rely even more than the Human Genome Project on "large-scale infrastructure and systematic curation" of data (IDC, 2007). Nanotechnology and synthetic biology depend on the collection, storage and processing of increasing amounts of data, components and knowledge from a variety of disciplines that will draw on metrics from a host of places, all of which will need to be verified stored and ownership issues established.

The ability to access large-scale databases and computer networks will either inhibit or foster greater innovation and development in these fields.

Open access to data and information sharing

According to the Nanoinformatics 2020 Roadmap[1], standardisation of and minimum requirements for data/information will facilitate sharing and evaluation of data sets, with industry playing an important role.

In 2009, the US Interagency Working Group on Digital Data released its report, "Harnessing the Power of Digital Data for Science and Society" (US Interagency Working Group, 2009) and found the following characteristics of the digital landscape:

- The products of science and the starting point for new research are increasingly digital and increasingly "born digital".
- Exploding volumes and rising demand for data use are driven by the rapid pace of digital technology innovations.
- All sectors of society are stakeholders in digital preservation and access.
- A comprehensive framework for co-operation and co-ordination to manage the risks to preservation of digital data are missing.

The report suggests that digital data can be amplified far beyond the original user. It provides the basis for doing science at new levels and in fields outside the original intent. For example, if weather, climate and public health data is designed for interoperability (the ability of two or more systems or components to exchange information) it can be integrated to predict the outbreak of an epidemic. Open access to data can lead to research being conducted all over the world for different purposes and in different contexts (OECD, 2007).

Interoperability and commitment to open access to databases is, therefore, crucial for international and interdisciplinary access and understanding of data for the development of convergence technologies.

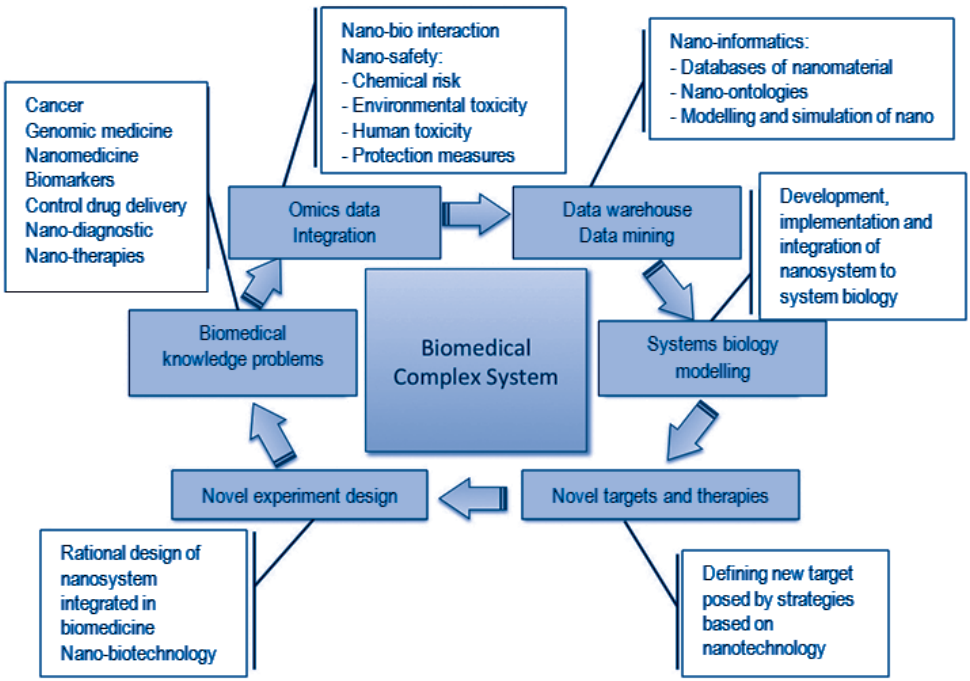
The emergence of a new informatics

The many different data challenges of converging technologies suggest the need for a new informatics area. Gonzalez-Nilo et al. note, for example, that new databases will be needed for "storage, processing and integrating physical, chemical, and biological properties of nanoparticles" in order to achieve all the promise of nanotechnology and the convergence of the x-informatics (Gonzalez-Nilo et al., 2011; Figure 10.2).

Today, biomedical research has branched out into hundreds of directions and research lines; each subdiscipline is developing the ability to manipulate structure and devices at the molecular scale, which can bring enormous and immediate benefits to medicine.

The scheme in Figure 10.2 shows how a range of different research lines and data components from biomedicine to nanobiotechnology converge around the study of a complex biomedical system.

Figure 10.2. Scheme for the convergence of different research lines from biomedicine to nanobiotechnology around the complex biomedical system



Source: Gonzales-Nilo et al. (2011), "Nanoinformatics: An emerging area of information technology at the intersection of bioinformatics, computational chemistry and nanobiotechnology", *Biological Research*, Vol. 44, 43-51.

Synthetic biology for example draws upon genomic data, computer science and engineering systems and data in order to design new biological parts. A critical issue is how to store the vast amounts of data that are being generated each day. One estimate suggests that the amount of digital data produced worldwide each year exceeds current storage capacity (IDC, 2007).

An additional serious barrier is incompatibility of technical and procedural standards. Differences in nomenclature and terminology by various research groups add inconsistencies to the growing number of databases available (Louridas, 2012).

Another unresolved aspect of digital databases and their effectiveness is who is responsible for them? There are vast amount of laboratories, companies, and communities that are involved in the creation and preservation of scientific data, each with their own protocols and with varying degrees of openness to outside users. The Interagency Working Group on Digital Data suggests that "responsibility for data stewardship should remain with the distributed collections and repositories that have a vested interest in their community's data" and that a "framework of government/private sector partnerships is required to link these distributed responsibilities into an effective system for digital preservation and access" (Interagency Working Group, 2009). A larger and still open question is what the intellectual property structure will look like as more and more distributed data is needed for convergence technologies. Ownership and control of data will ultimately determine who can innovate within this space.

While a unified database will need to be developed to incorporate the vast amounts of data being generated by not just proteomics but other convergence technologies dealing with DNA, RNA and other bioinformatics, a more pressing need is to be able to standardise, validate and make accessible the data that has already been generated. The formation of a new "negative" database of data that is usually discarded because it does not support a project's hypothesis, but may in fact be valuable for research, is also gaining support amongst researchers

OECD or other international standards agencies could influence these developments by establishing norms and procedures for data collection and analysis.

The contributions of converging technologies to a smarter health future

In the near term converging technologies will have a major impact on diagnostics, leading to new devices and sensing modes and augmenting existing methods (Johnson et al., 2008). Gonzalez-Nilo et al. also predict that implementation of nanoinformatics, which they define as the intersection of bioinformatics, computational chemistry and nano-biotechnology, will open the

door to personalised medicine by accelerating the design of highly specific biomedical treatments, increasing the efficacy, bioavailability and specificity of nanomaterials and reducing side effects (Gonzalez-Nilo et al., 2011).

New devices for point of care testing

Nanotechnology has led to significant technological advances in the miniaturisation of devices, particularly in point of care testing. These devices encompass a variety of applications from in vivo testing to hand held glucose tests. The market was worth USD 11.3 billion in 2007 and is predicted to grow to USD 18.7 billion in 2013 (Kricka et al., 2010). New lab on a chip manufacturing techniques are enabling them to be connected to and embedded in smartphones and USB drives, turning your phone into a portable diagnostic device capable of communicating directly with your doctor's office (Ruano, 2009). Macklis and Sharma predict that within the next few years nearly all medical devices will be controlled or monitored remotely or via internet-accessible interfaces, making the electronic medical records system a much more important monitor and response network with the potential for automated responses (Macklis and Sharma, 2011). Intra-body communication and personal network security is needed to evaluate and act upon the continuous test results that come with continuous monitoring, potentially leading to less aggressive and less expensive therapeutics (Zhu et al., 2009). Beyond point of care diagnostics, the nanomedicine market is estimated to reach USD 1 trillion by 2015 (Melo, 2011).

Box 10.1. Proteomics

Proteomics is the study of proteins expressed by a genome and will require access to the databases previously discussed. It provides methods for correlating the vast amounts of genomic data with protein information that is being produced through analysis of cells under normal and altered states. It consists of high throughput identification and characterisation of proteins and integrating it with genomic data. Characterisation of novel catalysts using proteomics will allow synthetic biologists to expand their protein toolbox in order to design bioprocesses for biopharmaceuticals and bio-products. One of the challenges is being able to identify the function of all the various protein parts within cellular systems, better identification of these parts will allow a better description of the entire biological system that could be used as a cell factory (Armengaud, 2010).

As bioinformatics and proteomics advance it is going to require the support of computational biologists, mathematicians, and statisticians to be able to analyse and interpret the vast amounts of data the field is generating (Weston, 2004).

The solution to many of the technical challenges in protein-based molecular diagnostics will also be solved with nanomaterials (Johnson et al., 2008). The resulting nano-proteomics will provide the platforms for the discovery of next generation biomarkers which, in turn, will enable the molecular diagnostics and personalised medicine fields to take off (Johnson et al., 2008).

Personalised medicine

Nanotechnology, along with systems biology and the convergence of the other "omics" technologies will play a critical role in the development of patient-specific therapies. Nanotechnology is predicted to "provide access to previously inaccessible data as related to "omic" technology components" and "enable innovative therapeutic modalities that leverage the validated systems biology outputs for exquisitely specific individualised therapy" (Sakamoto, 2010). Figure 10.3 (next page) shows how the convergence of the "omics" technologies makes possible the idea of personalised medicine. Personalised medicine is based on a systems biology approach utilising modern molecular medicine and the analysis of large data sets for complex diseases (Louridas, 2012).

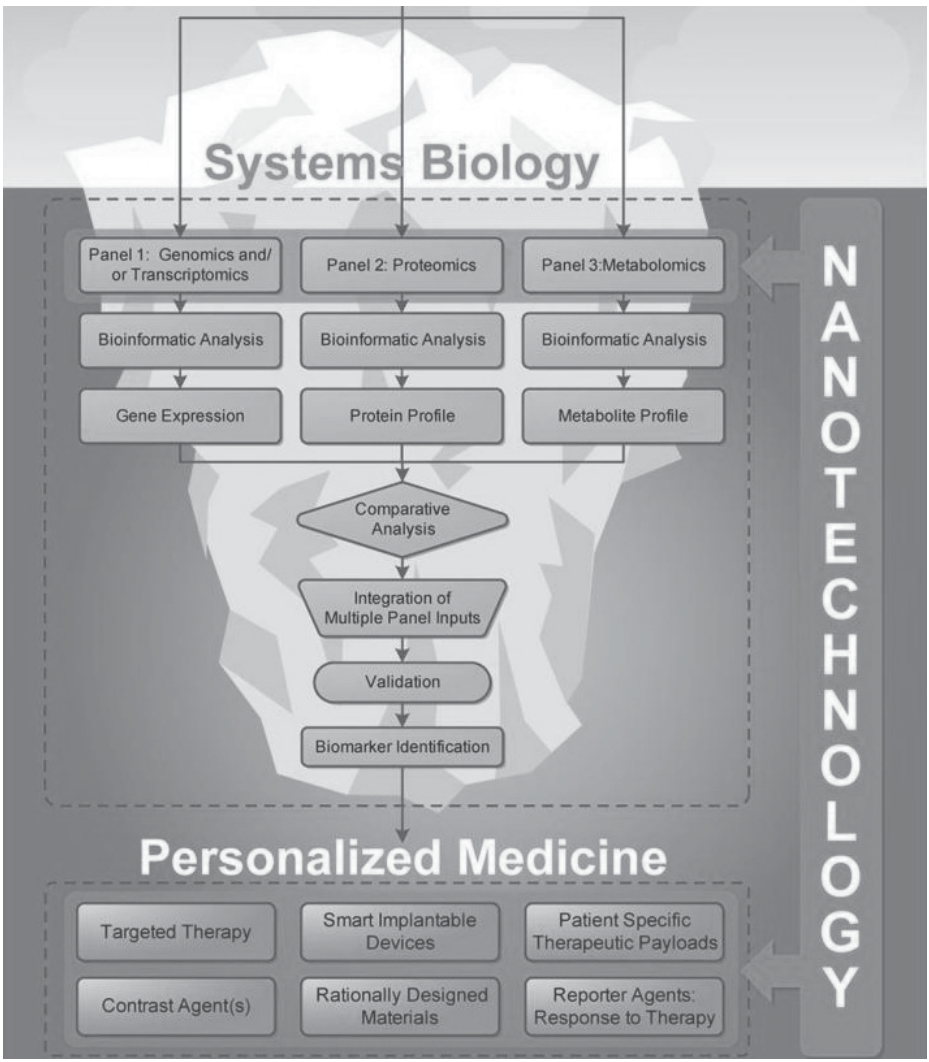
Personalised medicine will only be successful if medicines with subtle differences designed for individuals based on their genomic profile can be manufactured reliably and at small scales (IRGC, 2010). Miniaturised bio-medical devices and lab on a chip technologies will be necessary for the analysis of massive amounts of genomic data.

The ways in which nanotechnology will enable this are: early detection diagnosis, implantable drug delivery devices, nano-based injectable therapeutics, nano-based contrast agents, and tissue engineering (Mohamadi et al., 2006).

The need for new governance frameworks

While standards and guidelines are evolving, regulatory agencies like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) need a process for reviewing convergence technology products (Tozer, 2010), particularly to deal with the advances in personalised medicine that could potentially introduce thousands if not millions of individualised therapeutics that may need regulatory approval. The current drug approval process was not designed for individualised medicines. What should the approval process for these drugs look like?

Figure 10.3. Convergence of the "omics" technologies and nanotechnology will play a critical role in the discovery and validation of future biomarkers for personalised medicine



Source: Sakamoto et al. (2010), "Enabling individual therapy through nanotechnology", *Pharmacological Research*, Vol. 62, 57-89.

There is also the possibility that the drug is manufactured through synthetic biology techniques that, while still being debated, may fall within the scope of, for example, the genetically modified organisms (GMO) regulatory frameworks.

How would such a determination effect approval and uptake within countries that currently ban GMOs? As these technologies take hold, a new governance structure may be needed to regulate the transmission of medical data, the sharing of devices between users, the potential of "home-made" or hacked instruments, and the standardisation of results and analysis methods amongst various countries.

Lymberis (2010) suggests that micro and nanotechnologies will change the way that health care is organised, priced and ultimately remove the boundaries between medical and pharmaceutical practices, home care and test laboratories.

Patents, copyright and open source

Synthetic biology incorporates ideas and techniques from two major areas, biotechnology and computing, both of which are at the center of a public discourse about patents (Hey, 2009). The question becomes under which paradigm does the field and growing industry move towards: patents, copyright or open source; a combination of them or does an entirely new strategy need to be developed that enables the free flowing of information but also protects ownership and encourages innovation in the field?

Synthetic biology is built upon the idea of standardisation in the form of standardised parts, similar in a sense to the electronic and software industries which enables products and components to work together. However this can lead one particular "standard" being chosen over the other. Such was the case with VHS and Betamax, where one standardised video tape was chosen over the other. There are other examples where technological standards can be fragmented across various owners (cellular technology), or owned by no one (Linux). Henkel and Maurer argue that the Linux style openness is best suited for synthetic biology and also feasible to attain (Henkel and Maurer, 2009). The notion that synthetic biology will consist of hundreds if not thousands of standardised "parts" suggests that the intellectual property (IP) issues might mirror that of the mobile phone industry, where no single company owns all of the patents, which then forces all players to share through cross-cutting licenses.

As the synthetic biology industry develops, and the systems being designed become more complex, it seems unlikely that any one company or research laboratory will own all of the IP rights needed for a single research project.

Henkel and Maurer suggest four ways in which openness and sharing could be established in the synthetic biology community: wherever possible, use unpatented parts; donate parts to the commons; link public funding to the obligation to share; and create open parts licenses. The MIT Registry of Standardised Biological Parts and the Biobricks Foundation operate under the premise that "the fundamental building blocks of synthetic biology are freely available for open innovation".[2] The question becomes, how will patents affect these types of organisations and companies that operate under an open source framework?

The explanation Rai and Boyle offer for the difficulties computer programmes introduced to the copyright and patent realms is appropriate and similar to the issues synthetic biology will present:

> "Copyright covers original works of expression, explicitly excluding works that are functional. Patent law requires functionality; however, it had traditionally been understood to exclude formulas and algorithms. Thus, software – a machine made of words, a set of algorithmic instructions devoted to a particular function-seemed to fit neither the copyright nor the patent box." (Rai and Boyle, 2007)

In either case there is little to no discussion of synthetic biology in patent or copyright law which would enable a reviewer to make a direct correlation to previous filings and any correlation would have to be done by analogy.

Patent thickets may quickly become a problem for synthetic biology applications and devices as a product generated from synthetic biology could incorporate hundreds of separate parts, that could potentially all be patented individually and by separate patent holders. Golden rice for example had to secure the rights of over 70 patents (Potrykus, 2001). In order to check whether a part is covered by a patent, according to Rutz, these steps would need to be taken:

1. Sequence search in all available patent sequence databases.
2. Relevant hits would then need to be checked individually for the legal status of the underlying patent applications or patents (pending, refused, granted or withdrawn).
3. Check the geographical coverage of the patent (protection only exists for where the patent was issued).
4. For pending or granted patents, check which claims are currently being considered or are already granted (scope of claims can change during the patent proceedings).
5. Finally, check the part of interest against the granted claims to see if they are covered by the scope of the claims.

This would have to be done each and every time a new part was created and/or used in conjunction with other parts. More than 5 000 patents have been granted in the United States that cover ordinary DNA sequences (Hopkins et al., 2007).

There are millions of living species on this planet, potentially 30 million insect species alone, and numerous plants and animal species discovered every year in tropical rainforests, oceans and other previously unexplored areas of the earth, in effect, providing a cauldron of potential enzymes that could be utilised for biosynthetic products. Similar to synthetic chemists who used natural plant species to target, design and synthesise reagents and compounds, so to could synthetic biologists use this vast array of naturally occurring enzymes to make complex molecules for new drug discovery (Li and Vederas, 2009). If each of these newly synthesised enzymes are patented or worse yet, parts of these enzymes are patented, how would this affect the development of new drugs? Would an open source model stifle the large investments needed to develop new drugs?

An equally important question is what would the issuance of broad foundational patents have on synthetic biology?

Kumar and Rai suggest that synthetic biologists might argue that pieces of DNA are comparable to source code for a computer program and these "parts" could therefore be covered by copyright (Kumar and Rai, 2007). However, the statute that governs copyright of computer programming does not mention synthetic biology and according to Kumar and Rai, a court that wished to find pieces of DNA copyrightable would have to make that decision by analogy. In addition copyright does not cover functionality or methods of operation, suggesting that an open source model based on copyrighted material may not be suitable for synthetic biology.

The advantages and disadvantages of varying strategies of intellectual property regimes are shown in Table 10.1. What would a copyright model look like and how would it impact products like medicines that rely on patents to recoup the costs of research and development and the clinical trials necessary for FDA approval? These issues, while important and critical for the development of synthetic biology, could easily apply to nanotechnology, information technology or for future convergence technologies. These are questions that have yet to be answered and will help shape how the synthetic biology and converging technologies industry develops.

Table 10.1. Advantages and disadvantages of varying strategies of intellectual property regimes

Strategy	Advantages	Disadvantages
Patents (20 years from time of patent application to exclude others from use of invention)	Clear property right basis for copyleft license (license that requires improvements to be distributed freely)	Expensive (approximately USD 25 000 per patent in the United States for complex inventions)
Copyright (attaches immediately upon creation; exlusive right to copy and improve that lasts for 70 years after author's death, or if work of corporate publication) authorship, 95 years	Clear property right basis for copyleft license; inexpensive	Legal basis in the United States for assertion of copyright unclear – no explicit basis in the Copyright Act and some theoretical arguments against
Contract (terms vary)	Inexpensive	Copyleft license requires strict limits on information dissemination
Sui generis (one of a kind) legislation (e.g. for "open databases" or "social patents")	Narrowly tailored to problem	Legislative solutions are difficult and slow

Note: In all of the copyleft approaches, there are line-drawing issues. One has to be very careful regarding precisely what material is covered by the requirement.

Source: A. Rai and J. Boyle (2007), "Synthetic biology: Caught between property rights, the public domain, and the commons", *PLOS Biology,* Vol. 5, Issue 3, 389-393.

Breaking down silos

As technology innovation breaks down traditional scientific and technological silos the question arises whether or not a new paradigm is needed in terms of scientific research funding, how university departments are aligned (i.e. separate chemistry, biology, physics, engineering departments) along with governance structures, both local in terms of university systems and national (country specific) and international (through for example, regional organisations like the European Union). These issues were raised at a 2010 OECD workshop[3] where the consensus was that frameworks are needed to identify and support the move from silos of technology to an integrated ecosystem of smart solutions – including multidisciplinary approaches (integrating research on technologies, health care systems, and societal systems).

A more forward-looking and flexible governance structure is needed which can incorporate a systems approach that acknowledges convergence. This could avoid the current strategy where with each new technology platform that emerges a new governance strategy is debated and developed, which takes too long and tends to be outdated by the time it is adopted.

The key is enabling flexibility in the ability of funding organisations and governing bodies to be able to adapt as quickly as innovation in technology does. However current governance structures both nationally and internationally are limited in their ability to do this. The US Food and Drug Administration took a step in this direction recently when it updated its guidance towards nanomaterials avoiding the use of specific definitions – which enables some flexibility.

Any governance structure and funding programmes also need to incorporate the societal aspects of technology innovation. This goes beyond traditional environmental health and safety issues and should be based on proactive engagement incorporating ethical, legal and societal implications. In the absence of local or national governance structures for convergence technologies, businesses, particularly small start-up companies will have a difficult time navigating through all of the legal and regulatory hurdles.

Financing innovation

Many converging technologies incorporate basic elements of the traditional sciences, i.e. chemistry, biology, physics; yet require the combination of multiple disciplines. The key for funding agencies is to recognise the cross discipline nature of these convergence technologies and develop a funding structure which cross advertises calls for proposals or sets up a new pool of resources that is designated for convergence. This may require a directive from leadership within individual funding agencies or from a broader governance structure. Many of the traditional funding agencies and their "silos" will be reluctant to direct an ever shrinking research budget to areas outside of their traditional funding regimes. In addition these proposals should also incorporate environmental health and safety components, as many of these converging technologies introduce new concerns based on their manipulation of matter and biology. The earlier and more upstream potential ecological and human health risks can be identified; the easier and potentially less costly mitigation strategies can be developed. This also requires funding from multiple "silos" as both human and ecological health risks cross disciplines based on monitoring techniques, analysis and basic understanding of function and interactions. In addition, co-funding of data management systems is needed to establish a more robust system of databases that convergence technologies are both adding to and require in order to evolve.

Organisations such as the OECD could influence new funding paradigms by identifying good practice and by establishing standards of practice in terms of methodology, terminology, and access for the management of an ever increasing number of databases that convergence technologies rely on. An organisation like the OECD or the International Standards Organization could be a clearing house for such databases, if they can develop protocols in a time frame that keeps pace with the technologies development.

Conclusions

Technology innovation is breaking down traditional scientific and technological silos by design and necessity, creating the foundation for a new data-driven, smarter health future. Many of today's technological innovations and technology platforms like synthetic biology are interdisciplinary by design and require the knowledge, skills and technology platforms of various disciplines. According to Patton, building truly convergent technologies requires the co-ordination of a multidisciplinary team of experts, each of whom has a very different notion about how to build things and why things work.4 Interestingly the funding and governance structures need to mirror the development model of convergence technologies, utilising multidisciplinary teams, agencies, and regulatory tools that have the capability to evolve rapidly along with the technologies.

Technologies build upon one another, synthetic biology and the coming revolution in personalised medicine would not exist without genetic engineering, nanotechnology, information technology and proteomics. The technology of tomorrow will surely borrow and build upon the technologies of today. Technology convergence strategies, governance structures and funding models need to be flexible in order to adapt with the rapidly evolving trajectories of technology innovation. Current models of forming special working groups for individual technology platforms should be reconsidered in favour of models that evaluate technology innovation more broadly, that can build upon lessons learned from prior strategies and that recognise that many of the issues of the next great game changing technology may be similar to those that came before them.

Notes

1. http://eprints.internano.org/607/1/Roadmap_FINAL041311.pdf
2. The Biobricks Foundation: http://biobricks.org/
3. OECD Workshop on Better Health through Bio-medicine: Innovative Governance, 27-28 October 2010, Berlin, Germany, www.oecd.org/sti/biotech/workshoponbetterhealththroughbio-medicineinnovativegovernance.htm

References

Armengaud, J. (2010), "Proteogenomics and systems biology: Quest for the ultimate missing parts", *Expert Review of Proteomics,* 7(1), 65-77.

Ball, P. (2005), "Synthetic biology for nanotechnology", *Nanotechnology*. Vol. 16, R1-R8.

Chow-White, P.A. and M. Garcia-Sancho (2012), "Bidirectional shaping of convergence: Interactions between biology and computing from the first DNA sequencer to global genome databases", *Science, Technology, & Human Values* 37(1), 124-164.

Doktycz, M. and M.L. Simpson (2007), *Nano-enabled Synthetic Biology*, Vol. 3. 1-10.

Gonzalez-Nilo, F., et al. (2011), "Nanoinformatics: An emerging area of information technology at the intersection of bioinformatics, computational chemistry and nanobiotechnology", *Biological Research*, Vol. 44, 43-51.

Henkel, J. and S.M. Maurer (2009), "Parts, property and sharing", *Nature Biotechnolgy,* Vol. 27(12). 1095-1098.

Hey, T, et.al. (eds.) (2009), *The Fourth Paradigm: Data-Intensive Scientific Discovery*, Microsoft Research.

Hopkins, M. et.al. (2007), "DNA patenting: The end of an era?", *Nature Biotechnology,* Vol. 185.

IDC (2007), "The Expanding Digital Universe", *IDC White Paper*, March, www.emc.com/collateral/analyst-reports/expanding-digital-idc-white-paper.pdf (accessed August 2012).

Interagency Working Group on Digital Data (2009), *Harnessing the Power of Digital Data for Science and Society*, Report of the Interagency Working Group on Digital Data to the Committee on Science of the National Science and Technology Council, January.

IRGC (2010), "Guidelines for the Appropriate Risk Governance of Synthetic Biology", policy brief, International Risk Governance Council, www.irgc.org/IMG/pdf/irgc_SB_final_07jan_web.pdf.

Johnson, C.J., N. Zhukovsky, A.E.G. Cass and J.M. Nagy (2008), "Proteomics, nanotechnology and molecular diagnostics", *Proteomics,* Vol. 8, 715-730.

Jungmann, R., Renner, S., and Simmel, F.C. (2008) From DNA nanotechnology to synthetic biology. 2(2), 99-109.

Kricka, L.J. and G.H. Thorpe (2010), "Technology of handheld devices for point of care testing", in C.P. Price, A. St. John and L.J. Kricka (eds.), *Point of Care Testing: Needs, Opportunity, and Innovation*, AAAS Press, Washington, DC.

Kumar, S. and A. Rai (2007), "Synthetic biology", *The Intellectual Property Puzzle Texas Law Review*, Vol. 85, 1745-1768.

Li, J.W.H. and J.C. Vederas (2009), "Drug Discovery and Natural Products: End of an Era or an Endless Frontier?", *Science* Vol. 325, 161-165.

Louridas, G.E. and K.G. Lourida (2012), "The new biology: A bridge to clinical cardiology", *Hippokratia,* 16(2), 106-112.

Lymberis, A. (2010), "Micro-nano-biosystems: An overview of European research", *Minimally Invasive Therapy,* Vol. 19, 136-143.

Macklis, R.M. and N. Sharma (2011), "Convergence technology in cancer medicine", *Expert Review of Medical Devices,* 8(2), 263-273.

Marko, N.F., R.J. Weil and S.A. Toms (2007), "Nanotechnology in proteomics", *Future Drugs*, 4(5), 617-626.

Melo, M.R., S. Clark and D. Barrio (2011), "Miniaturization and globalization of clinical laboratory activities", *Clinical Chemistry and Laboratory Medicine,* 49(4), 581-586.

Mohamadi, M.R., L. Mahmoudian, N. Kaji, M. Tokeshi, H. Chuman and Y. Baba (2006), "Nanotechnology for genomics and proteomics", *Nanotoday,* 1(1), 38-45.

National Science Foundation (2011), "Nanoinformatics 2020 Roadmap", http://nanotechinformatics.org/nanoinformatics/index.php/Main_Page.

OECD (2007), Principles and Guidelines for Access to Research Data from Public Funding. www.oecd.org/science/sci-tech/oecdprinciplesandguidelinesforaccesstoresearchdatafrompublicfunding.htm.

Potrykus, I. (2001), "Golden rice and beyond", *Plant Physiology,* Vol. 125, 1157-1161.

Rai, A. and J. Boyle (2007), "Synthetic biology: Caught between property rights, the public domain, and the commons" *PLOS Biology,* Vol. 5, Issue 3, 389-393.

Roco, M. (2003), Nanotechnology: Convergence with modern biology", *Current Opinion in Biotechnology*. Vol. 14. 337-346.

Ruano-Lopez, J.M., M. Agirregabiria, G. Olabarria, D. Verdoy, D.D. Bang, M. Bu et al. (2009), "The SmartBioPhone, a point of care vision under development through two European projects: OPTOLABCARD and LABONFOIL", *Lab Chip*, Vol. 9, 1495-1499.

Sakamoto, J.H. et al. (2010), "Enabling individual therapy through nanotechnology", *Pharmacological Research*, Vol. 62, 57-89.

Tozer, D. (2010), "The challenge of product development and commercialization in a convergence technology world: Focus on regenerative medicine", *Drug Discovery Today,* 15(15/16), 587-589.

Weston, A.D. L. and Hood (2004), "Systems biology, proteomics, and the future of health care: Toward predictive, preventative, and personalized medicine", *Journal of Proteome Research*, Vol. 3, 179-196.

Zhu, H., Xu, R. and Yuan, J. (2009), "High-speed intra-body communication for personal health care", conference proceedings, *IEEE Engineering in Medecine & Biology Society*, 709-712.

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