COMMENTS ON

THE NUFFIELD COUNCIL ON BIOETHICS

MEDICAL PROFILING AND ONLINE MEDICINE: THE ETHICS OF 'PERSONALISED' HEALTHCARE IN A CONSUMER AGE

The Royal College of Physicians of Edinburgh is pleased to respond to the Nuffield Council on Bioethics on its consultation on *Medical profiling and online medicine: the ethics of 'personalised' healthcare in a consumer age*.

The College has considered the issues identified in the consultation and the following commentary reflects the medical perspective and the views of the College's Lay Advisory Group.

The consultation covers an interesting array of technologies and services which each provide their own, distinct ethical dilemmas. Whereas online information and tele-medicine is a technology that facilitates access to services, and the technology of itself comes at no risk, it contrasts with screening with scans that may emit significant doses of radiation. Therefore, it is problematical to group together interventions such as those in the consultation, as they are heterogeneous. Nonetheless, we believe that there are general principles to apply to the consultation, and we set them out prior to answering the specific questions in the consultation.

Several of the questions relating to personal use of a service or technology have been answered by doctors, but as consumers or potential consumers.

General Principles

- The public has a right to accurate information to facilitate "informed choice" and, to be advised that interpretation may not be straightforward.

- An individual can only take responsibility for their wellbeing if they are fully informed and, indeed, involved in decisions about care generally, rather than specific interventions without context.

- An individual has a right 'not to know', which can be compromised by a presumption in favour of more extensive medical profiling.

- Whilst upholding autonomy, there must also be a balance between consumer protection against harm and paternalism (which may limit personal choice). There are well developed frameworks of legal, regulatory and good practice systems that underpin consumer protection, both nationally and internationally.

- The importance of managing risk to a patient in the face of medical uncertainty and context of the person's life is one of the key professional roles of a doctor.

- Consumers use resources and customers exercise the right to purchase; the dynamics are different.

- Economic barriers exacerbate inequalities in health, and underlie several of the ethical matters behind consultation questions.

Introduction

Question 1: If an increasing number of medical products and services are becoming available as consumer goods - that is to say, as commodities which customers may choose to purchase provided they can meet the costs - is this development, on balance, desirable?

Framing the question acknowledges that there are no clear answers in favour or against. In the UK, it is essential to acknowledge the political and social backdrop, and the existence of the NHS, in identifying, arguing and weighing the consequences.

We recognise the increasing tendency to personal autonomy and the passing of a paternalistic era. Personal autonomy is a positive attribute in a consumer society providing that there are protections to consumers who are unaware of the consequences, able only to assimilate partial knowledge, or unable to access the technology. Therefore, the increasing range of products and services are a positive development, providing that transactions are fair and transparent, and the balance of argument is towards benefit. Health is therefore a consumer good, but the qualification is that its potential should be equitably distributed.

The framework of human rights case law is becoming increasingly clear on the matter that citizens have a right to health care within a properly agreed framework, but that they cannot expect the same rights and protections over health promotion interventions. Therefore, equitable distribution of products and services for care can be more easily supported than the discretionary matters of prevention and early detection.

The risks of negative consequences include:

- unequal access to beneficial technologies;

- easy access to potentially harmful technologies;

- inadequate regulation of technologies and interventions that are new, ill understood or experimental;

- products and services where the interpretation of information that it yields is partial or poorly managed;

- a service that increases anxiety through early detection of a condition for which there is no effective treatment, and the consumer did not wish to know (in retrospect, for instance); and

- an intervention that causes distress, wastes resources or emits radiation, has unplanned side-effects and exposes the consumer to risk out of proportion to the possible potential benefit.

Society in general needs to make distinctions between scientific value of a new development, and the production of knowledge; against clinical validity of an intervention - that is, the suitable application of knowledge. This is a continuing debate, of which this consultation is a welcome part.

There are remaining uncertainties within this debate. Recent changes permitting the integration of private and state funded care through co-payments encourage the citizen to push the boundaries and pay for new/experimental care not yet approved by the state or beyond its budgets. It remains unclear who has the responsibility to fund follow-up care after privately commissioned interventions but the NHS is the "provider of last resort" for essential patient care. It is an emerging pattern, indeed an inferred expectation, that the NHS now deals with the consequences of care identified by initial health care contact in the private sector.

Access continues to suffer from the "postcode lottery", particularly at the innovative end of the spectrum and inequalities abound through geographical, economic and educational barriers to services. Treating health as a consumer good will exacerbate these trends and may also bring questionable health gain to the population unless accompanied by full disclosure of benefits and risks.

In summary then, health care is and always has been a consumer good. The wisdom with which we apply knowledge, and protection from unscrupulous application of the knowledge (particularly in the for-profits sector without market constraints) leads us to advise that negative consequences for early technologies for which the benefit is unproven or controversial, have significant potential negative consequences.

Question 2: While much health related information is freely available to individuals, this varies greatly in quality and accuracy. Many of the lifestyle and health books and magazines that are currently available may contain medical information that is misleading or even incorrect from a scientific point of view. Do you think that information provided by DNA profiling and body imagine services raises different questions and should be subject to different regulations?

We encourage policy makers to make the distinction between free public-access publications such as health books and magazines, and specialist and higher cost interventions that are specific to populations and conditions - for instance, DNA profiling and body imaging

services. We believe that they raise different questions and should be subject to different, more stringent scrutiny and regulation.

However, the Internet age is one that invites uncontrolled access to general information. The framework of protection to consumers, particularly vulnerable people, is necessarily looser in ensuring the validity of information. While, in the UK, we have an advanced regulatory framework that includes advertising controls that are both statutory and self-regulatory, medicines regulation, Trade Descriptions and other consumer protection legislation, and leading institutions that consider and regulate emerging technologies (such as those in the area of assisted fertility), there has to be a proportionate approach taken to new products and services.

At the very least, there should be the ability to correct inaccurate and misleading information, and effective recourse to redress if the information leads to harm. There is much discussion relating to Internet law and intellectual property that has downside potential for holding the providers of products or services liable for harm. These systems and policies need to be developed to ensure that such new technologies, products and services such as DNA profiling and body imaging maximise potential for good, and minimise the potential for harm. DNA profiling is a classic case of an early technology which is available, but has very limited clinical validity in terms of individual or population benefit, other than for those with already high risk family or clinical indications for investigation that are already likely to be absorbed within general NHS provision.

On balance, therefore, there should be restrictions to availability of these technologies, particularly to protect vulnerable people and to avoid unnecessary investigation where there is potential for mental or physical harm. The level of regulation should be well above that envisaged for lifestyle and health books and magazines. The sorts of information that would require regulation might include:

- an accurate description of the technology;
- concise description of the purpose for which the product or service might be used;
- potential hazards; and
- risks and benefits from the information coming out of such profiling or imaging, to include the possibility of detection of incurable illness, trivial illness or benign conditions, significant illness for which no effective treatment is available, illness or risk of disease that could affect the health of third parties.

Each of these services, ideally, should be associated with the offer of appropriate expert and independent advice, and on-going support in the event of significant consequences, including the need for re-assurance.

Question 3: Many Governors argue that every individual has some responsibility to look after their own health, in their own interest and that of society at large, for instance in matters of lifestyle and diet. Do you think such individual responsibility should extend to the use of DNA profiling and body imaging services such that people in some circumstances should be expected, encouraged or obliged to have such tests?

There is the distinction between lifestyle matters, where the Government has a duty to advise and encourage, but rarely to enforce and protect. The use of DNA profiling and body imaging services are examples of technologies that have potential effects on third parties, use of important resource, the production of supporting information that is of uncertain validity, controversial and often unknown significance, and sometimes lacking in evidence base. People may be free to access such technologies in the realm of prevention as long as they are, or have access and are fully informed about, the full implications of the product or service they seek. If there are strong family or clinical reasons for seeking such a service by a preventable purpose, then there should be encouragement to the individual, with suitable consultation with those who have a family, caring or financial relationship with them. Potentially, such products and services could add value to the care of a person if it enhanced their quality of life, their sense of control over their health, and extension of personal choice. But, there has to exist beside the need for fairness and justice for taxpayers and others contributing to health insurance schemes. See the answers to earlier questions for qualifications and protections for people who consider access to these products and services.

Preventable interventions such as body imaging services that encourage screening are subject to evidence-base scrutiny of great rigour in the UK. With a view to cost to taxpayers and the value of interventions, such forums ought to be the determining gateway for the provision of screening services for defined populations, including those who have strong family and clinical reasons to undertake them. It is both possible and desirable, therefore, to ensure such checks and balances, and regulation as already exist seeks to ensure equitable and fair access and use of such services.

Question 4: Who Pays?

Public services are often the inevitable final pathway for people who detect abnormalities using private services for which they pay, then seek treatment, particularly if it is of high cost and long duration. The NHS accepts its duty of care to meet all patient concerns, but it is a matter for NHS policy-makers and, perhaps, also for the GMC and other health professional regulators to consider reasonable pathways of care for people who approach public health services by this route.

Any enhanced arrangement would be difficult to enforce, as many people who switched from private providers, then faced challenge of their use of public health services, could cite multiple sources of information and advice. While we accept the patient's right to choose for themselves, and they are a partner in care who may be fully involved in decisions about that care, there may be an argument for levies on private providers, or patients themselves, for

access to care over and above that deemed reasonable in the public health system as a consequence of profiling or scanning in the private sector.

Another option may be to require private providers to describe care pathways for findings from products and services that they offer, and to encourage patients to follow and engage with these pathways which limit exposure to the public purse in dealing with the consequences of the services that they offer "upstream".

Electronic Health Records

Question 5: Have you used online health recording systems such as Google Health?

Of those we consulted, nobody disclosed their use of online health recording systems. Respondents noted the expense and uncertainty, and sometimes misuse of public resources, in developing electronic health care records systems. There would therefore be an argument for private providers of electronic health systems to bear risk and some element of provision. On the other hand, in the UK system, the consensus of preference is that patients should not use such a service. The status quo is preferable, in that the health care provider - usually the patient's GP Practice - holds the overall health care record on behalf of the patient. The patient is therefore capable of "ownership" of the record, but may not possess it.

Future generations will probably expect all information to be held electronically and available quickly to those with appropriate permissions for access. In the UK, patients have not been responsible for maintaining their own health records. For this to become the norm will require a significant change in mind set when most of the population access health through a state run provider. If this changes, patient-maintained records may be the only viable solution to ensuring a complete record. However, this will also expose further sources of inequality through economic and educational differences.

In summary, therefore, any move to patient-held and maintained records should ensure universal coverage and capacity to maintain all records to the same high standard, allowing for differential commitment to maintaining and owning the record and ensuring its accuracy by the data subject.

Online Health Information

Question 6: Have you used online sources for diagnostic purposes, for instance those provided by Government agencies, patient groups, commercial companies or charities?

Several respondents have both used online sources for their own purposes, and most responding doctors have recommended it to their patients.

Managing risk and uncertainty is an integral part of medical training and provides one of the main distinguishing features of a doctor. Professional judgement protects patients in the face of such uncertainty. Online health information can support clinical decision making (for both

doctor and patient) but is a support tool and not a substitute for clinical experience for many patients.

The College would recommend that patients use and recognise sources of authoritative information that are capable of being specific to the context of the patient, and take into account this information, along with the views of independent experts familiar with the patient's general circumstances. Ideally, reliable sites might be listed and routed to the patient by online sources such as NHS24 or NHS Direct. There is the potential for the negative effects of information to consumers and patients from these sources, particularly where they are inaccurate or misleading.

Online Drug Purchases

Question 7: Have you purchased prescription drugs over the Internet?

The College expresses strong concerns over the availability of prescription drugs over the Internet. Unlike prescription drugs available over the counter or on prescription through "terrestrial" services where there is sophisticated regulation and assurance, this is not a protection that all consumers could expect from Internet sources. The biological potency or the purity of a drug can neither be ensured nor monitored, and there may be considerable variability in therapeutic activity. There is also the public health risk of inappropriate drug use and creation of resistance, particularly to disease-creating organisms (malaria, HIV etc).

A further risk is the potential for unexpected side effects or interactions with other drugs that people may be taking. Many patients have long-term conditions, or complex conditions, and/or are on multiple medicines and the provision of purchased prescription drugs over the Internet would add substantially to the risk and lack of safety attaching to the taking of medically active compounds.

In summary, then, we would not recommend for personal use, or to a relative or a friend, accessing prescription drugs over the Internet.

Question 8: Do you think it should be permissible to advertise prescription drugs direct to consumers?

The answer to question 8 follows from question 7 - where there is no market, is there a need for the advertisement of prescription drugs?

The NHS is demonstrably an equitable and fair system of health care provision. Within it, the primary care system is the most effective and efficient mode of health service delivery for entire populations. We recognise the provision of multiple sources of information to patients and consumers, and their ability to process and discriminate that information in partnership with their GP in ideal circumstances. The College also recognises that sophisticated checks and balances are already in place to restrict advertising and assure the quality and accuracy of their advertising. If there is a move to greater awareness amongst consumers of prescription

drugs, that should be in association with very strict caveats and regulation over and above that which is already in place.

It is also instructive to point out that the equitable framework in which for-profit organisations work, including health care providers and pharmaceutical companies, is different for that of the public access service such as the NHS. The protection of people who are vulnerable who are unable to foresee the consequences of their actions in taking prescription drugs and responding to such advertisements, should be part and parcel of the regulatory framework in which any advertising takes place.

Our concerns focus on induced demand for ineffective drugs, the opportunity to generate false hope for patients and their families and the pressure for branded products in a cash-limited NHS. Direct advertising of drugs to the general public is currently illegal in the UK, albeit such material is widely available on the internet. The College would caution against creating in the UK a demand for medication driven by commercial marketing.

Nonetheless, there may be opportunities for limited Internet use in this area. Regulated internet use, for instance, to provide prescribed medication offers an efficient option to deliver repeat medication to those needing it and should not be ruled out because of the dangers of abuse.

Telemedicine

Question 9: Have you used information technology to access individual health care expertise at a distance?

Information technology that supports tele-medicine has been widely used in clinical practice in this country for many years. Indeed, the technology underpinning telemedicine may be innovative but the practice is not new; the College holds a wonderful collection of medical correspondence generated by Dr William Cullen in the 17th Century - who may have been the first remote medical practitioner. Our contemporary Australian colleagues have worked with radio-based education and healthcare in more modern times. It offers a way forward for remote communities, to reduce the disruption caused by hospital and clinic appointments and to make optimal use of scarce skills.

Use of such technology comes highly recommended, with the usual qualifications that it should be properly evaluated and regulated for most effective use. There are strong and compelling reasons for the efficiency of such technology. Variables and concerns, therefore, include:

- the distance or lack or access to a face-to-face service;
- the type of condition;
- the credibility of the provider of care;

- clarity about the duty of care; and

- clarity about limitations of the technology and availability of frequently asked questions and answers for the consumer.

Question 10: Should remote access to GP services be provided through tele-medicine for those in remote and rural locations?

There is a strong consensus in favour of remote access to GP services through tele-medicine, in the right circumstances. Such a technology has the potential to greater efficiency, to cut costs, lower waiting times and also provide environmental benefits from travel costs avoided. The provider of care can regulate provision and should do so within a properly evaluated framework.

For those who are in special situations - isolated from health services by work or imprisonment, for instance - remote access of this type carries a very high value.

The College's view is that there is plenty of justification for tele-medicine to enhance equality of access to public health care, albeit with risks in offering lower than acceptable levels of care through tele-medicine if there are not the right checks, balances, regulation and evaluation.

We commend tele-medicine as a technology with great potential for public health good, and benefits for efficiency and the environment.

Body Imaging and DNA Profiling Services: Cross-Cutting Issues

Question 11: Have you used the services of a body imaging or DNA profiling company?

Of all the technologies framed within this consultation, respondents had the greatest reservations about body imaging and DNA profiling. There was no experience amongst respondents of use of these services. On thinking about using such services, we recommend that the following information should be available:

- the clear purpose of such a service, its scope and balanced arguments for and against its use;

- possible side-effects of the test, and also the information arising from the test;

- availability of expert and independent professional advice to interpret the findings and give appropriate counselling and assurance;

- a regulatory framework within which the service operates;

- avenues for redress; and

- placing the service within the context of overall health care provision, and the overall circumstances of the patient.

The information to receive services after the profiling should be encompassed by some of the above characteristics. It should include the information, what it means, and the option for further action on the basis of the information. Any re-assurance should be properly qualified, with honest appraisal of uncertainties, and a route for further approaches (ideally within the scope of the existing service, and at no extra cost) if the patient has further questions to ask remaining concerns, or the need for further treatment follow-up.

Question 12: Do you think it is satisfactory for DNA profiling and body imaging services to have to pass stringent evaluations before they are provided in the NHS, but for them to be readily available on a commercial basis without having to go through such evaluations?

We believe it is appropriate for there to be stringent tests, including evaluation and regulation. Some of these frameworks of regulation and consumer protection already exist. Ideally, such a framework of regulation, and availability, should be equal for the public and private system, but this is untenable in modern society. It should be clear, therefore, that any commercially driven service should be self-standing and should cover the regulatory and any other on-costs arising from the service. They should recognise that any adoption of the technology, or the consequences of finding through the technology, by the public health system (NHS in the UK), needs public money at comes at an opportunity cost.

However, availability of a technology and its appropriate application, are two different tests. The former is common to public and private providers, and the latter remains a private public interest.

The principle of autonomy does not come without conditions, nor does it come without the need for higher levels of scrutiny for new, unproven or potentially hazardous services to become available.

Characteristics of the service, subject to regulation, may follow those listed above under Question 11.

Question 13: The results of DNA profiling and body imaging may lead people to seek appropriate treatment. But it may also lead to harmful actions, such as inappropriate self-medication, or people may become more fatalistic, believing that there is no point in altering their lifestyles. In the most extreme cases, some people could become suicidal as a result of the predictive information they receive. Should providers ever be held responsible at law for such harms?

If there are failures in such services, there should be the ability for redress - see the answer to Question 11. Bear in mind also that there is redress in the courts; case law and precedent will be possible, particularly for direct-to-patient services. It will be more problematical to deal with services that are available through the Internet.

Therefore, proper regulation, and enforcement of such regulation, together with legal safeguards through common law, would be the principal protections.

Question 14: Some have criticised current commercially-available body imaging and DNA profiling services for giving information that is of limited quality and usefulness. Do you think more should be done to improve the quality and usefulness of body imaging and DNA profiling services?

We firmly agree that better information should be available in association with body imaging and DNA profiling services - see Question 11 for further characteristics. The provider of the service should ensure that adequate information is available, and should fund a suitable regulatory and quality assurance framework that underpins such a service. There should also be commitment to research in this area - the public understanding of such scientific knowledge requires attention and continued development.

Nonetheless, the principle of "buyer beware" applies when judging the quality of information and, in particular, how it is delivered.

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