The future is now: keeping pace with changes in how care is funded and delivered

> ‘Policies which are based on assumptions of how the world is today can limit our choices and put us in a position of constantly responding to change, rather than creating the conditions to achieve the future we want.’

Government Office for Science, 2021[82]

In this chapter we examine what we see as some lower profile, inter-connected risks that need attention. We also consider how the sector can become both more agile and better at anticipating extraneous developments that can affect professional judgement and practice.

The face of care in the UK and globally is changing fast, and regulation is struggling to keep up, resulting in new risks to patients and service users.

A growing proportion of care in UK is being delivered by the private sector,[83] as 'high street' providers such as pharmacies and opticians are contracted to deliver more and more primary care services. Health professionals such as osteopaths, chiropractors and physiotherapists are also taking on 'first contact' roles, and it is becoming more common for local pharmacies, surgeries and dentists to be owned by large corporate bodies. The Covid-19 pandemic, and its knock-on effects on NHS waiting lists, also mean that more people are turning to the private sector for hospital treatment such as routine operations.[84]

The overall percentage of NHS expenditure used to buy healthcare from an array of private providers – excluding GPs – is currently around 18%, or £21 billion a year.[85]

In the social care sector, there is a wide range of different service providers, whereas, within the adult social care sector, the vast majority of care is delivered by independent home care and residential care providers. These are mainly for-profit companies but also include some voluntary sector organisations.[86] Years of underfunding of social care in England have put pressure on the sustainability of this way of working, with over a quarter of care homes at risk of going bust – and voices in the sector have questioned whether the social care levy will be enough to deal with the pressures on the system.[87,88]

We are seeing large corporate chains accused of 'hard sell' tactics, and other questionable practices, that seem to prioritise profit over the best interests of both patients and registrants. However, the regulation of 'high street' providers of healthcare is complex and piecemeal, and may not be fit for purpose.

The rise of private healthcare is likely to increase conflicts of interest for individuals. This problem is particularly acute in medicine, where doctors sometimes have a financial interest in the businesses they refer patients to, or in carrying out individual procedures and where the potential for harm is most severe. Several prominent cases including the Ian Paterson case have raised the alarm,[89] but, as this chapter reveals, regulation covering financial conflicts of interest in healthcare can be weak and poorly enforced.

At the same time, technology is transforming both how we deliver care, and the techniques and services on offer. Remote and virtual consultations have become widespread in sectors such as primary care[90] and counselling[91] and people can now access a whole range of healthcare online, including pharmaceutical, optical and dental services. Artificial Intelligence (AI) and robotics are reshaping the healthcare landscape, and have the potential to markedly improve personalisation, accuracy and patient safety.

The rise of virtual care has the potential to improve access to the health sector and make it more convenient, but also opens up new avenues to poor or illegal practice. Evidence suggests that online healthcare businesses are underperforming against their 'physical' competitors in terms of quality of care[92,93,94] and sometimes engage in risky practices.[95]

Similarly, new technology such as robotic surgery and AI has huge potential but also carries significant risk. Technological failure or AI running on biased or inaccurate data put patients at tangible risk and may exacerbate existing inequalities: but lines of accountability are unclear.

While there are many benefits, these developments also present new risks to patients which may undermine public confidence in the professions. Professional regulation can be one part of the solution.

Regulating 'high street' providers of healthcare: the case for regulatory reform

> 'The legislation around business regulation is complex and does not provide for a clear and consistent system… We are currently restricted in our ability to enforce high standards in business regulation. It is relatively easy for a business to continue to operate even in the event of a serious sanction being applied.'

General Optical Council, 2013[96]

Healthcare is not just delivered in hospitals and GP surgeries. It is also delivered in thousands of opticians, pharmacies, dental practices, osteopathic practices and chiropractic clinics and many other settings up and down the UK's high streets. Several of the healthcare professional regulators also play a part in regulating these 'high street' providers. However, despite all regulators sharing the same overarching objective,*(1) regulators of high street practice have different powers, with no clear rationale for why. Outdated legislation and regulatory gaps can hinder regulators in holding healthcare providers to account, and the overall system of business regulation is fragmented and confusing.

There are three regulators with a significant role in overseeing business registrants. These are the pharmacy regulators the GPhC which covers Great Britain and the PSNI which covers Northern Ireland, and the optical services regulator for the UK, the GOC. The GPhC sets standards for, and inspects, individual pharmacy premises, working closely with the Medicines and Healthcare products Regulatory Agency (MHRA), the body responsible for regulating all medicines and medical devices in the UK. The GOC regulates optical businesses but has no powers of inspection.

In Northern Ireland, the Medicines Regulatory Group (MRG) within the Department of Health undertakes routine compliance visits to all registered pharmacies.*(2)

In contrast to the professional regulators, who largely have UK-wide mandates, are the devolved 'system regulators' such as:

- Care Quality Commission (CQC) in England
- Healthcare Improvement Scotland (HIS)
- Healthcare Inspectorate Wales (HIW)
- Care Inspectorate Wales (CIW)
- The Regulation Quality Improvement Authority in Northern Ireland (RQIA).

The GOC was created by the Opticians Act 1958, and its most recent governing legislation dates back to 1989, though it has been subject to piecemeal amendments.[97,98] As well as regulating individual registrant optometrists, dispensing opticians and optical students, the GOC also regulates optical businesses. It can take business registrants through fitness to practise procedures if they fail to meet its 'Standards for Optical Businesses'.[99]

* (1) The statutory overarching objective of the healthcare professional regulators (excluding the PSNI) is to protect the public. This includes: To protect, promote and maintain the health, safety and well-being of the public; To promote and maintain public confidence in the professions; and to promote and maintain proper professional standards and conduct.

(2) This is to ensure that the premises and the pharmacist on duty are complying with the standards of conduct and performance set by the PSNI and the Department and with obligations imposed on the profession of pharmacy under all medicines related legislation (see: Department of Health Northern Ireland, Medicines Regulatory Group enforcement actions. Available at: https://www.health-ni.gov.uk/articles/medicines-regulatory-group-enforcement-actions)

However, there are a number of shortcomings in the GOC's governing legislation which hamper its ability to regulate the optical sector fully or impose meaningful sanctions. Firstly, as outlined above, the GOC has no powers to inspect optical businesses. This makes it difficult to spot issues early and give businesses advice or conditions to help them improve. The capacity to identify issues before things go wrong could significantly improve the GOC's ability to get 'upstream' of problems.[100]

Secondly, limitations to the GOC's legislation mean that certain businesses fall outside the requirement for mandatory registration with the regulator. Registration with the GOC is only required for 'bodies corporate'*(3) with particular management structures; and even then only if they use certain protected titles such as 'optometrist' or 'dispensing optician' in their company or trading name.[101] What this means in practice is that optical businesses can avoid having to register; either by using an alternative term such as 'eye care' or by virtue of their corporate structure. In 2013, the GOC estimated that only 2,200 of around 6,400 optical businesses were registered with them.[102] This leaves customers without the assurance that all optical businesses are complying with the GOC's standards and means that optical businesses are not operating on a level playing field.

Thirdly, even where the GOC is in a position to take action against a corporate registrant, the maximum fine they are entitled to impose is £50,000 (although there are other actions they can take such as imposing conditional registration, suspension or striking off).[103] While this amount may be significant for a small independent practice, it is less so for a large corporate chain, and is unlikely to act as a deterrent as the GOC states it should.[104]

The inadequacy of the fine was brought into sharp relief in 2019 when the GOC imposed the maximum penalty on Boots Opticians, a company which in the same year recorded a profit of £167 million.[105]

The GOC has raised concerns[106] about these issues and is seeking an extension to its powers, to require all optical businesses carrying out restricted functions to be registered.*(4) It has asserted that 'compulsory registration will better protect the public by ensuring a consistent approach to those activities that tend to be within the control of businesses as opposed to individual registrants.'[107] In the meantime, it continues to encourage businesses to register even where they are not required to do so. The GOC is also considering asking for powers of inspection to ensure that optical business comply with business standards.[108]

The GPhC has more modern legislation, established under the Pharmacy Order 2010. Businesses engaged in things like selling or supplying Pharmacy or Prescription Only Medicines (POMs) are required to register with the GPhC or PSNI, depending on location.[109] The GPhC sets the standards for registered pharmacies in Great Britain and has the power to inspect individual premises to assess whether they are meeting the standards. Where there are discrepancies the GPhC can issue improvement notices or conditions, or ultimately, disqualify a pharmacy owner and remove all their premises from the register.[110]

The GPhC's inspection and enforcement powers are unique among the healthcare professional regulators. They give it significant scope to influence a number of areas including governance, risk management and safe staffing.

* (3) A body corporate is a limited company or limited liability partnership that has been incorporated with Companies House. This does not include non-limited liability partnerships (except in Scotland) and sole traders.

(4) 'Restricted functions' are those under Part IV of the Opticians Act 1989 – testing of sight, fitting of contact lenses and sale and supply of optical appliances.

However, there are also potential shortcomings in the GPhC's model. The Pharmacists Defence Association (PDA) says that 'treatment of pharmacy owners is in stark contrast with [GPhC's] treatment of individual registrants' and believes that 'the regulator should achieve a fair and balanced regulation regime that is equally demanding upon both pharmacists and the employers'.[111] The PDA believe that the GPhC is better equipped to use its powers against individual pharmacists than against pharmacy owners, and that as a result it is much more likely to take action against individual pharmacists than owners.

The picture is complex. In addition to the GOC and GPhC, there are other regulators overseeing registrants who primarily work in high street practices, but which have limited (or no) powers to regulate those businesses. The regulators of osteopaths and chiropractors have no powers in relation to the businesses that provide these services, but are not asking for these powers. Often these professionals work as sole traders, so regulating the business and the person are one and the same. On the other hand, dental practices, which are largely private sector businesses located on the high street, are inspected by the CQC. The GDC regulates the dental team across the whole of the UK but has no powers of inspection, and very limited powers to regulate business practices.[112] These sorts of disparities in the powers held by healthcare professional regulators make the regulatory landscape fragmented and confusing.

Adding to the confusion are the grey areas of practice available on the high street that sit between 'healthcare' and 'beauty treatments' such as aesthetic procedures including Botox and dermal fillers. Whilst regulated professionals can provide non-surgical, cosmetic treatments this is not always the case. This leaves the public with little assurance that practitioners carrying out potentially harmful procedures are competent to do so. There are growing concerns about practitioners administering non-surgical cosmetic treatments[113] with serious side-effects when they go wrong, such as scarring and infections. The UK Government aims to address these risks through a licensing regime which will 'introduce consistent standards that individuals carrying out non-surgical cosmetic procedures will have to meet, as well as hygiene and safety standards for premises.'[114]

Regulators face other challenges in holding corporate entities to account. Perhaps the most significant of these is the relative power imbalance between the regulator and some large corporations. Not only are regulators outstripped financially by large businesses, there is also the question of how feasible it would be, in practice, for regulators to impose the most serious sanction of erasure on a large chain. Boots for example has over 2,200 UK stores[115] Lloyds Pharmacy over 1,500,[116] and Specsavers almost 2,000.[117] These businesses play an integral role in the delivery of healthcare in the community. Were regulators to take the most extreme action of removing these businesses from the register it would leave a large number of people – in the short term at least – without a healthcare provider they can rely on. These businesses may, in effect, come close to being too big to fail.

Reform should be considered on two fronts: firstly, the powers of those regulators with a role in regulating businesses should be reviewed. This should focus on the effectiveness and adequacy of current powers (for example, inspection powers, powers to require businesses to register, levels of fines etc), and whether they are sufficient to protect the public and hold businesses to account.

Secondly, the UK Governments should consider extending business regulation powers to all regulators whose registrants work in 'high street' practices and, in doing so, should assess any regulatory gaps arising from the current system.*

* The Government committed to considering 'professional regulators' roles in regulating businesses and premises' in 2019 (See: Department of Health and Social Care, July 2019, Promoting professionalism, reforming regulation: Government response to the consultation. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

The Authority has previously called for healthcare professions and high street premises to be regulated together,[118] and in our view this remains the most logical approach.

The Governments should use the current programme of regulatory reform to review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses. It should also consider whether there is a case for extending business regulation powers to other regulators whose individual registrants work in 'high street' practices.

As the Governments have already set out their view that 'regulators should have broadly equivalent powers to maintain a level of consistency and effective public protection',[119] we hope these recommendations will support reform in this area.

Profit before patients? The role of healthcare professional regulators in scrutinising commercial practices

'At the opticians, the young woman testing my eyes declared I have cataracts… Without seeking to reassure me, the optometrist started a sales pitch for a treatment to cut off my cataracty old lenses and replace them with magical plastic ones. In fact, she priced up the operations right there: £4,000 for my left eye, £3,000 for the right… Upstairs choosing glasses, I was aggressively up-sold "varifocal" lenses… later I was called back. I asked the new optometrist about my cataracts. "You don't have cataracts," she said. "Your eyes are healthy." Nothing like a dose of rapacious private medicine to make you appreciate the NHS.'

Janice Turner, The Times, 9 February 2022[120]

High street healthcare establishments such as pharmacies and opticians provide an essential public service. They often carry out procedures and services which are directly funded by the NHS, such as free eye tests, hearings tests, and the provision of NHS prescriptions. However, as well as being an essential part of the healthcare landscape, they are also private businesses, whether as small independent providers, or as part of large multinational chains. In common with businesses across all sectors, they use techniques designed to optimise profits, such as sales targets and employee incentives, or managing costs by keeping staffing levels to a minimum. Businesses have been criticised for these approaches, at times, amid claims that profit is sometimes put before the best interests of customers. As regulated healthcare settings, these businesses must achieve a fine balance between the best interests of patients and that of their bottom line.

Healthcare professional regulators overseeing high street practices are clear that patients must come before profits. The GPhC Standards for Registered Pharmacies[121] recognise that whilst businesses are subject to competing demands, including commercial ones, medicines themselves are 'not ordinary items of commerce' and pharmacies are 'a fundamental healthcare service'. As such, commercial interests should never come before the best interests of patients, as stipulated by Standard 2.6: 'incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff'. Similarly, the GOC's Standards for Optical Businesses[122] state that 'as a healthcare provider…. the care, well-being and safety of patients must always be your first concern.'

However, while the standards set by regulators may be clear, there are longstanding and persistent concerns that some businesses are failing to adhere to either the letter or the spirit of these rules. Both pharmacies and opticians have been criticised for engaging in a range of practices that go against the best interest of patients. For the optical sector this includes 'hard sell' tactics to persuade customers to sign up for laser eye surgery, up-selling expensive lenses, or not always giving patients their prescription so that they can buy glasses elsewhere.[123] Examples of such practices were shown in a 2014 exposé of Optical Express,[124] which revealed that the company's training manual encouraged staff to use emotive language when discussing laser eye surgery, such as 'what price can you put on your eyesight?' A Which? investigation found repeated failures to explain the possible complications of the surgery.[125]

In the pharmacy sector, large chains such as Boots have been accused of failing to maintain safe levels of staffing as a deliberate tactic to increase profit margins[126] and of setting inappropriate sales targets.[127] Questions about unethical practice in the sector were brought into sharp focus during the Covid-19 pandemic when some pharmacies were found to be charging hugely inflated prices for essential products including hand sanitiser, face masks and paracetamol. This prompted the GPhC and the Competition and Markets Authority (CMA) to issue a joint letter warning pharmacies against 'unfair business practices.'[128]

Hard sell tactics, overcharging and failing to maintain safe staffing levels have clear implications for both public confidence and patient safety. However, patients and the public are not the only losers when healthcare businesses engage in questionable practices. Healthcare professionals employed by those businesses can be put in the difficult position of having to choose between meeting the targets set for them by their employers and upholding professional standards.

The GOC Registrant Survey 2021[129] found that almost a quarter (23%) of respondents had felt under pressure by an employer or a business to sell a product or service which they knew was not needed by the patient in the past year. Almost a third (29%) had felt pressure to meet commercial targets at the expense of patient care. People working for optical chains were more likely to report feeling under pressure than those working for an independent optician.

Similarly, the PDA 2021 Safer Pharmacies Survey[130] found that 46% of respondents stated that patient safety was placed above 'commercial or other operational considerations' only half the time or less.

Putting undue pressure on health professionals to meet commercial targets is likely to create a conflict between the demands of the employer and patient interests. While it should be clear that complying with professional standards must be the priority, it may be challenging for individual registrants to make this case, particularly where targets are set at a distance by a large corporation, and store managers may not be registrants and therefore not subject to the same professional standards.

As well as questionable practices among some high street providers of healthcare, there have been a number of reports and inquiries highlighting poor practice and profiteering in both the adult and children's social care sectors.The Winterbourne View serious case review found that profit was placed 'over and above decisions about the effective and humane delivery of assessment, treatment and rehabilitation'.[131] In South Wales the coroner ruling on the deaths of residents at Brithdir Nursing Home, due to neglect, stated that the owner was 'more concerned about his profits from the care home, than the well-being of the residents'.[132]

In addition, a recent CMA market study into children's social care found that the market was 'dysfunctional' and that large private sector providers were making unduly high profits.[133] There is no single professional

regulator overseeing care sector workers,with practitioners coming from varying backgrounds, including nursing, medicine, occupational therapy, and social work. No professional regulators have powers over social care providers. However, regulators will clearly have an interest in business practices that may have a negative impact on registrants or service users in the care sector.

How much 'commercial practices' in the health sector should be overseen or regulated by healthcare regulators is a contested area. The CMA has the power to take action against company directors if they breach competition law, focusing strongly on the pharmaceutical sector.[134] However, the CMA is also conscious of the need not to over-regulate and has made it clear that competition is the key mechanism for driving down prices and promoting innovation.[135]

The healthcare professional regulators have generally steered away from commenting on commercial practices unless they pose a clear risk to patient safety. The GPhC, for example, states that it will 'not usually take action on matters that are purely commercial in nature and have no medicinal or practice-related element'.[136] However, the PDA has criticised this approach, particularly the decision not to be prescriptive around what constitutes a 'safe staffing level.'[137]

The GPhC set aside its hands-off approach to commercial practices during the pandemic when it signed a joint CMA letter on overcharging. In this instance, it made its decision to intervene on the basis of its duty to uphold public confidence. The GPhC stated that 'retail practice can impact on public perceptions of pharmacy – and public confidence' and expressed a willingness to take action where there are 'broader issues that would impact on public confidence.'[138]

All healthcare professional regulators have a duty to uphold public confidence in the profession as one of their overarching objectives.[139] Many of the business practices described above could impact on public confidence, which would bring them clearly into the professional regulators' territory.

While scrutinising individual practices such as 'hard sell' tactics may be tricky for regulators, this does not mean that they should shy away from engaging with them altogether. There is a clear risk that the widespread use of these practices could undermine public trust; not only in the professionals using these tactics, but in the profession as a whole. They also risk creating conflicts for registrants between the demands of the employer and those of regulators.

Regulators should tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement.

Businesses have an important role to play in the delivery of healthcare and we know many take patient safety extremely seriously.The Independent Healthcare Providers Network (IHPN) the membership organisation for a range of independent healthcare providers across the UK has led work by the sector on patient safety. This has included supporting the implementation of the recommendations from the Paterson inquiry and encouraging independent providers to appoint a Freedom to Speak Up Guardian.[140]

However, the inherent tension between profit and patient best interest should be monitored. Regulators will need to consider whether they need to be more interventionist in their approach where it is in the best interests of the public.

Individual conflicts of interest – time to get tough?

> ‘MRI scans, PET, you name it, I have had every scan under the sun multiple times, because at the end of the day he [Ian Paterson] was raking in, Spire were raking in that money.’

Patient 69 treated at Spire hospitals, Report of the Independent Inquiry into the Issues raised by Paterson[141]

Conflicts of interest do not just occur within big businesses and corporate entities, they can just as easily arise between a single health or social care professional and the patient or service user in their care. Although they can occur across all health and social care sectors, the most high-profile cases often involve doctors, and there are several shocking examples of patients being harmed by doctors acting out of financial self-interest. While there are measures in place to mitigate risk, most notably professional codes and rules set by the CMA, these have been criticised for being both weak and poorly enforced. As a result there is a danger that patients are left exposed to an unacceptable risk of harm, which is only likely to grow as private practice continues to expand its share of the healthcare market and patients exercise their choice.[142]

It is estimated that around 17,500 consultants in the UK undertake some form of regular private work.[143] Arrangements vary but may involve them ‘renting a room’ in a private hospital or forming a joint venture business with a hospital. In the latter arrangement, consultants receive a share of the profits from treating patients in the form of a dividend, in addition to the fees they earn from treating individual patients.[144] A number of other arrangements made between private hospitals and consultants have been banned by the CMA within the past decade.[145] They include where consultants are required to refer their private patients to an individual hospital, or where financial rewards are based on the number of referrals they make.[146]

As consultants working in private practice may have opportunities to refer patients to that practice (to their own financial benefit) there is a clear risk of conflicts of interest arising. Healthcare professional regulators are alive to this risk, and in 2017 issued a joint statement making clear that professionals must put patients’ interests before their own and ‘ensure their professional judgement is not compromised by personal, financial or commercial interests…’.[147] Separate GMC guidance also states that ‘you must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.’[148] It goes on to say that where a medical professional refers a patient to an organisation in which they have a commercial interest they must tell the patient and record it in their medical record.

In addition to the guidance issued by professional regulators, the CMA oversees and governs the financial interests of doctors in private practice across the UK. It has raised concerns about how the private healthcare market operates, and in 2014 introduced rules restricting the financial stake consultants are permitted to have in private hospitals. Consultants are now prohibited from owning more than a 5% share of a company where they refer or treat patients. Further, doctors and private hospitals must declare any such financial arrangements on the hospital website.[149] The CMA rules sit alongside NHS guidance that conflicts of interest should be declared.[150]

However, these rules have been criticised for being insufficiently robust and poorly enforced, and there is evidence that financial conflicts of interest have led to patient harm in spite of them.

UK examples of patients being harmed by doctors apparently acting in their own financial interest include the cases of Mina Chowdhury, who falsely told parents their children had cancer and then referred them for private scans provided by his company,[151] Paul Miller, who inappropriately referred patients for treatment using a machine he owned,[152] and surgeon Ian Paterson who carried out hundreds of unnecessary surgeries from which he allegedly benefited financially.[153] Whilst such examples are thankfully rare they can nonetheless impact on many patients and have a significant impact on public confidence.

There is also substantial evidence of harm from countries with more developed private medical markets, such as the US. It has been found, for example, that doctors who received financial rewards for prescribing opioids prescribed substantially larger quantities,[154] contributing to the US opioid crisis. The CHPI cites further examples from the US of financial incentives in medicine subjecting patients to unnecessary treatment or other harm.[155]

Criticisms of the current system for managing conflicts of interest in medicine are twofold; firstly, that the rules which already exist are not properly enforced, and secondly that the rules themselves are inadequate.

In respect of the first point, research conducted by the CHPI has found that 'rules governing share ownership and the declaration of financial interests by private healthcare companies appear to have been breached… In some cases, [they] found that consultants own up to 20% of the private hospital facilities they work in, significantly more than the 5% limit imposed by the CMA'.[156]

*The CMA states that it enforces its Orders and Undertakings, including the Private Healthcare Market Investigation Order 2014, in accordance with its published guidance.

The CHPI further asserts that 'there is no evidence that the CMA* has dedicated any resource to monitoring or enforcing the law governing the use of financial incentives in the UK healthcare system'.[157] Commentators have also drawn attention to the fact that the GMC has declined to take action on breaches of the share ownership rules on the basis that no direct impact on patient care had occurred.[158]

While steps could be taken to ensure that existing rules are better enforced, would this, in itself, be sufficient to adequately manage the risks posed by conflicts of interest in medicine? There is a strong argument that such conflicts should in fact be banned where possible (accepting that some conflicts may be unavoidable). The US for example, with its long history of private medical provision, largely prohibits financial conflicts of interest, including physician ownership of facilities.[159]

David Rowland, Director of the CHPI makes this argument stating that merely requiring transparency about conflicts of interest, and then placing the onus on the patient to reach an informed decision, ignores the 'information asymmetries which exist between the patient and the doctor.'[160]

The predominance of the state sector in the provision of healthcare in the UK has meant that rules for managing conflicts of interest are relatively new and underdeveloped. However, the private healthcare market is expanding rapidly, with research conducted by the IInstitute for Public Policy Research (IPPR) finding that 'the UK is the G7 nation with the fastest rise in healthcare expenditure from out-of-pocket or voluntary insurance sources.'[161] For those who can afford it, private healthcare can offer a welcome and speedy alternative particularly when the NHS is going through a challenging period. However, the rapid growth of this sector means that issues arising from financial conflicts of interest are only likely to grow, and regulators must ensure they are equipped to deal with them robustly.

This is also an issue for the NHS. In its 2019 report looking at financial incentives and conflicts of interest in the UK's private healthcare system, the CHPI identified 481 medical consultants with equity stakes in 34 different joint ventures with private hospital companies – 73% of these consultants are employed directly by the NHS. Over the six-year period covering 2015 to 2020 these 34 joint ventures generated £1.24 billion in revenue and recorded an operating profit of £258 million.[162]

CHPI notes that 'as the majority of the doctors with equity in joint ventures work primarily for the NHS, there is a potential conflict of interest when NHS Trusts contract with these companies'.

More recently the potential for conflicts of interest to arise from the new Integrated Care Systems being brought in on the back of the Health and Care Act 2022 has been highlighted with the argument being made that they could undermine transparency of local decision-making.[163]

Concerns about financial conflicts of interest in the UK medical sector have gained prominence in recent years, particularly in the light of Baroness Cumberlege's review of medicines and medical devices. The Review highlighted concerns around the financial and other links between hospitals and other organisations, and the pharmaceutical and medical device companies, as well as with individual clinicians. This included a recommendation requiring transparency of payments made to clinicians and hospitals and the full declaration by clinicians of all financial and non-pecuniary interests.[164] The Department of Health and Social Care is currently implementing this recommendation, which we welcome. However, whilst this planned increase in transparency is positive, it is unlikely to be enough to address the issues arising as a result of conflicts of interest.

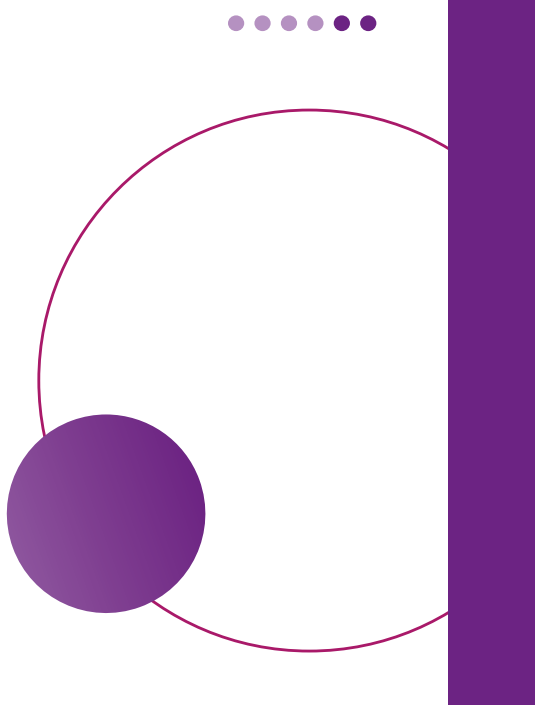
The current situation, where rules exist but are routinely breached without consequence, risks both the safety and the confidence of the public.

As a first step, existing CMA rules governing financial conflicts of interest should be enforced more consistently and breaches dealt with appropriately.

In the longer term we believe that there should be a cross-sector review of the effectiveness of current arrangements to address financial conflicts of interest among healthcare professionals. Any harm caused to patients as a result of a conflict of interest not only represents a gross breach of trust by the individual medical professional involved, but also risks damaging patient and public confidence in the profession as a whole.

As these issues cut across the NHS and independent sector, there will be the need for collaborative working to tackle these problems. The work ongoing to implement the Paterson Inquiry recommendations may provide a positive model for collaborative action.

Cumberlege's review of medicines and medical devices highlighted concerns around the financial links between hospitals and the pharmaceutical and medical device companies



Regulation fit for the future: regulating virtual healthcare and new technologies

> ‘Innovation is a key enabler of improvements in health and social care. Many of the things we now think of as essential to high-quality care were once considered new and innovative, and today’s innovations will be tomorrow’s best practice.’

Care Quality Commission, 2018[165]

The delivery of healthcare in both the UK and globally is changing rapidly. Technological advances mean that a vast array of healthcare services can be delivered virtually, from primary care, to consultations with a pharmacist, to some hospital services. The Covid-19 pandemic has undoubtedly accelerated what was already a growing shift towards online provision, with research suggesting that the pandemic brought forward digital adoption by up to seven years.[166] For patients, being able to access services from home will make them more accessible and convenient. Putting services online is also likely to reduce costs for both patient and provider.[167]

It is not just care delivery that is changing. Technology is also transforming the very nature of healthcare, and the role of the healthcare professional within it. Machines, such as those utilising AI, can now assist with complex surgery, diagnose cancer and even estimate risk of suicide.[168] They can far exceed the capabilities of humans, especially in tasks that involve processing high volumes of complex data.[169] Some within the healthcare world now predict a future in which patient data is automatically analysed via algorithms, with machines providing the diagnosis and the role of the doctor being transformed into one of ‘communicator’.[170]

The UK Government has signalled a clear intention to rapidly expand the use of technology across the NHS, with the recently announced merger of NHSX and NHS Digital with NHS England; all part of a plan to ‘put digital transformation at the heart of the NHS.’[171] When he was Health Secretary, Sajid Javid pledged to ‘use the power of digital to drive a new era of recovery and reform.’[172] If this were to go ahead, it would include increasing the use of clinical decision support software so that it becomes ‘the expected norm for all clinicians’ and the expanded use of ‘virtual wards’.[173] In Scotland, the Government has pledged a £20 million investment in surgical robots,[174] and Wales has announced increased funding for robot-assisted surgery as well as the establishment of an ‘All-Wales Robotic Assisted Surgery Network’.[175]

However, despite the benefits of online services and new technologies there are a number of risks to the quality and safety of care that require vigilance from regulators. There have been concerns across primary care, optical services, dentistry and pharmacy services that online providers often fail to meet basic standards, with the quality of care falling well below that achieved by physical providers.

A 2018 report on online primary care by the CQC highlighted significant, potential patient safety issues. These included online providers failing to perform proper patient identity checks, being unable to identify whether the patient understood or consented to treatment, taking inadequate medical history, and failing to contact the patient’s regular GP, including where medication was prescribed requiring monitoring or follow-up.[176] Of the 35 online providers inspected as part of the report, 30 did not fully meet the CQC’s safety standards.[177]

In the pharmacy sector, both the GPhC and the CQC have raised concerns about online provision. The GPhC has revealed that online pharmacies are significantly overrepresented in fitness to practise cases, making up more than

a quarter of the caseload, despite representing just 2.7% of pharmacies.[178] Recent inspection data shows that only 63% of online pharmacies meet the GPhC's standards, compared to the overall benchmark of 84%.[179]

Issues include allowing customers to effectively 'shop' for particular medicines, poor identity checking processes, and prescribing high risk medications through an online form. The GPhC has stated that of the online pharmacies it has taken action against, the majority were working with online prescribing services that were 'prescribing medicines which are liable to abuse, misuse and overuse to people, on the basis of an online questionnaire' and added that this 'puts patients at risk of serious harm or death.'[180]

In the recent case of Pharmacorp, an online pharmacy prosecuted by the CQC, the company was found to be posting prescription medication to patients based on an online questionnaire, with prescriptions issued by doctors based in Romania. The CQC stated that the service carried a 'real risk of misdiagnosis' and 'exposed patients to a significant risk of harm'.[181]

Regulators' ability to act against online providers is impeded by restrictions on their geographical jurisdictions. The CQC for example, only regulates providers based in England. This poses significant challenges when services are available in England but based outside, even if they are within the UK. The CQC describes the problem as follows: 'Regulators have limited opportunities to take action in response to harm by providers that are outside the scope of their legal powers. We are aware of the regulatory challenges arising from the easier delivery of cross-border health care… and the legal limits to our regulatory powers. We know there are challenges where organisations provide services online that are out of the scope of CQC's regulation.'[182]

The GPhC has highlighted the risks of online pharmacies working with prescribers who are not based in the UK and not registered with the relevant UK professional regulator, which they believe could 'create significant extra risks for patients and the public'.[183]

There are similar and longstanding concerns in the optical sector, with The Association of Optometrists having warned that unregulated online providers are selling unsafe and poorly fitting contact lenses, putting the public at risk.[184] While contact lenses should only be provided by a registered practitioner, websites run by companies based overseas are outside UK jurisdiction, allowing providers to circumvent UK rules.

The GOC has long been grappling with this issue, and have stated that both professional bodies and registrants have asked it to 'do more to protect the public from illegal online sales, both UK and non-UK.'[185] However, in practical terms the action they can take is limited, as they outlined in their 2022 call for evidence on the Opticians Act: 'The reality is that the enforcement of our legislation relating to sales – bringing a private prosecution in the magistrates' court – is not practicable for an organisation the size of the GOC or in relation to sales in a global online market. Moreover, it is not realistic to expect the GOC to achieve legislative reform that enables us to routinely act against non-UK sellers.'[186]

In the dental sector, the advent of 'remote' or 'direct-to-consumer' orthodontics has raised significant concern, with accusations that it may expose patients to risk of harm. A number of these services offer patients clear braces or aligners having assessed their suitability for treatment on the basis of a 'selfie' photograph uploaded online. Appliances are posted out without the patient ever having had a physical examination.[187] Many in the sector have warned that this can result in long-term damage to dental health.[188] The GDC has issued a statement reminding dental practitioners that 'clinical judgements about the suitability of a proposed course of orthodontic treatment must be based on a full assessment of the patient's

oral health' and that 'there is no effective substitute for a physical, clinical examination as the foundation for that assessment.'[189] Both the GDC and the CQC have issued statements stressing the requirement for both professionals and providers to be registered with the regulators.[190,191]

Online provision is just one of the technological changes presenting challenges for regulators. The development of new technologies and innovations, including robotics and machine learning is just as significant. These include robot assisted surgery, AI, nanotechnology, the ability to grow organs and tissues in a laboratory,[192] wearables and implants, online symptoms checkers, virtual agents and even bionic organs.[193] Technological advances have the potential to vastly improve patient care and help address some of the workforce challenges facing the NHS; but technology is not a panacea and there are still issues to address, including, crucially, where responsibility lies when technology fails.

Cases such as that of the Da Vinci surgical system have brought some of these issues to the fore. The robot is used to perform complex heart surgery in conjunction with a human surgeon. The manufacturer of Da Vinci has faced thousands of lawsuits because the robot had malfunctioned, including cases where the machine has burnt patients and where parts of it have broken off inside them.[194] The first time the Da Vinci robot was used in the UK in 2005 it resulted in a patient's death, with the Coroner finding that it was caused in part by 'robotic assistance.'[195] In cases such as this, where humans work in conjunction with robots, the issue of liability and accountability can be unclear.

Liability for medical errors is even more difficult to determine where AI, or machine learning, is involved. AI can be defined as 'the capability of a computer program to perform tasks or reasoning processes that we usually associate with intelligence in a human being.'[196] It can be an incredibly powerful tool, but it is only as good as the data and algorithms that drive it. Numerous concerns have been raised about the potential for biased algorithms to result in incorrect diagnosis or inappropriate treatment. Algorithms may also disadvantage certain groups and exacerbate health inequalities between populations as referenced in the chapter on inequalities. Where this happens, it is unclear where responsibility and accountability lies; 'If diagnostic AI trained on data that over-represents white patients then misdiagnoses a black patient, it's unclear whether the culprit is the machine-learning company, those who collected the biased data, or the doctor who chose to listen to the recommendation.'[197] It had been suggested that practitioners themselves will need to understand 'where the underlying data come from and what biases might be embedded in the algorithms.'[198] However, expecting each individual healthcare practitioner to build up a detailed understanding of every AI tool they use may be unrealistic.

The recent Law Commission review of the regulatory framework for automated vehicles might provide a useful foundation for medical regulators to build on. The review recommends that, where a car is authorised as being 'self-driving' the human driver should not be held legally accountable for accidents, with liability falling instead on the vehicle developers.[199] This could be applied to robotics and AI within healthcare, if we were to develop a similar system for determining liability.

The MHRA has recently announced a work programme to provide a regulatory framework for software and AI in medicine which will require many applications to be regulated as medical devices.[200] The programme aims to ensure that software is safe and effective and that AI models are 'sufficiently transparent to be robust and testable or are otherwise properly validated'. A post-market surveillance system which includes the capture of 'adverse incidents,' is also in train. The MHRA hopes to complete this work by Summer 2023.and we hope that the programme will also provide

greater clarity on where responsibility lies in relation to errors arising from the use of AI in healthcare.

AI also has the potential to redefine the role of the medical professional. Alastair Denniston, Consultant Ophthalmologist at University of Birmingham Hospital has asserted that 'AI and autonomous systems will have a much wider role in diagnostics and diagnostic support – we will increasingly get to a point where patient data is automatically analysed via algorithms increasing efficiency and accuracy – in this context the role of a doctor is more in communication of conditions and exploring different risk pathways for treating conditions with the patient.'[201]

This imagined future presents its own challenges as it involves health and care professionals ceding judgement and decision-making to robots. As one article notes, 'as AI improves, it gets harder for humans to go against machines' decisions. If a robot is right 99% of the time, then a doctor could face serious liability if they make a different choice.'[202] In this context, it is vital that we address the issue of the professional accountability of clinicians alongside these new technologies and communicate clearly about it with patients and service users, professionals and employers.

The Governments, regulators and registers should review how they will determine the lines of accountability for new technologies used in health and care.

The momentum of all these advances continues to build. Boots, which has been trialling online consultations since 2020, has recently announced a new training programme on digital healthcare for all its pharmacists,[203] and Amazon has registered its pharmacy operation.[204] Meanwhile technological solutions are still being rolled out across the NHS. On both fronts, regulators need to provide agile solutions to new problems and find ways of managing emerging risks proportionately. The current, ongoing review of regulatory powers will be an opportunity to close regulatory loopholes and address issues around jurisdiction.

The Governments should use the regulatory reform programme to ensure that regulators have the agility to address the challenges brought about by new technologies.

It will also be important for healthcare professional regulators, accredited registers, education providers, medical royal colleges and employers to ensure that education, training, and CPD for registrants adequately prepares them to interact with new technology, including robotics and AI.

The future is now: our conclusions

Each issue we identify in this chapter, from the increasing role of for-profit providers and the conflicts of interest this presents, to the rise in online services, to the expansion of new and innovative models of care, represents a growing trend away from established models of provision. As the delivery of healthcare continues to evolve and change, regulators need to be able to respond agilely to meet the challenges head-on.

By and large, healthcare professional regulators are alive to the issues and already taking action to manage risks and protect the public. However, they are sometimes reluctant or unable to intervene (for example in matters relating to commercial practices) even where there is a legitimate case for doing so. This is partially due to the risk of challenge if there is no specific duty to act. They are also hampered by outdated and overly prescriptive legislation, and some lack the powers they need to best protect the public.

The Governments' current programme of regulatory reform may provide regulators with more agility to respond to emerging risks. It is also an ideal opportunity to look at some of these issues afresh and assess whether more action is needed to address them. Governments and regulators should strive to be ahead of the curve in respect of new delivery models, rather than constantly struggling to catch up.

Appropriate oversight and action are made more challenging by the number and range of bodies involved, with no one entity able to take a bird's-eye view of the emerging risks to patients and service users and identify possible solutions. We need more reliable mechanisms, for anticipating changes that open up public protection gaps across the sector – it should not be left to individual bodies within their limited remits. These mechanisms must be developed in partnership with patients and service users.

Recommendations

We recommend that:

- Governments use the current healthcare professional regulation reform programme to:
  - **a.** Review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses
  - **b.** Consider whether there is a case for extending business regulation powers to all regulators whose registrants work in 'high street' practices
  - **c.** Ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies.
- Regulators tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement.
  A cross-sector review should be conducted of the effectiveness of arrangements to address financial conflicts of interest among healthcare professionals.
- Governments, regulators and registers review how they will determine the lines of accountability for new technologies used in health and care.

We have also identified a gap that would ideally be filled by the Health and Social Care Safety Commissioners referred to in the final section of this report. We recommend:

- The development of reliable mechanisms for anticipating changes in service provision that open up public protection gaps across the sector, and identifying ways to address them.

www.professionalstandards.org.uk/safer-care-for-all

Contact

Professional Standards Authority

T 020 7389 8030

E info@professionalstandards.org.uk

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