The authors

Dr Simon Peck is a doctor specialising in health fraud, waste and abuse who works in the UK private medical insurance sector. He is previous chair and a founder of the Health Insurance Counter Fraud Group and regularly lectures in the UK and abroad on the subject. He has been involved in a number of high profile cases some of which have had national press coverage. He submitted evidence to the Health Committee in 2015 on the failure by the General Medical Council to tackle the widespread incentive payments from private hospitals to doctors which appeared to be designed to encourage referrals and the ordering of tests and investigations. He is writing in a purely personal capacity and these views do not necessarily reflect those of any organisation with which he is associated.

Samuel Denyer is an investigator in the private insurance sector. He is currently studying for a Masters degree in Counter-Fraud and Counter Corruption studies at the University of Portsmouth Centre for Counter-Fraud Studies. He also worked on the investigation of incentive payments and is writing this submission in a purely personal capacity.

Introduction

The authors of this submission have watched the Science and Technology Committee hearing into research integrity with some interest. Whilst we do not have experience in the area of research fraud, we have significant experience in healthcare fraud generally, the underlying culture which drives it and in the limitations of the current regulatory system. This experience has been gained in the fee for service sector of healthcare. We note that the committee does not appear to have considered submissions from experts on fraud and corruption in healthcare which seems to be a considerable omission. For that reason, we believe that many of our observations are relevant to this inquiry. Amongst those who have given evidence, Dr Wilmshurst who is well known to us has more first-hand experience of this sort of misconduct than any other person we know of in the UK, but even he does not have a strong background in systematically tackling fraud and corruption or in the various causes of such behaviour that criminologists and behavioural scientists have studied.

In this short submission we will explain some of the features in medical practice which lead to misconduct including fraud in healthcare being more widespread than the Committee may appreciate. We have also made some suggestions which we believe may alleviate the problem although we emphasise again that our experience is in management of fraud not research per se.
Conflicts of interest

A particular area of concern which drives much bad behaviour and has the potential to corrupt research is that of financial conflicts of interest. These are widespread in healthcare and the damage done by such conflicts is not widely appreciated. Whilst we are not aware of any studies of the effects of financial interests on behaviour of researchers and it is hard to see how such studies might be undertaken, there has been significant research into how financial interests corrupt medical decision making generally (1). These studies all show that financial interests corrupt behaviour of healthcare professionals not at the margins but at a level which is measurable in the population as a whole. This fact is not appreciated by many and there is a degree of denial even within the profession about this with many believing that professionalism counters the effect of such conflicts when the evidence shows that it does not. In the opinion of the authors, any solution must include the creation of a compulsory register of doctors’ interests – something one of the authors has called for in the past.

The culture generally

It is important to disregard any preconception that doctors are somehow more inherently good or honest than other people. Such assumptions have no basis in evidence and the “mystique” which so profoundly affects how much trust patients put in doctors needs to be overcome to reach any objective conclusions about the prevalence of dishonesty. It is unsurprising that there is an unacceptable level of corruption in healthcare given

- The considerable sums of money to be made
- The trust society invests in healthcare professionals
- The knowledge gap between medical professionals and society generally
- The weak and ineffective regulation which currently exists; the General Medical Council in our experience is particularly ineffective, it deals often poorly with complaints on a reactive basis and lacks the skills to investigate and deal with serious matters.
- The lack of a reliable external authority that patients or staff can raise concerns with which has either the expertise or resources to independently investigate concerns.
- Sanctions for wrongdoing are very rare and appear to us to be disproportionately light when compared to the offences committed.
- Medical confidentiality which whilst undoubtedly important for patient welfare can be misused. Often the person with access to the information is also the person whose conduct is being checked.
- The reluctance of healthcare workers to report misconduct and the way in which those who do are persecuted by the system
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- The tendency of institutions to protect their reputations at the expense of public welfare combined with the culture amongst doctors to not question the judgement of other doctors
- The tendency for the public and others to take at face value advice and information provided.
- Financial conflicts of interest which are considerable and in the UK not disclosed in many circumstances.

We have seen at first-hand how weak regulation in the healthcare sector allows fraud and serious financial conflicts of interest to go unpunished. In 2010 and afterwards the authors have brought to the attention of the regulators large payments made by hospitals for referrals and also cases of significant financial misconduct. The Competition and Markets Authority (CMA) upheld the evidence submitted by the authors (i) and acted to ban such payments although it must be said that further arrangements have since developed which seem to have the effect of undermining the CMA order. The medical regulators however took no effective action either on the matter as a whole or on the individual schemes which we brought to their attention even though these were high value and in direct contravention of the GMC mandatory Duties of a Doctor. It would be naïve to suggest that doctors would necessarily behave honestly when conducting research when a substantial number accept payments in return for patients.

The following examples may assist the Committee in understanding how pervasive and harmful corruption and fraud in healthcare can be:

The BMJ reported in 1995 that a total of 250 German hospitals and about 1500 doctors and administrative directors were accused of having accepted bribes from the makers of heart valves, pacemakers, heartlung machines, and hip joints (iii).

In 2013 the BMJ published an article about Joachim Boldt an anaesthetist who produced numerous studies before an investigation demonstrated he had falsified nearly all his research. The article highlights 200-300 deaths a year in the UK from the use of a colloid plasma expander known as hydroxyethyl starch and that Boldt’s research had shifted the research consensus in favour of its use. Around 90 papers have been withdrawn. One of the authors of this submission used hydroxyethyl starch in his clinical practice. Although he was not personally influenced by Dr Boldts work (much of which occurred after he ceased practice) it is now clear that a considerable body of material has been published in mainstream journals which will have influenced doctors and which appears to have been fraudulent in nature (v).

The US is suffering from an opioid addiction epidemic which has been widely publicised. The Centre for Disease Control (CDC) reports more than 40 people a day die from prescription opioids in the US. Various states are currently suing the
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manufacturer of Oxycontin, Purdue Pharma. The case is not concluded and these are allegations only. The following extracts are from a press release by the New Hampshire Office of the Attorney General (‘

Purdue failed to disclose that there is no credible scientific evidence that opioids are safe or effective for chronic pain, misrepresented evidence regarding long-term use of opioids and misrepresented the drugs’ risks and benefits, including the risk of addiction….

....The overarching messages from these Purdue salespeople were that:

Opioids are effective in helping patients long-term and improve their ability to function, allowing them to resume their work and their lives; and
Opioids can be taken safely long-term, even at increasingly higher doses, without an unmanageable risk of addiction, abuse, or overdose….

The Committee has seen and heard evidence from Dr Peter Wilmshurst on his experiences with research fraud. We both know Peter personally and professionally – we have shared our experiences and concerns in many meetings and we feel there are some key points he might not have emphasised:

· Many of his experiences came about during his normal clinical practice. We do not think he is unlucky, rather our own work in investigating fraud in private healthcare leads us to believe his experiences are the norm.
· He is different from many of his peers because he is scrupulously honest and raises concerns about poor conduct even where there is potential for him to suffer considerable personal damage from doing so.
· Peter is not paid and never has been for highlighting wrongdoing. His only incentive is his personal dislike of such behaviour and his understanding of the harms that result from it.
· Although he has managed to pursue a career in medicine it has been in spite of his work highlighting misconduct and not because of it.
· In our experience with discussing wrongdoing with doctors who are witnesses or whistle blowers, all expect to face persecution as a result and most are reluctant to go on record

We feel it is of particular importance to highlight that the culture is highly protective with little to no interest in inviting regulatory scrutiny or oversight. Clearly bureaucracy is a concern given the impact that has on doctors’ time but it seems there is an underlying view that the medical profession can regulate itself. Unfortunately this means conduct which to an outsider appears highly inappropriate can be acceptable in medical practice. For example BUPA (an
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insurance company) highlighted that in private practice patients were more than twice as likely to receive a type of knee surgery compared to NHS patients (vi). Such variations in practice are not uncommon and, as mentioned earlier, there is well publicised evidence showing how financial interests (including the ability to charge on a fee-for-service basis) affect clinical behaviour.

Where we have encountered particularly serious wrongdoing during our own investigations it has more often than not been the case that the offender, even if operating in a harmful way, is well known about by their peers and other clinical staff. In a recent case – currently the subject of a police investigation, we have spoken to numerous witnesses to a surgeon having performed unnecessary surgery on a huge scale for over a decade. Staff at all levels in the hospital and fellow doctors all informed us that they knew or suspected what he was doing.

The same themes emerged in the case of Ian Paterson who was recently sentenced to 20 years imprisonment for performing unnecessary procedures. This is shortly to be the subject of an independent inquiry (vii) which we would urge the Committee to look at.

Suggestions for improvement

Firstly given the role that financial conflicts of interest play, it is necessary that we have a mandatory searchable register of doctors competing interests whose terms are drawn widely enough to ensure that the various schemes to pay doctors (sham consultancy or employment, contracts with connected parties etc) are encompassed and disclosed.

We would urge the Committee to consider the current Department of Health review into medical regulation in the UK (viii). Problems with regulation such as the fragmented nature of the regulators and their lack of investigations expertise have, in our view, contributed to the prevalence of dishonest behaviour amongst doctors. There is a need for a body which is able to look at serious fraud and corruption. The GMC in its current form is not able to deal with such matters effectively

Any solution to the issues with research fraud will need, in the case of medicine, to include considerations about wider problems in the sector which contribute towards dishonest behaviour. Given the harms that can result from misleading research it is essential that those intent on breaking the rules come to believe that the risks of doing so outweigh the benefits. In order to achieve that there are various suggestions we would make:
Remove the incentives. This would have the most benefit in our view. If research is to be conducted in a truly robust and unbiased manner, the funding needs to be separated as far as possible from those performing the research – ideally with salaried staff and a commitment to publish the results regardless of findings.

Remove the rewards. Scientists should be free from arrangements giving them an interest, either professional or financial, in the outcome of the research.

Audit. Prior to publication an external expert should audit the evidence on-site and certify the findings. The cost should be included in the funding.

Sanction. Any flawed research should be retracted with appropriate publicity and this must be mandatory. This would create an incentive for much greater care to be taken by researchers.

Regulate. Standards for research should be regulated and mandated. One requirement should be a consent to access all the records for any trial and for that consent to require on-site access for investigators.

Investigate. This is where regulation most often fails and it is an all too common problem. For regulation to be effective the regulator or regulators require an effective investigations function capable of obtaining, assessing and packaging evidence fit for submission to a court including obtaining witness statements, conducting surveillance, compelling financial disclosures testing and corroborating evidence and with experts available to interpret technical matters. There is great experience in the UK police forces and other law enforcement agencies as to how to conduct investigations in a professional manner. These skills appear to be lacking in the medical regulatory sector. The City of London Police operates a specialised unit – the Insurance Fraud Enforcement Department (IFED) to assist insurers with tackling fraud. There is no agency offering these skills and expertise in the regulatory sector.

In our view there is nothing preventing the Committee from introducing an effective strategy to fundamentally reduce fraud and dishonesty in research. Further steps to consider in addition to those above are:

- A statistically valid sample of research should be reviewed in order to understand the extent of misconduct in any given sector.
- The creation of an independent reporting line manned by investigators and widely publicized
- An investigations team led by someone with experience of complex fraud investigations (see above)
- Publication of any investigation findings
- Prosecution of offenders

Examples of effective fraud reduction strategies in the UK include those by the DWP and the NHS Counter-Fraud Service (as was). In both cases the model
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includes naming and shaming and aggressive prosecution of the most serious wrongdoing. Benefits fraud is nowadays widely known about and much reduced due to the efforts of the DWP.

Whilst it might seem uneconomic to approach the problem in this way the reality is the reduction can have huge financial benefits. For example if the NHS stops funding unneeded, dangerous or inappropriate medicines, medical devices or procedures it will save money and spare patients from harm. Currently medical regulators spend far too much of their resources on reacting to problems rather than tackling underlying causes. They are ineffective at tackling wrongdoing and need reforming. Part of that reform should include the creation of an investigations body which is independent from the regulators. Such a body should be closely aligned with law enforcement and should benefit from bringing cases against any company which seeks to unfairly influence those conducting research either criminally or via a civil route.

It is essential that where rules are created they are also enforced. Many of the contributors to the Committee’s review have demonstrated the importance of transparency, oversight, clear standards and peer review – which are essentially rules. We also note that the BMJ and Wiley have provided evidence from studies which indicate fraud is a significant problem. In contrast those contributors who have expressed doubt about the extent of fraud or who have stated that fraud is rare, have produced little evidence to back up those claims.

In our view the most effective model to tackle fraud and misconduct requires an acceptance that a proportion of people are prepared to mislead others in order to gain a personal advantage, but also that a far larger proportion of people will get drawn into wrongdoing if they believe it is normal or accepted practice. In other words there are two types of people who commit misconduct – committed fraudsters (a small minority) and opportunists. In order to tackle opportunists cultural reform is needed. In order to tackle committed fraudsters effective investigation and sanction is needed. These two go hand in hand as the aggressive pursuit of offenders including naming and shaming has a limiting effect on the behaviour of those who otherwise might be drawn into committing misconduct. Any investigating body needs to be equipped to tackle a range of conduct and it is therefore important they have access to both civil and criminal sanctions and the means to publicise their work.

As things stand in medical research the incentives to commit wrongdoing outweigh those to behave properly. Fraudulent or substandard research is cost effective, subject to limited scrutiny and has the effect (unless they get caught) of raising the profile and status of the author. The Committee should consider that one benchmark of “success” amongst doctors is the number of papers they have published.
As a closing and cautionary remark we would highlight the following comments by Professor Malcolm Sparrow (ix) in Transparency International's 2006 Global Corruption Report into the health sector.

**The dangers of rushing to structural solutions.**

Normally one would applaud policy-makers for seeking long-term structural solutions to integrity problems. Anti-corruption literature emphasises structural changes in incentives as a method of eliminating known forms of corruption and embezzlement. Many officials, concerned about fraud in the fee-for-service health structure, mistakenly assumed the advent of capitated managed care systems would eliminate the fraud problem by removing the financial incentives for overutilisation and overbilling. What they realise now is that changing the structure without removing the bad actors leads to criminal adaptation, and a whole new class of scams.

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3. BMJ. *The German Heart Valve Scandal Continues:* BMJ 1995;310:1160


