

Revocation of Medical Licences in the UK and Norway

A comparative investigation

Dr Alex Mears
Visiting Fellow
London South Bank University
London, UK

Hans Einar Hem
Associate Professor
Buskerud and Vestfold University College
Faculty of Health Science
Norway

**London and Vestfold
2014**



Dr. Alex Mears has since the project was undertaken changed to a position in NEL Healthcare Consulting which is a part of NHS. His current contact address is Alex.Mears@nelcsu.nhs.uk.

Associate Professor Hans Einar Hem's mother institution has undergone several mergers and are now University College for South-East Norway. His contact address is currently heh@hbv.no.

Table of Contents

Summary and conclusions	
Background	6
The project	7
Investigative model	8
Research questions.....	8
Descriptive analyses.....	22
Inferential analyses	28
Discussion	33
Stakeholder interviews: perceptions of and attitudes to the Fitness to Practice process in the UK.....	34
Methods.....	34
Results.....	35
Interview 1: General Medical Council.....	35
Interview 2: the British Medical Association	39
Interview 3: ex-health minister	43
Analysis of English results.....	49
Discussion: Overarching themes.....	49
Synthesis of two data sources for the English data.....	51
The FtP process.....	51
The misfeasing medics.....	51

Summary and Conclusions

This project has been conducted at the request of the Norwegian Board of Health Supervision (BHS), *Helsestilsynet*. The aim is to look into and compare the practice of revocation of authorisation for medical doctors in Norway and England. The assumption was that, while England has a fairly strict practice, practices in Norway are stricter.

We, Dr. Alex Mears, visiting Fellow at London South Bank University, and Associate Professor Hans Einar Hem, Buskerud and Vestfold University College, have used a mixed-methods approach. We have collected statistics from the UK Commission for Quality Care (CQC) and the Norwegian Board of Health Supervision (BHS) and have interviewed 4 experts in the English system and 5 in the Norwegian system. We have analysed 113 case reports from BHS.

The small numbers makes statistical analysis vulnerable. But for UK we have undertaken a fairly comprehensive analysis. In the case for Norway we did not find this feasible since the numbers are very small, and it would be impossible to make valid interpretations. Therefor we have gone through and analysed qualitatively the case reports decisions were based on.

The themes we have investigated have produced the following results and reflections (see Chapter1, “The project” and “Research Questions”):

- The phenomenon of revocation is fairly similar in England and Norway. It is practiced with great care in both countries; very few doctors have their licence revoked. However, the executing bodies, the UK General Medical Commission (GMC) and BHS differ somewhat in nature. While GMC is an independent, professional body, BHS is an arm of the government functioning as an audit for service quality. BHS works only according to law, while GMC has a wider perspective on code of conduct. The cases that lead to revocation in Norway are totally based on single case reports, while GMC at least has an intention of more risk-based assessments driving their work.
- The main difference between the systems in the two countries is in the organisational setup to perform the different functions. In Norway this is entirely driven by the government; even the Ombudsman for patient rights is employed by the government, though they are instructed to be independent (and we have found no evidence to the contrary). The medical doctors professional association, *Den norske legeforening* (DNL) is outside of this process. While they have a Code of Conduct and work on the ethical standards of medical work, they have no role in the inspection or regulation process. In England, the British Medical Association (BMA) is also outside the process, but the General Medical Council (GMC) is a professional body and we assume that the relation between BMA and GMC is different than the relation between BHS and DNL in Norway. In Norway the principle of independent audit developed in the 1990s and was firmly set by the government in 2001. The authority to revoke was linked to BHS and more legal bases in the laws.

What, then, drives the process of “Fitness to Practice”? What are the roles of trust and cultural norms, and what does the process of regulation and investigation produce?

We have given more space to the bumpy road NHS has gone down to illustrate why the regulatory approach has changed several times in UK. First and foremost, trust in

the idealistic, altruistic health service was brought down by several scandals. It seems the government and the regulatory system tried to address these scandals with new methods of regulation and monitoring based on risk assessment. This has not worked so well, and the government is now reverting to more comprehensive surveillance. In Norway the level of trust seems higher, and the regulation system has been under less pressure.

Even if the historical process of regulation and monitoring has been quite different in the two countries, the phenomenon of revocation seems to be rather similar: the number of cases is rather limited and there is a thorough process that often ends with a warning or partial revocation. It does not seem to be stricter in Norway than in England, but the Norwegian statistics may be somewhat misleading. The BHS use the revocation as a sanction for doctors who fail to deliver documentation in time, but they nearly always comply and get their licence back soon after. This cannot be seen as a means to reduce risk or secure quality.

In the UK, those medical doctors whose licenses are revoked are primarily male and the reasons are primarily due to misconduct. In Norway nearly all doctors are male but the cases are connected to drug abuse or alcoholism, some to sexual misconduct. Very few cases are related to clinical malpractice and, where they are, are almost always limited to a warning.

Revocation of authorisation has a rather limited role as a means of regulation, and we do not find significant differences in practice corresponding to the initial assumption that the practices in Norway are stricter.

Conclusions

Our conclusion is that revocation is conservatively used and the legal rights and legal security of doctors are unlikely to be violated in this process. Norway does not use revocation significantly more than England.

But this also means that revocation is not used to any large extent to regulate quality of practice or avoid risk. On the contrary, the quality of professional work is seldom punished with more than a warning. In the case of Norway, where we read the case reports, this pattern stands out clearly.

We find this to be sound. Analysing the risk system, revocation is hardly a very good instrument to regulate the whole system. As for now it is a small supplement.

London and Vestfold, Dec. 2014.

Due to various circumstances related to our work situations the final editing was not finalized before now.

Dr. Alex Mears has left LSBU and are now with NEL Commissioning Support Unit.
He can be reached at 'Alex.Mears@nelcsu.nhs.uk'
Hans Einar Hem can be reached at 'Hans.E.Hem@hbv.no'

London and Vestfold, Dec. 2015

1. The assignment and questions for investigation

The assignment

In the fall of 2011, Dr. Alex Mears (London South Bank University) and Associate Professor Hans Einar Hem (Vestfold University College) met with Geir Sverre Braut, Deputy Director of the Norwegian Board of Health Supervision (*Helsetilsynet*). Braut expressed concern regarding the efforts of the EU to ensure relatively free movement of EU citizens, including health personnel, within the EEA and the consequences of differing practices across countries with respect to revocation of authorisation to practice. He suggested that we review practices of revocation in Norway and England based on his assumption that, while the practices in Norway are stricter than those in England, England has a higher degree of revocation. Our working assumption was that significant differences between Norway and England would be a matter of concern and would also indicate a need to analyse variations in other countries.

We undertook to carry out a small and limited project on behalf of our institutions, London South Bank University and Vestfold University College¹, with funding from the Norwegian Board of Health Supervision. The project became bigger and more time-consuming than anticipated but we believe it has been worthwhile, especially since our findings differ from the initial assumptions.

Background

In a number of health and social care professions, practitioners, including medical doctors and nurses are required to hold a licence to practice. Such a licence implies that the practitioner has achieved a minimum level of competence in their profession, both theoretically and practically, and they are able to perform to a set of professional norms, often defined by a code of conduct. The level of competence and the code of conduct are agreed and set by professional bodies, educational institutions and relevant governmental agencies.

In order to ensure that the practice of professionally qualified staff remains within the boundaries defined by the competencies, quality of performance and code of conduct and that patients/users of care are not put at undue risk, regulatory mechanisms are in place to apply censure where appropriate, or in extreme cases, suspend or withdraw the licence to practice. These mechanisms are administered by the requisite professional body with governmental support, or by a government audit institution.

Examples in England include doctors whose licences have been revoked ('struck off the medical register') where they have caused the death of a patient through negligent practice, and those who have undertaken unethical research. Examples from Norway include inappropriate relations with patients of a sexual nature and drug or alcohol abuse.

All countries in Europe have such parallel processes and where a very small proportion of professionals fail to meet the level of competence or behaviour

¹ From 2014, merged to Buskerud and Vestfold University College

prescribed. These professionals have their licence to practice rightly revoked. Anecdotally the rate of revocation varies considerably, yet there is little current research that explores the magnitude of this variation, or the drivers behind it. The implications for practice are considerable, as doctors are now (as part of an EU directive²) able to travel and practice freely between nations, whilst at the same time the knowledge about fitness to practice does not necessarily follow, or even when it does its status is unclear³.

In the UK, registration of doctors is the responsibility of the General Medical Council (GMC) who set the criteria to be met before a doctor can begin to practice (appropriate qualification, fitness to practice, adequate insurance and payment of fees). The GMC also defines criteria for other practices, including continuing professional development. There is also a system in place to deal with medics who fall short of the behaviours expected in terms of:

- Misconduct
- Deficient professional performance
- Convictions and determinations by another regulator
- Adverse health

In all such cases, the Fitness to Practice (FtP) protocols are invoked (Law Commission consultation paper, 2012).

In Norway a national registry, *Helsepersonellregisteret*, administered by *Statens autorisasjonskontor for helsepersonnel* (SAK), registers all persons who meet the required academic and practical requirements. Registration denotes authorisation to practice as a health professional.

The project

This project explores this phenomenon using Norway and England as examples. We set out to:

- investigate the phenomenon of revocation, what it means in these two countries and how it is perceived by key stakeholders;
- describe the regulatory regimes of these two counties, looking into the risk-control mechanisms that drive regulatory processes;
- draw out the influence of regulatory approach on the revocation process;
- explore how cultural norms impact on what is deemed to be acceptable behaviour and what is not and may lead to revocation ;
- unpack the processes of licensing and revocation, and investigate the data to understand if artifactual effects are leading them to be lacking accuracy; and
- demonstrate the above by undertaking a comparative study across these two countries.

² https://ec.europa.eu/growth/single-market/single-market-services/free-movement-professionals/policy-developments/legislation-professional-qualifications_en

³ <http://careers.bmj.com/careers/advice/view-article.html?id=20004142>

Investigative model

Advised by Braut, we used the Hood Risk Comparison Control Theory (Hood, Rothstein, & Baldwin, 2001) to give structure to our investigation, specifically for cross-national comparison. This gives three control components that form the structure of our investigation:

- a) Information gathering
 - The triggering of the revocation process
 - Information flows into the revocation process
 - Involvement of other agencies
- b) Establishment of competencies and standards of behaviour
 - The process that leads to the establishment of competencies and standards
 - The bodies and individuals involved in the process
 - Content of the competencies and standards
 - The level of professional evaluation required
- c) Behaviour modification
 - The relationship between the revocation process and the legal/ judicial process
 - The process from initial complaint to revocation and step-off points between
 - Sanctions used
 - Use of non-revocation warnings

Research questions

1. How many medical professionals have had their licences revoked in the last 5 years (2006-2011) in the UK and Norway? How are these changing year on year?
2. What is the rate of revocation for Norway and the UK? How are these changing?
3. Are there demographic patterns in the medical personnel whose licences are revoked, and, if so, how do these differ between the comparator nations?
4. Are there patterns in the medical speciality of the doctors whose licences are revoked? Are these country-specific?
5. What are the reasons given for these revocations? Are these constant or changing? Do they differ by country?
6. What are the formal processes for granting and revoking licences in the UK and Norway and what are the key similarities and differences? Specifically those outlined in Hood's model (Hood et al., 2001).
7. Are there other mechanisms that are preventing a formal revocation in each country?

8. Are there cultural factors influencing revocation decisions?
9. Is the perceived role of the doctor influential in inappropriate behaviour coming to light?

2. The system and the function of revocation

Regulation vs. inspection

We are going to dwell a bit on the different aspects of the systems regulating health care in the two countries. Regulation and inspection may be seen as two different functions. Regulation includes working out the standards of competence and quality of performance. Inspection includes gathering information about actual performance. The third part of Hood's model, behaviour modification, was guided by regulatory norms but executed by sanctions following inspections.

The regulatory system has many mechanisms, and revocation of authorisation is just one of them. It is a strong one though, and could be seen as an important sanction in the system.

The Evolution of the English Regulatory System

Introduction: the need for regulation⁴

Throughout most of the post-war period, there existed an overriding belief that those working in the public sector acted as 'knights' in the Panglossian sense, and therefore there was little real interest in holding organisations to account for their performance. Healthcare workers were assumed to act only in the interest of their patients, in an essentially altruistic fashion. It was a scandal over ill treatment of patients at Ely hospital that began the sea-change of view that led to increased scrutiny and the establishment of the first real healthcare regulator. This set a pattern that arguably culminated with the events at Bristol Royal Infirmary that finally ended this assumption of 'knightly' behaviour.

Regulation plays a number of roles in a country driven by social purposes rather than economic ones. Economists argue that regulation is a response to market failure, while social policy theorists view it as fulfilling a number of socially desirable goals, outlined below:

- Accountability, particularly at a local level

A key role for regulation is to ensure that care-providing organisations are accountable for the care they deliver. This is particularly true in the NHS, where, as an organisation funded by central taxation, accountability is ultimately to the taxpayer. With some public sector enterprises, accountability at a central level is feasible; the NHS is devolved to the extent that this would be completely unfeasible. For the purposes of accountability, then, it is necessary to introduce a new agency that

⁴ We wish to thank Neil Prime, Head of Analytics, and Alex Griffiths, Team Leader, both in the Care Quality Commission, UK for important support in writing this chapter.

can examine organisations at the local level. An effective regulator will provide this through engagement at a local level in the form of inspection or visits.

- Driver of quality improvement

There is much evidence that publication of performance measures and/or censure from a regulatory agency is a driver for improvement of itself. Publication of comparative performance data is important to engender trust in the public body, and also provides additional accountability. In addition, while there is little evidence that publication of information is used directly as a means for patients to choose their provider, the threat that this might take place can be enough to drive improvement. Finally, most providers would not want the loss of kudos that goes with censure by a regulator.

- Investigation of service failure

In those few unfortunate cases where standards of care fall below that which can be reasonably expected and patients are put at risk, it is essential that there is an independent regulatory body to investigate the causes and put learning into action. The Healthcare Commission investigation into excess deaths at Mid Staffordshire NHS Foundation Trust in 2006 demonstrates clearly how far standards can fall and how important and effective an investigation can be.

- Assurance of minimum standards

A key role of a regulatory body, and one that has been a common thread throughout the history of regulation in England is the imposition and testing against some minimum set of standards of care. The source of the standards has varied, as has the mechanism for assurance of compliance, but the essential principles are consistent.

Regulatory paradigm

Regulation theory describes two polar opposite regulatory paradigms: the deterrence model and the compliance model, although most regulators sit between the two, displaying aspects of both. The former is based on the premise that all regulated organisations are ‘amoral calculators’ that will behave in a way to maximise their own benefit at the expense of all others. Deterrence regulators, therefore, are forced to monitor their self-interested charges very carefully and use draconian sanctions to make them behave properly. These regulators make extensive use of formal standards and inspections, and frequently resort to what amounts to punishment in the form of penalties for non-compliance. Relations between regulator and regulatees are often strained and antagonistic, and are likely to lead to sharp practice and avoidance behaviour. Compliance regulators, by contrast, see their providers as ‘good-hearted

compliers' who share the overall goals of the regulator. There is a presumption of trust and culture of support. Lack of compliance is assumed to be a result of incompetence or bad luck unless proven otherwise. The set of presumptions underpinning this approach share much with the 'Panglossian' view of healthcare professionals prevalent in the postwar period, an overriding belief that those working in the public sector acted as 'knights', and therefore there was little real interest in holding organisations to account for their performance. The compliance model creates good relationships between regulator and regulated, but can lead to over-familiarity, shared culturisation and lack of objectivity on the part of the regulator. Self-interest is seen as more important than the ultimate consumer- witness the allegations levelled at the Financial Services Authority and their role in the recent financial crisis.

A development of the deterrence-compliance dichotomy is the responsive model. This centres on a reactive approach to regulated organisations, rather than a one-size-fits-all approach. High performers, low performers, 'amoral calculators', 'good-hearted compliers' are all treated differently, according to their behaviour and performance. This approach necessarily depends on a high degree of organisational knowledge on the part of the regulator- without this, it would be impossible to determine where the regulated bodies sat within the developed typology. This typology determines the level and type of engagement that the supervisor enters into. For example, good performance can be rewarded with higher levels of autonomy and a lighter touch. The amoral calculator can be monitored more carefully to ensure compliance with broader system and societal goals.

Risk-based regulation is a further, more recent development of the responsive approach, and was in part a reaction to the deregulatory rhetoric of the 1990s, as well as some high-profile service failures. The rhetoric led to the Hampton Review in England, a wide-ranging review of regulatory principles. This review concluded that regulation ought to be risk-based so as to concentrate resources to areas that need them most; it should be transparent and proportionate, and accountable. Risk-based regulation enables the supervisor to spend most time with those organisations at highest risk of failure or non-compliance; it is also considerably cheaper than a full-coverage, cyclical model.

As has been stated, the majority of regulators in all sectors will fall between these two polar opposites, and organisations within will vary in their approach, which itself will change over time. In England, the model has always broadly compliance-based, although the relationship between the regulator and regulated is not what might be called collusive in the same way that allegations have been made with regard to financial regulation. There has historically been a sense of respect and perhaps fear associated with a visit from the regulatory body. That said, with any regulatory regime, there is a tendency for organisations to become overly familiar with the nature and content of inspections, and thus these become less of a concern as

organisations gear up to the specifics that will be asked of them - a form of low-level gaming. This has perhaps been less of an issue for organisations in England in more recent years, given the pace of change in regulatory approach.

An interesting philosophical question might be posed with regard to the regulatory paradigm: do organisations adopt a persona to fit how they are regulated, or does regulation evolve to meet the character of the regulated world? We shall revisit this below.

The evolution of regulation

For the sake of expedience we divide the history of regulation into three main phases:

1) pre Commission for Health Improvement (CHI), 2) CHI, and 3) & 4) post-CHI risk-based regulation.

1. Pre CHI, the early days of regulation

Up until the late 1960s, there was no regulator in healthcare as we would recognise it today. There existed a reliance on the ‘knightish’ behaviour of caregivers, couple with a multitude of policy documentation from the governmental centre. This changed in 1969, with the care scandal at Ely Hospital in Cardiff. The discovery of examples of very poor care led to a public enquiry and a recommendation to set up an independent inspectorate to monitor long stay institutions for the elderly and mentally ill (of which Ely was one) to ensure the quality of care [23]. The Hospital Advisory Service (HAS; later Hospital became Health) was created by the Secretary of State Richard Crossman to fulfil this role.

The role of HAS became to regulate care provision through the Health Authority, and followed a broad compliance model. A team of clinical secondees would undertake a programme of visits on a rotational basis, or ‘for cause’, where information had been received about a specific service. Inspections worked on a ten-year cycle, and the multidisciplinary team would be onsite for 2-5 weeks. HAS as the first real regulator met with early plaudits, but the familiarity with its methods led to a falling off of its profile. Criticism has been levelled that there was a high degree of inconsistency in the inspection reports [24], and that the use of clinicians led to an introspective approach with little involvement of other stakeholders. In addition, the familiarity with its methods led to gaming insofar as organisations were well geared up to presenting their best face to the inspectors. HAS had little in the way of enforcement powers, and was disbanded in 1997.

In addition to HAS, a number of other bodies were involved with healthcare regulation from the mid 1980s. The now defunct Audit Commission oversaw value for money aspects of service delivery and the National Audit Office oversaw

accounting and financial probity. Both adopted a broadly compliance-based approach, and published findings. Finally, the Health Service Ombudsman's office (ref) undertook investigations into maladministration, but was only involved in handful of cases where local resolution had failed. These investigations tended to be lengthy and complex, and gave the Ombudsman a powerful but quite limited scope.

A number of non-statutory bodies were also involved peripherally, with accreditation schemes or similar (for example Medical Royal Colleges, King's Fund).

2. CHI- star ratings and the clinical governance review

The rather piecemeal approach described above endured until the abolition of the HAS was followed in 1999 by the creation of the Commission for Health Improvement, commonly known as CHI [25]. In common with HAS, one of the drivers for the formation of CHI was a high profile service failure, this time at Bristol Royal Infirmary [26], where regrettably a number of very young cardiac patients lost their lives due to poor care. In contrast to HAS, CHI had a number of regulatory strings to its bow. It undertook inspections at all NHS organisations, based on a clinical governance review model [27], working on a full-coverage 4-year review cycle. A multidisciplinary team led by a review manager would spend a few weeks at the target organisation, using a variety of evidence-gathering tools to assess compliance with clinical governance best practice principles. In an important development, CHI used nationally collected and specifically analysed data to prioritise and guide areas of focus within review visits. In a development of the HAS-style role of a pure inspectorate, CHI acquired some additional responsibilities, to undertake in-depth investigations into serious service failures and to carry-out focussed national reviews of specific areas of delivery. In the latter period of its short life, CHI also led on the publication of NHS star ratings, which accorded each organisation a score derived from analyses of nationally available data such as targets. The targets-based rating system and the star ratings that derive from them have aroused much debate, but there is no doubt that this marked a very definite policy direction for healthcare regulation, and characterised the early years of the Blair government [28]. CHI had little in the way of enforcement powers, but the effect of the publication of review outcomes and particularly star ratings was extremely powerful and far-reaching [29].

3. Healthcare Commission- from full coverage to risk-based regulation

In 2002, the Department of Health issued *Delivering the NHS Plan* [30], which announced a new regulator, the Commission for Healthcare Audit and Inspection (CHAI). This new body, which would incorporate CHI as well as elements from the Audit Commission and the inspectorate of independent healthcare, the National Care Standards Commission (NCSC), came into existence in 2004, soon assuming the more familiar name of the Healthcare Commission (HC). It would expand the CHI

role, with a new broader assessment mechanism called the Annual Health Check using the newly defined Standards for Better Health [31] to deliver two overall scores for each NHS organisation: quality of service and use of resources. In addition, a direction of travel would be the ultimate alignment of the assessment systems for NHS and independent healthcare. From 2005, a risk-based approach to inspection was adopted to reflect concern about the burden of regulation and monetary issues, a risk-based methodology was adopted using a combination of self-certification by organisations and a surveillance-style analysis of existing data to identify those trusts most likely to be at risk of undeclared non-compliance. This new approach reflected the principles in the Hampton review of regulation [32] espousing a reduction in burden through a targeted review and proportionality.

The results of the Annual Health Check were still published, and continued to carry influence as star-ratings did before them. The programme of service-specific reviews and studies continued, as did investigations (including the most damning to date at Mid Staffordshire NHS Foundation Trust [33]). An addition to the regulatory armoury was analysis of mortality and other outliers to point to potential areas of concern. Finally the Health care Commission assumed responsibility for a stage of complaints handling between local resolution and the Ombudsman's office.

The clear and radical shift here is from the full-coverage cyclical model towards a risk-based methodology. Aspects of the previous regime remain, however.

4. CQC- registration and the QRP

Even while the Healthcare Commission was developing its methodologies, governmental plans were continuing, the aim to reduce burden and strengthen regulation further by merging health and social care provision into one super-regulator. As early as 2005, the Chancellor of the Exchequer announced plans to bring the Healthcare Commission together with the Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission (MHAC) to form what would become the Care Quality Commission (CQC [34]). Like the Healthcare Commission before it, the creation of CQC was politically driven, and not motivated by a scandal or service failure. Its birth did coincide with the report outlining the failures at Mid Staffordshire, but arguably while the events at that organisation were shocking, the detection and investigation thereof are from one perspective an example of how regulation was being effective.

With another change of regulator came another evolution of the regulatory approach. Continuing one theme from the HC, CQC's approach was to use data and analysis within a risk model to prioritise scarce fieldforce intervention resource. Instead of an annual cross-checking process against a self-reported declaration (the Annual Health Check model), the emphasis was on providing ongoing information to field operatives to facilitate local decision making and prioritisation. The mechanism for this process

was a device called a Quality and Risk Profile (QRP [35]); this is essentially a dashboard that presents risk estimates for a series of minimum care standards; the inspector can drill down from domain to standard and eventually to each data item to understand which is triggering the risk score. Through use of a common, consistent judgement framework [36] the inspector can use this information to prioritise their resource to the most appropriate organisation.

Perhaps the biggest change introduced with the CQC is the introduction of registration for all health and social care providers [37]. To register, organisations are assessed against a set of minimum standards- failure to meet these can prevent registration taking place if serious enough, or alternatively lead to registration conditions being imposed. Conditions will only be removed when that organisation had demonstrated improvement leading to compliance. Once initial registration has been achieved, the QRP is used to monitor ongoing compliance. The emphasis is away from the annual big-bang Annual Health Check that characterised the HC to an ongoing assessment regime heavy on local engagement. In introducing a registration system for health and social care, CQC has succeeded in aligning regulation for the NHS, independent healthcare and social care.

In common with CQC's emerging role as more of an inspectorate than a regulator, the complaints function has been completely expunged, and the national reviews function radically slimmed.

General Medical Council Fitness to Practice (FtP)

While CQC is the regulatory body, inspecting and overseeing the health care system, the authority to revoke medical doctor's licence is held by the General Medical Council. This is a independent professional body, but appointed by the government. Part of its role is to determine the acceptable standards for medical practice, and take action where a doctor does not meet these, through its Fitness to Practice procedures (FtP).

Information is received by the GMC in the form of enquiries, where a doctor's fitness to practice has been called into question.

Information received can lead to three outcomes:

- Closure: the information received does not raise an FtP question the case is closed, no further action taken.
- Stream 2: where the information of itself is not of sufficient concern to raise an issue, but could be if seen as part of a broader pattern. Stream 2 leads to enquiries of the doctor's employer or contractor to establish any concerns; depending on the outcome of that, a further investigation may be carried out.

- Stream 1: where the information received leads to immediate concerns re the doctor's FtP, a full investigation will be carried out.

Allegations investigated are presented to two case examiners, who decide on the next stage, which can be:

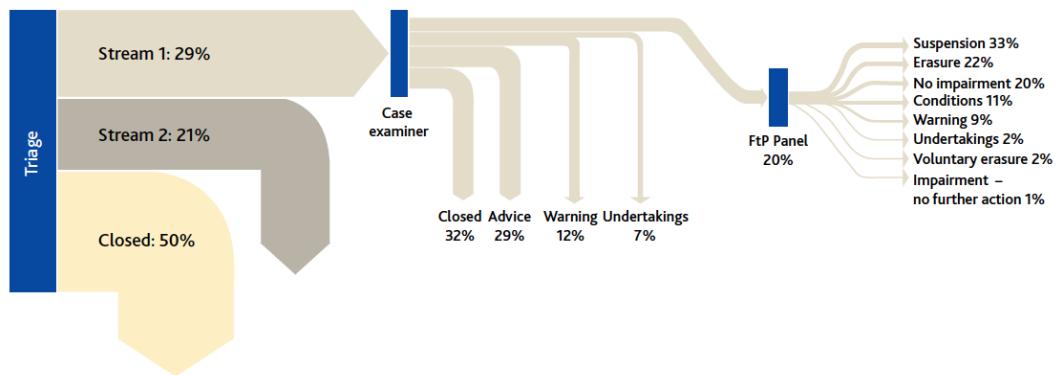
- No further action
- Advice to the doctor
- Issue of a warning
- Agree undertakings
- Refer the case to the FtP panel

A referral to panel can also be made where the doctor has not complied with the case examiners' requests. The FtP panel will hear the evidence around the case, and decide what action must be taken:

- Suspension
- Erasure
- No impairment
- Conditions
- Warning
- Undertakings
- Voluntary erasure
- Impairment- no further action

Figure 1 shows a schematic diagram of the case flow described above, with throughput derived from 2010 data.

Figure 1: schematic of the GMS FtP process, showing 2010 data



The Norwegian System⁵

Legal base and organisation

The Norwegian Board of Health Supervision (BHS)

The authority to revoke a medical doctors' authorisation is with the Board of Health Supervision (BHS), *Helsetilsynet*. Most legal regulations concerning the functioning of health personnel are set out in the Health Personnel Act from 1999 (Berfring & Ohnstad, 2010). The *reactions* are described in §§55 – 66. These paragraphs set out the legal authority of the Board to revoke (§57) after opening the case (§55), giving a warning (§56), and several milder reactions such as temporary suspension, limited authorisation, obligatory investigation, voluntary waiver, revocation of the right to prescribe medicines class A and/or B, temporary suspension from the right to prescribe these medicines, and action on information from other countries.

The BHS is a governmental body under the Ministry of Health. The translation 'health supervision' of the Norwegian '*helsetilsyn*' does not reflect the full association in English. '*Tilsyn*' means 'to look after'. BHS is the government audit unit for the quality of health services. In Norway the government is the primary provider of health services. While BHS is a government body, it is set up to be independent of the implementing directorate, the regional hospital companies and the municipalities. BHS has the authority, given to them by the government, to execute the above-mentioned paragraphs in the Health Personnel Act on behalf of the state. The medical doctors professional association (*Legeforeningen*) plays no role in this.

Severe cases are reported to the police and may be subject to public prosecution under criminal law. Regardless of the outcome of such prosecution, BHS must still carry out an independent evaluation and make an independent decision on whether a doctor that has been tried and found guilty according to criminal law shall be subject to revocation of authorisation.

The process

BHS comprises of 18 regional branches that used to be part of their organisation but are now formally under the Regional Commissioner. The Regional Commissioner is the representative of the central government in the counties, the regional level of government. The Regional Commission comprises of a division for health and social services, headed by the Regional Medical Officer (*Fylkeslegen*) and it is this division that conducts audits of health and social welfare services. Audits of the health services are carried out on behalf of BHS based on its legal authority.

There are two types of regional audits: planned (mostly system audits) or in response to concrete events (i.e., an event reported by the patient, the patient's family, the

⁵ Since this is a report for a Norwegian organisation, we expect most readers to be more familiar with the Norwegian system than the English system. We have therefore chosen to go into more detail on the English system. We describe the Norwegian system only to the extent necessary for the purposes of comparison.

patient's ombudsman, a whistle blower within the health service, or reported by the media). In the latter case, the Regional Medical Officer is responsible for investigating the case and has the authority to instruct service providers to make changes to avoid future risk behaviour. However, the Regional Medical Officer does not have the authority to revoke the licence from health personnel. When revocation may be an adequate response, the case is forwarded to the head office of BHS in Oslo where it is reviewed by a health expert and a legal expert before a decision is taken.

The BHS in Oslo relies on data and information collected at the regional level. Information is collected and the doctor under investigation is asked to give an opinion. He or she is always given a chance to meet BHS representatives in person, in a meeting. The doctor may bring a lawyer to the meeting.

After the process is concluded, a letter with the decision is sent to the doctor, who may appeal within 3 weeks to the Health Personnel Committee (*Helsepersonellnemnda*). They will review the case and have the authority to change the decision.

The Regulator

The Board of Health Supervision is, in the terminology of 'regulator vs. inspector', the inspector or auditor. When representatives from BHS carry out an inspection, they call themselves 'auditors'.

The regulator is the Department of Health, *Helsedirektoratet*. To set standards for competence and performance, they work actively with a clearinghouse to develop guidelines for practice. These are sent out to the service providers, mainly public sector.

While BHS may refer to these guidelines when they carry out inspections, their use is based in law. Norway has a strong legal direction in inspection work and one of the auditors is always a lawyer. The police and the legal system are never brought in to regulate the laws for health services.

3. Collected statistics and data

Method

This project looks into two systems that have the same function in society but differ significantly in size. The UK population is about 12 times greater than that of Norway. The National Health Service is—or has been—one of the biggest organisations in the world. This also reflects the methods of regulation and monitoring.

Above we have described some of the history of health service monitoring in the UK, and the shift from direct inspection to risk assessment through statistical analyses. This shift has meant that we also had access to good statistical data for the UK with sufficient numbers to carry out meaningful statistical analyses. Therefore, our main analyses of the situation in the UK are based on statistics from CQC.

To understand more of the reasoning behind the practice we interviewed the different parties as qualitative interviews of central actors. We have given a detailed account of these interviews below.

In Norway BHS publishes an annual report with statistics of revocation of licence for different groups. The numbers are so small that statistical analysis for correlation or regression would not meet any criteria of validity or reliability. Our approach to the data from Norway was to look more deeply into case reports that gave arguments for the decisions. We first looked at a sample of cases of revocation from 2006-2011, but found that we needed to see all cases, including those that resulted in just a warning. We asked for all the cases from one year, 2011, which from the numbers looked fairly representative. It proved both difficult and time consuming for BHS to provide these cases, but, in the end, they provided 73 out of 97 case reports.

We also interviewed people from BHS on the national and regional level, and a regional leader for the professional medical association.

The analyses and comparison between the two countries are difficult due to the difference in size, structure and history. Also we found a significant difference in general trust. Norway would be seen by social scientists as a country with high social capital while the UK would not be at the same level. This affects the health system.

The United Kingdom: Statistics and descriptions

Descriptive analyses

Where possible, for demographic variables, data are presented from the GMC⁶ to show the proportions reflective of all doctors currently on the register. In this way, it is possible to see how far the proportion of doctors in the FtP process mirrors the total population.

As described above, values given are for all outcomes or for individual doctors, as indicated.

In total, for the years 2007 to 2011, 1206 doctors were involved in a total of 3207 FtP events (a mean of 2.66 events per doctor).

- Age (by doctor)

The FtP sample breaks down by age as shown in Table 1:

Table 1: FtP Sample by Age

Age Group	Count	Percent
30 and under	30	2.8
31-40	223	20.9
41-50	295	27.7
51-60	260	24.4
61-70	206	19.3
71 or over	52	4.9

GMC data for age for all doctors on the register uses different age bands, and thus cannot be compared.

- Gender (by doctor)

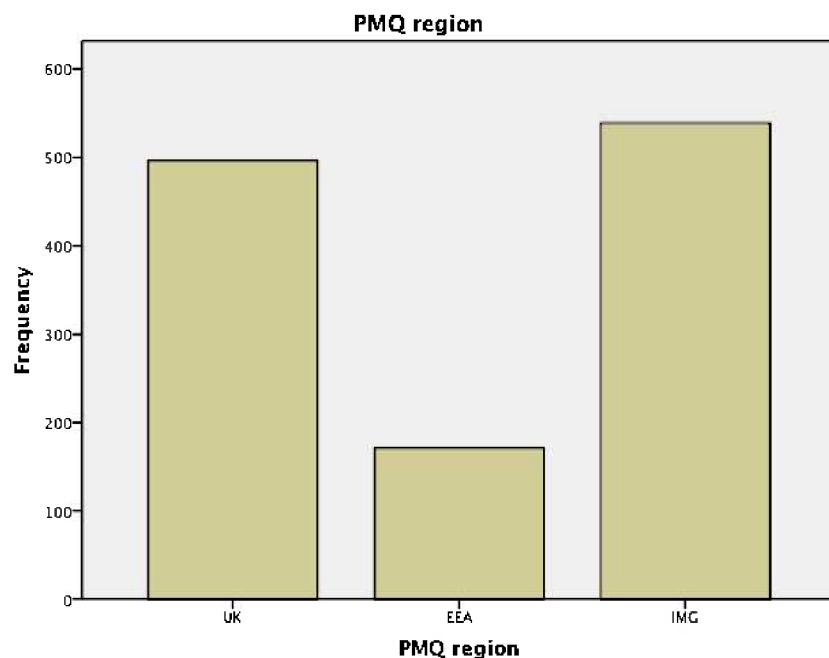
Males outnumbered females in the FtP sample making up 85.6%. This is much higher than the proportion of males within the population of medics on the register, which is 57.3%

- PMQ (by doctor)

⁶ www.gmc-uk.org/doctors/register/search_stats.asp

The distribution of PMQ can be shown graphically as shown in Figure 2:

Figure 2: PMQ by area

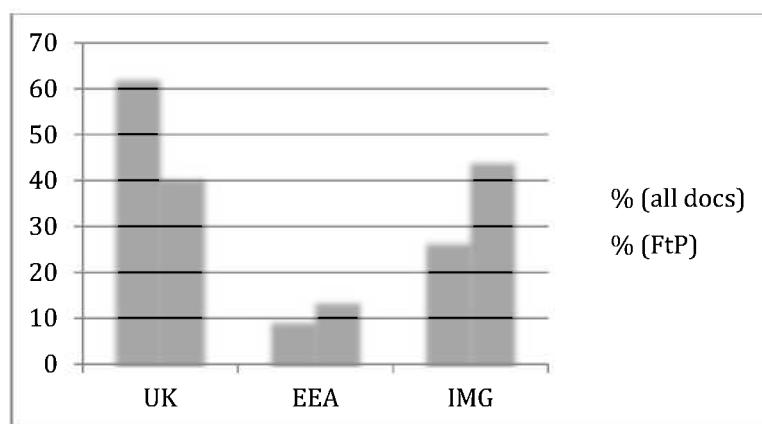


In Table 2 and Figure 3, we compare the proportion of doctors trained in these regions from the GMC FtP dataset, and the medical register as a whole:

Table 2: PMQ region- FtP v doctors on the register

PMQ region	All Docs		FtP	
	Count	Percent	Count	Percent
UK	154,509	62.8	496	41.1
EEA	24,636	10.0	171	14.2
IMG	66,919	27.2	539	44.7

Figure 3: PMQ region- FtP v doctors on the register



- Breakdown by year

We can plot two variables across the 5 year period that the data cover: outcome and allegation category.

- Allegation category

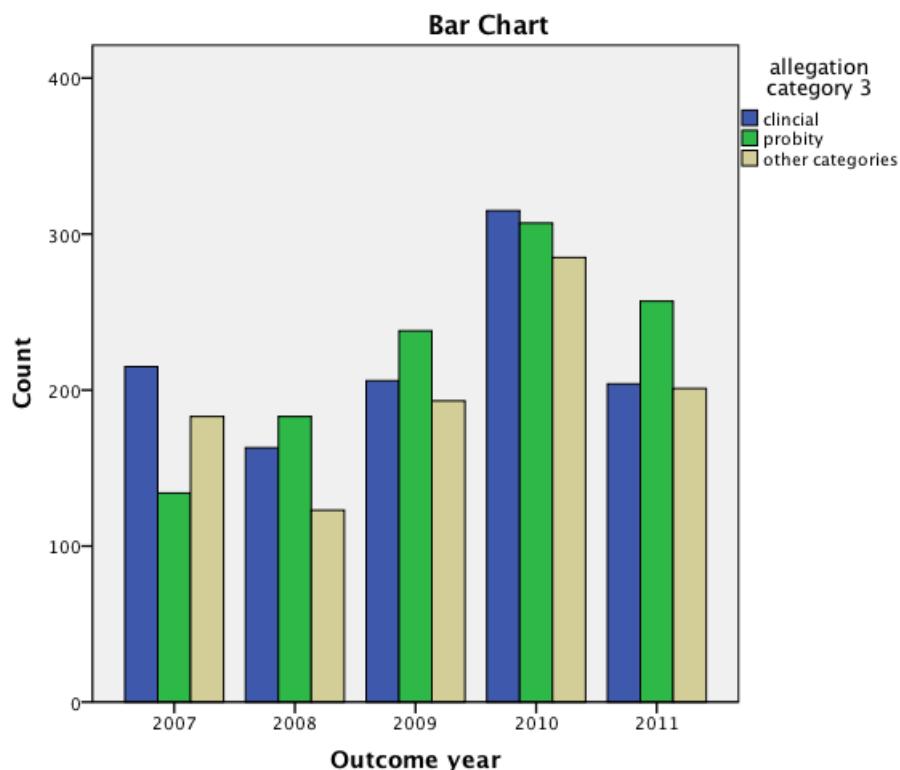
Table 3 and Figure 4 show the spread across years of allegation category

Table 3: Allegation category, 2007 - 2011

Allegation category 3 * Outcome year Crosstabulation

Count		Outcome year					Total
		2007	2008	2009	2010	2011	
allegation category 3	clinical	215	163	206	315	204	1103
	probit	134	183	238	307	257	1119
	other categories	183	123	193	285	201	985
Total		532	469	637	907	662	3207

Figure 4: allegation category, 2007 - 2011



- Outcome (ordinal)

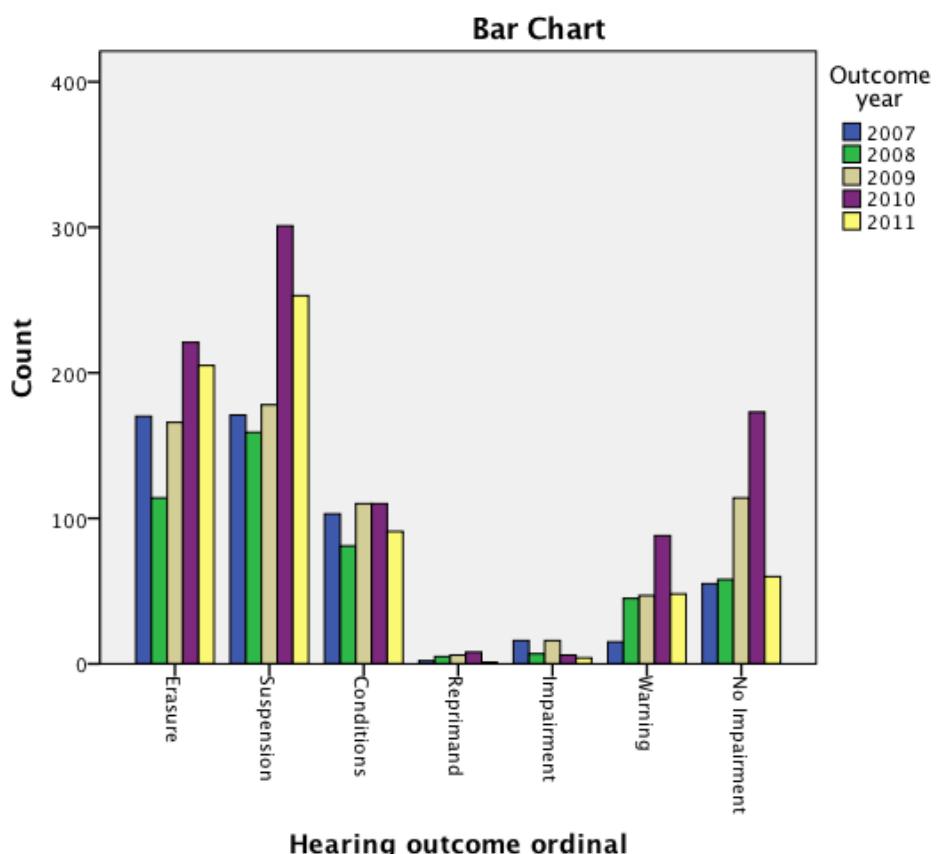
Table 4 and Figure 5 show outcome as an ordinal measure plotted across the years where data are available.

Table 4: Ordinal outcome measure, 2007-2011

Hearing outcome ordinal * Outcome year Crosstabulation

Count		Outcome year					Total
		2007	2008	2009	2010	2011	
Hearing outcome ordinal	Erasure	170	114	166	221	205	876
	Suspension	171	159	178	301	253	1062
	Conditions	103	81	110	110	91	495
	Reprimand	2	5	6	8	1	22
	Impairment	16	7	16	6	4	49
	Warning	15	45	47	88	48	243
	No Impairment	55	58	114	173	60	460
Total		532	469	637	907	662	3207

Figure 5: Ordinal outcome measure, 2007-2011



- Outcome (dichotomous)

Table 5 and Figure 6 show outcome reduced to a dichotomous variable across the available years

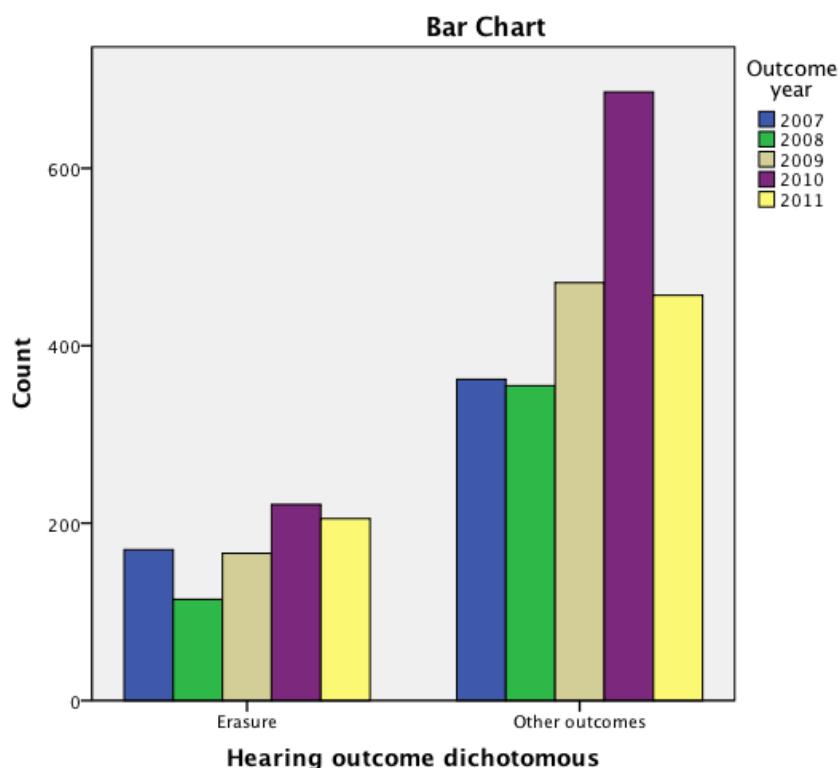
Table 5: Dichotomous outcome, 2007 - 2011

Hearing outcome dichotomous * Outcome year Crosstabulation

Count

		Outcome year					Total
		2007	2008	2009	2010	2011	
Hearing outcome dichotomous	Erasure	170	114	166	221	205	876
	Other outcomes	362	355	471	686	457	2331
Total		532	469	637	907	662	3207

Figure 6: Dichotomous outcome, 2007 - 2011



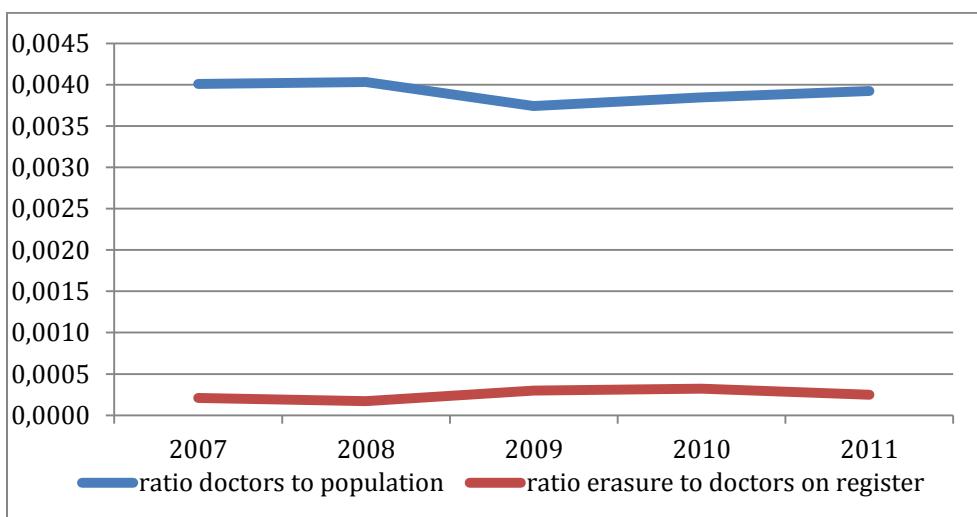
Using additional data from the UK census⁷, Table 6 and Figure 7 show the ratio of doctors to the UK population, as well as the ratio of erasure outcomes to doctors on the register.

⁷ Data from World Bank, via Google:
www.google.co.uk/publicdata/explore?ds=d5bncppjof8f9_&met_y=sp_pop_totl&idim=country:GBR&dl=en&hl=en&q=uk+population

Table 6: Broader statistics, 2007 - 2011

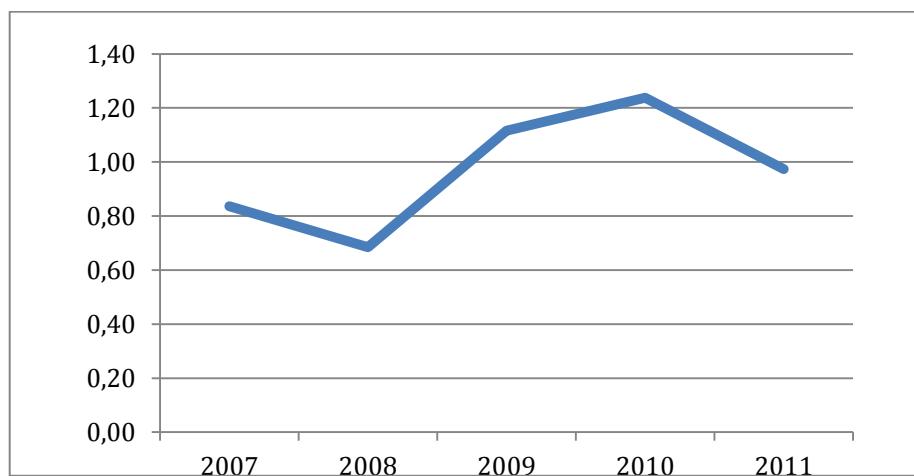
	2007	2008	2009	2010	2011
UK population	60.99m	61.39m	61.81m	62.23m	62.64m
Doctors on the register	244,537	247,530	231,415	239,292	245,918
Erasure	51	42	69	77	61
Suspension	60	73	76	99	91
Total loss of licence	341	273	344	522	458
Ratio doctors to population	0.0040	0.0040	0.0037	0.0038	0.0039
Ratio erasure to doctors on register	0.0014	0.0011	0.0015	0.0022	0.0019

Figure 7: Ratio of doctors to UK population and ratio of erasure outcomes to doctors



To give a different interpretation, Figure 8 shows the ratio of erasures per million population.

Figure 8: Erasures per million population, 2007 - 2011



Inferential analyses

In order to understand if any relationships exist within the dataset, inferential tests were carried out.

Of most interest is the relationship between other variables and the outcome of the hearing. Univariate and multivariate analyses were undertaken to test these relationships.

Univariate

Appropriate univariate tests were used to explore relationships.

- Outcome ordinal

One-way analyses of variance were performed to test for significant relationships between a series of independent variables, using the ordinal version of hearing outcome as the dependent variable.

Gender proved to have no significant relationship with outcome.

As can be seen in Table 7, the location of primary medical qualification showed a significant relationship with outcome:

Table 7: Anova output PMQ v hearing outcome (ordinal)

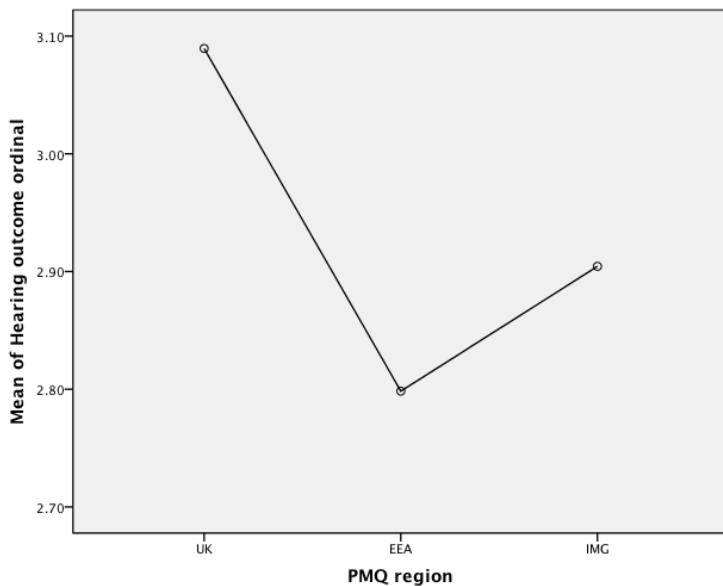
ANOVA

Hearing outcome ordinal

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	38.495	2	19.248	4.316	.013
Within Groups	14287.632	3204	4.459		
Total	14326.128	3206			

In figure 9, the means plot shows how this effect manifests:

Figure 9: Anova means plot, PMQ v hearing outcome (ordinal)



Doctors from the EEA or IMG are likely to have a more serious outcome than those trained in the UK.

Table 8 shows that the relationship between the allegation category and outcome was also highly significant:

Table 8: anova output, allegation category (3 categories) v outcome (ordinal)

ANOVA

Hearing outcome ordinal

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	520.030	2	260.015	60.342	.000
Within Groups	13806.098	3204	4.309		
Total	14326.128	3206			

Figure 10 shows that the bulk of the variance is between the clinical category and the others.

Figure 10: Anova means plot, allegation category (3 categories) v outcome (ordinal)

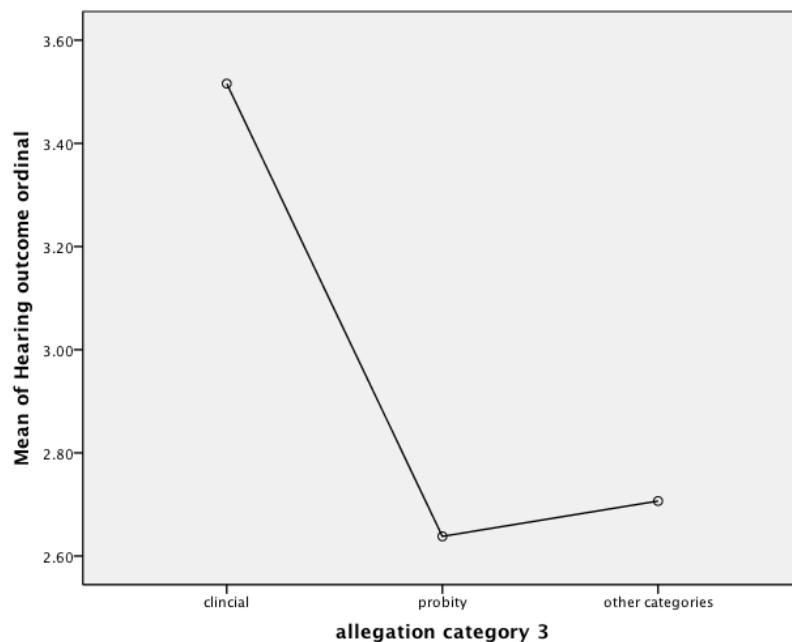


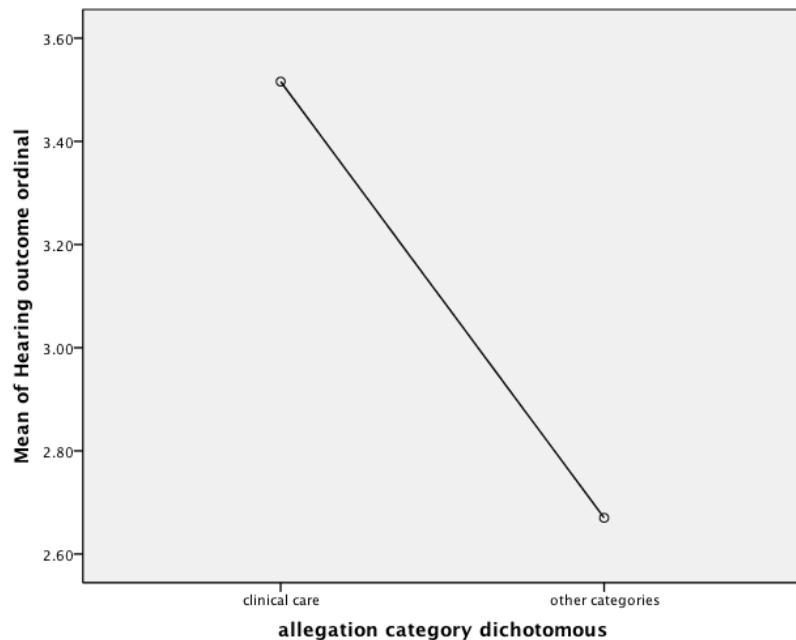
Table 9 and figure 11 show that where we use the dichotomous allegation category, this becomes clearer.

Table 9: Anova output, allegation category (dichotomy) v outcome (ordinal)

ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	517.570	1	517.570	120.129	.000
Within Groups	13808.558	3205	4.308		
Total	14326.128	3206			

Figure 11: Anova means plot, allegation category (dichotomy) v outcome (ordinal)



The effect of age group on outcome was tested using a Pearson's correlation, with significant result, as shown in Table 10.

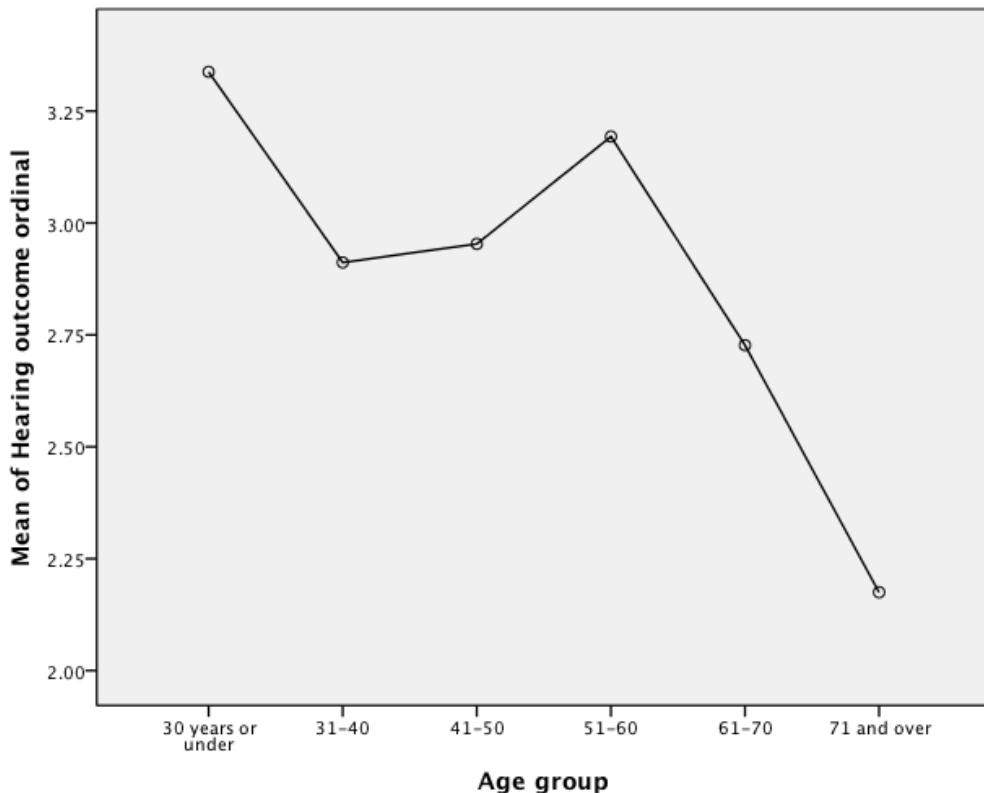
Table 10: Pearson correlation output, age group v outcome (ordinal)

		Correlations	
		Age group	Hearing outcome ordinal
Age group	Pearson Correlation	1	-.065**
	Sig. (2-tailed)		.001
	N		2798
Hearing outcome ordinal	Pearson Correlation	-.065**	1
	Sig. (2-tailed)	.001	
	N	2798	3207

**. Correlation is significant at the 0.01 level (2-tailed).

The plot of the means shows where the variance is located, as shown in figure 12.

Figure 12: Pearson correlation means plot, age group v outcome (ordinal)



Multivariate analyses

A logistic regression was used to look at the interaction of the independent variables on a dichotomous outcome variable (erasure v other outcomes).

The enter method was used, the following variables entered into the model

- agegroup (age group)
- PMQregion (local of primary medical qualification)
- Allegcatdi (dichotomous version of allegation category)
- Gender (gender)

The analysis output yielded a Nagelkerke R square value of 0.060, indicating that 6% of the variance within the dependent variable was accounted for by the model. The Hosmer-Lemeshow test for goodness of fit, however, gave a non-significant value (chi-square = 10.786, 7df, P = 0.148), indicating an acceptable fit to the data using that form of calculation.

All of the variables were shown to be having a significant effect within the model, as shown below in Table 11:

Table 11: Logistic regression output, erasure v other outcomes

Variables in the Equation						
	B	S.E.	Wald	df	Sig.	Exp(B)
Step 1 ^a	agegroup2	-.305	.038	63.203	1	.000
	PMQregion	-.102	.049	4.275	1	.039
	allegcatdi	-.537	.098	29.973	1	.000
	genderb	.441	.142	9.603	1	.002
	Constant	2.774	.323	73.772	1	.000
16.030						

a. Variable(s) entered on step 1: agegroup2, PMQregion, allegcatdi, genderb.

The beta weights (B) give an indication of the strength of the effect of each variable.

Discussion

It is important to note that the proportion of medics involved in FtP processes is very small in comparison to the number of doctors on the register. As Table 6 and Figure 7 show, the ratio is in the order of between one tenth and one fifth of one per cent of doctors. The rate of FtP occurrence as a ratio remains relatively constant over the test period, varying very little in absolute terms (in relative terms it does double from 0.0011 to 0.0022, demonstrating some degree of variation). The ratio of erasures by population varies a little more, but in absolute terms is tiny, hovering around 1 per million of the population.

The age distribution of the FtP group is normal, albeit with a peak (kurtosis), with the bulk of the outcomes occurring in those between 30 and 70 (which is not surprising given that this is the age that most doctors are practising). The Pearson correlation shows that there is a significant relationship between age and seriousness of outcome, with older doctors more likely to be at the more serious end.

An interesting finding is that the FtP sample is far more male than the general population of doctors, 86% v 57%. This would suggest that men are more likely to be in breach of the standards expected of medics, but statistical analyses suggest no significantly worse outcomes once within the process.

The effect of the location again has a dramatic effect, with those educated outside Europe making up a much higher proportion of the FtP sample than in the general population of doctors on the register. In addition, the ANOVA tests suggest that IMG trained doctors are significantly more likely to be at the more serious end of the outcome range.

Looking at the change in variables across the 5 years period under consideration, some interesting findings are visible. The three categories of allegation (clinical,

probity, other) show a degree of variability across the period, with a marked peak in 2010. Interestingly, while the other two show no clear trend that for probity allegations is clearly upward, increasing each year apart from the last (a short drop after the peak in 2010). One interesting question remains: the year 2010 shows a distinct peak of FtP activity, with no clear rationale as to why.

Unpacking the outcome variables, a mixed picture emerges from the ordinal level indicator, with a high degree of variability. Erasure shows a clear increase (albeit with a short drop after 2010, again that peak year). Suspension similarly shows a sharp increase. No other outcomes show a sustained increase as these two indicating that loss of licence is becoming a more likely outcome of the FtP process.

Allegation category shows an interesting interaction with the outcome variables, with probity allegations showing a significantly likelihood of worse outcome than clinical allegations. Taken with the earlier finding, what is emerging is a trend towards dishonesty displacing clinical misfeasance, with outcomes more serious for the doctors concerned.

The logistic regression did not yield a very powerful model, but all of the variables in the equation showed a significant interaction with the dependent variable (the dichotomous outcome variable). The model shows that the more likely the doctor is to be 1) male, 2) educated outside Europe, 3) accused of a probity-related offence and older, the more likely they are to have a more serious outcome.

Stakeholder interviews: perceptions of and attitudes to the Fitness to Practice process in the UK

Methods

In the first instance it was necessary to fit the qualitative component of this study in to the overall context of the research programme as a whole. The aim of these interviews was to gather information about the perceptions and attitudes of those involved in the revocation and Fitness to Practice (FtP) process, to understand more about those factors that influenced how, when and why doctors' licences to practice are removed. This would give a useful set of contextual clothes to the raw data skeleton on FtP events supplied by the GMC.

To clarify, the research question for this part of the study is:

'What are stakeholders' perceptions of and attitudes to the FtP process in the UK?'

This research question is broad enough to give the researchers flexibility in the interview setting, but narrow enough to focus the analysis on the key themes.

The population of stakeholders is very limited and the sample was restricted to those that could give a unique perspective of the FtP process. We identified 4 key viewpoints: the GMC as the owner of the FtP process, the BMA as representing doctors (those to whom the process is applied), the executive (as those whose policies interface/ gel/ interfere with FtP policy) and patient representatives (as the group who

are affected by the FtP process as receivers of care and secondary participants in the process.

These groups were represented by 4 individuals:

1. The deputy chief executive of the GMC
2. The assistant director of Policy at the GMC
3. The general practice committee chair at the BMA
4. An ex health minister (representing both the executive and patient views)

The overall methodology for the programme was a mixed methods pseudo case-study approach; for this specific study, the authors felt a conventional content analysis would give the most appropriate route into the data (Hsieh H, 2005). A semi-structured interview was felt to give sufficient flexibility in terms of interviewee response, while enabling the researchers to maintain focus on those key concepts central to our enquiries.

An interview schedule was drawn up, but it was felt that given the very different perspectives available from these interviewees, that a separate schedule was required for each. Within these schedules, there were certain common areas of questioning (influences on the FtP process, the fitness for purpose of the current process, exploration of competence and conduct as discrete barriers to fitness, self-regulation), to facilitate understanding of the different perspectives of a single concept. Other questions centred on the specific area of experience or expertise available to that interviewee only.

Results

We have chosen to report rather detailed on these interviews to lay out the results for the reader to evaluate.

Interview 1: General Medical Council

On the first coding read, the text from the data yielded 78 unique concepts. These were truncated into 19 first level categories, as follows:

- Being a doctor
- European issues
- GMC as driver of what good medicine looks like
- GMC cases
- GMC ethos
- GMC future
- GMC outputs
- GMC processes
- GMC regulatory approach
- GMC view of itself
- How society sees doctors
- Information
- Legislation
- Migrant medics

- Regulation in medicine
- Revalidation
- Risks
- Society's benchmarks
- The primacy of the patient

A second coding read reduced these further to 8 second level categories as follows:

- GMC & regulatory responsibility
- GMC culture
- GMC internal mechanics
- Medicine as a profession
- Outward facing risks
- Risks to regulation
- Society & medicine
- What influences GMC

GMC and regulatory response

Two of the first level categories mapped to this category: GMC regulatory approach and Regulation in medicine. Of the unique concepts, 9 mapped to this category.

The GMC is the regulator of the medical profession, and it is no surprise that these issues were important. This category deals with the GMC's approach to regulation and some broader regulatory issues. It includes concepts relating to the GMC's largely reactive approach: responding only when a complaint or referral has been made by a patient or other organisation, that essentially acts as a trigger to the FtP process. the GMC interviewees discussed the GMC as a single purpose regulator, as distinct from some of its European counterparts that regulated other professions or organisations in addition. This gives the GMC an additional focus, but may serve to limit the sectoral overview potentially? The relationship with other regulators (ie CQC) was also raised here, in the context of a potential shift towards a more risk-based approach. Medical regulation was described as a pyramid, with the GMC at the top, organisational clinical governance as a lower strata and individual clinicians at the bottom (with the ability to police each other); corporate governance is a strong theme within the pyramid and elsewhere, coming up several times. Finally, it was highlighted that the GMC sees as part of its role a depth of understanding of underlying causes of reported behaviours: for example where alcohol has been highlighted as an issue, the GMC would investigate the potential for addiction sitting beneath, and impose restrictions on registration to address that.

GMC culture

Twenty-three of the unique concepts mapped to this category, via the following first level categories: GMC as driver of what good medicine looks like, GMC view of itself, the GMC ethos, and the GMC future.

Culture is important to the GMC, both in terms of its own internal view of its own processes, and of how it seeks to influence the medical profession, and provide an independent set of exemplars of what sets of behaviours a ‘good’ doctor should aspire to.

Medicine should be ethical, with a high level of integrity, with doctors adhering to defined areas of competence (clinical performance) and conduct (non-clinical behaviours). Competence is seen as increasingly subjective in some cases, where the appropriateness of highly technical procedures can only be commented on by a similarly qualified individual.

The GMC sees itself as aspiring to provide a fair, efficient and proportional FtP process. It considers its role as a complex one, compared to other professional regulators, and has a role in guiding medicine to a more ethical standpoint, specifically with regard to culture shift towards safe whistleblowing. It is expensive, but of high value.

The ethos of the GMC includes stakeholder involvement in policy formation and other decision processes. All aspects of the FtP process are as transparent as possible, although more could be done with the data that is transparently available to track trends and patterns in FtP events.

The GMC’s future includes a more proactive and risk-based approach, with a leadership role with regard to ethical and moral guidance to the profession. It will be less passive.

GMC internal mechanics

This second level category maps to 5 of the first level categories, comprising 17 of the unique concepts.

Much of the discussion centred round the mechanistic aspects of the FtP process, with importance given to the production and dissemination of standards and guidance to doctors. The GMC controls both ends of the FtP process, unlike other regulators (ie CQC that inspects against standards developed by the Department of Health).

Cases coming into the GMC from complaints (i.e. from patients) or referrals (from NHS Trusts or the Police) are passed through a triage system for appropriate disposal.

Trends in the cases observed show an overall increase in FtP numbers, as well as increasing complexity and a shift towards competence- rather than conduct- based allegations.

Revalidation is lauded as a solution to several problems, particularly the lack of up-to-date information about where doctors live and work, and to promote a real-time exchange of information. Information is felt to be better available from private sector organisations.

Medicine as a profession

This maps to only one first level category, being a doctor.

The role of the doctor is a complex one, and the GMCs role in it complex too. There is a tension between the GMC's responsibility to effectively police the profession and its requirement to protect the privacy of doctors as far as is practicable. Doctors are felt to be highly autonomous, and should feel able and empowered to whistle blow poor practice, and take part in self-policing of themselves and other clinicians.

Outward facing risks

Two of the first level categories map to this, both with an overseas emphasis: European issues and migrant medics (comprising 8 unique concepts).

For Europe, the emphasis here is in two areas: the differences in culture between the UK and Europe, where the primacy of a doctor's privacy is far more powerful, and a sense of what is culturally acceptable in terms of a doctor's conduct. What might be acceptable in Germany say would lead to an investigation here. Particular issues exist with regard to the transfer of information between European neighbours, particularly around FtP.

The migration of medics to the UK is a challenge in terms of the sheer numbers coming and the risk presented by the lack of information about them and the paucity of official routes to test competence. There is consternation that the GMC cannot act until an incident has occurred.

Risks to regulation

One first level category (risks) and only two original concepts mapped here, both concerning single-handed practice. In the private sector, single-handed specialists are considered a risk as there is little information about their practice. In primary care, there is a hypothesis that bad doctors may gravitate towards single-handed work as there will be less scrutiny of their mistakes.

Society and medicine

Two first level categories (how society sees doctors and society's benchmarks) map to society and medicine, comprising 10 original concepts.

Doctors are under pressure from two distinct angles. The empowerment of patients and emergence of the 'expert patient' in the consultation and beyond means that they are no longer the final and unquestioned arbiters of clinical best practice. At the same time, scandals and other challenges have eroded the doctor's previous traditional unassailable position as trusted pillar of the community. The previous deference is no longer there.

There are clues to some of the drivers here, with recognition of society as a fluid, dynamic set of attitudes, preference and norms. What is considered as acceptable behaviour for anyone and specifically by a doctor is normalised and established, although this continually changes, and is subject to regional and probably demographic variation. The GMC must plot a course through this and remain a solid reference point for doctors. There is also a sense that doctors behaviour is increasingly viewed through a lens of an increasingly ambulance chasing and litigious public perception.

What influences the GMC?

Two first level categories map to this: legislation, legislation and the primacy of the patient, being 5 unique concepts. Legislation underpins the GMC's activity, in particular the Medical Act and European Convention on Human Rights (and therefore the Human Rights Act). The ultimate bottom line for all of the activity of the GMC has to be the protection of the patients, and minimisation of risks to safety.

Interview 2: the British Medical Association

On the first coding read, the text from the data yielded 75 unique concepts. These were truncated into 25 first level categories, as follows:

- conduct
- conduct v competence
- dichotomy of public perception
- doctor behaviour
- doctor morale
- doctor opinion on policy
- fear of GMC
- FtP process
- FtP process influences
- GMC approach to health and misuse issues
- GMC as a regulator
- GMC focus
- interviewee credentials
- need for speed in misconduct process
- performance measurement
- press as an influence of perception of medics
- professionalism
- public opinion of medics
- public perception of FtP
- regulation of medicine
- remediation
- type of misconduct
- unwitting misconduct
- witting misconduct
- young doctors

A second coding read reduced these further to 8 second level categories as follows:

- being a doctor
- FtP process and influences
- GMC: role and character
- interviewee credentials
- measurement
- Medic relationship with GMC
- misconduct and its types
- professionalism
- public perception
- young doctors

Being a doctor

Three first level categories map to this second level category (doctor behaviour, doctor morale and doctor opinion on policy), being 8 unique concepts in total.

The story from this category feels like a profession under siege: doctors are under attack and undervalued, with the situation so bad that industrial action was taken, for the first time in 77 years. Morale is low, and medicine is a tick-box exercise, with disillusionment about the NHS, how it is run and the direction it is taking. There is also a strong link to public perception and how young doctors are trained and find their own work ethos, linking to the later theme (young doctors).

Medic relationship with GMC

This maps to 1 first level category (fear of the GMC), and 4 unique concepts.

The overriding concept here is fear of the GMC and what it can do to a doctor. Even though this is described as disproportionate, for the vast majority of doctors, they fear discipline and this is personalised as the GMC. There is also an assertion that the FtP process itself is traumatising, more so than needs to be the case. This links to the following theme (FtP process), confirming that the process requires reform, on a number of levels.

FtP process and influences

Four first level categories map here (FtP process, FtP process influences, need for speed in misconduct process, remediation), being 11 unique concepts.

There is a sense here that the FtP process while not broken needs some serious rethinking. The whole process is too mechanistic and slow: for the inadvertent contraveners this is not such an issue but for the ‘bad harmers’ it is: they need to be taken out of practice as soon as possible, with more emphasis on pre- and early intervention across the board. The different types of misconduct are considered in more detail below. For those that are not ‘bad harmers’ there should be much more

emphasis on remediation, with an opportunity to use suspension time productively, and to rehabilitate to a point where the doctor is capable of re-entering practice. generally, the regulations need to be achievable and the focus on preventing harm and in no way on revenge on the misbehaving doctor. There are links again to the perception of the medical profession, and how misbehaving doctors are dealt with (see below). There is also a sense that the FtP process is a root cause of the low morale considered above (with the letters sent by the GMC described as ‘cruel’, and evidence that there is a culture of admission to wrongdoing to expedite the process regardless of blame by the insurers.

GMC: role and character

Four first level categories map to this (GMC approach to health and misuse issues, GMC as a regulator, GMC focus and regulation of medicine), being 13 unique concepts.

In a thread carried through from the previous second level category (FtP process), much is made here of how the GMC deals with medics who are suffering from health or misuse issues. This also coheres with the theme looking at the different types of misconduct. Where has an issue of this kind, it is argued that there should be a different process to deal with them, completely separate from how the ‘bad harmers’ are dealt with, one that is humane, swift to intervene and focused on rehabilitation.

The GMC is not held in high esteem by doctors and is characterised as out of touch with the needs of the profession. The GMC has ceased to be run by doctors, and has drifted towards being another governmental tool. This now means that essentially, medicine is not a self-regulating profession, which again will contribute to the low morale felt by the profession. Outcomes of this shift are a misaligned focus, an officiousness that pursues the innocent and ignores the guilty, concentrating on what has been characterised as the inadvertent contraveners and their minor transgressions, rather than the bad harmers. In a curious dichotomy, the relationship between the GMC and the British Medical Association is described as cordial.

Interviewee credentials

1 first-level category maps to this (interviewee credentials), being 7 unique concepts.

The interviewee, an eminent doctor and respected policy-maker, was interviewed as his unique position gave him the ability to respond to the interview questions with two perspectives, that of the lead in the BMA, and a working general practitioner. At the beginning of the interview, the interviewee gave a resume of his experience and the key roles he has played. This ensured that we could confirm that he would be able to comment and opine from these two important perspectives.

Measurement

1 first-level category (performance measurement) and 2 unique concepts map here.

Many aspects of care are measured for performance and quality now. To be useful and probative, the measures do need to be ‘intelligent’, that’s to say sensitive to real effects and standardised to ensure that medics are not penalised for taking more difficult cases. There is also a sense that too often the metrics employed to measure performance and quality are not good at capturing softer skills that are very important in medicine.

Misconduct and its types

Five first level categories map here (conduct, conduct v competence, type of misconduct, unwitting misconduct and witting misconduct), being 12 unique concepts.

This is a crucial area of consideration for this interviewee. Underpinning this is the sense that doctors are held to a higher level of account than other members of society, and this is necessary because of the nature of their work requires a high level of trust. We as patients expect a high level of morality from our medics, and care that is safely delivered in a safe environment. Doctors are expected to behave well and in a morally defensible way, not just in their practice but in the rest of their lives too. This links into the public perception of medicine, discussed below. Misconduct by doctors is therefore bad, but there is an important distinction to be drawn, and one that the GMC importantly does not make. It can be subcategorised into two principle types: unwitting and witting. Unwitting misconduct (the inadvertent contraveners mentioned above) is less serious, unintentional and doesn’t cause a great deal of harm. It is mostly hidden, yet widespread. It does not warrant a heavy-handed intervention and is most appropriately dealt with via education. Witting misconduct is far more serious, and very rare. Those medics that might engage in it, themselves rare, are put off by fear of the consequences of their actions, and the involvement of the GMC.

Within misconduct, there exists a second dichotomy: between competence and conduct. Competence is how well a doctor undertakes their medical duties: performing well, treating patients according to evidence and best practice, only undertaking interventions that they are trained to perform. There is a strong element of professionalism with competence, explored further below, essentially that a doctor knows what they are able to do and should not go beyond this. Conduct is related to non-medical activities, those elements of morality that link to the underpinning standard that doctors are held to. Honesty and integrity are central, as is trust (by the patients and public). Whereas competence is generally clear cut and simple to deal with, conduct is much less so, with sliding scales of morality and judgements made about specific incidents and events. There is even a high-level question about whether conduct is relevant to medical performance at all.

It is argued that the GMC is too focussed on conduct, even though it is harder to deal with. What should exist is a two-track process: a slower, less resource intensive route for conduct issues, and a fast track for competence. Competence, after all, can affect patient health; conduct is far less likely to.

Professionalism

Professionalism is a very important aspect of the doctor's ethos, and is ingrained with their self-regulation as individuals. That's to say, a doctor knows the extent of their knowledge and competence, and does not go beyond this; they know when they are too tired, hungry or ill to be effective. Along with this, there is a responsibility to remain up-to-speed with latest evidence, to ensure that patients are receiving the best possible care. In a parallel with the role of the GMC, there is a sense that the doctor as a self-regulating individual practitioner should be mirrored within the regulatory body for the profession as a whole.

Public perception

Very much the flipside of professionalism and highly linked to morale, it is felt that there is a dichotomy in the relationship between the public and doctors. Individually, doctors are highly rated, liked respected by people. We all can relate to this, know of a doctor that has helped us or someone we care about. As a collective profession, however, doctors are regarded as dishonest and greedy. The press are lambasted as a key driver of this collective negativity, with much publicity around those doctors that do transgress, although they can be a force for good, ensuring that the GMC to investigate alleged transgressions where these are real. To top this, there is a public misunderstanding about the FtP process, and what it is designed to do: not for issues outside the medic's control, or because their own self-regulation has led to a delay, for example. Doctors also don't help with regard to the flow of information: this contributes to the lack of understanding. For example, it is important to articulate that interventions are not always successful, and patients do die: this is generally not the fault of the doctor. To pick up on an earlier concept, trust, it is asserted that doctors do need to earn trust, but at the same time they should not be held to a higher account than the rest of society.

Young doctors

This maps to 1 first level category (young doctors), and 5 unique concepts.

Linking again to the concept of professionalism, young doctors are not developing the self-regulating skillset that they need to be autonomous. They need to be guided more than is optimal, and are less able to take self-generated decisions. The limitations on working hours, while avoiding the worst excesses that were observed in the 1990s, do mean that doctors are less able to understand where their limits are in terms of tiredness and effectiveness.

Interview 3: Ex-health minister

On the first coding read, the text from the data yielded 92 unique concepts. These were truncated into 39 first level categories, as follows:

- abuse as an issue

- accountability for transgressor
- admission of harm
- alcohol misuse
- behaviour
- complaint
- criminality
- data issues/ transparency
- FtP process
- GMC effectiveness
- GMC status
- higher standards for medics
- impact of error
- importance of apology
- information for carer
- insensitivity from trust
- lack of transparency process
- language issues
- MD practice
- medic role
- medical curriculum
- medical error
- mental illness in clinicians
- need for openness
- nurse knowledge
- nurse role
- outcomes for carer
- patient knowledge
- patient safety
- patient expectation
- remediation
- roles of involved parties
- sanctions for transgressor
- self-regulation
- superiority of medic
- support mechanisms
- trust actions
- unfit medics
- voluntary de-registration
- young doctors

A second coding read reduced these further to 15 second level categories as follows:

- competence
- conduct
- data
- GMC as entity
- GMC processes
- information for carer
- language issues
- patient safety
- perceptions of medicine
- practice
- roles of involved parties
- support for carer
- trust reaction
- wider impact of FtP
- young doctors

Competence

This maps to 4 1st level categories (abuse as an issue, alcohol misuse, medical errors and mental illness), and to 6 unique concepts.

The context for this discussion of competence is very different to previous ones and is less abstract and more example based, specifically on an individual case in which the interviewee acted as a member of parliament, supporting a constituent. The focus is very much on how a doctor behaves, and what behaviours constitute a competence issue. Discussion broadened away from a specific instance where alcohol was rendering an individual incompetent towards a consideration of more factors that will have a similar effect such as mental illness. Competence has two sided: those kinds of behaviours that can render a medic potentially incompetent (such as alcohol misuse and mental illness) and those actions that are indicative of incompetence (errors or abuse of patients).

Conduct

Conduct maps to 2 first level categories (behaviour and criminality), being 4 unique concepts.

There is a clear overlap between some criminal behaviours, and those that form a conduct issue for the GMC. There is a sense from this interviewee that while conduct will not necessarily directly affect competence, there is a broader view that must be taken, including looking at patterns of behaviour. There is also the possibility that conduct outside the workplace may be replicated within it, and would constitute a competence issue. Some conduct issues should be dealt within the trust using those mechanisms and not taken to the GMC (ie the stolen sandwich).

Data issues

One first level category maps here (data transparency), being a single concept. The message is that there is a tension between the competing demands of data transparency and data protection: information about patients and what happens to them from one perspective needs to be available following the requirements of transparency. At the same time, those involved have a right to privacy and this needs to be protected. This is linked to a later category, information for carers.

GMC as an entity

This maps to 3 first level categories (GMC effectiveness, GMC status and self-regulation), and being 8 unique concepts.

The GMC is not held in high regard by this interviewee, being criticised for its lack of independence from government and from the medical profession, and for not being effective. It is also felt to be detached from the public (the NMC- the equivalent body for nursing staff- is felt to be less so). Self-regulation by the profession is not felt to be appropriate at all, yet there is a sense that input from clinicians is needed.

GMC processes

This one maps to 8 first level categories (accountability of transgressor, complaint, FtP process, lack of transparency, need for openness, remediation, sanctions for transgressor, voluntary de-regulation), being 17 unique concepts.

The fitness to practice process currently in place is soundly criticised, and seen to be failing for the specific constituent that this MP was supporting through it. The root of this is the circumventing of any real role for the GMC where a medic voluntarily removes her/himself from the register, in this case where their actions had led to the death of a patient. There is a sense that while the doctor's career (in this country) is over, they hold no accountability: the GMC can do nothing and that is the end, unless a criminal prosecution or civil action are brought. This couples with a culture of not attributing blame even in the most blatant cases where compensation is paid, and a sense that the whole process is arcane and secretive, with a lack of transparency in the face of openness in the rest of the NHS. Remediation is felt to be a failing system.

Information for carer

Mapping to a single first level category (information for carer) and 4 unique concepts, this category is closely related to some aspects of the previous one: the lack of transparency around the FtP process segues into a profound lack of information for the carer(s) of those hurt or even killed by medical action. Case details are not readily shared and this adds to the sense of frustration and hurt, and potential psychological damage. In the case being discussed, it was over a year before the victim's spouse was even informed that the responsible medic has voluntarily de-registered.

Language testing for medics

This maps to a single first level category (language issues) and 2 unique concepts. The issue here is quite discrete, and concerns the language skills of migrant medics who have English as a second language. There are concerns that the language testing is insufficiently rigorous to exclude those with poor English skills.

Patient safety

Mapping to a single first level category (patient safety) and single unique concept, this category highlights the need to ensure that patient safety is the single most important consideration for all of healthcare, and needs to be protected at all costs.

Perceptions of medicine

This is the largest second level category, and maps to 8 first level categories (higher standards for medics, medic role, medical curriculum, nurse knowledge, nurse role, patient knowledge, superiority of medics, unfit medics) and 22 unique concepts.

Much discussion centred on the uniqueness of the role of the medic, and the perceived sense of superiority, and almost default view that the medic will be ‘in charge’. This seems to break down when a patient transfer is required, with some medics taking a narrow view of their responsibility (nurses taking a broader view). The superiority goes with a feeling that medics are held to a higher standard of behaviour, although it is unclear why this should be higher than for other clinicians for example. There is a sense that this superiority (trust?) is being eroded by exposure in the media (through reality tv and documentaries) and high profile failures, although it is still prevalent. Further erosion comes from encroachment of expert non-medics into domains previously the exclusive preserve of medics (despite the perception that nurses are far less knowledgeable). The secure, competent medics do not fear this, but the less so do (there is insecurity): a competent doctor values a competent and highly skilled nurse. In maternity, as an example, it is not commonly known that a doctor is only likely to be present at a delivery if there are complications. There is felt to be a sliding scale with older patients/ people less likely to question a doctor, and accept their judgement. Younger patients may be more empowered and informed, and more likely to want to take an active role in their care. One clear issue comes where the unfit medic can reappear and practice in another country.

Practice

This maps to 2 first level categories (multidisciplinary practice and patient expectations), being 6 unique concepts.

This category builds on concepts from the previous, centring on the lack of joined-upness of care when a patient requires transfer from one organisation to another, and this links to a culture of risk-aversion amongst medics in particular. On the converse, patients do not care who delivers care as long as it is of good quality and timely (but does this conflict with the preference/ superiority of medics highlighted above?)

Roles of involved bodies

This second level category maps to 1 first level and 4 unique concepts.

Here, involvement concerns the fitness to practice process, and those bodies involved in designing, policing and enforcing it. With regard to the design, there is a question as to the relationship between the GMC and the executive, and the GMC and the medical royal colleges (with a relationship to the medical undergraduate curricula too). For the administration of the process, there is a major grey area around the responsibility between the GMC and the employing NHS trust, and a big question: whose job is it to ensure medics are safe? Arguably the trust has an ongoing responsibility, but then revalidation brings the GMC into that.

Support for the carer

This maps to 4 first level categories (admission of harm, importance of apology, outcomes for carer, support mechanisms) being 10 unique concepts.

There is an overarching sense that there is little support available for the carer(s) of someone that has been the victim of a medical error, even if a death has been the outcome, with what there is needing to be fought for (and success only with a powerful advocate such as an elected representative). The unwillingness of anyone involved to apologise causes additional upset and appears to be a cultural response and is equated with an admission of guilt and/or culpability. Compensation whilst it can be welcome is not a substitute for accountability, culpability and therefore enabling of some form of closure. This is exacerbated by the lack of information generally available to carers (see above), and the lack of accountability and a hearing (for voluntary de-registration). As pioneered by Johns Hopkins Hospital in Baltimore: there is no harm in admitting harm has been done.

Trust reaction

This maps to 2 first level categories and 4 unique concepts.

How the employing organisation deals with an error leading to harm or death has a profound effect on the carer(s). in the case described the NHS trust reacted poorly, and the spouse of the victim had to fight hard for any concessions, even with regard to parking on the hospital site. The response of the trust is generally characterised as insensitive, with a focus on blame avoidance rather than helping the victim or their family.

Wider impact of error

This maps to 1 first level category (impact of error) and 2 unique concepts and really gives an insight into the broader impact of a medical error, beyond the victim to their spouse and family and the sometimes long battles that are fought, draining already diminished resources, psychological, emotional and even financial.

Young doctors

This maps to 1 first level category (young doctors) and 1 unique concept, and makes the point that younger medics are less likely to be part of the culture of medical superiority, aloofness and even arrogance.

Analysis of English results

Having undertaken the content analyses separately on these three interviews, the next stage is to draw out the common themes, explore the areas of congruence and dissonance, and draw some conclusions about the FtP process based thereon.

Discussion: Overarching themes

With such a diverse group of interviewees and a breadth of topics covered, there is much material to consider. Some themes emerge powerfully, and are considered below.

Influences on the FtP process

While the GMC holds responsibility for the development and implementation of the FtP process, there are underpinning influences and on-going relationships that will affect how it is operationalized. There is a legislative framework from both UK law and the European Convention on Human Rights, but beneath this the code of conduct upon which the process hangs is very much a GMC creation, although there are influences upon this, from the executive and powerfully from the medical profession. There are competing views of the role that medics should play. There is a strong argument that only those with medical expertise have the knowledge and understanding to know what good, bad and dangerous practice looks like, but as we have seen the behaviours that will lead to a fitness to practice issue are not often linked to clinical practice at all, but other related issues. The GMC view is that the balance is appropriate; the patient champion holds that while medical opinion is important, the profession cannot and should not be self-regulating because of the conflict of interest. The BMA view is that the profession should be more self-regulating, primarily because that is what a profession means. At the very least, the majority of the decision makers ought to be medics. This, amongst others, is an issue that is bound to see a spread of opinion. From the three interviews, it is clear that the balance is probably about right at the moment. Too much dominance from medics risks accusations of self-interest and nepotism. Insufficient medical input will not be acceptable to doctors, who have the specialist knowledge in this area.

The fitness for purpose of the current process

The FtP process in its current form is relatively well established. The GMC highlight its fairness and proportionality, and the underpinning ethos of patient safety and protection. A good FtP process is crucial to maintain trust in the medical profession. Other views are as might be expected polarised, but not in direct conflict. The BMA/

medics view is that the process is mechanistic, insensitive and in some areas cruel, although without meaning to be. Doctors live in fear of the bureaucracy that can take away their livelihood and that doesn't understand them or their work. The patient's perspective is that the process has a glaring hole where voluntary de-registration is concerned: if a medic voluntarily de-registers, then the GMC is effectively not involved in any processes from that point, there is no investigation and no learning. From the perspective of the patient or carer, in the absence of criminal or civil litigation, then there will be no real answers as to what happened and why. Where there is agreement is around the perceptions as to the purpose of the process and what it is for. There is a lack of information about the FtP process, and particularly how it fits with the other processes that can be invoked when there is a fitness to practice issue (trust complaints processes, criminal and civil litigation, ombudsman etc). There is also a duty somewhere to inform the patient carer about the case to let them know what happened and why: currently this does not appear to be clearly defined.

Competence and conduct as discrete and related fitness issues

All interviewees discussed the two primary categories of misconduct: competence and conduct. Competence is related to the medic's ability to perform medical procedures, and covers negligence, poor practice and behaviours likely to render them dangerous such as mental illness and substance misuse. Conduct issues are those that are not directly related to the doctor's ability to perform, but fall below the standard of behaviour expected and may be bordering on criminality or morally reprehensible. There is a grey area between these two, and some behaviours clearly cross the boundary invoking both.

GMC as a regulator

As with the process of regulation, the regulator itself is subject to a range of views. The GMC itself sees itself as stakeholder driven, transparent and fair. Doctors do not hold the GMC in high esteem, who feel it is out of touch and essentially a government tool that is too detached from working medics. The innocent are harried and guilty not expeditiously pursued, leading to resentment and distrust. The patient representative felt that the GMC is again detached, but this time from the public, and in fact too close to the medics; it is also felt to be ineffective.

The GMC is in a tricky position: it will always be hard for it to gain universal approval for its work. If it positions to appeal to the medics, it will be accused of being insufficiently independent and too close to its regulated body. If it moves away from the profession, it will be accused of being out of touch with the reality of medical life. It does appear that a more proactive approach and more stakeholder involvement on all sides would improve its reputation.

Medicine as a profession

Doctors have a complex, multi-role professional life, with many different demands and difficult decisions to make. They are educated to a high level and, and are held to a very high standard by their code of ethics. In days past, the doctor was, and to some

still is, a figure of authority and respect, whose judgement is beyond question, and who is perceived to act for altruistic reasons at all times. In a more modern world, this is being eroded by wide publicity of failures and transgressions; also, some patients are much better informed than ever, and highly empowered and desire to be a part of the decision making process in their care. Erosion also comes from other clinical staff having higher levels of education and extended responsibilities. There is an argument that progressive-thinking medics will welcome this, but that others may feel threatened.

Medics are educated to be highly autonomous, and are expected to therefore be aware of the channels for reporting poor practice by another doctor or other clinician, or behaviours that are transgressing any ethical code. From the perspective of the medic, there is a dichotomy of perception. Individually, they are respected and looked up to, but as a profession lambasted and pilloried by the press and media. Added to this, there is a perception that the culture of blame and litigation is growing, and altruism is being replaced by defensiveness and suspicion.

Synthesis of two data sources for the English data

These two data sources are disparate and tell us very different things, but there is interpretation that leads to learning about the FtP process in the UK. We pull out 5 key headings under which these interpretations can be considered

The FtP process

It is clear that the FtP process is dealing with doctors that have transgressed and meting out appropriate sanctions. It is not without challenges though, and both medics and patients and carers have concerns about the process. What has come out is that while it is important not to underestimate the damage that can be caused by a doctor that is not working to the required standard, the numbers of transgressions are actually very low. There is a feeling that the FtP process and those that transgress are raising a very large amount of concern and publicity for what is a tiny number of doctors, when viewed against the whole medical workforce, and the number of patient encounters that take place every day. The level of concern and focus in the media is mirrored by the level of concern amongst medics, who live in fear of the GMC and the process that they may be subjected to. From both perspectives, this is unhelpful: the FtP process is there to help both patients and doctors to ensure that poor/ dangerous practice is avoided, and that doctors are behaving with appropriate levels of moral and ethical integrity.

The misfeasing medics

The data from the GMC give us a useful picture of who are most likely to be misfeasers within the medical workforce. That they are more likely to be male should not be a surprise: much research supports the assertion that males are much more

likely to engage in criminal (prison stats), risk activity (ref), and substance misuse (NSUDH).

There is a strong relationship between education outside the EU and misfeasance. This coheres with concerns about the language barrier around medics that have English as a second language. Both of these concerns are legitimate: but it is important that they are handled with care.

Character of the misfeasance

Change of the medic's role

- Small numbers of doctors subject to FtP process
- Disproportionate level of publicity
- Disproportionate level of concern by doctors?
- Trend towards dishonesty replacing clinical misfeasance (competence replaced by conduct)
- Trend towards more serious outcomes
- Males more likely to be misfeasers
- Education outside Europe linked to misfeasance
- Debate as to role medics play in the GMC/ design of the FtP process
- FtP process mechanistic, insensitive, cruel, lacks meaning and involvement from victims/ carers
- Competence and conduct are discrete areas of unfitness, and require different approaches sanctions?
- GMC detached from both medics and patients/ carers
- Position of medic eroded by failures, transgressions, extended roles of other clinicians and empowered patients
- Requires progressive thinking: medic role is changing
- Culture of altruism replaced by defensiveness and suspicion

Norway: Statistics and descriptions.

In 2006, Norway had 18,576 registered medical doctors under the age of 67⁸. This gradually rose to 23,365 in 2013. Table 12 shows the number of doctors who lost their authorisation, as well as total number of reactions:

Table 12: Number of Revocations and Reactions

Year	Revocations	Total No. Reactions
2006	21	77
2007	22	76
2008	20	76
2009	28	102
2010	27	98
2011	24	97
2012	30	117
2013	25	102

This is from 0,11% – 0,091% of the total number of doctors. Actually it is less because doctors can practice and retain their authorisation until age 75.

It is not possible to work out statistical correlations or probability with such small numbers, so the comparison with the data from the UK was based on a different construction of data at the Norwegian side.

⁸ Numbers from 'legeforeningen.no', Norwegian Medical Doctors Professional Association's web page, table called 'Leger under 67 år registrert i Dnlf's legeregister etter statsborgerskap som bor og arbeider I Norge 2001-2014.'

Statistics compiled from the BHS annual reports are shown in Table 13:

Table 13: Reactions by Year

Reason for reaction	2006	2007	2008	2009	2010	2011	2012	2013
Drugs	7	4	10	10	10	11	14	7
Disease	3	1	1	2	0	1	1	1
Sexual misconduct	0	3	1	4	8	3	2	4
Behavior not fit for a doctor	3	4	0	3	2	0	3	6
#Theft of drugs								0
#Behavior in service							9	6
#Behavior outside service							6	4
Risk behavior	3	2	2	3	2	2	7	7
Not reacted to warning or request	2	5	3	4	2	6	6	4
Lost license in other country	3	2	2	2	3	1	2	3
Other reasons	0	1	1	0	0	0	NR	NR
Mixing roles							0	1
Professional fault							4	
Sum, some cases have several reasons							41	37
Sum revocation of authorisation	21	22	20	28	27	24	29	25

NR = not reported

Data

Since we found that statistical analysis would not make particularly valid or reliable results, we looked into concrete cases supplemented with qualitative interviews of key personnel.

Each case that goes to a formal reaction from BHS has a case description, a reason for the reaction based in the law, mainly the Health Personnel Act, the decision and information on how it can be appealed. Each case is worked on by a legal expert and a health expert and signed by the director of BHS.

We interviewed

- senior administrative staff, and a technical advisor in BHS in Oslo
- regional staff: one regional medical officer and one legal advisor
- regional leader of the Medical Association

We were given access to **113** case documents from BHS. We initially requested only cases of revocation, but were also provided with cases of warnings and limitation of authorisation, that we found to be just as relevant. We therefore asked for all cases from one year, 2011, to review the distribution of cases. It proved hard to sort out the cases from the administrative system, but we do think we have an adequately representative sample to be able to say something about the situation.

The case documents are from 5 – 35 pages.

Of the 113 cases, 6 were follow up for doctors that already had a case against them, so the total was **107** different doctors.

From the total of **97 reactions in 2011**, 73 are represented in our sample. One case for lost authorisation for the medical specialisation was not included in our sample.

We found this to give an adequate base for a qualitative analysis.

The 73 cases we have gone through from 2011 relates to **67** different doctors.

Reflections on these 67 doctors based on the case descriptions:

Gender:

The case descriptions do not specify information about gender, so we have assumed according to first names. Of the 73 names, 6 were not gender specific. For the 67 remaining, **9** are women and **58** are men.

Of the 9 women, 3 lost their authorisation, one whom is ethnic Norwegian. Two had long-lasting alcohol problems. One had problems communicating in Norwegian, and after several complaints, left Norway and her authorisation was rescinded.

Nationality / ethnicity

Of the 67, 38 are ethnic Norwegians, 32 of whom were educated in Norway and 6 educated abroad.

Out of the 29 non-Norwegians, 11 were Swedish or Danish, 2 may have been immigrants to Sweden based on their name, but we are not able to say if they were first or second generation immigrants.

So **18** of the 67 doctors practicing in Norway are of non-Scandinavian ethnicity. Out of these, 6 seem to have been educated outside Europe, later migrating to Norway.

Health service level

In Norway health services are organised on two levels; a local level as part of or under the auspices of the municipality, and a specialised level, with specialists in private practice or working in hospitals or other health institutions.

In the case documents, the place of basic professional education and the type of later specialisation are mentioned only in some. It is not clear why this is not indicated in all cases, but when it is not mentioned it seems irrelevant.

Out of the 67 doctors reported, the function or specialisation was evident from the report for 61 doctors. Many cases are connected to function in the local ER (*legevakt*). While service in the ER is available to all doctors, GPs under the auspices of the municipality may be ordered to serve. For those cases where nothing else has been stated and where the cause of reaction stems from work in the local ER, we have counted these doctors as 'service front line'/municipality based.

Out of the 61 where this was stated, **46** were in the municipality, **15** in hospitals or specialised services.

Geographic distribution

All cases are initiated in the regional part of the Board of Health Supervision. The Regional Commissioner (*fylkesmannen*) is the central government regional representative. In his or her organisation there is a division for health, headed by the Regional Medical Officer, and this division serves as regional branch of the Board of Health Supervision. There are a total of 18 Regional Commissioners covering populations that vary from Oslo and Akershus with nearly 1,2 million to Finmark with 75,000.

In our sample, all but two counties—the two smallest—were represented. Oslo and Akershus, representing about a quarter of the Norwegian population, had 24 cases;. Hedmark had 11 cases and stood slightly out as more relative to population, Vestfold had only 1 case, that is less relative to population.

There did not seem to be any geographical bias in our sample.

Reaction and reason

As described earlier the Health Personnel Act gives the Board for Health Supervision the authority to launch several reactions.

According to our experience from earlier research (Hem & Lodden, 2010), the regional branch, the Regional Medical Officer, is very dialog oriented and it is likely that a number of cases are sorted out between the doctor and the Regional Medical Officer. Some of the case documents also state that there has been a process over several years, with warnings from the employer and then the Regional Medical Officer before the case is sent on to the Board. For a few cases, it was noted that the Regional Medical Officer had given a warning, although such a warning would not have the same legal status as a warning from the Board.

The Board groups reactions in four categories, but we should be aware that they are quite nuanced:

1. Revocation of authorisation

The case document concludes with a decision; ‘you have lost your authorisation, please return your certificate’. This means—as in England—that the doctor is struck off the central register for authorised health personnel and may no longer practice. This is done according to The Health Personnel Act, § 57.

2. Limited authorisation to practice

The limitation is specific whereby, for example, a doctor is not seen fit to work in the ER with patients but may carry out other functions as a doctor. It is then up to the employer to determine other tasks for the doctor. Other reactions in this category include an obligation for further education, including language courses or therapy. It

is more than a warning, but the practical implications may be no more than for the doctor to take a course.

3. Limited right to prescribe medicine, types A and B

When a GP prescribes addictive medicines more often, over a longer period or to a larger extent than deemed normal or safe, he or she may lose the right to prescribe these medicines. Often this follows a warning and includes a request to make plans with the patients to reduce or discontinue the use of these medicines.

4. Warning

The warning serves as a detailed description of something that is wrong in the doctor's practice or behaviour, what needs to be done. It is documented for the employer to see. It has, however, no immediate effect on the doctor's work situation.

Table 14 Type of Reaction for Sample

Type of Reaction	2011	
	Sample	Total
Lost authorisation	20	24
Limited authorisation	5	5
Limited right to prescribe medicine	7	8
Warning	42	59
Total	73	96 *

*The 97th is the mentioned loss of authorisation for medical specialisation.

Analyses of the Reactions: Comparison of tables 13 and 14

Revocation of Authorisation

In 2011, 24 doctors lost their authorisation to practice that, according to Table 14 is average (from 2006-2013 the average has been between 21 and 29). It is reasonable to assume that these are random variations, with a slight increasing tendency. But so is the total number of doctors, so the relative amount seems to be fairly stable.

What is noteworthy is the increase for the reason '**Not reacted to warning or request**': from 2010-2011 this increased from 2 to 6, remained at 6 in 2012 and then decreased to 4 in 2013.

This looks from the case documents to be a rather automatic response when the doctor does not submit required documentation. Typically, there has been a concern over prescriptions of addictive medicine reported from a pharmacy. The Regional Medical Officer asks for patient journals on a number of patients, the doctor fails to send these in and, after warning the case goes to the Board, which then revokes authorisation.

There is no consideration of the risk here; rather, this is an administrative reaction to the doctor. In the total number of cases that we have had access to (all 113 case documents), 13 doctors lost their authorisation due to request of journals. In 2014, 12

of the 13 authorisations to practice were reinstated. We believe that such a warning is an effective sanction, but not really related to the prime goal of reducing risk and retaining public trust (as discussed in the introduction).

It may be questioned whether this is an adequate reaction. It removes the livelihood for the doctor, but the possibility of using revocation for health personnel ‘not complying with demands according to the law’ is clearly stated in the law.

What is interesting for our purpose is how this relates to the main purpose of the sanction, that is, to retain public trust and reduce risk. We would argue that, in this case, it does not. And given that authorisation for 6 of those doctors who lost their authorisation in 2011 were reinstated in 2014, that means that only 18 revocations in 2011 that relate to the primary aim of the law.

Lost authorisation in another country

The Norwegian Board of Health Supervision has an agreement with Sweden and Denmark for mutual reporting on changes in authorisation for health personnel (Helsetilsynet, No date). This means that a doctor who is authorised in Sweden or Denmark may apply for authorisation in Norway on the basis of the Swedish or Danish authorisation. Authorisation in Norway is fairly automatic. Since the original authorisation is the basis for the Norwegian authorisation, if the original authorisation is revoked, the Norwegian authorisation will also be revoked.

The case documents are short and do not go into any detail about the reasons or circumstances for the revocation. They just state that the Norwegian authorisation is based on the one from the other country, and when that is lost, the Norwegian one is lost automatically.

While there was only 1 such revocation in 2011, there have been 1-3 cases each year from 2006 to 2013. We would argue that such mutual reporting is effective.

In the case in 2011, the doctor voluntarily waived authorisation in the home country, and the Norwegian authorisation was automatically revoked.

Use of alcohol or drugs that make the doctor unfit for practice

This is the most common reason for revocation of authorisation, comprising **11** cases in 2011.

The cases are varied, some with a long history of alcohol addiction and with several complaints or reports of worry from patients, but no reported harm done to patients. Some cases have incidents of drunk driving, even treating a patient under the influence of alcohol measured to 2,96 0/00.

The other most common reason is drug abuse, mostly addictive medicines. Some of these are reported by pharmacies when a doctor prescribes more than normal for her/himself or a close family member.

These case studies reveal slowly evolving personal tragedies from drug or alcohol abuse to addiction. The warnings come from patients, colleagues, pharmacies, and, in some cases, the doctors themselves. In some cases, drug addiction was the underlying cause of a doctor's inability to do their job.

According to the Regional Leader of the Norwegian Medical Association (*legeforening*), alcohol and drug abuse are recognised problems in the medical profession, seen often as the result of work-related stress. The Medical Association addresses these problems through support activities including appointing colleagues in each municipality to inform, look out for and be of support to doctors who are developing such problems.

Norway has a culture with a very low tolerance for alcohol consumption on the job. A doctor with the slightest smell of alcohol in a job situation would be noticed and most likely reported.

Drug addiction can be more difficult to detect, since doctors can self-prescribe.

Those cases of alcohol or drug abuse that are reported here, are, in our view, handled thoroughly. They are worked on over time, in dialogue with the doctor. Warnings are given, limited right to prescribe addictive medicines may be issued, and less stressful jobs may be defined.

From the cases we have read, we find that the legal interest of the doctor is well taken into account and that solutions have been sought to make it possible for them to continue to keep their livelihood and to exercise their profession. One of our initial research questions was to determine if the moral standards in Norway are stricter than in other countries. We wondered if this would make it difficult to converge with the practices in other countries with higher tolerance for alcohol. But the cases we have reviewed do not indicate that these cultural differences play any role. These are doctors not fit for practice any more, to the best of judgement.

4.Theoretical framework and analysis

What is Revocation of Authorisation for Medical Doctors All About?

Risk

The late Ulrich Beck described ‘the risk society’ in his ground breaking 1986 book as a general attitude of risk aversion that runs through more and more of (western) society (Beck, 1992 (1986)). The popular support for political institutions is tied to their ability to secure the public and prevent risk.

Michael Power has described how this in turn has introduced control systems to the institutions that provide public services within most sectors, including health and welfare. This has developed to such an extent that he calls (western) states ‘audit societies’ (Power, 1997).

How can the revocation of authorisation of medical doctors be seen in this bigger picture? As we see it, the act of revocation is meant as a means to control risk factors in the health sector. In the case documents we have gone through, “risk” in the Norwegian system is a commonly used term to describe what this is about. It is therefore interesting to understand how the act of revocation may be seen in the general governance of risk in the health sector.

The ideal model of medical behaviour

The doctor as social actor

The German sociologist Max Weber developed a method for analysing and comparing social roles and positions. He called it *ideal types* and used it to analyse the modern bureaucracy at the last turn of the century. Constructing an ideal model of the professional role a medical doctor would include several variables. First, the ideal medical doctor is omniscient in her meeting with the patient regarding medical knowledge, she has a basic view of humanity in accordance with the dominating culture in society, and she lives by common moral norms.

The doctor’s view of her fellow human being cannot be totally one-dimensional. She should see the patient as an autonomous whole, as a goal and not a means in the Kantian sense. At the same time the patient is often coming with a bio-medical problem. And then there is the demand for fair and just treatment; all patients are equal. So the doctor should meet every patient every time as a whole, unique and autonomous person, focus on the problem, and treat everyone differently in a way that is preserved as equal in a just sense. This is, as we can imagine, no small task.

The doctor must be conscious of her position in society when she encounters the patient. She has been given status and power and entrusted to represent the society in a meeting with a vulnerable person. But the doctor is also a neutral representative of the state. She shall treat the patient as only a patient, not taking into consideration anything about the patient’s status in society or any personal knowledge or relation the doctor or patient may have outside the medical encounter.

Both GMC and BMA in the UK, and the Medical Association in Norway express an expectation of moral standards well above average. In the decision documents from BHS, the doctors are expected to be very conscious of their power position in relation to the patient.

When it comes to mastering professional knowledge, the doctor is expected to have full oversight of all relevant medical knowledge, to find out all relevant knowledge about the patient and his situation, to make an informed diagnosis and decision about treatment based on all possible solutions, all possible effects and side effects of all solutions, and rank all alternatives in a clear order that reflects values and priorities in society and in the health system, and the patient's own preferences. This is also no small matter.

Doctor – patient encounters during treatment

To be a patient with a condition that requires treatment usually demands several meetings with several medical doctors. The interaction will have the basic elements of problem solving: investigation of the problem, decision on a diagnoses, evaluation and planning of treatment, implementation of the treatment and possibly rehabilitation, and evaluation of the results.

In the meeting between patient and doctor there is always a double bind. The patient has a disease that should be sorted as a separate phenomenon, while the doctor at the same time shall look at the patient as a whole, autonomous person. Having a disease is in itself defined as abnormal, a problem the patient need help to handle.

The doctor therefore must treat the encounter both as a subject-object meeting and as a subject-subject meeting.

This rather complicated meeting will in the different stages of treatment also vary in organisational context.

Investigating the problem and deciding on the diagnosis

The first encounter between patient and doctor in a treatment process is ideally the patient approaching the GP, the responsible doctor in an ER, or the responsible doctor in an institution if the patient is already institutionalised. The ideal situation is an 'economic-man' decision process; the doctor will have access to all relevant information about the patient and process this information in a way that enables her to determine the right diagnoses.

Let us describe this in formal logical terms:

The ideal model for determining diagnoses is that it is a logical conclusion. Biomedical knowledge belongs to the natural sciences and is based on causal explanations. 'If you observe symptom S, it means the patient suffers from condition D'. The diagnosis is a causal explanation. The cognitive process is that the doctor observes a symptom or the patient describes it, the doctor infers from the symptom to a diagnoses via rules of inference: 'S means D'. The diagnosis is a theory of causal relations within the patient.

The second step of this process is to decide treatment of D. This demands a new set of rules of inference; D can best be treated with T.

It is, as mentioned, a process in several steps:

- investigate the problem and determine a diagnosis;
- evaluate and plan treatment;
- implement treatment and possible rehabilitation; and
- evaluate the result.

Every step includes collecting information or data as a basis for evaluation and conclusion/decision:

- diagnosis;
- plan for treatment;
- monitor treatment;
- evaluate the patient's condition after treatment.

Our point here is that every step in the process can be seen as a situation for making a decision, *ideally* this decision is 100% rational, what the economists call ‘economic man’: all information is accessible, all possible diagnoses will be considered, all possible types of treatment will be considered, all effects and side effects will be considered, during the treatment the patient’s condition will be monitored at all times, and the organisation around the patient can at all times reconsider and adjust the treatment.

This is the *ideal type*. Not reality. So why is it important? Here we have to address a significant aspect of the process: *professional judgement*. This description differs from reality in that it is *ideal*. In reality the doctor has to make quick judgments based on limited or ill-described symptoms. She cannot be expected to have full knowledge of every medical condition or treatment. The effect of treatment will at any rate vary with the patient’s individual condition.

Knowledge, common and professional, is always a combination of theoretical cognitive reasoning and life experience. Traditionally we have encouraged training of professional judgement, in clinical work we call it the *clinical gaze*. This has been connected to trust in the profession.

Risk and trust

In Norway, Jan Holden has designed a figure with two dimensions that illustrates the complexity of the risk phenomena (referred in (Lindøe, Kringsen, & Braut, 2012) p.63). The horizontal axis runs between ‘safety’ meaning accidents and catastrophes that we cannot totally prevent from happening, but for which we can be prepared and reduce the effect to some extent. The other end is about ‘security’, intended actions of people with evil will, like crime. On the vertical dimension he places ‘macro factors’

for making society safe as a collective, and in the other end ‘micro factors’ that are about individual safety and protection.

The point of the figure is of course that all these factors are connected.

Lindøe et.al. (Lindøe et al., 2012) discusses these factors in light of governmental regulation of risk. They describe the Norwegian system of governmental audit in various sectors. The basic principle in Norway is that audit is carried out by 30-40 governmental institutions. The English and Norwegian systems are described below.

Trust

An audit system can be seen to have several functions. Following Holden’s two-dimensional figure, a major function is to make the population feel safe, as safe as can be. This is about *trust* in society; trust that generates political legitimacy for the state. When there is a flood, and the government can prove that they did what they could to make barriers secure, there will be acceptance in the population over the fact that it is not possible to be 100% safe. Audit systems have as their function to ensure that safety measures are taken, that institutions act according to their responsibility, and if not, correct their performance. But the audit also helps to build public trust, or *social capital* as the social sciences would operationalize public trust. This is an important function in itself, because it makes society more effective by reducing transactional costs in the providing and consuming of public services.

Market

In England, audit has had another function. Its role is to secure that the services promised from private providers are what they claim to be and meet quality standards. This is important in a market-regulated service system to secure fair competition, and in that sense secure the optimal functioning of the market. This became a prime function in the implementation of New Public Management in the 1990s. This function was also promoted on the policy level by the government in Norway in 2003, but has, under the Social Democratic regime, been less emphasised. In England this will of course be a continuously focused function under the privatisation regime favoured in the reforms moving steadily forward around the NHS.

Historically, there are several reasons for the transition to a more market-regulated health service system. One was a belief in market solutions in general, political liberalism that had strong support in the late 1980s and 1990s. But it also reflects for our purpose a difference between England and Norway when it comes to trust in the government. In Scandinavia this trust is high, possibly higher in Norway than even the other Scandinavian countries. The reason usually given by historians is that the institution that was put in place in 1934-35 to regulate relations between labour and capital, with the government as an active ‘referee’; and the WWII experience strengthening ties between the classes. The development of a universal welfare state reinforced trust in the state. England has always had a much stronger class structure and a polarised political system. The building of a welfare state after WWII was also less successful. But compared to many other countries, the NHS had a strong standing for several decades.

What seemed to shake the public trust in the public health system were scandals at several major institutions starting with Bristol Royal Infirmary as described in Ch.2 above.

Norms and regulation

Norms and regulation are long, parallel trends, but may be described in a simplified way based on two principles: *professional* norms and *legal* regulation. This is described thoroughly by Grand in his book on ‘knights and knaves’ (Grand, 2003). In the development of professions, especially the medical profession, an ideal of disciplining ones own resulted in strong professional norms and disciplinary systems internally in the professional associations. This is based on the professionals as ‘knights’, fighting for the common good rather than self-interest. The audit society does not trust the professionals to be ‘knights’ any more.

This is relevant to our study in several ways. The revocation of authorisation can be seen as a new version of professional societies’ excommunication of unruly or undisciplined members. The authorisation system is in itself a contract between the state/society and the profession that the job in question has to be performed by someone in the profession. This ‘contract’ is supposed to give society the best quality service, but it gives the professional some privileges (position, status, career possibilities, salary level). The trust in these professions diminished in the 1980s and 1990s, and opened for a more market-regulated system with New Public Management.

Ragnar Löfstedt describes this as a post-trust society (Löfstedt, 2005). He points out four factors that need to be considered in a contemporary diagnoses of society: efficiency, knowledge competence, value fairness and legitimization. He describes four ideal types in meeting the demands these factors construct: economic balance, technological solution, political regulation and deliberation.

The post-trust, non-risk society

Going back to Beck’s diagnosis of contemporary society as a risk-avoiding society that through intense regulation of risk, actually increases it (he refers to the climate crisis), and Power’s diagnosis of a society obsessed with control and audit, we find a kind of post-trust, non-risk society. But even if Norway and England have some common features, these variables manifest themselves differently in the two societies. Many observers may not go so far as to call Norway a post-trust society at all, while England has persisted as a class society with checks and balances on the distribution of power, but not a particularly high social capital in terms of trust.

A Theoretical Framework for Comparison

It is difficult to compare the systems of health service regulation in two such different countries as Norway and UK. Size in population is of course the biggest difference, UK being twelve times Norway, but the systems themselves and their history within the context of two very different political systems all make it comparison difficult.

Christopher Hood and Associates have worked out a model to facilitate comparative studies of risk regulation regimes. Geir Sverre Braut pointed to this work when we discussed the assignment. We have therefore tried to see if the model can help us.

Different methods

We have used rather different methods to investigate the two national systems. The CQC was able to supply us with solid quantitative data for analysis. The Norwegian data sample was very small and we were not able to analyse the degree of variation in a statistical manner. One reason for variation may be the decision process itself. It seems to take a rather long time, and a cleaning up of a backlog from last year would look like a big variation. For this reason we have used document analyses to understand the process behind the decisions.

A model for comparing systems.

We will first discuss the phenomenon of regulation and in that revocation of licence (see ‘project questions’ in the beginning of this report).

Hood et. al.’s model:

We will look closer at the Hood et. al. model for comparison (Hood et al., 2001). Their model has three control components and two regime components, and each regime components have three subcomponents. The model is a matrix with 18 fields that consists of combinations of regime and control components.

		Control components		
		A. Information gathering	B. Standard setting	C. Behaviour modification
Regime context	1. Type of risk	1A	1B	1C
	2. Public preference and attitude	2A	2B	2C
	3. Organised interests	3A	3B	3C
Regime content	4. Size	4A	4B	4C
	5. Structure	5A	5B	5C
	6. Style	6A	6B	6C

From (Hood et al., 2001), p.29.

The variables:

Regime context:

1. Type of risk

This variable is about the inherent features of the risk itself. They include the source of cause, how familiar and well established it is, how easy it can be quantified, its timing and impact, the severity of its consequences, and the probability of its occurrence.

All risks connected to revocation of authorisation are tied to the person, the doctor and his or her actions. The underlying reasoning seem to be

- the doctor's professional skills
- the doctor's professional background, particularly socialisation to cultural and professional norms
- the psychological state of the doctor, either personality or a development of an addiction

The type of risks generated from the doctors personality and skills are of two main categories:

- risk of dangerous medical practice
- risk of doing harm to the patient in other ways

Dangerous practice can come from either lack of skills or the effects of drugs or alcohol.

2. Public preferences and attitudes

It seems that the risk of doing harm to the patient in other ways such as offending the patient or approaching the patient in a sexual way is seen as particularly serious. In the case reports from Norway several cases are described. The offenses are usually ambiguous acts such as massage or seemingly unnecessary intimate inspections. But this may also be due to relation that have developed between doctor and patient that the patient at some point wants to terminate and the doctor keeps in contact through SMS.

The rule, if we can read any out of the very few cases, seems to be that if the patient feels offended, BHS believes her and reacts. Sometimes there is a warning to the doctor, sometimes several incidents may come up, maybe even from other patients. All though the patient's rights seem secured in this process, also the doctors legal status seem to be well taken into consideration. There is a long and thorough process before the licence is revoked.

In the UK, GMC takes very seriously sexual offences and demonstrates a clear understanding for the psychological damage this can do to vulnerable patients.

GMC also expressed concern about other types of behaviour that they would see unfit for a medical doctor, such as criminal activity prosecuted by the police. There are also a few cases of this type in the Norwegian material. The general attitude seems to be that a medical doctor must meet a high moral standard, and that even acts unrelated to the medical practice can damage the general trust and reputation of the health system.

The main reason for revocation in Norway is drug and alcohol abuse. These cases are first straightforward alcoholism. The leader of the regional branch of the medical association in Norway expressed great concern for alcoholism as bigger problem among medical doctors than among the population in general. Stress and pressure in the work situation can be seen as possible explanations. The medical association asks their members to report on colleges in these cases, and they organise college support. The case reports indicate a clear but pragmatic attitude to this, where cases are developing over a long time, and the doctor get several chances to recover and come back to work. Then there are drug problems of two kinds; doctors that prescribes drugs to patients beyond safe medical practice, and doctors who prescribe drugs to them selves, and develop an addiction. Both draw strong reactions, usually revocation of right to prescribe, and then revocation of licence.

Both in England and Norway, non-clinical reasons form the basis for the majority of revocation cases. Case reports from Norway indicate that revocation of licence is not seen as a regulating tool for clinical or professional bad practice. The only act that draws an immediate revocation is failure to provide documentation such as patient journals when required to do so by BHS. But all these get back their licence as soon as they comply.

3. Organised interests

This refers to risk domains. We have earlier in this report referred to knights and knaves (Grand, 2003). Professional knights refer to the altruistic professional who only works for the common good. Medical doctors have been seen to fit this role. This general attitude of the profession also implies ownership for the handling of risk, and for the professional association to administer the (self-) discipline of its members. This is no longer the case and we found full consensus that the regulating body owns the risk domain.

Regime content

4. Size

Size as a property of the regime can be seen as both the size of the regulatory system and the strength of its reactions and sanctions. The level of tolerance of risk will determine the size of the system.

The size of the system to be monitored will also be relevant. Both Norway and the UK have fairly small control systems. Norway has its major regulator in the Department of Health, (*Helsedirektoratet*) that sets standards for quality and, to some extent, tolerance of risk. But the BHS is a small organisation with limited resources. All the same it seems adequate to do a thorough job. The decentralisation in county

branches gives BHS a position to review cases in a local context that for most of the controllers will be known.

In UK this is very different, and we have described in detail in ch.2 the problems change in method of the CQC led to.

5. Structure.

Structure is, as size, related to the regulatory system in Hood's model. One important element much discussed among experts, according to Hood, is the mix of public and private, state and market. In our case there is a small difference between Norway and UK, in that the Norwegian system is 100% state, while GMC claims a more independent role. But also GMC is appointed by the government, and as such a representative of the state.

The Norwegian structure is both centralized and decentralized. The mandate is totally centralized in BHS in Oslo, but the service of the county branches gives the process a local connection that makes the distance to the doctors and patients shorter. The Norwegian system will be seen as state run, legal in orientation but within the health sector and professional domain.

Even with division of labour between GMC and CQC, it is an overall state powered structure also in UK, and localized to the health system domain.

A very different structure can be found in USA and some other countries, where important parts of the regulatory process is transferred to the legal system, and disciplining and conflict resolution are made through the juridical system. That generates very different processes.

6. Style.

Style denotes the operational conventions and attitudes of those involved in regulation, and the formal and informal process through which regulation works. One aspect of style is how far the operation of regulation is rule-bound or discretionary, and how far it is based on 'command and control' approaches. Another is the attitudes and beliefs of the various regulatory actors, and the degree of zeal they show in pursuit of policy objectives.

Here there may be some differences between Norway and UK in the sense that Norway has one monolithic system in the BHS, while UK has both the GMC and the CQC. In Norway it will be the same people in the county, working for the Regional Medical officer, that distribute and inform national policy and standards, monitor the regional health system, and collects information for cases of revocation. They will be able to see more of the picture, to have a more holistic view. But the decision to revoke is done by the director of BHS in Oslo. The final cases are worked out by a small group consisting of both legal experts and medical experts. This makes it fairly certain that cases from all over the country are treated in the same way.

In UK the approach from CQC is different from the GMC, as described above. The style of GMC has been strongly debated as reflected in the interview we had with an ex-health minister, see analyses of interview 3 above.

Control components

a. Information gathering.

It is necessary to divide the information gathering into two types relating to the field in question. In Norway it is called *planned control* and *incidence driven control*. In UK CQC undertakes the activities corresponding to the planned control. That is planned, systematic gathering of information about an organisation's performance, either the process or the result.

Cases of revocation of licence are typically results of a report from a patient, kin to a patient, colleges, pharmacies or media. The case is then about an individual, an identified doctor, regarding a special incident.

In the UK these cases goes into the GMC's FtP-process. When a case reaches GMC as an inquiry, it is reviewed by the staff in GMC and found either not to be subject to further inquiries (50% of cases), or that it should. Where the information in itself is not of sufficient concern to raise an issue, but could be if seen as part of a broader pattern, stream 2 leads to enquiries of the doctor's employer or contractor to establish any concerns; depending on the outcome of that, a further investigation may be carried out. 21% of all cases are checked out of the process after this stage. This means that of all the cases reported to GMC, 71% are checked out of the process either based on the first information, or by the information collected by GMC.

The remaining 29% of cases goes on to further information gathering by GMC, and all the information are then reviewed by two case examiners, who make the decision of the next step. The final step is the FtP-panel in GMC that will hear the parties presenting the evidence around the case, and they will take a final decision (see figure 1).

This is parallel to the process in Norway. But while GMC claims to be an independent professional body, BHS is the state's own and integrated organ. In a white paper presented by the Norwegian government in 2003 on governmental audit systems (Stortingsmelding, 2002-2003) the minister argued for a greater autonomy and independency from the state bureaucracy. It was suggested that government audit-and control organs should move out of Oslo to separate them from the policy- and regulating bodies. This did not happen to the BHS, and with its branch organisations as part of the state's county administrations, the Norwegian BHS is very much seen as a governmental controller.

As in UK incidents are reported by the same categories, and in addition every county has an ombudsman for patients that also will report cases. There will be a process at the county level, where the regional medical officer will decide which cases to investigate. If in doubt he will consult the head office of BHS in Oslo. The case will then be investigated by the county branch, and a report with all collected documentation will be sent to BHS in Oslo. Here one medical expert and one legal expert will be case examiners and write out a case document and suggest type of sanction to the director who makes the decision. The doctor will be given the chance to defend himself, and also bring a lawyer since the decision has to be based in the law.

b. Standard setting.

While GMC plays a role in standard setting, BHS in Norway has to base all reactions in the law. But the law is wide and unclear when it comes to relevant themes. It states that doctors should act professionally responsible ('faglig forsvarlig') and that will not always be possible to define precisely.

The main setting of standards will be political though, defined in green and white papers, and further defined by the ministry and the different parts of the health system, both in Norway and UK.

Part of this is a need for clear orders when health services are privatized and bids are to be made. This is less common in Norway than UK. But the principal-agent system is to some extent also in operation in the Norwegian system.

c. Behaviour modification.

The whole point of evaluating risk, set standards and gather information is to regulate the system through behaviour modification. Hood et.al. discuss different approaches to this, one being a cybernetic systems approach. The health system can be seen as a system with balance points, or steady state, or homeostatic state. When something is brought out of balance, when the risk is too high, it has to be brought back through behavioural modification.

It is generally two main strategies, called in short ‘compliance’ and ‘deterrence’. The compliance strategy works through positive motivation, education and information. The deterrence strategy relies on punishment.

We see this as relating to culture and social capital. The control mechanisms and the sanctions connected to them are very important for the functioning of the health system. UK have gone more in the direction of market regulation than Norway, and plan to go even further. Norway benefit from a high social capital in the society and trust in the government. This means that the health system is less vulnerable to bad publicity. Even if the media reports on medical malpractice, it will not hurt the whole system so much. It is a very strong belief in Norway that the health system is one of the best, and that the government are capable of running it.

Does this model for comparison apply?

We have worked through our material with the model Hood et.al. developed in mind. This was suggested by Braut, and we find it to be a good model for comparing important variables.

But, we find that revocation of authorisation falls on the side of the model. Revocation is not used to regulate the system. It is the last resort when the situation is impossible to solve in any other way.

Revocation is hardly used to sanction bad practice at all. It is doctors that have problems of such a serious nature that they can't go on practicing. The regulation of the system is mainly through other parts of the audit system, with other types of sanctions.

It could be asked if revocation has a potential as a sanction in regulating behaviour. We think not.

7. Concluding remarks

Regulation of risk and quality in health services consists first of setting standards; a wide and complex task where professional bodies, bureaucratic organisations and political institutions all play a role. Secondly, it is about getting information of how it works, and thirdly react in a way that hopefully will modify behaviour that is seen as risky.

We have gone through the process of revocation of authorisation for medical doctors and UK and Norway, and found that it is rare, it is used with great care. The review of the case documents in Norway shows that the process is thorough and keeps the doctors legal rights well in mind.

It is not used systematically or to any significant extent to regulate risk. We see this as wise.

References:

- Beck, Ulrich. (1992 (1986)). *Risk Society. Towards a New Modernity*. London: SAGE.
- Berfring, Anne Kjersti, & Ohnstad, Bente. (2010). *Helsepersonelloven - med kommentarer*. Bergen: Fagbokforlaget.
- Grand, Julian Le. (2003). *Motivation, Agency, and Public Policy. Of Knights & Knaves, Pawns & Queens*. Oxford: Oxford University Press.
- Helsetilsynet. (No date). *Autorisasjonsforhold I de nordiske lande. Udveksling av opplysninger*. Oslo
- Hem, Hans Einar, & Lodden, Petter. (2010). "Slik kommunen ser det ... ". *Rapport fra et utviklingsarbeid om statlig tilsyn med kommunene*. Retrieved from Fylkesmannen i Vestfold og Kommunal- og regional departementet.: Hood, Christopher, Rothstein, Henry, & Baldwin, Robert. (2001). *The Government of Risk. Understanding Risk Regulation Regimes*. Oxford: Oxford UP.
- Hsieh H, Shannon S (2005). Three approaches to qualitative content analysis. *Qualitative Health Research, 15*, 1277 – 1287.
- Lindøe, Preben Hempel, Kringen, Jacob, & Braut, Geir Sverre (Eds.). (2012). *Risiko og tilsyn. Risikostyring og rettslig regulering*. Oslo: Universitetsforlaget.
- Löfstedt, Ragnar. (2005). *Risk Management in Post-trust Society*. London: Palgrave.
- Power, Michael. (1997). *The Audit Society. Rituals of Verification*. Oxford: Oxford University Press.
- Stortingsmelding, 17. (2002-2003). *Om statlig tilsyn*. Oslo: Stortinget.