

A Review of Research into Health and Care Professional Regulation

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Table of Contents

Tables and Figures	iii
List of abbreviations	iv
Executive Summary	vi
Part 1 - Introduction	1
1.1 Background.....	1
1.2 Aim and objectives.....	2
Part 2 – Study Design and Methods	3
2.1 Issue Scoping	3
2.1.1 Regulator interviews.....	3
2.1.2 Annual reports and other information from regulator websites	3
2.2 Rapid Evidence Assessment	4
2.2.1 Sources.....	4
2.2.2 Search Terms and Inclusion / Exclusion Criteria	4
2.2.3 Selection Process and Data Extraction	4
2.2.4 Screening.....	7
Part 3 - Key Findings from the interviews.....	11
3.1 Who conducts research?	11
3.2 Determining research priorities	11
3.2.1 Strategic priorities.....	11
3.2.2. Arising issues.....	13
3.3 Current research	13
3.4 Past research	14
3.5 Future research.....	15
3.6 Closed down areas of research	16
3.7 Collaborations.....	17
3.8 Summary points	17
Part 4 – Review of annual reports and position statements.....	18
4.1 Context.....	18
4.2 Coding scheme	18
4.2 General Optical Council	19
4.3 General Dental Council.....	20
4.4 Nursing and Midwifery Council.....	21
4.5 General Pharmaceutical Council	21
4.6 General Osteopathic Council	22
4.7 General Medical Council.....	22
4.8 General Chiropractic Council.....	24
4.9 Pharmaceutical Society of Northern Ireland	25
4.10 Social Work England	25
4.11 Health and Care Professions Council	26
4.12 Summary of analysis of annual reports	26
Part 5 – Rapid Evidence Assessment	28
5.1 Overview	28
5.1.2 Thematic organisation	28

5.2 Education and training	30
5.2.1 Summary information on the papers in this section	30
5.2.2 Evidence synthesis	31
5.3 Guidelines and standards	35
5.3.1 Summary information on the papers in this section	35
5.3.2 Evidence synthesis	37
5.4 Fitness to practise, misconduct, complaints and disciplinary measures.....	40
5.4.1 Summary information on the papers in this section	40
5.4.2 Evidence synthesis	42
5.5 Registration and the maintenance of registration.....	50
5.5.1 Summary information on the papers in this section	50
5.5.2 Evidence synthesis	51
5.6 Relations with regulatory body.....	53
5.6.1 Summary information on the papers in this section	53
5.6.2 Evidence synthesis	55
5.7 Harm prevention and patient safety	59
5.7.1 Summary information on the papers in this section	59
5.7.2 Evidence synthesis	60
Part 6 – Key Findings and Conclusions.....	64
6.1 Limitations and challenges	64
6.2 The nature of the research challenges in health and care professional regulation studies	65
6.2.1 Regulators’ resources for evidence-based policy development.....	65
6.2.2 Regulators’ in-house work.....	66
6.2.3 Commissioned work.....	66
6.2.4 Independent work by academics/clinicians.....	67
6.3 Opportunities.....	69
References	70
Appendices	80
Appendix 1 – Information Sheet.....	81
Appendix 2 – Consent Form	84
Appendix 3 – Interview Questions.....	85
Appendix 4 – Documents and reports to which interviewees referred us.....	86
Appendix 5 – Further Information on Search Strategy.....	87

Tables and Figures

Table 1: Summary of papers’ selection procedure.....	5
Table 2: Strategic priorities	12
Table 3: Arising issues	13
Table 4: Current research.....	13
Table 5: Past research	14
Table 6: Future research	15
Table 7: Key features of the regulators	18
Table 8: General Optical Council annual report	20
Table 9: General Dental Council annual report	20
Table 10: Nursing and Midwifery Council annual report.....	21
Table 11: General Pharmaceutical Council annual report.....	21
Table 12: General Osteopathic Council annual report	22
Table 13: General Medical Council annual report	22
Table 14: General Chiropractic Council annual report	24
Table 15: Pharmaceutical Society of Northern Ireland annual report.....	25
Table 16: Social Work England annual report	25
Table 17: Social Work England Consultation	26
Table 18: Health and Care Professions Council annual report	26
Table 19: Descriptions of themes.....	29
Table 20: Number of papers reviewed, by theme.....	29
Table 21: Country location of the papers	30
Table 22: The professional groups that were the subjects of the papers	30
Table 23: Year of publication.....	31
Table 24: Study type.....	31
Table 25: Country location of the papers	36
Table 26: The professional groups that were the subjects of the papers	36
Table 27: Year of publication.....	36
Table 28: Study type.....	36
Table 29: Country location of the papers	41
Table 30: The professional groups that were the subjects of the papers	41
Table 31: Year of publication.....	41
Table 32: Study type.....	42
Table 33: Country location of the papers	50
Table 34: The professional groups that were the subjects of the papers	50
Table 35: Year of publication.....	50
Table 36: Study type.....	51
Table 37: Country location of the papers	53
Table 38: The professional groups that were the subjects of the papers	54
Table 39: Year of publication.....	54
Table 40: Study type.....	55
Table 41: Country location of the papers	59
Table 42: The professional groups that were the subjects of the papers	60
Table 43: Year of publication.....	60
Table 44: Study type.....	60
Figure 1: PRISMA flow diagram detailing the search process.....	6

List of abbreviations

ACGME	Accreditation Council for Graduate Medical Education
AHPRA	Australian Health Practitioner Regulatory Agency
AI	Artificial Intelligence
ANP	Advance nurse practitioner
BAME	Black, Asian and minority ethnic
BME	Black and minority ethnic
CCE	Council of Chiropractic Education
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CME	Continuing medical education
CP	Chiropractic Programmes
CPD	Continuing Professional Development
CQC	Care Quality Commission
DN	District nurse
EDI	Equality, diversity and inclusion
EEA	European Economic Area
EL	Experience learning
EMT	Emergency medical technician
ENP	Emergency nurse practitioner
EPOC	Effective Practice and Organization of Care
EU	European Union
FoI	Freedom of Information
FtP	Fitness to practise
GCC	General Chiropractic Council
GDC	General Dental Council
GMC	General Medical Council
GOC	General Optical Council
GOSc	General Osteopathic Council
GPAQ	General Practice Assessment Questionnaire
GPhC	General Pharmaceutical Council
GP	General Practitioner
HCPC	Health and Care Professions Council
HE	Higher education
HEI	Higher education institution
IELTS	International English Language Testing System
IM	Intelligent monitoring
IPC	Interprofessional collaboration

ITP	Internationally Trained Pharmacist
LSA	Local supervising authorities
MT	Manual therapies
nGMS	new General Medical Services
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMC	Nursing and Midwifery Council
OPS	Osteopathic Practice Standards
PCO	Primary Care Organisation
PHECC	Pre-Hospital Emergency Care Council
PLAB	Professional and Linguistic Assessments Board
PSA	Professional Standards Authority
PSNI	Pharmaceutical Society of Northern Ireland
QA	Quality Assurance
QAF	Quality assurance framework
RCDSO	Royal College of Dental Surgeons of Ontario
REA	Rapid evidence assessment
RO	Responsible officer
SoM	Supervisor of Midwives
SOMEF	The state of medical education and practice in the UK
SWE	Social Work England
UK	United Kingdom
US	United States
WHM	Western herbal medicine

Executive Summary

Introduction

The authors of this report were commissioned by the Professional Standards Authority (PSA) to undertake a review of research into health and care professional regulation since 2011.

The key objectives of this study were to:

1. Source research in the area of health and care professional regulation in English since 2011
2. Evaluate the research and draw out what it has taught us
3. Identify any gaps in the research and areas that would benefit from deeper exploration in order to inform the focus of further research and continue to build the evidence base in relation to health and care professional regulation.

In this report we use 'research' in a broad sense, encompassing surveys, consultations, and periodic reviews as well as targeted, commissioned research.

Background

Previous research commissioned by the PSA identified that there was a shortage of studies on the impact of health and social care regulation (Quick, 2011). Over the last decade, changes in the culture and delivery of health and social care, public attitudes, and societal and demographic factors have all had an influence both on regulators and on regulated professions. There has been an increase in the production of guidance supplementary to general professional standards, a growth in numbers of published reports and joint statements, and research and data-gathering activity has gained pace. There have also been changes in legislation, practice and societal attitudes affecting how those working in the field focus their research activity. It is therefore timely to review the effect of this increased activity as reflected in the scholarly literature on regulation during the past decade.

Methods

This study was approved by the School of Social Sciences' Research Ethics Committee at Cardiff University.

Study methods comprised: a rapid evidence assessment, interviews and document review.

(1) The rapid evidence assessment

We collected references from four key databases: Scopus, Medline (including the Cochrane Reviews), PsycINFO and CINAHL. The initial list included 3833 records. After removal of duplicates, this reduced to 3179. To this list we added publications from a search of authors suggested by the PSA (in total 134 papers). After further removal of duplicates, the final list contained 3254 records. We used a four-stage screening process to:

- Review titles and exclude references based on clear lack of relevance to the study.
- Review abstracts and exclude references based on further evidence of methodological flaws, date of publication pre-2011, lack of clear research questions, or lack of evidence.
- Review full papers; we sorted these into two groups, one of which we designated the 'out group' to reflect that, while not completely irrelevant, some papers were of marginal interest only. These were set to one side in case further study is indicated.

The remaining 'in group' comprising 118 papers was analysed in detail and the 81 most relevant ones form the basis of the REA.

Key findings

The 'in group' contained a variable mix of (a) impact studies and (b) more general publications. The impact studies in the first group rarely used experimental designs but were more clearly focused on the gathering and interpretation of data, with a stronger focus on the evaluation, impact, effect, or implications of certain regulations. The general publications in the second group mostly provided overviews, snapshots of the current situation or discussions.

All papers could be linked to at least one aspect of the regulator's work.

Education and training

Sixteen papers were reviewed in this group. In summary:

- Generally, studies call for greater standardisation, harmonization and collaboration both in terms of intra-professional learning and internationally. Standardisation and harmonisation are seen as beneficial both for professionals and for patient safety.
- The importance of context appears in relation to the attempt to implement practical learning. Low financial support and reduced access to workplaces can hinder the practical application of learning.
- Studies stress the role of context in successful implementation of education reforms on curricula or CPD programmes. Educators and staff attitudes play a role in the successful application of intra-professional learning. Internal politics can influence the adoption of certain curricula or programmes instead of others.
- The effects of academisation vary according to the context of different professions: in the case of nurses it is described as a positive change. In the case of paramedics, it is felt as favouring academic knowledge over practical experience and creating competition between those trained under the "old" and "new" approaches.
- There is a general appreciation and recognition of the value of CPD, although there is scope to increase the practical application of learning.

Guidelines and standards

Eleven papers were reviewed. In summary, the main findings were:

- The papers in this group present analysis or comments on the functioning of guidelines and/or impact of changes in guidelines. Studies call for more reflection on the implications of certain provisions for the professionals.
- Other studies are more generally concerned with understanding the impact of changes in guidelines or the way in which implementation takes place.

- There is, in general, acknowledgement that clarity is essential (and sometimes lacking), and that in order to support implementation, different strategies or instruments have to be considered.
- The role of patients is not evident; only within midwives' studies where there is a clear reference to 'woman-centred' care (often in relation to the role of supervision).
- Studies of midwife supervision present mixed reviews of the statutory supervision. Findings confirm that the value of supervision depends on the expertise and relationship between midwives-supervisors and that there is need for a clearer division of responsibility between the local supervising authority and regulator in cases of investigation.
- Studies of doctors show that continuity may prevail even after changes in guidelines, in part because doctors seek to retain their autonomy.
- Competition seems to be a mechanism that can stimulate the adoption of changes designed to bring quality improvement.

Ensuring fitness to practise, misconduct, complaints and disciplinary procedures

There were 22 papers relating to this theme. In summary:

- Studies confirm that only a minority of health care professionals go through fitness to practise (FtP) procedures. However, certain demographics and professions are over-represented in complaints: male, older, overseas-trained, doctors, dentists, chiropractors, social workers and paramedics.
- Main complaints are common across professions, commonly related to clinical care (for example, errors in treatment). Unprofessional conduct or poor communication also feature. The proportion of these complaints changes according to different professions.
- Some studies show evidence that over-representation of certain groups in referrals is linked to country of origin or ethnicity (i.e. BAME) or language proficiency of the professionals. Almost all studies stress that more data on ethnicities are needed.
- Studies on the type of misconduct highlight that misconduct can have an individual as well as social and environmental (workplace) dimension. Environmental factors include: stressful and competitive work environments and work culture of blame rather than learning.
- Often FtP mechanisms or decisions are not clear for the professionals and this can create unnecessary stress for professionals. FtP investigations can result in psychological distress, which for some might lead to suicide.
- A UK government consultation addresses the need to simplify and clarify FtP procedures.

Registration and maintenance of registration

We reviewed ten papers on this theme. In summary:

- Registration and revalidation processes can be 'controversial'. Studies highlight flaws in registration procedures (such as excessive bureaucracy, gatekeepers hindering the process) and inconsistencies (as in the Australian case for midwives).
- Social relationships play a role in the different processes: from gatekeepers hindering processes, to midwives choosing options based on their patients and peers.
- To avoid unfairness and bias in licensure exams, studies recommend including stakeholders in the design of exams so that they are appropriate and sensitive to different contexts.

- However, studies on revalidation underline the lack of involvement or reference to patients in the development of the process.

Relations with the regulator

Fourteen papers were included in this theme. In summary:

- Despite some relationship difficulties, the broader context is of an appreciation of the importance of regulation and benefits (in terms of public safety and enhanced standards of practice).
- Negative feelings of the registrant towards the regulator included the regulator being perceived as remote, mistrusted, punitive and unsupportive, resulting in some professionals practising defensively. Evidence of inconsistent practice across regulators and across regions or countries can exacerbate negative responses and present implications for workforce mobility, patient safety and quality of care.
- The need for regulatory reform is indicated in a number of these papers. Calls are made for a less burdensome, simpler, more standardised approach to regulation and greater inter-regulator collaboration. However, in developing more common approaches, some warn against the dominance of the medical profession.
- Challenges to implementing reform are noted and authors argue for greater consultation and engagement with practitioners.

Harm prevention and patient safety

Eight papers were considered under this theme. In summary:

- The assessment and measurement of quality of care have conceptual and practical aspects that need to be taken into account. Time, training and sharing data from previous assessments appear to be aspects that support the effectiveness of solutions.
- Flexibility, and tolerance seem to be the useful strategies for leaders in managing risks and achieving compliance. Flexibility is also an important element for the risk management and safety of professionals.
- Inspections create tensions. Findings highlight that ‘economically efficient’ solutions such as statistical tools, do not always deliver the best results. Stable, committed teams of inspectors operate better and with less conflict than short term, ad hoc teams.
- A common system of language assessment may enhance patient safety.

(2) Interviews

We conducted semi-structured interviews with key research and policy leads for each of the ten regulators overseen by the PSA ((including the Health and Care Professions Council (HCPC) which covers 15 professions)).

Key findings

While regulators differ considerably in their size and resources, the overall picture is one of intense activity in the areas of policy development and data collection. No regulators reported that their research workload was decreasing though several wished that they had the resources to do more. Their strategic priorities were linked to core regulator functions and were generally in line with those proposed by *Right Touch Reform* (2017), but it was not always clear how research priorities were decided. The regulators reported conducting a mix of strategic research, related to their core activity, and responding to issues as they arise. The overwhelming majority of current projects is based on the collection of primary data (consultations and routine surveys) or re-evaluation of data

collected previously. Only three regulators mentioned engaging with existing literature as part of their research projects. Most reported key pieces of work that had informed current or future work although it was sometimes unclear how the impact of these influential projects had been evaluated.

In terms of themes, there is a sustained interest in fitness to practise, education and continuing professional development, and registrant surveys. There are differing views on the value of general registrant surveys: some see it as key source of information while others are shifting the focus to more targeted projects. Several regulators are responding to workforce recruitment issues by carrying out research in this area. In addition, there is also interest in the role of new technologies, professional regulation and the enhancement of registrant communication skills.

(3) Document review

We reviewed annual reports from the regulators' websites, plus additional resources sourced from the interviewees and personal contacts with key individuals.

Key findings

The analysis of the annual reports clearly shows that fitness to practise is the biggest concern; this regulatory function was in the top two in every annual report. However, this finding must be interpreted in the context of the current legislation. Several regulatory bodies expressed their frustration with the legislation around fitness to practise processes and noted that they would prefer to focus more on preventative rather than punitive measures. The newly established Social Work England's consultation report was the only document where fitness to practise did not play a dominant role. The other regulators reported a variety of measures introduced to reduce the volume of such procedures including new threshold criteria, an increase in dedicated staff, and policies for early closure of cases. There were also several regulators who have made commitments to provide support for registrants and reduce the mental health impact of proceedings. Another common theme was the discussion of recent high-profile cases and measures taken to address the underlying issues.

Conclusion

We conclude that many of the challenges we faced in the conduct of this review reflect that the study of the regulation of professionals in health and care does not yet have a strong and well-defined identity as an academic discipline/field of academic study and, as a result, the published evidence is diffuse and difficult to locate and interpret. We identified a number of key challenges for health and care professional regulation studies.

Resources: Regulators' resources for evidence-based policy development are variable but all face limitations on what they would like to achieve.

In-house staff: Despite resource challenges, all regulators were undertaking an impressive amount of routine data gathering and policy implementation and development. In addition, many were involved in offering support, advice and guidance on how to interpret their practice standards. However, we found that their engagement with the evidence base within the academic peer reviewed literature, both as contributors and as users, appeared to be weak or non-existent in some cases. This is unsurprising in view of the demanding workloads of those we spoke to and their teams; but the advancement of scholarly, evidence-based approaches to the setting of research and policy agendas is an area for continuing staff development.

Commissioning: Many regulators were commissioning high quality research from external research teams. However, the process of engaging with the academic community to commission research was found to raise challenges, particularly for smaller regulators. There were particular challenges around identifying and briefing the best research teams to provide the highest-quality and most cost-effective projects. It appeared rare for research project reports to be written up for journal publication.

The wider academic literature: This is characterised by small scale, local, agenda-driven and uni-professional projects. Many published papers lacked educational importance or relevance to the regulators' research priorities. Most were descriptive in their findings with few able to show effect or demonstrate how or why those effects are occurring. Regulators in health and social care need to be able to leverage the scholarly literature more effectively to inform their research and policy agendas.

Opportunities for the future

There are, however, a number of opportunities and signs of movement towards a more evidence-based approach to regulation. One clear conclusion emerged from our work; health and social care professional regulation studies is rapidly emerging as a new field but, as yet, it is still relatively amorphous compared with, for example, financial, legal or aviation regulation studies. The health and social care professional regulators have an opportunity to work together both to define and to set an agenda for this new field by engaging with the peer reviewed literature, developing and enhancing the skills of their policy and research teams around academic practice, and ensuring that as commissioners and consumers of research in health and care professions regulation they are seen to be demanding evidence of the highest possible quality on which to base their activities.

Part 1 - Introduction

1.1 Background

In commissioning this review of research into health and care professional regulation, the Professional Standards Authority (PSA) seeks to build on an earlier study it commissioned from Oliver Quick (2011). At the time of that work, there was little published literature exploring the impact of professional regulation on the behaviour of health and care professionals and Quick's study concluded that there was a shortage of studies directly addressing that question. Since that time, there have been seismic shifts in lay and professional attitudes towards the purpose, function and effectiveness of regulation.

Several high-profile incidents have led to growing calls for more robust evidence regarding regulation's effectiveness in preventing error and safeguarding patients and service users (Illingworth 2012; Reeves, Ross & Harris 2014). Pressure on resources coupled with increasing demand for services have prompted regulators themselves to become more reflexive about the role of regulation in the increasingly pressured environments in which health and care professionals work (PSA 2017). In addition, there is increased recognition of the value of involving patients, service users, carers and the public in working with practitioners and regulators to tackle distrust and strengthen confidence in health and care services (PSA 2019). The increased level of debate has also attracted international interest from governments, regulators and practitioners in researching professional regulation; and there has been significant engagement of regulators with research partners. As a result, regulators have developed guidance documents in addition to their professional standards (Cameron 2017); many of these will be based on research and evidence-gathering exercises. It is clear that a great deal of data-generating activity has been undertaken worldwide in the field of health and care professional regulation since 2011.

The drive towards a more evidence-based approach to regulation has developed alongside regulators' growing interest in the impact of systemic pressures on the behaviour of health and care professionals. There is an increasing awareness by regulators that their registrants, rather than seeing them as supportive partners in ensuring safe patient care, often view them as sitting in judgement on them and overly focused on fitness to practise (FtP) matters (Oikonomou et al. 2019; Gutacker et al. 2019). In consequence of this, regulators are seeking to move from a perceived punitive culture to one of supportive dialogue with registrants, as illustrated through the General Dental Council's (GDC) *Shifting the Balance* programme of reform which intends to create a more collaborative system of regulation based on partnerships with registrants (GDC 2017). This general movement is shared with other regulators and is exemplified in the growing number of consultation exercises, for example, the General Pharmaceutical Council's (GPhC) recent consultation on *Managing fitness to practise concerns in education and training* (GPhC 2019).

Over the past decade, the PSA has introduced, developed and promoted its concept of right-touch regulation in a number of key publications (PSA 2020), offering a simpler and

more problem-focused framework with which to consider challenges in regulation based on the goals of the regulatory organisation. This increased emphasis on and understanding of the role, function and purpose of the regulatory organisation has facilitated a renewed focus on the four main purposes of the regulator. *Right Touch Reform: A New Framework for Assessment of professions* (PSA 2017) advises that these four purposes should be seen as forming essential components of a holistic regulatory system:

- Harm prevention – activity that will reduce the number of harmful incidents and that will ensure that risks are identified and addressed before they occur.
- Fitness to practise – the processes regulators use to handle complaints or deal with concerns about registered practitioners.
- Quality assurance of higher education – activity to ensure that those qualifying from education and training courses are fit to practise and join the register for their profession. This may include inspection and approval of programmes of education and training against standards set by regulators.
- Maintenance of registers – activity to keep accurate and up to date the public registers of practitioners who are statutorily approved or qualified to practise in UK health and care.

We used these four areas as the basis of the analysis framework we applied to the large number of research articles we considered. We also include sections that expand on these areas of activity in recognition that they are interlinked. For example, revalidation is a major area of concern in the research literature that is closely associated with both registers and FtP but because of its size it was given a code of its own. Our thematic codes are discussed further in the methods section.

1.2 Aim and objectives

The primary aim of this study is to build the evidence base in relation to health and care professional regulation. The stated objectives of this commission are to:

- Source research in the area of health and care professional regulation in English since 2011
- Evaluate the research and draw out what it has taught us
- Identify any gaps in the research and areas that would benefit from deeper exploration in order to inform the focus of further research and continue to build the evidence base in relation to health and care professional regulation.

In this report we use 'research' in a broad sense, encompassing surveys, consultations, and periodic reviews as well as targeted, commissioned research.

In addressing these objectives, we acknowledge important differences between the regulators.

Part 2 – Study Design and Methods

The core part of this study was a desk-based rapid evidence assessment. A rapid evidence assessment (REA) was well-suited to the PSA's need to gain a speedy overview of the amount and quality of evidence and identify any evidence gaps and so inform future developments. Rapid reviews present a more streamlined approach to review and tends not to be as in-depth as a systematic review (Ganann, Ciliska & Thomas, 2010). They are, nonetheless, systematic in their approach to searching and assessing the evidence. In undertaking the REA, we made use of the Rapid Evidence Assessment toolkit devised by the Government Social Research Service (2014). We detail our approach to the REA in section 2.2.

To complement the REA and as part of our issue scoping phase, we made contact with each of the ten regulators that the PSA oversees and sought telephone interviews with relevant research or policy leads. As a second part of issue scoping, we looked at the websites of the ten regulators and analysed their most recent annual reports.

2.1 Issue Scoping

2.1.1 Regulator interviews

We conducted a total of ten interviews with senior, research-focused members of staff, one from each regulatory body¹. The intention was two-fold: to seek opinion on the regulator's direction of travel and to access relevant information or signpost us to key evidence. A copy of the Information Sheet and Consent Form can be found in Appendices 1 and 2. A copy of the question schedule is given in Appendix 3.

Most interviews were conducted via telephone; one used video conferencing; one was face-to-face. The interviews were audio recorded and totalled 5 hours and 30 minutes, with an average length of 33 minutes. To protect the anonymity of our participants, we do not name specific regulators in the write up of the interviews. Rather, we summarise the aggregated responses for each topic we discussed.

2.1.2 Annual reports and other information from regulator websites

Another aspect of the issue scoping was checking the regulators' websites. As a means of focusing our efforts, we located the most recent annual reports. From these we identified themes that allowed us to provide an overview of matters of current of concern.

Some of our interviewees also directed us to specific reports or documents located on their websites. These are noted in Appendix 4, and as time allowed, were analysed and referred to alongside our analysis of the annual reports.

¹ One interview was with two individuals, making a total of 11 people contributing to the interview data.

2.2 Rapid Evidence Assessment

2.2.1 Sources

With the expert assistance of Delyth Morris (subject librarian for Medicine at the University Health Library in Cardiff), we identified four databases for the collection of sources: Scopus, Medline, PsycINFO and CINAHL. The Cochrane Reviews are included in Medline.

We supplemented the publications review with an author search using lists of names supplied by Douglas Bilton, Assistant Director of Standards and Policy at the PSA, by the interviewees we spoke to, and through contact with representatives from regulators during the PSA Conference *Regulation in the Future – Will it Matter?* in London 5-6 March 2020.

2.2.2 Search Terms and Inclusion / Exclusion Criteria

Each database has similar but not identical ways to classify/index documents. We performed a number of exploratory data searches to understand which terms to include in the final Boolean query and how (i.e. either as text terms to be searched in the title and abstract, or as subject headings). Further information on the search strategy is given in Appendix 5.

The final Boolean query in all databases included:

- 1) a list of all the regulated professions (including all those regulated by the Health and Care Professions Council (HCPC)) searched either as subject headings or in text search terms (Boolean connector: OR);
- 2) any of the professions in the list searched in combination (Boolean connector: AND) with the term “regulation”, either as text term or subject heading;
- 3) and (Boolean connector: AND) specific terms, for example fitness to practi*, standard setting, standards of practi*, quality assurance, harm prevent*, patient safety.

In order to further focus the search, we included some limitations (either as subject headings, or advanced search options offered by the interface):

- 1) the geographical area of publications limited to the UK, Australia, Canada, Sweden, Germany, Netherlands, Norway, Switzerland, France, Ireland.
- 2) year: only publications since (and including) 2011.
- 3) type of publication: only journal articles, books, book chapters and systematic reviews.

2.2.3 Selection Process and Data Extraction

All the references collected from the databases were managed in a shared EndNote library securely stored on a Cardiff University server.

The initial list included 3833 records. After removal of duplicates, this reduced to 3179. To this list we added publications from a search of authors suggested by the PSA (in total 134 papers). After further removal of duplicates, the final list of papers (including papers

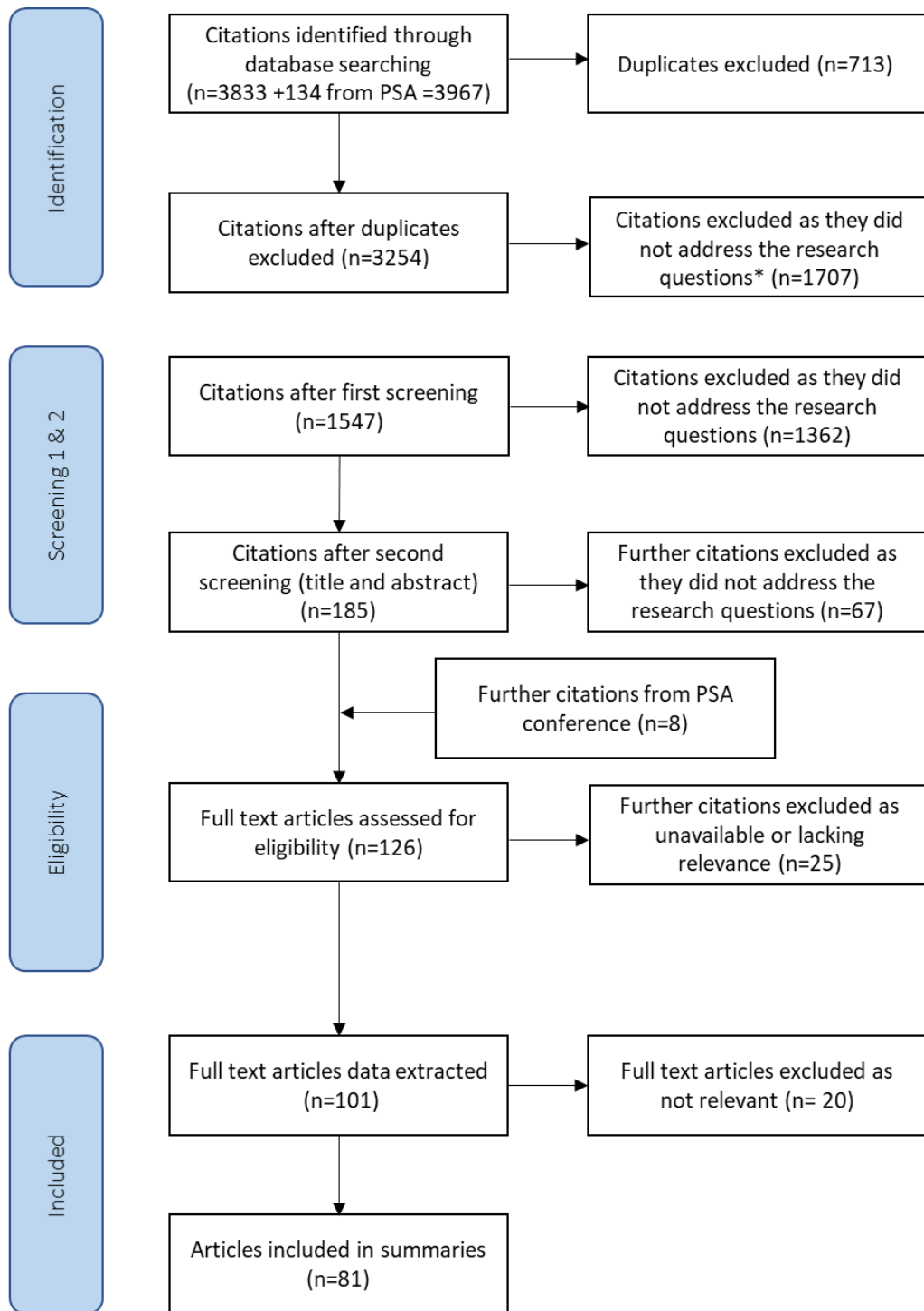
from databases and PSA list) had 3254 records (see Table 1). The process is outlined in Figure 1.

Table 1: Summary of papers' selection procedure

Dataset	Results	Filters
Scopus	1081	
Medline	1884	
PsycINFO	515	
CINAHL	353	
Total	3833	
Duplicates removal		
Total after automatic duplicates removal	3306	(filtered out = 527)
Total after manual duplicates removal	3179	(filtered out = 127)
Total+ PSA list (134)	3313	
Total after removal of duplicates	3254	(filtered out = 59)
First screening	From the list of references, we filtered out papers based on title: exclusion was based on geographical scope, healthcare context, papers clearly not on topic	
Total after first screening	1547	(filtered out = 1707)
Second screening	From the list of references, we filtered out papers that did not include in title or abstract any specific reference or link with regulatory bodies or reflections on the use and implications of regulations, or recommendations (see inclusion criteria above).	
Total result after second screening	185	(filtered out = 1362)
Division into sub-groups	The list of references was manually filtered. Each reference was assigned to sub-groups, in order to keep the most relevant ones in manageable groupings for data extraction.	
Selection by relevance	Only references marked with 4 or 5 – assigned based on relevance during manual filtering	
Total result after relevance selection	118	(filtered out = 67)
Total after additions following PSA conference	126	
Total number of full texts subject to data extraction	101	(filtered out = 25)
Total included in the report	81	(filtered out = 21)

For each publication we extracted and recorded: reviewer and date, citation, country of study; professional group; area addressed (such as harm prevention/patient safety, FtP); quality assessment; method, sample; main findings; conclusions.

Figure 1: PRISMA flow diagram detailing the search process



All the papers accessed in full text were analysed following the same data extraction format, and further classified on a scale of 1. Good evidence, 2. Fair evidence, 3. Expert opinions (peer reviewed). This approach is more suited to the types of documents (which will include guidance and policy documents) than an assessment of study design based on the hierarchy of evidence which ranks randomised controlled trials as the highest level with opinions and case reports as the lowest. Papers excluded at this point were ones that lacked relevance to our objectives or were individual opinion pieces. For the classification of evidence, we considered criteria based on the type of data used (i.e. primary, secondary), type and size of sample and method description and data analysis. Papers with 'good' evidence included primary or secondary data, with large size samples, and high response rates for questionnaire surveys, or large number of documents analysed and detailed analysis for document analysis/literature reviews or qualitative data. The methods and analysis seemed robust and were clearly described. Papers with 'fair' evidence included primary or secondary data, with smaller samples or quantitative studies that could not be generalised, or unclear descriptions of methods. We included some expert opinion papers even though they did not include an analysis of data (either primary or secondary); these were included on the basis of relevance to our research, such as those providing a critical interpretation of provisions or discussion by experts or representatives of regulatory body. Papers excluded at this point were ones that lacked relevance to our objectives or were individual opinion pieces, with no (or low) quality evidence and no explicit connection to our study's objectives.

2.2.4 Screening

In this section we describe the four stages of the screening process in more detail.

2.2.4.1 First Screening

All titles were screened: and where there was doubt about whether to retain a paper, we also read abstracts. We were able to filter out at this stage:

- Further duplicates.
- A small number of papers not in English.
- A large number of papers whose geographical scope was obviously not relevant to UK settings (such as papers addressing case studies in developing countries or countries where the healthcare system was radically different from the United Kingdom (UK)).
- Papers and publications strictly related to the United States (US) context where the main topic of interest was the financial aspects of regulation (e.g. Medicare, Medicaid publications) or where the topic was the regulatory system of specific federal states and therefore not generalisable to the wider context.
- Many papers that were clearly *not* on topic, such as publications focused on studies about specific diseases, procedures or protocols too specific for the scope of this study (e.g. implementations of protocols for treatments of diabetes, cancer, studies of antigens, cardiovascular surgery among the others).
- Publications related to the main issue of human rights and immigration issues, health insurance.
- Papers concerning the effects of state legislation (i.e. abortion, euthanasia etc).

After the first screening the original list was reduced to 1547 records.

2.2.4.2 Second Screening

In the second screening we looked more closely into the abstracts of the publications and began to read some of the full text articles to confirm our decisions on inclusion/exclusion. We discarded more papers - those without abstracts, those not in English and those that were found to have been published before 2011. A number of other publications were discovered to be lacking peer review. 'Journalism' and subjective pieces such as comments, opinions and editorials (not peer reviewed) were also consigned to the excluded group.

Those papers that remained after the second screening were further screened.

2.2.4.3 Third Screening – the 'Out Group'

After identifying and discarding those papers which were definitely of no relevance or which had insufficient methodological rigour to be of academic importance, we were still left with a large number of papers that, while not completely irrelevant, were of only marginal interest or value to the research objectives. We consigned these to a group we described as the 'out group' - papers which have not been completely excluded but which were not likely to be of sufficient relevance as to reward close analysis within the confines of this research project.

The 'out group' included papers concerned with:

Algorithms and big data (83): papers on the issue of Artificial Intelligence (AI) or algorithms and digital health data (e.g. health record storage and databases, patients' data registries, use of databases and AI for diagnosis, mobile health apps privacy and ethics).

Drug and Device regulations (772) This 'out group' section concerned the regulation of drugs and devices (such as regulations concerning the prescription of opioids, pharmacovigilance, the pharmacological market, advertising etc, and regulations concerning the use of specific devices or tools ranging from vaginal mesh to insulin pumps). The great majority were technical reports of drugs development or the evaluation of other clinical interventions; many of these were described as having roles in 'regulation' of certain physical functions, which explained why they had not been filtered out in our original search, but they were easily detected and found to be of no relevance. Others were easily excluded based on a search of key words in their titles – for example, 38 referred to the US 'Federal Drugs Agency' or other US 'Federal Agencies'; 79 used the words 'medical device' in the title; 34 concerned drugs pricing in relation to 'Medicare' and 'Medicaid' in the US. These could be set aside with confidence. Others in this group required more careful reading of the abstracts; for example, 27 concerned opioid prescribing, but in the context of the regulation of controlled drugs rather than to the role of the professional regulators. There were a large number of papers on telemedicine and telehealth, but again in the context of the regulation of telemedicine rather than the regulations affecting practitioners. Five of these concerned unregulated areas of professional practice such as the online sale of drugs and cosmetic treatments, such as dental aesthetics.

Literature related to fitness to practise: We found a small group of papers on ageing professionals (5) which were exclusively focussed on surgery, medicine and anaesthetics. Their main concern was how to identify doctors whose cognitive and motor skills were

declining and support them into retirement without unnecessarily losing competent older clinicians from the workforce. However, this was not primarily seen as an issue for regulators but for employers. Five papers on language proficiency (of international professionals) were also consigned to the 'out group'; two because they focussed on the role of the employer not the regulator, one because it focussed on acupuncture which is not regulated, and two opinion pieces criticising the European Union (EU) rules on freedom of movement for doctors and arguing that language tests should be more stringent. There was also a large group of papers on working hours regulations (53), which did not explicitly refer to regulatory bodies or larger implications for regulation. At least 36 of these related to junior hospital doctors (residents and trainees); within this number around two thirds were from the US and their chief concern was the effect of new duty hour recommendations and their effect on residents' ability to meet the Accreditation Council for Graduate Medical Education (ACGME) core competencies. Others discussed the potential impact on patient care of working hour restrictions on doctors, nurses and healthcare assistants in hospitals and nursing homes.

The 'out group' also included 22 papers discussing the history or context of litigation/remediation systems. Themes included the role of the tribunal or the legal team; frequency and nature of cases of professional misconduct, descriptions of deviations from code of conduct, or reflections on quality of care, that do not explicitly refer to regulatory bodies or wider implications for regulation.

Fourteen papers explored the attitudes and experiences of students/practitioners/professionals (14): these were qualitative papers exploring individuals' values or standards or about the experience of being a professional in a particular sector or about their scope of practice. For all of these, the role of the regulator was only marginally addressed: an example of this sort of paper would be: "What is the experience and effectiveness of nurse practitioners in orthopaedic settings"? This group also included practitioners' perspectives on patient advocacy, quality of service and experience of working interprofessionally or in new roles such as advanced practice nursing.

Unregistered professions (27): the 'out group' contained a section of papers advocating for the regulation of certain professions or clinical activities that are (or were at the time the paper was written) currently unregistered, such as physician associates (in the UK pre 2017), dental assistants, non-medical surgical assistants and assistants in nursing (in Australia), carers of the elderly (Canada and the UK), sonographers and practitioners of invasive complementary therapies, and sports trainers.

Fifty-two papers explored the challenges and opportunities presented by the recent increase in re-validation processes (52); some suggested that the additional data such processes provide could be helpful in monitoring patient outcomes (in conditions such as retinal detachment, inpatient psychiatry). Others explored the practical issues involved in particular areas of practice such as pharmacy, midwifery and psychiatry, while others were concerned with the effects on workforce in terms of recruitment, migration, retention and retirement, along with the additional workload that accompanies revalidation processes.

This 'out group' has been kept on file separately from the 'excluded' papers as it reflects ongoing concerns and debates in the field of regulation while not being of direct

relevance to the regulators or to our research focus. We are aware that the speed at which this REA has been conducted means that there are some papers included which retrospectively might better belong in an 'out group' and some in an 'out group' that we might have included.

2.2.4.4 Final screening - the 'In Group'

The documents that were left at the end of the multiple screening process formed our final 'in group'. These were the papers and documents that form the basis of the results and discussion section of this report.

2.2.4.5 Organisation and review of the final records

Based on selection by relevance (Table 1), our final 'in group' list contained 118 abstracts eligible for analysis. To this list we added an extra eight papers we identified from attending the PSA conference *Regulation in the Future – Will it Matter?* in London 5-6 March 2020. We proceeded to acquire the full texts where these were available through Cardiff University Health Library. A minority of papers were not available in full-text from our Library and the final list of full papers we obtained comprise 101 records.

We divided all papers the 'in group' initially between eight sub-groups both to facilitate analysis by themes and to allow all four researchers to gain an overview of the papers on a section by section basis and to cross check each other's interpretations. During the analysis some of the themes were re-merged (for example, harm prevention and patient safety; FtP and disciplinary issues) reducing the number of sub-groups to six (see below).

All of the 101 papers accessed in full-text were analysed and coded in data extraction sheets (according to the criteria described above). After this process we selected 81 papers as more relevant and with higher quality of evidence. These were summarised and presented in the REA (see Table 1).

Part 3 - Key Findings from the interviews

We report in brief the key messages from the interviews, broadly following the interview schedule (see Appendix 3). In reporting these findings, we first wish to draw attention to significant variation between the regulators in terms of the number of registrants and how long they have been established which has a bearing on the resources available for research (see Table 7). To protect the anonymity of the respondents, we aggregate the views on the topics discussed.

3.1 Who conducts research?

Two regulators reported relying primarily on in-house research, three on externally commissioned research, and five on a mixture of both. Two regulators noted that sensitive or controversial research requires a specialist approach, which is best provided by external commissions from independent sources.

In many interviews we also asked whether there has been a change in the amount of research commissioned. Where the topic was raised, most participants reported an increase in in-house research (three regulators) or overall research (one regulator).

It feels like perhaps we do more internally. We perhaps have the capacity and the skills to do a bit more stuff internally, than was the case maybe ten years ago.

Two regulators stated that the amount of research has remained consistent. One regulator reported that the volume of research has not changed, but research has become more targeted.

3.2 Determining research priorities

We asked several questions about research priorities and how regulators decide what research should be undertaken. The regulators reported conducting a mix of strategic research, related to their core activity, and responding to issues as they arise.

3.2.1 Strategic priorities

Strategic priorities were linked to core regulator functions and in line with *Right Touch Reform*. They fell into seven broad categories listed in Table 2. Each regulator gave an example of at least one strategic priority, with most mentioning two or three. Larger regulators mentioned more than three priorities.

Table 2: Strategic priorities

Priority	Number of regulators	Example quote
Fitness to Practice and complaints	4	<i>We're auditing our fitness to practise processes, which we do about every three or four years in some form or another.</i>
Education	4	<i>I will usually then have a conversation with the Policy Manager for the particular area to understand what support they might need. So that could be, for example, colleagues who are working on [a new form of assessment]. The development of that might come to us and say that they feel that it needs some research support for that policy development.</i>
Planned changes	4	<i>There's often policy initiatives that would require us to run a consultation. So our policy colleagues will very much be informing us. It all comes from our kind of strategic plan and our annual plan and our vision. So all the work is kind of planned out. So they would know that they would be looking to update guidance or update some of our standards work in the coming year. And would then work with us to set up the schedule of consultation.</i>
Upstream prevention	4	<i>Directions of travel for regulations such as try to be more preventative and upstream, for example, and working differently with the system, has generated projects in those sorts of areas, just as one example, but we try and link it to the strategic direction.</i>
Public opinion	3	<i>We haven't been terribly public facing or patient facing at all. We found it very difficult to engage directly with patients. So this is our attempt to kind of put that right really, and come up with some findings that will inform different areas of our work.</i>
Impact of changes	3	<i>So a large part of our strategy is then thinking, well how is this going about? How do we know people are doing this? How do we know we can trust that it's actually happening? That it's going to make a difference. You know, what's the impact of this? (...) So we want to try and know as far as we can, that the changes and policies that we make and implement have a difference really.</i>
Patient safety	3	<i>There's no good just coming up with a policy and saying well CPD has been changed. This is it. And then if people don't do it we just remove them from the register. The whole purpose of it is to try and enhance practice and to ensure that patients are safe and their health and wellbeing is looked after really.</i>
Risk	2	<i>Quite a lot of research has been based on sort of riskier areas of practise.</i>

3.2.2. Arising issues

Nine of the regulators gave examples of research into arising issues. We cannot include the subject of these inquiries in the report, as it would breach anonymity. We have categorised issue-based research on how the issue was identified or brought to the attention of the regulator. Registrants and the public are not listed here as potential groups because gathering views from these groups was a strategic priority for regulators.

Table 3: Arising issues

Source	Number of regulators	Example quote
Stakeholders	4	<i>We are obviously engaged regularly with our stakeholders in the profession and elsewhere and we make assessments as to what areas we think we need to look into and research and understand more.</i>
Previous research	4	<i>Trying to break the cycle of project start, project close, out - so we start a project, we finish a project and we move on - to a more virtuous cycle of monitoring, evaluation and learning, being evidence informed through that cycle.</i>
Horizon scanning	4	<i>So we very often will do a rapid scan for an issue that comes up through horizon scanning and we sometimes produce and occasionally publish papers. So more like working papers I suppose, than fully fledged research reports.</i>

3.3 Current research

Regulators spoke of a variety of current surveys, consultations, and research. Most of them were reviewing their FtP processes and analysing the demographics of their registrants. Equality, diversity and inclusion (EDI) matters were being explored in the context of FtP, registrant demographics, and student demographics. The overwhelming majority of current projects is based on the collection of primary data or re-evaluation of data collected previously. Only three regulators mentioned engaging with existing literature as part of their research projects.

Table 4: Current research

Research area	Number of regulators	Example quote
Education and Continuing professional Development (CPD)	9	<i>So last year, for example, was about the professional standards that we have, and the education and training standards, that we require providers of [professional] courses to meet and uphold.</i> ---- <i>We'll be monitoring and evaluating that enhanced CPD before we move onto actually making decisions about where we want to go next.</i>
FtP and complaints	7	<i>[We are doing research] around fitness to practise cases where the case had been closed and no action taken, to understand whether there were any factors that were prevalent in those cases that meant we could change our processes to close those cases at an earlier point.</i>

		<i>And there's two reasons for driving that; the first of which is the burden on registrants of going through a fitness to practise process; and the second is obviously good use of our resources. So making sure we're not focusing on cases where there isn't a risk and we wouldn't typically identify any action was required.</i>
General registrant survey	6	<i>So the most recent commissioned work that we have just completed was some research into our registrant survey just to understand a bit more about what they're doing in their roles and responsibilities.</i>
EDI	5	<i>I think that's the bit that probably links to the bits around BAME groups going to fitness to practice. I mean, we do analyse to a certain extent our fitness to practice data and the risk research that we did last year was more of a deep-dive than we have done previously into fitness to practice data.</i>
Public perceptions	3	<i>We have annual surveys of public and patients and of professionals.</i>
Workforce numbers	3	<i>They've done an awful lot of work to try and bring individuals back into the profession, to increase the numbers of professionals, particularly in areas where their numbers are too low. So we jointly commissioned a piece of research on returning to practice to look at the various aspects of that.</i>

3.4 Past research

Several participants explained how previous research identified areas that are currently being investigated or would be explored in the future. This is also reflected in the topics, many of which were discussed under current research.

Table 5: Past research

Research area	Number of regulators	Example quote
Public survey	4	<i>We ran public perception surveys periodically. We did the last one I think in 2018.</i>
CPD	4	<i>[A researcher] did some work around it in 2014/15. I think it was published in 2016. And that was instrumental in helping shape our thinking around our developing a CPD Scheme.</i>
Best practice	4	<i>And in order to provide appropriate guidance and policy positions ... we wanted to go back to basics and understand what the existing research data tells us before we commence work on that.</i>
Risky areas	4	<i>The most recent piece of major research that we did was risks in the [profession].</i>

Registrant survey	3	<i>I think the registrant survey helped us to monitor our progress with registrants and to understand how our registrants perceive us. So regulatory functions might take away findings from the registrant survey and improve internal processes or how we communicate with registrants.</i>
FtP	2	<i>[One piece of research] looked at kind of our fitness to practise outcomes and whether they differed according to ... ethnicity...but actually the research did take into account a number of different factors. ... And is essentially the precursor to the big EDI research that we're doing now.</i>
Workplace pressures	2	<i>And then questions around, in the 2016 survey, around challenges that they might face in the workplace, such as commercial pressures and how they see their role evolving over the next few years. So more kind of experience-y type questions that they might face in daily clinical practice.</i>

We also asked participants to name the most influential piece of research and explain the impact of it. In terms of topic, participants discussed research on FtP, EDI matters, and workplace pressures (each of these topics was mentioned by two regulators). Four regulators told us about research into particular practices that led to changes in guidance or standards. Two regulators stressed the importance of the patient voice, and two regulators pointed to research carried out by other regulators.

3.5 Future research

Most of the future projects were also listed as current or past projects, or arose from previous research projects.

Table 6: Future research

Research area	Number of regulators	Example quote
FtP	4	<i>The other piece of research that we will be doing is into fitness for practise cases and registrants from BAME background. So I think that this is work that some of the other regulators, I think [another regulator has] done some work around this... So it hasn't been scoped yet but it will be looking at registrants and whether there are any patterns or trends or issues or risks arising in relation to BAME registrants and complaints raised in our fitness to practise process.</i>
Education and CPD	4	<i>There are things that we know that we're going to be going out to the sector to talk about, such as CPD.</i>

Workforce numbers	4	<i>We're starting a programme of work to understand the international migration of [registrants] and the supply of [registrants], starting with an analysis of what seems to be the push and pull factors for [registrants] decisions to move countries.</i>
Registrant survey	3	<i>We're doing another Registrant Survey in a couple of months.</i>
New technologies	3	<i>I think other things, work that has been on-going in and around the internet and how members of the public are accessing health services over the internet and health care professionals, how you regulate that in future. I think there has been also a significant amount of focus, quite rightly, on artificial intelligence in terms of health care provision. And how, what is the potential for that and how might regulators interact with that sphere in the future.</i>
Communication skills	2	<i>For example, one of the things our risk research from last year highlighted was poor communication with patients was the theme that ran through a lot of fitness to practice cases. It might not have been the primary complaint but it was certainly a common theme that was mentioned. Which I think is quite similar to a lot of the other regulators. So if you then view this kind of poor communication with the rise of technology and remote consultations or AI, then communicating clearly with the patients, particularly those with complex needs will be ever more important.</i>

3.6 Closed down areas of research

We also asked the participants whether there were any areas of research that had been closed down. All of them stated that there were no topics that were off the table.

That's a good question. What doesn't need researching? I don't think we've really arrived at that conversation.

Two participants explained that priorities have changed or evolved over time, but not to the point of closing down any research. One regulator noted that certain topics may be 'paused' for a while, but they are likely to be reopened at a later date.

I mentioned earlier that we often undertake or we sometimes undertake research in response to the findings from public inquiries. And whilst we would all hope that the likes of the [name] issues would have been resolved, actually they can repeat at a later date with other issues instigating them. So there may be areas that we focused on in the past that are revisited and need to be opened up again.

One regulator shared that they are planning to decrease the frequency of general annual registrant surveys, as registrants are being bombarded with surveys and there is an issue with response rates. This regulator has decided that it is preferable to carry out more targeted projects rather than general ones.

Coming back to what have we closed down, that we're not going to do so much of - we are reviewing the frequency of our annual surveys for public and for registrants. They're bloody exhausted. You know, registrants are really over surveyed. We've got real issues with response rate and we're doing lots more bespoke research. We're doing bespoke research that is more beneficial to our registrants, and why do we need yearly surveys? So we're going re-look at the frequency of those surveys.

Conversely, another regulator stressed the importance of continuing such general annual surveys in response to the same question.

I think it's important that we carry on doing the sort of annual sort of tracking surveys or regular tracking surveys.

3.7 Collaborations

Seven regulators expressed an interest in collaborating with each other on topics that are relevant across the board within the healthcare professions, for example fitness to practise issues, EDI matters, and communication skills. These discussions referred to four ongoing projects as well as potential future ventures.

I think in the future there might be more scope for some of the regulators to probably carry out more joint research, particularly perhaps common areas like the regulatory functions like fitness to practise. And have more collaboration on, I guess, key issues and risks that might span across all of the regulators. Such as one that I highlighted before, like poor communication which I think is one that a lot of the other regulators have highlighted too. So I think moving forward that will be a really useful approach and one that we would really welcome.

3.8 Summary points

The regulators have a strategic research agenda, but they are also flexible and are responsive to issues as they arise. Strategic priorities are linked to the core regulator functions and *Right Touch Reform* (2017). All regulators consult regularly with their registrants, and the public and stakeholders also play an important role.

There were numerous examples where a piece of research led to more research down the line. However, these linked projects tend to stay within the scope of the individual regulators; very few participants mentioned relying on literature to inform their projects. This trend may be changing slowly as regulators appear to be interested in evidence synthesis or scoping reviews of the literature and in research carried out in the other healthcare professions. There are already a number of collaborative projects underway, and further inter-regulator projects are planned.

In terms of themes, there is a sustained interest in FtP, education and CPD, and registrant surveys. There are differing views on the value of general registrant surveys: some see it as key source of information while others are shifting the focus to more targeted projects. Several regulators are responding to workforce recruitment issues by carrying out research in this area. In addition, there is also interest in the role of new technologies and professional regulation and the enhancement of registrant communication skills.

Part 4 – Review of annual reports and position statements

This section presents the analysis of the latest annual reports (as of 03/02/2020) of the ten health and care regulatory bodies overseen by the PSA. In Appendix 4 we list other website documents and reports to which our interviewees referred us. Given the rapid nature of this review, we were unable to include detailed analysis of most of these, particularly those suggested by interviewees we spoke to later in the project time period.

To provide context, we begin by noting important differences between the regulators, which affect what is achievable in terms of research.

4.1 Context

There is significant variation between the regulators in terms of the number of registrants and the founding date. The information presented in Table 7 was taken from the websites of the regulators in late March 2020. The smallest regulator is the Pharmaceutical Society of Northern Ireland (PSNI), with 2,500 registrants and the largest, the Nursing and Midwifery Council (NMC), with 700,000 registrants. The General Medical Council (GMC) was the first to be established over 160 years ago and the newest one is Social Work England (SWE), which became independent less than 3 years ago. These aspects influence what is feasible for each regulator in terms of the resources they can draw on for research.

Table 7: Key features of the regulators

Regulator	Registrants	Founded in
NMC	700,000	2002
GMC	312,000	1858
HCPC	280,000	2003
GDC	110,000 (45,000 dentists, 65,000 DCPs)	1956
SWE	95,000	2017
GPhC	80,000 (14,000 pharmacies)	2012
GOC	30,000	1958
GCC	3,000	1994
GOsC	5,500	1993
PSNI	2,500 (500 pharmacies)	1925

* We list pharmacies because the GPhC and PSNI keep registers of premises as well as individuals

4.2 Coding scheme

We began with four codes that were identified as key areas in the *Right Touch Reform* report (PSA 2017): harm prevention, fitness to practise, quality assurance of education and training, and maintenance of registers. During the coding process, we added three further codes (patient safety, standard setting and revalidation/CPD). We begin by providing a description and example for each code.

We collected references to harm prevention in a broader sense and from the perspective of the professional:

“We will use our processes, data, intelligence to better prepare and support doctors in delivering high quality care and prevent harm to both patients and doctors.”

The fitness to practise code was the most common or the second most common in each of the annual reports:

“In particular, further improvements have been made with regards to how and when the GCC ensures all parties involved in a fitness to practise case are kept updated and supported to participate effectively throughout the process.”

Quality assurance of Higher Education (HE) refers to discussions about professional training before registration:

“We make sure doctors get the education and training they need to deliver high-quality care throughout their careers. We do this by setting standards for undergraduate and postgraduate medical education, and by monitoring training environments.”

The registers code was used for references to work around keeping registers of qualified professionals:

“In Registration, we have revised our suite of registration and retention forms to make them easier to navigate and process.”

The patient safety code was used for mentions of protecting patients and the safety of the public:

“We want to encourage openness and learning among health and care professionals to improve care and keep the public safe.”

Standards refer to mention of regulation through the setting of standards:

“We are encouraging all osteopaths to publicise to patients their registration and the standards they practise, to support raised awareness of the OPS [Osteopathic Practice Standards] with patients”

Formal requirements to continue training after registration were coded as CPD/revalidation:

“Require dental professionals to keep their skills up to date through our continuing professional development (CPD) requirements.”

The annual reports were downloaded from the homepage of each regulatory body. The analysis is presented in no particular order.

4.2 General Optical Council

In this report (2018/19, 67pp.) the main area of concern was clearly the issue of FtP cases. The report summarised the current processes and committees and highlighted a few key changes that were made during the year. Firstly, it was reported that statistically Black Asian and Minority Ethnic (BAME) registrants are more likely to be referred. This was noted as an issue to be addressed in the future. Secondly, the process was streamlined in order to reduce the number of cases resulting in a full hearing. This was achieved by removing the requirement for a contested hearing in the case of full

admissions and introducing new criteria to determine whether an allegation should be dealt with as a complaint or FtP case. Furthermore, new staff were hired to speed up the process of assessing cases. This was in response to an increase in timescales to reach a decision. The report states that further changes are to be expected.

Table 8: General Optical Council annual report

Code	n
Fitness to practise	16
Quality assurance of HE	8
Standard setting	7
Registers	6
Revalidation/CPD	5
Harm prevention	3
Patient safety	0

4.3 General Dental Council

The GDC report (2018, 92 pp.) noted that current legislation requires them to focus on FtP in the annual report, although they would like to change regulation to make it less reliant on investigation and enforcement.

“Regrettably, our ability to realise the full potential of a modern, principles-based system of regulation is hampered by what remains an antiquated legislative framework. During 2018 we continued to work with the DHSC [Department of Health and Social Care] on its proposed reforms. One of the many outdated features of the legislation is that it effectively requires the GDC’s annual reports and accounts to focus on fitness to practise, when in fact the most important story at this stage in our history is how we are changing the way regulation is done to make it less and less reliant on investigation and enforcement.” (p. 9)

Table 9: General Dental Council annual report

Code	n
Fitness to practise	14
Patient safety	8
Registers	7
Standard setting	5
Quality assurance of HE	4
Revalidation/CPD	3
Harm prevention	0

In terms of the changes during the previous year, they noted that the number of complaints had fallen. This was attributed to work done in encouraging local complaint resolution and dissemination of information about effective complaints handling. However, the number of ‘serious cases’ had not reduced. A review of the FtP processes is in progress. As a result of this, some changes have already been implemented; most

importantly the initial assessment time has been reduced significantly by establishing a dedicated team.

4.4 Nursing and Midwifery Council

The report (2018/19, 112 pp.) made several references to the Furness General Hospital case, stating that: “The year was marked by the publication of, and our response to, the Professional Standards Authority’s Lessons Learned Review into the way we handled concerns about midwives’ fitness to practise at Furness General Hospital”. In several places, they emphasised their commitment to providing more support during FtP investigations, improving transparency, and fostering a culture of openness and learning.

Table 10: Nursing and Midwifery Council annual report

Code	n
Fitness to practise	16
Registers	9
Quality assurance of HE	6
Patient safety	4
Revalidation/CPD	4
Standard setting	1
Harm prevention	1

4.5 General Pharmaceutical Council

The most common code in the report (2018/19, 72 pp.) was *patient safety*, with 12 separate references to reassuring the public about the safety of pharmacy services. The next most frequent areas of concern were *fitness to practise* and *revalidation*. The report described the FtP process, and promised changes to provide more support to registrants, improve communication with all involved parties, and explore the unintended impacts of such cases. The number of cases had increased. The GPhC has changed the threshold criteria and is evaluating the impact of these changes. A formal revalidation process was introduced for the first time for pharmacists, which was introduced as a reaction to the *Gosport independent Panel Report* (2018). It was intended to reassure the public that pharmacists are keeping their knowledge up to date.

Table 11: General Pharmaceutical Council annual report

Code	n
Patient safety	12
Fitness to practise	8
Revalidation/CPD	8
Quality assurance of HE	7
Standard setting	6
Registers	3
Harm prevention	1

4.6 General Osteopathic Council

The report (2018/19, 48 pp.) noted that current legislation makes it difficult to create an efficient and effective FtP process (p.8). Nonetheless, statistics about the timescales for following up complaints show an improvement. They too are revising their threshold criteria for following up complaints. They also indicated that hearings and investigations were the largest 'non-staff cost' in the budget (p.20).

Table 12: General Osteopathic Council annual report

Code	n
Fitness to practise	9
Standard setting	8
Patient safety	8
Revalidation/CPD	8
Registers	7
Quality assurance of HE	6
Harm prevention	3

4.7 General Medical Council

The report (2018, 96 pp.) emphasised that patient safety is always at the core of the GMC. They expressed frustration with the limits of the current legislation.

“Our work to protect patients and support doctors would be significantly facilitated if the legislation at the basis of our mandate were changed, to give us more flexibility in setting the principles and procedures that govern our work. However, we will continue to push the boundaries of what is possible within existing structures, where necessary, to fulfil our wider ambition to continuously improve the quality of patient care.”

The GMC commissioned a number of research projects on the experiences of doctors and found that the pressures have become so high that they are compromising patient safety. Doctors have been encouraged to report such concerns.

Table 13: General Medical Council annual report

Code	n
Patient safety	31
Fitness to practise	18
Quality assurance of HE	18
Harm prevention	13
Revalidation/CPD	10
Registers	8
Standard setting	7

The second most common code was tied between *fitness to practise* and *quality assurance of HE*. In terms of FtP, a scheme was launched to help the public direct

complaints to the most appropriate venue. This was instigated in response to the high proportion of cases made by the public that did not meet the threshold criteria to launch an investigation. The GMC intend to encourage local resolutions wherever possible to reduce the number of FtP cases. There are also efforts to reduce the stress for doctors being investigated by providing more support. They too noted that BAME doctors are over-represented in FtP cases, although the claim that a review has shown that the system introduces no bias.

In relation to training, there were a number of surveys and reports commissioned. These found that many doctors are suffering from long working hours and heavy workloads. Changes are planned for doctor training in response to changing demands of the role. There are also efforts to provide more support for doctors who have trained in other countries and have only recently arrived in the UK.

Other reports

Following the recommendations of our participants, we reviewed *The state of medical education and practice in the UK* (SOMEPE) reports from 2017, 2018, and 2019 and *The workforce report* from 2019. The 2017 SOMEPE report highlighted that there was a lack of doctors in the UK, particularly in general practice. It is noted that this problem is expected to worsen unless measures are taken. Comment is made about the relationship between the regulator and workforce planning:

“We are a professional regulator, not a workforce planning body. However, we want to be an active partner in helping each nation of the UK to have the right number of doctors with the right skills in the right place for patients – through our leadership in the healthcare system; the critical role that we play in doctors’ education, training and development; and the data and insights we can share with those responsible for workforce planning”.

Although overseas doctors contribute to easing some of the pressure, they are insufficient in number to solve the issue and some specialties are seen as “overly dependent” on overseas doctors. Furthermore, it is recognised that there is a notable decrease in new arrivals to the UK after the Brexit referendum. The GMC called for more support for non-UK trained doctors. This report also highlights that systemic workplace pressures are causing wellbeing problems for the workforce, which exacerbates staffing issues as people leave, take breaks, or move to part-time work.

It is noted in the 2018 SOMEPE report that the previously reported issues have not been resolved. Attention is also drawn to the numbers of doctors considering early retirement. They warn that there is a downward spiral: workplace pressures are causing people to leave, which puts more pressure on those remaining. Workforce supply was a key issue:

“The healthcare sector needs action. Not just more money, but a commitment to new ways of thinking about how workforce supply can be achieved. And how that workforce can be enabled to achieve the professional standards and consequent quality of care that should be expected 70 years on from the founding of the NHS”.

Further detail on these issues is included in the 2019 SOMEPE report. Evidence is provided to show that workplace pressures have become severe and endanger patient safety in

some cases. GPs are reported to be at a particularly high risk of burnout. A call is made for greater flexibility in doctor training, partly to combat burnout but also to ensure that future doctors are able to respond to changing healthcare needs

“Our data show the first years of postgraduate training can be the toughest for doctors. A high proportion of foundation trainees reported feeling burnt out, short of sleep at work, and forced to cope with work beyond their clinical competence”.

The 2019 *Workforce report* reiterates the need for flexible training and more “expert generalists”:

“A different mix of specialties is required for the future workforce. Meeting future patient demand requires more expert generalists, as well as more specialists identified in national workforce plans as being in increasing demand, such as psychiatrists and radiologists. Greater flexibility in training and job design is also needed”.

Furthermore, they warn about the serious implications of rising workplace pressures:

“There are significant threats to retaining existing doctors. We are struggling to retain substantial numbers of doctors who, in the face of pressures, are reducing their hours or intending to leave UK practice. This is especially serious for certain groups of doctors, such as GPs and international medical graduates in specialty and associate specialist and locally employed roles”.

These extracts demonstrate the particular pressures healthcare staff face.

4.8 General Chiropractic Council

The GCC report (2018, 56 pp.) made a promise to increase support for those involved in FtP investigations. Uniquely, they highlighted FtP investigations involving students as an area requiring improvement. They noted that the number of complaints had decreased compared to the previous year, and they expressed their support for *Right Touch Reform*.

Table 14: General Chiropractic Council annual report

Code	n
Fitness to practise	14
Quality assurance of HE	7
Registers	6
Standard setting	4
Revalidation/CPD	3
Patient safety	2
Harm prevention	0

In interview, we were referred to the GCC 2020 Business Plan (4pp). According to the Business Plan, the two main priorities are FtP and education. The aims include decreasing the number of complaints; recruiting additional committee members to shorten timeframes and increase diversity; and improve the efficiency of FtP processes. In relation to education, the goal is to bring standards in line with other regulators; improve

relationships with students; and improve support structures for newly qualified chiropractors.

4.9 Pharmaceutical Society of Northern Ireland

The introduction of the report (2018/19, 64 pp.) highlights two major areas of concern: one is responding to the rapidly changing expectations in healthcare by redesigning training and the second is the difficulty of operating without a Northern Ireland Executive and Assembly. They also refer to some recent high-profile cases which have apparently shaken the trust of the public in the profession. Training is being redesigned with the collaboration of the GPhC. The pre-registration training year is where most of the changes are to take place. There was also a public consultation about FtP processes resulting in a new framework that should “help the Statutory Committee make consistent, proportionate and reasonable decisions about what is an appropriate sanction when a pharmacist’s Fitness to Practise has been found to be impaired”.

Table 15: Pharmaceutical Society of Northern Ireland annual report

Code	n
Quality assurance of HE	11
Fitness to practise	10
Standard setting	9
Registers	8
Revalidation/CPD	8
Patient safety	5
Harm prevention	0

4.10 Social Work England

This report (Annual report, 2018/19, 61 pp.) was written at the time when SWE was being set up, but had not yet taken over from the HCPC. For this reason, there was little information in the report that was relevant to the codes. The bulk of the document is made up of the ‘Accountability report’ which describes the structure of the new regulator. The annual report makes reference to a consultation report, which details the changes made to the proposed standards following a large-scale consultation.

Table 16: Social Work England annual report

Code	n
Fitness to practise	6
Quality assurance of HE	6
Registers	5
Standard setting	3
Patient safety	3
Revalidation/CPD	1
Harm prevention	1

Consultation report

This document (titled *Reshaping Standards, Enabling Change: Consultation response; 99 pp.*) reports on the consultation process for the draft standards and rules and present the revised version with all changes highlighted. Overall, there was a lot of support for the proposed standards, with changes being mostly clarifications and further details added. The document also contained discussions of the standards for education and training in the sector and CPD requirements. In this document there is proportionally much less discussion of fitness to practise (FtP) than in the annual reports.

Table 17: Social Work England Consultation

Code	n
Standard setting	25
Quality assurance of HE	17
Revalidation/CPD	12
Fitness to practise	11
Registers	8
Harm prevention	2
Patient safety	0

4.11 Health and Care Professions Council

It was reported (2018/19, 71 pp.) that the first phase of a FtP improvement plan has been completed. This involved a change in threshold criteria, which have led to a reduction of cases that go to tribunal and therefore an overall reduction in timescales. These changes address issues that were identified in the last PSA standards review. There has also been a significant increase in the number of complaints received and the complexity of cases, especially for social workers.

Table 18: Health and Care Professions Council annual report

Code	n
Fitness to practise	12
Registers	5
Quality assurance of HE	4
Standard setting	4
Revalidation/CPD	2
Harm prevention	2
Patient safety	1

4.12 Summary of analysis of annual reports

The analysis of the annual reports clearly shows that fitness to practise is the biggest concern; this regulatory function was in the top two in every annual report. However, this finding must be interpreted in the context of the current legislation. Several regulatory bodies expressed their frustration with the legislation around fitness to practise processes and noted that they would prefer to focus more on preventative rather than punitive measures. The newly established SWE's consultation report was the

only document where FtP did not play a dominant role. The other regulators reported a variety of measures introduced to reduce the volume of such procedures including new threshold criteria, an increase in dedicated staff, and policies for early closure of cases. There were also several regulators who have made commitments to provide support for registrants and reduce the mental health impact of proceedings. Another common theme was the discussion of recent high-profile cases and measures taken to address the underlying issues.

Part 5 – Rapid Evidence Assessment

5.1 Overview

The ‘in group’ was explored in a final round of screening; we discovered that it contained a variable mix of (a) impact studies and (b) more general publications. There were very few experimental designs within the impact studies group. Papers tended to consist of analysis of previously gathered data (often collated for another purpose than the paper’s research aim), together with more empirical studies (commonly collecting data from interviews, questionnaires or a combination of methods) of professionals’ experiences or perceptions concerning the effects of specific regulations/curriculum, or impact of regulations, standards, or reforms on professionals.

The more general group of papers included articles and discussion papers debating principles of good regulation, ethical considerations and commentaries on developments within the field. It also included essays and opinion pieces about regulation which, though relevant to our study, did not include any empirical data. We found a substantial group of historical or international overviews of regulation frameworks, but again these studies lacked original data. We also included personal insight articles in this group, most of which reported professionals’ perception or experience concerning how they perform their role: many of these contained personal or local critiques of the role of the regulator or the way in which regulator guidance was interpreted locally.

The second group was much larger than the first. The impact studies in the first group were more clearly focused on the gathering and interpretation of data, with a stronger focus on the evaluation, impact, effect, or implications of certain regulations. The general publications in the second group mostly provided overviews or snapshots of the current situation or discussions.

5.1.2 Thematic organisation

We initially looked for papers that could clearly be assigned to the four primary roles of the regulators as outlined in *Right Touch Reform* (2017) but these categories had to be expanded when we found that some of the groups were becoming too unwieldy for effective analysis. The final groups were therefore:

- Education and training
- Fitness to practise, misconduct, complaints and disciplinary measures
- Registration and the maintenance of registration
- Harm prevention and patient safety

Plus

- Guidelines and standards
- Relations with the regulatory body

Table 19 outlines how each theme was interpreted and shows how some broad concepts which might at first appear to be synonymous, or at least closely related (such as Harm prevention and Patient safety, or Maintenance of registers and Disciplinary matters), could be sub-divided to ensure a greater coverage of complexities within the literature.

Table 19: Descriptions of themes

Themes	
Education and training	Approving education and training / quality assurance of Higher Education Changes in curricula, inspection and accreditation, overviews of HE, comparison of different CPD interventions, how curricula have changed/are changing; the impacts of regulatory/ organisational factors on CPD
Guidelines and standards	Updating code of conduct/standard setting, regulations. Descriptions of regulatory requirements, working hours regulations, ethical issues, how to apply the guidelines, impact on training
Fitness to practise and disciplinary issues	Papers concerning the issue of fitness to practise. Specific issues relative to fitness to practise: such as ageing in professions, language proficiency regulations, practitioners who become disabled, institutional bias and discrimination (e.g. impaired students, or BAME students). Dealing with disciplinary matters. Studies of incidence of FtP complaints, or analysis/assessments of misconduct where regulators became involved; risk, referrals, professionalism, degree of seriousness, misconduct.
Registration and the maintenance of registration	Maintenance of registers, revalidation, reaccreditation. Issues relative to registers and revalidation criteria (e.g. Maintenance of Certification)
Relations with regulatory body	Studies on impact, implication of regulations or studies commissioned or relative to previous studies commissioned by regulatory bodies.
Harm prevention and patient safety	Risk-based regulation or papers on the role of the regulators in harm prevention for professionals. Patient-centred care; involving the patient in regulation and safety initiatives; identifying risks to patients.

Table 20: Number of papers reviewed, by theme

Theme	Total number of full texts included in data extraction	Total number of texts (most relevant/ higher quality evidence) included in the REA report
Education and training	22	16
Guidelines and standards	16	11
FtP, misconduct, complaints and disciplinary measures	25	22
Registration and maintenance of registration	14	10
Relations with the regulatory body	16	14
Harm prevention and patient safety	8	8
Total	101	81

5.2 Education and training

5.2.1 Summary information on the papers in this section

A total of 16 papers were reviewed in relation to the theme “education”. The theme includes papers related to regulators’ setting of educational standards, assessments of curricula and overviews. In this section we also include a comparison of CPD requirements although we recognise that issues related to CPD clearly relate to maintaining registration (see section 5.5).

In Tables 21 to 24 we provide information on the country, study group, year of publication and methods used.

The geographical distribution of the papers reviewed for this section (see Table 21) is wider than for most of the other sections where a clear majority were UK based. This might suggest that the education theme is an international topic and/or the language and terminology is more readily comparable. Table 21 shows that most of the papers we consider derived from one of three countries: Canada, UK and Ireland. Three papers had a multi-country focus.

Table 21: Country location of the papers

Country	n
UK (of which 1 England, 1 Scotland)	4
Ireland	4
Canada	4
Multi-country	3
Australia	1
Total	16

The variety of professional groups covered by the publications is also wide, as visible in Table 22.

Table 22: The professional groups that were the subjects of the papers

Professional Group	n
Doctors	3
Nurses	2
Paramedics	2
Dentists	2
Chiropractors	1
Radiographers	1
Multi-profession (doctors, nurses, pharmacists, health professional students)	2
Other (Emergency medical technicians, Pharmacy technicians, Pre-hospital practitioners)	3
Total	16

Table 23: Year of publication

Year	n
2019	4
2018	1
2017	1
2016	3
2015	1
2014	4
2013	2
Total	16

Table 23 shows that the years of publication span from 2013 to 2019. Table 24 presents an overview of the types of data used in the studies. These studies commonly collected and analysed data from questionnaires or interviews.

Table 24: Study type

Type of study	n
Interviews	5
Questionnaire survey	5
Literature reviews (2 systematic)	3
Mixed method	1
Statistical analysis of assessment results	1
Document analysis (CPD objectives)	1
Total	16

5.2.2 Evidence synthesis

In this section we provide a synthesis of the evidence from these papers. We organise the papers into two main groups. The first group of papers presents issues more generally connected with HE programmes and curricula. The second relates to the theme of CPD and includes analyses of CPD requirements and assessments across different disciplines and regions.

5.2.2.1 HE and curricula

The issue of standardisation and harmonisation is frequent in education-related papers, and it relates to international as well as interprofessional harmonization. Collins and Hewer (2014) studied the development of standards in nursing education within the context of the Bologna process, concerned with the comparability of HE qualifications across the EU. From a review of the literature, the authors identify positive aspects for nursing education that derived from shifting nurse education from vocational training to university programmes (Collins and Hewer 2014). However, they also note challenges which include the need for a European integration of cultures of nursing and standardisation of scope of practice, as well as ensuring “technically competent

providers” and “sufficient support for educators who are novices in the higher education system” (Collins and Hewer 2014:155).

This focus on the educators is reflected in the work of Tregunno et al. (2014) who present the results of a series of interviews with medical, nursing and pharmacy teaching faculty, “regarding the factors that influence curricular integration and the preparation of safe practitioners” (Tregunno et al. 2014: 257). Main findings include: accreditation and regulatory bodies are driving factors in curricula change; and each discipline has a specific culture of patient safety depending on what they consider to be key challenges (for instance, doctors are more focused on communication, pharmacists on drugs, and nurses on the environment of care) (Tregunno et al. 2014: 261). However, the lack of harmonisation may prevent the preparation of safe practitioners. Hence they recommend greater harmonisation across health professional training programmes about patient safety educational opportunities (Tregunno et al. 2014).

Factors hindering curricula development are considered in a number of papers. Factors include financial and material access to workplaces, which can impede the implementation of some curricula developments. Jacob and Boyter (2019) carried out a questionnaire survey to determine “the current structure of Experience Learning (EL) in MPharm programmes in UK universities, and to assess how they meet the standards specified by the GPhC” (Jacob and Boyter 2019:2). The results show that while there has been an increase in the variety of placement sites and hours, universities face challenges in terms of financial support, availability of staff and access for placements in hospitals. The authors conclude that in order to improve students’ learning, quality assurance (QA) of EL programme needs to be standardised and regulated.

Other studies have explored factors that hinder the positive application of education policies. Crampton et al. (2019) analysed the intended and unintended consequences of GMC interventions for quality assurance in medical education. On the basis of their interviews, the quality assurance framework (QAF) appears as a positive, comprehensive intervention. However, the study also highlighted the importance of context for the positive application of QAF and patient safety. They highlight how “dissociative” contexts might result in unintended outcomes, for instance, blurred “roles and boundaries of multiple organisations between patient safety, medical education and training” and lack of transparency in data collection (Crampton et al. 2019:7).

Butcher et al. (2017) performed a systematic review of studies (from Canada, Australia and the USA) on the perception of intra-professional collaboration of pre-licensure students and educators within various entry-to-practice categories (Butcher et al. 2017). The authors found that students value intra-professional learning, as a way to develop team-building, communication, leadership and supervisory skills and develop trust and understanding others’ roles. At the same time, the authors identify challenges in educators and staff attitudes and in the “lack of clarity, poor communication, differences in clinical and academic education and exclusion of categories of students” (Butcher et al. 2017: 1035). The authors hence recommend greater collaboration, the inclusion of intra-professional learning as part of the student practice modules and curricula, and that more attention is given to the possible obstacles to collaboration. They also recommend

further research to help disrupt normalising or dominating discourses and assumptions that reproduce power inequities (Butcher et al. 2017).

To investigate the impact of educational reforms (academisation and professionalisation) on paramedics, Givati et al. (2018) explored their narratives. Through interviews and focus groups, the authors found that the reform of paramedic education had given rise to a number of tensions between pre-existing ideas and values about the practice and the new ones resulting from the reform. For instance, the reform put emphasis on academic knowledge rather than practice and experience, which was seen as breaking the 'socialisation' aspect of the workplace and created a tension between paramedics who gained their training and experience prior to the introduction of the reform, and university graduates. The authors argue that even if the reform of education opened greater job opportunities to the new graduates, "it may have a negative impact on job-retention and on the sustainability of the paramedic workforce" (Givati et al. 2018:360), as they are now less autonomous as a profession.

In 2010, the NMC introduced the inclusion of patients and carers in the assessment of nursing students' clinical practice and the impact of this was explored by Haycock-Stuart et al. (2016). They explored the views and perceptions of nursing lecturers and preregistration nursing students in an interview-based study. Participants expressed concern about the lack of evidence base for involving users and carers in assessment, whom they considered as not prepared for clinical assessment.

In an interview-based study, Innes et al. (2019) explored the experience and beliefs of experts of (re)-accreditation standards and processes of Chiropractic Programmes (CP). Respondents were, in general, satisfied with Council of Chiropractic Education (CCE) accreditation standards, graduating competencies, and processes. The findings reveal the presence of different perspectives which, according to the authors, correspond to the internal division between evidence-based and non-evidenced-based chiropractors. The authors noted that participants omitted any mention of the implications for patient safety, values and outcomes.

5.2.2.2 CPD

The studies report participants' general positive attitudes towards CPD, although one study (Legare et al. 2015) includes reference to recommended improvements.

Knox et al. carried out two surveys (in 2013 and 2014) about proposed continuing professional competence requirements for emergency medical technicians (EMTs) in Ireland (2013) and for paramedics (2014): both professions that are registered under the Ireland's Pre-Hospital Emergency Care Council (PHECC). The results were similar. In general, they found that participants were supportive of introducing formal continuing professional competence requirements for registration (Knox et al. 2013) and that most participants had been attending courses and keeping records voluntarily. Scenario-based training covering practical and clinical skills was thought to be most useful. Online only training was viewed less favourably, although e-learning was seen as a useful addition to practical courses. In a later paper by Knox et al. (2016), they report a literature review and argue for the benefits of formal continuing professional competence requirements

for all practitioners registered within the PHECC (i.e. paramedics or advanced paramedics, EMTs and others).

Also in Ireland, Walsh and Craig (2016) addressed the topic of CPD for radiographers. Based on a survey, they conclude that CPD programmes should be developed further and this requires funding and increased staffing.

Wenghofer et al. (2014) examined whether participation in CPD programmes correlates with positive revalidation outcomes among Canadian doctors. They found a positive correlation, especially among those who participated in group-based CPD activities. However, they could not conclude that CPD was the cause of good performance at revalidation – it was possible that both CPD and positive assessment were due to an underlying commitment to lifelong learning.

In a study by Bourgeois-Law et al. (2019) the idea of remediation as CPD was explored in interviews with stakeholders from a variety of institutions in Canada. The main finding was that remediation is conceived in two different ways: on the one hand, remediation is seen as part of the educational continuum, not different from continuing medical education (CME) and CPD. On the other, remediation is perceived as an imposition, a de-professionalising regulatory process which removes an individual's autonomy and which is associated with stigma. In order to lessen stigma, the authors argue for “restructuring remediation”, enabling the retention of autonomy and increasing organisations’ support of the process (Bourgeois-Law et al. 2019: 282).

In Legare et al.’s (2015) study, the authors analysed the learning objectives of CPD activities offered by medical associations, regulatory bodies, and academic institutions in Quebec (Canada) using Bloom’s taxonomy of learning (Legare al. 2015). The authors found that the majority of learning objectives in the CDP activities corresponded to the lower levels of Bloom’s taxonomy (i.e. “knowledge” and “comprehension”), suited to introductory rather than more advanced courses. The authors recommend including more “putting knowledge into practice” activities, stimulating analysis and evaluation of information and “planning operations that lead to behavior change” (Legare al. 2015: 200).

Bullock et al. (2013) explored the formal CPD requirements for dentists across the EU based on literature review and survey of participants from 30 EU countries. About half of the countries had mandatory CPD requirements, while others had optional or recommended CPD hours. Overall, the respondents were unclear about the requirements for CPD accreditation but agreed that CPD should be obligatory for all dentists. The authors suggest that standardised requirements would increase both dentist mobility and clinical safety.

Summary points

- Generally, studies call for greater standardisation, harmonization and collaboration both in terms of intra-professional learning and internationally. Standardisation and harmonisation are seen as beneficial both for professionals and for patient safety.
- The importance of context appears in relation to the attempt to implement practical learning. Low financial support and reduced access to workplaces can be hindering factors for the practical application of learning.
- Studies stress the role of context in successful implementation of education reforms on curricula or CPD programmes. Educators' and staff attitudes play a role in the successful application of intra-professional learning. Internal politics can influence the adoption of certain curricula or programmes instead of others.
- The effects of academisation vary according to the context of different professions: in the case of nurses it is described as a positive change. In the case of paramedics, it is felt as favouring academic knowledge over practical experience and creating competition between those trained under the "old" and "new" approaches.
- There is a general appreciation and recognition of the value of CPD, although there is scope to increase the practical application of learning.

5.3 Guidelines and standards

5.3.1 Summary information on the papers in this section

A total of 11 papers were reviewed in relation to the theme of guidelines. The papers in this group present analysis or comments on the functioning of health care professionals' guidelines and/or standards or on the impact of changes in guidelines on professions. Guidelines are often discussed in relationship to the issue of implementation (for example, the importance of clarity of provisions) or impact (for example, on quality assurance, or professional autonomy).

In Tables 25 to 28 we provide information on the country, study group, year of publication and methods used. We note that three of these papers did not include an analysis of data.

Among the papers selected, the majority focus on UK cases; of these, one specifically focuses on Wales, one on Northern Ireland and one on Scotland and England.

Table 25: Country location of the papers

Country	n
UK	9
Netherlands	1
Sweden	1
Total	11

As far as the professional group was identified, the majority of papers concern midwives and nurses, with others focused on doctors and a single paper on psychologists.

Table 26: The professional groups that were the subjects of the papers

Professional Group	n
Midwives/Nurses	9
Doctors	2
Total	11

The majority of publications are from 2013 and 2015. None of the publications postdate 2017.

Table 27: Year of publication

Year	n
2017	1
2015	4
2014	1
2013	4
2011	1
Total	11

An overview of the types of data used in the studies we reviewed is given in Table 28. Two papers did not include an analysis of data; one of these was an analysis of clauses in a policy document; the other was expert opinion. These are not included in the table below.

Table 28: Study type

Study type	n
Questionnaire survey(s)	4
Interviews	3
Secondary data analysis (systematic review)	2
Total	9

The majority of papers reported data collected either from interviews or surveys.

5.3.2 Evidence synthesis

We report the evidence synthesis under a number of themes. The first relates to the statutory supervision of midwives, both before and after the King's Fund report (Baird et al. 2015) which signalled the end of the dual regulation by both the NMC and local supervising authorities (LSA). This was a key issue at the time. The second theme focuses on papers which evidence a need for clarity, which is sometimes lacking in the guidelines. Evidence related to implementation and the impact of changes to guidelines is the third theme we consider.

5.3.2.1 Statutory supervision of midwives

Several publications about midwives are related to the issue of statutory supervision, and the recommendation issued by the King's Fund report in 2015 to end midwives' double layer of regulation (i.e. the combined NMC and LSA). The recommendation was based on the limited evidence found in support of supervision as an effective instrument for safe practice or woman-centred care, and the negative impact created by the lack of clarity and accountability of a double layer system in case of investigations. These concerns, together with the number of incidents, led the NMC to separate the function of midwifery supervision from regulation from 31 March 2017, and all FtP referrals are now addressed exclusively to the NMC.

Before the publication of the King's Fund report, Henshaw et al. (2013) performed a systematic review of literature on statutory supervision of midwives in the UK, and highlighted that midwives generally support supervision. At the same time, the authors found that midwives' and supervisors' interpretation and implementation of the statutory framework varied significantly across the UK, and across time (Henshaw et al. 2013). The authors found that the lack of clarity regarding boundaries between supervisory and management was often a problem, and that the relationship of trust between midwives and supervisors was fundamental for the role to have positive effects on standards of clinical practice and women safety (Henshaw et al., 2013). Also they highlighted that more research was required in this area, as the majority of the studies they reviewed were conducted before 2004.

On the necessity of clearer boundaries between supervision and other roles (e.g. management for instance), Ness and Richards (2014) from the Local Supervising Authority (LSA) in Wales published a policy paper explaining the revised model of Supervisor of Midwives (SoM) introduced in Wales. The revised model created a specific role for the SoM, based on a rotational period of 18 months, which freed them from the workload pressure created by the responsibility of their substantive post.

Roseghini and Olson (2015), both supervisors of midwives at Guy's and St Thomas' NHS Trust, in preparation for the annual audit of the Local Supervising Authority (LSA), surveyed the midwives in their unit. Drawing on Henshaw et al. (2013) and in reaction to the King's fund recommendation, they were interested in ascertaining midwives' views regarding the effectiveness of supervision (Roseghini and Olson, 2015). The findings of

their survey show a positive assessment of supervision, where the majority of midwives find supervision valuable for professional support (Roseghini and Olson, 2015).

More in line with the King's fund report, the study by Wier (2015) presents a complex picture. The main findings show that respondents (midwives) generally support supervision, however a minority of respondents (6% in the survey, but more in the interviews) believed statutory supervision is not the best method to regulate the profession and support the provision of quality care (i.e. safety in practice, accountability and woman-centred care). Specifically, some issues were highlighted with regard to: 1) the value of supervision too dependent on supervisors' expertise; 2) the discretion of supervisors in investigation; 3) general inconsistencies in the annual review; and 4) a tendency of the supervisor to focus on the demands of service rather than woman centred care (Wier, 2015). The author recommends that in new regulation, the NMC addresses "the duplication, confusion and tensions that currently exist across the range of regulatory mechanisms, and create new strategies to determine poor practice, which are fit for purpose" (Wier, 2015: 294).

5.3.2.2 Need for clarity

In the field of nursing, a number of studies demonstrate the importance of clarity in relation to guidelines and standards. In 2017, Snelling published the analysis of four clauses from the revised NMC Code of practice: "consent and its documentation, relationships with patients, confidentiality and the meaning of inappropriate" (Snelling 2017: 395). The analysis of the clauses highlight that the meaning is vague. The author suggests that the clauses concerned with the complexity of professional practice need to be complemented by explanations and guidance (Snelling 2017) and recommended that the NMC clarifies "which guidance from other organisations [such as the GMC] is considered authoritative and capable of being taken into account by fitness-to-practice hearings" (Snelling 2017: 403).

McConnel et al. (2013) used a questionnaire survey to determine the role and scope of emergency nurse practitioners' (ENPs) practice in Northern Ireland and establish the extent to which they could fulfil the criteria of an advance nurse practitioner (ANP). In the findings the authors highlight that even though ENPs deliver care beyond the remit of the "traditional nurse" (McConnel et al. 2013:77) - especially in direct patient care roles- they do not meet the NMC's criteria for the ANP. In the conclusion, the authors urge the regulator (the NMC) to consider either the inclusion of roles undertaken by ENPs in the ANP or introduce an additional level of practice (McConnel et al. 2013).

Need for greater clarity is a common issue also in other geographical contexts. In Sweden, Craftman et al. (2013) highlight the importance of clarity in guidelines and regulations, by addressing the issue of district nurses (DN) and delegation of medication management to unlicensed personnel working in municipal social care. The findings from the interviews indicate that most DNs consider delegating responsibility a burden, since they found the statute regulating delegation hard to follow and incompatible with reality, mostly due to lack of time (Craftman et al. 2013: 574). Delegation was regarded as an assignment which is better suited to nurses who are actually employed in the municipality (Craftman et al. 2013: 575).

5.3.2.3 Implementation and impact

Other studies are more generally interested in understanding the impact of changes in guidelines or the way in which implementation takes place. Kennedy et al. (2015) reviewed the *Scope of Nursing and Midwifery Practice Framework* document which provides a practical guide for nurses and midwives in decision-making about their scope of practice in the Republic of Ireland (An Bord Altranais 2000). Based on an international comparison, the authors isolate two main approaches to the regulation of the scope of practice and associated decision-making frameworks. One behaviour oriented, based on policy and regulation; the other based on notions of autonomous decision-making, professionalism and accountability. One of the interesting findings is that neither approach emphasises patient choice, and that the focus is on technical rather than aesthetic aspects of care (Kennedy al. 2015).

In the Netherlands, Breimeier et al. (2013) undertook an empirical cross-sectional study in Austrian, German, and Dutch hospitals to investigate interventions adopted to translate guidelines into nursing practice. They used an online questionnaire based on the conceptual framework of implementation interventions from the Cochrane Effective Practice and Organization of Care (EPOC) data collection checklist. They found that written materials (a professional intervention) and changes in the patient record system (an organisational intervention) are the most used interventions. They conclude that implementation efforts focus mainly on professional and organisational interventions, and they recommend nurse managers and other responsible personnel to focus to a broader array of implementation interventions using the four different categories of the EPOC conceptual framework (which in addition to professional and organisational interventions, include financial and regulatory mechanisms).

In their comparative longitudinal case study of medical professionals' response to National Institute of Health and Clinical Excellence (NICE) guidelines, Spyridonidis and Calnan (2011) identify the emergence of 'hybrid-professionals' who perform 'boundary work' (e.g. doctors who become managers) (Spyridonidis and Calnan 2011: 406). However, the evidence found support the claims that notwithstanding changes in professionalism, continuity prevails over change. They report that both General Practitioners (GPs) and hospital doctors' adopted strategies to avoid top-down modes of control suggested by the NICE guidelines. Some respondents perceived NICE guidelines as imposing unacceptable restrictions on their professional right of clinical judgement and self-regulation. According to the authors, the ways that the medical profession responded to the introduction of NICE guidelines lessened any major shift in the structure or the creation of new professionalism, revealing instead the rising of multiple occupational identities (Spyridonidis and Calnan 2011: 406).

Grant et al. (2015) examined the impact of the 2004 new General Medical Services (nGMS) performance management mechanisms designed for managers of Primary Care Organisations (PCO) to measure and improve general practice work. Although about contracts, rather than guidelines or standards, we include it here as another mechanism for influencing or managing performance. The authors considered four PCOs and eight general practices in England and Scotland. Although local practices in both countries had responded to the nGMS in broadly similar ways, with local competition as the major

driver for quality improvement, the approaches taken by the countries differed, with the English PCOs developing more market-based approaches than in the Scottish PCOs. The authors recommended that the impact of these macro-level changes on the delivery of general practice care is monitored at meso-levels and micro-levels, and the relationship between these levels considered (Grant et al. 2015).

Summary points

- The papers in this group present analysis or comments on the functioning of guidelines and/or impact of changes in guidelines. Studies call for more reflection on the implications of certain provisions for the professionals,.
- Other studies are more generally concerned with understanding the impact of changes in guidelines or the way in which implementation takes place.
- There is, in general, acknowledgement that clarity is essential (and sometimes lacking), and that in order to support implementation, different strategies or instruments have to be considered.
- The role of patients is not evident; only within midwives' studies was there is a clear reference to 'woman-centered' care (often in relation to the role of supervision).
- Studies of midwife supervision present mixed reviews of the statutory supervision. Findings confirm that the value of supervision depends on the expertise and relationship between midwives-supervisors and that there is need for a clearer division of responsibility between the LSA and regulator in cases of investigation.
- Studies of doctors show that continuity may prevail even after changes in guidelines, in part because doctors seek to retain their autonomy.
- Competition seems to be a mechanism that can stimulate the adoption of changes designed to bring quality improvement.

5.4 Fitness to practise, misconduct, complaints and disciplinary measures

5.4.1 Summary information on the papers in this section

A total of 22 papers were reviewed in relation to this theme. In Tables 29 to 32 we provide information on the country, study group, year of publication and methods used.

Table 29: Country location of the papers

Country	n
Australia	6
Canada	1
UK	15
Total	22

In this section, although the majority of the papers we considered were from the UK, a notable number were from Australia (see Table 29). As is clear from Table 30, several papers do not have a focus on a single regulated group. Of those that do, the majority in this set focused on doctors, dentists or nurses/midwives.

Table 30: The professional groups that were the subjects of the papers

Professional Group	n
Doctors	6
Dentists	3
Nurses/Midwives	4
Paramedics	1
Social Workers	1
Multiprofessional	
- medicine, nursing/midwifery, dentistry, pharmacy and psychology	
- chiropractors, osteopaths, and physiotherapists	
- nurses, social workers, teachers	
- doctors, nurses and midwives, and allied professionals	5
Total	20*

*Two papers are not included in the Table because they address the topic from a general perspective, without mentioning specific health care professions.

The majority of papers were published from 2017 (Table 31).

Table 31: Year of publication

Year	n
2020	2
2019	3
2018	3
2017	5
2016	4
2015	2
2013	1
2011	2
Total	22

An overview of the types of data used in the studies we reviewed is given in Table 32.

Table 32: Study type

Study type	n
Document analysis (primary data)* (qualitative)	2
Mixed methods	4
Interviews	2
Policy review	1
Questionnaire survey	2
Secondary data analysis (qualitative)	3
Secondary data analysis (quantitative)	8
Total	22

*considered primary data as collected under freedom of information (FOI)

Papers in this section tended to report secondary analyses of existing data, and the majority of these were quantitative in nature. Typically, they were analyses of FtP cases. Of those papers reporting studies based on the collection and analysis of primary data, commonly mixed methods were used (for example, the inclusion of data from interviews or focus groups plus questionnaire data).

5.4.2 Evidence synthesis

We organise the evidence within this section under three main headings: FtP mechanisms in higher education institutions (HEIs) (where the focus is on nurses and midwives); studies of FtP and discrimination (including disability and BAME); studies of FtP which focus on specific healthcare professions (social workers, paramedics, dentists, and doctors); and studies of FtP across professions or geographies.

5.4.2.1 FtP mechanisms in HEIs

Unsworth (2011) examined the FtP policies and procedures in place within UK HEIs which provide educational courses leading to registration within the NMC (Unsworth 2011: 468). In the context of the NMC not being prescriptive about the format of the FtP policies, he suggests that HEIs could be open to challenge which could call into question the process of self-regulation. He recommended: 1) including a clear threshold for referral to a full hearing; 2) including explicit reference to a duty to give reasons at each stage of the process; and 3) making clear the system for appeals (Unsworth 2011: 471). He also recommended “that all policies should make explicit that action should be taken against students thought to be professionally unfit to practise in order to protect the public and to uphold the standards of the professions and to maintain the public's confidence” (Unsworth 2011:471).

Focused on midwives, Hastings (2015) considered the issue of double investigatory procedures whereby investigations are undertaken by both the employer and the Local Supervising Authority (Hastings 2015: 59). The study found evidence in support of the supervisory investigation process being the sole investigator, and noted the importance

of examination “by an SoM who is an experienced clinical midwife, not a manager who may be neither a midwife or a clinician” (Hastings 2015: 63).

5.4.2.2 Studies of complaints, FtP and discrimination

Archibong et al. (2013) accessed Trusts’ disciplinary data to examine the involvement of Black and minority ethnic (BME) staff as subjects of disciplinary procedures. The article reports findings from part of a larger research study (Archibong & Darr, 2010) funded by the NHS Institute for Innovation and Improvement in the UK, conducted by the Centre for Inclusion and Diversity, University of Bradford, in collaboration with NHS Employers. The authors found that of all the Trusts from which data could be obtained for auditing, BME staff were almost twice as likely to be disciplined compared to their White counterparts (Archibong et al. 2013: 11). They report that this difference reflected “a lack of confidence among managers in dealing with issues relating to staff from different ethnic backgrounds”, suggesting underlying racism, visible when “BME staff could identify comparable cases in which there was differential treatment of White staff” (Archibong et al. 2013:19). The results show that even though regulatory bodies’ representatives were convinced of the effectiveness and fairness of FtP procedures, they did not have accurate data to assess whether ethnic groups were disproportionately represented in such cases. Regulators considered language proficiency and cultural difference influencing the behaviour and interaction with patients as factors that might lead to disciplinary action. For this reason, the authors recommended clarifying the difference between “disciplinary, capability, and performance issues” (Archibong et al. 2013: 21). Furthermore, they recommended addressing the lack of diversity in investigating panels (mainly dominated by middle-class White males) and that “members of minority ethnic groups should be involved in the development and evaluation of disciplinary procedures on a regular basis” (Archibong et al. 2013: 21).

Indications of discrimination were reported by West et al. (2017) on the basis of a quantitative analysis, funded by the NMC, which showed that BME nurses and those of unknown ethnicity were more likely to be referred than White and Asian nurses and to progress through the FtP process. Other factors that increased the risk of referral were: the origin of training (higher referral rates for those trained in Africa), age (older are likely to be referred) and gender (male are more represented in referrals). According to the authors, the main finding is that the relationship between ethnicity and FtP is mediated by referral by the employer, and that the working environment is the factor that leads to an over-representation of BME nurses in the FtP process. Although underrepresented in referrals and less likely to progress through the process, the authors found that Black nurses were more likely to be given a severe penalty at adjudication. However, ethnicity is known only for 60% of referrals, indicating a need for better data. The authors also recommend that these results are considered in NMC’s codes and policies (West et al. 2017).

Funded by the GMC, Mehdizadeh al. (2017) investigated the number of times doctors’ had to go through assessments by the GMC because of performance complaints. The results show that non UK-trained doctors had significantly higher rates of GMC assessments related to complaints about their performance than UK-trained doctors, but the authors were not able to isolate single factors (e.g. doctors' sex, age, length of time

working in the UK, and English language skills) leading to this result. For this reason, they call for further research capable of shedding light on the actual difference in preparation, especially in the context of the UK leaving the EU.

Tiffin et al. (2017) studied the role of language competency, clinical skills and knowledge in reducing rates of FtP issues in international medical graduates. They found that, albeit mainly via indirect effects, demographic (i.e. gender) and Professional and Linguistic Assessments Board (PLAB) performance were independent predictors of FtP referral and eventual censure (Tiffin et al. 2017:11). Language proficiency (i.e. and International English Language Testing System –IELTS- tests scores) was more complex, and seemed to show that lower English language ability may increase the risk of a complaint to the GMC, but was not itself strongly associated with a risk of professional misconduct (Tiffin et al. 2017). In order to prevent international doctors from being exposed to stressful, but ultimately groundless, complaints and investigations, the authors recommend that medical regulators develop some evaluation of knowledge and behaviour in relation to medical professionalism in a UK context as part of the PLAB test or wider registration process (Tiffin et al. 2017).

Failure to disclose disability, particularly unseen disabilities such as those related to mental health, is an issue highlighted in the literature which may impact on FtP (Stanley et al. 2011). Without disclosure, employers will not make appropriate adaptations and adjustments. Stanley et al. (2011) found that disclosure of disability (in particular in the case of mental health needs) was often perceived as having the potential to exclude participants from their chosen profession. Thus professionals may withhold or provide only partial information about the extent and impact of their disabilities, jeopardising the gatekeeping role of regulatory bodies. Issues related to the disclosure of mental health have been confirmed by Winter et al.'s (2017) study of medical students. The authors found that medical students are particularly reluctant to disclose mental health issues, since they generally believed that mental illness is associated with weakness and failure. The medical environment, especially the culture of "presenteeism" amongst senior clinicians, distrust of medical school staff, and expectations about conduct, act as reinforcing mechanisms.

5.4.2.3 Studies in specific healthcare professions

Commissioned by the HCPC, Gallagher et al. (2020) investigated the reasons for the disproportionate number of FtP complaints concerning social workers, relative to other professional groups regulated by the HCPC. The findings, from interviews and focus groups, place significant weight on professional, and systemic reasons for FtP referrals. With regards to social workers, Gallagher et al. (2020) comment:

“What emerges is a picture of an occupational group whose job is inherently challenging and frequently misunderstood, operating in a climate of increasing need, limited resources and growing managerialism. Compared with many of the other professions regulated by HCPC (e.g. dietitians, physiotherapists, radiographers), it is unsurprising that more referrals are made to the regulatory body about social workers” (Gallagher et al. 2020: 12).

The authors argue that there is a need for public education regarding the role and function of social workers and for regulators to have more proactive engagement with registrants and employers.

Similarly, Van der Gaag et al. (2018) investigated the disproportionately high number of referrals reported in the case of paramedics and the associated emotional distress. In most cases, paramedics are reported for behaviours outside of work. Among the contributing factors, the authors point to a general lack of understanding of the HCPC guidance and lack of adequate support and supervision associated with problems in communications. Lack of resources, a highly demanding work environment and a general culture of blame and punishment rather than learning from errors were also cited as explanatory factors (Van der Gaag et al. 2018). Since the publication of the report, the regulator has begun a targeted programme of work with employers on when to refer and when not to refer, and has undertaken to work with other stakeholders.

A number of studies have investigated the most recurrent complaints raised against dental practitioners. The study by Brown (2015) showed that, in the context of “only 2% of complaints in Victoria (Australia) concern dental practitioners”, “75% of cases have been made on the basis of inadequate record keeping, most often in combination with other breaches of conduct” (Brown 2015: 497). The findings suggest that the problem might be linked to handwriting or typing entries into patient records, and the author suggests that technology (intraoral and extraoral photography and audio-recording of patient interactions) may provide helpful means of addressing record keeping problems (Brown 2015: 497).

In another Australian study, Thomas et al. (2018) compared rates of complaints about dental practitioners and other health practitioners. They found that dental practitioners are the health profession most at risk of complaint in Australia, with “treatments, procedures and fees being the most common grounds for complaint”, whilst “relatively few complaints raised concerns about the health of the practitioner” (Thomas et al. 2018: 292). These findings are in some contrast to those reported by Brown (2015) as problems with record keeping is not specifically mentioned. Thomas et al. (2018) also note that 4% of the dental practitioners were responsible for the majority of complaints. Relatively few complaints raised concerns about the health of the practitioner: among these complaints mental illness and substance misuse were the issues most commonly raised (Thomas et al. 2018). They recommended collaboration between educators, professional dental associations and health regulators in:

“supporting early resolution of patient concerns; enhancing clinical communication skills, among male practitioners in particular; identifying and remediating performance concerns among the small group of dentists who account for a disproportionate share of complaints; addressing concerns about fees through improved financial informed consent and more equitable funding for dental services; and ensuring that advertising of dental services is fair, accurate and supports patients to make informed choices” (Thomas et al. 2018: 292).

Also focused on dental practitioners, this time in Canada, Roerig et al. (2019) analysed complaints made by the public to the Royal College of Dental Surgeons of Ontario

(RCDSO). They used a taxonomy similar to the complaints' classification used in Thomas et al. (2018), although they did not include the professional's health among the issues). The results are in some way aligned to Thomas et al.'s (2018) findings. Similarly, Roerig et al. (2019) found that the majority of complaints concerned clinical outcomes/ errors, safety of dental services, and issues relating to the behaviour of any member of a clinic's staff towards the patient (Roerig et al. 2019). The lowest number of complaints, by contrast, were focused on areas like management and access to care. These findings are again in contrast to Brown's (2015), where the major cause for complaints was record keeping. Roerig et al. (2019) recommended that the RCDSO: 1) continue to gather data about complaints; 2) compare findings to gain a more in-depth understanding about the nature, severity and factors contributing to complaints; 3) create, or enhance, educational materials; and 4) "develop an evaluation protocol to measure the impact of interventions on complaints for quality assurance purposes" (Roerig et al. 2019:13).

Harrison et al. (2016) investigated the type of complaints made against doctors. Complaints were grouped into three domains: clinical (i.e. treatment), management, and relationships (i.e. interpersonal, conduct). Similar to other studies, they found the majority of complaints are related to inadequate treatment and errors. In contrast, they found that communication issues accounted for a minority of complaints (Harrison et al. 2016: 242). However, they noted that while a coding taxonomy helps measurement, it cannot reflect the full spectrum of issues, and it might not capture some important information. Furthermore, many issues were interrelated and multi-faceted. This, they suggest, raises questions about how well complaints are captured in analysis.

On the topic of under reporting, Rea and Griffiths (2016) were interested in understanding general practitioners' "perceptions of the barriers to incident reporting and whether the process of significant event analysis supports the reporting of incidents" (Rea and Griffiths 2016: 411). They found that among the reasons for under reporting, the reputation of the practice, especially in a competitive environment, appeared as the main concern. GPs referred more to the potential embarrassment and loss of patient confidence rather than fear of disciplinary action or litigation. They distinguished under reporting within the practice from under reporting to external bodies: under reporting within the practice was linked to time constraints, fear of embarrassment and ambiguity of definition. Under reporting to external organisations was related to fear of blame, damage to reputation and patient confidence, lack of clarity over who to report to and lack of feedback (Rea and Griffiths 2016). The study also highlighted a lack of knowledge and mistrust of reporting to external organisations (Rea and Griffiths 2016). The authors recommended that GPs adopt robust data collection systems and emphasis that the focus should be on learning from incidents (Rea and Griffiths 2016).

On the topic of complaints, Bourne et al. (2016) studied the effects of complaints on doctors. The results highlight that the complaints procedure creates very negative psychological experiences for doctors, often reducing empathy or compassion for patients and worsening patient care. Doctors generally perceived that complaints procedures lacked transparency and fairness, and they noted the presence of vexatious complaints. Drawing on these results, the authors recommend changes in the culture and processes associated with complaints procedures, and akin to Rea and Griffiths's (2016)

recommendation, movement towards a system focused on learning, one more able to provide feedback and an opportunity to improve.

Casey and Choong (2016) investigated rate of suicide among doctors in FtP investigations (following a Freedom of Information request from a psychologist). They found a failure to investigate FtP as a distinct risk factor for doctors' suicide. According to the authors, coroners and the GMC's system of FtP proceedings had a role to play in identifying the trend, supporting the physical and mental health of doctors and providing adequate support to the doctors whilst investigations are on-going.

5.4.2.4 Studies of complaints, misconduct and FtP across professions or geographies

In a study of the five most populous regulated health professions in Australia, the goal of Millbank's (2019) study was to map the relationship between type of misconduct and the outcome. Millbank found significant variations in the outcome even where the misconduct was the same. Doctors were more frequently represented in misconduct cases (although they faced less severe outcomes than other professions), and male practitioners. The misconduct more likely to lead to restrictive actions was failure in clinical care. The study shows variation/inconsistency occurring at the level of boards (whose membership is dominated by the professional group), in external tribunals (chaired by a legal or judicial member), as well as across jurisdictions, in different states and territories. Millbank (2019) concludes that national law is not applied in a uniform manner.

Ryan et al. (2018) analysed all formal complaints about all registered chiropractors, osteopaths, and physiotherapists in Australia lodged with health regulators between 2011 and 2016. They found that chiropractic, osteopathic and physiotherapy professions differ in the type of complaints by source, issue and outcome. As in other studies, the findings show that the vast majority of practitioners (above 90% in all three professions) were not subject to any complaints to regulators during the study period. However, within the three professions analysed, chiropractors were at higher risk complaint to their practitioner board. Independent practice, male sex and older age were significant risk factors for complaint in all the three professions. According to the authors, the high proportion of complaints from fellow health practitioners "may reflect less inter-professional integration of the profession, anti-competitive behaviour by other practitioners, or the diversity of practice perspectives within the chiropractic professions" (Ryan et al. 2018:7). The authors state that in order to reduce the complaint rate for this profession, it is necessary to develop an approach capable of greater understanding, and able to assist them to meet their regulatory obligations.

Searle et al. (2017) analysed 6,714 FtP cases in three health professions (doctors, nurses and midwives, and allied professionals) in the UK. They found cross-profession similarity, with the same type of most frequent misconduct recurring across professional groups. Collectively the same 11 misconduct charges were the most frequent in these professions, and often one case had multiple charges: for instance, sexual misconduct was consistently strongly associated with the failure to maintain professional boundaries (Searle et al. 2017:58). The authors show how misconduct can have an individual as well as social and environmental dimension. Knowing the role of these dimensions can help

regulators to prevent a chain reaction that might increase levels of wrongdoing (Searle et al. 2017:59). In particular, the authors found that regulators show inconsistencies in “the type of misconducts being recorded” and “in the level and type of sanctions administered by regulators; specifically, the use and duration of being struck-off” (Searle et al. 2017:59).

Walton et al. (2019) studied complaints from five of the most common health professions in Australia (dentistry, medicine, nursing/midwifery, pharmacy and psychology, which together represent 85% of the overall health workforce). Results are mostly in line with previous studies: generally there is a low rate of complaints. Among the complaints, demographic factors (male gender, overseas country of origin and ethnicity) are predictive factors for complaints shared by all professions. Among professions, doctors and dentists are the most likely to have complaints and nurses and midwives the least. The most frequent types of complaints are similar across professions, but with different distributions. Similar to other studies of single professions (see Thomas et al. 2018 and Roerig et al. 2019), the most frequent type of complaints across all professions is “clinical care” (44% of all complaints). Medication accounted for 10% of complaints and health impairment of the practitioner for 8%. In contrast to other studies, health impairment appears to be one of the most common types of complaints, especially for nurses (in Thomas et al. 2018 it was the least frequent case of complaints for dentists, and in other studies it is not mentioned). The authors recommend educators and regulators develop education programs that help reduce these complaints (Walton et al. 2019:23).

In the UK, the Government published the response to the consultation on *Promoting Professionalism, Reforming Regulation* (Department of Health and Social Care 2019), concerned with the need to simplify/clarify procedures, giving more autonomy to professional regulatory bodies. The report indicates that the responses to the consultation “showed clear support for changes to the legislative structure that underpins the regulatory bodies”. It is stated that the government will prioritise changes to the regulators’ FtP processes and operating framework. These changes aim to deliver: “modern and efficient fitness to practise processes; better support for professionals; and more responsive and accountable regulation” (p.5): “The most significant change will enable regulators to resolve fitness to practise cases without the need for a full panel hearing where it is appropriate to do so” (p.6).

Considering the main issues highlighted in the other studies, these proposals to simplify procedures (including reduction of regulatory bodies and increased cooperation and sharing of data question) and expand regulatory bodies’ range of powers for resolving FtP cases, should go some way towards addressing these concerns. However, a majority of respondents to the consultation thought improvements to discrimination would not be seen.

Summary points

- Studies confirm that only a minority of health care professionals go through FtP procedures. However, certain demographics and professions are over-represented in complaints: male, older, 'foreign' (overseas trained), doctors, dentists, chiropractors, social workers and paramedics.
- Main complaints are common across professions, commonly related to clinical care (for example, errors in treatment). Unprofessional conduct or poor communication also feature. The proportion of these complaints changes according to different professions.
- Some studies show evidence that over-representation of certain groups in referrals is linked to country of origin or ethnicity (i.e. BAME) or language proficiency of the professionals. Almost all studies stress that more data on ethnicities are needed.
- Studies on the type of misconduct highlight that misconduct can have an individual as well as social and environmental (workplace) dimension. Environmental factors include: stressful and competitive work environments and work culture of blame rather than learning.
- Often FtP mechanisms or decisions are not clear for the professionals and this can result in unnecessary stress and FtP investigations can create psychological distress, which for some might lead to suicide.
- The UK government consultation addresses the need to simplify and clarify FtP procedures.

Further research and monitoring

- More data are needed on psychological effects of investigations
- More data need to be collected on the ethnicity of subjects of complaints
- Taxonomies and classifications of complaints aid comparison but overlook nuances.

5.5 Registration and the maintenance of registration

5.5.1 Summary information on the papers in this section

A total of 10 papers were reviewed in relation to the theme of registration. The group includes studies of registers and registration related issues, as well as revalidation criteria or maintenance of registration. In Tables 33 to 36 we provide information on the country, study group, year of publication and methods used.

Among the papers selected, the majority focus on the UK; other studies are from Australia, and one from Canada (see Table 33).

Table 33: Country location of the papers

Country	n
UK	5
Australia	4
Canada	1
Total	10

In terms of the professional groups studied, Table 34 shows the majority of papers concern doctors, midwives or nurses.

Table 34: The professional groups that were the subjects of the papers

Professional Group	n
Doctors	4
Midwives	3
Nurses	2
Social workers	1
Total	10

The publication period spans from 2013 to 2019 (see Table 35)

Table 35: Year of publication

Year	n
2019	1
2018	2
2017	1
2016	1
2015	2
2014	2
2013	1
Total	10

The majority of studies use primary data, from interviews see Table 36.

Table 36: Study type

Type of study	n
Interviews	4
Mixed methods	2
Questionnaire survey	2
Qualitative content analysis	1
Secondary data analysis (qualitative)	1
Total	10

5.5.2 Evidence synthesis

We report the studies in two groups: one relating to the topic of registration, reporting issues connected to the registration process in different professional settings; the second relating to revalidation and the maintenance of registration.

5.5.2.1 Registration

The registration process for nurse practitioners in Australia was studied by MacLellan et al. (2015) who adopted an ethnographic approach that included interviews. Participants lamented a number of issues: the registration process appeared to be excessively bureaucratic, complicated and time-consuming, lacking consistency. Moreover, the findings show that other health professionals can exert power over applicants and hinder progress; participants reported working to appease gatekeepers in order to be successful.

A study of the media portrayal of a new licensing exam for nurses in Canada was conducted by McGillis Hall et al. (2018). The exam was based on an equivalent exam in the USA. Overall, the media coverage was negative due to the much lower pass rate. They criticised translation problems, a lack of preparation materials in French, inconsistencies with Canadian practices, and a lack of stakeholder engagement in the development of the new exam.

5.5.2.2 Revalidation and the maintenance of registration

A common issue in the papers appeared to be the involvement of patients in the process. Archer et al. (2015) explored attitudes to the newly-introduced revalidation system for doctors in the UK. The authors conducted a critical discourse analysis of interviews with policy makers involved in revalidation. They argue that the reason why revalidation policy has been so controversial is that there is a tension between the purpose of “catching bad doctors” and seeing revalidation as an aspect of professionalism. Although revalidation is meant to protect the public, patients are not actively involved in the process. The authors recommend “genuine patient participation (...) not only in feedback to individual doctors but also in actively shaping the policy and the process” (Archer et al. 2015: 92). In the same interviews as reported by Archer et al. (2015), participants were asked to create

drawings of the revalidation process. Guillemin et al. (2014) report that very few of the drawings included patients or doctors, which further supports the idea that patients are not involved in the process.

In the UK, as part of the revalidation process, GPs are required to explore general patient experience. Roland et al. (2013) tested a new patient questionnaire (the General Practice Assessment Questionnaire (GPAQ-R)) and found it to meet the GMC's requirements for surveys to be used in revalidation of doctors and NHS requirements. The survey potentially reduces the number of surveys that GPs need to issue in their practice.

Bryce et al. (2018) examined the role of responsible officers (ROs), doctors involved in the decisions about revalidation of other doctors. They found that this group has formed a new governance elite within the medical profession. They conclude that ROs are focused on monitoring other doctors' fitness to practise, "seemingly expanding professional regulation into the organisational sphere" rather than defending professional autonomy (Bryce et al. 2018: 104).

A particular issue related to dual registrations was raised by the introduction in Australia of the Health Legislation Amendment Act in 2010, establishing the Australian Health Practitioner Regulatory Agency (AHPRA) and creating two separate registers for nurses and midwives. In a longitudinal study, Gray et al. studied the reaction of midwives to the changes introduced by the 2010 legislation. In the 2014 paper, they focus on the decisions that registered midwives were making about their CPD, re-registration and practice context (Gray et al. 2014). They found that midwives' approach to CPD influenced their decision of maintaining dual registrations or reverting to single registrations. They found that participants were motivated to undertake specific types of CPD (and hence qualify for revalidation) because of their personal connections with patients and peers. More recently, Gray (2019) found that most midwives still maintain dual registrations, which makes the revalidation process more complicated.

In a paper published in 2016, Gray et al. focused on the midwife role and found that there is misalignment between the 2010 legislation and ideal practice for midwives. For example, midwives wanted to be with their patients for the whole 'birth continuum', but new regulations encourage midwives to specialise in one stage (pregnancy, birth, or puerperium) which makes it difficult for some to attend births, which were seen as the key event for midwives.

Summary points

- Registration and revalidation processes can be ‘controversial’. Studies highlight flaws in registration procedures (such as excessive bureaucracy, gatekeepers hindering the process) and inconsistencies (as in the Australian case for midwives).
- Social relationships play a role in the different processes: from gatekeepers hindering processes, to midwives choosing options based on their patients and peers.
- To avoid unfairness and bias in licensure exams, studies recommend including stakeholders in the design of exams so that they are appropriate and sensitive to different contexts (McGillis Hall et al. 2018).
- However, studies on revalidation underline the lack of involvement or reference to patients in the development of the process (Guillemin 2014, Archer et al. 2015).

5.6 Relations with regulatory body

5.6.1 Summary information on the papers in this section

We reviewed 14 papers in relation to this theme. In Tables 37 to 40 we provide information on the country, study group, year of publication and methods used.

Table 37: Country location of the papers

Country	n
Canada	6
UK	4
Australia	2
Norway	1
Europe (9 countries)	1
Total	14

Although the majority of the papers we considered for this section were from Canada, several from the UK were included, as well as two from Australia (see Table 37). As is clear from Table 38, several papers do not have a focus on a single regulated group. Of those that do, the majority in this set focused on nurses/midwives (Table 38).

Table 38: The professional groups that were the subjects of the papers

Professional Group	n
Nurses/Midwives	4
Doctors	2
Social Workers	1
Osteopaths	1
Multi-professional	
- nurses and doctors	
- health related regulated professions (2)	
- doctors, nurses and allied health professionals	4
Other (naturopathy & Western herbal medicine; registered massage therapists)	2
Total	14

The papers reviewed for this section were distributed across the period 2011 to 2019 (Table 39).

Table 39: Year of publication

Year	n
2019	3
2017	1
2015	2
2014	2
2013	3
2012	1
2011	2
Total	14

An overview of the types of data used in the studies we reviewed is given in Table 40. Four papers include no analysis of data. Of the others, most were interview based studies or used mixed methods.

Table 40: Study type

Study type	n
Mixed methods	4
Interviews	4
Questionnaire survey	2
Document analysis (inc historical, political)	4
Total	14

5.6.2 Evidence synthesis

In this section we report evidence from papers that include some reference to relations with the regulatory body. Usually these studies concern the relationship between the regulator and the registrants (sometimes referred to as members), but we also include papers concerned with the relationship between the regulator and the public, with government and with other institutions (for example, academic institutions). Given the reference to regulator relationship with the public, there is an overlap between this section and others.

Although some of the papers we cite draw attention to difficulties in the relationship between regulator and registrants, that needs to be understood in the wider context of an appreciation of the importance of regulation. Baumann et al. (2014,) in an interview-based study of nurse and medical chief executives of regulators from provinces in Canada, sought to explore how regulatory bodies understand accountability to their stakeholders. Although there appeared to be no agreed definition of accountability, the respondents (n=22) agreed that as regulators (known as Colleges) they were accountable to the public, government and their members. Although this function was recognised as fundamental to their role, they felt that the public had little understanding of their function and that some of their members, notably younger registrants, believed that the College represented the unsupportive “the dark side.” The respondents thought that their members needed to understand that the regulators “support them in their practice and make their practice better” (p128).

A sense of mistrust of the regulator (the College of Registered Nurses of British Columbia) was reported by Bungay & Stevenson (2013) in another Canadian interview-based study with nurse leaders from diverse regions in British Columbia. This mistrust was one of a number of factors that lead to policy implementation challenges (reported below). In another study (Weir 2017), which explored the influence of the NMC on the practice of midwives, although participants were supportive of the need for regulation the regulator was described as “remote” and “punitive”. Data in this research were collected from interviews (n=20) and an online survey (n=132) of UK midwives. Clearly the relationship the NMC was “uneasy” for some who “claimed to practise defensively, due to a fear that they could be removed from the register”. To address this, participants thought that the regulator should develop a better understanding of the midwife role.

Despite these challenging perceptions, there is a clear indication that registrants value regulation. One indication of this is from reports of studies of professions not yet regulated. Naturopathy and Western herbal medicine (WHM) is not regulated in Australia. Data from an online survey of naturopaths and WHM practitioners (n=479 replies) showed most in favour of regulation; 85% strongly agreed or agreed that practitioners should be formally registered to safeguard the public, and most open comments described the benefits of registration (increased public safety, enhanced standards of practice) (Braun et al. 2013). In Canada, massage therapists are registered in some provinces but are challenged by unregulated 'bodyworkers' and are in 'identity crisis' (Shroff & Sahota 2013). From their interview-based study of representatives from manual therapies (MT), colleges in British Columbia and public and private health insurers (n=28), the authors argue that establishing more of a research basis and degree status for practitioners would be welcome. The need to strengthen research partnerships (including between regulators and academic centres) was one finding from a survey-based study of the feasibility of implementing recommendations for emergency medical services research in Canada (Jensen et al. 2015)

Detailing the history of social work development and education in the UK, Welbourne (2011) notes how the "poor state" of social work regulation has been addressed. However, the authors suggest that the reforms have created other difficulties which Welbourne argues have arisen from policy reform driven by government rather than reflecting the values and ethos of social work.

A number of papers draw attention to the need for regulation reform, primarily arising from inconsistent practice across regulators and across regions or countries, which have potential implications for patient safety and harm prevention. In a recent detailed analysis, Oikonomou et al. (2019) mapped the patient safety regulatory landscape in the NHS. From their systematic review of publicly available documents, the websites of all regulatory agencies and through discussion with NHS regulatory compliance teams, the authors found variability, overlap and a lack of a coordinated approach. The complex regulatory landscape included regulators of services (e.g. the Care Quality Commission (CQC)), statutory regulators (e.g. the GMC) as well as organisations with what they describe as regulator influence (e.g. Royal Colleges). They note that "a number of organisations and commentators have called for reform, proposing that the regulatory system needs to be simpler, organised around a common approach to regulation and less burdensome for providers" and reference the work of Edwards (2016) and the PSA (2015) (p1). Although the statutory regulators have "common set of functions yet there are differences in legislation, standards, approach and efficiency" (p2).

Regulatory inconsistencies were reported in a cross European study. Risso-Gill et al. (2014) worked with the GMC to develop a set of professionalism vignettes which they used to explore what action medical regulatory bodies in nine European countries would recommend. The vignettes presented quality and patient safety scenarios, including out of date practice, surgical errors, sexually inappropriate behaviour, and abuse of colleagues. The scenarios included information on the duration and seriousness of the behaviour and the doctor's response. The responses of the participants from the regulators varied considerably: some were punitive where others took a more holistic

view of the doctor's performance. The authors conclude that lack of consistency has implications for workforce mobility, patient safety and quality of care.

A report by Lemmens & Ghimire (2019) details the regulation of health professionals in Ontario, drawing attention to the role of the regulatory colleges and the Ministry of Health in defining scope of practice, disciplinary and appeal procedures. Although the authors indicate that the "state imposed" scope of practice was developed in an "exemplary inclusive and deliberative process involving all the different health professions", they also reveal inadequacies and conclude:

"Although there are efforts to streamline the process, severe coordination problems occur as various health-professional colleges are in charge of investigations and disciplining health professionals. At a time when ...there is an increased emphasis on collaboration among the various health professions, a model that reflects ...insulated health professions, with clearly delineated professional roles ...appears outdated" (p155-6).

They point to tensions arising from professional self-interest and power relations in a system where the medical profession still dominates. Self-interest and power-relations are seen as potentially impacting on quality control.

Healthcare hierarchy was reported as an issue in a discussion paper by Harvey et al. (2011) who examined the effects of the streamlining of regulation in Australia in 2010 for nurse practitioners. Nursing & midwifery is one of 10 (at the time of the study) health professions (medical, chiropractic, dental, physiotherapy, optometry, osteopathy, pharmacy, podiatry, psychology) regulated by one national authority – the Australian Health Practitioner Regulation Agency. The authors argue that although the new legislation rationalised regulation, it did nothing to shift the medical hierarchy and the result is that how nurse practitioners are 'endorsed' remains "complex and exhaustive...entwined in legislation that has used the medical script to describe nursing practice that no longer fits with traditional nursing definitions" (p2481).

The scale of the regulatory reforms in Australia is remarkable. What is also reported in the literature is the different barriers to policy implementation. A number of these are identified by Bungay & Stevenson (2013; see above) who refer to 'relentless revisions' to the Nurses (Registered) and Nurse Practitioners Regulation, as well as a disconnect between "policies affecting health service delivery and real-time practice" (p73) and limited support for "nurses to have the professional development time to undertake the certified practice education while simultaneously maintaining... services" (p75).

Lessons to learn for future regulatory policy implementation include consultation between the profession and the regulator, greater awareness of the "important contextual factors regarding competing job demands and resultant human resource and workforce issues" (p75), and better understanding of "contrasting and competing demands of the health systems and regulatory organizations" (p76).

Consultation or engagement with staff was suggested as one part of the means of addressing implementation challenges around improving the quality of care for nursing

home residents in Norway (Marie Sandvoll et al. 2012). The ethnography revealed that the staff from the two study care homes knew little about the new quality regulations, and that it is challenging to change “everyday action and thinking”. In this study, although the staff met the new requirements unwittingly, the authors conclude that “it is naive to expect regulations alone to be an effective instrument driving change”. What is needed, they argue, is better engagement with staff, alongside understanding the “importance of existing routines” and gaining a “critical mass of change champions”.

Another study from Ontario, Canada, this time focused on interprofessional collaboration (IPC), also reveals implementation challenges. Regan et al. (2015) analysed college documents pertaining to IPC (n = 355) and interviewed representatives from 14 colleges. They found “no evidence... of joint standards between colleges” and although participants “discussed the importance of IPC for professional practice and examples of key attributes of IPC were found in the documents, there was little discussion of what constitutes collaboration within a regulatory context” (p3). The barriers to IPC they identified included protection of scope of practice ‘turf’, conflicting legislation, and lack of knowledge of other health professionals’ roles. One conclusion is that IPC cannot be mandated.

One paper from the UK was of particular interest because it originated from a team of researchers employed by the General Osteopathic Council, which funded the study jointly with the General Dental Council (Browne, Bettles, Clift & Walker 2019). The authors reported a novel series of workshops involving approximately 80 participants (including patients, practitioners, representatives of other regulators, and the academic and research community), which explored and identified practitioner and patient values and the subsequent development of approaches and tools aimed at increasing awareness and understanding of values-based practice. This is the start of a programme of research in which resources for both patients and practitioners will be developed and evaluated to enable each to articulate more effectively what is important to them in a consultation. The paper represents an interesting shift in focus by a regulator, which has created an intervention aimed at engaging regulator, patients and practitioners simultaneously in a single programme. The aim of the programme is not simply to disseminate and embed regulatory changes to the *Osteopathic Practice Standards* (2019) but a much broader and more ambitious attempt to bring about measurable and lasting changes in how osteopaths and their patients interact during consultations.

Summary points

- Despite some relationship difficulties, the broader context is of an appreciation of the importance of regulation and benefits (in terms of public safety and enhanced standards of practice).
- Negative feelings of the registrant towards the regulator included the regulator being perceived as remote, mistrusted, punitive and unsupportive, resulting in some professionals practising defensively. Evidence of inconsistent practice across regulators and across regions or countries can exacerbate negative responses and present implications for workforce mobility, patient safety and quality of care.
- The need for regulatory reform is indicated in a number of these papers. Calls are made for a less burdensome, simpler, more standardised approach to regulation and greater inter-regulator collaboration. However, in developing more common approaches, some warn against the dominance of the medical profession.
- Challenges to implementing reform are noted and authors argue for greater consultation and engagement with practitioners.

5.7 Harm prevention and patient safety

In this sub-group are papers addressing the topic of risk management and policies, for the protection of professionals and patients, as well as papers on assessment procedures and policies about the quality of care. In total, we reviewed eight papers. All of them included some data analysis. The small number of papers might be the result of the difficulty of isolating this theme from other larger themes, such as fitness to practise.

5.7.1 Summary information on the papers in this section

In Tables 41 to 44 we provide information on the country, study group, year of publication and methods used. Six of the eight papers reviewed were from the UK (see Table 41).

Table 41: Country location of the papers

Country	n
UK	6
Australia	1
Canada	1
Total	8

Only four papers specifically address a professional group: either doctors/clinicians (Chatburn et al. 2018, Woodcock et al. 2019), pharmacists (Ziaiei 2018) and nurses (Beardwood and Keiner 2015) (see Table 42).

Table 42: The professional groups that were the subjects of the papers

Professional Group	n
Clinicians	2
Nurses	1
Pharmacists	1
Total	4

Half of the papers (n=4) were published recently, from 2018 onwards (Table 43).

Table 43: Year of publication

Year	n
2019	1
2018	3
2017	1
2016	1
2015	1
2012	1
Total	8

The studies in this set tended to either be based on interviews or used mixed methods (Table 44).

Table 44: Study type

Study type	n
Interviews	4
Mixed methods	3
Secondary data analysis - quantitative	1
Total	8

5.7.2 Evidence synthesis

The evidence in this section is reported in two main sections. In the first, we report papers concerned with quality of care and its assessment of measurement. In the second, we consider issues related to the improvement of compliance. In a final section we draw attention to language proficiency though the inclusion of a paper on the topic because of its implicit implications for patient safety.

5.7.2.1 Assessing care quality

A number of papers concerned with safety discuss the issue of measures and assessments of care quality. Some studies are linked to programmes or funded by the Health Foundation or by the CQC. They describe issues arising from the lack of expertise of those using the assessments or from the poor understanding of key concepts when implementing patient safety programmes.

Woodcock et al. (2019) studied challenges faced by clinical teams in undertaking measurement in the context of the Safer Clinical Systems improvement programme. They found that measurement is a highly technical task requiring a degree of expertise and teams without that expertise experience difficulties. They recommend that local clinical teams are better supported, for example by granting them access to repositories of validated measures. They also recommend that the measurements used in reports are made more transparent (Woodcock et al. 2019).

In another study funded by the Health Foundation, Chatburn et al. (2018) assessed the impact of the Measurement and Monitoring of Safety Framework. Their findings highlight the positive impact of the Framework, reporting that participants appreciated sharing a common language, and a more “inquisitive and holistic approach to safety” (Chatburn et al. 2018: 821). However, they also noticed that conceptual changes did not automatically translate in safety practices. They found that the best results were achieved when leaders understood changes at the conceptual level and hence, they recommend also allowing staff adequate time (Chatburn et al. 2018).

Focussing on the NHS in England, Beaussier et al. (2016) examined why risk-based policy instruments fail to improve the proportionality, effectiveness, and legitimacy of healthcare quality regulation. In particular, the authors describe preconditions for successful risk-based regulation: goals must be clear but flexible. Regulators must be able to assess adverse outcomes and to deploy tools in proportion to risk, together with a general “political tolerance for adverse outcomes” (Beaussier et al. 2016: 207).

Griffiths et al. (2017) addressed an issue connected to the rise in cuts to health and social care, i.e. the use of statistical software tools to assess quality risks in hospitals. In the study they evaluated the reliability of the CQC’s tool, called Intelligent Monitoring (IM), in checking which hospitals should be prioritized for inspection. In their findings, the IM tool failed three statistical tests and could not predict the outcome of NHS hospital trust inspections. They conclude that since the IM statistical surveillance tool cannot be used as a way to decide the prioritization of inspection for the assessment of quality of care, it is necessary to develop a new approach (Griffiths et al. 2017).

Boyd et al. (2018) evaluated a new regulatory model for acute hospitals in England, implemented by the CQC. The purpose of their study was to understand the functioning and challenges of inspection teams conducting surveys in hospitals. The study highlighted some tensions between inspectors, healthcare professionals, people and data analysts. It concluded, however, that stable committed teams have fewer issues than temporary, heterogeneous ones (Boyd, et al. 2018).

5.7.2.2 Risk and protocol compliance

Professional risk is understood differently by regulators, unions, professional associations and frontline nurses. In a study of risk in professional nursing practice, Beardwood and Kainer (2015) focused on professional risk, in particular the implications for nurses violating nursing practice standards. The study examined the views of three professional nursing bodies on the professional codes governing the right of nurses to refuse dangerous work, using as a case study the 2003 SARS flu epidemic in Ontario, Canada. They concluded that the case of frontline nurses is a typical example of individualisation of risk. In order to follow professional protocols prioritising patient care and professional responsibility, nurses were asked to ignore systemic, unpredictable and dangerous circumstances affecting them. The authors state that guidelines and codes of conduct do not address these types of situation and could serve to complicate the issue. The authors conclude by stressing that employers and governments have a responsibility to create a safe work environment for nurses.

Using a qualitative research design and 'responsive regulation' theory, Healy (2012) analysed the strategies used by hospital leaders to improve compliance with the five steps protocol defined by the Australian Health Ministers in 2004: "ensuring correct patient, correct site and correct procedure protocol" (Healy 2012: 88). The study showed that hospital leaders managed to reduce non-compliance by moving between 'soft' interventions (persuasion, training, reminders, rewards) and sanctions, concluding that a nuanced multi-pronged approach is the most effective in promoting compliance.

5.7.2.3 Language proficiency

The inability of some healthcare practitioners to communicate clearly and sensitively with patients can negatively impact on patient safety. Ziaei et al. (2018) explored employer views of the communicative proficiency of Internationally Trained Pharmacists (ITPs) whose first language was not English. They found that currently, there is no one standard procedure in place to check the communicative competence of European Economic Area (EEA) pharmacists. The findings from this study suggest that there is a need to establish a uniform assessment system so all the EEA pharmacists could be tested consistently and fairly (Ziaei et al. 2018).

Summary points

- The assessment and measurement of quality of care have conceptual and practical aspects that need to be taken into account. Time, training and sharing data from previous assessments appear to be aspects that support the effectiveness of solutions.
- Flexibility, and tolerance seem to be the useful strategies for leaders in managing risks and achieving compliance. Flexibility is also an important element for the risk management and safety of professionals.
- Inspections create tensions. Findings highlight that 'economically efficient' solutions such as statistical tools, do not always deliver the best results. Stable, committed teams of inspectors operate better and with less conflict than short term, ad hoc teams.
- A common system of language assessment may enhance patient safety.

Part 6 – Key Findings and Conclusions

6.1 Limitations and challenges

This project was carried out over a period of 12 weeks between January and March 2020. Two months is usually seen as the shortest possible time in which to carry out a review of academic literature and this informed our decision to undertake a rapid evidence assessment rather than the more traditional systematic review. Rapid evidence assessments have a different focus from systematic reviews: their aim is to provide interpretation and critique and to deepen understanding rather than to address narrowly focussed questions by summarising data according to a pre-set protocol (Greenhalgh, Thorne & Malterud 2018).

Rapid evidence assessments are not less demanding than systematic reviews. The openness of the research aims, combined with the need to include large numbers of professional groups, the international scope and the need to search back to the start of 2011 led to an enormous number of initial results. As an example, a relatively simple search for papers combining professional regulation and nursing produced hundreds of thousands of titles. This was partially mitigated by a detailed and comprehensive specialist-designed search strategy to ensure focus. Even following the application of targeted search strings, the numbers of papers retrieved was extremely high, leading to potential false positive and negative results. The challenges created by the size and scope of the results were mitigated by a detailed four-stage screening process that we developed as a team to improve the likelihood that only the highest quality, most relevant papers would be selected for analysis. To ensure that lower-quality papers of less relevance that were beyond the scope of this study were not completely excluded, we set these to one side for future research, should that be required.

One unanticipated challenge that we faced was that the study of the regulation of professionals in health and care does not yet have a strong and well-defined identity as an academic discipline/field of academic study. This means that the places where research in regulation was to be found were wide-ranging and diverse, suggesting that scholars in health professions regulation may struggle to find publication opportunities. There are some general journals on regulation but on examination their content is primarily law and finance based. We located only one peer-reviewed journal with a specific focus on the regulation of health and care professions, *Journal of Nursing Regulation*, and that was uni-professional and US-focused (National Council of State Boards of Nursing, 2020). This lack of a clearly recognisable locus for the publication of research in the field is in sharp contrast to other areas of professional regulation such as risk regulation, aviation, banking, digital technology, finance, gambling and law.

The challenges we encountered in the search for relevant literature were reflected in the data from the interviews, annual reports and the included studies. There was a strong sense of health and care professional regulation studies as an extensive and important area of activity and practice that, as yet, lacks the status of an identifiable field of academic practice, and as a result the published evidence is diffuse and difficult to locate and interpret.

We uncovered many factors that impact on the ways in which data are generated, collated, analysed, synthesised and disseminated and these are discussed in the next section.

6.2 The nature of the research challenges in health and care professional regulation studies

Regulators and professional bodies need high quality research on which to base their decisions. Quick (2011) in an earlier study commissioned by the PSA outlined the difficulties in locating high quality explanatory and data-based evidence among a large amount of descriptive and small scale work; nearly ten years later we find that the position has not changed. We discuss some of the possible reasons for this.

6.2.1 Regulators' resources for evidence-based policy development

While some of the very large regulators we spoke to have considerable staff resources available to apply to research, the majority told us that their 'research' and 'policy' teams (various titles were used but these were the most common) were very small – as few as one or two people in some cases. Some research and policy teams were undertaking additional duties such as project management, strategy development and stakeholder engagement activities, with research often receiving less priority than service delivery.

Most of our interviewees reported that they were actively gathering large amounts of routine data. The primary responsibility of the regulators' research and policy teams was to collect and collate basic data on their members, usually in the form of routine annual electronic membership surveys, surveys of trainees and trainers, and occasionally surveys to explore service user and stakeholder attitudes and awareness of regulatory issues within the profession. All regulators collected data on fitness to practise statistics. The implications of this for research are inevitable; that those things which may be measured most expeditiously are most likely to be reported; but analysis of these is unlikely to bring about transformational changes (Panzer et al. 2013), and a number of our interviewees acknowledged this as a challenge.

The degree to which each regulator was able to apply additional staff resource towards examining other issues of interest (such as the performance of ethnic minority groups, the challenges posed by fitness to practise processes, the extent to which practitioner behaviour is governed by regulatory factors etc) was variable; but most regulators we spoke to regretted that they were unable to do more than their current resources permitted. One respondent told us that while they had good datasets from their routine collections, they were unable to analyse them in as much depth as they would like. In particular, analysing trends and achieving historical comparisons presented logistical challenges for which they did not have resources. For some, it also raised data quality issues.

A complicating factor for research into regulation of health and care professionals is the nature of the data; some data – especially around professional lapses or vulnerable groups - are highly sensitive. While some regulators may be wary of releasing such data

to external research teams, there are likely to be concerns about performing such analyses themselves. This exacerbates the difficulty of making decisions on whether to commission research and if so, how to go about it (see section 6.2.3 below).

A promising response to these challenges is the recent rise in collaborative studies between and among regulators, where one regulator shares data with another to achieve a larger dataset, or where two or more regulators combine to commission external research (GMC 2017). This is discussed further below.

6.2.2 Regulators' in-house work

Despite the resource challenges discussed in 6.2.1 above, there is an impressive amount of policy development and routine data reporting being carried out. Every regulator was active in producing, not only the standard reports required by law such as annual reports and accounts, but additional documents containing advice and guidance for practitioners and the public. Many of these were statements of fundamental principles for professional practice, against which an individual's fitness to practise or continued licensure would be assessed (see, for example General Medical Council 2013, Nursing and Midwifery Council 2018). One would not expect that these publications would cite research literature to support these essential declarations, which are a public expression of the collective contract that a profession has with those it serves (Browne, forthcoming 2021). However, we found examples of additional guidance or information which, although of high quality, could have been more effectively presented as credible, evidence-based scholarly reports if they had contained a clear statement of authorship, acknowledgements, review processes and, where applicable, funding and commissioning details, supporting references and citation information.

Research papers in the peer-reviewed literature with regulators as authors were extremely rare, and although individual authors employed by regulators might be publishing work based on research and evaluation done in the course of their day-to-day work, we found scant evidence to suggest that this was common practice. Moreover, although some individuals we spoke to were knowledgeable about the evidence base in regulation of health and care professionals, and all could name key reports and policy statements within their field, most did not refer us to any reliable sources of published research evidence in the academic literature. When we asked for the basis on which policy decisions were made, the answers we received suggested that many regulators are basing their research and policy decisions on feedback from their members and through strategic agendas set by their governing bodies and councils; few reported that published evidence played a strong part in how these decisions were made. This is unsurprising in view of the demanding workloads of those we spoke to and their teams; but the advancement of scholarly, evidence-based approaches to the setting of research and policy agendas is an area for continuing staff development.

6.2.3 Commissioned work

The great majority of the research literature we explored had not been grant-funded either by funding bodies or by the regulators themselves. This finding was not unexpected. The regulators we interviewed had already spoken of their difficulties in

finding additional research moneys, and where additional resource was available, they had usually chosen to increase internal capacity. Despite this, many regulators were commissioning external research, and those that did not aspired to be involved in such projects.

More than one interviewee mentioned that a significant challenge for commissioning work externally was that it was sometimes difficult to know whom to approach to undertake a research project. Again, this reflects the lack of a widely established academic presence for research into *health and care* professional regulation (as opposed to financial and legal governance of healthcare). Consequently, although research teams and individuals are likely to be willing to undertake research contracts if they are aware of them, advertising tendering opportunities, compiling and costing a research brief, targeting scholars in the most appropriate field, and identifying the highest-quality and most cost-effective tenders all presented challenges for some of the smaller regulators.

It is known that funded work tends to be of higher quality than articles and papers that are not supported by funding (Reed et al 2007). Indeed, many of the reports commissioned by regulators from external research providers were of high quality. They were usually published on the commissioning regulator's website, and it appeared rare for such reports to be written up as research papers and published in the peer reviewed literature.

6.2.4 Independent work by academics/clinicians

In the light of points 6.2.1 to 6.2.3 above we conclude that the great majority of the papers we retrieved were neither funded nor commissioned by regulators, nor were they produced within academic departments of health and care professions regulation. The consequences of these factors meant that such work tended to be small-scale, local, uni-professional and usually of low generalisability to other settings or professions. It often appeared to be the product of individual postgraduate research projects or, where it originated from higher education institutions or clinical departments, arose from quality assurance processes.

As we noted in our discussion of the literature, there was also a sizeable quantity of largely un-funded work that had been undertaken with a clear agenda – for example, to advocate for the registration of unregistered groups, to point to areas of regulation that were deemed unsatisfactory, or to demonstrate the success (or lack of success) of a regulatory initiative. While we made efforts to exclude purely opinion pieces such as editorials, commentaries and letters to the editor, we did not exclude all discussion papers because these sometimes provided a learned perspective available on a topic.

The methods used, where these were described, were mainly survey, focus group or interview. If quantitative data were present it was rare for the researchers to have collected these themselves; most papers containing quantitative data relied upon the analysis of previously collected data, such as numbers of complaints to regulators, numbers of disciplinary cases, licensure exam results and so on. Experimental studies were infrequent. A small group of papers were desk-based studies – reviews and

document analysis. Qualitative studies tended to focus on participants' perceptions or attitudes towards regulation.

Most studies were therefore positivist in their epistemology, involving the study, categorisation and description of existing phenomena. Few of the papers we studied achieved the level of exploring whether the effects of regulation had any impact (either on the behaviour of the regulated professional or on their patients or clients), and still fewer were able to show the mechanisms by which regulation actually impacted patient or client care.

In 2008, Cook, Bordage and Schmidt (2008), analysing a random sample of 110 studies in the field of medical education, categorised them as description ('what was done?'), justification ('did it work?') or clarification ('why or how did it work?') and found that the majority of papers (83%) were simple descriptive studies. Around 16% of the papers they analysed asked 'did it work?' while only 12% of studies aimed at the highest level of analysis, asking 'how?' or 'why?' questions. By dint of careful selection and targeted searches we ensured that around half of the papers we studied were descriptive with the remaining half (those showing impact) primarily reporting on justification questions (basic assessments of whether something worked) with only a small number asking clarification questions. Nevertheless, as with educational studies, regulation studies face a difficult task - to show, not just the effect of an intervention on the immediate recipient (student or regulated professional), but also the secondary effect on the patient or public.

This latter point is important because when we divided the papers we selected for final consideration into themes, it will be recalled that papers addressing patient safety and harm prevention comprised the smallest group. Moreover, the analysis of the regulators' own reports indicated that fitness to practise, maintenance of the registers and standard setting were the most frequently mentioned themes. Yet when we spoke to representatives from the regulators, their chief concern appeared to be the far more difficult-to-address 'upstream' questions - of how and why regulation can and does work to support good professional practice and safeguard patients, clients and the public.

The challenge for the regulators is that while many of the tens of thousands of published papers in the field of regulation in the last decade are of good or high quality, our search has shown that the great majority are of only tangential relevance to the regulators and the bulk of the work does not address their primary concerns. Of those that are relevant, a majority report or describe what is already happening, with few able to show effect or demonstrate how or why those effects are occurring. Regulators in health and social care need to be able to leverage the scholarly literature more effectively to inform their research and policy agendas.

6.3 Opportunities

Seven of the regulators we spoke to told us that they were already actively collaborating with other regulators to conduct or commission research work; the remainder all indicated that they would like to do this. For most this appeared to be a relatively recent innovation and reflected more general recognition of the regulators' shared agendas combined with the increased interprofessional and team-based work their registrants perform.

In the age of electronic communication, it is easier than ever to gather very large datasets. The larger regulators have hundreds of thousands of registrants and none we spoke to had fewer than a thousand. The ability to collect, store and analyse personal, educational and performance related data from members quickly and securely has offered great opportunities to regulators to advance and monitor their work, and to use those data to help them develop strategy and policy in areas where their evidence shows that action needs to be taken. There is now a further opportunity for some regulators to build on their successes by reflecting on their scholarly research outputs, refining their lines of enquiry to include more clarification questions, exploring the opportunities of collaboration to produce sustained programmes, and finally communicating their results, not just through their own websites but more widely in the peer-reviewed literature.

One clear conclusion emerged from our work; health and social care professional regulation studies is rapidly emerging as a new field but as yet it is still relatively amorphous compared with, for example, financial, legal or aviation regulation studies. The health and social care professional regulators have an opportunity to work together both to define and to set an agenda for this new field by engaging with the peer reviewed literature, developing and enhancing the skills of their policy and research teams around academic practice, and ensuring that as commissioners and consumers of research in health and care professions regulation they are seen to be demanding evidence of the highest possible quality on which to base their activities.

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Appendices

Appendix 1 – Information Sheet

Research in professional regulation

PARTICIPANT INFORMATION SHEET

You are invited to take part in a study of research in professional regulation in the UK. Before you decide whether to take part, please read the following information carefully. If you have any questions, please contact Alison Bullock or Julie Browne whose contact details are provided at the end.

What is the purpose of the research?

Our aim is to source studies in the area of health and care professional regulation since 2011, to evaluate the research and to draw out what it has taught us. We will identify areas that would benefit from deeper exploration in order to inform the focus of further research and continue to build the evidence base in relation to health and care professional regulation.

Much of this study is desk-based literature searching and review. However, we are seeking interviews with a policy lead in each of the regulators that the PSA oversees. These interviews will provide value perspectives on current issues and developments and help us to check that we are identifying relevant documentation to include in the review.

Who is organising and funding this research?

The study is commissioned and funded by the Professional Standards Authority (PSA). It is co-led by Professor Alison Bullock, School of Social Sciences and Mrs Julie Browne, School of Medicine, both at Cardiff University.

Why have I been invited to take part in the study?

You have been invited to participate due to your role with a regulator and your knowledge of the regulator's interest in research in professional regulation.

Do I have to take part in the study?

No, your participation is entirely voluntary. If you *do* decide to participate in the study, we will ask you to sign a consent form. You will be free to withdraw from participation at any time, without giving reason and any data previously collected from you will not be included in the study.

What will taking part involve?

Taking part in the study will involve participating in a telephone interview where you will be asked about your organisation's engagement with and contribution to research in the area of professional regulation alongside your perspectives on current issues and development in professional regulation. You are not expected to provide any information or opinion which you do not feel comfortable sharing. You should not share information that might breach your confidentiality agreement with the PSA. Before giving consent, we will ask you to take note of the additional consent requirements as set out by the PSA.

We would also be interested in receiving your suggestions of evidence - other than published literature - which may be relevant.

Should you provide permission freely, the interview discussion will be recorded for later transcription at which point all data will be anonymised.

Will I be paid anything for taking part?

No, there are no payments for taking part in this study.

What are the possible benefits of taking part?

Your participation in this study will involve sharing your views on the research base in professional regulation. Although there are no direct benefits to you as a result of your participation, we anticipate that this study will assist the PSA to inform Government policy-making and to share learning with regulators, registrants and others involved in the assurance of patient safety.

If you decide you *do not* wish to participate, you do not have to provide a reason.

The only personally identifiable data collected from you and retained will be your consent form (should you provide it), which will include your name and signature. This information is collected only so we know who has consented to participate in the study. All information provided by you will be anonymous and will not be matched to the information in your consent form. Any personal information you provide will be managed in accordance with data protection legislation. Your consent form will be retained in accordance with Cardiff University research ethics requirements and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised data will be kept for a minimum of 5 years, or at least 2 years post-publication. Although this research study is funded by the PSA, raw data will not be shared with them unless it breaches their confidentiality requirements.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. The University Data Protection Officer can be contacted at inforequest@cardiff.ac.uk. Further information about Data Protection can be found at: <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>. In providing data for this research, we will process it on the basis that it is part of our public task as a university established to advance knowledge and education through its teaching and research activities.

What will happen to the results of the study?

The principal output of the study will be a report documenting findings about research in the field of health and care professional regulation. This report will be shared with the PSA. It is also our intention to report the results in academic journals and at relevant conferences. All data will remain anonymous and participants will not be personally identified in any report, publication or presentation.

What if there is a problem?

Research team members, Alison Bullock and Julie Browne, will be available to answer any questions or queries regarding any aspects of the research study. If you wish to complain or have concerns about the way you have been approached or treated during the course of this study, please contact the research ethics committee at socsi-ethics@cardiff.ac.uk.

Who has reviewed this study?

This study has been reviewed and given a favourable opinion by the School of Social Sciences' Research Ethics Committee at Cardiff University.

What are the possible risks of taking part?

The only foreseeable potential risk of participation in this study is some discomfort you may feel in sharing your views on current research in professional regulation. It is not our intent to cause discomfort and you are encouraged to only contribute opinions you feel comfortable sharing.

Will my taking part in this study be kept confidential?

All data that you provide in the interview will be anonymised on transcription. Data collected from you during the study will be kept strictly confidential but please take note of the consent requirements as set out by the PSA.

What will happen to my personal data?

Should you have any questions or queries relating to this study, please contact:

Alison Bullock Telephone: 02920 870780 Email: bullockad@cardiff.ac.uk
Cardiff University School of Social Sciences, 12 Museum Place, Cardiff, CF10 3BG

Julie Browne Telephone: 029206 87901 Email: BrowneJ1@cardiff.ac.uk
Cardiff University School of Medicine, Neuadd Meirionnydd, Heath Park, CF14 4YS

Thank you for considering participation in this study.

Appendix 2 – Consent Form

PARTICIPANT CONSENT FORM: Research in professional regulation

Title of study: **Research in professional regulation**

Name of Researchers: **Professor Alison Bullock and Mrs Julie Browne**

Please
initial box

I confirm that I have read and understood the Information Sheet dated 3 February Version 1 for the above study and have had the opportunity to ask questions and these have been answered satisfactorily.	
I understand that my participation is voluntary, and I am free to withdraw the study at any time without giving a reason and without any adverse consequences.	
I consent to the processing of my personal data provided in this consent form. I understand that such information will be held in accordance with all applicable data protection legislation and in strict confidence unless disclosure is required by law or professional obligation.	
I understand who will have access to the personal information I provide, how the data will be stored and what will happen to the data at the end of the project.	
I understand that the focus group discussion will be audio recorded and that anonymised excerpts and/or verbatim quotes from my focus group may be used as part of the research report.	
I understand how the findings and results of this study will be written up and disseminated.	
I give consent freely to my participation in this study.	

Name of participant (print)

Date

Signature

Name of person taking consent
(print)

Date

Signature

THANK YOU FOR PARTICIPATING IN OUR RESEARCH.

Appendix 3 – Interview Questions

Questions for general context

- Do you commission any research, or do it in-house, or both?
- How do you determine what research you do (whether commissioned or in-house)? (eg linked to annual strategic plan; other agendas that drive decisions).
- Would you say that you been doing or commissioning more or less research in recent years?

Direction of travel

- What are you currently working on?
- Do you have any on-going consultations?

- What research work have you undertaken recently? Could you describe it in terms of themes?
- What's driving your current commissioning – why these areas of research interest?

- Of the research you have undertaken in the recent past, what has been most influential / had greatest impact?

- What are you committed to do in future?
- Are there other aspects that you think need researching in future? Why these areas?

- Have you closed down any lines of research? Why?
- Is there anything else you think does not need researching at present?

Key evidence

- Are there any particular published journal articles or reports you would like to draw our attention to for possible inclusion in our review?

Appendix 4 – Documents and reports to which interviewees referred us

GMC	Recent SOMEP reports [included]
SWE	Response to consultation on standards (Shaping Standards, Enabling Change) [included]
GCC	(General) research on CPD; 2020 business plan [included]
GOsC	<p>Browne, F., et. al. (2019). “Connecting patients, practitioners, and regulators in supporting positive experiences and processes of shared decision making: A progress report”. <i>Journal of Evaluation in Clinical Practice</i> 2019: 1-11. [included]</p> <p>Gerry McGivern, Bill Fulford, Michael Concannon, Stacey Clift; National Council for Osteopathic Research website; https://www.ncor.org.uk/</p> <p>How Touch is Communicated (2019); https://www.osteopathy.org.uk/news-and-resources/news/how-touch-is-communicated-in-the-context-of-manual-therapy-new/</p> <p>Public and patient perceptions (2018); https://www.osteopathy.org.uk/news-and-resources/research-surveys/gosc-research/public-and-patient-perceptions/</p> <p>Thematic Analysis of Boundaries Education and Training (2017) https://www.osteopathy.org.uk/news-and-resources/document-library/research-and-surveys/thematic-analysis-of-boundaries-education-and-training/</p>
HCPC	People like us? Understanding complaints about paramedics and social workers (2017); https://www.hcpc-uk.org/resources/reports/2017/people-like-us-understanding-complaints-about-paramedics-and-social-workers/
NMC	<p>Research on BME representation in Fitness to Practise process (2017); https://www.nmc.org.uk/news/news-and-updates/research-on-bme-representation-in-fitness-to-practise-process/</p> <p>Evaluation of revalidation for nurses and midwives (2019) https://www.ipsos.com/ipsos-mori/en-uk/evaluation-revalidation-nurses-and-midwives-final-evaluation-report</p>
GPhC	Professor Zubin Austin of University of Toronto - https://www.pharmacy.utoronto.ca/faculty/zubin-austin
GOC	No specific recommendations
GDC	No specific recommendations
PSNI	No specific recommendations

Appendix 5 – Further Information on Search Strategy

Here is a summary of the queries performed in the different datasets:

1. Scopus (n=1081, last search 30.01)

In Scopus, following the exploratory study we developed the following query. With the help of DM, we developed a list of search terms for the in-text queries (TITLE-ABS=title and abstract), followed by a limitation based on temporal dimension, geographical, and subject areas.

1. List of professions, as in text terms search

(TITLE-ABS(orthopt* or "physical therapist" or "arts therapist" or "biomedical scientist" or "clinical scientist" or "hearing aid dispenser" or "operating department practitioner" or nurs* or optom* or dent* or midwif* or pharma* or medica* or osteopath* or chiropract* or "social work*" or chiropod* or podiatr* or dieti* or "occupational therap*" or paramedic* or physiotherap* or psycholo* or prosthet* or orthot* or radiograph* or "speech and language" or doctor* or physician* or "general practitioner*" or "welfare work*" or "health care profession*" or "healthcare profession*" or "health-care profession*" or "health and care profession*"))

2. Regulation search terms

AND ((TITLE-ABS(regulat*)))

3. List of policy terms, as in text terms search

AND ((TITLE-ABS("fitness to practi*")) or (TITLE-ABS("standard setting" OR "standards of practi*")) or (TITLE-ABS("standard setting" OR (standard* W/2 practi**))) or (TITLE-ABS("quality assurance*")) or (TITLE-ABS(regist* W/2 profession*)) or (TITLE-ABS(prevent* W/2 harm*)) or (TITLE-ABS((client* or patient*) W/2 safet*))))

AND

Geographical limitations

(LIMIT-TO (AFFILCOUNTRY,"United States") OR LIMIT-TO (AFFILCOUNTRY,"United Kingdom") OR LIMIT-TO (AFFILCOUNTRY,"Australia") OR LIMIT-TO (AFFILCOUNTRY,"Canada") OR LIMIT-TO (AFFILCOUNTRY,"Sweden") OR LIMIT-TO (AFFILCOUNTRY,"Germany") OR LIMIT-TO (AFFILCOUNTRY,"Netherlands") OR LIMIT-TO (AFFILCOUNTRY,"Norway") OR LIMIT-TO (AFFILCOUNTRY,"Switzerland") OR LIMIT-TO (AFFILCOUNTRY,"France") OR LIMIT-TO (AFFILCOUNTRY,"Ireland")) AND (LIMIT-TO (DOCTYPE,"ar") OR LIMIT-TO (DOCTYPE,"re"))

AND

Subject area limitations

(LIMIT-TO (SUBJAREA,"NURS") OR LIMIT-TO (SUBJAREA,"MEDI") OR LIMIT-TO (SUBJAREA,"SOCI") OR LIMIT-TO (SUBJAREA,"HEAL") OR LIMIT-TO (SUBJAREA,"PHAR") OR LIMIT-TO (SUBJAREA,"BUSI") OR LIMIT-TO (SUBJAREA,"PSYC") OR LIMIT-TO (SUBJAREA,"MULT") OR LIMIT-TO (SUBJAREA,"DENT"))

AND

Extra limiters:

Publication limitations: year and type and language

(LIMIT-TO (PUBYEAR,2020) OR LIMIT-TO (PUBYEAR,2019) OR LIMIT-TO (PUBYEAR,2018) OR LIMIT-TO (PUBYEAR,2017) OR LIMIT-TO (PUBYEAR,2016) OR LIMIT-TO (PUBYEAR,2015) OR LIMIT-TO (PUBYEAR,2014) OR LIMIT-TO (PUBYEAR,2013) OR LIMIT-TO (PUBYEAR,2012) OR LIMIT-TO (PUBYEAR,2011)) AND (LIMIT-TO (LANGUAGE,"English"))

The dataset reports 1081 documents, which we downloaded in RIS format.

2. Medline (n=1890 last search 30.01)

We accessed MedLine through the portal offered by Ovid. With the help of DM we developed a list of subject headings for professions, policy terms and geographical limitations applicable to this database. When possible, we expanded the subject headings to include lower levels terms.

Exp= subject heading expanded, (TI=title and AB=abstract, in search terms for in text queries)

1. List of professions, either as subject heading or in text terms search (all connected by OR)

1. exp Nurses/
2. nurs*.ti,ab.
3. exp Optometrists/
4. optom*.ti,ab.
5. exp Dentists/
6. dent*.ti,ab.
7. exp Midwifery/
8. midwif*.ti,ab.
9. exp Pharmacists/
10. pharm*.ti,ab.
11. medica*.ti,ab.
12. exp Osteopathic Physicians/
13. osteopath*.ti,ab.
14. exp Chiropractic/
15. chiropract*.ti,ab.
16. exp Social Workers/
17. social work*.ti,ab.
18. exp Podiatry/
19. chiro*.ti,ab.
20. podiatr*.ti,ab.
21. exp Nutritionists/
22. dieti*.ti,ab.
23. exp Occupational Therapists/
24. occupational therap*.ti,ab.
25. exp Allied Health Personnel/
26. paramedic*.ti,ab.
27. exp Physical Therapists/
28. physiotherap*.ti,ab.

29. exp Psychology/
30. psycholo*.ti,ab.
31. prosthet*.ti,ab.
32. orthot*.ti,ab.
33. radiograph*.ti,ab.
34. exp Speech Therapy/ or exp Language Therapy/
35. "speech and language".ti,ab.
36. exp Physicians/
37. doctor*.ti,ab.
38. physician*.ti,ab.
39. exp General Practitioners/
40. general practitioner*.ti,ab.
41. welfare work*.ti,ab.
42. exp Health Personnel/
43. health care profession*.ti,ab.
44. healthcare profession*.ti,ab.
45. orthopt*.ti,ab.
46. physical therapist*.ti,ab.
47. arts therapist*.ti,ab.
48. biomedical scientist*.ti,ab.
49. clinical scientist*.ti,ab.
50. hearing aid dispenser*.ti,ab.
51. operating department practitioner*.ti,ab.

AND

2. Regulation search terms(all connected by OR)

53. Social Control, Formal/
54. regulat*.ti,ab.

AND

3. List of policy terms, either as subject heading or in text terms search (all connected by OR)

56. fitness to practi*.ti,ab.
57. standard setting.ti,ab.
58. standards of practi*.ti,ab.
59. (standard* adj2 practi*).ti,ab.
60. exp Quality Assurance, Health Care/
61. quality assurance*.ti,ab.
62. (regist* adj2 profession*).ti,ab.
63. (prevent* adj2 harm*).ti,ab.
64. ((client* or patient*) adj2 safet*).ti,ab.
65. exp Patient Safety/

AND

Geographical limitations (all connected by OR)

69. exp United Kingdom/

70. united kingdom.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
71. uk.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
72. (england or english).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
73. (wales or welsh).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
74. (scotland or scottish).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
75. (irish or ireland).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
76. exp United States/
77. (united states or US or USA or america*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
78. exp Australia/
79. australia*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
80. exp Canada/
81. canada*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
82. exp Sweden/
83. (sweden or swedish).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
84. exp Germany/
85. german*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
86. exp Netherlands/
87. (netherland* or holland or dutch).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
88. exp Norway/
89. (norway or norwegian*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
90. exp Switzerland/
91. (swiss or switzerland).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
92. exp France/
93. (french or france).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

AND

Extra limiters:

Publication limitations: year and type and language (connected by AND)

limit 67 to yr="2011 -Current"

limit 95 to english language

The results of this query are 1890 documents

3. PsycInfo (n=515, last search 30.01)

We accessed PsycInfo through the portal offered by Ovid. Initially we run the same Medline query's list. It showed that subject headings do not coincide between the two databases. For this reason, using PsycInfo's indexation we selected a number of equivalent subject headings to the ones found in MedLine. In particular:

1) The subject heading 'Osteopathic Physicians' was reported invalid in the database. // Instead we included the subject heading 'Osteopathic medicine'. (Definition from the database: A system of therapy and medicine based on the theory that diseases are chiefly due to a loss of structural integrity, which can be restored by manipulation of the skeleton and muscles).

2) The subject heading 'Chiropractic' was reported invalid in the database. Since nothing else was found, we removed it from the subject line list of the search.

3) The subject heading 'Podiatry' was reported invalid in the database. Since nothing else was found, we removed it from the subject line list of the search.

4) The subject heading 'Nutritionists' was reported invalid in the database. The only possible replacement was nutrition: and we did not include it.

5) 'Social control, Formal' was reported invalid in the database. We replaced it with the subject heading 'Social control'. (Definition from the database: Power of institutions, organizations, or laws of society to influence or regulate behavior or attitudes of groups or individuals. Consider POWER to access references that describe the control an individual has over other persons.)

6) The subject heading 'Quality Assurance, Health Care' was reported invalid in the database. We replaced it with the subject heading Quality of care. (Definition from the database: Quality of medical or mental health care.) Also: we include a broader term; 'health care delivery' (Definition from the database: Practices, policies, or referral processes that contribute to making mental and/or medical healthcare personnel, services, or facilities available to persons in need of such care.)

And the related term clinical governance. (Definition from the database: Structure or guidelines most commonly used by the United Kingdom's National Health Service (NHS) to measure, monitor, and improve the quality of health care).

7) Standard settings, which in MedLine was not present as subject heading, was associated with the subject heading Professional Standards. (Definition from the database: Minimally acceptable levels of quality professional care or services maintained in order to promote the welfare of those who make use of such services.)

8) In PsycInfo there are no subject heading for countries in this database, so we limited the research with the in-text search of geographical terms.

We included temporal and language limitations.

Here is the query list of terms. Exp= subject heading expanded, in search terms for in text queries (TI=title and AB=abstract)

List of professions, either as subject heading or in text terms search (all connected by OR)

1. exp Nurses/
2. nurs*.ti,ab.
3. exp Optometrists/
4. optom*.ti,ab.
5. exp Dentists/
6. dent*.ti,ab.
7. exp Midwifery/
8. midwif*.ti,ab.
9. exp Pharmacists/
10. pharm*.ti,ab.
11. medica*.ti,ab.
12. exp Osteopathic Medicine/
13. osteopath*.ti,ab.
14. chiropract*.ti,ab.
15. exp Social Workers/
16. social work*.ti,ab.
17. chiro*.ti,ab.
18. podiatr*.ti,ab.
19. dieti*.ti,ab.
20. exp Occupational Therapists/
21. occupational therap*.ti,ab.
22. exp Allied Health Personnel/
23. paramedic*.ti,ab.
24. exp Physical Therapists/
25. physiotherap*.ti,ab.
26. exp Psychology/
27. psycholo*.ti,ab.
28. prosthet*.ti,ab.
29. orthot*.ti,ab.
30. radiograph*.ti,ab.
31. exp Speech Therapy/ or exp Language Therapy/
32. "speech and language".ti,ab.
33. exp Physicians/
34. doctor*.ti,ab.
35. physician*.ti,ab.
36. exp General Practitioners/
37. general practitioner*.ti,ab.
38. welfare work*.ti,ab.
39. exp Health Personnel/
40. health care profession*.ti,ab.
41. healthcare profession*.ti,ab.
42. orthopt*.ti,ab.
43. physical therapist*.ti,ab.
44. arts therapist*.ti,ab.
45. biomedical scientist*.ti,ab.

- 46. clinical scientist*.ti,ab.
- 47. hearing aid dispenser*.ti,ab.
- 48. operating department practitioner*.ti,ab.

AND

Regulation search terms (all connected by OR)

- 50. exp Social Control/
- 51. regulat*.ti,ab.

AND

List of policy terms, either as subject heading or in text terms search (all connected by OR)

- 53. fitness to practi*.ti,ab.
- 54. standard setting.ti,ab.
- 55. exp Professional Standards/
- 56. standards of practi*.ti,ab.
- 57. (standard* adj2 practi*).ti,ab.
- 58. exp Quality of care/
- 59. exp Health Care Delivery/
- 60. exp Clinical Governance/
- 61. quality assurance*.ti,ab.
- 62. (regist* adj2 profession*).ti,ab.
- 63. (prevent* adj2 harm*).ti,ab.
- 64. ((client* or patient*) adj2 safet*).ti,ab.
- 65. exp Patient Safety/

AND

Geographical limitations (all connected by OR)

- 67. united kingdom.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 68. uk.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 69. (england or english).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 70. (wales or welsh).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 71. (scotland or scottish).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 72. (irish or ireland).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 73. (united states or US or USA or america*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 74. australia*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
- 75. canada*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

76. (sweden or swedish).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
77. german*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
78. (netherland* or holland or dutch).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
79. (norway or norwegian*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
80. (swiss or switzerland).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]
81. (french or france).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures, mesh]

AND

Extra limiters

Publication limitations: year and type and language (connected by AND)

84. limit 83 to yr="2011 -Current"

85. limit 84 to english language

4. CINAHL (n=353, last search 30.01)

We accessed CINAHL through the portal offered by EBSCO. We selected a list of subject heading from the ones suggested by the portal, exploding the subject heading, i.e. including the lower categories of terms (when possible). To that list we added the Boolean query previously used in SCOPUS and MedLine (including eventual changes in spelling, preferred terms as in the case of physician rather than doctor). We run the search terms for in-text queries in the title and abstract (TI=title and AB=abstract).

We reduced the number of results by including geographical criteria (i.e. same as in the other queries), type and years of publications (i.e. Journal articles from 2011 until today) and English language.

1. List of professions, either as subject heading or in text terms search (all connected by OR)

- (MH "Medical Technologists")
- (MH "Emergency Medical Technicians")
- (MH "Health Personnel+")
- (MH "Physicians+")
- (MH "Language Therapy")
- (MH "Speech Therapy+")
- (MH "Psychologists")
- (MH "Physical Therapists")
- (MH "Allied Health Personnel+")
- (MH "Occupational Therapists")
- (MH "Nutrition Services+")
- (MH "Podiatry")
- (MH "Social Workers")

(MH "Chiropractic+")
(MH "Osteopaths")
(MH "Pharmacists")
(MH "Midwifery+")
(MH "Dentists+")
(MH "Optometrists")
(MH "Nurses+")
(MH "Radiologic Technologists")
(MH "Dietitians")
(MH "Surgical Technologists")
(MH "Hearing Aid Fitting")

(TI ("Nurs*" OR "optom*" OR "dent*" OR "midwif*" OR "pharm*" OR "medica*" OR "osteopath*" OR "chiropract*" OR "social work*" OR "chiro*" OR "podiatr*" OR "nutrition*" OR "dieti*" OR "occupational therap*" OR "Allied Health Personnel" OR "paramedic*" OR "Physical Therapists" OR "physiotherap*" OR "psycholo*" OR "prosthet*" OR "orthot*" OR "radiograph*" OR "Speech Therapy" OR "Language Therapy" OR "speech and language" OR "doctor*" OR "physician*" OR "general practitioner*" OR "welfare work*" OR "Health Personnel" OR "health care profession*" OR "healthcare profession*" OR "orthopt*" OR "physical therapist*" OR "arts therapist*" OR "biomedical scientist*" OR "clinical scientist*" OR "hearing aid dispenser*" OR "operating department practitioner*")

OR

(AB ("Nurs*" OR "optom*" OR "dent*" OR "midwif*" OR "pharm*" OR "medica*" OR "osteopath*" OR "chiropract*" OR "social work*" OR "chiro*" OR "podiatr*" OR "nutrition*" OR "dieti*" OR "occupational therap*" OR "Allied Health Personnel" OR "paramedic*" OR "Physical Therapists" OR "physiotherap*" OR "psycholo*" OR "prosthet*" OR "orthot*" OR "radiograph*" OR "Speech Therapy" OR "Language Therapy" OR "speech and language" OR "doctor*" OR "physician*" OR "general practitioner*" OR "welfare work*" OR "Health Personnel" OR "health care profession*" OR "healthcare profession*" OR "orthopt*" OR "physical therapist*" OR "arts therapist*" OR "biomedical scientist*" OR "clinical scientist*" OR "hearing aid dispenser*" OR "operating department practitioner*"))

AND

2. Regulation search terms

TI regulat* OR AB regulat* OR
(MH "Professional Regulation")

AND

3. List of policy terms, either as subject heading or in text terms search (all connected by OR)

(MH "Patient Safety+")
(MH "Harm Reduction")
(MH "Professional Recognition")
(MH "Quality of Health Care+")

(TI("fitness to practi*" OR "standard setting" OR "standards of practi*" OR "(standard* n2 practi*)" OR "quality assurance*" OR "(regist* n2 profession*)" OR "(prevent* n2 harm*)" OR "((client* or patient*) n2 safet*)" OR "Patient Safety"))
OR (AB ("regulat*" OR "fitness to practi*" OR "standard setting" OR "standards of practi*" OR "(standard* n2 practi*)" OR "quality assurance*" OR "(regist* n2 profession*)" OR "(prevent* n2 harm*)" OR "((client* or patient*) n2 safet*)" OR "Patient Safety"))

AND

geographical limitation as subject heading (all connected by OR)

(MH "France")

(MH "Switzerland")

(MH "Norway")

(MH "Netherlands")

(MH "Germany")

(MH "Sweden")

(MH "Canada+")

(MH "United States+")

(MH "United Kingdom+") OR (MH "Great Britain+")

Extra limiters

Published Date: 20110101-20201231;

English Language;

Exclude MEDLINE records;

Geographic Subset: Australia & New Zealand, Canada, Continental Europe, Europe, UK & Ireland, USA;

Publication Type: Book, Book Chapter, Journal Article, Systematic Review; Language: English