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Regulating Physician Associates (PAs) and Anaesthesia Associates (AAs): a rapid review

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Summary

Background

- A Physician Associate (PA) is a 'new healthcare professional who, while not a doctor, works to the medical model, with the attitudes, skills and knowledge base to deliver holistic care and treatment within the general medical and/or general practice team under defined levels of supervision'
- In 2014 the name was changed from Physician Assistants to Physician Associates in the UK. This was to enable the role to proceed to statutory regulation, and to provide some distance from other categories of practitioners who work as technicians rather than clinicians
- In the UK, PAs are currently educated to postgraduate diploma level for two years (applicants most hold an undergraduate degree in health or life science subject)
- In July 2019, the smaller group of PAs working in anaesthesia services as PA(A)s were formally named Anaesthesia Associates (AA) in recognition of their role within the anaesthesia team and within the medical associate professions (MAPS)
- By the end of 2020, the NHS interim People Plan estimated there would be over 2,800 PA graduates, and projected that numbers would rise further to over 5,900 by the end of 2023
 - The PA workforce is much larger than the AA group: in 2019, there were 180 AAs working in the NHS
 - PAs are concentrated in Acute rather than NHS Community services; in March 2019 there were just 167 FTE (194 Headcount) PAs employed in general practice.
- A large mixed-methods study investigating the role of PAs in hospitals found patients were satisfied with their encounters with PAs in general. They were seen to provide continuity of patient care, even if their role was not always clear to patients
- By August 2019, the General Medical Council (GMC) was formally announced as the PA and AA UK regulator
- At the time of writing, PAs must complete 50 hours of Continuing Professional Development (CPD) annually to maintain their Physician Associate Managed Voluntary Register (PAMVR) registration.

What is regulation seeking to achieve?

- Several potential policy goals of regulation have been highlighted, including increasing public confidence in the role, public protection and safety, and protection of title and accountability, as well as benefits to the development of PAs in enabling and requiring regular accredited continuing professional development
 - The inability of PAs to prescribe medication and request ionising therapies has been seen as limiting their effectiveness and in turn their ability to be employed
 - Despite positive feedback about PAs, the unregulated status has been suggested as leading to caution in using PA staff to their fullest potential
 - A very large US study comparing Nursing Practitioners (NP) and PAs with primary care physicians found outcomes for patients were largely comparable, and suggested that it may be cost saving to employ PAs and NPs rather than primary care doctors who are hard to recruit to health centres
- The lack of regulation has been seen as hampering the ability of PAs to becoming senior decision makers, and thus ultimately a waste of their expertise and experience.

Remaining concerns over PA regulation in the UK

- Some doctors, especially junior doctors, are reported to be very concerned about the role of PAs and how they fit in the healthcare teams, and feel that their roles and rotas should be more clearly defined so they complement and do not substitute for doctors
- Other possible impacts relate to patient safety concerns owing to the context in which PAs may be working with vulnerable people on their own, posing 'high potential risk' to patients
- The costs of Continuing Professional Development (CPD) activities for PAs do not appear to have been considered, or their effectiveness.

Further Questions

- What is the profile of the current UK PA workforce and where should the NHS seek PA recruits – the US and Canada have recruited former military personnel, are these a possible recruitment pool for PAs in the UK?
- Is a new pool of staff being recruited to the NHS workforce as PAs or AAs or are they coming from traditional NHS applicants? What are the aspirations for any 'new labour pools' in terms of progression?
- What is the potential to use data from GMC regulation to find out more about the PA profile, recruitment sources and trends, and retention/progression, or by making links with the NHS Electronic Staff Record (ESR)?
- Is there a career pathway for PAs and what are their expectations and opportunities?
- What will be the impact of regulation and what is the evidence to permit greater scope of practice for PAs?

At the end of this report we outline a possible research agenda.

Context

A Physician Associate (PA) is a 'new healthcare professional who, while not a doctor, works to the medical model, with the attitudes, skills and knowledge base to deliver holistic care and treatment within the general medical and/or general practice team under defined levels of supervision' (Health Education England, 2012). While there are far fewer Anaesthesia Associates (AAs) (formerly known as Physician Assistants (Anaesthesia) until July 2019) this review also covers this role, distinguishing it where possible. AAs are defined as a separate profession 'with a different set of competencies which enable them to work under the supervision of anaesthetists within the operating theatre environment' (Royal College of Physicians, <https://www.fparcp.co.uk/about-fpa/faqs>).

NHS Employers describes PAs as part of the new medical associate professions (MAPs) working across multi-professional teams (NHS Employers <https://www.nhsemployers.org/your-workforce/plan/medical-associate-professions>) and comprising:

- advanced critical care practitioners
- anaesthesia associates
- physician associates
- surgical care practitioners.

Their growth in numbers was referred to as a 'key workforce initiative' in the NHS (NHS England 2015).

At the end of 2019 we were commissioned by the Department of Health and Social Care (DHSC) to provide a rapid review of research on the potential impact of the proposed regulation of Physicians Associates and Anaesthesia Associates in the UK. This report addresses the questions set by DHSC and discussed with their analysts. It was updated in the context of the coronavirus pandemic (October 2020). We are not aware of any studies of the work of PAs during the coronavirus pandemic, however the newsletter of the Newcastle University PA programme (Newcastle University PA Studies Newsletter 2020) presents a vivid account of their stepping up to work in local services.

The Introduction of Physician Associates (PAs) in the NHS

Physician Assistants (the former title) were developed as part of the healthcare workforce in the United States (US) in the 1960s, mostly drawn from former military personnel who had been trained to provide medical support in the field of war. The first training provision was established at Duke University, in Durham, North Carolina, in 1965 (the university continues to host the workforce's historical archives: <https://fmch.duke.edu/about/history>).

Two PAs were first recruited to the NHS from the US in 2003 to work primarily in 'underserved primary care practices' in the Midlands region of England (Aliello and Roberts 2017). Following the perceived success of this demonstration project (according to Woodin et al 2005) and the generally positive reception of this new role (Paniagua, 2004; Armitage and Shepherd, 2005), a second pilot was undertaken in Scotland (Farmer et al. 2011).

In 2014, the role's name was changed from Physician Assistants to Physician Associates (hereafter PAs) to 'enable the profession to proceed to statutory regulation, and to distance

them from other categories of practitioners who work as technicians rather than clinicians' (RCP, Faculty of Physician Associates, 2014). In the UK, PAs are currently educated to postgraduate diploma level for two years (applicants must hold an undergraduate degree in a health or life science subject, for example: biology, biomedical science, or an allied health degree). On qualification, they are permitted to work in any medical setting supervised by a doctor. PAs are trained to take medical histories, conduct physical investigations, diagnosis and treatment, as agreed with their supervisors (Drennan et al. 2019a).

The Royal College of Anaesthetists notes that Physicians' Assistants (Anaesthesia) (PA(A)s) were introduced into the UK in 2004 and suggests that they are 'now established within many NHS hospitals' (Royal College of Anaesthetists <https://www.rcoa.ac.uk/training-careers/working-anaesthesia/anaesthesia-associates>). As with PAs, there has been a change of name with PA(A)s formally becoming Anaesthesia Associates (AAs) in July 2019 in recognition of their role within the anaesthesia team and within the medical associate professions (MAPs).

PA training programmes were initially established in the universities of Hertfordshire, Wolverhampton, and at St George's University of London, with their first cohort of graduates emerging in 2007 (see Aliello and Roberts 2017 for more detail of the context of the role and educational provision in the UK). There was a further growth in numbers of educational providers of such programmes in 2009 (Ross et al. 2012), with Ritsema et al. (2019) describing this growth in PA education as an 'explosion'.

Undoubtedly the PA and AA workforce has grown in the UK (Aliello and Roberts 2017) with a substantial increase from very small numbers in 2015/16 when government financial support for numbers of PAs in training increased from 24 in 2014/15 to 205 in 2015/16 (Drennan et al. 2019b)¹. A 'National Physician Associate Expansion Programme' was also established in 2015 which involved the recruitment of 200 US trained PAs (Mathews-King 2015). In an editorial, McKimm et al. (2019) reported Health Education England (HEE) data on PAs which estimated their numbers would be just under 600 qualified PAs in the UK by the end of 2018, with an expectation that this number would grow to 3,200 by the year 2020. By the end of 2020, the NHS Interim People Plan estimated that there would be over 2,800 PA graduates and projected that numbers would rise further to over 5,900 by the end of 2023 (NHS Interim People Plan 2019). As of 2019, there were 180 AAs working in the NHS (British Medical Association <https://www.bma.org.uk/collective-voice/policy-and-research/education-training-and-workforce/medical-associate-professions>). However, a Health Education England (2020) report on the 'future doctor' does not mention PAs nor does the NHS People Plan (NHS England 2020).

Globally, the numbers of PAs are growing, with the role now existing in The Netherlands, Canada, Israel, South Africa, and Australia (Aliello and Roberts 2017).

Physician Associates in practice

The NHS settings in which PAs work are mainly in the acute and hospital sectors although 28% work in primary care (Brown et al. 2020a). The main study of PAs in **primary care**

¹ Current (2020) financial support often includes a travel grant and eligibility for a postgraduate loan, but arrangements vary locally.

(Drennan et al. 2011; Drennan et al. 2014; Drennan et al. 2015; Drennan et al. 2017a) offered clear evidence that ‘physician assistants were found to be acceptable, safe, effective and efficient in complementing the work of general practitioners (GPs)’.

The potential for PAs to assist in primary care mainly relates to their potential to support general practitioners (GPs) and was suggested by NHS England (2015) as part of ‘new ways of working’:

NHS England, HEE and others will work together to identify key workforce initiatives that are known to support general practice - including e.g. physician associates, medical assistants, clinical pharmacists, advanced practitioners (including nursing staff), healthcare assistants and care navigators. We will agree a shared programme of key pilots at scale in primary care, to invest in and trial new ways of working for these roles, demonstrating how they work across community, hospitals and within GP surgeries to support safe and effective clinical services for patients. This will support current GPs in managing their workload, as well as piloting new ways of working for the future (NHS England 2015, page 5)

In March 2019, there were 167 Full Time Equivalents (FTEs) PAs employed in general practice (194 PAs in total headcount) in England, being an increase of 97 FTEs over the year (NHS England 20 May 2019). This is a very small proportion of the primary care workforce, given that there are 7,000 GP practices in NHS England. Moreover, this is rather less than an earlier NHS England report that cited Health Education England as envisioning that by 2020 there could be as many as 1,000 PAs working in primary care, reported in one of the case studies referenced in the General Practice Forward View (NHS England <https://www.england.nhs.uk/gp/case-studies/the-physician-associate-will-see-you-now-new-role-to-assist-patients-in-primary-care/>). The General Practice Forward View (NHS England 2016) also suggested a target of 1,000 more PAs in that sector, although with no definitive date (NHS England <https://www.england.nhs.uk/gp/gpfv/>).

Reactions to PAs

Responses from other healthcare professionals to the introduction of PAs to the UK healthcare workforce are largely positive about the impact they can have on continuity of care and staffing pressures (particularly in primary care; Drennan et al 2014). However, PAs are not universally welcomed, as reported by personal views expressed in the professional press (e.g. Bhardwa 2015). Illustrating one of these views, McCartney (2017, page 315) observed:

The RCP (Royal College of Physicians) also says that PAs should be involved in service design, act as clinical placement leads for students, undertake minor operations, and take part in education and quality improvement projects. No wonder many junior doctors in secondary care - paid less for taking more responsibility and doing more unsocial hours - are concerned about this and the threat to their training opportunities. I’m sceptical that having more PAs join the health service will cut levels of burnout among junior doctors in secondary care.

A large mixed-methods study investigating the role of PAs in **hospitals** found patients were satisfied with their encounters with PAs in general (Taylor et al. 2019). They were seen to provide continuity of patient care, even if their role was not always known by patients (see also Drennan et al. 2019a/b). Moreover, while employers were willing and keen to employ PAs in hospitals as they provided continuity of care to patients, there remained practical and attitudinal barriers to overcome, including PAs not being able to prescribe medications and to request radiographs, as well as a lack of evidence of their effectiveness and safety and a limited pool to recruit from (Halter et al. 2017b; Drennan et al. 2017c).

More recently, the Faculty of Physician Associates at the Royal College of Physicians (FPARCP) website (23/8/19) reported:

One of the motions at this year's British Medical Association (BMA) junior doctors conference focused on the growing role of 'medical associate professions' (MAPs). The grouping of MAPs includes physician associates (PAs), surgical care practitioners, advanced critical care practitioners and anaesthesia associates. The seven-part motion split the opinion of the medical community, as it called for the BMA to oppose MAPs being placed on the medical rota, oppose MAPs being permitted to sit any postgraduate medical examination, and oppose MAPs being used to fill medical locum vacancies and rota gaps. (Faculty of Physician Associates <https://www.fparcp.co.uk/about-fpa/news/the-evolving-medical-team-physician-associates-and-junior-doctors>).

This same website reported the wish of the new president of the Faculty of Physician Associates, Kate Straughton, that 'Statutory regulation provides a real opportunity for trainees and PAs to take stock of the relationships they have'. Writing with others (Watkins et al. 2019, page 177), she observed that:

It is abundantly clear that while a PA practices medicine, they are not a doctor, with no like-for-like equivalency and therefore cannot replace a doctor. However, working in the medical team will mean that there is overlap of knowledge and skills between professional groups. Acknowledgement and maximisation of this overlap can be advantageous for the team in the redistribution of the workload, provision of training opportunities for all staff and, ultimately, benefit patients, ensuring that the right person, with the right skills, sees the right patient at the right time.

Nonetheless, there remain views about elements of MAPs' equivalence that are critical in tone and substance, including an opinion expressed by Briffa (2019a) that many of their university courses are 'substandard and provide poor value for these new professionals'.

The evolution of regulation of PAs and AAs

In 2017 a Physician Associates (Regulation) Bill was laid before Parliament as a Private Members' Bill (Ballot Bill), whose Sponsor was Anne Marie Morris, MP. It reached 2nd reading stage in October 2018 but failed to complete its passage through Parliament before the end of the session. This Bill made no further progress.

A Summary of the failed Physician Associates (Regulation) Bill 2017-19 (Parliament publications <https://services.parliament.uk/Bills/2017-19/physicianassociatesregulation.html>) described it as making provision for the regulation of PAs; to make physician associate a protected title; and for connected purposes. The Bill's sections covered the following sections capturing the remit of regulation typical of the regulation of health and care professions, namely:

1. Regulation of physician associates
2. Register of physician associates
3. Code of conduct and licences to practise
4. Offence of pretending to be a physician associate
5. Qualifications and training
6. Report on the regulation and responsibilities of physician associates
7. Rules
8. Short title, commencement and extent

Despite the failure of the Bill to progress, the need for PA and AA regulation had been accepted by Government following a public consultation in 2019 on:

- the proposed statutory regulation for PAs;
- evidence on the most proportionate level of regulation for PA(A)s.

Over 3,000 responses to the consultation were received (DHSC 2019) (the vast majority being from healthcare professionals) and in February 2019 the DHSC reported that the case for regulation had been made. However, the precise regulator – either the Health and Care Professions Council (HCPC) or the General Medical Council (GMC) – had yet to be determined. By August 2019, the choice had been made. The GMC was formally announced as the PA and AA UK regulator (Hammond 2019), with the Minister describing it as an 'important step towards meeting workforce commitments in each of the four countries including the interim NHS People Plan in England' (Hammond 2019, col 55WS).

While regulation is now agreed, this followed a decade of efforts to ensure safety and public confidence in the role of PAs, as well as providing assurance to potential employers that the qualification is approved and awarded. In 2005, the UK Association of Physician Associates (UKAPA) was established, acting as a professional body for PAs. Notably, a Physician Associate Managed Voluntary Register (PAMVR) was established in June 2010 by the Faculty of Physician Associates (FPA), hosted by the Royal College of Physicians (Faculty of Physician Associates weblink 2), with the following aims:

The PAMVR is to provide public protection and safety, set standards for post graduate education and development, and to advance towards statutory regulation. The FPA reviews applications to join the PAMVR, and establishes whether the physician associate applying is fit to practice in the UK. If a physician associate is listed on the PAMVR, then employers, members of the public, supervisors and other healthcare professionals can be safe in the knowledge that they are a fully qualified and approved physician associate. (Physician Associate Managed Voluntary Register weblink)

In Wales, a Physician Associate Governance Framework (NHS Wales 2018) was developed to provide an assurance mechanism to Health Boards/Trusts, managers, staff and patients. At the time of writing (Autumn 2020), PAs must complete 50 hours of Continuing Professional Development (CPD) annually to maintain their PAMVR registration.

This review

We conducted a rapid review (2019- 20) of the evidence to establish the likely impacts of regulating PAs and AAs, and options on the parameters of a possible longer-term evaluation. Specific research questions included:

- What are the possible impacts of regulating PAs and AAs?
- What are the options for a longer-term (2-3 years) evaluation of the impact of regulating PAs/AAs in the UK?
- What does international evidence tell us about impacts of regulating PAs?

This rapid review followed the guidance set out by Varker and colleagues (2015) which stipulated three main phases as helpful; these are summarised in Figure 1 below.

Figure 1: Summary of the three phrases of a rapid review (Varker et al. 2015, page 1200)

Development Phase	1. Review initiation (forming a team and needs assessment)
	2. Question development
	3. Methods development a) develop inclusion criteria b) search strategy
	4. Information retrieval / management
Processing Phase	5. Screening step 1 of 2: titles/abstracts - retrieval of papers –
	6. screening steps 2 of 2: full paper - Data abstraction –
	7. Assess the quality of the evidence
Reporting phase	8. Report results

The research question was developed using the PICO framework (Population, phenomenon of Interest, Context, and Outcome; Glasper and Rees, 2013). For this review, these were:

P – physician associates (PAs) and anaesthesia associates (AAs),

I – regulation

C – UK NHS and international evidence on regulation

O – regulation impacts.

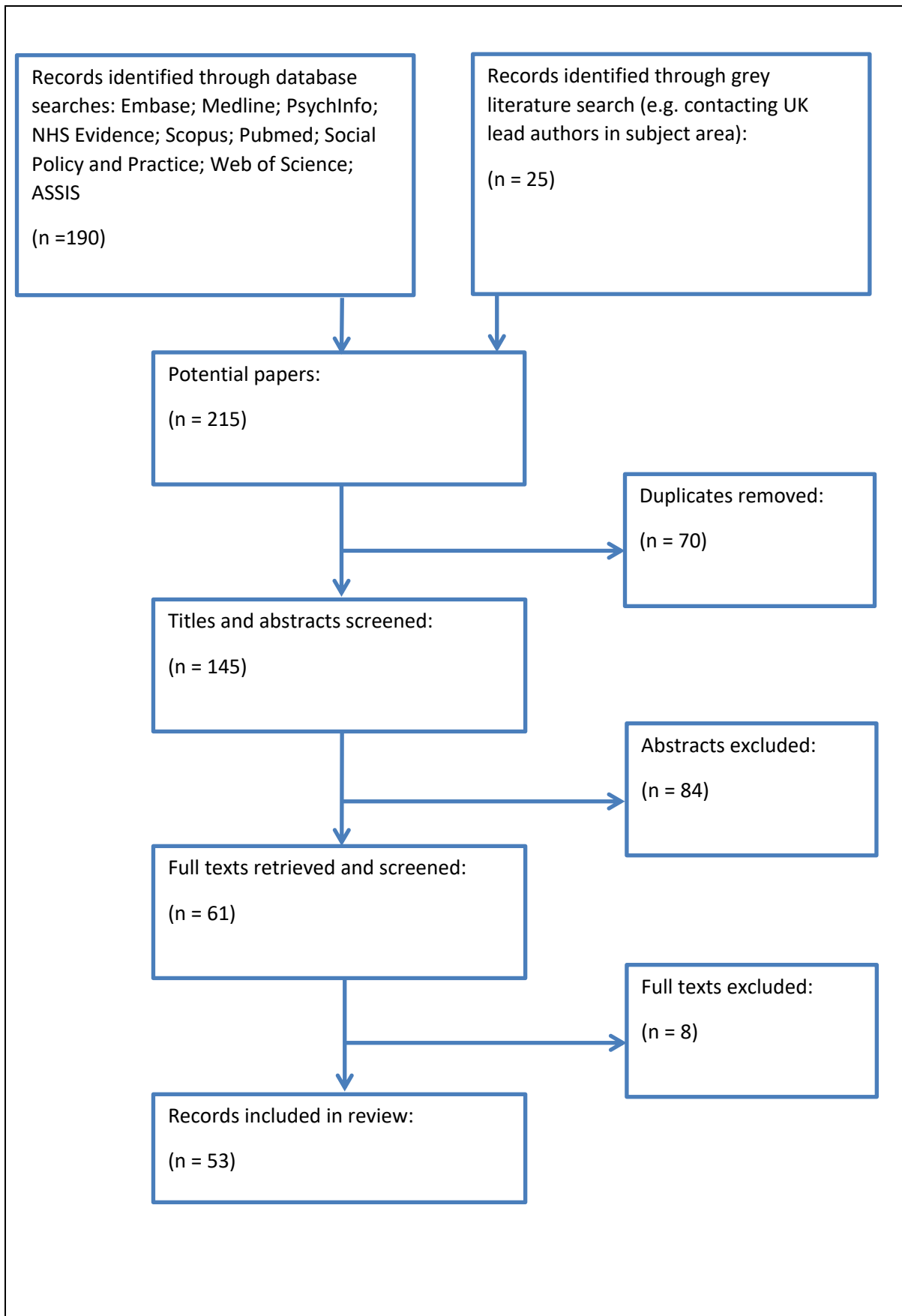
We searched a range of databases, including EMBASE, MEDLINE, PsychInfo; Global Health; Social Policy and Practice; Web of Science; ASSIS; NHS Evidence; Scopus; PubMed for relevant publications, and searched Hansard.

Findings

Figure 2 represents the papers identified through systematic searching of databases and harvesting of relevant reference lists.

A total of 53 papers were included in this review. Eleven of these were commentary pieces, editorials or letters capturing and reflecting on current views of the healthcare community at that present time. Two large-scale empirical UK studies by largely the same group of investigators, one set in primary care (Drennan et al. 2014) and one in hospitals (Drennan et al. 2019), produced seminal reports as well as several papers (six and four respectively) that are all included in this review; however, the main report is cited where relevant. A further nine empirical studies were included, and the remaining are official documents produced by the Department of Health and Social Care (formerly Department of Health), its arms-length bodies, or the NHS.

Figure 2: Flowchart of papers identified through systematic searching



Reactions to regulation of PAs and AAs

‘The lack of statutory regulation is a major barrier to physician associates' effectiveness’ declared Szeto, Till and McKimm (2019). Others have argued that current legal frameworks may be limiting PAs’ effectiveness and potential contribution to the NHS as they are not permitted to prescribe medication or request ionising radiation (X rays and CT scans) and need to check activities with a supervisor. This is not a recent claim. Farmer and colleagues (2011) had warned that the lack of statutory regulation in the UK would be a barrier to PAs’ effectiveness. In addition, Hodgson (2014, page 219) suggested that registration would ‘protect the public from alternative, potentially less stringent, models of PA training’ which he said might be established.

Writing about this, the Editor-in-Chief of the *British Journal of Nursing* (Peate 2018) observed that ‘statutory professional regulation offers a level of assurance that can deliver increased public protection’ (page 1215). Similarly, a PA, who is a regular blogger (with the name of Jim) on the site of a company providing PA training, supported the commitment to regulation, stating ‘I firmly back regulation to ensure quality standards are maintained for PAs, and only qualified PAs, that is those who have passed both components of the national exam, are working under the PA title’ (Jim 2019). However, as Jim noted, such regulation would not necessarily address all the calls for rights to prescribe and suggested that continued attention was needed to this area of practice and authority. Curran and Parle (2019) likewise maintained that while professional regulation is an urgent need, subsequent consideration of how PAs can attain the right to prescribe will be needed (page 311).

Other PAs have also articulated the possible positive impacts of regulation noting its value in protection of title, accountability, consistency, and public protection and confidence:

Regulation, it is expected, would lead to physician associates being given the power to prescribe – on completion of additional training – as well as bring protection to the title. Jeannie Watkins, a physician associate who [...] was one of the first qualified in the UK, has worked both in primary and secondary care and is now president of the faculty board, says: “Professional regulation is vitally important; it would protect the physician associate title and provide the legal and professional accountability and authority for the standards of behaviour, competence and education that they must meet. This will mean that the public are appropriately protected, and encourage public and professional confidence in the role. ... Regulation will make a huge difference, we can then work towards prescribing rights. This will also give us the assurance that all physician associates are working to the same framework, the role is standardised and that the physician associate title is protected. (NHS England <https://www.england.nhs.uk/gp/case-studies/the-physician-associate-will-see-you-now-new-role-to-assist-patients-in-primary-care/>)

Other possible impacts relate to patient safety concerns owing to the context in which PAs may be working with vulnerable people and on their own with them, thus posing ‘high potential risk’ to patients. Such factors led the DHSC to distinguish PAs from other MAPs which it decided not to regulate (DHSC 2019).

Regulation may enhance confidence levels in PAs. Nelson and colleagues found that PAs were least experienced clinically (in a comparison study with two other new 'non-medical' roles, Assistant Practitioner and Practice Pharmacist), although many reported feeling less confident in general practice compared to secondary care placements, perhaps due to the independent nature of work in the former (Nelson et al. 2019). Some reported that they did not feel their two-year course and the short placement design of the PA scheme equipped them adequately (ibid.).

In summary, several potential policy goals of regulation have been highlighted, including increasing public confidence in the role, public protection and safety, and protection of title and accountability, as well as benefits to the development of PAs in enabling and requiring regular accredited (linked to regulation imperatives) continuing professional development (CPD) (Drennan et al. 2019a).

The regulation decision

In August 2019, NHS Employers declared:

We welcome this news and fully support the regulation of these roles. It will provide a standardised framework of governance and assurance for clinical practice and professional conduct to enable these healthcare professionals to make a greater contribution to patient care. (NHS Employers weblink 2)

Announcing the agreement of the GMC to take on the regulation of PAs and AAs in the House of Commons, the justification for this was summarised by the Minister of Health, Stephen Hammond MP, who stated:

Regulation will enable these groups to work to their full potential and provide the very best care to patients as part of a multidisciplinary clinical team, contributing to the development of a safe and flexible workforce. This is an important step towards meeting workforce commitments in each of the four countries including the interim NHS People Plan in England. (Hammond 2019, col 55WS)

While much of the debate over regulation mentions PAs, the largest group, the FPARCP highlighted that there are differences between PAs and AAs:

We are really pleased that the GMC have made clear that while they have been charged with leading the introduction of regulation for PAs their ethos, as we move ever closer to regulation, will be one of co-creation. This ensures that we create a regulatory approach which is fit for the future and one that understands the nuances between the two roles (PAs and AAs). (Faculty of Physician Associates weblink 3)

Finally, while PAs and AAs are to be regulated, Briffa (2019b) argued that regulation could have included greater professional oversight of other MAPs, such as surgical care practitioners, and their omission was a missed opportunity. As noted above, these professionals were not included in the plans to regulate PAs and AAs (see DHSC 2019).

What would regulation achieve? What metrics are we expecting to change?

Prescribing rights

The inability of PAs being able to prescribe medication and request ionising therapies was seen as a huge stumbling block to their effectiveness and in turn their ability to be employed (Drennan et al 2019 a/b). Although Drennan and colleagues (2019) observed that the restrictions on PAs' role were more apparent in some specialities than others; they nevertheless argued that the PA role in hospitals could be better optimised with an appropriate level of regulation, giving PAs the authority to both prescribe medication and request ionising radiation, as well as undertake complex medical procedures (e.g. inserting a chest drain) (Halter et al. 2017c; Drennan et al. 2019a/b).

The statutory regulation of the PA workforce will have to be followed by further consultation before any responsibility for the supply of medicines or prescribing is added to the role. Changes will require amendments to the Human Medicines Regulations (2012). Such changes may benefit patients, reduce doctor workloads, but potentially increase risks associated with all medicine provision. Consultation will surface other possible outcomes. Registration and possibly thereby assigning PAs with rights to prescribe medication are described as potentially conferring a new status to the role, thereby highlighting the long-held view by some, that PAs may offer a realistic solution to some of the workforce challenges currently faced by the NHS (Ross et al. 2012). It is suggested that the potential impact of PAs being able to prescribe may be felt in out of hours services and in-home visits where the lack of immediate access to a prescriber is described as acutely felt (Farmer et al. 2011; Halter et al. 2017a).

What can be measured or assessed?

A multi-method study would address prescribing patterns and clinical impact or outcomes, with exploration of costs and risks (building on the work of Halter et al 2020, for example). It would be sensible to engage with pharmacists and patient safety experts to build up metrics. Examination of problems brought to the attention of the GMC would be another source of data to consider possible mentions of medication errors or similar. Studies would need to address both primary, secondary and hospital settings.

Employment

Drennan et al (2019b) suggested lack of regulation [and 'attendant lack of authority to prescribe medicines and request ionising radiation' (such as chest x-rays and CT scans)] was an inhibiting factor for Trusts in employing PAs. They concluded from their multisite hospital-based study of PAs:

Their utility in the hospital setting is unlikely to be completely realised without the appropriate level of regulation and authority to prescribe medicines and request ionising radiation within their scope of practice.

Earlier, Williams and Ritsema (2014) had concluded from their survey of all known PA supervisors conducted in late 2012 that, despite positive feedback about PAs, the unregulated status has meant more caution in using PA staff to their fullest potential. This, along with some general reluctance and caution as noted in the debates above, may change with regulation providing PAs with more confidence and effectiveness in the workplace.

In primary care, PAs who can prescribe may have greater scope to address patients' needs and thus be highly employable. Anecdotal views on this are mixed, as PAs may take a longer time to see a patient (even with a minor problem), which may negate any time or cost savings arising from fewer interruptions to senior doctors for approvals and supervision (as suggested by McCartney 2017). However, the powerful evidence from Drennan et al (2015) found that PA consultations for same-day appointments in general practices in England resulted in similar outcomes for similar consultations by GPs at a lower consultation cost. They suggested that deploying PAs to see patients who were aligned with their expertise, while freeing up GP time to see more complex cases, was a realistic step forward (Drennan et al 2015; de Lusignan et al 2016; Drennan et al 2017a). A very large US study comparing Nursing Practitioners (NPs) and PAs with primary care physicians found outcomes for patients were largely comparable, and suggested that it may be cost-saving to employ PAs and NPs rather than primary care doctors who are hard to recruit to health centres (Kurtzman and Barnow, 2017). They observed 'our findings should heighten policymakers' confidence in the contributions of NPs and PAs to high-quality care and inform their decisions regarding occupational licensing and regulation, payment reform, and health professions' education' (page 620).

King (2019) argued that not regulating would hamper the progression of PAs into becoming senior decision-makers, which would ultimately be a waste of their expertise and experience gained on the job. She felt that challenging traditional medical hierarchies to ensure that patient care remained at the centre of their work was necessary for PAs' advancement.

What can be measured or assessed?

The composition of a professional register and the workings of registration lend themselves to study, particularly over time, to see how these processes are embedded in everyday practice and any long-term impact. There will be scope to work with the GMC to consider the uses of the register's data and possible comparisons with other registrants. The scope for analysis of the Electronic Staff Record in the NHS is considerable when addressing matters such as movement between employers, progression, drop out, pay and pensions.

Data from and about educational providers do not appear extensive and would be important to consider in terms of entry requirements, placements, educational effectiveness, quality, and student experience. Despite the importance of international exchange in the history of PAs the current impact of proposed migration rules does not appear to be widely canvassed.

PA integration into the NHS workforce

The lack of regulation of PAs was proposed by some stakeholders as having a significant inhibitor on PAs' ability to engage in team-work and skill mix, thereby compromising their successful integration into the workforce (Williams and Ritsema 2014; Halter et al. 2017b; Wheeler et al. 2017; Halter et al. 2018). However other studies of the views of the wider healthcare team suggest that lack of familiarity with PAs in settings where they have not previously been deployed also plays a part in uncertainties about their role and capability (Roberts et al. 2020).

In a comparison study with other 'new non-medical roles' in primary care (Advance Practitioner, Practice Pharmacist), the PA role was the least familiar and trainees reported in qualitative interviews that some primary care practices were unclear how to place PAs, as they were a new role and lacked 'an existing point of reference' (Nelson et al. 2019). The level of ambiguity made it further challenging to inspire confidence in the role (ibid.). Some have argued that there is an overall need for clarity about all non-medical practitioner roles (MPAs) in terms of titles and job descriptions to ensure effective workforce integration (Abraham et al. 2016). Uncertainties over their identity, and some negative experiences in the workplace, meant that many identified with doctors according to a recent study (n=19) that also found that PAs were considering moving into this profession (Brown et al. 2020b). A larger study of 89 first year trainee PAs also found that they experienced a lack of understanding around the PA role in clinical settings (Howarth et al. 2020).

Some doctors, especially junior doctors, are reported to be very concerned about the role of PAs and how they fit into healthcare teams (see above), and feel that their roles and rotas should be clearly defined so they complement and not substitute for doctors with medical degrees (Mahase 2019). Regulation may go some way towards equipping the PA role with higher profile, and their work across traditional role boundaries may enhance integration (Jackson et al. 2017; Drennan et al. 2017b), and potentially create sustainable team dynamics (Malik 2019). Whether PAs will complement and not substitute for doctors remains a concern for some (Mahase 2019) and may be one question area that will impact on their effective workforce integration (McKimm et al. 2018).

What can be measured and assessed?

At the level of employers and teams (national data have been covered above), there is the potential to build on Drennan and colleagues' studies (2015; 2019a) as baseline and to replicate methods so that comparisons are feasible and valid. Their studies have also drawn on clinical data (Halter et al. 2020) providing other sources of evidence about comparisons with certain doctors. Other reports suggest the value of PAs in holding part of the organisational/service memory that doctors on rotation do not (Kim and Bloom 2020). There may be data from GMC hearings or referrals about the context of any possible concerns and complaints about PAs, following the current work of the Nursing and Midwifery Council (NMC) to take notice of contexts when considering such matters. The work being done by Health Education England and others on PA and AA development to increase the numbers of PAs through education support allowances and so on, could be addressed as an example of policy implementation to distil its learning and possible messages for other developments in new workforce roles. Exploration of the student profile and registrant data may help see if applicants to PA training are similar or different to other pre-qualifications healthcare professionals. The career progression of PAs remains under-explored.

PAs and patient trust

The NHS has generally assumed that the PA role will provide continuity of care to patients (Jackson et al. 2017). Although the definition of what counts as 'effectiveness' remains to be interrogated, according to Halter and colleagues (2017a), PAs are reported to be generally welcomed by patients in primary care, particularly if patients are provided with information

and clarity about their role. The underlying reasons for these generally positive views about PAs were not always clear to the researchers (ibid), and perhaps require further investigation. Drennan et al (2019a) interviewed patient representatives in hospital settings, most of whom expressed an expectation that PAs/AAs should be regulated like other medical professionals such as GPs; future studies may pick up on this expectation. One study (Zaman et al. 2018) from England has recorded very high levels of hospital patient satisfaction with PAs, with patients commenting favourable on their attitudes, professionalism and medical knowledge.

Similarly, from the hospital patient point of view, Drennan and colleagues (2019a/b) reported positive patient satisfaction from two international studies set in trauma and orthopaedics settings. An earlier large US study (Dill et al. 2013) provided evidence that many health care consumers (patients) were familiar with PAs and nurse practitioners and were happy with them. They contrasted this general acceptance with State disputes over 'scope of practice'. Such studies share a common feature of not distinguishing PAs from other allied practitioners (in the UK context MAPs) and generally making comparisons of them with physicians or family doctors. This may indeed be how many patients see the world. More precisely, therefore, Kartha and colleagues (2014), when comparing nurse practitioners and PAs in acute hospitals, reported: 'Patient satisfaction is a complex amalgam of various factors including patient expectations, sociodemographics, emotional and physical state, quality of care, and physician communication'. In primary care settings in the NHS, Cottrell et al. (2020) reported that most patients did not understand the PA role; a finding also made in respect of some primary care staff such as receptionists.

What can be measured and assessed?

In a regulatory context, patient trust may be enhanced, although other studies of professional regulation generally find that most people are unaware of professional regulation (see for example, over social work, DHSC 2018). In the DHSC (2019) consultation, while there were over 3000 responses, only 18 % were from people who were not professionally associated with the role or similar. There may be scope for working with local bodies such as Healthwatch to consider their views as well as discussions with patient representative bodies. Any larger evaluations may wish to consider how to address concepts of trust of healthcare professionals amid wider social attitudes and in a post-regulatory context these would need to address similar challenges faced in other studies that sought patient views (such as ability to complete measures and the importance of organisational contexts that promote PA continuity).

Regulation costs

While it is generally considered that PAs are likely to be cost-effective for employers (Halter et al. 2017c), cost-effectiveness in respect of one form of regulation over another is generally not a policy goal associated with regulation processes or decisions about where the costs of regulation will fall. There may be opportunities to learn from whether paying registration fees for employees is a recruitment or retention incentive for NHS employers with specific shortages. The costs of Continuing Professional Development (CPD) activities for PAs do not appear to have been considered, or their effectiveness.

The expansion of regulatory responsibilities

As Una Lane (2019), head of the General Medical Council (GMC), observed about the registration of PAs and AAs:

This is the first time in our 161-year history that we've taken on the regulation of new professions, so we'll need to introduce some new processes. This isn't going to be a cut and paste approach, but we won't reinvent the wheel unnecessarily. Where processes and guidance work for both doctors and associates, we will apply that consistently. (General Medical Council UK weblink)

She stated that the process of registration would be easier for those already on the voluntary registers; that there would be no cross-subsidy from doctors' fees and that the process of registration would be based on a set of principles that will underpin a proportionate approach to regulation. Furthermore, PAs/AAs will be treated with the 'same esteem' accorded to the other registrants with the GMC. The GMC was reported to be scoping out the process with the Department of Health and Social Care in February 2020. These commitments from the GMC may be worth considering.

What is the international evidence of regulation?

As Hooker (2020) noted, PA roles vary widely internationally and 'are expanding in ways unpredicted' (see also Kartha et al. 2014) but they may come from different professional backgrounds (or none). In Israel for example, PAs are recruited from the paramedic workforce. A first cohort of PAs in Israel was run by the Ministry of Health 2016-2017, with 34 PA trainees, mainly to work in emergency departments. Surveyed at the start and end of their training, Maoz-Breuer and colleagues (2019) found that the subject of their limited authority was emerging as a 'substantial difficulty for the new PA trainees' and advised the Ministry to explore this perceived problem and create a uniform policy on it.

In Germany, a study of GPs' use and attitudes to VERAHs ('healthcare assistants in the family practice' which the authors considered had similarities to PAs internationally), described VERAHs as already part of the healthcare workforce (Mergenthal et al 2016). The VERAH qualification may be undertaken by those who have already undergone three years of vocational training (much of this in practice) to become a health care assistant. After two years in post, HCAs can undertake the VERAH qualification (at a cost ranging from €1850–2600). They are deployed variously in primary care with the GP remaining legally accountable for their work. This study indicated the complexities of making international comparisons among practitioners who may initially be thought similar to PAs (Mergenthal et al 2016).

PAs in the US and The Netherlands can prescribe and request iodising radiation (Cawley and Hooker 2013; Netherlands Association of Physician Assistants 2018). There has been consideration of the legal context of regulation in both settings (see Wiler and Ginde (2015) on the impact of state laws in the emergency medicine context). Regulation of PAs in The Netherlands took effect 1st July 2018, and evidence here may usefully build on the earlier studies by Timmermans and colleagues (2016) in this national context. The title Physician Assistant in The Netherlands is a protected title restricted to PAs who have successfully completed an accredited Master's degree, Physician Assistant. As from July 2018 each PA is

listed in a public register. A major evaluation was planned ahead of this move (see De Bruin-Geraets et al. 2014). In reporting its first findings, De Bruin-Geraets et al. (2018) suggested the possibility of making international comparisons using their methods:

Another strength of this study is its potential for crosscountry comparison. The frameworks used for both quantitative and qualitative data are internationally accepted and applied. Besides, the study design captures the impact of the regulation on generic outcome.

Cross-cultural studies of regulation (see eg Bourgeault and Grignon 2013; World Health Organisation 2016) may offer insights but, of course, regulation reflects local contexts, cultures and jurisdictions. In The Netherlands, for example, the extension of regulation included not just PAs but also Nurse Practitioners. Nonetheless, the De Bruin-Geraets et al (2018) evaluation found very positive outcomes of registration (termed full practice authority – FPA):

Informal practice was legalised. The opportunities to independently perform catheterisations, injections, prescribing, punctures and small surgical procedures were highly used. Care processes were organised more efficiently, services were performed by the most appropriate healthcare provider and conditions were met. This led to the recommendation to continue with FPA.

Appleton-Dyer et al (2015) conducted an extensive multi-methods study of the very few PAs in New Zealand. These were employed in four demonstration sites. In their second phase report, the research team observed general satisfaction with this workforce development, particularly in rural and remote areas with ageing populations. Although this report acknowledged it was not commissioned to address regulation, commenting on regulation it noted:

With the unregulated role of PAs, and the responsibility for patient care residing with the supervising doctor, some degree of caution by the supervising GPs is understandable. Where relationships have been successfully established, there is a tendency for growing levels of delegation to occur; one PA spoke of this developing organically rather than directly negotiated. (page 13)

In this initiative the PAs had been recruited from the US. The evaluation concluded that if there were to be ‘home grown’ PAs in New Zealand then regulation and medico-legal issues would need to be addressed (page 83).

Likewise, in Canada, where the early Physicians Assistants were recruited from ex-military personnel, some uncertainties about scope of practice and liability were identified in a small study of doctors’ views and usage of Physicians Assistants (Taylor et al. 2013). These included questions about ‘how to delegate an appropriate level of autonomy, liability, insurance, and the application of medical directives’. The authors concluded that professional regulation of PAs, would likely lead to ‘an increased number of employable PAs, and the development of sustainable funding models, (thus) it is likely more physicians will choose to hire PAs in their practices’. The Canadian Associates of Physicians Assistants

(<https://capa-acam.ca/pa-employers/legislation/>) lists early regulatory requirements in Canadian provinces for the nation's approximately 300 PAs, mainly working in the provinces of Manitoba and Ontario. However, a key point of debate in Canada appears to be continuing questions about the necessity of regulation – on the grounds that Physician Assistants do not work unsupervised. In a blog, Physician Assistant Taylor (2014) reported how this was unfolding, with many nursing stakeholders arguing that there was no need for Physician Assistant regulation. She concluded:

With the PA role so new to Canada, and with so many bugs still to be worked out before they are fully integrated, I think it will be decades before PAs in this country demand the kind of autonomy that seems so core to the nurse practitioner role. PAs work with and are supervised by physicians. We're okay with that, and it appears that physicians hire them, not for the stipends the RAO (Registered Nurses' Association of Ontario) takes umbrage with, but to improve patient access to care.

Patient perspectives have been addressed internationally, with a small recent study from Ireland, for example, reporting that its findings were consistent with those in other countries where the PA role is more embedded. 'In meeting the patient's needs, an important aspect of care given by both doctor and PA seems to be keeping the patient informed and behaving in a professional manner' (Joyce 2019, page 222). The pilot introduction of four PAs in Ireland revealed the necessity to explain their role to colleagues (Joyce et al. 2019) confirming others' perceptions of what helps implementation. Whether behaving in a professional manner will be encouraged by regulation remains to be seen in the UK but registration does offer routes for patients to complain if they feel that this is not evident.

Other international studies are relevant to the UK in going beyond the debates about prescribing and referring for tests. Kepka et al (2014), for example, compared US primary care physicians (PCP) and advanced practice registered nurses (APRN), physician assistants (PAs) in activities related to cancer prevention and screening. They found that 'Seeing a PCP alone, or in conjunction with an APRN/PA is associated with patient receipt of guideline-consistent cancer prevention and screening recommendations. Integrating APRN/PA into primary care may assist with the delivery of cancer prevention and screening services'. This suggests new opportunities to look more closely at the effectiveness of PAs, as currently being undertaken by the NIHR Policy Research Unit on Cancer Awareness, Screening and Early Diagnosis.

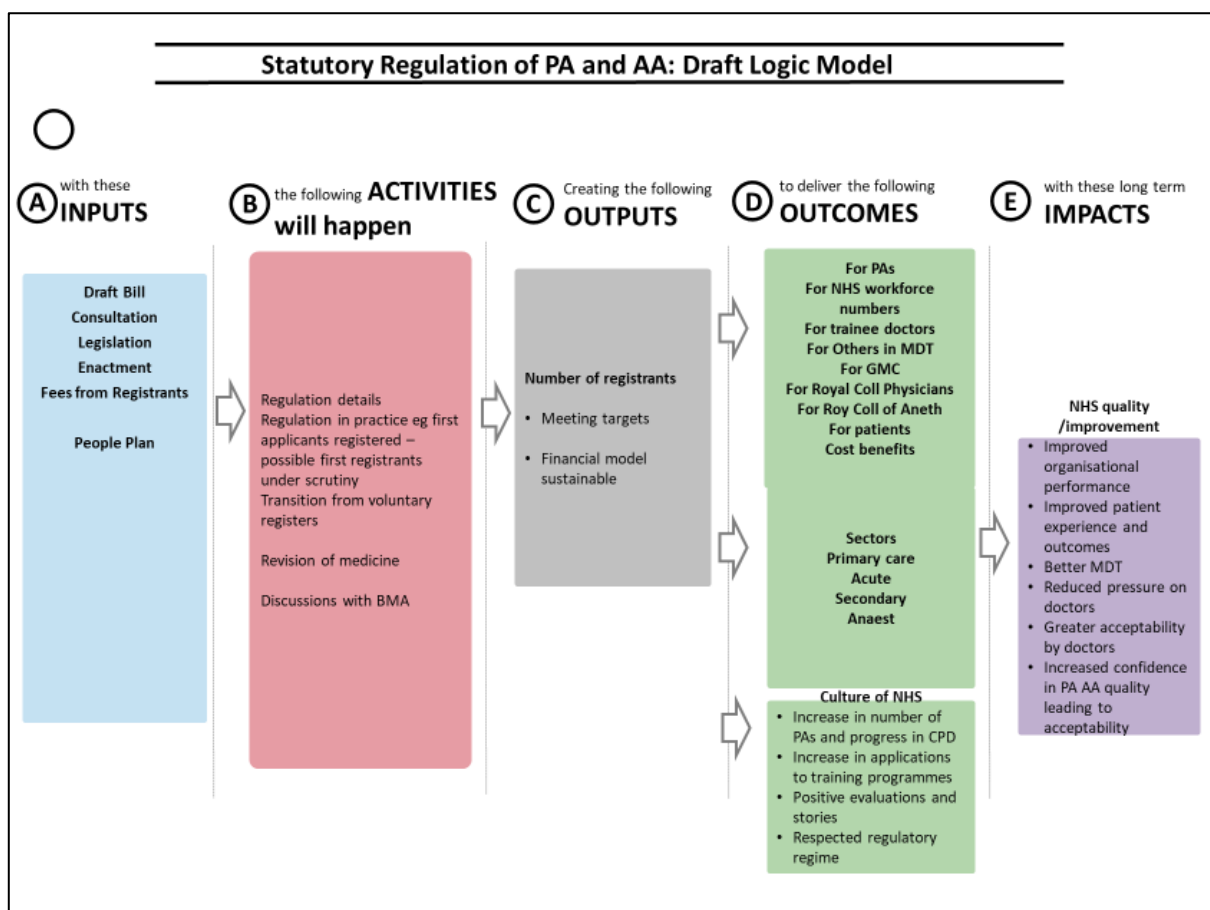
Formulation of a logic model

A logic model is a graphic that represents how an intervention may produce desired outcomes. It simplifies and represents a 'theory of change' about how a specific intervention works. Logic models demonstrate how an intervention produces change and arrows indicate where any causal relationships may lie.

In this review, the intervention in question is the regulation of PAs and AAs. Evidence from this review has been collated to produce the logic model presented below (Figure 3).

With inputs such as further consultation, legislation and enactment, fees from registrants, and the NHS Interim People Plan, the following activities can be expected: regulation details being released and seeing the process of registration in practice, in the form of the first applicants registering. There will be a transition from voluntary registers, and discussions with the BMA are continuing. These activities are presumed to result in numbers of registrants increasing and finding out whether the financial model is sustainable (fee levels for registration) as it currently stands, all to deliver a wide range of outcomes for PAs, in different sectors, and a shift in the culture of the NHS. A longer-term impact on NHS quality and improvement is expected, in terms of improved organisational performance, improved patient experience and outcomes, better multidisciplinary team working, reduced pressure on doctors, greater acceptability by doctors and overall increased confidence in PA and AA quality leading to acceptability.

Figure 3: Logic model representing theory of change with regulation of PA and AA roles.



Further research questions

This review also highlights questions not directly related to regulation, but possibly crucial to estimating the effectiveness or impact of the PA/AA role (and as discussed above in the sections on what can be measured and assessed?). These are summarised below as potential avenues for future research in this field:

- What it is the profile of the UK PA workforce? As is widely reported, the initial PAs in US and Canada were former military personnel who were trained to provide medical

support in the field during their service. Are military veterans a possible recruitment pool for PAs in the UK too, perhaps asking Step Into Health (NHS England Step Into Health <https://www.militarystepintohealth.nhs.uk/>) to explore this?

- Is a new pool of staff being recruited to the NHS workforce as PAs or AAs? Such aspirations for 'new labour pools' reflect long-standing worries about shortages in the NHS workforce.
- What is the potential to use data from regulation to find out more about the PA profile, recruitment sources and trends, and retention/progression, with perhaps making linkages with the NHS Electronic Staff Record data for comparative purposes? Is there a career pathway for PAs and is this being followed?
- Beyond regulation, are other staff's sometimes negative attitudes changing? What is the extent and nature of these concerns? Is there more of an appetite to ask other members of teams, besides doctors, about their experiences of working with PAs to discuss team-working more comprehensively?
- Other than regulation, how can PAs demonstrate accountability for their work?
- How are the costs of regulation being managed by PAs and by employers?
- What are the intentions of sequencing developments such as prescribing rights?

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