

## ANNEX 2: EVIDENCE OF PROBLEMS WITH AAs AND PAs

### Problems relating to patient safety generally

1. In 2017, Health Education England ('HEE') produced a risk assessment [SB2/J/57/907-910] identifying PAs as 'high' risk practitioners in all 3 domains examined (intervention, context and accountability), adding "*the types of intervention PA(A)s make on a routine basis are high risk.*" AAs were identified as presenting a 'high' risk in the intervention category and 'medium' risk in the accountability category: Marks 1, §§71-74 [CB/C/15/217-220].
2. Practitioners have expressed concerns about the risks associates pose to patient safety:
  - (1) Responses to the GMC's 2020 'Community of Interest' survey of 1,140 doctors and associates repeatedly raised concerns about the impact of associates on patient safety: Marks 2, §§52, 71, 82 [CB/C/18/285; 289; 292].
  - (2) The BMA called for an immediate halt to the recruitment and expansion of associate roles given patient safety concerns in November 2023; and again in its Parliamentary briefing on the 2024 Order: McAlonan 1, §10 [CB/E/30/367-368]. Some 87% of replies to the BMA's 2023 survey of c. 19,000 doctors said that how associates work in the NHS is a risk to patient safety: Marks 1, §138 [CB/C/15/238]; McAlonan 1, §11(a) [CB/E/30/368]. The BMA received 622 entries reporting patient safety concerns on its online member portal for the Leng Review: McAlonan 2, §7, 10 [CB/F2/33/505], correcting McAlonan 1, §23 [CB/E/30/373] and see entries at in DM2/1 at [SB6/M/257/5000-5066].
  - (3) 66% of respondents to the RCoA's 2024 survey of 6,000 anaesthetists expressed concerns about the impact of AAs on patient safety: Marks 1, §140 [CB/C/15/238-239].
  - (4) 81% of the 5,100 GPs surveyed by the RCGP in 2024 said that PAs in general practice had negative effects on patient safety and 50% were aware of specific examples of patient safety already having been compromised: Marks 1, §141 [CB/C/15/240].
  - (5) The overarching concern of respondents to the 2023 survey by the Doctors Association UK of 680 doctors was that PAs were compromising patient safety and multiple specific examples of patients coming to serious harm were given: Kneale, §20 [CB/C/17/260-263].
3. As for Royal Colleges:
  - (1) The RCoA has long been concerned about the impact of AAs on patient safety, responding to the 2017 consultation by raising these concerns: Marks 1, §§34-6, 39, 79-80 [CB/C/15/208-209; 209; 221].

- (2) The RCGP's concerns are long-held. In 2024 its members voted against PAs working in general practice and its 2024 SoP sought to limit what PAs could do because of the risks and lack of evidence for the safety of PAs in general practice: Marks 1, §§165-166 [CB/C/15/247].
- (3) The RCP's working group on PAs noted in 2024 that the failure on the part of the GMC to define, deliver and maintain national standards poses a risk to patient safety: Marks 1, §162 [CB/C/15/246]. Its response to the Leng Review notes concerns that the short PA training period affects their preparedness to provide clinical care and notes the lack of robust evidence to fully evaluate their safety: Marks 2, §20 [CB/C/18/277-278]; Response pp.5, 7-8 [SB6/M/252/4830; 4832-4833]).
- (4) The RCP of Edinburgh raised concerns in October 2024 that the quality assurance of PAs would be insufficiently robust or consistent to ensure patient safety: Marks 1, §169 [CB/C/15/248--249].

4. Coroners have indicated that:

- (1) Poor treatment by PAs has caused deaths: e.g. had the PA who treated Emily Chesterton referred her immediately to a hospital emergency unit she likely would have survived: Chesterton Report [CB/D/20/330].
- (2) *"There is no national framework for how PAs should be trained, supervised and deemed competent, which is placing patients...at risk"*: Pollitt Report, §3 [CB/D/22/335].
- (3) It is of concern that *"no policy or protocol exists within the Trust as to when patients may or may not be discharged from the Ambulatory Care Unit without a medical review taking place"*: Peters Report [CB/D/21/332].

5. Academics have found that:

- (1) There is currently no UK-based research evidence which directly examines the safety of PAs, which has erroneously been interpreted to mean there are no safety concerns, *"an error of logic which, if not corrected, is likely to cost lives"*: see Marks 2, § 19(1) [CB/C/18/277] (discussing Professor Greenhalgh's systemic review at [SB6/M/250/4599]).
- (2) There are significantly higher rates of death from peri-operative cardiac arrest if an AA is present: Marks 1, §61 [CB/C/15/215] (discussing the 2024 paper in 'Anaesthesia' by Cook *et al* [SB5/M/224/4397-4408]).

Problems relating to limits on practice

6. The HEE risk assessment [SB2/J/57//907-910] noted *“we understand that a proportion of PA(A)s work beyond the agreed scope of practice for the role, performing additional tasks with limited supervision, such as regional anaesthesia blocks and undertaking sedation lists”*: Marks 1, §§71-74 [CB/C/15/217-220].
7. Trust practice indicates that, despite the RCoA 2016 SoP guidance (Marks 1, §§35-42 [CB/C/15/208-211]):
  - (1) Dudley: AAs are permitted to conduct skilled and potentially very risky procedures with material risks of injury or death that are outside the RCoA 2016 SoP: Marks 1, §51 [CB/C/15/213].
  - (2) Northumbria: using its own SoP to allow AAs to perform spinal anaesthesia, including on minors (both outside the RCoA SoP): Marks 1, §§54, 56 [CB/C/15/213; 214].
  - (3) Southport and Ormskirk: using its own SoP to allow AAs to carry out ‘extended roles’, including being part of cardiac arrest teams, specialised assessments, regional anaesthesia and eye blocks (all outside RCoA SoP): Marks 1, §58 [CB/C/15/214].
8. As for practitioners:
  - (1) The BMA has long been concerned about the lack of a national SoP for associates: McAlonan 1, §9 [CB/E/30/367]. 80% of respondents to the 2023 BMA survey stated that they were occasionally or frequently concerned that a PA or AA they worked alongside was working beyond their competence: Marks 1, §138 [CB/C/15/238]. The BMA’s Chair stated in November 2024 that there must be a national SoP and that, without one, there is a *“free-for-all”*, which means hospitals have become a *“postcode lottery”*: McAlonan 1, §20 [CB/E/30/371]. A further survey of 14,000 members in February 2025 found 95% agreeing that there should be nationally determined SoPs for PAs and AAs, with 87% disagreeing that this would negatively impact patient care: McAlonan 1, §12 [CB/E/30/368-369]. 287 of entries on the BMA’s 2025 online member portal reported patient safety concerns directly linked to associates working beyond a safe SoP by replacing doctors on medical rotas: McAlonan 2, §10 [CB/F2/33/505] and see entries at Exhibit DM2/1 [SB6/M/257/4956-4999].
  - (2) Responses to the GMC’s 2020 ‘Community of Interest’ survey expressed: concerns about *“AAs and PAs acting beyond their competency or role”* (a theme *“was closely linked to the lack of clarity around scope of practice”*); reports that the RCoA 2016 SoP was not being adhered to and that *“Local organisations seem to be able to make up their own rules”*; concerns that AAs and PAs lacked insight into their own limitations; a conflict *“between the PA/AA wanting to expand their role and the impact of that on patient safety”*: Marks 2, §§69-71 [CB/C/18/289]. The

report concluded that if GMP was to be extended to associates, SoP needed to be “clearly defined”: Marks 2, §§84-86 [CB/C/18/292-293];

- (3) The GMC’s External Advisory Group noted that “it is difficult for colleagues to understand where PAs and AAs are up to in their career progression and what they are allowed to do that is within their scope of practice”: Marks 2, §90 ([CB/C/18/294].
- (4) DAUK raised concerns with the GMC in 2023 about the “alarming” lack of a national SoP (Kneale, §15 [CB/C/17/259]), then again in response to the 2024 consultation, that PAs and AAs are occupying roles traditionally carried out by doctors with more and more adverts for PA posts in roles that would be deemed suitable only for specialist registrar level and above doctors (Kneale, §26 [CB/C/17/265]). The DAUK’s 2023 survey found: PAs being used to fill gaps for doctors; confusion about what they can and cannot do; PAs undertaking roles that should be staffed by a senior doctor (including running resuscitation cases, conducting unsupervised ward rounds for prolonged periods and performing complex surgical procedures) (Kneale, §20(d)-(m) [CB/C/17/260-262]).
- (5) The account given by AAs of their practice given in a GMC Workshop reveals total disregard across multiple trusts for the limits set in the RCoA 2016 SoP: Marks 1, §62 [CB/C/15/215] (presentation transcript: [SB5/M/232/4453 - 4462]).
- (6) Senior AAs at a 2023 presentation at Lancaster University’s ‘Introduction to AAs’ event stated that trusts “bend the rules”: Marks 1, §62 [CB/C/15/215] (presentation transcript: [SB5/M/233/4463 - 4464])

9. As for the Royal Colleges:

- (1) The RCoA recognised AAs reluctantly, giving guidance about their SoP (in the form of the 2016 RCoA SoP) and establishing a voluntary register: Marks 1, §§35-44 [CB/C/15/208-211]. It responded to the 2017 and 2018 consultations with concerns that its guidance was not being adhered to (Marks 1, §§ 79-81 [CB/C/15/221-222]); in 2023 it requested that recruitment of AAs be paused until there was a detailed post-qualification SoP (Marks 1, §133 [CB/C/15/236-237]); it responded to the 2023 Skills for Health consultation stating that a national SoP was essential (Marks 1, §135 [CB/C/15/237]). The RCoA’s December 2024 Interim SoP mentions concerns about patient safety as a result of anaesthetic departments employing AAs to work beyond the RCoA’s 2016 SoP (at p.2) [SB1/I/M/55/862].
- (2) The RCP’s Trainees’ Committee recommended (in June 2024) that advanced scope for PAs, including ceilings on practice, must be nationally defined on a specialty-by-specialty basis; the RCP committed to working to clarify the SoP, following its working group’s finding

that the GMC had failed to define, deliver and maintain national standards in relation to this issue; it also recommended that further expansion of PA roles be limited until an SoP was in place: Marks 1, §§161-2 [CB/C/15/246-247]; McAlonan 1, §47(d) [CB/E/30/383-385]. The RCP's response to the Leng Review stated that PAs must have "*a clearly defined national scope and ceiling of practice*", the lack of which was a recurring concern in its visits to trusts in 2024; it also cited evidence that "*many PAs are working as de facto doctor substitutes, including for senior decision making*", identifying the risks of their being confused with resident doctors, and describing a "*failure of local governance process*" in identifying and investigating risks to patients safety: Marks 2, §20 [CB/C/18/278] (and response itself, pp.3-5, 7-9 [SB6/M/252/4829-4830; 4832-4833]). In its response to the Susan Pollitt PFD Report, the RCP stated that "*a comprehensive, national, safe and clear scope of clinical practice for PAs is essential*" (McAlonan 1, §49 [CB/E/30/385]).

- (3) The RCP of Edinburgh noted concerns about the proliferation of different SoPs for PAs which will cause confusion and risk harm to patients in October 2024: Marks 1, §169 [CB/C/15/248-249].
- (4) The RCGP's HoL briefing described an "*urgent need for clarity on the scope of practice*" and that the PA role in GP practices "*must be approached with extreme caution*": McAlonan 1, §47(c) [CB/E/30/381]. The same was said in the response to the Skills for Health consultation in 2024: Marks 1, §136 [CB/C/15/237-238]. 60% of GPs surveyed by the RCGP in 2024 said that PAs act as the first point of contact for potentially serious conditions and 24% said that they were aware of the RCGP's 'red lines' being crossed such that greater clarity was needed on SoP and recruitment should be halted (which members voted for): McAlonan 1, §47(c) [CB/E/30/381-382]. See also the RCGP response to the Leng Review: Marks 2, §20 [CB/C/18/278] (letter at [SB6/M/244/4545 - 4546]).
- (5) The Royal College of Surgeons ("RCS") said in February 2024 that there was an urgent need to define a national SoP given concerns about variability in trusts: Marks 1, §158 [CB/C/15/245].
- (6) The Royal College of Emergency Medicine released updated guidance in February 2025 reducing the tiered level at which PAs could work, having already called for a halt in recruitment of PAs into emergency medicine: McAlonan 1, §47(e) [CB/E/30/385].

10. Patients have indicated:

- (1) At the GMC's Patient Forum, that 50% of associates go beyond their SoP and there was a need for standards of competency after qualification on a national basis: Marks 2, §65 [CB/C/18/288].

- (2) That associates are essentially filling roles doctors would ordinarily undertake and have poor insight into their limitations (e.g. the associate who saw Emily Chesterton twice for a 'GP' appointment, did not conduct proper checks, identify 'red-flag' symptoms or refer her to emergency care, and showed little insight: Chesterton 1, §§46, 50, 53-4 [CB/C/13/178; 179; 179-180].

11. Coroners have indicated that:

- (1) “[G]iven their limited training and in the absence of any national or local recognised hospital training for Physician Associates once appointed, this gives rise to a concern they are working outside their capabilities” e.g. the PA who treated Mrs Marking, who was being treated by the Trust as “clinically equivalent to a Tier 2 resident doctor without evidence to support this belief” and who did not appreciate the relevance of her serious symptoms: Pamela Marking PFD Report, §§2; 4 [CB/D/28/357; 356].
- (2) PAs are being signed off as competent without adequate proof of that in all aspects of care e.g. the PA treating Mrs Pollitt, ignorant of basic safety rules for inserting ascitic drains when signed off as competent at that task: Susan Pollitt PFD Report, §§4, 5 [CB/D/22/334].

12. Academics have indicated that the “lack of nationally defined scope of practice may contribute to inappropriate deployment (PAs/ AAs being asked to do things they are not confident or qualified to do), staff confusion (leading to negativity towards individual PAs/AAs), and over- or under-confidence among PAs and AAs”: see Greenhalgh at p.10, Table 2 [SB6/M/250/4599].

13. The national press has investigated and reported:

- (1) In March 2024 the Telegraph reported that 31 NHS hospitals in England were allowing associates to replace doctors on rotas, and counting them towards the minimum safe number of medics on shift, which is made easier by the lack of a SoP: McAlonan 1, §21 [CB/E/30/372].
- (2) In October 2024 Channel 4 reported that 11 trusts were using associates to cover rota gaps, and 14 did not keep any data on this issue: McAlonan 1, §22 [CB/E/372-373].

Problems relating to supervision/delegation

14. Trust practice does not adhere to the RCoA 2016 SoP's strict ratios of AA supervision and rule that a consultant be present in the theatre suiteable to attend in 2 mins (Marks 1, §§35-42 [CB/C/15/208-211]):

- (1) Dudley allows indirect supervision with a consultant available by telephone even for high-risk matters outside the RCoA SoP eg. induction of anaesthesia: Marks 1, §§50-51 [CB/C/15/213].

- (2) Northumbria does not mandate where consultant must be or ratios, but states that consultant must be available to attend within 2 minutes: Marks 1, §55 [CB/C/15/213-214].
- (3) Southport and Ormskirk permits indirect, even “*distant*” supervision (consultant within the hospital but not necessarily in the same Department or building): Marks 1, §59 [CB/C/15/214].

15. As for practitioners:

- (1) The GMC’s 2020 ‘Community of Interest Survey’ revealed concern that doctors are unsure how to delegate to and supervise associates given difficulties calibrating their competency compared with doctors, especially in a busy department or for a locum and given local variance: Marks 2, para §§51-52 [CB/C/18/285]. Most disagreed that delegation and supervision happens safely and effectively, in part given the lack of clarity around SoP; doctors are “*uncomfortable*” signing prescriptions within reviewing patients and concerns about the lack of guidance: Marks 2, §§74-78 [CB/C/18/290-292]. The report found that if GMP was to be extended to associates, supervision requirements needed to be clarified: Marks 2, §§84-86 [CB/C/18/292-294].
- (2) DAUK’s survey results found evidence of PAs carrying out high-risk work without supervision and a general lack of clarity about supervisor responsibilities, many respondents reporting that PAs worked independently or with “*token, inadequate supervision*”; 74% of respondents had been asked to prescribe for PAs and expressed concerns about being pressured into doing so without being able to exercise meaningful clinical judgment, undermining patient safety: Kneale, §20(n)-(r) [CB/C/17/262-263].
- (3) AAs’ own accounts of their practice in a GMC Workshop reveal total disregard across Trusts for the limits set by the RCoA in terms of safe supervision levels: Marks 1, §62 [CB/C/15/215].
- (4) Speakers at a 2023 presentation by Senior AAs at Lancaster University’s ‘Introduction to AAs’ event stated that they have autonomous sessions, running their own unsupervised lists: Marks 1, §62 [CB/C/15/215] (transcript of presentation at [SB5/M/233/4463 - 4464]).
- (5) A 2024 research paper in the journal ‘Anaesthesia’ by Cook et al reported AAs working in isolation, including at induction of anaesthesia, with only indirect supervision in almost half of cases where the AA was the senior anaesthesia care provider (this occurring in 1 in 6 cases involving an AA): Marks 1, §61 [CB/C/15/215].

16. As for Royal Colleges:

- (1) In 2017-2018, the RCoA knew that AAs were working without both the supervision and SoP envisaged by the 2016 RCoA SoP (Marks 1, §80 [CB/C/15/221]); its consultation responses showed that inadequate supervision was a problem (Marks 1, §§81 [CB/C/15/221-22]).
  - (2) In May 2024, the RCP working group reported that the GMC had failed to define, deliver and maintain national standards on this topic and recommended that further expansion of PA roles be limited until clear guidance on supervision was in place; in June 2024, the Trainees Committee asked for clear guidance for doctors on supervisory roles and the College committed to working to clarify supervision issue: Marks 1, §§161-2 [CB/C/15/246]; McAlonan 1, §47(d) [CB/E/30/383-385]). The RCP told the Leng Review that in visits to trusts in 2024, medical teams were unclear about what PAs can do; that PAs were being employed in roles without proper oversight, where PAs themselves don't comprehend their own limitations, creating a "*material risk to the ability of some PAs to escalate concerns appropriately without a clear ceiling of practice*"; and that senior doctors did not have adequate capacity to supervise: Marks 2, §20 [CB/C/18/277-278]; RCP response to Leng Review, pp.5, 7-9 [SB6/M/252/4830; 4832-4834).
  - (3) The RCGP said when responding to the Skills for Health consultation in 2024 that PAs must always work under supervision of a fully qualified GP and that supervision must be properly designed and resourced (Marks 1, §136 [CB/C/15/237-238]); 25-30% of GPs surveyed by the RCGP in 2024 said that no time was scheduled for regular supervision and only 25% said associates had an annual appraisal (McAlonan 1, §47(c) [CB/E/30/381-383]). The RCGP's 2024 SoP notes that there are fewer opportunities in primary care to seek contemporaneous guidance from senior colleagues, making this a high-risk environment (Marks 1, §166 [CB/C/15/247]).
17. Patients and their families have raised concerns about the inadequate supervision of PAs: e.g. the PA who saw Emily Chesterton was not supervised in her appointments, nor were her decisions reviewed, and the GP who signed off on her dangerous prescription had hundreds to sign off that day and it "*slipped through the net*" (Chesterton 1, §§47-48 [CB/C/13/178-179]); the PA who treated Mrs Pollitt was effectively unsupervised and her family believe proper supervision would have prevented her mistakes (Pollitt, §§19, 36 [CB/C/14/192; 195]).
  18. Coroners have indicated that:
    - (1) The systems for signing PAs off as competent at a given task may not suffice e.g. if it relates to the technical aspect and not wider aspects of care: Pollitt Report, §5 [CB/D/22/335].

- (2) In the case of Mrs Marking, the PA was “*effectively acting independently in the diagnosis, treatment, management and discharge...without independent oversight by a medical practitioner*”, which “*gives rise to a concern that inadequate supervision or excessive delegation...compromises patient safety*”: Marking Report, §5 [CB/D/28/357].

19. Academics have indicated that:

- (1) Research suggests that PAs struggle in more autonomous roles (such as primary care) where supervision arrangements are more challenging: Greenhalgh review p.8 [SB6/M/250/4597]
- (2) AAs were working as the senior anaesthesia care provider with supervision only available indirectly in almost half of cases in a study of 18 recent incidents of peri-operative cardiac arrest (Marks 1, §61 [CB/C/15/215], discussing the paper of Cook et al).

Problems relating to informed consent

20. Trust practice indicates that consent is not being addressed in their SOPs (see Dudley: Marks 1, §53 [CB/C/15/213]; Northumbria: Marks 1, §57 [CB/C/15/214]; Southport and Ormskirk: Marks 1 §60 [CB/C/15/214]).

21. As for practitioners:

- (1) 92.5% of respondents to the GMC’s 2020 ‘Community of Interest’ survey’ disagreed that the PA/AA role is well understood by patients, with concerns raised about lack of awareness as a patient safety concern: Marks 2, §§81-83 [CB/C/18/292].
- (2) 86% of respondents to the BMA’s 2023 survey felt that the public did not understand the difference between associates and doctors at all: McAlonan 1, §11 [CB/E/30/368].
- (3) DAUK’s 2023 survey noted a lack of transparency about the PA role: 84% of respondents said that PAs introduced themselves vaguely or implied they were doctors and were often introduced to as, or mistaken for, doctors: Kneale, §20(a)-(d) [CB/C/17/260].
- (4) Senior AAs speaking at a 2023 presentation at Lancaster University’s ‘Introduction to AAs’ event stated that they introduce themselves only as “*part of the anaesthetic team*” because their title is too confusing: Marks 1, §62 [CB/C/15/215] (transcript of presentation at [SB5/M/233/4463]).

22. As for the Royal Colleges:

- (1) The Academy of Medical Royal Colleges responded to the 2023 consultation highlighting its concerns about the GMC’s proposals as the distinction of medical practitioner vs.

associate was not obvious to patients or the wider healthcare team: Marks 1, §108 [CB/C/15/228].

- (2) The RCGP amended its position statement on 8 March 2024 to raise significant concerns that regulation by the GMC “*could increase confusion amongst patients about the differences between doctors and PAs*”: McAlonan 1, §47(c) [CB/E/30/381-383].

23. Patients and their families have explained that they were not aware that they were not seeing a doctor e.g. Emily Chesterton, who believed she had seen a GP and whose family would have insisted on a second opinion had they known that was not the case (Chesterton 1, §§55, 47 [CB/C/13/180; 178]); and Mrs Pollitt, whose family thought the PA treating her was a doctor until an investigation took place (Pollitt, §§19, 26 [CB/C/14/193; 193]).

24. Coroners have indicated that:

- (1) There is “*limited understanding and awareness*” of the role of PA, and that “*the lack of distinct uniform and the title “Physician” gives rise to confusion as to whether the practitioner is a doctor*” (Pollitt Report, §4 [CB/D/22/335]).

- (2) Mrs Marking’s family was “*under the mistaken belief that the PA was a doctor by this title in circumstances where no steps were taken by the Emergency Department or the Physician Associate to explain or clearly differentiate their role from that of medically qualified practitioners*” (§1), and that “*issues of informed consent*” were raised as the public were not aware they were being treated by a PA, which might hinder requests to seek an opinion from a medical practitioner: Marking Report, §§1; 3 [CB/D/28/356].

25. Academic research shows that patients wish to be informed if the person seeing them is a PA (Greenhalgh Review, p.7 [SB6/M/250/4596]). This accords with the GMC’s recently disclosed “Empathy Mapping” produced for the GMC Council Away Day some time before July 2023: [SB4/M/150/3828], the genesis and wider results of which are not addressed in GMC evidence.