



Bleeding through Legal Boundaries: Anticoagulants, Atrial Fibrillation and Intracranial Haemorrhage

- A Policy and Practice Analysis

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Abstract. The expansion of Direct Oral Anticoagulant (DOAC) therapy has transformed stroke prevention in atrial fibrillation[1], but introduced new complexities in death certification. Frail patients on DOACs are increasingly represented in cases of fatal bleeding, particularly intracranial haemorrhage, triggering coronial referrals under the Notification of Deaths Regulations (2019)[2]. This practice-informed analysis explores how Medical Examiners in England and Wales can support proportionate, legally defensible decision-making at the interface of preventive medicine and coronial law. It argues for structured scrutiny, national guidance, and system-level reform to ensure that referrals reflect genuine contribution and public interest, rather than ambiguity or misinterpretation of regulatory thresholds.

Keywords: Direct oral anticoagulants (DOACs), intracranial haemorrhage, coronial referrals, Medical Examiner Service, Notification of Deaths Regulations 2019.

1 Introduction

The rapid expansion of Direct Oral Anticoagulant (DOAC) prescribing represents one of the most consequential public health interventions of the past decade. As NHS England reported in late 2023, the “Detect, Protect and Perfect” initiative contributed to generating 24 million DOAC prescriptions between January 2022 and November 2023, potentially preventing 17,000 strokes and 4,000 deaths annually[3]. Yet the very success of this preventive strategy has produced a parallel and less anticipated development: a growing number of deaths in which anticoagulation may have contributed to fatal bleeding, particularly intracranial haemorrhage, and which therefore fall within the statutory ambit of the Notification of Deaths Regulations (2019). This convergence of preventive medicine, frailty, and coronial law has created a new frontier of medico-legal complexity that since the statutory roll-out of the Medical Examiner Service in September 2024, is one that medical examiners (MEs) are now required to navigate.

This paper examines how MEs should interpret and apply the Regulations in cases where DOAC therapy may have contributed to death, with a particular focus on frail or

elderly patients who experience intracranial haemorrhage. The analysis adopts a doctrinal and policy-oriented approach, drawing on statutory frameworks, NICE guidance, clinical evidence, coronial caselaw principles, and practice-based reflections from a busy ME office. It does not present patient-level data or empirical audit findings; rather, it seeks to illuminate the structural tensions that arise when biomedical innovation reshapes the legal and organisational systems responsible for certifying, investigating, and learning from death

2 Preventive Medicine Meets Legal Duty

Stroke occurs 100,000 times annually in the UK [4]. 85% are ischaemic strokes, where a blood clot or atherosclerotic plaque blocks an artery cutting off blood flow and oxygen to part of the brain, causing brain cells to die quickly[5]. Atrial fibrillation (where the heartbeat is irregular and abnormally fast) promotes clot production through the incomplete emptying of the heart with each heartbeat: DOAC therapy is an effective means of reducing the risk of clot-formation in these patients[6]. The demographic most likely to benefit from DOAC therapy – older adults with multimorbidity and frailty – is also the demographic most vulnerable to falls, trauma, and spontaneous intracranial haemorrhage. Frailty affects around 10% of people over 65 and up to 50% of those over 85[7], amplifying susceptibility to minor trauma and bleeding complications. Meanwhile, intracerebral haemorrhage accounts for up to a fifth of all strokes and carries a one-year mortality approaching 60%[8]. Although DOACs do not necessarily increase the initial volume of haemorrhage, they can prolong the period of haematoma expansion, often for 24–48 hours, thereby increasing the likelihood of fatal progression[9]. These clinical realities intersect directly with the legal requirement to report any death related to the use of a medicinal product[2]. The statutory rollout of the ME Service in 2024 has brought greater consistency to the scrutiny of non-coronial deaths, and with it a foreseeable rise in referrals involving anticoagulation. The question is not whether this rise will occur, but how the system should respond to it.

3 Causation, Contribution and the Coroner's Threshold

Please The legal threshold for coronial referral is deliberately broad. A death must be reported if a medicinal product contributed more than minimally to the outcome, or if the death was unnatural, including those involving trauma-related intracranial haemorrhage. Crucially, it is the coroner (not the ME) who determines whether a death is unnatural, whether an investigation is required, and how causation should be articulated in law. The ME's role is pre-coronial: to provide independent scrutiny, clarify clinical circumstances, identify regulatory triggers, and communicate transparently with families. It is not the ME's function to make findings of fact or to act as a gatekeeper to reduce coronial workload. Yet the practical challenge is substantial. In many cases of

intracranial haemorrhage, particularly unwitnessed collapses, it is impossible to determine whether trauma precipitated the bleed or occurred as a consequence of it. Where a head trauma has occurred, current NICE guidance recommends all people on anticoagulant or antiplatelet therapy, including those with no history of amnesia or loss of consciousness, have a CT or MRI within 8 hours of injury[10]. A single scan however offers only a snapshot, not a trajectory. Given that DOACs prolong haematoma expansion and thereby increase mortality, their contribution will often exceed the “more than minimal” threshold. In gastrointestinal bleeding too, the failure of endoscopic or interventional measures to control haemorrhage may indicate a material contribution from anticoagulation[11]. In such contexts, referral is not merely defensible but necessary. However, having made the medical decision that a death related to a DOAC qualifies as notifiable, our Medical Examiners Office frequently receives follow-up questions of which this is an example:

‘The coroner has asked if you could please clearly clarify the answers to the main questions being:

1. Did the anticoagulation medication cause the stroke, or otherwise did it increase the extent of the bleed?

2. Are you able to state whether the anticoagulation meant that this was a fatal event?

If you could please provide a clear response to these questions as soon as possible, it would be very much appreciated’[12].

In our experience, responding with the observation that whilst the DOAC did not directly cause the bleed, it may have contributed negatively to the outcome, is insufficiently didactic to support the coroner towards a judicial decision.

4 The Systems-Level Consequences of DOAC Expansion

The scale of DOAC prescribing, combined with an ageing population and the statutory embedding of ME scrutiny, makes a substantial increase in coronial referrals not only plausible but structurally inevitable. Even a modest rise in anticoagulation-related deaths by 5–10% would translate into thousands of additional referrals annually. This is not a reflection of practitioner error but a predictable systems-level consequence of preventive medicine intersecting with legal duty. Whilst there remains no national database of coroner referrals in England and Wales, inference may be drawn from Prevention of Future Deaths (PFD) reports, which reflect 1.5% of inquests conclusions. A study in 2022 reviewed PFD reports identifying 113 related to anticoagulation therapy in the seven years between 2013 and 2019[13]. A basic review of the PFD website demonstrates 57 anticoagulation-related reports in the three years between 2023 and 2025, representing an 18% increase[14]. This could be a sign of things to come. Safeguards against under-referral also become essential. Where uncertainty exists, particularly in unwitnessed collapses or unexplained intracranial haemorrhage, referral should be the default. Transparent documentation of ME reasoning, clear communication with

families, and recognition of the coroner's ultimate authority all serve to maintain public protection and trust.

5 Towards Proportionate, Legally Defensible Practice

The ME Service has the potential to bring clarity and proportionality to this evolving interface. By embedding structured, clinically informed scrutiny into the certification process, MEs can help coroners understand the plausible mechanisms by which anticoagulation may have contributed to death. They can identify when trauma is a realistic possibility, articulate the uncertainties inherent in unwitnessed events, and ensure that the Regulations are applied consistently across cases and institutions. What they cannot do, and should not attempt to do, is override statutory triggers or reduce referrals through interpretive narrowing. The goal is not to limit coronial oversight but to ensure that each referral is justified, proportionate, and aligned with the public interest. In this sense, the ME Service becomes an adaptive mechanism within the wider system of death investigation, enabling the legal framework to evolve in step with clinical progress rather than in reaction to its unintended consequences.

6 Policy Directions for a Future-Ready System

A future-oriented response requires national coherence. Shared guidance between MEs and coroners on interpreting “more than minimal contribution” in anticoagulation-related deaths would reduce ambiguity and variation. Standardised terminology (eg ‘bleed’ vs ‘haemorrhage’, ‘intracranial’ vs ‘intracerebral’) and structured scrutiny notes explicitly addressing mechanism of death, plausible contribution of anticoagulation, presence or absence of trauma and the uncertainties requiring coronial oversight would support clarity and comparability. Joint training could foster a shared understanding of frailty, anticoagulation, and causation thresholds. Early dialogue in complex cases would prevent unnecessary delay. At a systems level, the collation of ME-identified patterns could inform public health initiatives in frailty prevention, falls reduction, and safer prescribing. Research partnerships between ME services, stroke physicians, and coronial offices could refine understanding of DOAC-related mortality. Legislative review may ultimately be required to ensure that the Notification of Deaths Regulations remain proportionate in the era of large-scale preventive medicine (Table 1).

Table 1. Table captions should be placed above the tables.

National Consensus Guidance on DOAC-Related Deaths	Joint ME - Coroner Training and Early Dialogue Mechanisms	Review and Clarify the Notification of Deaths Regulations (2019)
Establish unified ME–coroner guidance for interpreting “more than minimal contribution” in anticoagulation-related deaths, particularly intracranial haemorrhage. This should include standardised terminology, structured scrutiny notes, and a national decision-support framework to ensure clarity, consistency, and defensible practice across jurisdictions.	Introduce routine collaborative training on anticoagulation, frailty, and causation thresholds, alongside mechanisms for early case discussion. This will foster shared understanding, reduce delays, and support proportionate referrals grounded in clinical and legal nuance.	Undertake legislative review to ensure the Regulations remain proportionate in the context of modern preventive medicine. Consider statutory clarification of the contribution threshold and explore ME-led early resolution pathways for clearly natural deaths, preserving coronial independence while enhancing system efficiency.

Taken together, these recommendations speak directly to the wider concern with how biomedical innovation reshapes the social, legal and organisational systems around it[15]. The expansion of DOAC therapy exemplifies a future in which preventive medicine saves lives at scale yet simultaneously generates new forms of complexity for death investigation, regulatory oversight and public accountability. By strengthening national guidance, enhancing ME/coroner collaboration and embedding safeguards that protect both families and the public interest, the system can evolve in step with clinical progress rather than in reaction to its unintended consequences. In this sense, the Medical Examiner Service becomes not merely an administrative addition but a critical adaptive mechanism that helps ensure that advances in population health are matched by equally thoughtful advances in the structures that govern how we understand, certify and learn from death.

7 Conclusion

The expansion of DOAC therapy represents a major public health achievement, preventing thousands of strokes each year and reshaping the clinical landscape of atrial fibrillation. Yet this success has also created a predictable and growing interface with coronial law, particularly as frailty, falls, and anticoagulation increasingly converge in an ageing population. The statutory implementation of the Medical Examiner Service provides a unique opportunity to bring clarity, consistency, and proportionality to this interface. Our analysis highlights that DOAC-related deaths frequently meet the “more

than minimal contribution” threshold under the Notification of Deaths Regulations (2019), especially in cases of intracranial haemorrhage where anticoagulation prolongs haematoma expansion. In such circumstances, coronial referral remains both necessary and appropriate. However, variation in understanding of the Regulations, uncertainty about causation, and the absence of structured guidance have historically contributed to inconsistent referral patterns. The Medical Examiner Service is not a mechanism for reducing coronial workload: its value lies in improving the quality of information available to coroners, supporting transparent reasoning, and ensuring that referrals are made for the right reasons. By embedding clinical context, clarifying uncertainty, and articulating plausible mechanisms of contribution, MEs can help coroners make timely and well-informed decisions while maintaining public confidence in the death-investigation system. As preventive medicine continues to expand, the intersection between therapeutic benefit and legal duty will only become more complex. A system-level response is therefore essential. Strengthening national guidance, improving ME-coroner communication, and developing shared frameworks for interpreting contribution in anticoagulation-related deaths would support more consistent practice and reduce avoidable ambiguity. Ultimately, the goal is not to limit referrals but to ensure that each referral is proportionate, justified, and aligned with the public interest.

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References

1. British Heart Foundation. What are direct oral anticoagulants (DOACs) and how do they work? <https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/drug-cabinet/doac> (accessed 4 January 2026).
2. UK Government. The Notification of Deaths Regulations 2019 (SI 2019/1112). <https://www.legislation.gov.uk/uksi/2019/1112> (accessed 4 January 2026).
3. Wilkinson, E.: Rapid DOACs rollout for AF ‘six years ahead of target’. Pulse Today. <https://www.pulsetoday.co.uk/news/clinical-areas/cardiovascular/rapid-doacs-rollout-for-af-six-years-ahead-of-target/> (accessed 4 January 2026).
4. National Institute for Health and Care Excellence (NICE). Prevalence | Background information | Stroke and TIA. <https://cks.nice.org.uk/topics/stroke-tia/background-information/prevalence/> (accessed 4 January 2026).
5. Stroke Association. Ischaemic stroke. <https://www.stroke.org.uk/stroke/types/ischaemic> (accessed 4 January 2026).

6. National Institute for Health and Care Excellence (NICE). Atrial fibrillation: diagnosis and management (NICE guideline NG196). <https://www.nice.org.uk/guidance/ng196/chapter/Recommendations> (accessed 4 January 2026).
7. Office for National Statistics (ONS). Older people living in care homes in 2021 and changes since 2011. <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/ageing/articles/olderpeoplelivingincarehomesin2021andchangessince2011/2023-10-09> (accessed 4 January 2026).
8. Stroke Association. Haemorrhagic stroke. <https://www.stroke.org.uk/stroke/types/haemorrhagic> (accessed 4 January 2026).
9. Broderick, J.P., Brott, T.G., Duldner, J.E., Tomsick, T., Huster, G.: Volume of intracerebral hemorrhage: a powerful and easy-to-use predictor of 30-day mortality. *Stroke* 24, 987–993 (1993). doi: 10.1161/01.STR.24.7.987
10. National Institute for Health and Care Excellence (NICE). Head injury: assessment and early management (NICE guideline NG232). <https://www.nice.org.uk/guidance/ng232/resources/head-injury-assessment-and-early-management-pdf-66143892774085> (accessed 4 January 2026).
11. Martin, A.-C. et al.: Management of gastrointestinal bleeding and resumption of oral anti-coagulant therapy in patients with atrial fibrillation: a multidisciplinary discussion. *American Journal of Cardiovascular Drugs* 23, 407–418 (2023). doi: 10.1007/s40256-023-00572-9
12. Coroners Office: Email to Medical Examiners Office. Personal communication (3 March 2024).
13. Anis, A. et al.: Deaths from cardiovascular disease involving anticoagulants: a systematic synthesis of coroners' case reports. *BJGP Open* 6, BJGPO.2021.0150 (2022). doi: 10.3399/BJGPO.2021.0150
14. Courts and Tribunals Judiciary. Reports to Prevent Future Deaths. <https://www.judiciary.uk/courts-and-tribunals/coroners-courts/reports-to-prevent-future-deaths/> (accessed 4 January 2026).
15. Kosiol, J. et al.: Revolutionising health and social care: innovative solutions for a brighter tomorrow – a systematic review of the literature. *BMC Health Services Research* 24, 809 (2024). doi: 10.1186/s12913-024-11099-5

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