

Dental
Protection



Closing the AI liability gap: AI, safety, and the case for legislative change

June 2026

Executive Summary

The law has always struggled to keep up with technological change. With AI, the pace of change is so rapid that this gap feels less like a step and more like a widening gulf.

A recent White Paper¹ - produced through a collaboration between the MPS Foundation, York University's Centre for Assuring Autonomy, and the Improvement Academy at the Bradford Institute for Health Research - highlights how clinicians could find themselves exposed when their decisions are influenced by AI recommender systems. Such systems analyse patient data and suggest personalised treatment plans, diagnoses, or medications.

There are also concerns about who might be held liable in the event of a claim relating to AI scribes, automated documentation assistants, triage algorithms, and other forms of clinical decision support. These all share a common feature: they shape clinical reasoning, records, and workflows without taking autonomous responsibility for the outcomes.

Under the current legislative framework, there is a risk that dentists could be held wholly liable if an AI suggestion turns out to be wrong and they have followed it. That's because the existing product liability regime was never designed with AI in mind.

Clinicians could be left in a bind. If they reject an AI output and things go wrong, there is a real and significant risk that they could face allegations of negligence if the AI output was deemed to be appropriate. But if they follow an inappropriate recommendation and the outcome is still poor, they risk becoming the 'mark' or the 'liability sink' - the obvious target for a damages claim. All of this despite having little control over, and perhaps only a limited grasp of, how the AI system reaches its conclusions. We think that's inequitable. When harm arises from a defective AI product, system, or algorithm, responsibility shouldn't fall squarely on the clinician's shoulders. Clinicians should be given the same clarity as they would in instances of defective physical medical equipment.

The law needs to evolve. Clinical negligence rules, product liability, and new regulatory frameworks must be updated to ensure accountability is fairly shared with developers, manufacturers, and suppliers where defects in the AI tool have led to demonstrable harm.

We urge the government to develop legislation that would classify AI systems as products subject to strict liability, taking inspiration from the EU's revised Product Liability Directive whilst being tailored to the UK context.

We see four clear benefits from reform:

- 1. Unlocking AI's potential.** If dentists can trust the tools at their disposal and be clear about where liability sits if things go wrong, they're more likely to use them. That means faster uptake, greater efficiency, and better patient care - in line with the Government's own ambitions for AI in healthcare.
- 2. Introduction of safer AI tools.** Clearer liability arrangements would align responsibility with control. In other high-risk and highly regulated sectors such as pharmaceuticals, aviation, and medical devices, this alignment has historically driven higher safety standards. Applied to AI, it would create stronger incentives for developers to prioritise safer design, ongoing testing, and deployment, rather than externalising risk to users or downstream organisations.
- 3. Fairer outcomes when things go wrong.** Such reform would strengthen the liability framework by ensuring that responsibility for harm caused by defective AI systems can be properly attributed to developers, manufacturers, importers and distributors, rather than defaulting to clinicians through

¹ The MPS Foundation (2025) *Avoiding the AI 'off-switch': Make AI work for clinicians, to unlock potential for patients*. Available at: [The MPS Foundation](#)

clinical negligence claims. This would support a fairer and more transparent allocation of responsibility across the AI supply chain and its end users, and without undue compromise or delay in the primary objective in compensation being paid to patients.

4. **Protection for the NHS and healthcare professionals against the cost of claims when harm arises from a defective AI product.** This would apply to the NHS - where taxpayers ultimately foot the bill - and to clinicians who indemnify or insure themselves against claims.

This paper aims to set out the challenges we expect clinicians will face, and the action policymakers can take now to make sure AI delivers benefits without leaving dentists unfairly exposed.

Case studies

The potential opportunities created by AI for advancements in dentistry are exciting and only limited by one's imagination. It is though still important to consider what could go wrong, and the ways in which the use of AI could result in a claim.

Clinical negligence claims can take a long time to arise. While AI has been used in dentistry for some time, it may take a number of years before we know the volume and nature of claims that will arise linked to this current period of rapid increase in AI usage. Included below are two hypothetical case studies. These illustrate how there is a real and significant risk that a claim could be brought against a dentist in relation to the use of AI tools. Under the current product liability framework in the UK, there is a risk that clinical negligence claims could be brought against the clinicians in these cases and that they would be held wholly liable.

Case study 1: delayed diagnosis of lesions for dental patient under a remote monitoring system

When providing orthodontic treatment, Dr. W uses a remote AI monitoring system for reviewing the progress of orthodontic patients.

The system enables patients to take and share intraoral images which the AI software analyses to check the progress of the orthodontic treatment. It also highlights any identified problems with the patient's oral health and prompts review or treatment.

Guided by the outputs, Dr W has reduced the frequency of face-to-face appointments when no adverse issues are identified which has been welcomed by patients.

One patient, Ms. K, had diligently uploaded her images throughout treatment and the AI system reported no concerns in relation to the progress of treatment or her oral health. Reassured by these outputs, Dr W reduced the frequency of the face-to-face appointments. As Ms K has difficulty attending appointments due to work commitments, some of the scheduled face-to-face appointments were further delayed.

6 months after the last orthodontic clinic appointment, Ms. K attends her general dentist for a routine check-up. The dentist identifies that several of her posterior teeth have carious lesions.

Ms K is unhappy to learn that she needs multiple restorations and pursues a claim against Dr W for failure to identify the deterioration in her dental health whilst orthodontic treatment was ongoing.

In this case, the AI system's failure to flag oral health deterioration contributed to the delayed identification of disease, so some responsibility should also lie with the AI developer/manufacturer.

Case study 2: failure to diagnose a dental patient when using an AI radiography diagnostic tool

Dr P, a dentist at a busy private practice has recently integrated an AI radiography diagnostic tool into her workflow. The system was promoted as improving efficiency and consistency in diagnosis including highlighting early caries on radiographs.

Mr L attends for a routine examination and complains of sensitivity around his upper right first premolar. The initial clinical examination reveals no obvious pathology and Dr P takes a radiograph and uses the AI system to assist in reporting. The AI system indicates there are interproximal caries between the upper right first and second premolars.

Set against the history of sensitivity and the radiograph report, Dr P advises the tooth should be restored. On accessing the distal surface of UR4, Dr P does not find any caries and explains the situation to Mr L. Although initially understanding, Mr L's pain does not resolve and the restored tooth then fractures requiring further restoration.

Frustrated by the incorrect diagnosis and ongoing pain, Mr L visits a second dentist who identifies a failing restoration at the upper right first molar – once restored, the pain settles.

Dr P subsequently receives a claim for avoidable damage to UR4 and failure to diagnose and treat the correct cause of the pain.

In this case, the AI system made an incorrect diagnosis that directly influenced treatment, so liability should also lie with the AI manufacturer/developer.

These case studies illustrate a recurring problem: where an AI system contributes to harm, current UK law could leave the clinician as the primary focus of a claim, creating a real and significant risk that liability would fall disproportionately on them. This raises concerns about fairness and the long-term sustainability of AI adoption in healthcare. It seems unfair to make clinicians solely responsible given the limited control they have over the design, performance, and ongoing behaviour of these technologies.

Legislative context

Consumer Protection Act 1987

Product liability in Great Britain and Northern Ireland is governed by the Consumer Protection Act (CPA) 1987 and by the Consumer Protection (Northern Ireland) Order respectively, both of which implement the 1985 EU Product Liability Directive.

The Act was drafted for a world of static, physical products and does not readily accommodate AI systems. Some shortcomings of the CPA 1987 when considering AI include²:

- **It can be difficult for patients to bring a claim.** The CPA 1987 defines 'product' as primarily tangible goods and AI would not appear to readily qualify as product under this law, which inadvertently makes it hard for patients to bring claims against developers or suppliers of AI tools.
- **Clinicians have the potential to become 'liability sinks'.** The legislation is triggered if a product is 'defective'. With AI tools, it may be difficult to prove how or why a decision was defective. Clinicians are

² Sproul, P. and Gibson, M. (2025) *Challenges for Consumers in the Existing UK Product Liability Framework – Part 1*. Available at: [Lexology](#)

expected to exercise judgement when using AI tools but if a 'defect' occurs, the clinician could absorb the legal liability without even being aware that a defect occurred at the time. The CPA does not apply to software, and so AI developers are 'protected' from CPA liability rules and thus having to explain any defect in their product. This 'loophole' clearly presents a risk to patient safety.

Product Regulation and Metrology Act 2025

The Product Regulation and Metrology Act (PRMA), passed in 2025, is intended to provide a mechanism for the UK Government to manage product safety while giving it legal powers to regulate risks arising from technological developments where those technologies form part of a product or influence how a product behaves. Whilst not explicit, the Act could potentially apply to AI-enabled tools. However, the PRMA falls short of what is required in several areas:

- **The Act defers substantive reform rather than delivering it.** It operates as an enabling framework, delegating broad powers to Ministers to introduce future secondary legislation on product safety and compliance, and with those decisions to be made through secondary legislation subject to more limited parliamentary oversight. While this allows flexibility as technologies evolve, it also postpones key policy decisions and provides limited certainty for sectors such as healthcare. In particular, the Act does not itself address how responsibility or liability should be allocated where AI-enabled products or systems cause harm.
- **AI systems aren't clearly defined as products.** Although Clause 2(2)³ of the Act includes 'product components' and allows regulations to reference 'technical standards' which could be used to cover software, depending on how secondary legislation is drafted, it does not explicitly state AI systems as unique products. This creates uncertainty over whether decision-support systems in healthcare fall under the definition of a regulated product, particularly in the case of standalone software.
- **It isn't decisive on liability.** Clause 2(3)⁴ of the Act does not establish rules for liability, i.e. who is legally responsible when AI outputs cause harm in healthcare. It defines who may be subject to product regulations but does not impose liability or define how liability will be allocated in the event of harm caused by AI-assisted decisions, like those found in the EU's revised Product Liability Directive. This leaves healthcare providers, developers, and insurers operating in a grey zone for now.

Medicines and medical devices do not appear to be the target of the Act. Its powers are framed so as not to displace existing specialist regulatory frameworks. Medicines and medical devices continue to be governed by comprehensive, sector-specific regimes overseen by the Medicines and Healthcare products Regulatory Agency, including the Human Medicines Regulations 2012 and the UK Medical Devices Regulations 2002.

³ *Product Regulation and Metrology Act 2025*, s. 2(2). Available at: [Legislation.gov.uk](https://legislation.gov.uk)

⁴ *Product Regulation and Metrology Act 2025*, s. 2(3). Available at: [Legislation.gov.uk](https://legislation.gov.uk)

The EU Product Liability Directive

The new EU Product Liability Directive 2024/22853 is replacing the Council Directive 85/374/EEC and modernises the European product liability framework to take account of emerging technologies, including artificial intelligence.

Key changes that the new Directive introduces include:

- **AI ‘products’ subject to liability regime.** Software, including standalone AI systems and AI components embedded in devices, is expressly included within the definition of a “product.” This ensures that AI systems are subject to similar liability regime as physical goods.
- **Defectiveness redefined.** The assessment of whether a product is defective expressly considers characteristics specific to AI, such as post-sale learning, updates, cybersecurity vulnerabilities, and the way a system interacts with users.
- **Broader scope of liable actors.** Liability may attach not only to manufacturers, but also to importers, software developers, fulfilment providers, online marketplaces, and those responsible for substantial post-sale modifications (for example, through software updates).
- **Ongoing responsibility.** The framework clarifies that liability may arise from events occurring after a product has been placed on the market, including unsafe updates or subsequent changes in the behaviour of AI systems that continue to learn.
- **No contractual limits on liability.** Economic operators cannot limit or exclude their liability through contracts or national legal provisions. Any contractual terms seeking to cap or waive liability are prohibited, ensuring that manufacturers cannot use contracts with patients, clinicians, or healthcare organisations to dilute their responsibility for harm caused by defective AI products.
- **Reduced burden of proof for claimants.** Where a claimant faces excessive difficulties in proving defectiveness or the causal link, in particular due to technical or scientific complexity, such as with AI systems, courts may presume defectiveness and/or causation, where it is at least probable. This reduces the evidential burden on claimants in complex cases.

In effect, for EU member states, the new Directive closes gaps that previously left AI outside the traditional product liability regime. It imposes continuing obligations on those who design, update, and distribute AI systems, while potentially making it easier for claimants to pursue redress where harm arises.

Countries within the EU will now have to transpose the provisions of the new Directive into national law by 9 December 2026. With the UK no-longer being a member of the EU, the UK is not required to implement the Directive, and the government has not indicated that it is likely to introduce legislation along these lines.

It is important to note however, the unique position of Northern Ireland. Under the Northern Ireland Protocol (as amended by the Windsor Framework), EU product liability law continues to apply in Northern Ireland, and any updates would take effect automatically. This means the new Directive is expected to apply in Northern Ireland from 9 December 2026, even without formal transposition into Northern Ireland law by Westminster.

This may lead to legal divergence within the UK, with a different product liability framework operating in Northern Ireland compared to Great Britain. This could create uncertainty around applicability, jurisdiction and enforcement of liability rules, including how responsibility is allocated and how claims involving AI systems are brought and resolved in practice.

What needs to happen

We propose that the law of negligence, product liability, and emerging regulatory frameworks should evolve to ensure liability is properly allocated to developers, manufacturers, and suppliers where it can be shown that defects in AI have contributed to demonstrable harm.

Specifically, we urge the UK government to develop legislation that would classify AI systems as products subject to strict liability, taking inspiration from the EU's revised Product Liability Directive whilst being tailored to the UK context.

We see four clear benefits in making such a change:

- 1. Unlocking AI's potential.** If dental professionals can trust the tools at their disposal and be clear about where liability sits if things go wrong, they're more likely to use them. That means faster uptake, greater efficiency, and better patient care - in line with the Government's own ambitions for AI in healthcare.
- 2. Introduction of safer AI tools.** Clearer liability arrangements would align responsibility with control. In other high-risk and highly regulated sectors such as pharmaceuticals, aviation, and medical devices, this alignment has historically driven higher safety standards. Applied to AI, it would create stronger incentives for developers to prioritise safer design, ongoing testing, and deployment, rather than externalising risk to users or downstream organisations.
- 3. Fairer outcomes when things go wrong.** Such reform would strengthen the liability framework by ensuring that responsibility for harm caused by defective AI systems can be properly attributed to developers, manufacturers, importers and distributors, rather than defaulting to clinicians through clinical negligence claims. This would support a fairer and more transparent allocation of responsibility across the AI supply chain and its end users, and without undue compromise or delay in the primary objective in compensation being paid to patients.
- 4. Protection for the NHS and healthcare professionals against the cost of claims when harm arises from a defective AI product.** This would apply to the NHS - where taxpayers ultimately foot the bill - and to clinicians in private practice who indemnify or insure themselves against claims.

There does seem to be a growing acknowledgement of the need for action to address this issue.

The MHRA is carrying out a review of the regulation of AI in healthcare, including a public call for evidence that seeks views on accountability and how responsibility and liability should be allocated between manufacturers, healthcare organisations and clinicians when AI tools are used.

The Law Commission has also confirmed it is undertaking a review of the product liability regime, including its application to digital products and emerging technologies such as AI. A formal public consultation on proposals for reform is expected in the second half of 2026, with further recommendations to follow.

Dental Protection will engage with both of these reviews and continue to raise the need for action with policy makers more broadly.

Further information

AI: The Safer Practice Framework

Dental Protection has developed a two-part 'AI safer practice framework' that can help dental professionals to navigate the challenges that might be presented when using AI in practice when it comes to consent, accountability, and clinical judgement. It can also help guide dental professionals in making informed decisions and ensuring records support them in case of any dentolegal challenge.

Further information is available on our website: [AI Safer in Practice](#)

Avoiding the AI 'Off-Switch': Make AI Work for Clinicians, to Deliver for Patients

We have been proud to support the publication of a groundbreaking white paper in 2025, developed in collaboration between York University's Centre for Assuring Autonomy, the MPS Foundation, and the Improvement Academy hosted at the Bradford Institute for Health Research

The white paper sets out a range of recommendations for Government, AI developers, and regulators to urgently consider, including:

- Urgent reform to product liability, due to significant difficulties in applying the current product liability regime to an AI tool.
- AI tools to provide information rather than recommendations to clinicians. This will reduce the potential risk to both clinicians and patients, prior to product liability reform.
- Clinicians to be fully involved in the design and development of the AI tools they will be using to ensure they are usable, useful, and safe.

The paper is available on the MPS Foundation website: [Avoiding the AI 'off-switch': Make AI work for clinicians, to unlock potential for patients.](#)

About Dental Protection

Dental Protection is a registered trademark and a trading name of The Medical Protection Society Limited ("MPS"). MPS is the world's leading member-owned, not-for-profit protection organisation for doctors, dentists and healthcare professionals.

Founded in 1892, we exist to protect and support the professional interests of more than 300,000 members around the world, helping them to understand and navigate the ongoing challenges of modern practice. Today we proudly support members in the United Kingdom, Ireland, South Africa, New Zealand, Australia, Hong Kong, Singapore, Malaysia, the Caribbean and Bermuda.

Our in-house experts can assist members with the wide range of legal and ethical problems that can arise from their professional practice. This can include assistance with clinical negligence claims, complaints, medical and dental council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries.

Our philosophy is to support safe practice in medicine and dentistry by helping to avert problems in the first place. We do this by promoting risk management through our workshops, e-learning, clinical risk assessments, publications, conferences, lectures and presentations.

We also actively campaign for regulatory and legal reforms that benefit members and the wider healthcare professions.

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