MDDUS RESPONSE TO THE DEPARTMENT OF HEALTH AND SOCIAL CARE CONSULTATION PAPER

APPROPRIATE CLINICAL NEGLIGENCE COVER (DECEMBER 2018)

SUMMARY

The Government's consultation on appropriate clinical negligence fails to make a compelling case that there is market failure in relation to clinical negligence indemnity cover that has to be addressed by the proposed reforms.

In particular, the policy development process is flawed in that it does not appear to have been developed in line with Best Regulatory Practice, in that:

- there is no analysis or evidence of actual market failure; the issues identified are theoretical;
- there is no evidence that the full range of potential responses to a market failure have been considered;
- the proposals are not supported by a cost-benefit analysis nor Equalities Impact Assessment.

If government persists with these proposals it is likely that the cost of indemnity cover will increase. CNSGP is being introduced because government is concerned about the rising cost of indemnity for GPs. That concern is not extended to the 1.5m+ healthcare professionals who will in all likelihood see an increase in the cost of their professional indemnity cover.

INTRODUCTION

MDDUS is one of three medical defence organisations that provide indemnity and a range of other services to healthcare professionals. It is the main provider of such indemnity in Scotland, although the substantial majority of its members work in the rest of the UK. The MDDUS provides occurrence-based indemnity to its members allowing for claims to be met even after the conclusion of a membership period, as long as the incident occurred during the member's period of membership.

MDDUS is a 'not for profit' organisation, owned by its members and not shareholders. MDDUS reserves membership funds responsibly to ensure that they are sufficient to meet current and future claims against the current and former membership.

Throughout its history, providing support and guidance to our members has been core to our approach – "our members come first – they are the focus of all we do". For patients, the ethos is to pay claims promptly where we recognise that they have been harmed by a member's negligence.

There are some significant issues and changes that are already having an impact on the medical indemnity market and these current proposals will introduce more restrictions and cost which could prevent the not-for-profit, member-focused firms from flourishing. For example, the cost of clinical negligence claims has been adversely affected directly by government action (changes to the Personal Injury Discount Rate) and inaction (failure to address much needed tort reform). Increasing claims cost is inevitably leading to increased subscriptions for indemnity cover.

The introduction of the Clinical Negligence Scheme for General Practitioners in England and Wales may address Government's concern about the cost of indemnity for English and Welsh GPs, but it is not a direct replacement for the cover currently provided by MDOs. MDO membership brings with it more than indemnity cover in the event of a claim. For example, it provides access to professional medico-legal advice, assistance and representation in complaints and disciplinary matters and proceedings before the regulatory bodies. These services are valued by members and are often intrinsically linked to a claim. In separating the indemnity element from these other services, there is a risk that when in need of support, and at a time when they could be vulnerable, a GP could be confused as to what is provided and by whom. It also inevitably makes the integrated individual decision-making needed in seeing the problem in the round considerably more difficult, even if roles and responsibilities are understood.

To support its own analysis of the proposals, MDDUS commissioned Oxera Consulting to consider the consultation paper and provide views on:

- whether the proposals have been developed through an appropriate assessment framework;
- a critical review of the issues raised in the consultation paper;
- whether there were other options and issues that should have been considered.

Annex A sets out a technical review of the proposals based on advice we received and should be read alongside the answers to the specific questions set out in this paper.

A FLAWED APPROACH TO POLICY DEVELOPMENT

The imposition of regulation is one response for dealing with problems in markets. It inevitably involves cost for which someone – usually at the end of the chain – pays. It can also lead to restrictions (some intended, some potentially inadvertent) on the relevant market.

The Government has therefore confirmed that, before making a decision, there should be a full market analysis to evaluate whether market failure causing significant consumer detriment is really occurring, or whether the proposals are a response to a theoretical risk only.

MDDUS' view is that there is no market failure here. However, to the extent that a contrary conclusion is evidenced by government, there should be proper consideration of;

- the issue to identify the real problem;
- the full range of potential interventions to address the problem;
- the measures to assess the success of the intervention.

The touchstone of any intervention should be proportionality. Government should start from an assumption that problems in most markets should respond to informational remedies, which build consumer understanding and enable them to exercise more choice and so enable more effective market signalling to suppliers. There is evidence from a variety of sectors that such intervention is best achieved by a self-regulatory or co-regulatory approach, underpinned by a clear regime of transparency. The OECD Report 'Industry self-regulation: role and use in supporting consumer interests' (March 2015)[1] includes a number of case studies where such an approach has been used; while recognising that there are challenges, the report also notes that self-regulation can be an advantageous complement to government policies, potentially providing benefits to both industry and consumers.

To the extent that the Government evaluation points to the need for intervention, normal practice would be to seek to advance competition, for example by removing any barriers to entry where they exist or the provision of information to empower consumers and encourage switching - as opposed to creating new regulatory impediments. The fact that the market is so contested at the moment, with at least 25 companies active, suggests that no such barriers exist.

Any other initiatives, whether of a consumer protection or price management intervention, need the most rigorous cost-benefit justification and investigation from a behavioural economics perspective to demonstrate that the extra cost burden on firms (in this case healthcare professionals) and the potentially chilling effects on innovation are not to significantly outweigh any perceived benefits.

This consultation paper does not demonstrate that a proper analysis of the problem has been considered – indeed, it recognises that there are only a very limited number of cases where any clinical indemnifier has used its discretion not to support a member and that, in all likelihood, the patients of Ian Paterson would not have been able to secure redress had the indemnity cover been through a regulated insurance contract.

[1] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/CP(2014)4/FINAL&docLanguage=En

Section 2 of Annex A contains an analysis of the approach that has been taken to the development of policy in this area. Our main conclusions are:

- The assessment framework set out in the consultation paper is lacking in two main areas:
    - the design of the interventions is not strongly linked to the underlying problem of increasing clinical negligence costs;
    - de-regulation, do nothing options and bespoke solutions do not receive sufficient or any real consideration at all.
- The issues raised in the consultation are mainly speculative in nature – while theoretically valid concerns, there is no involved discussion on the nature, likelihood or cause of the perceived market failures
- There is no analysis against the Better Regulation Principles and is inadequate in its analysis of the proposed solutions – and in particular no cost benefit analysis. The little commentary on costs and benefits is inadequate to support even the narrow range of options that are presented.
- Two future policy options are presented for consideration on a crude, all or nothing basis. However, the consultation does not explain any other options that were considered and why they have been discounted. While a "status quo" option is put forward, this is inadequately considered.
- Concerns raised could be resolved without the proposed interventions. For example, requirements on the data and information to be shared with members could address concerns about transparency and clarity of cover.
- Relevant issues that have not been considered include:
    - The impact of increasing indemnity subscription rates on the workforce;
    - Ensuring access to professional indemnity;
    - Competition impacts;
    - The likely narrowing of scope of cover in a regulated insurance market – unlike MDOs, most commercial insurers must have mechanisms which enable them to exercise discretion in "hard" cases. The very existence of those mechanisms demonstrates that the supposed benefits of "certainty" are achieved only at the cost of exclusion in many cases – precisely the effect that the Government says it wishes to avoid.

All of these elements would not simply be good practice in policy development, but an essential prerequisite before any proposals were put forward for public debate.

We therefore conclude that, in the absence of a proper analysis, the conclusion that there is a systemic issue that needs to be addressed is not proven.

SPECIFIC QUESTIONS RAISED IN THE CONSULTATION

6.1 What are your views on the proposed options for meeting the Government's policy objectives?

The policy objectives may be legitimate but, respectfully, we do not consider that the proposed intervention will deliver them.

Patients can access appropriate compensation

Patients who have suffered harm as a result of clinical negligence should of course have access to compensation. There is little evidence to suggest that this is not happening under the current arrangements and it is unclear how changing the basis of indemnity cover will improve what appears to be a currently effective system.

Stable and sufficiently funded clinical negligence healthcare cover

MDOs are member-owned organisations. MDDUS's management and Board recognise the trust that is placed in them to act as stewards of the members' money in such a way as to ensure that when the member calls on the services that membership provides it is available to them. While there is no *requirement* on us to maintain and manage reserves, we consider – and have always considered – that this is an essential part of our stewardship of members' money.

We publish an Annual Report and Accounts (which includes the IBNR figure) so enabling members – and prospective members – who want this level of assurance to satisfy themselves as to our financial stability.

Regulated healthcare professionals have greater clarity and confidence about the security and terms of their cover

A membership agreement between an MDO and its members sets out the basis of the agreement between them, expressed in language that they understand; we would contend that it is clear to our members what is and is not covered. While the discretionary nature of the relationship does bring with it a small element of uncertainty, as the consultation paper recognises, there are very few examples where MDOs have declined to assist members. On a "plain English" test, the MDDUS Membership Agreement – and those of our two main competitors – compares very favourably with the regulations just published by Government which seek to implement the Clinical Negligence Scheme for General Practice. Furthermore, with a membership agreement there is greater flexibility to adjust the terms as new issues emerge and so bring greater clarity as to scope of cover.

While setting out the cover in a regulated insurance product might mean that there is more contractual certainty, this does not in itself mean that it will be clear nor that it will not be challenged; there will always be cases where insurers will seek to avoid the claim on the basis that it is not within the terms of the contract. This might arise, for example because of exclusions in the contract (we note that the new CNSGP regulations contain an entire clause of such exclusions and that the Scheme itself is also expressed in permissive terms which enable, rather than compel, action by the Secretary of State) or because of false declarations by the policyholder. It might also arise where consumers (either wilfully or ignorantly) seek recompense where it is not due. Of the 38,155 new insurance complaints that the Financial Services

Ombudsman (FOS) received in 2016/17[2], 59% were about claims – so even where the contract is a regulated one for which there are disclosure requirements, there is still a significant number where there is uncertainty as to scope of cover.

The current discretionary model allows MDOs scope to deal with claims that fall outside a tightly worded insurance policy. Of course, MDOs will not always get it right (though we have low complaints; 26 for MDDUS in 2018) and we do recognise the value and importance of dispute resolution mechanisms. This could be achieved through a voluntary scheme, a commitment to arbitration or a FOS voluntary jurisdiction scheme, which MDDUS has proposed on a number of occasions in recent years.

While a change to insurance might mean that there greater certainty that a claim meeting contractual requirements will be paid, this comes at the cost of greater uncertainty around market coverage. Owing to the very significant capital requirements to support occurrence-based insurance, such a change is likely to lead to a "claims made" market standard which can leave 'incurred but not reported liabilities' with the policyholder. In the event of wider insurance market conditions deteriorating, there may be a sudden decrease or failure of market supply in medical malpractice cover which could leave doctors and other healthcare providers uninsured on both a prospective basis and in respect of future claims that will arise from past practice, but which have not been notified. Paradoxically the "uncertainty" that comes with the MDO model has, through the operation of mutuality and an essentially common purpose to serve the membership and professions as a whole, ensured availability of indemnity to the vast majority of doctors and dentists over a period of many years. The number of declined claims is very small and likely to compare favourably in a future environment of 'commercial' insurers writing business for profitable cohorts.

Patients have greater clarity and confidence in their recourse to compensation

The consultation paper provides no evidence that patients lack clarity or confidence on the availability of compensation in the current market. It might even be argued that the promotional activities of claims management companies create an expectation – potentially a false expectation – that compensation is readily available.

6.2 What are your views on the potential costs and benefits of the options

In April this year the Government will introduce the Clinical Negligence Scheme for General Practitioners (CNSGP). One of the key drivers of that proposal has been the increasing cost of indemnity cover. Those costs concerns do not seem to extend to regulated healthcare professions covered by this proposal. Annex A to the consultation paper identifies nine healthcare professional regulatory bodies who collectively regulate in excess of 1.5m registrants, many of whom do not work exclusively in the NHS. If these proposals are taken forward it is likely that they will see an increase in the cost of their indemnity cover.

The consultation does not contain a full cost-benefit analysis. It's imperative that this is done together with a regulatory impact assessment - which should itself be subject to full consultation and debate – before arriving on any decision on the proposals.

[2] https://www.financial-ombudsman.org.uk/publications/annual-review-2017/pdf/Annualreview-fullreport-AR2016-17.pdf

While we have not quantified the financial impact of these elements we have identified the following areas in which we would expect to incur additional costs as a result of the proposals:

- Cost of capital;
- Application process for PRA and FCA authorisation – this would include the application fees, cost of management and adviser time in making the application;
- Ongoing regulatory fees;
- Financial Compensation Scheme Levy. While we recognise that this would be a safeguard for patients seeking compensation, it would represent an additional cost and there is the contagion risk of failures on other parts of the general insurance market;
- Financial Services Ombudsman levy and case fees (though given our low complaint numbers we would expect the latter to be low);
- Costs arising from additional reporting and audit requirements;
- Development and maintenance of enhanced internal audit/compliance capability.

This is all likely to lead to increased costs to members in the form of higher premiums – which would be compounded by the addition of Insurance Premium Tax on the increased premium.

6.3 Are there other options that the Government should consider?

As we mention above, we are surprised by the lack of articulation of alternative options in the consultation paper.

While we have not undertaken any detailed analysis of the potential alternatives – and all would have both costs and benefits - other options which could address the policy objectives might include:

- A system of self-regulation or co-regulation. This could cover requirements and expectations around the holding of reserves and Member Fair Treatment Policies or signing up to the requirements of trade bodies. For example, MDDUS is a member of the Association of Financial Mutuals which involves transparent statements about meeting the requirements of the Mutual Version of the Combined Code, even though we are under no statutory obligation to do so;
- A greater transparency regime for MDOs in terms of financial reporting, including a requirement that IBNR is disclosed;
- A greater transparency regime for the professions through a requirement on regulators to maintain and publish a register of professionals and their indemnity providers;

- Dispute resolution mechanisms, either a voluntary arrangement with one of the existing Ombudsman Schemes, or the appointment of an expert independent adjudicator whose decisions the MDO would be contractually bound to follow;

- Member panels. The terms of reference of such a panel could include providing input to MDOs on key professional issues, a requirement that it be consulted on specified issues, consultation on Board recruitment and producing Annual Report for membership on its activities.

All other options should be fully evaluated and costed before a final decision is taken on the way forward.

6.4 *Do you agree with the Government's preferred option for ensuring that all regulated healthcare professionals in the UK hold appropriate clinical negligence cover that is subject to appropriate supervision by the FCA and the PRA?*

The consultation does not provide sufficient evidence that the proposed solution is the most appropriate solution.

It is also not clear that, even if regulation was desirable, that the supervisory model adopted in financial services regulation is the appropriate one. Professional regulators already specify that professionals must hold "appropriate" indemnity or insurance. Before placing an entirely new regime in place, professional regulators might be asked to consider providing greater definition and specificity in their requirements. To the best of the MDDUS' knowledge, no professional medical regulator has judged it necessary to make such a statement. The absence of such intervention from bodies charged with patient protection responsibilities is, of itself, evidence that the case for a high level of intervention does not exist.

6.5 *Do you have any further insight or data on the types of indemnity insurance cover held by healthcare professionals?*

We note, as Government did in its 2016 report GP Indemnity Review[3], that the market for indemnity and insurance is now heavily contested with commercial insurers offering a range of both claims made and occurrence based products and that a range of run off cover options are also available. We note also that a number of healthcare organisations are active as purchasers of insurance and indemnity for their directly employed staff and for contractors. This variety and contestability of products and providers seems more likely to ensure high standards and good value across the board than regulation which would have the effect of compelling essentially "plain vanilla" products.

If government pursue option 2

6.6 *What would be the benefits and implications of introducing regulation via*

(a) changing professional standards so that professionals have to hold a regulated insurance contract

[3] https://www.england.nhs.uk/wp-content/uploads/2016/07/gp-indemnity-rev-summary.pdf

(b) changing financial services regulation so that any organisation offering clinical negligence cover would need to authorised to do so

(c) changing both financial and professional regulation

As described above, our view is that this consultation fails to provide a persuasive argument of the benefits of the proposals.

6.7 *Do you have any views on when regulations should come into force and should these involve a transitional period, considering the potential impact on indemnity providers and healthcare professionals*

Since the consultation does not contain any strong evidence that the current system is broken, there is certainly no need for a quick fix. In any transitional period, it will be important to reassure both the public and healthcare professionals that while a change is to be effected, the current arrangements are not failing.

Should Government persist with this proposal, then it should do so by allowing a very considerable lead time in order to enable regulators to learn the basics of a market of which they currently have limited knowledge or experience, and Government time to work out arrangements for compensating professionals for the extra cost being imposed on them. It should be axiomatic that the Exchequer should not benefit from this change.

Both changes should be introduced at the same time to ensure that MDOs are not put at a competitive disadvantage. The transition period should be sufficient to allow those MDOs which wish to seek authorisation as an insurer the opportunity to secure PRA and FCA authorisation so that they can continue to participate in the market from Day One.

6.8 *Are there any measures that could mitigate the potential risks to introducing regulation (in terms of stable transition for regulated healthcare professionals and indemnity providers, mitigating potential cost impacts and run-off cover)?*

The nature and level of intervention necessary to lessen – but not remove – the adverse effects of regulation are such as to cast doubt on the validity of the entire approach. Such measures might include the exclusion of clinical indemnity cover from IPT, a requirement for purchase of run-off cover (with potentially a state-backed fall back to protect patients of healthcare professionals who do not, although the moral hazard properties of such an arrangement would need to be carefully considered), backed by a strong monitoring and enforcement regime to ensure that patients are not jeopardised and the development of a bespoke regulatory regime, recognising the difference between this sector and most general insurances. Such measures illustrate the danger that, imposing regulation in the absence of a truly compelling case, only leads Government and regulators into ever more detailed interventions to minimise its ill-effects.

6.9 *Specifically on the transition risk, are there measures that could support the run-off on the indemnity providers existing liabilities on a discretionary basis, and given the potential impact with overseas business?*

It should be a key principle that regulation, like legislation in general, should not be retrospective. Hence any requirements should be imposed on forward looking business only and the regulator should not have any jurisdiction in relation to how discretionary business is managed.

The simplest solution would be for any existing liabilities to be remain with the MDOs on a discretionary basis from Day One – though we do recognise that there is a risk of confusion for a member who 'renews' with the same MDO. This would be mitigated by clear communications with the member explaining the different basis of cover.

However, one consequence of this might be that the MDOs would need to hold capital to be confident that future claims could be met and this might have implications for satisfying the Solvency II requirements for authorisation and preclude or restrict the MDO from participating in the future market.

6.10 *Specifically, given the potential risk with claims-made and claims-paid policies (run off) should the government specify the type of insurance or regulated product required for healthcare professionals?*

Run-off cover – or rather the lack of run-off cover – is a risk in any professional indemnity insurance (PII) market and before proposing solutions, government should explore how this risk is mitigated in other markets.

There are a range of insurance products (claims-occurring, claims-made, claims made with built in run-off cover) that could meet the demands and needs of regulated healthcare professionals. All of these have different costs and benefits and it should be left to providers to develop products in response to market demand. It is not for government to specify the type of product.

6.11 *Should Government and/or professional healthcare regulators specify a minimum standard of regulated cover that should be required for regulated healthcare professionals (e.g. minimum level of cover for each claim and in aggregate, depending on the healthcare professional)?*

Even within a single healthcare profession, individuals can face a range of different risks depending on their practice. Setting a minimum level runs the risk that it is too high for some (and so they are paying for cover that they do not need) or too low so that it might not be adequate in the event of a valid claim. Fixing minimum criteria may also impact on the market's willingness and/or ability to supply indemnity to some – and perhaps many – categories of clinicians.

The requirement should be framed in such a way that the regulated healthcare professionals are required to hold as much cover as they need, taking into consideration the risks and scope of their own professional practice. This approach is already adopted by a number of the professional bodies (six of the nine listed in Annex A to the consultation paper). Professional bodies could then produce guidance to assist their members in calculating the appropriate amount of cover.

If it is to be a professional standard requirement that professionals must hold adequate regulated insurance to practice, then failure to do so should be a matter of professional misconduct. We consider that such an approach would be seen as a less interventionist, and therefore more proportionate, form of intervention than detailed supervision of firms; if there is to be regulation, a financial services regulatory model should not be put in place until the adequacy of a professional regulatory-based regime has been assessed in practice after a significant period of time, certainly not less than 5 years.

6.12 Are there any equalities issues that arise in relation to each of the options, particularly option 2?

6.13 Is there any discriminatory impact arising from the proposed options that would engage the Equality Act 2010 and Section 75 of the Northern Ireland Act 1998?

6.14 What is the impact, if any, on any group of persons who share one or more of the protected characteristics set out in section 149 of the Equality Act 2010 when compared to persons who do not share the protected characteristics?

We expect that any proposal which would result in the introduction of new regulation would include an Equalities Impact Assessment – we note that this paper has no such Assessment. Given the gender and ethnicity profiles of staff in the healthcare sector, we consider that this is a serious omission which should be rectified before any decisions are made.

6.15 What are the potential consequences for the conduct of clinical research of the proposals set out in the document?

No comments

28 February 2019

Annex A

MDDUS response to the Department of Health and Social Care consultation paper

APPROPRIATE CLINICAL NEGLIGENCE COVER (December 2018)

TECHNICAL REVIEW APPENDIX

INTRODUCTION

In October 2017, the former Secretary of State for Health announced plans to introduce a state-backed indemnity scheme for general practice in England with effect from April 2019, noting that the rising cost of clinical negligence is a great source of concern for GPs, and has a negative impact on the GP workforce. In May 2018, the Welsh Government also announced its intention to introduce a state scheme for general practice in Wales with effect from April 2019.

While the scheme proposed by the Department of Health and Social Care (DHSC) is solely for general practice in England, the Department has expressed concerns about the security of clinical negligence cover held by regulated healthcare professionals practising in the UK who will not be covered by any state-backed scheme. This includes dental professionals and doctors in private practice.

As a result, the DHSC published a consultation in December 2018[1] to consider the future of clinical negligence cover for regulated healthcare professionals practising in the UK.

The Medical and Dental Defence Union of Scotland (MDDUS) asked Oxera to review the consultation and comment on the issues and recommendations. Based on the advice from Oxera, this note presents a review of the DHSC's consultation. In addition, it considers a qualitative cost-benefit analysis of the proposals offered in DHSC's consultation document, and raises other potentially relevant issues not considered by the DHSC.

The technical review appendix is structured as follows:

- section 2 comments on whether the DHSC's consultation succeeds in applying an appropriate assessment framework in its review of clinical negligence cover arrangements;
- section 3 critically evaluates the issues raised in DHSC's consultation and sets out the potential costs and benefits of the recommendations;
- section 4 considers other potentially relevant considerations to be discussed as part of this consultation;
- section 5 draws on lessons from other professional indemnity insurance markets to inform the appropriate course of action going forward.

[1] DHSC (2018), 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December.

THE NEED FOR AN APPROPRIATE ASSESSMENT FRAMEWORK

To ensure that regulatory policies best promote the public interest, the government requires policy proposals to be subjected to a comprehensive but proportionate assessment. The standard approach to assessing the justification for intervention in markets is described in the Treasury's 'Green Book',[2] and other regulators, such as the Financial Conduct Authority (FCA),[3] have presented similar methodologies.[4] These set out principles for effective regulation, to determine intervention that is proportionate and appropriate.

In designing effective intervention, the three recommendations are:[5]

- **diagnose the problem** – identify the issues of concern, the causes of 'market failure', and the desired outcomes and objectives of an intervention;
- **design interventions** that are closely linked to the identified issues, and are proportionate and targeted;
- **assess outcomes** – defining the appropriate measure of success and identifying which interventions are most effective at delivering improvements while minimising unintended consequences.

Applying this logic to the issue at hand therefore points to the appropriate analytical framework for evaluating actions in the markets for medical and dental indemnity. The assessment could result in recommendations for no change to the market, deregulation, increased regulation, or other actions (such as nationalisation).

Based on this approach, each of the three elements for effective regulation is considered in turn below, in the context of the DHSC consultation. This looks at what might be expected in terms of analysis and evidence compared to what the DHSC has presented at this stage. This comparison highlights areas where the DHSC consultation does not appear to be supported by the analysis and evidence that one might reasonably expect in order to support a policy recommendation of this nature.

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[2] HM Treasury, 'The Green Book', in particular sections 3–5.

[3] For example, see Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation'.

[4] The Better Regulation Executive also provides relevant guidance, with its objective 'to ensure that the regulation which remains is smarter, better targeted and less costly to business'. The Prudential Regulation Authority (PRU) also has an objective to promote effective competition in the markets for services – for example, as explained in 'The Prudential Regulation Authority's approach to insurance supervision', March 2016.

[5] Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation'.
A slightly different characterisation of this is given in HM Treasury, 'The Green Book, which has the following five steps.

1. Justifying action: ensure that there is a clearly identified need and that any proposed intervention is likely to be worth the cost.
2. Setting objectives: set out clearly the desired outcomes and objectives of an intervention.
3. Option appraisal: identify the full range of options that may be available to achieve the objectives and evaluate the costs and benefits of these options, including considering competitive effects.
4. Developing and implementing a solution: use decision criteria and judgement to select the best option or options and refine this into a solution.
5. Evaluation: undertake an ex post evaluation of the implemented policy against the objectives.

The three main elements outlined by the FCA correspond to steps 1–3 above.

Problem diagnosis

At the problem diagnosis stage, it is necessary to understand the specific outcomes that are of concern, and identify the associated underlying market failures, such as the lack of appropriate information on the nature of cover generating information asymmetries.[6] Importantly, without understanding these drivers, any interventions are likely to deal with only with the symptoms of the issues, rather than solving their causes.

Once the specific ways in which the market is not working well have been identified, along with the nature of the consequent harm, the rationale for intervening should be considered. This includes an evaluation of whether any poor outcomes could be expected to improve over time without any intervention and whether there is sufficient understanding of the problems such that suitable interventions can be designed (given the costs and economic distortions that government intervention might introduce).

Identifying market failures that could result in outcomes of concern requires an assessment of the current trends in the market and the potential issues for concern, and then a deeper dive into the causes of the issues.

Observations on the DHSC consultation

The consultation mentions a number of potential market failures behind the outcomes of concern, including:

- asymmetric information between indemnity providers and healthcare professionals on the nature and extent of cover;
- rising number of medical negligence claims;
- increasing costs of indemnity cover;
- the risk of patients (who are making a claim) not receiving adequate remedy due to discretionary indemnity and/or medical defence organisations (MDOs) not being financially resilient to large claims.

There is, however, no involved discussion of the nature, likelihood or causes of these market failures; nor does the DHSC clearly rank their relative importance.

In general, the DHSC consultation presents little by way of data-led analysis to support the validity of the concerns being raised. There is also no clear link between the analysis and

[6] 'Market failure' refers to a situation where the market cannot be expected to deliver an efficient outcome. Market failures typically fall into one of the following categories:

- information asymmetries: one party knows more than the other and exploits this information advantage;
- market power: one provider (or more than one in combination) can act to set prices or quality without being challenged in the marketplace by consumers or other providers;
- externalities: some impacts of a market transaction on third parties – such as other firms or the taxpayer – are not reflected in the price or other terms of the transaction. These externalities can be negative or positive;
- behavioural distortions: some inherent behavioural biases or capability limitations materially distort market participants' ability to pursue their economic interests;
- regulatory failures: some existing regulations distort the market and do more harm than good.

See Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation', p. 12.

specific market failure outcomes. Even the DHSC's underlying premise for this consultation – i.e. rising costs – is not well explored.

In raising a concern about discretionary and contractual cover, the DHSC acknowledges that there have been only a limited number of instances when MDOs have exercised discretion, and, even then, there is no obvious instance when their actions could have been deemed to have been an abuse of their discretionary powers. In this respect, it is worth noting that MDDUS rarely exercises discretion to deny cover to members – indeed, it is our understanding that MDDUS, in its 116 years of activity, has never exercised its discretion to deny a valid claim related to the practice of medicine or dentistry because of financial difficulties.

Furthermore, the consultation discusses the financial security of indemnity cover. Here, the DHSC argues that the absence of capital requirements on indemnity providers exposes the providers to the risk of being unable to meet future claims payments. However, the basis for this concern is not well evidenced. While the DHSC fails to provide a single example of this situation ever arising, or any quantitative assessment of the soundness of MDOs' finances, data from MDDUS suggests that it has never been in financial distress resulting in insolvency or endangering its status as a going concern in more than a century of its existence.

Another allegedly problematic outcome is the lack of regulatory oversight and transparency. According to the DHSC, since MDOs are not required to disclose their full financial position, members might be insecure about the extent of their protection against claims. As a consequence, the general public could face uncertainty about the possibility of recourse for clinical negligence. Yet again, this comes across as a hypothetical concern. The consultation does not back up this argument with any evidence of adverse outcomes due to the absence of regulation.

Finally, the government argues that healthcare professionals might face unfair treatment from indemnity providers because the latter do not have to comply with the FCA's Principles for Business, in particular with respect to the customers' interests clause. In this case, the DHSC presented evidence in the form of a survey, suggesting that 57% of GPs are unaware whether their cover is on a claims-made, claims-occurring or claims-paid basis.[7] However, there does not appear to be a clear connection between the engagement of GPs with their indemnity and the risk of unfair treatment. It is also worth noting that the same survey indicates that 80% of GPs have confidence in their cover, which seems to indicate that unfair treatment is not particularly salient.[8] Additionally, the consultation appears to overlook the fact that the MDOs are non-profit mutuals owned by the members, and that the risk that a mutual would mete out unfair treatment to its members is low.

As a result, the DHSC does not appear to have conducted a considered diagnosis of the outcomes of concern; nor has it identified the market failures underlying these outcomes.

[7] Ipsos MORI on behalf of Department of Health and Social Care (2018), 'Primary care indemnity survey – GPs, nurses and pharmacists perceptions and awareness', November, p. 24.
[8] Ibid., p. 50.

The approach followed by the DHSC relies mainly on listing hypothetical issues. As such, the DHSC does not provide a sufficient basis to understand what interventions would address these issues.

Design of interventions

Before starting to design interventions, the goals for intervention should be clearly stated, based on the problem diagnosis. For example: 'What specific features or behaviour does an intervention need to change to make the market work better and reduce the harm caused?'[9] All interventions should be closely linked to the issues identified in the first stage of the evaluation.

In the early stages of intervention design, it is typical to begin to consider options for remedies to ensure that 'efficient but unconventional ways of intervening are not overlooked'.[10] Interventions could be identified by looking at the types of policy implemented in other contexts or countries, to the extent that the issues to be addressed are similar. There should also be extensive consultation with stakeholders, formally or informally, to ensure that industry expertise is drawn upon in the development of intervention options.[11] Different levels of intervention should be considered that lead to more or less restricted markets (via restrictions on consumers, providers or innovation). In addition, 'do minimum' options and options for deregulation should be considered.

In the UK, there is a long tradition of putting options for intervention to consultation 'before firm proposals have been developed, to ensure that stakeholders' views and expertise are taken into account'.[12]

Observations on the DHSC consultation

The consultation suggests amendments to professional standards legislations to require all healthcare professionals not covered by state-backed indemnity to hold policies of insurance for clinical negligence risks. Furthermore, it recommends amending financial regulation to bring the provision of clinical negligence cover in the UK into the scope of the Regulated Activities Order (2001).

These reforms would remove the possibility of healthcare professionals purchasing discretionary cover. Therefore, the perceived risk of MDOs exercising their discretion to deny cover to a member, in a manner that would not be possible for a regulated insurer (see below – there is effectively still some discretion in insurance provision), would subside. Additionally, bringing medical indemnity provision within PRA and FCA regulation would ensure the maintenance of adequate reserves to cover claims, as well as mandating financial disclosure and ensuring fair treatment of customers.

[9] Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation', p. 25.
[10] Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation'.
[11] HM Treasury, 'The Green Book', para. 5.4.
[12] Better Regulation Task Force (1997), 'Principles of Good Regulation', p. 5.

Therefore, the interventions being proposed in the consultation document could, in theory, address the issues of concern identified by the DHSC. Furthermore, the channels of intervention appear to be reasonably well outlined.

However, it is not clear how any of the proposals would resolve the concern about the rising costs of indemnity cover. In fact, there is no discussion in the consultation document on how the DHSC proposes to remedy the concern about rising costs; paradoxically, the DHSC appears to acknowledge that some of the proposed interventions could actually result in higher costs to members. For instance, with respect to the proposed requirement for MDOs to comply with prudential regulation, the DHSC admits that 'this could lead to an overall higher cost of cover for the professional'.[13]

The DHSC also does not assess how the perceived threat of discretion would be addressed by its proposals, as it does not consider how the provision of indemnity might change when provided within regulated insurance contracts, compared with the current defence union provision.

Furthermore, the DHSC largely offers a binary choice between its proposed reforms and a 'do nothing' scenario, without considering a spectrum of intervention levels. This approach fails to consider any unconventional intervention that goes beyond extending current regulations or restricting the access of healthcare professionals to indemnity products.

Another important shortfall is the absence of any reference to regulatory experiences in other countries or other markets, which might inform the nature and extent of intervention required (if any).

'Do minimum' options are considered only in the form of maintaining the status quo, and a no deregulation route is presented. The consultation provides a qualitative list of costs and benefits underpinning this option, and does not argue clearly why the former outweigh the latter. Rather, it discards discretionary indemnity cover solely on the basis of hypothetical concerns.

Overall, there appears to be no involved analysis or adequate thinking supporting the DHSC's propositions, and there is a significant risk of these not representing the Pareto-optimal solution.

Assessment of outcomes

Once a set of interventions has been designed, these should be carefully assessed to ensure that all potential associated costs and benefits are considered, including dynamic effects. This assessment should involve the following steps.[14]

1. Define the baseline against which the effects will be assessed.
2. State what the direct effects of the intervention will be – e.g. compliance costs, product bans, or purchasing efficiencies.

[13] DHSC (2018), 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December, p. 32.
[14] Financial Conduct Authority (2016), 'Occasional Paper 13: Economics for Effective Regulation', p. 31.

3. Consider how market participants will respond – i.e. how consumers or providers will change to re-optimise their behaviour under the new market structure.

4. Summarise the effects on market outcomes – such as the impact on the issues identified and competition in the market, and any unintended consequences.

5. Assess and, where appropriate, quantify the costs and benefits, both financial and non-financial.

The types of impact assessed will depend on the types of intervention considered. For instance, where policies may significantly affect competition, the supplementary guidance on reviewing competition effects should be consulted.[15] In these cases, evidence on the extent of benefits achieved from competition, such as lower prices, higher-quality services and increased innovation, need to be considered in the review of policy options.

Once this assessment has been undertaken, decision criteria and judgement should be used to select the best option or options, including taking into account how exposed each option is to future uncertainty.[16] The option(s) chosen should then be refined into an overall solution.

With respect to the five criteria outlined above, the performance of the DHSC's regulatory approach is mixed at best.

The baseline case appears to be well defined as the status quo for the market for indemnity cover for medical professionals. The interventions are consistently contrasted against the status quo, although sometimes presented as achieving a desired outcome without explaining how or why the current scenario fails to do so. For instance, the DHSC claims that requiring healthcare professionals to hold regulated clinical negligence cover and give up discretionary indemnity would 'remove the associated risk that an indemnity provider may exercise its discretion not to support a member'.[17] However, no evidence is offered of this possibility having arisen in the past, or the probability of this occurring at some point in the future. There is a reference to a specific case of criminal malpractice, but this is weak at best, and the DHSC itself recognises that criminal malpractice is unlikely to be covered under its preferred option of insurance cover either.[18] Therefore, the government does not provide a sufficient basis to conclude that its proposal comprehensively addresses a materially relevant risk.

On the need to state the direct effect of the interventions, the consultation is clearer. It lays out two pathways to carry out the desired intervention and considers the legislative implementation process for both. In addition, it performs a separate cost-benefit analysis for each route.

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[15] Office of Fair Trading (2007), 'Completing competition assessments in Impact Assessments: Guideline for policy makers', OFT876, August. See also Office of Fair Trading and HM Treasury (2007) 'Guidance on how to assess the competition effects of subsidies', OFT829, January.
[16] HM Treasury, 'The Green Book', paras 5.57–5.60.
[17] DHSC (2018), 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December, p. 31.
[18] Ibid., p. 19.

The government takes into account the response of parties such as indemnity providers, UK and foreign insurers, and healthcare professionals. Yet, we note a tendency to overlook the effect of such reactions on market outcomes. For instance, in describing intervention through professional regulation, the DHSC mentions that existing indemnity providers will cease to operate. Worryingly, it does not express particular concerns about the implications of this outcome and accessibility for medical professionals to purchase cover.

The consultation also fails to analyse in detail the effects of intervention on market outcomes. While it considers the impact of potential entry in the clinical negligence cover market by general insurers, it stops short of discussing or analysing the effect on premiums. Since the core issue that prompted the consultation is the increase in negligence cover costs, this omission limits the seriousness of the recommendations.

Finally, while the DHSC does list potential risks and benefits of the proposed intervention, it does not provide any quantitative assessment, even where this would be feasible and relatively straightforward. A relevant example is the impact of the additional cost of the Insurance Premium Tax for indemnity providers under the government's proposed recommendations.

Therefore, the consultation does not appear to follow a comprehensive procedure to assess the outcomes of the proposed interventions, as is desirable under best-practice guidelines.

Conclusion

In summary, the assessment framework provided by the DHSC is lacking in two main respects:

- the design of interventions does not seem to be strongly linked to the underlying problem of increasing costs of negligence cover. Deregulation, 'do nothing' options and bespoke solutions do not receive enough attention either;
- the cost-benefit analysis does not follow best practice in terms of response of market participants, consideration of market outcomes, and a well-constructed quantitative assessment.

Following a proper intervention design process is crucial for the success of any regulatory action. There are many examples of much more comprehensive assessments for the need for intervention, including the need for FCA regulation to be introduced.[19] On the other hand, a cautionary tale on the dangers of poorly designed interventions is provided by the introduction by the energy regulator for Great Britain, Ofgem, of limits to the tariff structures of energy providers amid rising retail energy prices in 2009 (see the box below).

Ofgem intervention in regulating customer tariffs

[19] For example, the decision to move the regulation of claims management companies (CMCs) from the Ministry of Justice to the FCA followed the recommendations from the 2016 Brady review. This review included a much more extensive assessment of the need for regulation than is provided in this DHSC consultation. See 'Independent review of claims management regulation: final report', March 2016.

In 2009, Ofgem introduced a non-discrimination condition forbidding suppliers to charge different tariffs to consumers unless this was driven by service cost differentials. Two years later, Ofgem mandated that all tariffs should have a two-part structure, and limited them to four different tariffs per fuel (gas and electricity) per provider.

The results were arguably negative for consumers. In a 2016 review of the energy market, the CMA concluded the following:

> [Suppliers withdrew] a number of tariffs and discounts and changing tariff structures, which may have made some customers worse off. … The RMR [Retail Market Review] four-tariff rule limits the ability of suppliers to compete and innovate and provide products which may be beneficial to customers and competition. … [The RMR rules] dampen price competition by limiting the ability and incentives of suppliers to respond to competition by offering cheaper tariffs or discounts (which means that they, in turn, put less competitive pressure on their rivals).[20]

Another result of the tariff reforms relevant to this consultation was the halving in the difference between the incumbent's price and the best non-incumbent price, which might have reduced consumer switching. In conclusion, the intervention seems to have relaxed the constraint on incumbents increasing their prices, which was likely to have come 'at the "absolute" expense of just those consumers whom the regulator sought to protect'.[21]

In its 2008 Energy Supply Probe, Ofgem labelled price differentials as an unfair strategy to gain excess profit, unless driven by cost differences. However, price differentials in the energy market were arguably used as a competitive tool. Providers tried to retain active consumers and attract new business from rivals with low prices, while recovering the costs via higher charges for disengaged consumers.[22]

It is also important to note that the fast-rising energy prices in 2008 were due to 'unprecedented increases in world fuel prices which have flowed through into record increases in wholesale and retail gas and electricity prices'[23], according to Ofgem. However, the probe did not provide a detailed economic discussion of the link between wholesale and retail prices. Such an analysis should have pointed out that the retail energy price increases were due to reasons outside of energy suppliers' control, and not to a failure of retail energy markets.[24] In addition, in its intervention planning, Ofgem failed to identify the possible adverse reaction in the form of suppliers withdrawing popular tariffs, nor did it acknowledge the possible negative effects on competition and consumer choice. Therefore, Ofgem's approach had shortcomings in both problem diagnosis and outcome assessment.

[20] Competition and Markets Authority (2016), 'Energy market investigation, final report', June, p. 41.
[21] Waddams Price, C. and Zhu, M. (2016), 'Non-discrimination clauses: their effect on GB retail energy prices', *The Energy Journal*, 37, pp. 111-132.
[22] Littlechild, S. (2018), 'Competition, regulation and price controls in the GB retail energy market', *Utilities Policy*, 52(C), pp. 59-69.
[23] Ofgem (2008), 'Energy supply probe: initial findings report', October, p. 5.
[24] Littlechild, S. (2018), 'Competition, regulation and price controls in the GB retail energy market', *Utilities Policy*, **52(C)**, pp. 59-69.

There is a clear parallel in Ofgem's misguided intervention with the DHSC's proposed reforms, in the improper diagnosis of the underlying adverse outcome. Just as with energy prices in 2008, medical indemnity cover costs may appear to be rising because of factors outside the control of providers. This argument was made by the DHSC itself in the 2016 review of the GP indemnity market, and the Department has provided no alternative explanations of this phenomenon since then.[25] Therefore, an intervention designed around regulatory requirements for indemnity providers without a detailed analysis of the economic causes underlying adverse outcomes is likely to complicate matters, not simplify them.

[25] NHS England (2016), 'GP Indemnity Review', July, para. 5.1.

CRITICAL REVIEW OF THE ISSUES RAISED IN THE DHSC'S CONSULTATION

This section explores and assesses the relevance and validity of the policy concerns raised by the DHSC.

At the heart of the matter is the increasing cost of clinical negligence cover, which is the cause for some concern among healthcare professionals.

Having good indemnity cover is becoming increasingly important for medical professionals, given the ascent in litigious behaviour by consumers. A survey commissioned by the Medical Protection Society (MPS) found that 88% of healthcare professionals are increasingly fearful of being sued, which has led to more conservative behaviour by practitioners.[26] Indeed, the same survey also found that 75% of GPs and dentists ordered more tests or referrals as a result of their conservatism.[27] Additionally, 64% of professionals interviewed stated that the fear of being sued has made them consider their future in the profession.[28]

It would therefore appear that the societal shift towards more litigious behaviour has not only increased the importance of indemnity cover, but most likely has also contributed to the increase in premiums.

Review of DHSC's concerns with current indemnity cover

The DHSC raised four issues regarding the current state of clinical negligence cover for healthcare professionals.

1. Discretion – indemnity providers who cover healthcare professionals operate on a discretionary basis, so they have no contractual obligation to meet any claim.
2. Financial resilience – indemnity providers are not legally required to hold reserves to cover the cost of current and potential future claims.
3. Regulatory oversight and transparency – there is no requirement for indemnity providers to disclose their financial situation, potentially leaving members unaware of the nature and extent of their negligence cover.
4. Financial conduct and fair treatment – medical defence organisations (MDO) do not face regulation on financial conduct and fair treatment. The DHSC argues that, as a result, healthcare professionals are exposed to risk of unfair treatment.

Interestingly, and as noted previously, the root concern of rising costs of access to indemnity cover do not feature in the subsequent discussion.

The sub-sections below elaborate on each of the issues.

Discretion

MDOs that provide indemnity cover do so on a discretionary basis, while insurance providers are contractually obliged to meet any claim falling within the boundaries of the insurance contract. The government argues that discretion makes healthcare professionals less secure about the extent of their protection. If the indemnity provider denies cover, professionals

[26] Medical Protection Society (2017), 'The rising cost of clinical negligence: who pays the price?', June, p. 13.
[27] Ibid., p. 5.
[28] Ibid., p. 13.

might lack the means to cover claims autonomously, especially against the backdrop of increasing average awards from claims. As a secondary consequence, patients could see their right to receive compensation for harm compromised.

However, the consultation recognises that indemnity providers exercise their prerogative to deny cover in only a limited number of cases (a majority of which involve deliberate malpractice, which an insurance contract would also be unlikely to cover either). The DHSC provides no evidence of this risk materialising, save for the Paterson case, which is largely irrelevant for the issue at hand since it involved criminal behaviour by the professional in concern. [29]

It is also worth noting that, while different in principle, MDOs' terms and standard professional indemnity insurance (PII) policies contain similar clauses. For instance, both the MDDUS Membership Agreement and the Hiscox Professional Indemnity Policy Wording exclude liability for breach of certain legislation.[30] [31]

The available evidence indicates that the discretionary nature of cover is a problem only in theory. A relevant example is provided by MDDUS, which, as noted earlier, has never used discretion to deny a valid claim for clinical negligence cover. The rationale for these statistics is likely to be the relationship of trust between members and indemnity providers that lies at the foundation of mutual organisations. The DHSC consultation fails to recognise that the MDOs are mutuals formed of the members, by the members, and for the members. The 'raison d'être' for these organisations is member welfare, not seeking economic rent. The self-governing nature of a mutual provides a powerful check on poor outcomes for members. This is again corroborated by MDDUS data on member complaints numbering fewer than 30 per year (on average over the last three years) and largely pertaining to administrative issues.[32]

A further example of the viability of mutual models can be drawn from the experience of the Bar Mutual Indemnity Fund (BMIF), which provides PII to barristers. A report prepared by Oxera highlighted that, despite concerns about the lack of efficiency incentives, BMIF manages to operate at a relatively low cost and to maintain stable premiums. Furthermore, Oxera's analysis found no concern of moral hazard through undesirable conduct by barristers, which is in theory plausible due to the lack of risk pricing.[33] As such, irresponsibly denying claims would significantly damage the reputation of MDOs, which appears to provide a high enough incentive for reliable cover, even without contractual obligations.

Therefore, our assessment is that, while the prospect of discretionary cover might raise a red flag in theory, it needs to be considered in light of the legal set-up of MDOs and the

[29] Independent Inquiry into the issues raised by Paterson, https://www.patersoninquiry.org.uk/terms-of-reference/, accessed 21 January 2019.
[30] MDDUS Membership Agreement, https://www.mddus.com/about-us/membership-agreement, accessed 21 January 2019.
[31] Hiscox Professional Indemnity Insurance Policy Wording, https://www.hiscox.co.uk/sites/uk/files/documents/2017-09/15583-professional-indemnity-wording.pdf, accessed 21 January 2019.
[32] Information as of 19 February 2019.
[33] Oxera (2016), 'Assessment of the current regulations of the provision of PII to barristers', p. 23.

strong track record. Based on evidence available from MDDUS, on the analysis of its Articles of Association (AoA) and on its robust track record, exercise of discretion does not appear to be a cause for significant concern for the security of protection from claims available to healthcare professionals.

Financial resilience

Currently, there is no legal obligation for discretionary indemnity providers to hold sufficient financial resources to pay contingent liabilities. Conversely, general insurers must comply with Solvency II prudential regulation.[34]

The lack of prudential regulation implies that MDOs might not be incentivised to implement financial prudence, and, hence, undermine their ability to meet future liabilities. According to the consultation, this situation exacerbates the uncertainty of healthcare professionals about their cover. In turn, if indemnity providers fail, patients are ultimately left without compensation for clinical negligence.

While, on the face of it, the DHSC's concern regarding financial prudence in the absence of regulation seems valid, the lack of any formal analysis or evidence to further substantiate this concern is surprising.

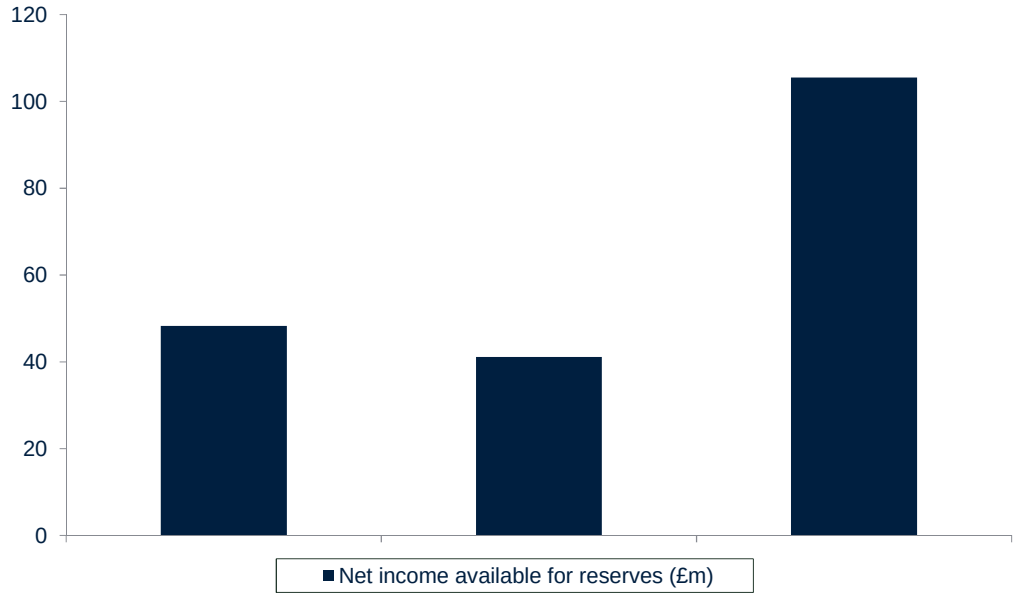
Examining evidence made available by MDDUS suggests that this concern may not be as critical as initially thought. MDDUS does not have to comply with prudential regulation. However, as a member-owned mutual organisation, its incentives are well aligned with those of the medical professionals it supports. Therefore, it is in MDDUS's interest to hold sufficient reserves to cover both existing and expected future claims, and it does so as common practice. For example, it set aside £357.3m as a provision for incurred but not reported claims and non-claims in 2017, in the face of £16.1m in claims costs.[35] It is also worth noting that MDDUS has never faced a claim larger than £11m, while the second largest amounted to £7m.[36] In addition, its net assets totalled £519.m in 2017.

As evidenced in the figure below, MDDUS has been building up a significant and increasing amount of reserves in the last few years, carrying over as much as £105.5m in 2017.[37] Therefore, its financial situation appears robust. Furthermore, in its entire history, MDDUS has never been in a position of financial distress that prevented it from meeting claims or compromised its status as a going concern.

Therefore, based on MDDUS's robust financial situation, both currently and historically, we believe that there is little cause for concern with regard to the financial security of clinical negligence cover.

[34] European Parliament and Council (2009), 'Directive 2009/138/EC on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II)', December, Section 3, Article 13.
[35] MDDUS (2018), '2017 Annual Reports and Accounts', pp. 4 and 12.
[36] Information as of 16 January 2019.
[37] MDDUS (2018), '2017 Annual Reports and Accounts', p. 4.

MDDUS net income available for reserves



Source: MDDUS Annual Reports and Accounts 2015, 2016, 2017.

Regulatory oversight and transparency

Providers of discretionary indemnity are not currently required to disclose their full financial position, and do not face oversight by regulators such as the FCA or the PRA, unlike insurance companies.

The government argues that the absence of oversight makes healthcare professionals insecure about the extent of their protection. In turn, patients allegedly face significant uncertainty about the availability of compensation.

The DHSC also claims that healthcare professionals are largely unaware of the terms of their protection, and of the difference between discretionary and contractual cover. It provides appropriate evidence for this assertion in the form of a survey of GPs that it commissioned.[38]

While there is no obligation to disclose information, in practice MDOs generally seem to have data accessible to members. In particular, MDDUS lets both members and potential clients easily access the full Membership Agreement and AoA on its website. Moreover, it publishes annual reports and accounts and minutes of annual general meetings. Furthermore, it believes that its complaints data does not raise any concerns regarding transparency (or lack thereof).

However, we acknowledge that there continues to be a perception that professionals' knowledge of the nature of indemnity cover does not seem to match MDOs' efforts towards accessibility of information. A shift towards greater transparency may then be deemed desirable. For instance, it may prove informative for medical indemnity cover providers to consider allowing data access to price comparison websites in order to ease comparison of

[38] Ipsos MORI on behalf of Department of Health and Social Care (2018), 'Primary care indemnity survey – GPs, nurses and pharmacists perceptions and awareness', November.

the prices and terms of cover offered by competing providers. While it is not clear what precisely is entailed in the DHSC's definition of transparency, MDDUS's recent press release has acknowledged a willingness to increase levels of transparency and to cooperate to promote competition where it may be deemed necessary.[39]

Fairness

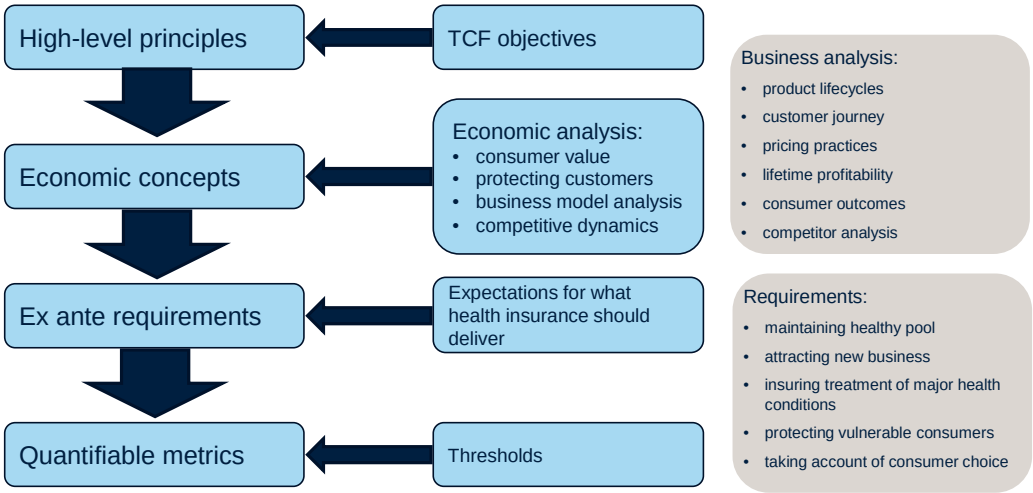
Since indemnity providers are not subject to FCA oversight, they do not have to comply with the FCA's Principles for Businesses, such as integrity, financial prudence, market conduct, customers' interests, communications with clients, and relations with regulators.[40] According to the DHSC, the absence of statutory duties and dispute resolution mechanisms exposes healthcare professionals to risk of unfair treatment by their indemnity providers.

The consultation concedes, however, that the AoA prescribing the responsibilities of MDOs with respect to their members could mitigate this risk in practice. In addition, no evidence of unfair treatment is presented, so the concern is at best speculative. Since mutual organisations routinely set out precise duties towards members in their statutes, the risk of unfair treatment seems negligible. In the case of MDDUS, this is supported by the low levels of complaints (fewer than 30 complaints per year), almost none of which relate to unfair conduct by MDDUS.[41]

That said, there is no reason why MDOs should not continuously review and update their AoA. It may also help if they apply a best-practice fairness framework in line with the FCA's Treating Customers Fairly (TCF) initiative. The FCA wishes to see that firms are meeting the objectives of its TCF programme, and, more broadly, that they are ensuring that markets function well. Its approach is informed by empirical analysis, using a toolkit of behavioural economics, competition economics, business model analysis and quantitative techniques. This toolkit, in turn, could provide MDOs with the basis for translating high-level TCF-based principles into operational pricing policies and decisions. The diagram below provides the building blocks of what such a framework could look like.

[39] MDDUS (2018), 'Indemnity reform – another missed opportunity', 6 December.
[40] Financial Conduct Authority (2019), 'Principles for Businesses', accessed 22 January, p. 9.
[41] Information as of 19 February 2019.

Building blocks of the TCF Framework



Source: Oxera.

It is not evident whether MDOs have adopted a formal fairness framework in assessing their business processes, and this is one area to consider for future enhancement of market functioning. However, there is a strong commercial incentive to do this, absent any regulatory compulsion.

REVIEW OF DHSC'S RECOMMENDATIONS

In this section, we describe and assess the DHSC's recommendations and provide an indicative analysis of the potential costs and benefits. Following the approach used in the consultation, we compare the proposed intervention with the 'do nothing' option.

Summary of interventions proposed by the DHSC

The consultation weighs the benefits and risks of maintaining the status quo, ultimately arguing against it. The reasons in favour of intervention relate to a potential threat to patient recourse, the insecurity of healthcare professionals' financial cover, and the lack of transparency regarding the nature of indemnity cover.[42] The consultation also mentions the possibility of achieving the government's goals through non-legislative changes, such as issuing guidance on the different forms of clinical negligence cover. However, this option is considered inferior because it provides limited certainty of achieving the policy goals.

The DHSC suggests enacting secondary legislation to bring clinical negligence cover within the supervision of the FCA and PRA, and lays out three routes to achieve this.[43]

1. Amendments to healthcare professional standards legislation – this option would require healthcare professionals not covered by state-backed indemnity to hold insurance policies by regulated providers.
2. Amendments to financial regulation – changes to financial regulation would bring the provision of indemnity cover under the Regulated Activities Order 2001 and within the scope of prudential supervision by the PRA.
3. A combination of the above.

The government concludes that its preferred option is ensuring that all regulated healthcare professionals not covered by state-backed indemnity hold clinical negligence cover subject to supervision by the FCA and PRA.

Benefits

All proposed routes of intervention entail benefits with respect to the desired outcome of ensuring stable and financially secure negligence cover. The government highlights the removal of uncertainty on the extent of cover, higher transparency on the financial stability of cover due to PRA regulation, and certainty of fair treatment according to the FCA's Principles for Business.

It may be argued that the DHSC's proposals would result in benefits by potentially addressing the perceived concerns. However, the actual value of these benefits is debatable and likely to be small, given that the key issues of discretion and financial resilience are not currently relevant in the first place. Any material benefits arise only in a future hypothetical scenario, where market conditions evolve such that these concerns become a reality.

[42] DHSC (2018), 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December, pp. 25-26.
[43] Ibid., p. 28.

However, there may be other benefits of the DHSC's interventions that have not been explored in the consultation. In addition to the positive effects outlined by the DHSC, there is scope for a substantial increase in competition after the proposed intervention. Exposing MDOs to competition on an equal footing with insurers could spur innovation in the clinical negligence cover market. The potential for more sophisticated product offerings would also be likely to increase.

More generally, the benefits of increased competition could materialise in the form of lower prices, assuming that the market will feature price competition. Product diversification, instead, would benefit all stakeholders, by better allocating the risk of clinical negligence between practitioners and providers.

To assist the DHSC's case, these additional benefits would need to be explored more thoroughly and quantified.

Costs

Enacting the reforms suggested in the consultation would result in a number of adverse consequences. In the consultation, the DHSC recognises several potential costs, as described below.

Insurance Premium Tax – under the proposed regulatory changes, MDOs would have to provide insurance products, and hence be eligible to pay the 12% Insurance Premium Tax. Assuming current income levels, the cost to the three major MDOs would be approximately £102m per year.[44] This is a significant extra cost, which would almost certainly be directly passed through to members.

Regulatory compliance and capital costs – bringing MDOs under Solvency II prudential regulation would require them to raise and maintain considerable amounts of capital, the need for which is not immediately evident. While MDDUS currently satisfies the Minimum Capital Requirement, it would incur significant costs to meet the more stringent Solvency Capital Requirement. Aside from capital costs, indemnity providers would have to upend their businesses and effectively turn themselves into insurers. The transition would undoubtedly prove difficult and the resulting costs (amending business processes and operational standards and re-training staff, among others) could be high.

Run-off cover – MDOs normally provide cover on a claims-occurring basis, while insurers typically do so on a claims-made or -paid basis. The proposed intervention would equate insurers with indemnity providers from a regulatory perspective. We might then possibly witness an acceleration in the existing trend towards claims-made cover by MDOs. In such a scenario, healthcare professionals could incur significantly high costs to obtain additional run-off cover. Such cover has proved to be a particularly thorny issue in other professional

[44] We calculated 12% of income from members' subscriptions in 2017, as reported in the financial statements of MDDUS, the MPS and the Medical Defence Union (MDU). Since MDDUS does not report income from members' subscriptions separately, we used MDDUS's total income. Since MDU and MPS do not report income from overseas subscriptions separately, we used total subscription income as reported in the financial statement. See the 2017 annual reports and accounts of MDDUS, MPS, and MDU.

indemnity insurance markets.[45] Given the lack of awareness of the nature of cover among healthcare professionals, it seems likely that they would be caught unawares by the arising need to procure run-off cover. They could then fail to do so and remain exposed to serious financial risk, and with concomitant risk to patients if they are not in a position to meet their obligations. While the current pricing of indemnity cover on a claims-occurring basis does take into account the cost of cover for claims that occur during the period of cover but are made at a later date, medical professionals would be likely to face a higher cost to secure separate run-off cover, for two orders of reasons:

- even if run-off cover were provided by the same company offering the main claims-made cover, there would be additional administrative costs associated with a new policy, which would be likely to be passed through to customers;
- if run-off cover were provided by a different insurer, it may know less about the individual risks associated with the medical professional than the provider of the main policy does. The insurer may therefore assign a higher risk premium to the medical professional, which would result in a higher cost for the run-off cover.

The requirement to procure additional run-off cover could be a source of systemic risk as well. Given the likely difficulties of acquiring it through traditional insurers, some professionals may well remain uncovered for claims made after the end of their practice. The lack of mechanisms to ascertain that all retired healthcare professionals hold run-off cover would exacerbate the problem. Ultimately, this risks depriving consumers of recourse for clinical negligence, one of the very outcomes that the DHSC is seeking to avoid with its intervention.

In addition to the costs identified in the DHSC's proposal, other potential risks arising from the DHSC's preferred intervention include the following.

Loss of flexibility – as the consultation recognises, flexibility is an important advantage of indemnity cover.[46] MDOs, as non-profit mutual organisations, could reasonably be expected to exercise their discretion in favour of their members. For instance, they might provide cover even in situations when an insurance contract with a comparable premium would not.

Hollowing-out of contracts – as noted in general insurance markets (e.g. car insurance), intense market competition can lead to a hollowing-out of contracts due to exclusions and excess features. Bringing indemnity providers within the same regulatory perimeter as insurers, and encouraging market competition, could aggravate this phenomenon. As a result, healthcare professionals could see the actual extent of their cover greatly reduced, worsening one of the key problems that animated the consultation in the first place.

Entry from unreliable competitors – another aspect of encouraging competition could be entry by unscrupulous or financially unsound profit-seeking firms without the necessary expertise and commitment to the welfare of members typical of a mutual organisation. A recent example of this can be seen in the energy retail market, with a number of electricity

[45] See the case of run-off cover for solicitors presented in the Appendix.

[46] DHSC (2018), 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December, p. 19.

and gas providers having gone bankrupt in the past 12 months.[47] [48] We also note well-documented cases of much-trumpeted entry into, and rapid exits from, the medical malpractice market by commercial insurers in the past.

Incomplete cover —as discussed further below, other professional indemnity markets have faced issues with insufficient availability of cover, as the market has struggled to operate effectively. The risk of a lack of cover needs to be considered carefully, as it could stifle the number of practising medical professionals and lead to much wider issues of accessibility to doctors and dentists.

Conclusion

Overall, the consultation raises issues that appear to be mainly speculative in nature and of limited practical relevance. They are theoretically valid concerns, but the DHSC provides little or no evidence to demonstrate the practical relevance of its concerns.

Given MDDUS's fairly robust track record, some of the concerns raised by the DHSC could be resolved without the proposed interventions. For instance, on the transparency and clarity of cover, simple directives elaborating the data required to be shared with members or changes in the detail of the communication being provided could remedy these concerns without the need for wholesale interventions. Similarly, on financial resilience, the DHSC could indicate the levels of capitalisation required for the industry and if these are above current reserves, the members of the MDOs would be likely to direct the mutuals to strengthen their balance sheets. Simply imposing FCA/PRA regulation to resolve specific concerns has the potential to create additional costs that ultimately fall on members.

While a detailed quantification of the effects of the proposed interventions is outside the scope of this technical review appendix, the potential costs of the proposed interventions could well be significant. Run-off cover, regulatory compliance costs and the Insurance Premium Tax stand out as the most significant costs of the DHSC's preferred course of action. In particular, additional run-off cover is likely to impose a disproportionate burden on MDOs if weighed against the limited benefits of the proposed intervention.

[47] Ofgem (2018) 'Extra Energy Supply Limited – Notice of revocation of an electricity supply licence', 27 November, https://www.ofgem.gov.uk/publications-and-updates/extra-energy-supply-limited-notice-revocation-electricity-supply-licence, accessed 28 January 2019.
[48] Ofgem (2018) 'Spark Energy Supply Limited – Notice of revocation of an electricity supply licence', 29 November, https://www.ofgem.gov.uk/publications-and-updates/spark-energy-supply-limited-notice-revocation-electricity-supply-licence, accessed 28 January 2019

FURTHER THOUGHTS ON THE MARKET FOR CLINICAL NEGLIGENCE COVER

In this section, we analyse other concerns beyond discretionary cover, financial resilience, regulatory oversight and transparency, and fairness. The goal of the following is to highlight and discuss possible issues that have not been explicitly identified in the DHSC consultation, and the potential implications for appropriate policy for this market.

Increasing indemnity subscription rates

The consultation does mention rising indemnity cover prices as a worrying phenomenon, but it is left mostly in the background and not addressed analytically as a concern separate from the other four.

The cost of indemnity for GPs in England and Wales has been increasingly steadily over time. This upward trend in subscriptions was identified as a key concern of GPs by the General Practice Indemnity Review of 2016.[49] This trend is not apparent in subscription rates in Scotland, however, which have been broadly stable over the past 20 years.

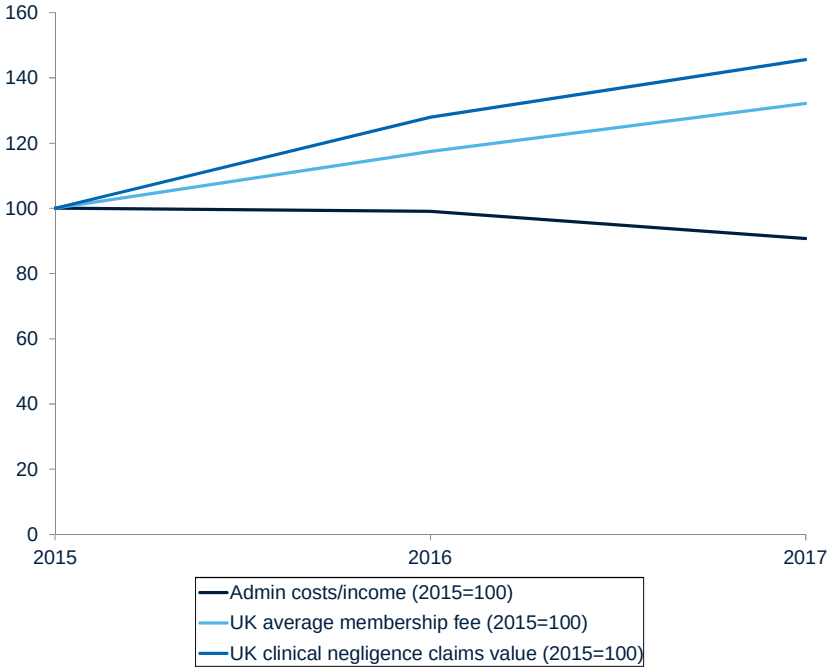
The higher subscription rates in England and Wales are a direct result of increases in claims paid out (and expected future claims costs) and increased legal costs. These increases are due to GPs providing more care, as well as there being a higher frequency of claims and an increase in the average pay-out amount.[50] In addition, the Ogden ruling, which reduced the real discount rate for claims to -0.75%, significantly increased the future size of claims.[51]

While the costs of claims and legal costs have increased, the NHS England review 'did not find evidence to suggest that market inefficiency is a cause of rising indemnity premiums'.[52] The increase in subscriptions is instead a function of the increase in the cost of claims and legal costs, and therefore the drivers of the increase can be addressed only through reform of tort law (and the Ogden ruling) and through changes in the behaviour and performance of GPs.

Data from MDDUS seems to confirm this view. The figure below shows that in the 2015-17 period, the ratio of administrative expenses over income declined, while MDDUS's average UK-wide membership fee increased in line with the total value of clinical negligence claims made in the UK.

[49] See NHS England (2016), 'GP Indemnity Review', July
[50] See NHS England (2016), 'GP Indemnity Review', July, section 5.
[51] The government plans to amend the methodology for calculating the discount rate, although the timetable for this is understood not to be certain at this time.
[52] NHS England (2016), 'GP Indemnity Review', July, para. 3.6.

MDDUS premiums and operational efficiency



Source: MDDUS Annual Reports and Accounts 2015, 2016, 2017. MDDUS internal documents. National Audit Office (2017), 'Managing the costs of clinical negligence in trusts', September.

These trends suggest that higher premiums can reasonably be attributed to external factors rather than to any operational inefficiency.

Consequently, substantial change in clinical negligence cover costs are likely to be achieved only in the longer term.

The proposals outlined in the consultation do not appear to address this fundamental issue as they are aimed at outcomes that are not obviously linked to the legal, demographic and policy drivers of the cost increase. Indeed, the proposals in the consultation would be likely to add further to the cost of indemnity cover.

Ensuring access to professional indemnity

In the wider market for professional indemnity, one of the key concerns is related to the lack of access to professional indemnity – for example, in markets such as midwifery (see the box below) and solicitors in the UK.

Feasibility and insurability of independent midwifery

Under Directive 2011/24/EU, independent midwives are required to hold negligence claims cover. However, they struggle to purchase it from commercial insurers despite trying since 1994. The main reason is the perceived high risk of claims, with awards of around £6m not uncommon.[53]

A report by Flaxman Partners commissioned by the Royal College of Midwives and the Nursing and Midwifery Council found that:

> Insurance of medical practitioners is regarded by the entire insurance industry as high risk. Commercial insurers offering cover to medical practitioners do so in the knowledge that if the claims experience deteriorates beyond a commercially profitable level, they can simply withdraw further insurance. This has happened on several occasions in the last ten years.[54]

Flaxman Partners also notes that the commercial insurance market does not offer 'fully comprehensive' insurance of the type currently provided by MDOs. The loss of this option could be detrimental to healthcare professionals.

Other healthcare professionals might be deemed to face a level of risk similar to that faced by independent midwives when practising outside of the NHS. Consequently, they could be exposed to the same reluctance by insurers to provide cover, which may be exacerbated by the increasing willingness of solicitors and patients to pursue clinical negligence claims.

Currently, traditional insurers show little appetite to enter the clinical negligence cover market. This suggests that healthcare professionals might find it difficult to obtain commercial insurance. Such a development may leave medical professional exposed to financial distress in the case of medical negligence claims, and in turn consumers would be left with no redress. Therefore, the very outcomes the DHSC is seeking to avoid may materialise if the option of indemnity cover is eliminated.

The challenges that have arisen in providing professional indemnity in the case study described above can be linked to two key factors.

1. Tail risk – especially when indemnity is provided on an occurrence basis, the provider of indemnity faces a potential risk of future claims being much higher than expected, requiring significant reserves to be held against 'incurred but not reported' liabilities. For example, the challenges in providing indemnity cover and midwives have been linked to significant tail risk.

2. Affordability – for many professionals facing a high risk of claims due to the nature of their work (which was again the case for midwives, as discussed below), commercial insurance may not provide a viable solution. The problem is the number and size of

[53] Flaxman Partners Ltd. (2011) 'The feasibility and insurability of independent midwifery in England', September, p. 9.
[54] Ibid., p.13.

claims, which can be addressed only through relevant legislation. Without the driver of the costs being addressed, there can be a breakdown of the market, which can leave professionals without insurance in the absence of alternative solutions.

These concerns are closely related to the profit-seeking nature of commercial professional indemnity, which incentivises providers to price policies based on risk assessments. In turn, this can lead to unaffordability of cover, a concern that the consultation mentions explicitly.[55] In promoting a shift towards a commercial model, the DHSC overlooks the intrinsic benefits of indemnity provision by mutual organisations. For example, mutuals do not need to employ detailed risk-based pricing. This feature is partly due to their very goal of pooling risk among members. However, another likely explanation is membership being restricted to licensed medical practitioners, whose professional behaviour is strictly regulated by standards boards such as the General Medical Council. In the case of indemnity cover for healthcare professionals, this argument is further supported by MDDUS experience that the risk of clams is more strongly correlated with the external legal environment than with the professional track record of members.

The DHSC proposals would not address the issues outlined above, which may become more acute in view of the increased costs that the proposals would be likely to introduce.

Competition

The market for clinical negligence cover for non-NHS work is relatively concentrated, albeit with some growth of new indemnity providers in recent years. MDDUS has a market share of approximately 85% among Scottish GPs and 30% of UK GPs. [56]

In general, new competition is to be welcomed in the market – indeed, MDDUS itself has grown its market share outside of Scotland considerably in recent years. We believe that new competition can help to spur innovation in the form of more tailored insurance products. As a result, better allocation of risk between indemnity providers, healthcare professionals and potentially re-insurers could arise.

This dynamic is already apparent in the market for indemnity cover for healthcare professionals, given the growth of new entrants. However, the DHSC's proposals would appear to do little to encourage competition further, as the proposals would limit the range of offerings available. Consequently, additional potential issues in the market for indemnity cover do not appear to provide additional reasons for supporting the DHSC's proposals.

[55] DHSC (2018) 'Appropriate clinical negligence cover. A consultation on appropriate clinical negligence cover for regulated healthcare professionals and strengthening patient recourse', December, p. 23.
[56] MDDUS internal document.

CONCLUSION

We believe that, based on available evidence, the DHSC consultation presents a number of shortcomings.

First, the problem diagnosis is based chiefly on speculative concerns not backed by sufficient evidence. The design of interventions is also lacking, as they do not address the key problem of increasing clinical negligence costs, nor do they draw from regulatory experiences in other sectors or jurisdiction. Finally, another significant flaw in the intervention design lies in the assessment of outcomes. It fails to consider the effects of intervention on economic outcomes and does not carry out any quantitative analysis.

The issues raised in terms of discretionary cover, financial resilience and fairness of treatment do not appear to have much practical relevance, as little to no supporting evidence is provided. On the contrary, the only pieces of evidence that the government does mention (the Paterson case and the Membership Agreements) seem to indicate that there is little cause of concern in terms of discretionary cover and fairness of treatment. The consultation does, however, identify one relevant concern, backed by survey data, in the poor awareness that healthcare professionals appear to have in relation to the nature of discretionary indemnity.

Furthermore, the reforms favoured by the DHSC do not address the most practically relevant issues. While the reforms would, in principle, address the problems raised in the consultation, there is no immediate link with the failures in the market that we identify.

In addition, the case has not been made for why the potentially heavy costs of the proposed regulations are justified in terms of benefits.

Based on the analysis carried out in this technical review appendix, there may be a case for developments that further promote transparency about the nature of indemnity cover. Competitive trends could also potentially benefit healthcare professionals in terms of product innovation leading to a better allocation of risk. Improved transparency could solve the market failure of asymmetric information between providers and professionals, and empower the latter to make informed choices.

Interventions that address the root causes of increased clinical negligence costs would also be desirable. For instance, tort law reform has proved effective in the USA and Australia (see the box below), and has been identified in the 2016 GP Indemnity Review as an 'effective way to significantly bring down indemnity cost over the long term'.[57]

Tort law reform in the USA and Australia

In the late 1990s, the exponential rise of clinical negligence costs made professional liability insurance for medical professionals harder to obtain in Australia. This affordability crisis ultimately reduced the availability to the public of some medical services (e.g. obstetrics). In 2002, Australian States and Territories launched independent tort law reforms after failing to

[57] NHS England (2016), 'GP Indemnity Review', July, para. 9.2.

agree to a common framework.[58]

Most states introduced exclusions from claims (such as the cost of raising a child), an increased duty to inform patients, caps on legal fees, and shortened statutes of limitations.

A report by MPS on clinical negligence cover costs judges these steps as mostly positive, in that they ushered in a 11% nationwide decrease in the volume of claims from 2003 to 2004, with the caveat that results varied widely by states. Furthermore, the reforms do not seem to go far enough, as the average claim size increased by 21% over the same period.[59]

In the early 2000s, amounts awarded for negligence claims in Texas were extremely high, and professional insurance premiums for doctors became unsustainable. As a result, many doctors abandoned the profession or moved to other states.

The HB4 tort law reform of 2004 limited non-economic damages in medical to $250,000 per doctor and $500,000 per healthcare facility, as well as imposing a statute of limitations of two years from the discovery of malpractice. Ten years later, the number of doctors increased twice as fast as the general population, successful or settled malpractice claims dropped substantially, and indemnity costs for doctors decreased.[60]

Reforms in other states (California, Colorado, Florida, Hawaii, Idaho, Indiana, Kansas, Louisiana, Nevada, Ohio, and Tennessee) typically included limits on non-economic damages and attorneys' fees, statutes of limitations and a compulsory pre-litigation panel.

The key takeaway from these two experiences in tort law reform is the desirability of interventions that target the core cause of the adverse outcome while limiting externalities. In both cases, just as in the current UK situation, the affordability of clinical negligence cover lay at the heart of the matter. Tort law reforms in Australia and the USA were correctly identified as the source of the large increase in claims.

In the UK market for clinical negligence, adopting the same principle of a targeted intervention that solves the core problem without leading to undesirable externalities is an option worth considering.

In conclusion, the course of action proposed in the DHSC consultation does not appear to follow best practice with respect to problem diagnosis, regulatory design and assessment of outcomes. In addition, the proposed interventions do not seem to be able to fruitfully address the market failures behind adverse outcomes. Going forward, the key steps to design a more effective regulatory framework include drawing lessons from other regulatory experiences and performing a more detailed economic analysis of the market failures.

[58] Medical Protection Society (2017), 'The rising cost of clinical negligence: who pays the price?', June, pp. 16-17, 26-32.
[59] Ibid., June, p.28.
[60] Ibid., pp. 33-36.