

Agenda item:	4
Report title:	Reviewing our approach to Insurance and Indemnity
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Action:	For decision

Executive summary

In light of the recent DHSC consultation on appropriate clinical negligence cover, and the introduction of the new clinical negligence scheme for GPs in England and Wales, this paper sets out some options for further work that could increase our assurance that licensed doctors have appropriate insurance and indemnity arrangements in place. It sets out the options along with the benefits and challenges of each approach.

Recommendation:

The Executive Board is asked to consider the options outlined in the paper and determine which, if any, we should we take forward.

Background information

- 1** Background information set out in Annex A includes:
 - a** The background and history leading to the introduction of a statutory duty for doctors to have in place appropriate insurance or indemnity.
 - b** Doctors' current legal and professional obligations regarding insurance and indemnity (I&I).
 - c** The GMC's approach to insurance and indemnity for doctors.
 - d** What we know about doctors' insurance or indemnity arrangements.
 - e** The impact of external work on insurance and indemnity.

Reviewing our approach to indemnity and insurance

- 2** This paper outlines some options for further work that could provide greater assurance that doctors have appropriate I&I arrangements in place.
- 3** We've obtained internal legal advice on the benefits and challenges of the options. This is referred to in the discussion of the options below.
- 4** It is worth noting that no additional work on I&I is planned in the 2019 business plan, so any further work agreed would be scheduled to commence in 2020, unless we reprioritise other work or recruit additional resources to take this forward.

Option 1 - introduce a check of insurance and indemnity arrangements in certain fitness to practise cases

- 5** We could check a doctor's I&I arrangements if they are involved in certain types of fitness to practise (ftp) cases. For example, if we know there are high numbers of patient complaints about the doctor or they are involved in innovative or contentious practice.
- 6** Currently, we only ask a doctor for evidence of I&I arrangements during an ftp investigation if the complaint includes an allegation* that the doctor has absent or inadequate insurance or indemnity.
- 7** This new approach could potentially cover two types of cases:

* Between August 2015 and February 2019, we investigated 51 allegations that a doctor had absent or inadequate insurance or indemnity.

- a** specific cases where there is an allegation that a doctor did not have I&I in place meaning the information that would be requested is under our powers in section 35A of the Act as it is information which assists us in carrying out our fitness to practise function
- b** other cases that have certain features where this will 'trigger' consideration of requesting I&I information (even if no specific concerns have been raised).

Benefits

- 8** This option would enable us to obtain greater assurance about groups of doctors that we have objectively categorised as a higher risk and would enable us to target resources accordingly. It would also go some way to mitigating the risk to patients if an uninsured or inadequately insured doctor caused harm to a patient.
- 9** We could potentially request the information in accordance with our section 35A powers (under ftp processes) or we could rely on our powers under regulation 4A of the 2012 Licence to practise regulations. This provides us with quite a wide power to request information about I&I arrangements.

Challenges

- 10** Internal legal advice suggests that we would need to have clearly defined criteria for the type of cases where we would ask for I&I information, and objective evidence to support this. We would also need to consider what action we would take if the doctor failed to provide the information when requested.
- 11** Requesting information about I&I as part of a fitness to practise investigation when this is not relevant to the allegations under investigation, and not routinely asked of doctors not under investigation, may leave us open to challenge as to the reasons or justification of this approach. It could also add to the negative image of our fitness to practise procedures with very limited benefits. If we decided to take this approach we would also need to consider the potential impact on any vulnerable doctors who may be part of this cohort and take this into account when we devise our processes.
- 12** Additionally, we would need to establish that doctors who fall into this category are undertaking the work on a private basis (and not covered by a state backed scheme) before making enquiries about their arrangements.
- 13** We would also need to consider the information governance implications of collecting data about doctor's I&I arrangements, including what information we request, what we use it for and how we record and store it.

- 14** Finally, we investigate a very small proportion of doctors each year (less than 1% of doctors on the register). We would need to consider the value (in terms of assurance about I&I) that obtaining evidence from such a small percentage of doctors would provide. This would need to be considered in light of the additional staff resource which would be necessary to introduce this requirement.

Option 2 – introduce an insurance and indemnity check by ROs as part of revalidation

- 15** We could propose an amendment to the Responsible Officer (RO) regulations (which are currently being reviewed by the DHSC) to include a requirement for ROs to assure themselves that doctors have I&I in place. We feel it would be disproportionate to expect ROs to assess the adequacy of I&I across a doctor's scope of practice as this would in effect be passing on the challenges that we have encountered, to ROs who are no better equipped to make such an assessment.

Benefits

- 16** This would provide a relatively efficient way to obtain some further assurance that all licensed doctors have I&I arrangements in place (albeit only at the time they last revalidated and would not be a check of adequacy).
- 17** It would add an additional layer of checks and assurance for I&I at the local level. This means we could identify and manage gaps in cover or concerns about adequacy through local governance processes in the first instance rather than the matter being initially referred to the GMC.
- 18** Additionally, this approach may encourage doctors to be more vigilant in checking their I&I arrangements if they knew a check would be carried out as part of their revalidation.

Challenges

- 19** Internal legal advice indicates that the main challenge will be obtaining legislative reform from DHSC to make it a requirement for ROs to assure themselves that I&I is in place. However, we are currently engaged with DHSC on reforming the RO regulations and could raise this as a further area we would like them to consider.
- 20** If the change was made, ROs would have a statutory responsibility to assure themselves about the I&I cover of their doctors. They would require some time to implement changes to their governance processes to support this new responsibility including updating local policies, contracts and disciplinary processes. We may also see an increase in revalidation deferrals if ROs are not able to access this information in advance of making a revalidation recommendation for a doctor.

- 21** If a doctor refused to provide this information to the RO, we could be notified of this and we could exercise our powers under Regulation 4A to require the individual to provide the information to us. The RO would inform the doctor in advance that that is the likely outcome if no I&I information is provided.

Option 3 – introduce an indemnity and insurance declaration as part of the required supporting information for appraisal and revalidation

- 22** We could amend our required supporting information for appraisal and revalidation to include an annual I&I declaration. Licensed doctors would be required to declare at each appraisal that they have reviewed their I&I arrangements to ensure that it remains adequate and appropriate across their scope of practice. An annual I&I statement would sit alongside the other annual declarations in appraisal relating to health and probity.

Benefits

- 23** This would reinforce that it is a doctor's responsibility to ensure that they have adequate and appropriate I&I arrangements in place.
- 24** It would provide an efficient check using existing local clinical governance processes to obtain assurance that all licensed doctors have I&I arrangements in place. If it subsequently came to light that the doctor did not have I&I or that it was inadequate, the signed declaration would provide evidence for any GMC investigation.
- 25** A declaration could be implemented without the need for legislative change and independent of any proposals to amend the RO regulations.

Challenges

- 26** ROs would require some time to implement changes to their governance processes including updating local policies and appraisal processes.
- 27** ROs and doctors may perceive the addition of an I&I statement as a further regulatory burden linked to revalidation.

Option 4 – the absence of indemnity or insurance would trigger a referral to Fitness to practise Directorate for investigation

- 28** We could revise the trigger points between our fitness to practise and registration processes to ensure that instances of failure to have appropriate I&I would automatically be referred for further investigation under ftp processes.

- 29** When we are made aware that a doctor has failed to obtain or maintain adequate I&I cover, our licensing and registration powers are limited. We can only take action in relation to a doctor's licence to practise (rather than registration) and this action is prospective in that the assessment is whether a doctor has adequate and appropriate cover to *continue* to practise.
- 30** Currently there is also little that we would do from an ftp perspective in these circumstances unless the doctor has lied about their cover or there has been a related clinical misconduct issue. The simple absence of I&I cover is currently not sufficient to trigger a fitness to practise investigation.

Benefits

- 31** Including the absence of I&I in the ftp thresholds for investigation would strengthen our messaging and available options in responding to I&I concerns.
- 32** FPD has the capability to investigate retrospective concerns and assess whether the doctor was in breach of their duties set out in Good Medical Practice.

Challenges

- 33** Internal legal advice suggests that it would be challenging to show that a failure to have I&I amounts to serious professional misconduct, according to the definition developed through case law* – namely conduct that involves some act or omission, falling short of what would be proper in the circumstances, which is linked to the profession of medicine, though not necessarily occurring in the carrying out of medical practice, and is serious. Or conduct which is removed from the practice of medicine but is of a sufficiently immoral or outrageous or disgraceful character to amount to misconduct. However, it is worth noting that if a doctor completed an I&I declaration as part of appraisal (if we introduce this) and it transpired that they did not have adequate I&I in place at that time, the completed declaration would be primary evidence we could rely on as part of a ftp investigation.
- 34** Additionally, while an ftp allegation will consider retrospective concerns, the focus is on current impairment of fitness to practise. Legal advice suggests that it would be difficult to show that a previous failure to have I&I in place for a period of time would give rise to *current* impairment, particularly in the absence of any other concerns (or repetition of the behaviour). If the period of failure to have I&I is remedied and there are no further instances, then this issue is unlikely to meet the realistic prospect test

* See for example, *Calhaem v GMC* [2007] EWHC 2606 (Admin) and *Roylance v GMC (No.2)* [2000] 1 AC 311

in terms of it leading to a finding that the doctor's fitness to practise is currently impaired.

- 35** While the threshold may be met to *open* an investigation, in many cases this may not ultimately result in action on the doctor's registration. Referral to a hearing in these instances may not be the most efficient use of our resources. However, it would remain open to us in these cases to issue a warning in this scenario which would publicly reinforce the importance of having appropriate I&I cover in place.
- 36** There is also a risk that this approach could be challenged, for example by way of judicial review of a decision to open an ftp investigation against a doctor for the absence of I&I, where there are no factors to indicate 'further' misconduct, such as dishonesty, or trying to obstruct the patient's access to compensation (etc.). Although an absence of I&I is a breach of GMP, we would need to have a clear rationale, supported by objective evidence of concerns in this area to justify a change in approach, and to show that the approach is a proportionate means of achieving a legitimate aim.

Option 5– requesting confirmation or evidence of insurance or indemnity – sample basis

- 37** We could develop a process for auditing the I&I arrangements of licensed doctors on a sample basis. We could request evidence of I&I arrangements from a selected sample (either random or risk based to prioritise certain groups, areas of practice or types of cover) which we would then review to assess if the cover was adequate and appropriate.

Benefits

- 38** This would provide assurance about the arrangements of some registered and licensed doctors.
- 39** This approach may encourage doctors to check their cover more rigorously if they thought we would be reviewing their arrangements on an audit basis.

Challenges

- 40** Internal legal advice indicates that we would need to be clear on what legal powers we would rely on to obtain this information, and how it links to our statutory function. We could use our powers under regulation 4A of the 2012 Licence to practise regulations to obtain this information. However, to date we have developed policy that we will only request this where we have concerns about absence or adequacy of an individual doctor's I&I arrangement. If we were to interpret this power as allowing us to request on a general rather than specific basis, through a sampled audit, this

would be a departure from our traditional policy approach. We would need to have a clear rationale and support this with objective evidence if we are challenged on this.

- 41** An audit approach would require a significant investment of resources to develop a process that would enable us to routinely review and make decisions on the adequacy of I&I cover given that:
- a** We don't have policy on what we consider to be 'adequate' in terms of I&I.
 - b** We would need the doctor to provide a detailed declaration of their full scope of practice to enable us to assess adequacy, and also find a way of verifying that declaration, for any assessment to be meaningful.
 - c** Notwithstanding the point above, we don't currently have expertise in-house to undertake an assessment of the adequacy of a doctor's arrangements. We would need to either recruit a new team to undertake this work, or consider commissioning an external organisation (such as an MDO) to complete the work on our behalf.
- 42** Additionally, depending on the sampling approach, there would be a number of equality and fairness issues and impacts that would need to be considered.

Option 6 – requesting confirmation or evidence of insurance or indemnity – annual return or revalidation cycle

- 43** We could develop a routine return (annual or each revalidation cycle) requiring doctors to update a range of information (for example, scope of practice, EDI data or I&I) through their GMC online account. This could include a declaration from the doctor that they have reviewed their I&I arrangements to ensure that it remains adequate and appropriate across their scope of practice.
- 44** This approach could be further strengthened if we could secure legislative reform to require doctors to hold a GMC online account and to keep it up to date. This would be similar to existing requirements in the Medical Act for a doctor to maintain an up to date registered address with us.

Benefits

- 45** Developing a separate declaration would reinforce the responsibilities on doctors to have adequate and appropriate I&I. If concerns came to light that a doctor had lied or misled about their cover, a routine signed declaration would provide more evidence to support any decisions about a fitness to practice investigation.

- 46** This approach would provide the most comprehensive assurance about the I&I of the widest range of doctors and may encourage doctors to check more rigorously if they thought we would be reviewing their arrangements on a regular basis.
- 47** This approach could support a range of projects underway or planned within the GMC including gathering or expanding our data in relation to equality and diversity and work on scope of practise.

Challenges

- 48** While doctors pay an annual retention fee, we do not require a doctor to complete an annual return for any purpose. Developing a routine return would be a complex, cross directorate project for the GMC which would require significant investment of resources. We would need to analyse the costs/benefits/value/burden of pursuing this option.
- 49** The regulations give us a power to request information about a doctor's I&I arrangements – however our policy position is that we will only do so if we have concerns that the doctor does not have adequate and appropriate arrangements in place.
- 50** If a doctor provides us with a declaration about their I&I arrangements it will only be valid at that point in time they make the declaration (given that a policy can be cancelled at any time). This limits the reliance we could place on a regular return as being an accurate reflection of a doctor's I&I status.
- 51** Finally, any statement would only provide limited assurance given that it is a self-declaration and we would be making no assessment of adequacy.

Equality and diversity

- 52** The I&I requirements and the duty set out in GMP applies to all registered and licensed doctors. The application of the requirement does not have a negative impact on particular cohorts of doctors. However, if we adopt an approach of requesting information from doctors based on specialty, type of work or type of I&I arrangement (even if this is based on objective criteria) we would need to consider whether those cohorts share a protected characteristic and if so what we could do to mitigate the impact.
- 53** Pending the Executive Board's view on the options set out in the paper, we will undertake further work to develop the options. An equality analysis will be part of that work.

4 – Reviewing our approach to insurance and indemnity

4 – Annex A

Background and history

- 1** The Department of Health England (DH(E)) commissioned an independent Review Group in 2009 to look at insurance and indemnity (I&I) for healthcare professionals. It reported in 2010 and recommended making I&I a statutory condition for access to the healthcare professions. The report also recommended that, while legislation should be harmonised across the healthcare regulators, it should be for each regulator to decide how to exercise its powers.
- 2** In February 2013, DH(E) published a UK wide consultation paper 'Health Care and Associated Professions (Indemnity Arrangements) Order 2013', accompanied by a draft Order, which set out the Government's plans to amend existing legislation and introduce new legislation to implement the Review Group's recommendations.
- 3** DH(E)'s proposals also implemented Article 4(2)(d) of the European Union Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. The Directive requires Member States to have systems of professional liability insurance or similar arrangements in place in relation to provision of cross-border health care.

Doctors' current legal and professional obligations regarding insurance and indemnity

- 4** Doctors have both a statutory duty in respect of having in place appropriate insurance or indemnity and a professional duty under GMP (paragraph 63). The legal duty is found in section 44C of the Medical Act 1983:

(1) A person who holds a licence to practise as a medical practitioner, and practises as such, must have in force in relation to him an indemnity arrangement which provides appropriate cover for practising as such

(2) For the purposes of this section, an "indemnity arrangement" may comprise-

(a) a policy of insurance;

(b) an arrangement for the purposes of indemnifying a person;

(c) a combination of the two.

(3) For the purposes of this section, "appropriate cover", in relation to practice as a medical practitioner, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.

- 5** Section 44C(4) also provides us with the power to make regulations as to the information to be provided to the Registrar in respect of a person seeking a licence to practise ('LTP') as to whether they have in force (or will have in force) an indemnity arrangement which provides appropriate cover. The GMC (Licence to Practise and Revalidation) Regulations in passed in August 2015 inserted into the 2012 LTP regulations explicit powers for us to check that a doctor practising in the UK has appropriate insurance or indemnity in place.
- 6** In terms of a failure to hold insurance or indemnity, our powers are provided for at section 44C:

(9) Where a person who holds a licence to practise is in breach of subsection (1) or there is a failure to comply with regulations made under subsection (4)(b) in relation to him—

(a) a licensing authority may withdraw that person's licence to practise;
or

(b) the breach or failure may be treated as misconduct for the purposes of section 35C(2)(a), and the Registrar may accordingly refer the matter to the Investigation Committee under section 35C(4).

GMC approach to insurance and indemnity for doctors

- 7** As currently drafted section 44C permits us to treat a failure to have appropriate cover when practising as a doctor either as a purely licensing issue or as an FTP issue. What we have sought to do therefore is draft policy to establish parameters on when the issue will be considered under each regime. Generally, an 'innocent' failure to have I&I in place will be dealt with primarily as a licensing issue and a more serious allegation that a patient was lied to about the doctor's I&I status is more likely to lead to FTP action.

Fitness to practise

- 8** Policy colleagues in FTP drafted guidance, [Insurance and Indemnity guidance for decision makers](#). This identifies when a failure to have insurance or indemnity in place may raise a fitness to practise concern. This sets out:

- a** A failure to maintain adequate insurance or indemnity cover may in a limited set of circumstances raise concerns about a doctor's fitness to practise. This will be because it falls within one of the categories of impairment in the Medical Act. In most cases this will be because it amounts to misconduct as a result of the doctor being dishonest or misleading about their insurance or indemnity cover. This may be because:
- i** A patient has been awarded compensation for negligence for which the doctor's insurance or indemnity cover has been found to be inadequate, as this demonstrates that the doctor's failure to maintain adequate insurance or indemnity cover has placed patients at risk, or
 - ii** In the course of investigating allegations of clinical misconduct, evidence emerges that the doctor treated the patient in circumstances where they knew or should have known that they did not have adequate insurance or indemnity cover in place, or
 - iii** The doctor has lied about insurance or indemnity cover being in place, as this undermines the public's trust in the profession.
- 9** In addition to this legal duty, doctors also have a professional duty to have adequate insurance or indemnity arrangements in place. This has been in existence for some time. Paragraph 63 of Good Medical Practice states that, *You must make sure you have adequate insurance or indemnity cover so that your patients will not be disadvantaged if they make a claim about the clinical care you have provided in the UK.*

Registration

- 10** Following the introduction of the statutory requirement to have appropriate I&I in 2015, we developed a regulatory approach that was proportionate and not overly burdensome for doctors while still protecting patients (this was supported by DH(E)).
- On applying for registration doctors declare 'I have in place, or will have in place, at the point at which I practise in the UK, insurance or indemnity arrangements appropriate to the areas of my practice'.
 - We decided that we would not keep a record of a doctor's I&I status.
 - We decided that we would not require doctors to provide evidence of their arrangements either at the point of registration or on an annual basis.
 - The wording of the declaration addresses situations where doctors apply for registration but do not immediately start work in the UK. These doctors would not have arranged or have evidence of insurance at the point of registration.

- 11** We have a power to check a doctor's I&I arrangements, we do not ask for details about their arrangements routinely. We will investigate when we become aware of a concern about the doctor's arrangements or planned arrangements.
- 12** We can refuse to grant or remove a doctor's licence to practise if they do not have – or will not have – appropriate cover.

What we know about doctors' insurance or indemnity arrangements

- 13** Full liability indemnity is in place across secondary care in the NHS through the Clinical Negligence Scheme for Trusts (CNST). A comparable, Clinical Negligence Scheme for GPs (CNSGP) in England and General Practice Medical Indemnity (GPMI) in Wales was introduced for primary care on 1 April 2019.
- 14** Using prescribed connections as a proxy indicator of employment, around 85% of doctors have indemnity cover provided through these state backed schemes.
- 15** In response to the introduction of CNSGP in England and GPMI in Wales, the Medical Defence Organisations have changed their offer to GPs with two new products, one to cover professional liabilities and the other to cover private practise and other non-NHS activities. The cost of indemnity cover for most GPs in England has decreased by 80-90%.
- 16** Doctors who undertake private or independent practice must arrange their own indemnity or insurance. The majority obtain cover through the three main medical defence organisations but a small proportion purchase insurance products.

The impact of external work on insurance and indemnity

- 17** On 1 April 2019 the CNSGP and GPMI came into effect. It provides indemnity for GPs, trainee GPs and locum GPs working in England and Wales under a medical services contract. The scheme will be administered by NHS Resolution in England and NHS Wales Shared Services Partnership in Wales.
- 18** We are members of the DHSC Indemnity Standing Group that supports the implementation of the CNSGP scheme in England.
- 19** In preparation for the introduction of the CNSGP, GPMI and Brexit, we have reviewed our existing I&I guidance for doctors. The messaging in the guidance has been updated and strengthened:
 - a** to reinforce that it is both a statutory requirement and professional obligation for doctors to obtain adequate I&I

- b** to highlight that state backed indemnity will not provide doctors support in the event they are involved in an inquest, disciplinary process or GMC investigation
 - c** to advise doctors to review their I&I arrangements to ensure they are covered for an historical liabilities that may arise before they join any state backed scheme (i.e. run off cover)
 - d** to advise EEA doctors with EU wide cover to check that it will cover any practise in the UK to an adequate and appropriate level
 - e** to provide information for GPs in England and Wales about the introduction of the state backed indemnity scheme including a link to the new NHS Resolution and NWSSP webpages and associated communications materials.
- 20** We will also be writing to all GPs in England and Wales to this month to note the introduction of the state backed schemes and reinforce our key messages and expectations of doctors in relation to I&I.
- 21** In December 2018 the government published a [consultation](#) on their proposals to ensure that all healthcare professionals in the UK hold appropriate clinical negligence cover. The consultation sought views on two options:
- a** Option 1: Leave arrangements as they are (do nothing).
 - b** Option 2 (Government preference): Change legislation to ensure that all regulated healthcare professionals in the UK not covered by a state-backed indemnity scheme hold appropriate clinical negligence cover that is subject to appropriate supervision, in the case of UK insurers, by the Financial Conduct Authority (FCA) and Prudential Regulation Authority (PRA).
- 22** We submitted a [response to the consultation](#) which is summarised below:
- a** In principle we would support changing the legislation to require doctors to hold an insurance product providing appropriate clinical negligence cover (option 2).
 - b** We would advise that a significant period of notice and transition period is provided to enable those impacted to understand the requirements and make the necessary arrangements.
 - c** Additionally, should the government introduce option two; we would want to ensure that the current insurance offerings provide sufficient assurance to healthcare professionals and ultimately, compensation to affected patients.

Data about referrals

Registration

23 Between August 2015 (when we introduced the statutory requirement) and February 2019, we received 41 referrals to the R&R operational team to check the absence or adequacy of a doctor's arrangements.

- a** 14 of these referrals related to GPs and were about the adequacy of their arrangements.
- b** Overall, we've withdrawn 1 doctor's licence following an investigation.
- c** There has been one instance where (following an investigation) an Assistant Registrar made a decision to withdraw a doctor's licence for reasons relating to insurance/indemnity. However this doctor subsequently arranged adequate cover and sent us confirmation of this, so we took no further action.

24 Most enquiries are closed after further investigation because either:

- a** we are satisfied that the doctor's policy covers the full scope of their practice and provides sufficient cover for their work (we make that decision based on information and discussions with our Employer Liaison Service and NHS(E) about average claims for the areas of medicine in question) or
- b** the doctor subsequently arranges insurance or indemnity which covers the full scope of their practice or
- c** the doctor has erased their registration or relinquished their licence to practise or ceased to undertake the work in question.

Fitness to practise

25 Between August 2015 and February 2019 there were 51 cases investigated by FPD with an allegation that a doctor has absent or inadequate insurance or indemnity. A breakdown of case outcomes is set out in the table below.

Case outcome	No of cases
No further action	18
Advice	4
Sanctions applied without a hearing	3
Warning	
Undertaking	1
Sanctions applied at hearing	
Suspension	4
Erasure	1
In progress	19
Voluntary erasure	1