Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill

BMA Scotland

Introduction

The British Medical Association (BMA) is a registered trade union and professional association representing doctors from all branches of medicine. The BMA has a total membership of around 150,000 representing around two-thirds of all practising doctors in the UK. In Scotland, the BMA represents around 16,000 members.

We welcome the opportunity to submit written evidence to the Health and Sport Committee’s scrutiny of the Health (Tobacco, Nicotine etc and Care) (Scotland) Bill.

Part 1 – Tobacco, nicotine vapour products and smoking

The BMA supports the bill’s approach to nicotine vapour products.

It is widely recognised that the health risks associated with electronic cigarette use are likely to be significantly lower than the well-established risks associated with smoking tobacco. The BMA therefore recognises e-cigarettes’ potential for supporting tobacco harm reduction. There is, however, a lack of robust research and evidence in this area and the public health benefit is not yet established. This highlights the importance of a strong regulatory framework for e-cigarettes to ensure that:

- All products on the market are effective in helping smokers cut down, with the aim being to quit.
- Their marketing and promotion does not appeal to children/young people and non-smokers, or make any claims of effectiveness as a smoking cessation aid unless approved for that purpose by the UK Medicines and Healthcare Products Regulatory Agency (MHRA).
- Their use does not undermine smoking cessation and prevention or reinforce tobacco smoking behaviours.

Sale and purchase of nicotine vapour products

The BMA supports an age restriction for the purchase of e-cigarettes and their refills and agrees that they shouldn’t be sold to anyone under the age of 18 years, in line with current tobacco regulation. We also support making ‘proxy purchase’ of nicotine vapour products an offence and welcome the enabling power to extend vending machine prohibition to include nicotine vapour products.

Doctors have expressed significant concern over the proliferation, promotion and increasing availability of nicotine vapour products in the form of e-cigarettes. We are concerned that these products are likely to appeal to children and young people, and have the potential to increase the risk of them using tobacco. It is estimated that the number of 11-18 year olds in Great Britain who have ‘ever’ tried e-cigarettes increased from five per cent in 2013 to eight per cent in 2014, though ‘regular’ use of e-cigarettes among children
has remained low.\(^1\) Data from Wales demonstrate an association between e-cigarette use and weaker anti-smoking intentions among 10-11 year olds.\(^2\)

There is also evidence internationally suggesting that e-cigarettes may act as a gateway to smoking. Experiences in other countries (such as Italy, Korea and the US – where e-cigarette use has rapidly increased over a similar time period as in the UK) highlight the need to closely monitor use among children and young people. \(^3\)\(^4\)\(^5\) Research based on the US national youth tobacco survey indicates that ‘ever’ e-cigarette use doubled among high school students between 2011 (3.3%) and 2012 (6.8%).\(^6\)\(^7\) Twenty per cent of US middle school students, and seven per cent of high school students who had ever used e-cigarettes were found to have never tried a tobacco cigarette, amounting to an estimated 160,000 young people.\(^8\) Various evaluations of the US national youth tobacco survey have suggested that adolescents using e-cigarettes are more likely to intend to use conventional cigarettes, more likely to be current or heavy smokers, and less likely to quit or attempt to quit smoking.\(^9\)\(^10\)\(^11\)

While we have concerns around the potential for e-cigarettes being portals to tobacco use and addiction, there have also been concerns raised by BMA members of the risks associated with inhaling the components of e-cigarette vapours. The components include nicotine, as well as a range of other chemicals. While the BMA supports the use of licensed nicotine replacement treatment as a smoking cessation aid, it should be recognised that the consumption of nicotine is not entirely risk-free.

\(^1\) Action on Smoking and Health (2014) Fact sheet. Use of electronic cigarettes in Great Britain. London: Action on Smoking and Health
\(^6\) Centres for Disease Control and Prevention weekly report (06.09.14) Notes from the field: electronic cigarette use among middle and high school students – United States 2011-12
\(^8\) Centres for Disease Control and Prevention weekly report (06.09.14) Notes from the field: electronic cigarette use among middle and high school students – United States 2011-12
\(^9\) ibid
Inclusion of electronic cigarettes on the Scottish Tobacco Retailer Register

The BMA agrees that e-cigarettes and their refills should be an age restricted product and therefore supports the need to extend the Scottish Tobacco Retailer Register to include these items, allowing for guidance and advice to be directed at those trading in these items to avoid illegal sales, and for easier enforcement of the law.

Advertising and promotion of e-cigarettes

Concerns have been expressed by BMA members over the e-cigarette marketing methods used across a range of advertising media and locations that are likely to appeal to children, young people and non-smokers. These include point-of-sale displays; advertising via television, radio, in print media and online; on billboards near schools; at university freshers’ fairs; and the marketing of flavoured e-cigarettes. The BMA is also concerned that e-cigarette marketing may have an adverse impact, reinforcing conventional cigarette smoking habits, as well as indirectly promoting tobacco smoking and increasing the likelihood of young people starting to smoke.

Analysis of the growing market for e-cigarettes suggests that marketing targets two distinct audiences: current smokers who want to quit, and children/young people and non-smokers. For children/young people and non-smokers, e-cigarettes are positioned as socially attractive appealing and popular, using flavouring, promotional discounts, sports sponsorship and celebrity endorsement to attract new customers. A review by the US Senate in 2014 concluded that e-cigarette companies are employing the same marketing tactics that the tobacco industry first pioneered to attract young customers to their products: sponsored sports and music events; free samples; television advertising during youth programming; sports events or daytime television; celebrity spokespeople and endorsement; social media presence; and product flavouring. The review noted the rapid increase in marketing spending by e-cigarette companies in the US, and the lack of regulation of sales to children under 18 years of age.

12 English PM (2013) Re: EU policy on e-cigarette is a “dogs dinner” says UK regulator (rapid response). BMJ 347: f6821
14 National Institute for Health Care Excellence (2013) Tobacco: harm reduction approach to smoking Manchester, NICE
16 Ibid
For smokers, e-cigarettes are marketed as healthier, safer, cheaper and a way for smokers to cut down or stop smoking.\textsuperscript{21, 22} In the UK media, e-cigarettes are frequently portrayed as a healthier and cheaper alternative to tobacco cigarettes, and encouraged use to circumvent smoke free laws.\textsuperscript{23} The UK Advertising Standards Authority (ASA) has previously ruled that certain e-cigarette advertisements were considered misleading and made unsubstantiated claims relating to health.\textsuperscript{24}

**Part 2 – Duty of Candour**

BMA Scotland believes that just as all NHS staff must be honest and transparent in everything that they do in order to best serve and protect their patients, the organisations that they work in should equally always be open and honest with patients about their care.

We have significant concerns, however, around the potential administrative burden and additional costs on NHS bodies of introducing the additional responsibilities for a Duty of Candour, as set out in this bill, at a time of increasing pressure on the NHS. Any additional workload would need to be fully resourced, particularly training and ongoing support for NHS staff, and any new procedures implemented in such a way as to avoid introducing unnecessary bureaucracy that might divert scarce resources away from frontline patient care.

Particular consideration should be given to the impact of this proposed duty on individual GP practices where the additional workload and requirements set out in a statutory duty of candour would have a disproportionate effect on individual practices and could create significant levels of unfunded work which would divert GPs and their staff away from their core clinical activities.

We would welcome the opportunity to consider a comprehensive analysis of the expected impact of the introduction of this new duty in terms of administrative, resource and time burden against the expected gain for patients, over and above the existing provisions already in place to protect both patients and healthcare professionals.

**Duty of candour procedure**

Any incident/near miss which occurs should be seen as an opportunity for improvement and learning and this should be set out as a fundamental objective of the process. Supporting guidance should demonstrate how this can be achieved.

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\textsuperscript{24} www.asa.org.uk/Ruling/Adjudications/2013/Nicocigs-Ltd/SHP_ADJ_219974.aspx (last accessed October 2014)
Existing provision

Within the medical profession, doctors are expected to be open and honest with patients when things go wrong. Doctors are strictly regulated under the Medical Act 1983 by the General Medical Council which is an independent, accountable regulator and has a duty to ensure proper standards in the practice of medicine. The GMC’s Good Medical Practice Guidance clearly sets out the principles and values on which good practice is founded and these principles together describe medical professionalism in action. The guidance is addressed to doctors, but it is also intended to let the public know what they can expect from doctors. If doctors do not adhere to the principles outlined in Good Medical Practice, their registration can be called into question.

The GMC and NMC (Nursing Midwifery Council) have also just published guidance on duty of candour for health professionals.

Apologies

We support the role of a meaningful apology which can help repair a damaged relationship and restore dignity and trust, but thought needs to be given to how to handle this appropriately where there is a dispute over where fault lies. When things go wrong, doctors apologise at the earliest opportunity as this is a key professional duty. Research shows that most poor outcomes are due to system rather than individual failures. Apologies should be couched in those terms if this is to be a process that is truthful and appropriate.

BMA Scotland requires clarity on how this legislation would work in practise with GMC standards and their investigative and adjudicatory processes. There is a real risk, irrespective of the status of such an apology in Scottish law, that the GMC as a UK-wide regulatory body, might consider one as an admission of fault or evidence of poor performance in the course of their pursuance of individual cases. Professional regulation is a reserved matter and as such, the Scottish Government has no direct authority over the GMC. Therefore it is unclear at this stage how this legislation could prevent such an apology made by a doctor being inadmissible or immune to investigation in the professional regulatory situation.

The BMA has recently provided evidence to the Justice Committee for its Stage 1 deliberation of the Apologies (Scotland) Bill. A copy is attached as Annex A to this submission.

Reporting and monitoring

IT resources would need to be in place to support reporting of instances across health (primary and secondary) and social care, with an emphasis on confidentiality. Instances of harm may cross health and social care boundaries and therefore funding and capacity would need to be available to

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allow everyone involved in individual cases to attend reviews. It would also require the establishment of an integrated centralised reporting system which is also accessible by those working in primary care. Reporting needs to be made as simple as possible, to encourage staff to report all events including ‘avoided events’. A reporting system that is straightforward to use will ensure that sufficient information is fed in to allow monitoring of weaknesses, “one off” incidents and emerging patterns.

As noted above, there should be appropriate communication with all service providers involved to ensure they are informed and supported throughout the process. At present our members tell us that sometimes those who report an adverse event can feel unsupported and there are concerns that there is no follow-up or communication afterwards to explain what has been done to prevent similar problems from recurring. The current system should be improved so that staff feel their opinions and input are valued and where appropriate, acted upon, which would encourage them to engage in a system intended to improve the care of patients.

In general practice, appropriate resourcing for staff training and implementation would need to be identified and agreed prior to the introduction of a statutory organisational duty of candour.

The need for legislation

A duty of candour may be a mechanism to ensure that organisations are clear about their obligations to report incidents and have effective arrangements in place to do so. However, legislation to make this a statutory duty is not necessarily the most effective means to create and develop a transparent and open culture, especially since there would be no sanctions (either criminal or civil) for non-compliance. There needs to be an overarching culture of quality, a focus on patient safety which is underpinned by a shared set of values. It is vital that doctors and all workers feel they can speak up for patient safety without risking hostility from colleagues, management or the media. There have been high-profile cases where doctors have been ignored or even punished by their employers after raising safety issues. In order to address an underlying culture that may discourage people from speaking up, employers should have a duty to listen to staff when they do report concerns, and to protect them if necessary. Staff should be encouraged and recognised for following their professional guidelines, but more training may be necessary to help people communicate more effectively when, for example, treatment has not gone as well as expected or an error has occurred in the process of their care. More effective policies addressing bullying are also necessary.

Part 3 – Ill treatment and wilful neglect

While the BMA supports the broad principles of person-centred care and safe care which lie behind the proposals set out in this part of the bill, we have some serious concerns about the rationale for the specific proposals, the hurdles to implementation, and the balance of benefit against the costs and unintended consequences/risks.
We are not aware of any evidence that the wide range of existing criminal, civil and professional sanctions have proved to be inadequate to deal with serious failings in health care delivery in Scotland.

There is a lack of clarity about what the expected benefit of the legislation would be – in particular, the problem it would directly resolve and the potential unintended consequences it might introduce. There is no clear definition of what counts as “ill treatment” or “wilful neglect” in the bill and without firm definitions there could be inconsistencies in the way this part of the bill is allied to individual cases.

**Offences by care workers and care providers**

The BMA would welcome assurances that a criminal conviction would not be imposed on someone accused of wilful neglect because of issues outwith their control. For example, where a unit is so understaffed that an individual is unable to provide adequate cover. There would need to be very clear guidelines in place outlining the circumstances in which prosecution would follow. Appropriate safeguards would also need to be in place to protect effective clinical management and decisions about the best use of resources in the interests of all patients.

The development of a culture where open and transparent reporting is the norm requires employers to establish clear, no-blame incident reporting systems from which to learn and improve. The threat or over-use of criminal prosecution seems likely to deter the development of such a culture, and to deter information sharing at the “near miss” level. Again, clear guidelines defining the grounds for prosecution would need to be set out to ensure that medical professionals were not deterred from reporting cases of neglect.

**Existing processes**

Introducing this offence could create conflict with existing regulatory processes. There is a risk that potential criminal activities could be investigated before the actions of professional regulators such as the GMC. Regulatory actions for doctors provide greater protection for the public in that they are taken under the balance of probabilities standard of proof whereas in the criminal context, the court will have to prove *beyond reasonable doubt* that all the elements of the offence of wilful negligence are present. This is a much higher standard of proof, and a finding of impaired fitness to practise that results in erasure from the register will effectively end that healthcare professional’s career.

**Need for legislation**

One difficulty in supporting this part of the bill is the implication that there is a widespread problem of ill-treatment and wilful neglect in Scotland which requires greater legal protection. From a medical perspective, this is not the case. Doctors can already be subject to multiple investigations relating to a single incident, and adding a criminal offence would not provide any additional protection for patients. We would like to see a cost/benefit analysis for each sector of the formal health and adult social care workforce, alongside an
assessment of the relationship any such new process would have to the existing regulatory frameworks already in place for each profession/sector of the private and public formal workforce.

We are concerned about the impact this new offence will have on the clinical decision making of doctors in particular. We rely on doctors to make treatment decisions for individuals based not only on their individual and specific symptoms, but on a more holistic assessment of their needs, the potential quality of life improvements which would result from treatment, and on the much wider assessment of whole population prioritisation. Any mechanism which incentivises doctors to err on the side of caution to protect themselves by over-prescribing or over-treating will not be in the best interest of the patient, wider population or in the quest to achieve a sustainable healthcare system for the future within a finite resource. Similarly fears over criminal proceedings could make health professionals less willing to give evidence to their regulatory bodies. Concerns over court action could stand in the way of regulatory bodies ensuring that lessons are learned from incidents.

*Duty of candour alongside ill-treatment and wilful neglect*

We are concerned that the new offence of wilful neglect and ill-treatment may contradict the duty of candour provisions in the bill. If a reportable patient safety incident occurs then health professionals need to be confident they can offer an apology without fear of criminal proceedings.

*BMA Scotland*
ANNEX A

Apologies (Scotland) Bill: Stage 1

BMA Scotland written submission to the Scottish Parliament Justice Committee

May 2015

Introduction

1. In the NHS, a poor response to a complaint can be frustrating for patients and their relatives. Many people raising a complaint want to receive a fair hearing and to receive an apology at the very least, and in many cases to be reassured that lessons have been learned by the individual or organisation. Indeed, in many cases, if there had been an early apology, the person/people affected would not have felt the need to make a formal complaint. The provision in this Bill to provide legal protection from litigation to those who give the apology will no doubt be reassuring to staff working in the NHS. However, as detailed in our response below, we would encourage the Committee to consider how this legislation would work in practise in relation to professional regulatory bodies, such as the General Medical Council.

2. As well as providing for the removal of the possibility of an apology being used as evidence of liability, the Bill also seeks to change the culture of public sector organisations by making it easier for people to make apologies without fearing ‘blame’. The BMA has actively supported the introduction of a no fault compensation scheme, which from a similar perspective, seeks to move away from the blame culture that pervades the NHS, as well as providing a more streamlined and effective means for patients and their relatives to seek compensation when things go wrong.

3. NHS Scotland provides a single route for making a complaint against any NHS service. The complaints process is intended to provide an investigation, explanation, and where appropriate, an apology. The NHS has taken great strides to improve the NHS complaints process for patients (and relatives). Efforts have also been made to improve communication and transparency and clinical governance structures are in place to assure that apologies are dealt with appropriately.

4. The Patient Rights Act (2011) modernised the NHS complaints process to provide independent support for patients wishing to take a complaint forward and ensure that organisations learn from their mistakes.

5. The NHS has also introduced measures which it claims will improve the culture within the NHS to support and encourage staff to speak out when things go wrong. PIN guidelines, an anonymous whistleblowing phone line where staff can raise concerns, and existing professional regulatory standards have all tried to end the culture where staff feel that they are unable to speak up without consequences for their career
or reputation. Only recently, the Scottish Government has announced its intention to legislate for a statutory Duty of Candour in the NHS and it would be interesting for the Committee to consider how this duty of candour might work alongside this piece of proposed legislation if both were to be introduced.

6. The BMA would also ask the Committee to consider whether this legislation on its own would drive cultural change or whether our experience within the NHS (and the wider public sector) is a clear indication that there are other, more significant factors that may help to build a more positive culture for staff.

Below please find the BMA’s responses to the questions set out in the Committee’s call for evidence:

Is there merit in providing legal protection to an expression of apology as set out in the Bill?

7. Yes, the BMA believes that there is potential merit in creating a situation where individuals feel that they are able to speak up to express regret or apologise where something has gone wrong without fearing legal recourse.

Do you agree with the legal proceedings covered under section 2 of the Bill, and the exceptions for fatal accident inquiries and defamation proceedings?

8. N/A

Do you agree with the definition of apology in section 3 of the Bill?

9. N/A

Do you agree that the Bill will facilitate wider cultural and social change as far as perceptions of apologies are concerned, as suggested in the Policy Memorandum on the Bill?

10. As set out in the introduction to this response, the NHS has attempted several times to improve the way that individuals and organisations deal with situations where something has gone wrong. Changes to the NHS complaints process, the introduction of PIN guidelines about raising concerns and other schemes to support staff to speak up when things go wrong have all been introduced in recent years. However despite all this, there remains a culture where many staff are unwilling to admit to mistakes or acknowledge when things go wrong, not just for fear of litigation, but also in fear of their jobs and their position within their team.

11. Within the medical profession, doctors are already expected to be open and honest with patients when things go wrong. The General Medical Council’s Good Medical Practice Guidance states:
12. “30. If a patient under your care has suffered harm or distress, you must act immediately to put matters right, if that is possible. You should offer an apology and explain fully and promptly to the patient what has happened, and the likely short-term and long-term effects.

13. “31. Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an explanation and, if appropriate, an apology. You must not allow a patient’s complaint to affect adversely the care or treatment you provide or arrange.”

14. Although this guidance is not statutory, Good Medical Practice clearly sets out the principles and values on which good practice is founded and these principles together describe medical professionalism in action. The guidance is addressed to doctors, but it is also intended to let the public know what they can expect from doctors. If doctors do not adhere to the principles outlined in Good Medical Practice, their registration can be called into question.

15. The BMA agrees that removing the threat of litigation could encourage more and better communication between doctor and patient in explaining the nature and cause of any mishap to the patient concerned, encouraging accountability by the doctor to his/her patient in line with professional guidelines.

16. However, BMA Scotland requires clarity on how this legislation would work in practise with GMC standards and their investigative and adjudicatory processes. There is a real risk, irrespective of the status of such an apology in Scottish law, that the GMC might consider one as an admission of fault or evidence of poor performance in the course of their pursuance of individual cases. Professional regulation is a reserved matter and as such, the Scottish Government has no direct authority over the GMC. Therefore it is unclear at this stage how this legislation could prevent such an apology made by a doctor being inadmissible or immune to investigation in the professional regulatory situation.

17. GMC investigative processes are often a very stressful experience for doctors and not infrequently take many months or longer to conclude. There is a real risk that a well-intentioned Bill could be to the significant detriment of some doctors who have no performance related problems, and also raises the possibility that fear of investigation may discourage doctors from making an otherwise sensible and desired apology.

18. Detailed discussion with the GMC is, in our view, absolutely necessary in this regard. The BMA would therefore caveat any general welcome of this Bill with caution based on the above concerns.

19. It is also not clear where this legislation would fit alongside the Scottish Government’s proposals for a Duty of Candour and we would
encourage the Committee to consider this as they approach this member's Bill.

Are there any lessons that can be learned from how apologies legislation works in practice in other legislatures?

20. N/A