The Scottish Parliament
Pàrlamaid na h-Alba

HEALTH AND SPORT COMMITTEE

AGENDA

24th Meeting, 2015 (Session 4)

Tuesday 15 September 2015

The Committee will meet at 9.15 am in the James Clerk Maxwell Room (CR4).

1. **Palliative Care:** The Committee will take evidence on 'International comparisons in palliative care provision: what can the indicators tell us?' from—

   Professor David Clark, Welcome Trust Investigator, School of Interdisciplinary Studies, University of Glasgow.

2. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill:** The Committee will take evidence on the Bill at Stage 1 from—

   Norman Provan, Associate Director, Royal College of Nursing Scotland;

   Dave Watson, Head of Bargaining and Campaigns, Unison;

   Councillor Peter Johnson, Health and Social Care Spokesperson, and Beth Hall, Policy Manager, Health and Social Care Team, COSLA;

   Brenda Knox, Health Improvement Lead, NHS Ayrshire and Arran;

   Donald Harley, Deputy Scottish Secretary, BMA Scotland.

3. **Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (in private):** The Committee will consider the main themes arising from the oral evidence heard earlier in the meeting.

4. **Carers (Scotland) Bill (in private):** The Committee will consider a draft Stage 1 report.

5. **Smoking Prohibition (Children in Motor Vehicles) (Scotland) Bill (in private):** The Committee will consider a draft Stage 1 report.

HS/S4/15/24/A

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The papers for this meeting are as follows—

Agenda Item 1

Link to Report will be available on 15 September	HS/S4/15/24/1

Agenda Item 2

Written Submissions	HS/S4/15/24/2
PRIVATE PAPER	HS/S4/15/24/3 (P)

Agenda Item 4

PRIVATE PAPER	HS/S4/15/24/4 (P)

Agenda Item 5

PRIVATE PAPER	HS/S4/15/24/5 (P)

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.

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[1] Action on Smoking and Health (2014) *Fact sheet. Use of electronic cigarettes in Great Britain.* London: Action on Smoking and Health

[2] Welsh Government Social Research (2014) *Exposure to second-hand smoke in cars and homes, and e-cigarette use among 10-11 year old children in Wales: CHETS Wales 2.* Cardiff: Welsh Government Social Research

[3] Gallus S, Lugo A, Pacifici R et al (2014) E-cigarette awareness, use, harm perception in Italy: a national representative survey. *Nicotine and Tobacco Research*

[4] Lee S, Grana R * Glantz SA (2014) Electronic cigarette use among Korean adolescents: a cross sectional study of market penetration, dual use and relationship to quit attempts and former smoking. *Journal of adolescent health* 54: 684-90

[5] Sutfin EL, McCoy TP, Morell HER et al (2013) Electronic cigarette use by college students. *Drug and Alcohol Dependency 131 (3): 214 – 221*

[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*

[7] Dutra LM & Glantz SA (2014) Electronic cigarettes and conventional cigarette use among US adolescents. A Cross –sectional study *JAMA Paediatrics* 168:610-7

[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

[10] Dutra LM & Glantz SA (2014) Electronic cigarettes and conventional cigarette use among US adolescents. A Cross –sectional study *JAMA Paediatrics* 168:610-7

[11] Bunnell R, Agaku IT, Arrazola R et al (2014) Intentions to smoke cigarettes among never-smoking US middle and high school electronic cigarette users, national youth tobacco survey, 2011-13 *Nicotine & Tobacco Research* (Epub ahead of print 20.08.14)

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.[12] 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.[13] [14] [15]

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.[16] [17] 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.[18] [19] 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.[20]

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[12] English PM (2013) Re: EU policy on e-cigarette is a "dogs dinner" says UK regulator (rapid response). BMJ 347: f6821

[13] Andrade M, Hastings G and Angus K (2013) Promotion of electronic cigarettes: tobacco marketing reinvented? *BMJ* 347:F7473

[14] National Institute for Health Care Excellence (2013) *Tobacco: harm reduction approach to smoking* Manchester, NICE

[15] Cancer Research UK (2013) *The marketing of electronic cigarettes in the UK.* London: Cancer Research UK

[16] ibid

[17] Cobb NK, Brookover J & Cobb CO (2013) Forensic analysis of online marketing for the electronic nicotine delivery systems. *Tobacco control* (Epub ahead of print 13.9.13)

[18] Grana R, Benowitz N, Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* 129: 1972-87

[19] Cancer Research UK (2013) *The marketing of electronic cigarettes in the UK.* London: Cancer Research UK

[20] US Senate report (14.4.14) *Gateway to addiction? A survey of popular electronic cigarette manufacturers and targeted marketing to youth.*

For smokers, e-cigarettes are marketed as healthier, safer, cheaper and a way for smokers to cut down or stop smoking.[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.[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.[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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[21] Grana R, Benowitz N, Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* 129: 1972-87

[22] Cancer Research UK (2013) *The marketing of electronic cigarettes in the UK.* London: Cancer Research UK

[23] Rooke C & Amos A (2013) News media representations of electronic cigarettes: an analysis of newspaper coverage in the UK and Scotland. *Tobacco Control* (Epub ahead of print 24.7.13)

[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.[25] 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

[25] Guidance to the GMC's Fitness to Practise Rules www.gmc-uk.org/DC4483_Guidance_to_the_FTP_Rules_28626691.pdf

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 doctor 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

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

NHS Ayrshire and Arran

NVP's and smoking in hospital grounds

1. Do you support the Bill's provisions in relation to NVP's?

   Yes. NVP's as an alternative nicotine product, may be less hazardous than smoking (research is ongoing into this) and provide health benefits for smokers who are not motivated, or cannot otherwise cease from smoking. NVP's as an alternative to smoking, may also have some potential over the long-term to address aspects of health inequalities, given the higher levels of smoking prevalence in more deprived communities. There remain significant concerns from a public health point of view in relation to NVP's. These centre in particular on the promotion of NVP's to non-smokers and children which voluntary codes tend to not be effective in addressing. These proposals address these issues through age restriction/ verification, outlawing proxy-purchase and restrictions on advertising.

2. Do you support the proposal to ban smoking in hospital grounds?

   Whilst we support legislation in relation to banning smoking in hospital grounds in their totality, we would not support a perimeter ruling. In NHS Ayrshire & Arran we have moved in a step change manner since the ban on smoking in public places - from a 15metre rule (which permitted smoking outwith 15 metres of a building) - to smoking in designated shelters only - to smoke free grounds. Our experience of the 15 metre rule was it was not well complied with and it created confusion as to where people could and could not smoke.

   Without legislation, we have established smoke free grounds with a good degree of success and to put in place a perimeter ruling, would in our opinion be a retrograde step and cause confusion amongst those who access our premises.

   In addition we have worked hard to create our own bespoke branding for smoke free ground at a considerable cost to the organisation. Any generic national signage provided, may challenge our own current signage, again adding to potential confusion and significant costs.

3. Is there anything you would add/remove/change in the Bill with regards to NVP's or smoking in hospital grounds?

   We would want to add - the ban on smoking to include <u>all</u> of NHS grounds and not just the perimeter of buildings as proposed in the bill. Also include other public sector organisations such as local authorities within the legislation.

   Consideration should be given to the potential of NVP's to become medical devices for smoking cessation purposes (dependant on

evolving research in relation to NVP's being used for harm reduction or smoking cessation), and the use of NVP's within NHS grounds. A national approach to this would be beneficial to avoid different health boards making different local decisions on this.

Duty of candour and willful neglect

1. Do you support the proposed duty of candour?

   Yes. This reflects the consultation position where 80% of respondents supported outlining this in legislation and with findings from significant enquiries. Cognizance of new and existing codes of practice/conduct and professional ethics should be taken into account should this legislation proceed. Training and support for staff and incorporation of the legal framing of this duty into professional codes of practice/conduct will be required. There will be associated resourcing requirements for this.

2. Do you support the proposal to make wilful neglect or ill-treatment of patients a criminal offence?

   Yes. Again this is in keeping with consensus around the consultation on this proposal. This would provide protection across sectors for people not at present covered under mental health and incapacity legislation.

3. Is there anything you would add/remove/change in the bill with regards to these provisions?

   No.

General Comments

Discussions on this bill have been had locally with members of our Pan Ayrshire Tobacco Control Strategy Group. Comments included that to implement these proposals effectively, Councils and the NHS will require to work closely together.

As with the original ban, an initial period of education/awareness raising would be useful, and this could be done in the run up to the legislative change – a high profile campaign led by NHS nationally, locally and facility-specific would be important.

NHS Ayrshire and Arran

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

COSLA

COSLA welcomes the opportunity to respond to this call for evidence but would point out that the very tight timescales imposed on the call of written evidence, particularly during the holiday season, mean that some elements of this response may not have been subject to the usual rigorous discussion through our committees and therefore our response should be considered with that caveat.

NVPs and smoking in hospital grounds

COSLA is committed to the actions set out in the current national strategy *"Towards A Generation Free From Tobacco"* and is generally supportive of the objectives of this Bill. However, we suggest that the proposals outlined in the consolation will need to be properly resourced if we are to continue to make progress toward the strategic goals.

1. **Do you support the Bill's provisions in relation to NVPs?**

   In terms of a proposed minimum purchase age of 18, a ban on the sale of NVPs via vending machines, a requirement for NVP retailer to register on the tobacco retailer register, a prohibition on 'proxy-purchasing' for under 18s, a restriction on domestic advertising and promotions (except for point of sale advertising), the introduction of an age verification policy for the sale of NVPs age verification, and a ban on staff under the age of 18 selling tobacco and NVPs; we would support the proposals set out in the Bill.

2. **Do you support the proposal to ban smoking in hospital grounds?**

   At this time it is unclear whether legislation is necessary or indeed practicable. Actions to achieve this outcome are currently being progressed by health boards and local authorities as part of the existing national smoke free strategy. Further time is needed to identify effective local approaches to this within a context of nominal resources.

   Organisations like health boards and local authorities may use internal disciplinary provisions to 'enforce' this policy for their employees if they want to prevent their employees smoking in the grounds of NHS property.

3. **Is there anything you would add/remove/change in the Bill with regards to NVPs or smoking in hospital grounds?**

   We support a more flexible and localised approach which builds on public support rather than prohibition.

Duty of candour and willful neglect

4. Do you support the proposed duty of candour?

COSLA and the Scottish Government are jointly committed to ensuring that people using health and social care services can expect to be safe from harm. We are fully supportive of continuous improvement in relation to quality and safety across health and social care standards and recognize the need for the disclosure and remedy of harm. However, it is not clear that legislation is the most effective or only way to achieve this policy objective.

Safety, support and protection are writ large through both NHS and local authorities' existing statutory duties, for example in relation to child protection, adults with incapacity and adult support and protection. Openness, safety and protection are also key drivers of national policies on quality and central to the outcomes we expect the new Integration Authorities to deliver over the coming period.

Both the NHS and local authority social work services have a long-fostered a culture of openness and candour where things go wrong in a person's care or support. The General Medical Council and Nursing and Midwifery Council standards explicitly require their members to be candid with people harmed by their practice and updated guidance is expected later this year. Furthermore, a range of the duties placed upon the social work profession require open and honest discussion of circumstances with the potential to cause harm, for example in relation to adult support and protection.

Evidence base

The evidence base for introducing legislation in England, and for the duty proposed for Scotland, are both focused upon the healthcare system with data for social care being scarce. This is perhaps not surprising. There is a strong argument that the framework of duties and regulatory regime which social care services operate within, have driven a culture of candour in adult social care for some time.

Councils have statutory duties in relation to adult support and protection which necessitate open discussion and joint management of risk of harm, irrespective of its source. Councils and third party providers are also required to report a wide range of notifiable harmful incidents to the Care Inspectorate. Furthermore, policy drivers such as self-directed support pass choice and control to the service-user within the context of continuous review of whether support is meeting agreed outcomes. Within that context, very early discussion of when things are going wrong is the norm, and would normally take place before any harm occurs.

The less episodic nature of adult social care, as compared with healthcare, tends to mean that people are supported by social care providers for longer periods of time. The establishment of longer term relationships that

results from this also tends to promote candour in practice, as something that is accepted as the 'right thing to do.' This, coupled with the factors outlined above, may suggest that there is less of a requirement for legislation to ensure candour within the social care setting.

Improvement approach

That is not to say that there is not room for improvement, however this may better-achieved through guidance and training across the new health and social care partnerships. This would obviously have resource implications, however additional guidance and training may be a far more cost effective way of realizing the policy intent.

Furthermore, ensuring a consistent approach across health and social care will require time for new integration arrangements to bed in, with the type of change sought being a shift in cultures towards one of openness and transparency across all services. Securing this change will require bespoke improvement support which is sensitive to local circumstances and can support partnerships to develop flexible approaches. Introducing a blanket duty with prescribed bureaucratic requirements can mitigate against such approaches.

Children and young people

The concept of harm, and therefore of an incident which would activate a duty of candour procedure, may need to be given separate consideration within the context of services for children and young people. Local authorities have specific protection duties in relation to children and young people, and systems already exist for anticipating harm and mitigating against it. Introducing a separate duty on top of these systems and duties risks duplication and could serve to diminish the focus on outcomes which is at the heart of our policy focus for children and young people, as expressed through Getting It Right For Every Child.

Resourcing and capacity

Should Parliament decide to proceed with the Bill proposals, four interconnected issues arise. Firstly, councils (in partnership with NHS Boards) would need to review existing systems against the requirements of any new duties. We do not agree with the financial memorandum's assertion that existing systems would be sufficient to ensure fulfillment of a new duty. As a minimum, there would be a need for infrastructure investment in staff training and additional administration.

Secondly, even if existing systems were deemed to include the required components, there remains the question of capacity. Should a new duty of candour lead to an increased volume, there will be an increased burden on that system and it risks becoming unsustainable.

Thirdly, volume (and therefore capacity) is driven by the definition of incidents which would activate a duty of candour. The Bill's description of

such incidents is reasonably clear in respect of specific types physical harm, however psychological harm and the shortening of life expectancy are more difficult to define or to attribute. This means that it is difficult to estimate the likely volume of incidents triggering the duty of candour and associated procedures.

For example, psychological harm may be more difficult to define within the context of adults who lack capacity or who are suffering from a mental health problem. Constructing a clear definition and guidance and dealing with events within this context will necessarily be more complex. This could lead to both an unintended impact on care planning and risk management, more complex processes for dealing with 'trigger' events, and an increased volume in cases.

Finally, employer's liability insurance and personal indemnity insurance could be affected by the act of apologising. While this is clearly not an acceptable reason for failing to apologise, the financial implications of liability do need to be fully considered and clearly set out.

Conclusion

The social care profession has a long history of operating with culture of openness that supports frank discussion of potential harm, the management of risk and the effectiveness of different interventions within that context. It is not clear that a new duty of candour on health and social care services is the best or only way of securing a culture of openness and transparency across the newly-integrated health and social system. Careful consideration of all other avenues for achieving this policy intent is required, and it may be that securing the desired culture change should be a matter for guidance, training and bespoke improvement support, rather than legislation.

5. Do you support the proposal to make willful neglect or ill-treatment of patients a criminal offence?

As previously stated, COSLA and the Scottish Government are jointly committed to ensuring that people using health and social care services can expect to be safe from harm. Safety, support and protection are writ large through both NHS and local authority statutory duties; they are also a key driver of national policies on quality and central to the outcomes we expect the new Integration Authorities to deliver over the coming period.

In addition to this focus on support and protection, the Mental Health (Care and Treatment) (Scotland) Act 2003 (s.315) and the Adults with Incapacity (Scotland) Act 2000 (s.83) set out offences of wilful neglect or ill-treatment in respect of mental health patients and adults with incapacity. Additional protection duties are conferred by the Adult Support and Protection (Scotland) Act 2007, and children and young people are provided with specific protection via the Children (Scotland) Act 1995 and the new Children and Young People (Scotland) Act 2014. Furthermore, providers

of care across all sectors are also under a general duty of care, enforceable by law and subject to regulatory control.

Against this backdrop, the case for further legislation needs careful consideration in terms of its likely utility, interface with existing legislation, and the potential for unintended consequences. COSLA has a long-standing view that any piece of proposed legislation should have to pass a high bar in order to make it into statute and so we would want to ensure that the Scottish Government responds to the following questions:

- If the legislation is, in part, designed to facilitate the prosecution of ill-treatment or wilful neglect in a way that has not been possible within the current statute, is there evidence or case studies that can be cited to demonstrate the necessity of the proposed legislation?

- If the legislation is, in part, designed to deter people from ill-treating or wilfully neglecting people they are paid to care for, is there evidence that the proposed legislation would have this effect?

- Can the definition of ill-treatment and wilful neglect be drawn tightly enough to satisfy the intent of the legislation but avoid unnecessarily criminalising people or organisations, who otherwise would simply have been censured for poor practice?

COSLA is absolutely committed to the principle that the state should take strong action against ill-treatment or wilful neglect and should the case be made that new legislation will aid prosecution, enhance deterrence and avoid criminalising poor practice, then we would recommend to our members that we should support the central thrust of the legislation.

The case for legislation

COSLA is committed to ensuring that people who receive health and social care services can expect to be safe from harm and are supported in an environment which respects individuals' dignity and promotes openness and transparency, including when things go wrong. If we are to realise this policy intent, careful consideration of the evidence base regarding the most effective means of achieving these aims is required. This should include an examination of best practice in relation to leadership and organisational culture, workload, staff training and support, support for families, and strong advocacy services.

Cases such as the ill-treatment of people with learning disabilities at Winterbourne View care home in 2012, would suggest that the presence of the facility to prosecute has limited impact on staff behaviour. Indeed, the Winterbourne View Report highlighted issues of leadership, staff training and support, organisational culture and the need for strong advocacy services. It is not clear that legislating is the best or only way to achieve the necessary change in these areas. We think, therefore, that the onus is on the Scottish Government to more fully articulate the deterring impact of its proposed legislation.

In some cases, criminal penalties may have the unintended consequence of negatively impacting on a culture of openness and willingness to whistle blow. Within this context it is important to recognise that the likely interface between a new offence of wilful neglect and proposals to introduce a duty of candour could produce unintended consequences. For example, while a culture of greater openness and transparency is clearly desirable, the simultaneous introduction of a wider-reaching criminal offence of neglect could actually mitigate against that culture.

Should Parliament decide to proceed with legislation, issues relating to the definition of wilful neglect and ill-treatment and the scope of the proposed offence will require to be considered. These are discussed in the remainder of our response below.

Definition

COSLA agrees that any offence of wilful neglect or ill-treatment should be based on conduct and not outcomes. This is in line with the similar offences set out in the Mental Health and Adults with Incapacity Acts, which places the focus on an individual's actions and the extent to which they carry the risk of harm, rather than whether that risk was in fact realised. This allows for greater protection of individuals in that the realisation of harm is often as the result of an individual's actions plus external factors which may or may not be present at any given time. In striving to prevent the risky behaviour in the first place, greater protection may be afforded overall. Focusing on conduct rather than outcomes may also act as a greater deterrent.

In focusing on conduct, there is a need to clearly define what conduct would be considered to constitute 'wilful neglect' or 'ill-treatment'. While there appears to be no clear definition presented within the Bill, wilful neglect implies that deliberate acts of omission would be within the scope of criminal wrongdoing. While we would agree to this as a general principle, it does raise questions about how generously this definition could be applied, either at the level of individual inaction or organisational inaction – and how easy it would be to disentangle where liability rests within this context. We think it is important to err on the side of a tight definition of wilful neglect.

Scope

The circumstances leading to wilful neglect or ill-treatment are often complex and can include organisational issues such as lack of support or training for staff, inadequate staffing ratios, organisational culture and poor leadership. Indeed, there have been cases where such circumstances have been deemed to amount to an organisation breaching its duty of care. If we are to ensure that people receiving health and social care are safe from harm, it will be important to consider the factors which can contribute to such care worker / care provider behaviour.

The Scottish Government's consultation on proposals for an offence of wilful neglect raised the question of whether an offence should apply only in 'formal' care settings. It doesn't appear to be clear whether a person's home would be considered an informal or formal care setting for the purposes of the Bill. It is our view that any legislation should apply to care provided in a person's home. Our joint policy ambition, expressed by the new national health and wellbeing outcomes, is to shift the balance of care from institutional to community settings and support people to live independently in their own home for as long as possible. Care will therefore be increasingly provided in person's own home and protection should therefore be extended to this setting.

'Formal' and 'informal' care is also conceived of in terms of the person providing it. It is not clear whether the Bill's provisions would apply to 'informal' carers such as family members and volunteers. The use of the term 'care worker' would suggest they do not, however clarification is needed. It should be noted that in some cases family members can be employed as carers through self-directed support, for example as a personal assistant. It is our view that the offence should extend to family members in these circumstances, insofar as they are acting as a paid employee with attendant responsibilities and liabilities – again, the Bill should be clarified in this respect.

Resources

Should Parliament proceed with legislation, there will be financial implications for local authorities (and other care providers) in terms of staff training and awareness-raising. We do not agree with the statement in the financial memorandum which asserts 'there will be no new costs falling on local authorities'. The financial impact on councils will require full and proper consideration and, in line with our current political agreement, all costs to local authorities arising from new duties or policy initiatives the Scottish Government wishes to introduce must be met in full by the Scottish Government.

6. Is there anything you would add/remove/change in the Bill with regards to these provisions?

Yes see above.

COSLA

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

UNISON

Introduction

UNISON is Scotland's largest trade union representing around 155,000 members working in the public sector. We represent over 60,000 health staff as well as social workers, social care staff, mental health officers, etc, most of whom would be affected by the Scottish Government's proposals. We also represent members working in health and care in the community and voluntary sector.

UNISON Scotland welcomes the opportunity to respond to the Scottish Parliament's Health & Sport Committee on their Call for Written Evidence.

NVPs and smoking in hospital grounds

UNISON has consistently supported the Scottish Government in its ambitions to curtail smoking across the Scottish Population since its first consultation paper in 2004.

Whilst there is as yet no definitative advice on the use of Nicotine Vapour Products (NVPs) we believe it is a worthwhile aim to regulate the selling and use of these products. We think there may be some benefits in assisting people to stop smoking tobacco products in general, but until there is actual proof of the harm or otherwise of NVPs it is preferable to restrict their use and sale. We believe that the measures proposed in the Bill will contribute towards this.

We also believe that there is no place for smoking in hospital grounds where many sick people and those visiting them can carry the smoke into patients' surroundings. However, care must be given to the way in which the regulations are monitored, and individual members of staff asking patients or members of the public to desist need to be given training on the best ways to carry out their duties.

Duty of Candour

UNISON supports the proposals for a Duty of Candour and proposals for an offence of Wilful Neglect and provided submissions on both consultations to the Scottish Government.

However, whilst we welcome the introduction of a Duty of Candour we believe that the desired outcome should emphasise the aim to drive up standards and improve organisational cultures rather than just a monitoring tool to see what reports are submitted.

UNISON welcomes the commitment in the Bill to place the emphasis on organisations and not individual practitioners. We welcome the recognition that Health and Social Care Professionals already have a regulatory and ethical obligation to be open and candid with their patients and service users.

However UNISON members are concerned that despite placing the emphasis on organisations, the unintended consequences of such an approach, could make employers more risk averse and will lead to an increase in dismissals, regulatory referrals and potential litigation against individual practitioners as well as organisations.

UNISON believes that careful consideration should be given to whether whistleblowers need added and specific protection within the Regulations given. We are concerned that where there is not an open and welcoming culture within the organisation, staff who make legitimate concerns known will find themselves being pressurised or even sanctioned because they have highlighted problems. We would, therefore wish to see this included in the legislation.

Offence of Wilful Neglect

UNISON supports the proposals in the Bill for an offence of Wilful Neglect by providing for a offence against care workers and against care providers, including supervisors. We are particularly pleased that there will be an opportunity for those organisations which provide care to be prosecuted in circumstances where their policies, including staffing, lead to harm for the service users. In addition, if the offence applies to organisations, we believe that they will monitor and regulate staff more closely.

We are disappointed that the offences only cover adult health and social care services as we believe the penalties should extend to services provided to children who are particularly vulnerable in care and hospital settings. We would recommend that all residential settings for children including care homes, schools, nurseries; and children's health care including mental health services be included in the legislation.

UNISON Scotland

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

Royal College of Nursing

The Royal College of Nursing (RCN) Scotland welcomes the opportunity to provide written evidence to the Health and Sport Committee on the Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill.

The Royal College of Nursing (RCN) is the UK's largest professional association and union for nurses, with around 425,000 members, of which over 39,000 are in Scotland. Nurses and health care support workers make up the majority of those working in health services and their contribution is vital to the delivery of the Scottish Government's health policy objectives.

Our written evidence relates specifically to Parts 2 and 3 of the Bill on Duty of Candour and Ill-treatment and wilful neglect respectively and provides answers to Questions 4, 5 and 6 in the call for written evidence.

Duty of Candour *– The Bill proposes to place a duty of candour on health and social care organisations. This would create a legal requirement for health and social care organisations to inform people (or their carers/families) when they have been harmed as a result of the care or treatment they have received.*

4. Do you support the proposed duty of candour?

Broadly, we support the creation of a legal requirement for health and social care organisations to inform people (or their carers/families) when they have been harmed as a result of the care or treatment they have received and support the principles of transparency, honesty and openness.

We agree that people harmed should be informed and putting a duty of candour on statutory footing will help close the gap between what is good practice and what may be happening in some instances 'on the frontline'. By requiring and supporting those currently unwilling to disclose and discuss errors, it should prompt an organisational shift and positively encourage a culture of openness, learning and ongoing improvement to the benefit of all those who use our health services.

A statutory *organisational* duty would, we believe, be more effective at achieving a consistent approach across all health and care services than the individual duties imposed by individuals' codes of professional conduct and/or related guidance.

It is clear from the Policy Memorandum and the Bill that the intent of the Duty of Candour is an organisational – not an individual – duty. As long as this is the case, we broadly support the principle of the Bill, but raise a number of points for clarity in answer to Question 6 (below).

Ill-treatment and wilful neglect *– The Bill would establish a new criminal offence of ill-treatment or wilful neglect which would apply to individual health*

and social care workers, managers and supervisors. The offence would also apply to organisations.

5. Do you support the proposal to make wilful neglect or ill-treatment of patients a criminal offence?

We do not agree that a new offence should be created now. Our primary concern about the creation of a new criminal offence, even if it is intended for only the most exceptional cases of neglect or ill-treatment, is that it will have the opposite effect to that intended. We believe there is a significant risk that the threat of criminal proceedings against an individual will encourage organisations, staff, patients, their families and carers, to 'look for someone to blame'. This could halt any moves, either by individuals or organisations, towards greater openness when something goes wrong in health care. We know that greater openness enhances patient safety[26]; and we believe that the existing criminal and civil law or professional sanctions for addressing neglect or ill-treatment, when applied properly, can deal with any serious failings in health care delivery.

When care falls below the required standards, nurses most commonly report to us[27] that this is as a result of factors such as low staffing levels, lack of training and development, poor support and ineffective or misguided leadership. So the legal focus on the individual – as proposed – could detract attention away from wider organisational issues.

In Scotland, there is already provision in both criminal and civil law as well as protecting vulnerable groups (PVG) legislation and professional or regulatory disciplinary measures and sanctions to address instances of 'patient abuse' or ill-treatment. So we believe the justice and professional regulatory systems (such as the NMC and GMC) can already deal effectively with cases of deliberate neglect or mistreatment when they arise. The creation of a new offence is therefore unlikely to add anything of value to those existing remedies – and there is no evidence, either, that the perpetrators of neglect or ill-treatment have gone unpunished or not been held to account.

According the NHS Scotland staff survey[28] only 57% of staff currently feel that it is safe to speak up and challenge the way things are done. In our view, therefore, staff will be less open and less honest when things go wrong out of fear that they may expose themselves or their colleagues – and this would be compounded if criminal charges and years of uncertainty and the stress of our adversarial criminal justice system could result.

There are also other risks. This new offence could cause some healthcare professionals to practice inappropriately, where the patients who shout the loudest are treated more favourably, so that staff protect themselves from possible accusations of wilful neglect.

[26] 87 Etchegaray, JM., Gallagher, TH., Bell, SK et al. (2012). Error disclosure: a new domain for safety culture assessment. BMJ Quality and Safety, 21, 594-599
[27] http://www.rcn.org.uk/__data/assets/pdf_file/0003/551343/Scotland_survey_2013_final.pdf
[28] http://www.gov.scot/Publications/2014/12/8893/6

So, while we broadly support the statutory duty of candour, we believe the new culture of openness as a result should be allowed to become embedded before further consideration is given as to whether making wilful neglect or ill treatment a criminal offence is necessary. We also find it slightly contradictory that both the Duty of Candour and Wilful Neglect are presented in a single Bill, when the fear of prosecution might stifle people's adherence to Duty of Candour.

6. Is there anything you would add/remove/change in the Bill with regards to these provisions?

Rather than introduce a new criminal offence of ill-treatment or wilful neglect which would apply to individuals if things go wrong, the introduction of restorative justice should be considered, where the consent of the patient, health professionals and organisation is sought and the skills of a mediator or facilitator independent of the organisation are used.

As regards the Duty of Candour provisions:

- We would like to see how the statutory duty of candour will fit in the current legislative and policy framework, i.e. how will it fit with organisations' existing policies and procedures, for example, on whistleblowing, grievances, the current reporting of adverse events/incidents and the CNORIS scheme.
- There should be clarity and further guidance on the requirement to publicly report incidents to avoid identifying individuals and how to take into account organisations' duties in relation to personal data under the Data Protection Act 1998.
- The proposed definition of Duty of Candour is broad. This may cause difficulties with statutory interpretation, as well as with recognising such an event in practice. Clarity on the meaning of 'unintended' and 'unexpected', for example, would need to be clear.
- Given the integration of health and social care, where care provision will be increasingly flexible and may cross the boundaries between heath and social care, there needs to be clarity about where duty of candour responsibilities lie between health boards, local authorities and integration joint boards.
- The Bill proposes that monitoring of duty of candour will be carried out by Healthcare Improvement Scotland, the Care Inspectorate and Scottish Ministers. There needs to be mechanisms in place to ensure consistency of monitoring compliance.
- We support the Bill's provision to make regulations around staff training and support. The Duty of Candour would be an organisational responsibility, so the organisation must ensure staff have the required training, support, knowledge and skills to implement the duty of candour, and this must apply to all relevant staff.

Royal College of Nursing