

SPICe Briefing

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

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The Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill contains four broad proposals:

- To introduce restrictions on the sale of nicotine vapour products (NVPs) such as e-cigarettes. These restrictions will include; a minimum purchase age of 18, the power to prohibit their sale from vending machines, making it an offence to purchase and NVP on behalf of someone under 18, a requirement for NVP retailers to register on the tobacco and nicotine vapour product retailer register, and the power to restrict or prohibit domestic advertising and promotions. It also places further controls on the sale of tobacco.
- To make it an offence to smoke in a designated zone outside of buildings on NHS hospital sites.
- 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 when they have been harmed as a result of the care or treatment they have received.
- To establish new criminal offences of ill-treatment or wilful neglect in health and social care settings; one offence applying to individual health and social care workers, managers and supervisors, and another applying to organisations.

This briefing sets out the current position with regards to each proposal, what the Bill proposes to do and the key issues to arise from the Health and Sport Committee's call for evidence.



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EXECUTIVE SUMMARY

The Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill has four broad proposals:

1 - To control the sale, advertising and promotion of Nicotine Vapour Products such as e-cigarettes and apply further controls on the sale of tobacco

Nicotine Vapour Products (NVPs), such as e-cigarettes, are devices that are designed to produce vapour for inhalation. They may or may not contain nicotine but they are reportedly a commonly used smoking cessation aid. Their use has grown significantly over the last decade. The health benefits and the health harms of NVPs are the subject of much debate but research evidence for either is currently limited. While some argue that they are an effective tool for quitting or cutting down on smoking, others have concerns that they may be a gateway to smoking, particularly among young people (see [pp5-6](#)). This has led to calls for greater regulation of NVPs.

In light of the uncertainty around the health effects of NVPs, the Bill adopts something of a precautionary approach and is proposing a number of restrictions on the sale, advertising and promotion of NVPs (see: [pp7-8](#)). These include:

- a minimum purchase age of 18,
- the power to prohibit their sale from vending machines,
- making it an offence to purchase an NVP on behalf of someone under 18 ('proxy purchasing')
- a requirement for NVP retailers to register on the tobacco and nicotine vapour product retailer register,
- a requirement that registered retailers should operate an age verification policy, and
- the power to restrict or prohibit domestic advertising and promotions.

The majority (61%) of respondents to the Health and Sport Committee's call for evidence supported all of the provisions relating to NVPs. Notably there was almost universal support for restricting their sale to over 18s. The provisions with less support included requiring those who sell NVPs to register as a retailer and prohibiting proxy purchasing altogether (i.e. including parents of young smokers) (see [pp8-9](#)).

The provision with the most opposition was the plan to give Ministers the power to restrict domestic advertising and promotion of NVPs. These responses argued that this would be disproportionate to their harms and could potentially undermine the public health benefit of such products (see pp [10-11](#)).

2 - To make it an offence to smoke tobacco outside of buildings on NHS hospital sites

At the moment, the NHS in Scotland operates a smoke free policy across all of its grounds. However, the NHS does not have any powers to enforce the policy and compliance is reported to be an issue.

The Bill would make it an offence to smoke within a designated no-smoking area around buildings in NHS hospital grounds. The area will be immediately outside of buildings on hospital sites and bounded by a perimeter of a specified distance (to be determined in regulations) (see [p12](#)). The Bill would allow Ministers to make exceptions. Outside of the perimeter, NHS Boards would have the discretion as to whether or not to apply a no-smoking policy.

The majority (79.5%) of respondents to the Health and Sport Committee's call for evidence were in favour of the proposal. Generally these responses felt that it would support compliance by giving the NHS the backing of the law. However for those opposed to the proposal, it was felt to be unnecessary, uncompassionate, difficult to enforce and a potential safety risk (pp [12-13](#)).

3 - To introduce a duty of candour for health/care organisations

Following a number of reviews in England, there have been calls for greater candour amongst health and care organisations when things go wrong (see [p13](#)). As a consequence, the Bill proposes to give health, social care and social work organisations a 'duty of candour'. What this would mean is that, in the event that a person experiences (or could have experienced) an unintended or unexpected harm from their care, the organisation would have a duty to tell that individual. The Bill would also allow an apology to be given without it amounting to an admission of negligence or a breach of a statutory duty (see [pp14-15](#)).

The majority (58.5%) of the respondents to the Committee's call for evidence were in favour of the proposal. Those in support felt that it would engender a culture of openness and learning.

Criticisms made of the duty included that legislation is not the way to create an open culture and the defined harms are very broad and could encompass very minor events, thereby resulting in a significant drain on resources (see [pp15-16](#)).

4 - To introduce offences of wilful neglect and ill treatment for health/care professionals and organisations

Following a review of patient safety in England, it was recommended that there should be an offence of wilful neglect or ill treatment which is on a par with that covering mental health patients in the UK. Consequently, the Bill proposes to create new offences of ill-treatment or wilful neglect; one which would apply to adult health and social care workers, and another which would apply to adult health and social care providers (see [pp17-18](#)).

The majority (60%) of respondents to the Committee's call for evidence supported the proposal, generally expressing the opinion that it would send a clear message to staff and organisations. Some criticisms made of the provision however, included that; there are already avenues for redress by those with mental capacity and it is not clear what would constitute ill-treatment or wilful neglect. Others also expressed concern that it could potentially undermine the duty of candour, in that it might make organisations more likely to hide things for fear of prosecution (see [pp18-19](#)).

INTRODUCTION

The Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill was introduced in the Scottish Parliament on 4 June 2015 by the Cabinet Secretary for Health and Wellbeing, Shona Robison MSP (Scottish Parliament, 2015a, 2015b, 2015c).

The Bill is in 3 parts and proposes to:

1. Introduce controls on the sale of Nicotine Vapour Products (NVPs), such as e-cigarettes, as well as powers to restrict or prohibit domestic advertising of NVPs. It also proposes further controls on the sale of tobacco and seeks to make it an offence to smoke tobacco outside of buildings on NHS hospital sites.
2. Introduce a 'duty of candour' for health/care organisations
3. Introduce offences of wilful neglect and ill treatment for health/care professionals and organisations.

The following briefing deals with each part of the Bill in turn. It sets out the current situation, what the Bill is proposing and the key issues to emerge from the Health and Sport Committee's call for written evidence.

PART 1 – TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING

Background and Policy Objective

The Policy Memorandum (PM) describes the main objectives of Part 1 of the Bill as supporting the aims of the tobacco control strategy (Scottish Government, 2013). This strategy has a target of reducing smoking prevalence to less than 5% by 2034 and the PM states that this can only be achieved by preventing the initiation of tobacco use.

In relation to NVPs, the PM states that the approach in the Bill is in part "precautionary". This is in light of the debate that exists around NVPs which has concentrated on the potential for NVPs to act as a 'gateway' to combustible tobacco products such as cigarettes, and whether NVPs such as e-cigarettes might 're-normalise' smoking behaviours. The PM does state however, that the Scottish Government recognises the potential health benefits of NVPs as they are likely to be less harmful than conventional cigarettes and are potentially an effective aid to stopping smoking.

What are Nicotine Vapour Products?

NVPs are perhaps more commonly known as 'vaping products'. The British Standards Institution recently defined 'vaping products' as a:

"Product, and/or part of product, which is used within a device designed to produce vapour for inhalation, and which may or may not contain nicotine" (BSI, 2015)

The Bill uses the term 'nicotine vapour product' but the definition used in s1 of the Bill would also include products which do not contain nicotine. The most commonly known vaping products are 'e-cigarettes'. For a more detailed discussion on e-cigarettes then please see [SPICe briefing SB14-83](#) (Evans & Payne, 2014).

CHAPTER 1 - SALE AND PURCHASE OF TOBACCO AND NICOTINE VAPOUR PRODUCTS

Current Situation

At the moment there are no specific public health restrictions on who can sell NVPs or who can buy them. While many retailers do not sell to under 18s, and many products are marked with warnings to that effect, there is no statutory age restriction in the UK.

NVPs are also available from a variety of outlets and due to the fact that they are regulated as a general consumer product, there are no specific restrictions on who can sell them.

Over recent years there has been much debate about the potential benefits and harms from NVPs such as e-cigarettes. The following sections discuss the research evidence around this. Note that it should not be taken as an exhaustive overview of research in this field

Potential Health Benefits of NVPs

The market for NVPs, in particular e-cigarettes, has grown significantly since their UK introduction in 2006 and much of this increase has been driven by the idea that they are a healthier alternative to smoking and a useful smoking cessation aid.

In relation to the evidence for such claims, a recent systematic review of the research looked at whether e-cigarettes helped smokers to quit or cut down on their smoking (McRobbie et al, 2014). It concluded that use of an e-cigarette containing nicotine increased the chance of stopping smoking over the long-term, compared to the use of an e-cigarette without nicotine. It also found that a higher number of people using e-cigarettes containing nicotine were able to reduce their cigarette consumption by at least a half, compared to those using non-nicotine containing e-cigarettes or those using nicotine patches.

It should be noted however that the review found the quality of evidence to be low due to the small number of studies and it recommended the need for further research.

In terms of whether or not NVPs are a healthier alternative to tobacco products, due to the fact they are a fairly recent innovation, there have been no longitudinal studies into the physical effects of prolonged use.

However, there does appear to be a general view that they are likely to be less harmful than tobacco. Following a recent review of the available evidence, Public Health England concluded:

“While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger. It had previously been estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate.” (Public Health England, 2015, page 80).

In light of the available evidence, Public Health England concluded that:

“Emerging evidence suggests some of the highest successful quit rates are now seen among smokers who use an e-cigarette and also receive additional support from their local stop smoking services.”

Potential Health Harms of NVPs

One of the key concerns about NVP products is that they will act as a ‘gateway’ to smoking amongst non-smokers, in particular children and young people, and that they could re-normalise smoking. There are also concerns about the physical effects of nicotine which can be toxic.

Data released by the Office for National Statistics found that e-cigarettes were almost exclusively used by smokers and ex-smokers (Office for National Statistics, 2014). Over half of users said they were using them to quit smoking, and about one in five said the main reason for their use was that they thought they were less harmful than cigarettes.

In relation to young people, a recent survey showed that 81% of 13-18 year olds were aware of e-cigarettes (ASH Scotland, 2014) but other surveys have shown that the use of e-cigarettes in young people is generally confined to current and former smokers (Scottish Schools Adolescent Lifestyle and Substance Use Survey, 2014). This survey showed that 3% of those who had never smoked had tried an e-cigarette once, and 1% of those who had never smoked had tried an e-cigarette a few times.

The concept of a ‘gateway drug’ is controversial in the field of addiction studies and disagreements persist as to whether any progression in drug use is evidence of causality, that is, does the use of one drug cause a person to use another? In relation to whether e-cigarettes can re-normalise smoking, the World Health Organisation contends that the existence of a gateway or re-normalising effect can only be assessed with empirical data, which it believes is, currently very limited (WHO, 2014)

The Public Health England review of the evidence discusses the problems of ascertaining whether an e-cigarette can act as a gateway to smoking and concludes:

“The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field. Whilst never smokers are experimenting with [e-cigarettes], the vast majority of youth who regularly use [e-cigarettes] are smokers. Regular [e-cigarette] use in youth is rare. “

In relation to re-normalising smoking, the PHE review highlights that smoking prevalence has declined in adults and young people since e-cigarettes were introduced to the market. This is also discussed by ASH Scotland (2014b) which highlights that this does not necessarily mean that e-cigarettes have been responsible for the decline, but it does state that the findings appear inconsistent with the concern that e-cigarettes ‘would prolong’ smoking.

Bill’s Provisions

Definition of Nicotine Vapour Products

The Bill defines an NVP as a device which is intended to enable the inhalation of a vapour, whether it contains nicotine or not. The definition also covers other component parts of the device, such as filler cartridges, as well as any substance for use within it. The definition would not cover any licensed medicinal product or device. It would appear that there is only one NVP licensed as a medicine in the UK but it is currently not on sale to the general public¹.

¹ VOKE 0.45mg Inhaler – see:

<http://www.mhra.gov.uk/spc-pil/?prodName=VOKE%200.45%20MG%20INHALER&subsName=NICOTINE&pageID=SecondLevel>

Sale and Purchase of Tobacco and Nicotine Vapour Products

The Bill would make it an offence to sell an NVP to a person under the age of 18 and anyone found guilty of such an offence could be liable to a fine of up to £2,500. However, the Bill would allow a defence that the accused had taken reasonable steps to establish that the customer was over 18 if they had been shown convincing documentation of their age. The Bill would not make it an offence for someone under the age of 18 to attempt buy or possess an NVP.

Other provisions in this part of the Bill include:

- A requirement for a tobacco or NVP retailer to operate an age verification policy - the policy set out in the Bill is the 'Challenge 25' scheme, whereby the retailer must ask for proof of age from anyone who looks to be under 25. A retailer found guilty of not operating an age verification scheme could be liable for a fine of up to £500.
- Making it an offence for an adult to buy an NVP on behalf of a person under the age of 18 (also known as a 'proxy purchase') - a person found guilty of such an offence could be liable for a fine of up to £5000.
- A power to ban the sale of NVPs from vending machines – this would be in line with tobacco products.
- Prohibiting someone under the age of 18 from selling tobacco products or NVPs unauthorised.

Register of Tobacco and Nicotine Vapour Product Retailers

The Bill would require those selling NVPs to register on the Scottish Tobacco Retailers Register (STRR). The Bill would rename the register the Scottish Tobacco and Nicotine Vapour Product Retailers Register.

The Bill would extend the penalties used currently for breaches of the STRR, to NVP retailers. These penalties include that if a retailer commits three or more offences (such as selling to people under 18) within a two year period, a local authority can apply to the Sheriff for a retail banning order. The order prevents a retailer from selling both NVPs and tobacco for up to two years and results in the retailer being removed from the register.

The Scottish Government in the Policy Memorandum explains that the register will be useful for local authority officers to identify retailers of NVPs in order to "assist with advice and enforcement functions".

Key Issues

The Committee's call for written evidence received 93 responses. Of these responses, 69 submissions addressed the questions regarding NVPs. Table 1 shows a breakdown of the responses to the question 'Do you support the Bill's provisions in relation to NVPs?'. Not all of the submissions answered the question with a direct 'yes' or 'no' and for these submissions a judgement had to be made by SPICe on the basis of the comments provided.

Table 1: Support for NVP Provisions

Response Category	Number (%) ²
Supports all of the provisions	42 (61%)
Supports specific provisions but not all	17 (25%)
Unclear	7 (10%)
Generally supportive but with some comments/reservations	2 (3%)
Generally unsupportive	1 (1%)

This shows that 61% of respondents supported all of the NVP provisions; 25% supported some; 10% did not make their opinion clear; 3% were generally supportive but had some comments or reservations and 1 respondent was unsupportive of the proposals.

There was almost universal support for the restrictions on age of purchase. In relation to the other provisions in Chapter 1 however, support was more mixed. The following highlights some of the areas where there were differences of opinion.

Requirement to Register as a Retailer

The requirement for retailers of NVPs to register was the most common criticism of this part of the Bill. While most submissions supported it, some felt it to be disproportionate. This is because they felt the harms of NVPs are not on a par with tobacco. Some also felt therefore that mirroring the offences and penalties for tobacco products was not proportionate. Other submissions expressed the desire for a separation in the register to show tobacco retailers and NVP retailers. This was suggested so that the harms of tobacco are not conflated with NVPs.

Prohibiting proxy purchase

While most submissions welcomed the provisions on proxy purchasing, some thought that this could potentially close off a route out of smoking for young smokers. While they agreed that those under 18 should not buy NVPs, some felt it acceptable for a parent to do so on behalf of their child but under the Bill this would not be permitted.

Vending Machine Ban

Most submissions expressed support for a ban on selling NVPs through vending machines. However some did not and thought it would hamper adults being able to purchase NVPs in this way. Some submissions used examples of other methods to prevent young people accessing age restricted products via vending machines, for example, by placing machines in areas that under 18s are not allowed. These comments came primarily from those involved in the NVP industry.

² Percentages do not add up to 100 due to rounding

CHAPTER 2 – ADVERTISING AND PROMOTION OF NICOTINE VAPOUR PRODUCTS

Current Situation

NVP advertising in the UK is currently dealt with under the general UK Advertising Codes and the UK Advertising Standards Agency (ASA) enforces the rules in response to complaints from the public. There are two sets of codes:

- The CAP Code for all non-broadcast marketing which is written and maintained by the Committee of Advertising Practice (CAP)
- The BCAP Code for broadcast marketing (i.e. TV and radio) which is written and maintained by the Broadcasting Committee of Advertising Practice (BCAP).

The system is a mixture of self-regulation for non-broadcast advertising (i.e. the system is paid for by industry members who draft the rules) and co-regulation with the statutory regulator Ofcom for broadcast advertising.

From May 2016, broadcast advertising of NVPs will have to comply with the Tobacco Products Directive (TPD) (2014/40/EU) which will effectively ban the cross border advertising and promotion of NVPs, including; TV and radio advertising, newspaper adverts and sponsorship of events such as televised sport.

However, the Directive does not cover non-broadcast advertising (often referred to as ‘domestic’ advertising) such as billboards and point-of-sale adverts. These will continue to be regulated in line with the CAP code. The Directive will also not apply to vaping products that do not contain nicotine.

Up until recently, neither of the Codes contained specific rules on e-cigarettes. Instead, e-cigarette advertising had to comply with the general rules, for example, that advertising should not be misleading and that any health/smoking cessation claims have to be substantiated.

New rules specifically dealing with e-cigarettes have, however, recently been adopted following a public consultation (Committees of Advertising Practice 2014c, Annex 2). These are set out in CAP and BCAP’s Joint Regulatory Statement entitled “New rules for the marketing of e-cigarettes” (CAP and BCAP 2014) and came into force on 10 November 2014.

The new non-broadcasting rules include provisions which require e-cigarette advertisements to:

- Be socially responsible
- Not to promote any design, imagery or logo that might be associated with a tobacco brand
- Not to promote the use of a tobacco product or show the use of a tobacco product in a positive light
- Make clear that the product is an e-cigarette and not a tobacco product
- Not to undermine the message that quitting tobacco use is the best option for health
- Not to encourage non-smokers or non-nicotine users to use e-cigarettes
- Not to feature characters likely to resonate with youth culture or to appeal to under 18s.

The new rules on e-cigarettes will be reviewed towards the end of 2015.

Bill's Provisions

The Bill contains a power for Scottish Ministers to make regulations which would restrict or prohibit the domestic advertising and promotion of NVPs. It also gives Ministers the power to specify offences and penalties for contravening any such regulations. The Bill sets out the maximum penalties that may be in regulations, namely:

- On summary conviction³, imprisonment for no longer than 12 months or a fine not exceeding the statutory maximum (£10,000) or both
- On conviction on indictment⁴, imprisonment for no longer than 2 years, a fine or both.

Although the Bill does not indicate how these powers will be used, the PM to the Bill states:

“The Scottish Government believes that a comprehensive ban on all NVP domestic advertising and promotion is required to complement the TPD, but allowances should be made for advertising at point of sale where NVPs are sold. A display of NVPs, the purpose or effect of which is not to promote a NVP, should not be regarded as an advert or promotion, and therefore should not be prohibited.” (Scottish Parliament, 2015b, page 16)

The Bill would also give Ministers the power to regulate free distribution and nominal pricing on NVPs for promotional purposes as well as regulate sponsorship by NVP companies.

Key Issues

As indicated previously, the majority of submissions (61%) to the Committee's call for evidence supported all of the NVP provisions in the Bill. Of those that supported some of the proposals (25%), the proposed restrictions on advertising and promotions were the provisions that such submissions were most likely to disagree with.

For the submissions that supported restrictions on advertising and promotion, it was usually on the grounds of protecting young people and non-smokers from being encouraged to use NVPs. Many acknowledged the lack of evidence around long terms harms but were sympathetic to a precautionary approach.

However, some of these submissions also argued that some advertising and promotion to current smokers is desirable in order to achieve the potential public health benefits NVPs may bring.

³ Criminal procedure (ie the procedure for the investigation and prosecution of crime) is divided into solemn and summary procedures. Summary procedure is used for less serious offences (with the charges set out in a complaint) and may ultimately lead to a trial before a sheriff or, in justice of the peace courts, before a bench of one or more lay justices. Trials under summary procedure are conducted without a jury. Solemn procedure involves the most serious of criminal cases and may ultimately lead to a trial on indictment, either before a judge in the High Court or before a sheriff in one of the sheriff courts. Trials under solemn procedure are conducted with a jury.

⁴ Ibid

The main reasons given for opposing the provisions were:

- The current regulatory system provides the correct level of protection, reflects current evidence and will be reviewed shortly anyway
- An advertising ban only serves to protect the tobacco industry from competition
- NVPs need to be promoted as an alternative to tobacco in order to realise their public health benefit
- Further restrictions are unjustified given the level of harm associated with NVPs
- Regulation on a par with tobacco will mean the public will view them as being as harmful as tobacco
- The lawfulness of the advertising ban proposed in the TPD is currently being assessed by the courts⁵.

Others felt that without knowing how the powers will be used, it is difficult to know whether to support or oppose the provisions.

CHAPTER 3 – SMOKING OUTSIDE HOSPITALS

Current Situation

At the moment, the NHS in Scotland operates a smoke free policy across all of its grounds including GP surgeries, health centres, NHS car parks or gardens. The use of NVPs such as e-cigarettes is also not permitted, either inside or outside of NHS premises.

The NHS does not have any powers to enforce the ban other than to ask the person smoking to stop or to leave the grounds. There is no data collected on breaches of the policy. The PM to the Bill reports that it is having a positive impact but that compliance is an issue.

Bill's Provisions

The Bill would make it an offence to smoke within a designated no-smoking area around buildings in NHS hospital grounds. The area will be immediately outside of buildings on hospital sites and bounded by a perimeter of a specified distance (to be determined in regulations). The Bill would require that no-smoking notices are conspicuously displayed at the entrance to hospital grounds and at every entrance to hospital buildings.

The Bill will make it an offence to smoke within the designated zone and those caught will be liable, on summary conviction, to a fine not exceeding level 3 on the standard scale (up to £1000). NVPs are not included in these provisions.

The Bill would also make it an offence for someone with management and control of the no-smoking zone to knowingly permit someone to smoke there. The Bill allows a person a defence that they took all reasonable precautions to prevent the person from smoking or that there was no lawful or reasonably practicable means by which they could prevent the other person from smoking.

The person committing the offence would also be allowed the defence that they did not know - and could not reasonably be expected to know - that they were smoking in the no-smoking area. The Bill also includes a power to exempt certain buildings or grounds. The PM cites psychiatric hospitals, the State Hospital and hospices as examples of possible exemptions.

⁵ [Case C-477/14 – Pillbox38 \(UK\) Limited, trading as “Totally Wicked” v Secretary of State for Health](#)

Outside of the designated zone, NHS Boards would have the discretion to continue operating a no-smoking policy, although it would not be an offence to smoke in these areas if they chose to apply such a policy.

The restrictions would be enforced by local authority officers.

Key Issues

Of the 93 submissions to the Committee's call for evidence, 44 responses addressed the question on the smoking in hospital grounds provisions. Table 2 shows a breakdown of the responses to the question 'Do you support the Bill's provisions in relation to smoking in hospital grounds?'. Not all of the submissions answered the question with a direct 'yes' or 'no' and for these submissions a judgement had to be made by SPICe on the basis of the comments provided.

Table 2: Support for smoking in hospital grounds ban

Response Category	Number (%)
Supports the provisions	35 (79.5%)
Does not support the provisions	7 (16%)
Opinion unclear	2 (4.5%)

Table 2 shows that the majority (79.5%) of responses supported the proposed restrictions on smoking in hospital grounds, with 16% opposing them and the remainder (4.5%) not stating a clear opinion. Almost all of the NHS and Local Authority responses were in favour of the proposal.

Some of the reasons given for opposing the restrictions were:

- The legislation is not needed and the existing policy should be retained.
- It is cruel and uncompassionate as often hospital visits are stressful and highly emotive.
- It raises potential safety risks from concealed smoking and patients/staff travelling outwith the perimeter to smoke.
- It is potentially unworkable with patients who have mental health problems or diminished capacity.

Other comments made by both those in support and opposed to the proposal included that:

- Enforcement would be difficult and would stretch local authority resources. Some questioned how it could be enforced without a constant presence from local authority officers.
- A perimeter approach would be more difficult to enforce. Some submissions in favour of the proposal called for it to be applied to the whole of the hospital grounds.
- It would create inequity in the approach to the terminally ill who may not be receiving treatment in an exempt facility.
- It is not fair to expect staff to police the actions of patients and visitors and be prosecuted for 'permitting' someone to smoke.
- It will need to take account of the integration of health and social care and jointly managed facilities. Some wanted it to be applied to all public buildings.

For those in favour of the proposals, it was viewed as being consistent with the smoke-free Scotland agenda and likely to lead to better compliance.

PART 2 – DUTY OF CANDOUR

Background and Policy Objective

Part 2 of the Bill relates to a proposed ‘duty of candour’ for health and social care organisations. What this would mean is that such organisations would have a duty to inform people when something had gone wrong. A number of recent reviews in England produced recommendations which highlighted the need for honesty and candour with patients, namely:

- **The Francis report** – this is the report from the public inquiry into the failings at Mid Staffordshire NHS Foundation Trust where there was poor care and high mortality rates. The inquiry report recommended greater openness, transparency and candour amongst NHS staff (Mid-Staffordshire NHS Foundation Trust Public Inquiry, 2013).
- **The Dalton Williams review** – following the Mid-Staffordshire public inquiry, the UK Secretary of State for Health commissioned this review of proposals to enhance candour in the NHS (Dalton & Williams, 2014).
- **The Berwick report** – this report was commissioned by the UK Government to undertake a review of patient safety in England. The report highlighted the need for greater honesty, transparency and candour, although it advised against an automatic ‘duty of candour’ (National Advisory Group on the Safety of Patients in England, 2013).

The PM outlines that the policy objective of the duty is to support a consistent response across health and social care providers when there has been an unexpected incident which has resulted in death or harm.

Current Situation

At the moment, NHS Boards are required to implement ‘Learning from adverse events through reporting and review’ (Healthcare Improvement Scotland, 2015). This framework sets out a national approach to identifying, reporting and reviewing adverse events and is drawn from best practice.

In addition, health and social care professionals are ethically required to disclose instances of harm. In 2014, the regulators of health care professionals signed a joint statement on the professional duty of candour. In this, they promised to promote the duty to its registrants and committed to reviewing standards and updating them where necessary in order to strengthen the requirement for openness and honesty (Chief Executives of statutory regulators of healthcare professionals, 2014). Some regulators already have explicit candour requirements in their standards (e.g. General Medical Council and the Nursing and Midwifery Council).

Bill’s Provisions

The Bill proposes to give a duty of candour to ‘responsible person[s]’ who are defined as:

- NHS Boards
- Anyone (other than an individual) contracted by an NHS Board to provide a health service (e.g. GP practice, community pharmacy)
- The Common Services Agency (currently known as National Services Scotland)

- Anyone (other than an individual) providing independent health care services
- A local authority
- Anyone (other than an individual) who provides a care service or a social work service.

In the event that a person in receipt of health, social care or social work services experiences an unintended or unexpected incident which, in the opinion of a registered health professional, results (or could have resulted) in death or harm, the Bill would require the responsible person to implement the duty of candour procedure. The health professional would need to be someone who was not involved in the incident.

The types of harm which would trigger the procedure are set out in the Bill as follows:

- Death
- Severe harm;
- Harm which is not severe but requires further treatment, changes the structure of the person's body, shortens life expectancy or impairs sensory, motor or intellectual functions for at least 28 continuous days,
- Pain or psychological harm lasting at least 28 continuous days, or
- The person requires treatment by a doctor to prevent their death or any of the other outcomes above.

The Bill does not set out what the procedure should be but instead gives Scottish Ministers the power to set this out in regulations. Such regulations may include provisions about (among other things); the notification procedure, the apology to be provided, and the actions which must be taken.

The Bill specifies that any apology given as a result of the duty of candour procedure would not in itself amount to an admission of negligence or a breach of a statutory duty.

The Bill would also require that the responsible person must report annually on the duty of candour. This report would set out information on the number and nature of incidents in which the duty was invoked and any changes to policies and procedures that resulted from the incidents.

Key Issues

Of the 93 submissions to the Committee's call for evidence, 41 commented on the duty of candour. Table 3 shows a breakdown of the responses to the question 'Do you support the proposed duty of candour?'. Not all of the submissions answered the question with a direct 'yes' or 'no' and for these submissions a judgement had to be made by SPICe on the basis of the comments provided.

Table 3: Support for a proposed duty of candour

Response Category	Number (%)
Supportive	24 (58.5%)
Broadly supportive but with some comments/reservations	5 (12%)
Unsupportive	5 (12%)
Broadly unsupportive	2 (5%)
Opinion unclear	5 (12%)

Table 3 shows that the majority of respondents (58.5%) were in favour of the proposed duty and 12% were not.

For those in support of the duty, they generally felt that it would enhance a culture of openness and learning which should improve care.

Those opposed to the duty expressed the following views:

- Legislation is not the way to create a culture of openness and candour
- It is not clear that the legislation is needed as there are already requirements to be candid
- The aim of the provision is best achieved through a supportive approach rather than a punitive approach
- The duty is very broad and could encompass very minor events
- It could be a significant drain on resources and have a large administrative burden

Other key points made by both those in support and opposed to the duty are outlined below.

Harms that would trigger the duty of candour

Many of the submissions had questions about the harms that would trigger the duty of candour procedure. For example, the inclusion of increased treatment time as a harm that would trigger the procedure was mentioned and questions were asked as to whether that would include everyday prioritising and triage of patients. That is, if one patient had to wait longer because they were judged to be less of a priority than another patient, would that be considered a harm under the Bill? Some felt that the inclusion of every near miss or minor event may actually serve to undermine confidence in the service. It was suggested that disclosure should be limited to significant harm. These points were also usually accompanied by concerns that the volume of incidents that would trigger the procedure could place a large administrative burden on services.

Apologies

Many submissions commented on the provision regarding an apology given during the duty of candour procedure. While most that commented welcomed the provision, others questioned how it might be viewed by other regulatory systems such as fitness to practice panels. The Scottish Public Services Ombudsman expressed concern that it would result in apologies only being given in the context of the duty of candour. He called for the provision to be removed and either included in broader legislation or to include all of the public sector. In addition, the Law

Society expressed concern that it potentially duplicates the Compensation Act 2006. Others were concerned that it would lead to apologies being given to the letter of the law, but not in the spirit of the law.

Independent Health Professional

Some respondents questioned the requirement for an independent health professional to provide an opinion on whether or not an incident resulted/could have resulted in any of the harms laid out in the Bill. These submissions wanted to know what the process would be and how that person would be identified. Some felt it more appropriate that it should be someone involved in the person's care as otherwise the responsibility is taken away from the person providing the care. Others questioned why it would have to be a health professional and argued that this would not be appropriate in a social care or social work environment.

PART 3 – ILL-TREATMENT AND WILFUL NEGLIGENCE

Background and Policy Objective

Following the Francis report, the UK Government commissioned a review of patient safety in England. One of the recommendations of this review was that there should be an offence of wilful neglect or ill treatment which is on a par with that covering mental health patients in the UK (National Advisory Group on the Safety of Patients in England, 2013). The relevant provision in Scotland is s315 of the Mental Health (Care and Treatment) (Scotland) Act 2003.

The offence of wilful neglect and ill treatment came in to force in England and Wales earlier this year⁶.

Current Situation

At present, any professional's behaviour judged as constituting ill treatment or wilful neglect could be sanctioned through disciplinary procedures or professional regulation. However, these routes would not lead to criminal sanctions but instead would carry penalties such as suspension or being 'struck off'. However, patients may also be able to seek redress through the civil courts, for example, by pursuing an action for damages. In addition, if a professional carries out an act which constitutes assault, it is possible that the Crown Office could start criminal proceedings.

At an organisational level, existing avenues for protecting service users include the use of regulators such as the Care Inspectorate and Healthcare Improvement Scotland. In terms of legislation which offers routes for redress, this potentially includes the Adult Support and Protection (Scotland) Act 2007 and the Human Rights Act 1998.

Bill's Provisions

The Bill proposes to create new offences of ill-treatment or wilful neglect. There is one offence that would apply to adult health and social care workers and another that would apply to adult health and social care providers. At present, these proposed offences would not cover children's services. However, the Scottish Government has recently consulted on whether the provisions should also apply to children's services with a view to possibly introducing an amendment at stage 2 of the Bill.

⁶ Criminal Justice and Courts Act 2015

Care Worker Offence

A care worker offence would apply to any individual who provides care to another individual and ill-treats or wilfully neglects that individual. Workers covered by the provisions include employees and volunteers providing health and social care, as well as supervisors, managers and directors of provider organisations. It would not cover unpaid/informal carers such as family members. The Bill does not define what constitutes either ill-treatment or wilful neglect. In addition, it does not set a threshold of harm at which point an offence has been committed.

If found guilty of such an offence, the individual would be liable, on summary conviction⁷, to imprisonment for not more than 12 months and/or a fine up to the statutory maximum (currently set at £10,000). Where an individual is convicted on indictment, they would be liable to imprisonment for up to 5 years and/or an unlimited fine.

Care Provider Offence

The care provider offence would cover providers of adult health and social care services, including both statutory providers such as the NHS and local authorities, as well as contractors and voluntary services.

A care provider would commit an offence if:

- An individual providing care for the provider ill-treats or wilfully neglects someone in their care
- The provider organises its service in such a way that it amounts to a gross breach of its duty of care to the individual who has been ill-treated or neglected and, in the absence of that breach, the ill-treatment or neglect would not or would have been less likely to have occurred.

If found guilty of the offence, a court may make, in addition to any other legal remedies, a remedial order and/or a publicity order.

A remedial order would require the care provider to undertake specified actions to remedy any breach of its duties of care, or any deficiency in its policies, systems or practices which have contributed to the breach.

A publicity order would require the care provider to publicise that it had been convicted of such an offence, the details of the case and any sanctions imposed.

Key Issues

Of the 93 submissions to the call for evidence, 40 submissions commented on the proposal to introduce a new criminal offence of wilful neglect or ill treatment. Table 4 shows a breakdown of the responses to the question 'Do you support the proposal to make wilful neglect or ill treatment of patients a criminal offence?'. Not all of the submissions answered the question with a direct 'yes' or 'no' and for these submissions a judgement had to be made by SPICe on the basis of the comments provided.

⁷ Summary procedure is used for less serious offences (with the charges set out in a complaint) and may ultimately lead to a trial before a sheriff or, in justice of the peace courts, before a bench of one or more lay justices. Trials under summary procedure are conducted without a jury.

Table 4: Support for a proposed offence of wilful neglect or ill treatment of patients

Response Category	Number (%)
Supportive	24 (60%)
Broadly supportive but with some comments/reservations	3 (7.5%)
No view	1 (2.5%)
Unsupportive	5 (12.5%)
Broadly unsupportive	1 (2.5%)
Opinion Unclear	6 (15%)

Table 4 shows that the majority of respondents (60%) support the proposed offence and 12.5% oppose it.

Of those who oppose the offence, the most common reason given was that it is not needed due to existing avenues for redress. These submissions felt that the case had not been made that the existing avenues were somehow inadequate or failing. Some also pointed out that the offence which currently relates to mental health patients is required because of their particular vulnerability and diminished capacity. They felt that this is not needed for other patients with capacity.

However, those in support welcomed the proposal and felt that patients with capacity can be just as vulnerable in care settings and may be reluctant to complain due to fear of it affecting the relationship with those looking after them. They felt that the provisions would send a clear message to health and care staff.

There were a variety of other points made by both those in support of the proposal and those opposed to it. These included:

Definition of wilful neglect and ill treatment

Questions were raised in the submissions about what would constitute wilful neglect or ill-treatment. For example; could ill-treatment include genuine errors? Or could wilful neglect include resource allocation decisions like not funding a particular treatment? Some wanted assurances that individuals would not be held accountable for system failures outwith their control. The most common example given was under-staffing. It was suggested that the definitions should reflect the conduct of the offender as opposed to the outcome for the patient.

Undermines the duty of candour

Some submissions felt that the inclusion of the proposed offence alongside the duty of candour is contradictory and could undermine the culture of openness and honesty that is being sought. These submissions were concerned that the offence could perpetuate the blame culture and actually deter people from coming forward and highlighting mistakes.

Inclusion of volunteers and exclusion of unpaid carers.

The Bill would include volunteers within the proposed new offence but it would not include informal/unpaid carers. The approaches to these two groups resulted in mixed opinions. While some welcomed the inclusion of volunteers, others were concerned about the effect it might have on volunteering. In relation to carers, the carers' organisations welcomed that they are not included in the provisions but two submissions specifically called for them to be included.

Children

Of the submissions that mentioned whether or not these provisions should be extended to children, all of them thought that they should. This was usually on the grounds that they could not see why children should not be afforded the same protection as adults.

Publicity orders

Some respondents felt that publicity orders as laid out in the Bill would not add anything and could just lead to a culture of fear. Some thought that they might actually work against the duty of candour and lead to organisations hiding things.

Summary conviction

The use of summary procedure was criticised by a few submissions. These respondents felt that as a conviction is likely to end a person's career it should be triable on indictment only⁸.

⁸ Criminal procedure (ie the procedure for the investigation and prosecution of crime) is divided into solemn and summary procedures. Summary procedure is used for less serious offences (with the charges set out in a complaint) and may ultimately lead to a trial before a sheriff or, in justice of the peace courts, before a bench of one or more lay justices. Trials under summary procedure are conducted without a jury. Solemn procedure involves the most serious of criminal cases and may ultimately lead to a trial on indictment, either before a judge in the High Court or before a sheriff in one of the sheriff courts. Trials under solemn procedure are conducted with a jury.

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