

Consultation Analysis Report: on the Role of a Patient Safety Commissioner for Scotland

December 2021



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Consultation on a Patient Safety Commissioner Role for Scotland: Analysis of Responses - Summary

Scottish Ministers committed, in *Protecting Scotland, Renewing Scotland: The Government's Programme for Scotland 2020-2021*, to establishing the role of a Patient Safety Commissioner. The *Consultation on the Establishment of a Patient Safety Commissioner Role for Scotland* sought the views of the public and other interested parties on what that role should look like; who the Patient Safety Commissioner (PSC) should report to; and how the role should function.

This report provides an analysis of responses to the Scottish Government's consultation on a PSC role for Scotland, which ran from 5 March 2021 to 28 May 2021.

96 responses were received of which 46 responses were from organisations and 50 responses were from individuals. A total of 88 responses were published on the Scottish Government website and all responses are included in the analysis.

Below is a summary of the main responses and themes.

Should the initial focus of the Patient Safety Commissioner be on medicines and medical devices? And in the future?

- Most respondents agreed that the Patient Safety Commissioner role should initially focus only on medicines and medical devices, as recommended in the Cumberlege review. However, it is clear that there is support for the role expanding at some point.
- When the role does expand, it was suggested that the PSC should cover communication; policies, processes and systems such as adverse event reviews; learning; and accountability.
- Specific topics were also mentioned, such as ensuring the safety of healthcare products, or specific conditions such as mesh.
- Other suggestions were that the PSC should focus on patient safety in general terms or that the PSC once established should determine their own priorities.

Independence and accountability

- There was strong support for the role being independent of both the Scottish Government and the NHS, and accountable to the Scottish Parliament.

Existing processes and policies

- A list had been provided within the consultation document setting out some of the policies, processes and pieces of legislation that are already in place to support the patient voice within the healthcare system. The narrative highlighted the fact that it will be important that the PSC does not duplicate what already exists.

There is a varying level of awareness of existing processes and respondents also highlighted the challenges of engaging with these, including: inaccessibility and complexity and/or time consuming nature of many of the processes.

- Lack of awareness or promotion of options for feeding back/complaining.

- Trust issues - patients being dismissed or not believed and a lack of trust or confidence in current systems and processes as not independent.
- Concern about reprisals/anonymity.
- Systems and/or processes seen as tokenistic with no action taken, or patients not given feedback on actions that are taken.
- Agencies not being joined up, so patients have to give the same feedback to numerous agencies.

Main functions and skills of and support for the PSC?

- In terms of functions, the PSC should provide a clear route for patients to express concerns and should listen to and act upon the patients' voice as well as ensuring learning and change happens as an outcome of patients raising concerns. Investigating or intervening in the care and treatment of patients (including holding organisations to account, scrutiny, reporting and monitoring) was also seen as important. There was also an emphasis on the PSC acting quickly as some of the existing processes are seen as taking a long time.
- Some of the skills highlighted were compassion, caring, empathy, lived experience, political acumen; knowledge of the NHS, self-confidence, ability to lead.
- In terms of support, responses highlighted the need for an office system to support the role as well as different kinds of expertise, including analytical, communications, IT, professional, clinical, legal, safety, ethics, equalities and human rights experts.
- Alongside these the PSC will need support and input from other organisations and individuals, particularly patients, as well as sufficient financial resources to ensure that they are able to carry out their role.

Should the PSC role be established in legislation?

- There was strong support for the role being set out in legislation. Reasons given included: to ensure that the PSC has the necessary powers; to protect the role and ensure independence; to provide assurance to patients; and because this is what was recommended in the Cumberlege Review.

Consultation on a Patient Safety Commissioner Role for Scotland: Analysis of Responses

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About this report

This report provides an analysis of responses to the Scottish Government's consultation on a Patient Safety Commissioner (PSC) role for Scotland, which ran from 5 March 2021 to 28 May 2021. We are grateful to everyone who took the time to respond.

The consultation paper can be accessed at <https://consult.gov.scot/healthcare-quality-and-improvement/patient-safety-commissioner-role-for-scotland/>.

It is worth noting that, throughout the analysis, time has been taken to identify trends in the responses where possible and appropriate.

Chapter 1: Introduction

On 8 July 2020 *First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review* (the Cumberlege Review) was published. The review examined how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices, and made recommendations on how to respond to concerns more quickly and effectively in the future.

Although the report focussed on England, the issues covered within it relate to all four of the UK nations, and people from Scotland also gave evidence to the review. The Scottish Government, therefore, accepted all of the recommendations within the report, and agreed to implement them, where it is within devolved competence to do so.

A key recommendation within the report is:

Recommendation 2: The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.

Scottish Ministers committed, in *Protecting Scotland, Renewing Scotland: The Government's Programme for Scotland 2020-2021*, to establishing the role of a PSC. This consultation sought the views of the public and other interested parties on what that role should look like; who the PSC should report to; and how the role should function.

Chapter 2: Overview of responses

A total of 96 responses were received. Of these, 46 were from organisations and 50 were from individuals.

Responding organisations included NHS Boards, Health and Social Care Partnerships, other NHS organisations, health professional bodies, independent and care bodies and patient interest/support groups.

A full list of the organisations that responded can be found at **Annex A**.

88 of the responses have been published, and these can be found at https://consult.gov.scot/healthcare-quality-and-improvement/patient-safety-commissioner-role-for-scotland/consultation/published_select_respondent. The remaining respondents did not want their responses to be published, however all responses have been included in this analysis, irrespective of whether or not they have been published.

The consultation paper included 16 questions, 5 of which were closed, offering specific response options, followed by a free text box for further comments. The remainder of the questions were open, for free text responses only. The full set of questions can be found at **Annex B**.

Chapter 3: Responses on the Patient Safety Commissioner role

The recommendations in 'First Do No Harm' focus specifically on medicines and medical devices, with recommendation 2 stating that 'the Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices'.

There were 2 questions in the consultation document which related to the scope of the PSC role in Scotland, and whether this should expand beyond medicines and medical devices.

This analysis follows the layout of the consultation document.

Question 1: Do you agree that the Patient Safety Commissioner role should first focus on medicines and medical devices, as set out in the Cumberlege Review?

Answer	Organisations	Individuals	Total
Yes	15	30	45
No	12	17	29
Don't Know	3	2	5
Not Answered	16	1	17
Total responses	46	50	96

Most respondents who answered the question (57%) agreed with the proposal, with the main reason being that this is what the Cumberlege review recommended, although other reasons were also given, such as that a narrower scope initially would provide time and opportunity to learn.

For those who answered no (37%) there were a variety of reasons, including that patient safety is broad and cannot be broken up into parts and also that this approach would exclude those individuals who suffer from other conditions.

For both individuals and organisations, more agreed than disagreed.

The organisations who agreed were made up of a mixture of NHS bodies and patient organisations, whereas those who disagreed were almost all those who represented patients.

Question 2: If the role were to expand in the future, which specific aspects of patient safety do you feel the Patient Safety Commissioner should focus on?

This was a free text question and 81 respondents answered. The organisations that responded were again a mixture of NHS bodies and other organisations. All respondents' comments were wide ranging and highlighted communication; policies, processes and systems such as adverse event reviews; learning; and accountability. Some respondents also mentioned specific topics, such as ensuring the safety of healthcare products, or specific conditions such as mesh. Other respondents felt that

the PSC should focus on patient safety in general terms or that the PSC once established should determine their own priorities.

Chapter 4: Responses on independence of the Patient Safety Commissioner

There were 3 questions in the consultation document which related to the independence and accountability of the PSC role in Scotland.

Question 3: Do you believe that the Patient Safety Commissioner should be independent of the Scottish Government?

Answer	Organisations	Individuals	Total
Yes	26	39	65
No	1	3	4
Don't Know	2	7	9
Not Answered	17	1	18
Total	46	50	96

A significant majority of those who responded to this question (83%) believed that the PSC should be independent of the Scottish Government, with some saying it was '*absolutely essential*'. Reasons given for this view included concerns about conflict of interest and political interference and to ensure transparency and impartiality. The organisations that responded and answered yes to this question again were a mixture of NHS bodies and other organisations. The few respondents that were not of this view generally thought that the PSC and Scottish Government would need to have some relationship to each other.

Some respondents answered '**don't know**' to question 3, citing uncertainty about the pros and cons of what 'independent' actually means. One respondent suggested that the role should sit within the Scottish Government but with a representative in every NHS Board.

Other respondents did not choose a particular option, but provided comments nonetheless, such as the need for the PSC to be accountable to someone, whether Scottish Government or not, and also whether it would even be possible for the role to be completely independent of Scottish Government.

Question 4: Do you believe that the Patient Safety Commissioner should be independent of the NHS?

Answer	Organisations	Individuals	Total
Yes	28	40	68
No	2	4	6
Don't Know	0	5	5
Not Answered	16	1	17
Total	46	50	96

Again a significant majority of those who responded to this question (86%) believed that the PSC should be independent of the NHS. Those individuals who responded offered views such as that the PSC would thereby bring a fresh perspective to issues or that the PSC by definition would be investigating the NHS, so needed to be

independent. Others highlighted the fact that their personal experiences did not lead them to trust the NHS, and impartiality and objectivity were recurring themes in the responses.

Again, organisations who responded yes were a mixture of support organisations and NHS bodies. As with individual respondents, impartiality, objectivity and trust were key themes.

'It is important to ensure that the work of the Commissioner is led by patients and their experiences.'

One organisation made the point that the issues under consideration will also cover independent healthcare providers, so will not be restricted to the NHS.

The small number who responded no were a mixture of NHS bodies and individuals and were of the view that the work of the PSC would need to link up with the NHS in some way and would need to have experience and understanding of the issues.

Question 5: Who should the Patient Safety Commissioner be accountable to?

82 respondents answered this question (35 organisations and 47 individuals). This was an open question inviting free text responses. The organisations who responded offered a mix of views, but the majority thought that the PSC should be accountable to the Scottish Parliament, citing the example of other Commissioners such as the Commissioner for Children and Young People or the Prisons Inspectorate. Some felt that it could usefully be aligned to the Scottish Public Services Ombudsman (SPSO) and several made the point that the internal governance of the organisation should include patients.

As with organisational responses, some of those individuals who responded suggested also highlighted accountability to the Scottish Parliament. However those responding as individuals offered a wide variety of views including an independent Board or elected body; patients and the people of Scotland; the Chief Medical Officer; or the Scottish Government.

Chapter 5: Responses on functions of the Patient Safety Commissioner

There were 5 questions in the consultation document which related to the functions and set-up of the PSC in Scotland.

Question 6: How much do you know about existing policies and organisations already in place to support patients' voices to be heard within the healthcare system?

This was a closed question which offered specific response options. A list had been provided within the consultation document setting out some of the policies, processes and pieces of legislation that are already in place. The narrative highlighted the fact that it will be important that the PSC does not duplicate what already exists. The list of policies etc is reproduced at **Annex C** for reference.

The table below sets out the levels of awareness of these and the responses to question 7 below expands on the challenges associated with these existing policies and processes.

Answer	Organisations	Individuals	Total
Not aware at all (I have not heard of any)	2	3	5
Not very aware (I have heard of a few of)	3	14	17
Quite aware (I have heard of most of them)	10	22	32
Very aware (I have heard of all of them)	12	10	22
Not answered	19	1	20
Total	46	50	96

Question 7: In your view, despite the existing ways patients can make their voices heard, why do think people still feel that this is not happening?

55 respondents answered this question (8 organisations and 47 individuals). This was an open question inviting free text responses.

Some of the issues raised were around accessibility or otherwise of the existing systems; the complexity and/or time consuming nature of many of the processes (including issues around difficulties for people with certain conditions which make these processes more inaccessible, or tiring; difficulties for those wrestling with health issues or grief; general difficulties around literacy and health literacy; language barriers; digital exclusion; and finding the processes daunting).

“A lot of them rely on patients taking ownership and being proactive in feeding into a system. A Patient Safety Commissioner's role should be to act on patients' behalf”.

There was also limited awareness or promotion of the options for feeding back and a concern that you might be complaining about the person handling the complaint.

Some respondents felt that they had been dismissed or not believed when they had tried to raise issues. Others expressed lack of trust or confidence in current systems and processes (including concerns that many of these processes are not independent, so not on the side of the patient, or a feeling that there is no point as past complaints have made no impact; concern about professionals closing ranks, lying or covering things up).

Other issues highlighted by respondents were that agencies are not joined up, so patients often have to give the same feedback/complaints to numerous people/agencies. Trends in complaints and feedback are not picked up so systemic issues are not considered - only individual instances of patient concern.

Question 8: In your view, what should the main functions of the Patient Safety Commissioner be?

51 respondents answered this question (6 organisations and 45 individuals). This was an open question inviting free text responses.

Those individuals who responded were clear that the PSC should provide a clear route for patients to express concerns and should listen to and act upon the patients' voice as well as ensuring learning and change happens as an outcome of patients raising concerns. There was also an emphasis on the PSC acting quickly as some of the existing processes are seen as taking a long time.

Investigating or intervening in the care and treatment of patients (including holding organisations to account, scrutiny, reporting and monitoring) was also seen as important.

As well as the above, the responses from organisations were generally of the view that the PSC should be proactive as well as reactive and should investigate patterns and trends of concern. Some responses from NHS bodies suggested that the PSC should work with Boards to improve patient safety and to provide a national platform for learning.

Question 9: What skills and expertise do you think the Patient Safety Commissioner needs to carry out their role?

78 respondents answered this question (32 organisations and 46 individuals). This was an open question inviting free text responses.

There was not a great deal of difference between the responses from individuals and those from organisations, nor amongst organisations between NHS bodies and others. Some of the skills highlighted were compassion, caring, empathy, lived experience, political acumen; knowledge of the NHS, self-confidence, ability to lead and work with others, advocacy expertise.

One respondent was concerned about the suggestion that the PSC could come from a legal background but others were supportive of a legal or clinical background.

There were also some responses from individuals who were of the view that the PSC should **not** come from a clinical background.

A number of responses highlighted the fact that no one individual could meet all the requirements and so it would be necessary for the PSC to be supported by a wider network of experts. This was dealt with further in the following question.

Question 10: What support do you think the Patient Safety Commissioner would need?

70 respondents answered this question (28 organisations and 42 individuals). This was an open question inviting free text responses.

As would be expected there was an extensive list given by respondents of the support the PSC would need. From the responses it was clear that some people envisaged the PSC as being an individual and others envisaged the PSC as being an organisation, either centralised or dispersed across Scotland with representation in different Boards or localities.

Either way, respondents were clear on the need for an office system to support the role as well as different kinds of expertise. The list included analytical, communications, IT, professional, clinical, legal, safety, ethics, equalities and human rights experts. Alongside these the PSC will need support and input from other organisations and individuals, particularly patients, as well as sufficient financial resources to ensure that they are able to carry out their role.

Some respondents also mentioned the need for Parliamentary and political support and backing, which will need to be balanced with the fact that they will be independent.

Chapter 6: Responses on powers of the Patient Safety Commissioner

There was 1 question in the consultation document which related to the powers of the PSC in Scotland. 80 respondents answered this question (31 organisations, 49 individuals). This was a closed question offering specific response options.

Questions 11: Do you think that the Patients Safety Commissioner role should be established in law?

Answer	Organisations	Individuals	Total
Yes	27	43	70
No	0	3	3
Don't Know	4	3	7
Not Answered	15	1	16
Total	46	50	96

'It will get nowhere if it doesn't have a statutory status. Needs to be able to investigate and needs to have powers to ensure improvement'.

The majority (88%) of those who responded to this question were of the view that the PSC role should be established in law.

Organisations and individuals were in agreement on the reasons for this, including: to ensure that the PSC has the necessary powers; to protect the role and ensure independence; to provide assurance to patients; and because this is what was recommended in the Cumberlege Review.

All of those who answered no to this question were individuals and gave different reasons, including a suggestion that the PSC should not be established in law immediately but at a later stage.

One respondent was of the view that it is impossible to legislate for culture change.

Chapter 7: Responses on impact assessments

The remaining questions related to the impact assessments to be carried out on the policy of establishing the Patient Safety Commissioner role in Scotland. All were open questions inviting free text responses.

Question 12: What are your views on how creating a Patient Safety Commissioner might affect the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief and sex?

68 respondents answered this question (30 organisations and 38 individuals).

Respondents were generally of the view that creating the PSC role would have a positive impact on protected characteristics or at least would not have a negative impact.

Question 13: The Fairer Scotland Duty places a legal responsibility on certain public bodies in Scotland to actively consider how they can reduce inequalities caused mainly by people's financial situation. What are your views on how having a Patient Safety Commissioner might affect this inequality?

66 respondents answered this question (27 organisations and 39 individuals). A significant number were of the view that the PSC should have a positive impact on reducing inequalities caused mainly by people's financial situation or would not have a negative impact. However, others were unsure and felt they needed a clearer understanding of the role before being able to comment.

Question 14: If you live in an island community, what are your views on how having a Patient Safety Commissioner might affect access to safe, high-quality public services where you live?

23 respondents answered this question (11 organisations and 12 individuals). A number of those who responded were of the view that the establishment of the PSC would have a positive impact or no negative impact on island communities, whereas others were unsure or felt they could not comment.

Question 15: What are your views on how having a Patient Safety Commissioner might affect respecting, protecting and fulfilling the rights of children and young people as set out in the UN Charter for the Rights of the Child?

57 respondents answered this question (21 organisations and 36 individuals). About half of those who responded were of the view that the PSC would have a positive impact on the rights of children and young people or no negative impact. Other respondents were unsure or commented on the need to consider the relationship between the PSC and the Commissioner for Children and Young People.

Chapter 8: Responses providing final comments

Question 16: Do you have any further comments on the Patient Safety Commissioner role that you haven't covered in your responses to the previous questions?

54 respondents provided further information in response to question 16 (31 organisations and 23 individuals). This was an open question inviting free text responses. Most of the comments have already been reflected elsewhere in this analysis and additional comments are included below.

- Need to ensure the development of the PSC role takes account of proposed changes to the health and social care landscape.
- Set up of the role should not focus solely on Cumberlege recommendations - other inquiries should have a bearing.
- Role needs to look at harm as a result of a lack of knowledge of particular conditions, and prevent this in future.
- Need to clarify how the PSC role relates to existing policies and organisations.
- Consideration should be given to whether the role is actually needed, and how to ensure it does not duplicate other roles.
- Consideration needs to be given to increased workload and resource requirements within NHS as a result of the role (e.g. new reporting, data collection, etc.).
- Need to consider how it is ensured Health Boards are not subject to multiple complaint processes in respect of the same matter.
- Consideration to be given to risk of PSC being asked to consider vexatious or ill-founded complaints.

List of organisations that responded

Aberdeen City Health and Social Care Partnership
Age Scotland
Aortic Dissection Awareness UK & Ireland / Think Aorta
ASAP-NHS
Association of Personal Injury Lawyers (APIL)
Care Inspectorate
Citizens Advice Scotland
Diabetes Scotland
Directors of Pharmacy, NHS Scotland
Epilepsy Scotland
General Dental Council
General Medical Council
General Pharmaceutical Council
Glasgow City Health and Social Care Partnership
Haemophilia Scotland
Healthcare Improvement Scotland (HIS)
Justice for the Innocents
Law Society of Scotland
Marie Curie
#MEAction Scotland
Mental Welfare Commission for Scotland
MJ Reid Ltd
National Pharmacy Association
NHS Ayrshire & Arran (provided 2 responses)
NHS Education for Scotland (NES)
NHS Grampian
NHS Greater Glasgow and Clyde
NHS Highland ADTC Medicines Safety Sub Group
NHS National Services Scotland
PAMIS
Parkinson's UK Scotland
Patient Safety Learning
Professional Standards Authority
Royal College of Physicians of Edinburgh
Royal College of Psychiatrists
Royal College of Surgeons of Edinburgh
Royal National Institute for Blind People (RNIB) Scotland
Royal Pharmaceutical Society
Scottish Ambulance Service
Scottish Public Services Ombudsman
Scottish Women's Convention
The 25% ME Group
The Association of the British Pharmaceutical Industry
The Health and Social Care Alliance Scotland (the ALLIANCE)
The Nursing and Midwifery Council (NMC)

List of questions asked

1. Do you agree that the Patient Safety Commissioner role should first focus on medicines and medical devices, as set out in the Cumberlege Review?
2. If the role were to expand in the future, which specific aspects of patient safety do you feel the Patient Safety Commissioner should focus on?
3. Do you believe that the Patient Safety Commissioner should be independent of the Scottish Government?
4. Do you believe that the Patient Safety Commissioner should be independent of the NHS?
5. Who should the Patient Safety Commissioner be accountable to?
6. How much do you know about existing policies and organisations already in place to support patients' voices to be heard within the healthcare system?
7. In your view, despite the existing ways patients can make their voices heard, why do you think people still feel that this is not happening?
8. In your view, what should the main functions of the Patient Safety Commissioner be?
9. What skills and expertise do you think the Patient Safety Commissioner needs to carry out their role?
10. What support do you think the Patient Safety Commissioner would need?
11. Do you think that the Patient Safety Commissioner role should be established in law?
12. What are your views on how creating a Patient safety Commissioner might affect the protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sex?
13. The Fairer Scotland Duty places a legal responsibility on certain public bodies in Scotland to actively consider how they can reduce inequalities caused mainly by people's financial situation. What are your views on how having a Patient Safety Commissioner might affect this inequality?
14. If you live in an island Community, what are your views on how having a Patient Safety Commissioner might affect access to safe, high-quality public services where you live?
15. What are your views on how having a Patient Safety Commissioner might affect respecting, protecting and fulfilling the rights of children and young people set out in the UN Convention on the Rights of the Child?
16. Do you have any further comments on the Patient Safety Commissioner role that you haven't covered in your responses to the previous questions?

Annex C

Below describes some of the policies, processes, organisations and areas of legislation that aim to support patients' voices in the healthcare system in Scotland.

The Patient Safety Commissioner role will need to add benefit for patients, rather than duplicating what already exists.

Name or title	Description
Patient Rights (Scotland) Act 2011 (see 2 below)	The act aims to improve your experience of using health services and to support you to become more involved in your health and healthcare. It gives you the right to know that the healthcare you receive will consider your needs and what would most benefit your health and wellbeing. It also encourages you to take part in decisions about your health and wellbeing, and gives you the information and support you need to do so. It sets out that NHS bodies should encourage patients to give feedback or comments, or raise concerns or complaints, on healthcare.
Charter of Patient Rights and Responsibilities	Under the Patient Rights (Scotland) Act 2011, Scottish Ministers have published a Charter of Patient Rights and Responsibilities, which summarises the duties of relevant NHS bodies and the behaviour expected from people using services. The charter states that everyone's needs, preferences, culture, beliefs, values and level of understanding will be taken into account and respected when they use NHS services. You have the right to ask those providing your care whether the care they suggest is right for you and if they can suggest any alternatives. The charter also states that you have the right to be given all the information you need about your medicines, any possible side effects, and other options which may be available, in a way you can understand. Also, it states that you have the right to be involved in decisions about your care and treatment, and be able to take an active part in discussions and decisions about your health and treatment.
NHS complaints process	As set out in the Patient Rights (Scotland) Act 2011, you have a right to give feedback on, or to make a complaint about, the care you have received from the NHS, and your NHS Board should encourage you to do so.

	<p>You should make your complaint to the person or organisation that you are complaining about (for example, if it is a complaint about a GP, make your complaint to the surgery). If you do not want to make a direct complaint, or your complaint has not been sorted out, you should contact your local Health Board or Special Health Board.</p>
<p>Scottish Public Services Ombudsman (SPSO)</p>	<p>The SPSO is the final stage for complaints about most devolved public services, including the NHS.</p> <p>If you are unhappy with the Health Board's final decision about your complaint (see above), you can ask the SPSO to review it. The SPSO can look at what your complaint is about and the decisions medical professionals made. They can make recommendations on how individuals' complaints can be resolved and on how systems can be improved.</p> <p>The SPSO is also the complaints standards authority. They have a duty to monitor, share best practice on complaints handling, and set up complaints procedures for organisations, including the NHS, and they must follow these procedures by law. In this role, the SPSO provides support and training for those handling complaints.</p> <p>The SPSO's services are free and independent, and their powers and duties come mainly from the Scottish Public Services Ombudsman Act 2002. The SPSO is a Scottish Parliamentary Supported Body, with the same level of independence as the commissioners mentioned in chapter 3.</p>
<p>Patient Advice and Support Service (PASS)</p>	<p>For help and advice with complaints, you can contact your local PASS.</p> <p>PASS was set up by the Patient Rights (Scotland) Act 2011 to provide advice and support services to patients and other members of the public in relation to the health service.</p> <p>PASS:</p> <ul style="list-style-type: none"> • promotes an awareness and understanding of patients' rights and responsibilities (and in particular, promotes awareness of the Charter of Patient Rights and Responsibilities); • advises and supports people who want to give feedback or comments or raise concerns or complaints about healthcare; • provides information and advice on matters it considers people using the health service would be interested in; and

	<ul style="list-style-type: none"> • makes people aware of and, if appropriate, directs them to: <ul style="list-style-type: none"> • other sources of advice and support; and • those who can represent them (for example, advocates).
Care Opinion	<p>The Care Opinion website allows you to share your experience of health or care services online, and is another way of providing feedback on services provided by the NHS.</p> <p>Care Opinion is a non-profit community-interest company. They read the stories they receive and, where appropriate, publish them on their website. They also try to email relevant staff in the services a copy of the story (if these services are signed up to Care Opinion). Often staff will reply to the stories on the website.</p>
Regulatory bodies	<p>You can complain to the relevant healthcare professional bodies (see 3 below) (for instance, the General Medical Council, General Pharmaceutical Council and Nursing and Midwifery Council) if you have serious concerns about a health or care worker's fitness to practise.</p> <p>These bodies hold the lists of healthcare professionals who are licensed to practise in the UK</p>
Organisational Duty of Candour Procedure	<p>The organisational Duty of Candour legislation (see 4 below) sets out the procedure that organisations providing health services, care services and social work services in Scotland must follow by law when there has been an unintended or unexpected incident that results in death or harm (or further treatment is needed to prevent injury that would result in death or harm). The purpose of the legislation is to make sure that organisations tell those affected that an unintended or unexpected incident has happened, apologise, involve them in meetings about the incident, review what happened so they can find areas that could be improved, and learn from the incident (taking account of the views of relevant people).</p>
Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme	<p>Through the Yellow Card Scheme, patients and members of the public can report a suspected problem with a medicine or medical device to the MHRA.</p> <p>The MHRA regulate medicines, medical devices and blood components for transfusion in the UK.</p>



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