

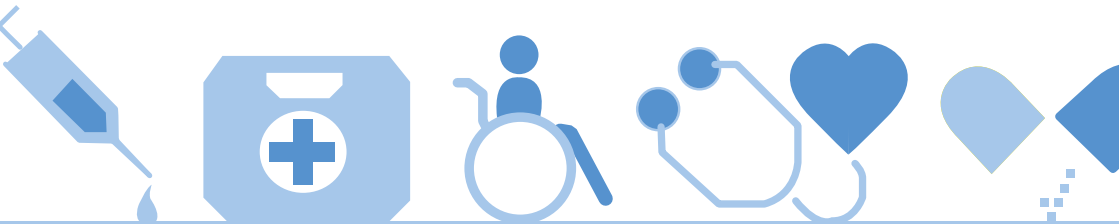


Llywodraeth Cymru
Welsh Government

Putting Things Right

Guidance on dealing with concerns about the NHS from 1 April 2011

Version 4 – May 2023



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Executive Summary

This guidance is produced for the NHS in Wales to enable responsible bodies to effectively handle concerns according to the requirements set out in the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Regulations”).

Please note that all references to regulation numbers relate to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

These Regulations came into force on 1 April 2011 except Part 7, which came into force on 1 April 2012.

This guidance applies to all Health Boards in Wales, NHS Trusts in Wales, Welsh Special Health Authorities¹, independent providers in Wales providing NHS funded care and primary care practitioners in Wales. The Redress elements of the Regulations and the guidance relating to those aspects do not apply to primary care practitioners or to independent providers.

The guidance will assist staff in interpreting the Regulations and provide practical advice on applying best practice at the various stages of handling and investigating a concern.

The term “concern” is used throughout and should be taken to mean any complaint, claim or reported patient safety incident (about NHS treatment or services) to be handled under these arrangements. It also includes concerns which may also trigger the candour procedure as set out in the Duty of Candour Procedure Regulations 2023.

These arrangements represent a significant culture change for the NHS in Wales in the way in which it deals with things that go wrong, introducing a single and consistent method for grading and investigating concerns, as well as more openness and involvement of the person raising the concern. The concept of Redress forms part of the arrangements, with Welsh NHS bodies (Health Boards and NHS Trusts) being placed under a duty to consider when a concern notified contains an allegation that harm has or may have been caused whether they have caused harm to a patient through a

¹ Excluding cross-border Special Health Authorities such as NHS Blood and Transplant

breach in duty of care and if so whether the Redress arrangements set out in Part 6 of the Regulations and explained in Section 7 of the guidance apply.

Finally, the arrangements will play a significant role in improving patient safety and experience, with an explicit requirement to show how services have improved as a result of concerns that have been notified and dealt with under the arrangements.

This guidance will be updated regularly as the new arrangements are embedded. The latest version will always be available at:

NHS Wales complaints and concerns: Putting Things Right.

<https://www.gov.wales/nhs-wales-complaints-and-concerns-putting-things-right>

Section 1 - Introduction

Putting Things Right

1.1 *Putting Things Right* was established to review the existing processes for the raising, investigation of and learning from concerns. Concerns are issues identified from patient safety incidents, complaints and, in respect of Welsh NHS bodies, claims about services provided by a Responsible Body in Wales. The aim is to provide a single, more integrated and supportive process for people to raise concerns which:

- Is easier for people to access;
- People can trust to deliver a fair outcome;
- Recognises a person's individual needs (language, support, etc.);
- Is fair in the way it treats people and staff;
- Makes the best use of time and resources;
- Pitches investigations at the right level of detail for the issue being looked at; and
- Can show that lessons have been learnt.

1.2 The person raising the concern needs to know that they are being listened to and that their concern is being taken seriously. If people feel that staff are not being honest or appear to be covering up the truth, this can often be worse than the original issue. In these instances, people are more likely to resort to legal action to obtain information and

explanations, when there really should be no need for such action.

- 1.3 The way a concern is initially handled can have an impact on everything that happens afterwards, so being open and providing a sympathetic and listening approach may often be all that is needed to satisfy the person raising a concern.
- 1.4 The principles of *Being Open* are at the heart of the Putting Things Right arrangements, and also the Duty of Candour arrangements which go hand in hand with Putting Things Right arrangements, both of which support improvements in the management of concerns.
- 1.5 The benefits of the approach adopted in these arrangements include:
 - Learning from concerns leads to better quality and standard of care;
 - Reduced incidence of similar issues arising again;
 - Improved patient safety;
 - Better experience for people wishing to raise a concern;
 - Reduced number of concerns that are escalated;
 - Better focus of specialist advice;
 - Potential reduction in the cost of legal fees and
 - Increased public confidence in the services provided by the NHS.

For more information about Putting Things Right, the project and principles behind it, visit:

[Intranet Site - Putting Things Right](#)

[Internet - Putting Things Right](#)

- 1.6 From 1 April 2011 the previous NHS complaints procedure set out in the 2003 Directions to Local Health Boards and NHS Trusts in Wales and in the guidance "*Complaints in the NHS – a guide to handling complaints in Wales*", April 2003 should not be used for the handling of concerns.

The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

1.7 The Regulations underpin the new arrangements for the handling of concerns and should be read in conjunction with this guidance. You can access the [Regulations](#) here. Please note that:

- Parts 1 to 6 and 8 to 10 of the Regulations came into force on 1 April 2011.
- Part 7 of the Regulations, which contain provision for the cross-border application of Redress, came into force on 1 April 2012.
- Issues which pre-date 1 April 2011 but which have never been notified to an NHS organisation, may be handled under the new arrangements so long as they are not excluded for any reason (e.g. because they are out of time).

1.8 Regulation 2 sets out the various definitions of the terms used throughout the Regulations. As of April 2023, the Regulations and, therefore, the Guidance also apply to Special Health Authorities in Wales.² However, with respect to Health Improvement and Education Wales (“HEIW”), which is a Wales-only Special Health Authority, the application of the Regulations is limited to the provision of health care by that body.

1.9 We would encourage responsible bodies to read these definitions carefully, and would draw your attention to the following definitions in particular as this is important in gaining an understanding of where and when the arrangements apply:

“Responsible Body” is defined as a Welsh NHS body, a primary care provider or an independent provider;

“Welsh NHS body” is defined as a local health board or NHS trust managing a hospital or other establishment or facility wholly or mainly in Wales and a Special Health Authority (but does not include any cross-border Special Health Authority);

“primary care provider” is defined fully in the Regulations and essentially covers general practitioners; dentists; persons providing ophthalmic services and pharmacists who provide services under arrangements with local health boards.

² Excluding cross-border Special Health Authorities such as NHS Blood and Transplant

“independent provider” means a person or body who (a) provides health care in Wales under arrangements with a Welsh NHS body and (b) is not an NHS body or a primary care provider.

1.10 All of the Regulations apply to Responsible Bodies except Parts 6 and 7 relating to Redress, which only apply to Welsh NHS bodies. Certain Regulations within Part 7 also place obligations on English NHS bodies.

1.11 The Regulations support the process of managing and investigating concerns by ensuring:

- There is a common method of investigating concerns which is proportionate to the issue raised;
- The person raising the concern is properly and appropriately supported, for example, through access to advocacy support at all stages of the process, both from Llais (Citizen Voice Body for Health and Social Care, Wales) and more specialist advocacy services where needed;
- People receive a prompt acknowledgement and a timely response to their concern;
- Concerns are dealt with openly and honestly;
- Concerns are consistently, thoroughly and appropriately investigated;
- People receive a detailed response including clarity about next steps and actions to address their concern;
- Responsible bodies in dealing with concerns, consider how they will investigate and respond to concerns and, in the case of Welsh NHS bodies, consider, in accordance with Regulation 23(i) of the Regulations, the likelihood of a qualifying liability arising and the potential application of the Redress arrangements;
- People are properly informed in relation to any offer of Redress made or if, on investigation, it is determined that there is no qualifying liability, the refusal to make an offer;
- Arrangements are in place for Redress where care is provided by NHS bodies in England, Scotland or Northern Ireland on behalf of the Welsh NHS bodies;
- Welsh NHS bodies provide free specialist legal advice for people where it is considered there is or may be a qualifying liability for which Redress may be available i.e.

in respect of cases where it is estimated that the general damages and special damages that could be awarded would, in total, be £25,000 or less;

- Responsible bodies demonstrate that learning and improvements have resulted from the process; and
- Where a person remains dissatisfied with the outcome of the investigation of a concern, they can refer to the Public Services Ombudsman for Wales.

Concerns dealt with at the point of service delivery (“early resolution”)

1.12 There are some concerns which will not be handled under the new arrangements. These are listed at paragraph 5.13 below and are set out in Regulation 14. This includes any concerns which have been resolved to the satisfaction of the person who notified the concern by the end of the next working day, (previously this only included concerns notified verbally). We refer to these concerns as having been dealt with “early resolution”. In many cases, these sorts of concerns relate to relatively easy to address issues and the person who raised the concern must be satisfied with the immediate actions agreed in order to remedy the concern raised. It is important for staff to check if the person is happy because if they are not, then they should be advised to raise a concern formally under the arrangements set out in the Regulations and this guidance.

1.13 Where a concern has been satisfactorily dealt with “early resolution”, as is often the case now, the mechanisms for capturing this information will currently vary between organisations. Simple arrangements will need to be put in place within organisations to allow operational staff easy access to recording information in a timely manner. A suggested template for recording a concern that has been satisfactorily dealt with “early resolution” is attached at [Appendix A](#). Organisations should have local arrangements in place to ensure themes and lessons can be drawn from this process to facilitate shared learning.

1.14 Any queries relating to the Regulations or any matter in this guidance may be addressed to the Putting Things Right

Section 2 - Organisational arrangements

- 2.1 Responsible bodies are required to have in place organisational arrangements that meet the requirements of the Regulations. Responsible bodies are required to have in place a structure to reflect an integrated approach to dealing with concerns, led by a Senior Investigation Manager, reporting to a Responsible Officer (who in accordance with Regulation 7 is required to be an executive director or officer; chief executive officer; sole proprietor or partner, depending on the nature of the Responsible Body).

Strategic Oversight

- 2.2 Within responsible bodies, an individual must be charged with keeping an overview on how the organisation's arrangements are operating at a local level and ensuring that they comply with the management of concerns as outlined within the Regulations. In the case of a local health board or a NHS trust, this will be an independent member of the board. For other responsible bodies, another equivalent person as appropriate may be designated to this role.

Responsible Officer

- 2.3 Each Responsible Body must designate an individual as Responsible Officer who is charged with overseeing the day to day management of these arrangements and ensuring that they operate in an integrated manner. In the case of a local health board or a NHS trust, this will be an executive director/officer. For other responsible bodies, this individual could be the chief executive officer (CEO) or a sole proprietor of an organisation, a partner or person in charge of, or responsible for, the management of that organisation.
- 2.4 The Responsible Officer ensures arrangements are in place to:

- deal with concerns in line with the Regulations;
- (in the case of a Welsh NHS body) allow for the consideration of qualifying liabilities; and
- provide for incidents, complaints and claims to be dealt with under a single governance arrangement.

2.5 The responsibilities of the Responsible Officer can be delegated to another authorised person for operational purposes; however, the Responsible Officer remains the accountable person in any situation.

Senior Investigations Manager

2.6 The actual handling and consideration of concerns in accordance with the Regulations will be the responsibility of the Senior Investigations Manager³ (this role may be known as another job title within your organisation, or there may be more than one person occupying this role). As well as the handling and consideration of concerns under the Regulations, part of the Senior Investigations Manager's role will require them to undertake other functions in relation to dealing with concerns and to co-operate with other persons or responsible bodies, e.g. primary care providers, to facilitate the handling and investigation of concerns. This role will be supported by additional suitably trained staff as part of the integrated arrangements.

2.7 The responsibilities of the Senior Investigations Manager can be delegated to an authorised person to act on their behalf. The role can also be undertaken by a counterpart in another Responsible Body as agreed by both the Responsible Body and the other organisation, e.g. independent provider or primary care provider.

2.8 A template of the Senior Investigations Manager's job description is attached at [Appendix B](#).

Concerns Team

2.9 At a local level within NHS organisations, the people involved in the handling of concerns as described at 2.6 above may be

³ Senior Investigations Manager is the term used in the Regulations but operationally this could be a Senior officer or Investigation Manager

referred to as the central 'concerns team', although organisations may choose to use a different name. This team of people will work with a range of other managers and administration staff throughout the organisation. These members of staff will assist in investigations as required under the overall direction of the concerns team.

All Staff

- 2.10 The Senior Investigations Manager should ensure that staff throughout the organisation know who to contact in the concerns team, as they will be a useful point for support or advice when dealing with concerns, particularly those raised on the ward or in clinics, etc.
- 2.11 In addition, any member of staff can raise a concern in accordance with the Regulations, and they should be made aware of their organisation's local policies and procedures so that they know what to do.

Section 3 - Organisational Development and Training

- 3.1 Staff at all levels within responsible bodies and across all areas of work must receive appropriate training to enable them to comply with the Regulations. This will require staffing levels and skills suitable to both conduct and oversee robust and appropriate investigations as well as (in the case of Welsh NHS bodies) to be able to consider issues such as liability and settlement of claims in appropriate cases where the Redress arrangements are engaged. Training should be provided following local training needs analysis and in accordance with training strategies. The level of training required by individual staff will need to be arranged according to their specific roles and responsibilities. Refresher training needs of staff must be determined at a local level and based on local training needs analysis.
- 3.2 It is envisaged that the delivery of training for the new arrangements will be approached locally and through a selection of national training resources, where applicable. These include:

- *PowerPoint* presentations;
 - digital stories;
 - use of training videos and
 - classroom and e-learning methods.
- 3.3. The mix of training methods will be decided locally, although many of the materials on which to base local sessions have been provided on an all-Wales basis either via the Putting Things Right e-learning training on learning@NHS.Wales.uk or the [Patient Safety Wales website](#).
- 3.4. This training may feature as part of existing organisational training and development programmes, including induction, and be linked to the NHS Knowledge and Skills Framework.
- 3.5. Examples of training which are of relevance to the Putting Things Right arrangements include:
- Customer Care;
 - Communication;
 - Duty of Candour training
 - Records Management;
 - [NPSA-RCA Training](#) – (which includes tools for proportionate investigations as well as comprehensive investigation);
 - [How to learn lessons from concerns](#) (Patient Safety Wales);
 - [NPSA - Being Open](#);
 - [1000 Lives Plus - Being Open](#);
 - [Legal training/awareness - L&RS presentation](#);
 - [Putting Things Right e-learning training](#) (See your Senior Investigations Manager for enrolment key);
 - Safeguarding Children and Vulnerable Adults;
 - Sensory awareness - Links to [RNIB](#) or [Action Hearing Loss](#);
 - Equality and diversity.
- 3.6 In accordance with the Duty of Candour Procedure (Wales) Regulations 2023, staff will also undergo relevant training to ensure they are aware of and are able to implement the requirements of the duty of candour. The training is graded: ranging from all staff basic training to more detailed training for staff who manage concerns. See further in the

statutory guidance for the duty of candour for more information on the training requirements.

- 3.7 For further information on training, contact your organisational lead for training and development.

Section 4 - General Principles and Requirements

Principles that apply to the handling of concerns

- 4.1 Regulation 3 covers the general principles for handling and investigating concerns. Responsible bodies must not disclose personal data to persons who are not the data subject (unless that person is a representative of the data subject). “Data subject” and “personal data” have the same meaning as in the Data Protection Act 2018 (see section 3 of that Act).”
- 4.2 Any local arrangements set up under the Regulations must ensure that the following principles are applied to the management and investigation of concerns. Most of these areas are covered in more detail later in the guidance. A person should:

Be able to notify their concern through a single point of entry

- 4.3 This means that however the concern is notified it will be directed to the same place for initial handling. The Responsible Body should provide a single postal address, phone number, e-mail address, fax and text numbers for contact and publicise these.

Have their concern dealt with efficiently and openly

- 4.4 This means that people should not have to chase organisations for answers or be left waiting for long periods of time without contact. It also places a requirement on responsible bodies to be open and proactive in their approach.

Have their concern investigated properly and appropriately

- 4.5 This general requirement means that responsible bodies should take a reasoned and appropriate approach to the investigation of concerns, remembering that not all issues will

require the same level of investigation. However, it must also be remembered that what might seem like a trivial or unimportant matter to one person is of great significance to another. The handling of the concern needs to be sensitive to this and dealt with appropriately.

Have their expectations and involvement in the process established early on

- 4.6 The way that people are treated at the outset can set the tone for the whole investigation. It is also important that people do not develop unreasonable expectations about what the process might deliver. It is therefore essential that some of these issues are covered in the early stages following the receipt of any concern.

Be treated with respect and courtesy

- 4.7 People raising concerns should be treated with respect as a matter of course. Recent reports, such as those published by the Patients Association and the Older People's Commissioner for Wales have highlighted cases where issues of dignity have been the main matters of concern (see also paragraph 4.32 below on Safeguarding). Families who are worried about their loved ones in such situations can understandably become very upset and matters can quickly escalate. In these situations, particularly in a clinical setting, it can be difficult to contain the situation and staff could find themselves either responding angrily or refusing to discuss the matter. This needs to be avoided at all costs and help can be sought from the concerns team if necessary.

- 4.8 Whilst NHS staff should not have to accept or put up with unreasonable behaviour, attempts should always be made to understand why someone is behaving in a particular way, for example, because they have been bereaved and/or they are angry about what happened.

Be given advice on the availability of assistance to pursue their concern, and where they may obtain it

- 4.9 People who raise concerns should be told about the availability of advocacy services through Llais (Citizen Voice Body) in Wales. Llais advocates can provide support and

guidance to people raising concerns and can also signpost them to more specialist advocacy services if necessary.

- 4.10 For members of staff who raise concerns or who are the subject of concerns, organisations will need to consider what level of support they might need. Staff might feel anxious about having raised a concern and might need reassurance and support as the investigation progresses. This is also true of staff who have been complained about or involved in an incident. This should be addressed clearly at the start, involving the person's line manager.
- 4.11 Where the duty of candour is triggered in relation to the concern, patients (or their representative) should be provided with details of any services or support which the responsible body reasonably considers may provide assistance to them, taking into account their needs. For further information on the duty of candour, see the statutory guidance.

Have a named contact throughout the handling of the concern and know how to contact that person

- 4.12 This is one of the ways in which a Welsh NHS body can be seen as more approachable, and should minimise people's annoyance at being passed around. This should also encourage a "caseload" approach to investigations within organisations. The contact should be someone who can be obtained easily and arrangements should be made for cover if the person is away from the office.
- 4.13 Where the duty of candour is triggered in relation to the concern, patients (or their representative) should be provided with the name and contact details of the person nominated as the point of contact in respect of the candour procedure. For further information on the duty of candour, see the statutory guidance.

If an investigation reveals that there is a qualifying liability, the Welsh NHS body must give consideration to the application of the Redress arrangements

- 4.14 This is covered in more detail at Section 7 on [Redress](#). However, this general requirement provides that Welsh NHS bodies should, when investigating concerns that have been

notified in accordance with the Regulations, be proactive in considering whether there may have been harm caused through the fault of the organisation. In particular, if it has been alleged in the initial expression of concern that harm has or may have been caused, then the Welsh NHS body is under a duty to consider whether a qualifying liability exists and the whether the Redress arrangements set out in Part 6 of the Regulations apply. This is covered specifically at Regulation 23(1)(i).

Receive a timely and appropriate response to their concern and be kept informed if there is a delay

4.15 In the majority of cases, concerns should be acknowledged within 5 working days and responded to within 30 working days ‘beginning on the day upon which it received notification of the concern’. Where the duty of candour applies, ‘the day upon which it received notification of the concern’ equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

4.16 Responsible Bodies may have longer than 30 working days to respond if this proves necessary. However, in any case where there might be a delay, then an explanation must be provided to the person raising the concern in accordance with the Regulations.

Be informed of the outcome of the investigation

4.17 Anyone raising a concern under these arrangements must receive an appropriate response which sets out what was investigated and what that investigation found.

4.18 Similarly, when the candour procedure applies, the patient (or their representative) should be informed of the outcome of such investigations.

Be assured that appropriate action has been taken as a result of raising their concern and lessons learnt

4.19 The need to know that lessons have been learnt and that other people will not go through the same experience is what drives many people to raise a concern in the first place. It is therefore essential that information about this is set out clearly in the response. Vague phrases such as “you can be

certain that lessons have been learnt” are not acceptable. Actions should be meaningful and expressed in plain language so that people can understand what is being done.

Have their concern managed and investigated in line with guidance issued by Welsh Ministers

4.20 This ensures a consistency of approach to the handling of concerns across Wales, so that people will know that they are not being treated differently depending on where they live.

Providing Information widely and in accessible ways

4.21 Under these arrangements responsible bodies must put in place systems and processes to receive, manage, investigate and respond to concerns. Organisational policies and procedures will specify local arrangements for dealing with concerns in accordance with the Regulations. To take account of the needs of individuals when handling and investigating concerns, organisations must publish and display information:

- In a variety of formats e.g. leaflets, posters, websites;
- Free of charge;
- In English and Welsh;
- In other languages as required;
- In other formats as required e.g. Braille, large print, audio, Easy Read, child-friendly, etc.

4.22 Bilingual (English and Welsh) posters and leaflets entitled *Putting Things Right - Raising a concern about the NHS from 1 April 2011* must be displayed in public areas detailing how people can raise a concern. Leaflets should also be provided on request to individuals when they raise a concern.

4.23 A stock of leaflets and posters are maintained by the individual Concerns Teams as personalised PDF leaflets have now been provided for each Welsh NHS Body.

4.24 To access the generic leaflet in a variety of formats see the [Putting Things Right website](#).

Equality and diversity

- 4.25 Consideration must also be given to reaching other members of the community who may wish to raise a concern, but who might feel the process is not accessible to them. Staff should develop an understanding of why people might be reluctant to raise a concern, including some of the cultural, social, gender and other reasons, and look for ways to assure people that it is safe for them to do so.
- 4.26 We would refer organisations to the Welsh Government's Equality Impact Assessment document, which highlights the sorts of issues that might act as barriers to people raising a concern, asking that awareness of these issues is raised amongst staff.
- 4.27 It is worth mentioning in particular the many thousands of people in Wales who may have hearing or sight loss and the difficulties they often encounter in their dealings with the health service. One in five people in Wales have some form of sensory loss and these numbers are set to increase as people live longer. People with sensory loss may miss crucial information about their healthcare because information has not been communicated to them effectively and this can lead to them being put at risk and concerns being raised. Much of this could be averted altogether by better communication and by making suitable adjustments to cater for the needs of people with sensory loss. Welsh NHS bodies should ensure that staff are familiar with the barriers faced by people with sensory loss. When concerns are raised, then people should be provided with information in the format they need and also should be offered support as appropriate.

Welsh Language

- 4.28 When dealing with concerns, organisations need to take account of their statutory duties in relation to the provision of services in Welsh. NHS organisations' Welsh Language Schemes should explain what services are offered in Welsh and normally, people can expect to receive certain services in Welsh, such as:

- Telephone services;
- Face to face services;
- Letters;
- Forms;
- Websites and interactive services;
- Public meetings.

4.29 In a health setting, concerns relating to the Welsh Language may be about the provision of health services (for example, that a particular service has not been provided through the medium of Welsh and therefore the person's needs have not been met) or about whether the organisation has complied with its Welsh Language Scheme. Both can be handled under the Regulations.

4.30 It is important that in cases where the Welsh Language is a significant part of the concern that people are advised that as well as the Public Services Ombudsman for Wales, they can take their concern to the Welsh Language Commissioner if they remain unhappy.

4.31 When issuing a response to an individual regarding a concern about the Welsh Language, the following text should be included:

[Name of organisation] has agreed on a statutory Welsh language scheme with the Welsh language Commissioner. If you are still dissatisfied following our enquiries and response, you can refer your concern to the attention of the Welsh Language Commissioner or the Public Services Ombudsman for Wales [insert address/e-mail].

4.32 Staff should be additionally sensitive to the requirements of first language Welsh speakers in the handling of their concerns and arrangements should be in place to ensure that they are able to raise their concerns, discuss them with Welsh speaking members of staff and receive a response in Welsh.

Using Interpreters and communication support

- 4.33 Where there is limited availability of interpreters or communication support assistants in a particular area, Welsh NHS bodies should be aware that it might be the case that the interpreter may be known to the person who raised the concern. This could make discussion of confidential health matters very difficult.
- 4.34 Where a person expresses the need for an interpreter or communication support, the NHS organisation should inform the person of the interpreter's name as soon as possible, so that any conflicts of interest can be identified, and an alternative interpreter made available where possible.

Accessing Advice and Support

- 4.35 When information is provided, it must include details about key sources of advice and support, such as:
- Advocacy assistance from Llais (Citizen Voice Body) – this is available to anyone over the age of 18 wishing to raise a concern;
 - Specialist advice and advocacy for people with mental health problems or who lack capacity – this is available for specific issues relating to services provided to people in these groups;
 - Advocacy support for children and young people who wish to raise a concern – this is arranged by local health boards in accordance with the Welsh Government's 'Model for Delivering Advocacy Services to Children and Young People in Wales'. Directions have been issued to Local Health Boards to require them to make these arrangements.
- 4.36 A list of advocacy contacts in Wales can be found at Appendix D.

Safeguarding

Section 5 - Raising a concern

- 4.37 Safeguarding

- 4.38 The Wales Safeguarding Procedures for children and adults at risk of abuse and neglect detail the essential roles and responsibilities for practitioners to ensure that they safeguard children and adults who are at risk of abuse and neglect
- 4.39 All practitioners should be aware of the definitions of abuse and neglect in the Social Services and Well-being Act (Wales) 2014⁴
- 4.40 Organisational policy and guidance should provide practitioners with local information and access to support to carry out their duties under the [Social Services and Wellbeing \(Wales\) Act 2014](#) and statutory safeguarding guidance [Working Together to Safeguard People](#).
- 4.41 There is a statutory duty to report to the local authority or police any concerns that a child under 18 or an adult-at-risk is, or is at risk of abuse, neglect or other kinds of harm. Managing immediate safety risks must also be included. Junior colleagues may seek advice from their managers or their corporate safeguarding teams. Safeguarding incidents occur out of hours and there must be a recognition of how to escalate safeguarding incidents within organisations and to emergency duty teams within local authorities.
- 4.42 The Social Services and Well-being (Wales) Act 2014 s.128, specifies the duty placed on ‘relevant partners’ under section 162 of that Act to report both adults and children, including unborn children, where they have reasonable cause to suspect are at risk of abuse.
- 4.43 Agencies that are not included as ‘relevant partners’ above are still expected to report any safeguarding concerns in the same way as those with a specific duty to report.
- 4.44 It is important that practitioners do not ignore or dismiss suspicions about another practitioner or colleague who may be abusing, neglecting, or causing harm to a child or adult at risk.

⁴ <https://www.legislation.gov.uk/anaw/2014/4/section/197/enacted>

- 4.45 Every practitioner has a responsibility to safeguard adults and children at risk and that includes protection from abuse by a professional, paid carer or volunteer. Therefore, the duty to report any concerns about suspected abuse and neglect applies in these situations. This duty also covers situations when abuse is only suspected.
- 4.46 Practitioners are expected to report to the relevant local authority (social services) for both adults and children at risk. The relevant authority is the one in which the safeguarding concern is thought to have occurred. This may mean reporting to a local authority that is not in the same area as that in which the practitioner works.
- 4.47 The provision of training for Practitioners is crucial to determine the most effective way in which to safeguard an adult or child at risk. Practitioners should be aware of the different stages of the safeguarding process:
- identification of the concern;
 - gathering information;
 - assessment and analysis of early help, care and support or care and support protection needs;
 - decision-making and planning the most appropriate intervention;
 - actions and interventions
 - evaluating effectiveness of the actions and interventions.
- 4.48 Practitioners are bound to follow the Wales Safeguarding Procedures which details the roles and responsibilities of practitioners and relevant bodies regarding planning and delivering interventions and escalation to meet the care and support, protection needs of an adult and child at risk.
- 4.49 Where there is any uncertainty as to whether a Putting Things Right investigation should be commenced, legal advice should be sought from Legal & Risk Services.
- 4.50 NHS bodies have a legal duty to ensure that their functions are discharged having regard to safeguard and promote the welfare of children and adults-at risk. Detailed arrangements for protecting children and adults-at-risk are set out in the Wales Safeguarding Procedures, and Working Together to Safeguard People

Suggested Resources

The Social Services and Well-Being (Wales) Act 2014

<https://www.legislation.gov.uk/anaw/2014/4/contents/enacted>

Working Together to Safeguard People Volume 1 – Introduction and Overview

<https://www.gov.wales/safeguarding-people-introduction>

Working Together to Safeguard People Volume 5 – Handling Individual Cases to Protect Children at Risk

<https://www.gov.wales/safeguarding-children-risk-abuse-or-neglect>

Working Together to Safeguard People Volume 6 – Handling Individual Cases to Protect Adults at Risk

<https://www.gov.wales/safeguarding-adults-risk-abuse-or-neglect>

Wales Safeguarding Procedures

<https://safeguarding.wales/en/>

How a concern can be raised

- 5.1 The single address, phone number, mailbox, text service for raising a concern must be clearly publicised within NHS organisations.
- 5.2 People can raise concerns in a variety of ways to any member of staff employed by the Responsible Body in the provision of health care services:
 - In writing (by letter, on a concern form);
 - Electronically (by e-mail or text);
 - Verbally (by telephone or in person).
- 5.3 Where a concern is raised verbally, for example, because the person cannot or does not wish to put matters in writing, then the details of the concern must be recorded by a member of the concerns team or the person who deals with concerns before going on to being considered under the Regulations. A copy of the written record of the concern must be given to the person who notified the concern. If the person who raises the concern verbally does so in Welsh, the copy of the written record of the concern given to this individual should be provided in Welsh. An example template for recording concerns that have been made verbally can be found at [Appendix E](#). This template can also be adapted and included when posting out the Putting Things Right leaflet, to aid the person raising a concern as to what they need to let the Welsh NHS body know.
- 5.4 Local policies and procedures on record keeping and management of records should be adhered to all times.

Record keeping is fundamental to the effective handling and investigation of concerns and where records exist, they must be accurate, complete, understandable and contemporaneous in accordance with professional standards and guidance.

5.5 Where the duty of candour applies in relation to a concern, regulation 9 the Duty of Candour Procedure (Wales) Regulations 2023 requires NHS bodies, to whom those regulations apply, to keep an accurate written record for each notifiable adverse outcome in respect of which the candour procedure is followed. The written record must include every document and piece of correspondence relating to the notifiable adverse outcome, including but not limited to:

- the notification of the duty;
- attempts to contact the service user/person acting on their behalf.
- any decision by the service user/person acting on their behalf not to be contacted in relation to the duty of candour; and
- all documentation relating to the investigation of the and review of the notifiable adverse outcome, that is undertaken by the NHS body, giving rise to the triggering of the duty, including the response or interim report issued under regulations 24, 26 or 31 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

5.6 Where it is decided that a concern does not trigger the duty of candour, it is considered good practice to record the reasons why that decision was taken. It is important that accurate records are kept supporting quality assurance mechanisms needed to identify areas for learning and improvement and also to enable NHS bodies to comply with their reporting requirements under the Act which are considered in Chapter 4 of the statutory guidance on duty of candour.

5.7 It is envisaged that the Datix Cymru system will be utilised for the purposes of reporting and recording keeping of all concerns and patient safety incidents.

Who can raise a concern

5.8 Almost anyone can raise a concern and the Responsible Body will be under a duty to consider whether it can be investigated. However, it might not always be possible to share the full details of the investigation with the person raising the concern, for instance, if they are not the patient or not their next of kin and would otherwise contravene the UK GDPR.

5.9 As set out in Regulation 12, concerns can be raised by:

- a service user/ patient who is receiving or has received services from a responsible body;
- people affected or likely to be affected by the actions, errors or decisions of the Responsible Body;
- staff members of responsible bodies;
- independent member (non-executive director or non-officer) of a NHS body;
- partners, e.g. a partner in a GP practice;
- a representative acting on behalf of a person who is unable to raise a concern e.g. a young child or someone who lacks capacity to act on their own behalf; or because that person wants someone else to represent them.
- a representative on behalf of a person who has died.

Concerns raised by a representative

5.10 Where a representative is acting on behalf of another e.g. a child or someone who lacks capacity, if there are reasonable grounds to conclude that they are not suitable to act on the behalf of the service user, for example because it does not appear to be in the patient's best interests, then they must be advised of this in writing. However, even where the Responsible Body has made a decision that the third party is not a suitable person to act on behalf of someone else, it may still choose to investigate the concern – in particular, regard must be had to safeguarding issues as highlighted at paragraph 4.32 above. In this instance they are under no obligation to provide a detailed response to the person who raised the concern unless it is reasonable to do so.

Concerns raised by or about children and young people

- 5.11 Where a concern is notified by a child or young person, he or she must be reasonably supported and assisted to pursue their concern. There may be a need for specialist advocacy to be offered to assist the child or young person and this should be arranged in accordance with the Welsh Government's *'Model for Delivering Advocacy Services to Children and Young People in Wales'* as outlined in paragraph 4.30 above.
- 5.12 In many cases, someone else (parent/carer/guardian) will raise a concern on behalf of a child or young person. This does not remove the right of the child or young person to take the concern forward themselves, with support. The Responsible Body should therefore satisfy itself as to whether the child or young person wishes to raise a concern themselves, with assistance or if they are happy for the person who raised the concern to represent them. If the child or young person is not willing to allow the concern to be investigated, then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Once again, particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so.

Concerns raised by prisoners

- 5.13 Prisoners have access to the same quality and range of healthcare services as the general public receives from the NHS in Wales. Where a prisoner raises a concern, the Responsible Body must handle and investigate the concern in the same way as it does for anyone else. Prisoners will also have access to the advocacy services provided by Llais (Citizen Voice Body) however this does not in any way affect the prisoner's right to raise a concern at any stage with the Independent Monitoring Board.

Concerns raised by staff

- 5.14 These arrangements may be used by members of staff who wish to report (e.g. via an incident report form) that something

has gone wrong with care or treatment provided to a patient or patients, with a view to learning lessons. This is not the same as reporting concerns about another member of staff in terms of suspected wrongdoing, criminal activity or unprofessional behaviour which still need to be dealt with via organisations' local "staff raising concerns or speaking up" policies and procedures.

5.15 Where a concern is notified by a member of staff and initial investigation determines that there has been moderate or severe harm or death, the patient (or their representative) must be:

- notified of the concern unless they have already been notified under Regulation 4(1) of the Duty of Candour Regulations; and
- Involved in the investigation of the concern unless it is not in their interests to be involved under Regulation 12(8) of the Regulations.

What people can raise as concerns under these arrangements

5.16 . Concerns can be notified to:

- a Welsh NHS body ⁵ about any matter connected with the exercise of its functions.
- a primary care provider about the provision of services under arrangements (i.e. such as a contract) with a Welsh NHS body.
- an independent provider about the provision of services that are under arrangements with a Welsh NHS body.
- a Local Health Board about any matter connected with the provision of services by a primary care provider under a contract or arrangements with the Local Health Board.

There are however a number of types of concerns which are excluded from consideration under the Regulations and are described in paragraph 5.14 below.

⁵ A Welsh NHS body is defined as a Local Health Board, an NHS Trust or a Special Health Authority (excluding cross-border Special Health Authorities).

What people cannot raise as concerns under these arrangements

5.17 Not all concerns can be dealt with under the arrangements for dealing with concerns. Matters excluded are set out at Regulation 14 and are:

- Concerns notified by a primary care provider relating to a primary care provider's contract or arrangements under which they provide primary care services - these issues are dealt with through different mechanisms relating to the Regulations covering primary care;
- Concerns where a member of staff has an issue with their employment contract – these matters would be dealt with under the organisation's HR policies and procedures;
- Where the concern is being or has been investigated by the Public Services Ombudsman for Wales; except where the Public Service Ombudsman for Wales recommends following their investigation that a Responsible Body considers the concern for redress.
- Where the Responsible Body has not complied with the Freedom of Information (FOI) Act 2000 – such concerns would be dealt with by the Information Commissioner's Office;
- Disciplinary proceedings identified as a result of the investigation – these would be looked at under local HR processes;
- any concern resolved to the satisfaction of the person who notified it by the end of the next working day after the day on which it was notified
- Where someone tries to re-open the same concern that they have already agreed was dealt with satisfactorily "early resolution" – unless an organisation considers it needs to look into the issue again and then it must follow the process for handling and investigation of concerns;
- Where the concern has already been investigated under the previous complaints procedure, that is, complaints that were reported pre 1 April 2011 and concerns that have already been considered under the Regulations;
- Concerns which are the subject of civil proceedings, including the pre-action stage of those proceedings. If court proceedings are issued when a concern is already

under investigation in accordance with the Regulations, all further investigation of the concern must stop.

- Where a concern relates to an individual patient funding treatment request, that is, requests for funding of services not usually provided on the NHS in Wales – these concerns will be dealt with under a separate all-Wales process for decision and review.
- Where the responsible body is Health Education and Improvement Wales, a concern which does not relate to the provision of health care by that body

5.18 With the exception of a concern that has been resolved “early resolution”, if the concern is excluded from the arrangements as indicated above, the person who raised the concern must be informed in writing of the reason why their concern cannot be considered.

5.19 If any excluded matter forms part of a wider concern, then there is nothing to prevent the other issues being looked at under the Regulations, so long as they are not excluded as well. If a concern is excluded under the Regulations then the person must be advised that the matter cannot be dealt with.

Time limits for notification of a concern

5.20 A concern can be notified no later than **12 months** from:

- The date on which the concern occurred, or
- If later, 12 months from the date the person raising the concern realised they had a concern.

5.21 To investigate a concern after the 12 month deadline, the Responsible Body must consider whether the person raising the concern had good reason not to notify the concern earlier and whether, given the time lapse, is it still possible to investigate the concern thoroughly and fairly.

5.22 The discretion to consider a concern that has been notified outside the 12 month period referred to in paragraph 5.16 above is subject to the provisions of Regulation 15(3) which provides that a concern cannot be notified **3 or more years** from the date the concern occurred or 3 or more years from the date the person became aware of the matter, which the

concern is about. This time limit was chosen as it is consistent with the limitation period which is in place for the consideration of clinical negligence claims (which is usually three years), but there are exceptions to the rule such as:

- if the person who raised the concern is a child at the time of the injury the three-year period does not begin to run until the individual reaches the age of 18. In these cases, the period will expire on the eve of the person's 21st birthday;
- if the person who raised the concern lacks capacity under the Mental Capacity Act 2005, the three-year period may never begin to run, or it can start at the date of recovery.

5.23 In some cases where there is an exception to the rule, the Responsible Body should make it clear to the person who has raised the concern that the investigation may be limited in some aspects based on the information available, particularly in situations where key staff have left the organisation.

Withdrawal of concerns

5.24 A concern may be withdrawn at any time by the person who notified the concern. The withdrawal of the concern can be made:

- in writing;
- electronically; or
- verbally in person or by telephone.

5.25 If a concern is withdrawn verbally, the Responsible Body should write to the person as soon as possible to confirm their decision.

5.26 However, even if the concern has been withdrawn, if it is felt that the investigation of the concern is still appropriate, the Responsible Body can continue to investigate.

Section 6 - Handling and Investigating Concerns

6.1 The vast majority of concerns are likely to be about the services provided by one Responsible Body. In those cases, the procedure described from paragraph 6.19 can be commenced immediately.

6.2 However, there will be situations where services provided by more than one Responsible Body form part of a concern (for example, a local health board and NHS trust. It is also possible under the arrangements for people to raise concerns with local health boards about the services provided by primary care practitioners, and additionally, for those practitioners to ask local health boards to undertake investigations for them. In these instances, other preliminary work (for example joint discussions, agreeing handling arrangements, who the lead organisation is, timescales etc) is needed before moving on to investigate the concern under the Regulations. This is covered in Part 4 of the Regulations and is described below. An adaptable template for use in these situations is available at [Appendix F](#).

Concerns which involve more than one Responsible Body

6.3 Regulation 17 covers concerns which involve or may involve more than one Responsible Body. In practice it is likely that the person has only raised the concern with one of the bodies. However, it is possible that they might have raised the concern with both, and this must be checked carefully to ensure that there is no duplication of effort on the part of any organisation. If it seems clear to the Responsible Body receiving the concern that the matters involve another Responsible Body as well as itself, then it must **within 2 working days** of first receipt:

- inform the person raising the concern that another Responsible Body is or may be involved in their concern, and
- seek consent from the person raising the concern to contact and notify the other Responsible Body that they are involved in the concern.

6.4 Once consent has been received, the second Responsible Body must be informed **within 2 working days** of receiving the consent, that a concern has been received. All organisations involved with the concern should then co-operate to agree:

- which of the organisations will act as the lead in co-ordinating and investigating the concern in accordance with the Regulations;
- who will directly communicate with the person who raised the concern and keep them updated;
- a joint response to the concern, issued by the lead organisation;
- the sharing of information relevant to the concern, subject to consent which should be obtained at the outset;
- appropriate representation of the organisations at any relevant meetings.

Concerns raised with a local health board about services provided by a primary care provider

6.5 Regulations 18 to 21 deal with concerns notified to a Local Health Board about the services provided by a primary care provider under a contract or arrangements with that Health Board. Regulation 19 prescribes the action to be taken by a Health Board when it receives notification of a concern about a primary care provider from a patient or his or her representative. Regulation 20 prescribes the action to be taken by a Health Board when a primary care provider notifies a concern in respect of which he or she is the subject of concern and requests that it be investigated by the Health Board. Regulation 21 sets out how Health Boards must communicate decisions made under Regulations 19 and 20.

Concerns raised with a Local Health Board by a patient or his or her representative about services provided by a primary care practitioner

6.6 When a local health board receives a concern relating to NHS services provided by a primary care practitioner in their area they need to decide in the first instance whether it is more appropriate for it to investigate a concern, or whether the primary care provider should do so. Before making this decision, the local health board must first of all **within 2 working days** contact the person who raised the concern to:

- ask whether the concern has already been raised with and had a response from the primary care provider and

- seek consent for details of the concern to be sent to the primary care provider.
- 6.7 If the concern has already been dealt with by the primary care provider and a response issued in accordance with Regulation 24, then the local health board must not investigate it again. The person should be advised of this and reminded of their right to take the matter to the Public Services Ombudsman for Wales.
- 6.8 If the concern has not been looked at by the primary care provider and the Local Health Board considers that this is a concern that it would be appropriate, in principle, for it to investigate, a Local Health Board must get the consent of the person who raised the concern with them to allow the Local Health Board to send details of the concern to the primary care provider who is the subject of the concern.
- 6.9 If the person who notified the concern does not consent to details being passed to the primary care provider, the Local Health Board cannot investigate the concern. The rationale for such a policy is that, in the vast majority of cases, it would not be possible for a Local Health Board to investigate a concern without the co-operation of the primary care practitioner, and primary care practitioners should, in the interests of fairness, know when a concern about them is being investigated.
- 6.10 The only exception to this is if the Local Health Board is of the opinion that an issue is so serious that it would merit an investigation anyway, without the direct involvement of the primary care practitioner, or the consent of the individual patient. It will be a matter for Local Health Boards in individual cases to determine when notifying a primary care practitioner might prejudice their consideration of a concern.
- 6.11 In terms of deciding whether it is appropriate for the local health board or the primary care provider to investigate a concern, this will be a matter of judgment for the local health board to make in light of the issue concerned. For example it may be that matters relating to the administration (appointments, etc.) and staffing (attitude, training, etc) of a practice should be referred back to the primary care provider to deal with, but more fundamental issues around clinical care should be looked at by local health boards. Similarly, if it

appears that relationships between the patient and practice are failing, then it might be more appropriate for the local health board to investigate the matter. It might also make sense for a Local Health Board to handle an entire concern if it involves both primary and secondary care. There are no rules relating to this, so careful consideration will need to be given to each case.

- 6.12 A local health board has **5 working days** to make the decision about who will investigate the concern and to inform the patient or his or her representative and the primary care provider who is the subject of the concern. This timescale starts from the date that the matters in paragraph 6.6 above have been determined. Local Health Boards must provide reasons for the decision it reaches in respect of who is most appropriate to investigate the concern.
- 6.13 If a local health board decides to investigate a concern about a primary care provider, then it will let the person who raised the concern and the primary care provider know and then carry out an investigation in accordance with the Regulations and with the process described from paragraph 6.19 below. Primary care providers are under an obligation to cooperate with investigations undertaken by the local health board. However, local health boards may not make any determination about the liability in tort of a primary care provider. If such matters are alleged by the patient or arise during the investigation, then the primary care provider will be advised to involve their medical defence organisation. The patient will need to be advised that the local health board cannot become involved in those aspects of any concern about a primary care provider.
- 6.14 Where it is decided that the primary care provider is best positioned to investigate the concern, the local health board must let the person and the primary care provider know of this decision and why the decision has been made. The person raising the concern may be unhappy with this decision so, as part of the local health board's decision letter, they must be informed of their right to take their concern to the Public Service Ombudsman for Wales.

6.15 The primary care provider must then manage the concern in line with the handling and investigation of concerns as outlined in this guidance.

Local health board asked by a primary care provider to undertake an investigation

6.16 Regulation 20 sets out the procedure to be followed when a primary care provider requests that a local health board investigates a concern that has been notified to the primary care provider. The process to be followed by the local health board when it receives such a request is very similar to the one described above for concerns raised with the local health board by patients about primary care providers.

6.17 Where the primary care provider asks a local health board to investigate a concern about services provided by them, the local health board, **within 2 working days** needs to:

- check with the primary care provider that the person who has raised the concern consents to the local health board considering the concern; and
- establish whether the concern has been considered by the primary care provider and whether a response has already been issued by the primary care provider under Regulation 24.

6.18 If the person who notified the concern is unwilling to consent to the Health Board considering the concern or if a primary care provider has already issued a response under Regulation 24, then the local health board cannot investigate the concern and must let the primary care provider know. If the person who notified the concern is content for the Health Board to consider the concern and a response has not been issued under Regulation 24, the local health board has **5 working days** to make the decision about who will investigate the concern and the process described at paragraphs 6.12 to 6.15 above will apply.

Investigation of concerns in accordance with the Regulations

- 6.19 When a concern is received by a Responsible Body, the date of receipt must be carefully noted. This is because the date of receipt is used to calculate the number of days it will take to respond. In cases where Redress may be considered, it will also be the date from which the limitation period is suspended – this is covered in more detail in the section on Redress below. In cases involving concerns notified to local health boards about primary care providers, described above, the date of receipt is still the date on which the concern was first received. It is acknowledged that the preliminary work required in these cases will “eat into” the time available to investigate and respond to the concern. However, it would be too complicated to apply a different overall target in different cases.
- 6.20 Where the duty of candour applies, ‘the day upon which it received notification of the concern’ equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

Acknowledgement of Concerns

- 6.20 Unless a concern has been satisfactorily dealt with “early resolution”, all concerns must be acknowledged within **5 working days** of first receipt in accordance with the Regulations.
- 6.21 For concerns involving primary care providers to be investigated by a local health board, once the local health board has decided that it will investigate, then they will send a formal acknowledgement letter outlining the concern to be investigated, as required by this guidance.
- 6.22 In terms of concerns reported by staff, it will be necessary to adapt this stage to ensure that they also receive an acknowledgement and an opportunity to discuss the concern. Staff are often reluctant to report concerns because they either do not know what will happen as a result or they are unclear what will change. This underlines the importance of providing feedback for staff who report concerns and provide adequate support for them.

- 6.23 Where a concern is raised by a member of staff, the person to whom the concern relates or his or her representative, must be advised and be involved in the investigation of the concern in accordance with Part 5 of the Regulations.
- 6.24 Duplicate notifications to patients (or their representative) should be avoided where the Duty of Candour procedure has already been followed which may cause unnecessary distress.
- 6.25 The acknowledgement of the concern must be in writing and if received electronically can be acknowledged electronically. Verbal concerns that are not managed “on-the-spot” must also be acknowledged in writing.
- 6.26 It is important that at this stage, the Responsible Body provides the person who raised the concern with a **named contact** for use throughout the handling of the concern and details of how to contact that person. At the outset, the person raising the concern must be offered the opportunity to discuss:
- any specific needs they may have which should be taken into account as the investigation proceeds;
 - the way in which the investigation will be handled;
 - how long it is likely to take and when a response can be expected and
 - the availability of advocacy and support.
- 6.27 As a matter of good practice, the discussion should also seek to establish:
- what the person who raised the concern is expecting as an outcome and
 - that the person understands the patient’s clinical records will be looked at as part of the investigation.
- 6.28 The discussion can take place by telephone or at a meeting. This offer of a discussion needs to be included in the acknowledgement letter. Example template letters to patients acknowledging receipt of a concern(s) can be accessed at [Appendix G](#).
- 6.29 If there is to be a meeting with the person raising the concern at this stage, it is useful to remember that it is more likely to

be successful if the person knows what to expect from the meeting and is able to offer some suggestions towards how the matter can be resolved for them. The person raising the concern should always be encouraged to bring a relative or friend, or an advocate to any meetings.

- 6.30 On rare occasions, a meeting alone may be sufficient to resolve a concern. If the meeting is successful and the actions to resolve the concern are agreed by all parties the concern can be considered as resolved and no further investigation may be required. The meeting must be followed-up by a full written response based on the discussions and include confirmation that the concern is now resolved. If any follow-up actions were agreed, then the person who raised the concern must be told when they can expect to receive information about the outcome of these actions.
- 6.31 In most cases, a meeting will serve the purpose of establishing some basic information and agreeing a way forward. The investigation will then proceed.
- 6.32 If the person does not want to discuss their concern, the Responsible Body determines how they will manage the concern and then inform the person in writing of the proposed actions to manage their concern.
- 6.33 Any person who is the subject of a concern must be given a copy of the concern unless:
- they have already been sent a copy by the person raising the concern, or
 - informing the person of the concern, would, in the reasonable opinion of the Responsible Body, prejudice its consideration of the matters raised by the concern.

Duty to be open

Duty of Candour

- 6.34 The underpinning principles of these arrangements are openness and transparency. It is important to ensure that when incidents occur that the patient or their representative is involved as much as possible in the investigation and is assured about lessons learned. This is also the same for any

complaint received. Engagement and excellent communication are essential to the successful management of any concern, regardless of grade or complexity.

- 6.35 In addition to the Being Open principles, the Health and Social Care (Quality & Engagement) (Wales) Act 2020 (the “Act”) places a legal duty of candour on NHS providers in Wales.⁶ The duty seeks to promote a culture of openness and improves the quality of care within the health service by encouraging organisational learning.
- 6.36 Where a service user suffers an adverse outcome which has or could result in unexpected or unintended harm that is more than minimal (i.e., moderate or severe harm or death), and the provision of health care was or may have been a factor, the Responsible Body must, in accordance with the Act and the regulations made thereunder⁷ notify the service user or his or her representative of the concern. This should be managed in accordance with the organisation’s Duty of Candour procedure and advice set out in the Duty of Candour Guidance.⁸
- 6.37 It is intended that the requirements in the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (“the Regulations”), such as the requirement to undertake an investigation, will follow the candour procedure. NHS bodies should, however, avoid duplicating any processes in complying with the candour procedure and the procedure required by the Regulations to avoid causing any unnecessary distress to the patient or their representative, and to ensure that the processes are properly streamlined. For example,
- 6.38 Where a concern is notified by a member of staff, there remains a requirement in Regulation 12(7) of the Regulations to advise the patient to whom the concern relates, or his or her representative, of the notification of the concern where the Responsible Body’s initial investigation determines that there has been moderate or severe harm or death. However, if the patient or their representative has already been notified of the

⁶ This includes Local Health Boards, NHS Trust, primary care providers and Special Health Authorities (not including Special Health Authorities other than NHS Blood and Transplant)

⁷ The Duty of Candour Procedure (Wales) Regulations 2023

⁸ [Link to guidance](#)

concern in accordance with the Duty of Candour Regulations there is no requirement to inform the patient or their representative again.

- 6.39 However, there may be some necessary duplication in fulfilling other regulations such as regulation 24 which requires an apology to be given after the investigation has been completed.
- 6.40 Regulation 12(7) of the Regulations also requires that the Responsible Body involves the patient or his or her representative in the investigation of the concern unless Regulation 12(8) applies, and it is not in the interests of the patient to involve them in the investigation. This may be the case for example, if involving them could cause deterioration in their physical and/or mental health. In line with the general principles of the Duty of Candour, there, is still a need to inform a patient of the concern. Hence, where there has been moderate or severe harm or death, the investigation would commence straightaway and as part of this discussion, consent should then be sought to access medical records.

Accessing Medical Records and Consent

- 6.41 In the majority of cases, the investigation of a concern requires access to medical records, and so the issue of consent will need to be considered. The Information Commissioner provides advice called Health Data – use and disclosure and organisations must have due regard to any advice that might apply.
- 6.42 When completing records under duty of candour staff should remember that any records made in relation to the incident may be disclosable to the individual under UK GDPR (if their personal data) or to the general public under the Freedom of Information Act (if not personal data). Staff should also involve their organisation Data Protection Officer (DPO) when a concern appears to involve a personal data breach as there may also be reporting requirements to the Information Commissioners Office under UK GDPR.
- 6.43 The UK General Data Protection Regulations (“UK GDPR”) provides that personal data must be processed in accordance

with seven key principles: lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy; storage limitation; integrity and confidentiality; and accountability. Processing means “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction”.

6.44 For the purposes of the UK GDPR, health records will constitute “special category” or “sensitive” personal data and requires a higher level of protection than ordinary personal data. The UK GDPR includes conditions for processing special category data including where there is explicit consent. If you do not have consent, legal advice should be sought as to whether there is any legal basis for accessing the person’s health records.

6.45 Where the patient him/herself raises the concern, then in doing so, they should be asked to consent to an investigation. This will also apply if a concern is raised by a representative who has shown proof that they are legally entitled to act for the patient/data subject (e.g. the representative has a Power of Attorney). However, in order for individuals to be clear in the knowledge that their medical records may need to be accessed, this should be explained in the acknowledgement letter so that they have the opportunity to indicate if they do not want their health records accessed.

6.46 Where a third party has raised a concern on behalf of someone else, then the patient or their representative will have to be asked to give written consent to the access to medical records and the conduct of an investigation.

6.47 Where the next of kin/personal representative raises a concern in respect of a deceased person, the investigating officer should be satisfied that the person is entitled to act on behalf of the deceased.

6.48 Where someone other than the next of kin/personal representative raises a concern in respect of a deceased

person, the written consent of the next of kin or personal representative should be obtained.

- 6.49 In the event that the patient/personal representative contacts the Responsible Body after raising the concern to say that they are not happy for consent to be inferred and they do not want their records to be accessed, then the Responsible Body must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. Responsible bodies should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.
- 6.50 Further information about when to seek consent, including when a concern is raised on behalf of a person who is a child or lacks mental capacity is set out in the paper in [Appendix H](#).
- 6.51 In terms of concerns raised which relate to patient safety incidents reported by members of staff, the UK GDPR allows for certain sensitive personal data (i.e. medical records) to be processed without the consent of the data subject (i.e. patient) to allow for legitimate activities such as the internal investigation of a patient safety incident to take place. In these situations there is no need to seek the consent of the individual to the use of their medical records in an investigation.
- 6.52 In any investigation and in line with data protection legislation and the [Caldicott Principles](#), only information relevant to the investigation of the concern should be accessed and then only by those people who have a demonstrable need to have access.
- 6.53 In addition, being open from the outset and providing a person with access to their own medical records can often help them understand what has happened and avoid any suspicions developing.
- 6.54 It is important to ensure that at all times the requirements of the UK GDPR are adhered to when accessing, processing and disclosing service user information. In cases where a representative is acting on behalf of a service user with

capacity, consent for the representative to act should be obtained in writing and be kept under review throughout the process

6.55 Therefore, a person notifying a concern can request access to any personal records that a Responsible Body may hold, as long as they are the data subject or have consent to do so from that person. No fees will be charged where a person inspects written records, but a fee may be charged if they want copies.

6.56 A person has the right to have access to personal information held about them in written records and on computer e.g. medical and nursing notes, X-ray reports or blood results. Where a person requests to view medical records, the person must be accompanied and appropriate assistance made available to explain any questions around procedures and terminology.

6.57 However, access can be refused if:

- following discussion with a health professional the provision of access would seriously harm the physical or mental well-being of the person or any other individual involved with the concern, e.g. member of staff such as a health professional; or
- the request for access has been made by someone who is not the data subject (such as the parent of a child) where the information was provided in the expectation that it would not be disclosed to the applicant. This includes the results of any examination or investigation which the patient has requested should not be disclosed.

6.58 If access is denied, the individual can complain to the Information Commissioner or, if still not satisfied, individuals may seek remedy through the courts. Local policies and procedures will provide further information on accessing and disclosure of medical records or staff can contact their organisational information lead.

Investigations

6.59 All concerns, where the Regulations apply, (including those which may also give rise to the duty of candour) must be managed and investigated in the most appropriate, efficient and effective way as outlined in Regulation 23. Welsh NHS bodies should note in particular Regulation 23(1)(i) which states that where the concern notified includes an allegation that harm has or may have been caused it **must** consider:

- the likelihood of any qualifying liability arising;
- the duty to consider Redress in accordance with Regulation 25; and
- where appropriate, give consideration to the additional requirements set out in Part 6 of the Regulations.

6.60 When considering the “additional requirements of Part 6”, Welsh NHS bodies should be mindful of the current financial limit of £25,000 applied to offers of Redress under Regulation 29. Where it is clear from the outset that, regardless of the fact that there is or there may be a qualifying liability, that damages if a qualifying liability were to be established would exceed £25,000 the Redress arrangements should not be triggered and the person who notified the concern should be advised to seek legal advice and be given the contact details for Llais (Citizen Voice Body). If they choose to pursue a claim for compensation they can do so in the usual way, outside the provisions of the Regulations. This advice would go in the response required under Regulation 24. However, all concerns need to be investigated in accordance with the principles of handling and investigating concerns as outlined in the Regulations, in particular at Regulation 23.

Establishing the Investigation and Initial Assessment of a Concern

6.61 An initial assessment of the concern will be undertaken in accordance with the principles outlined in Regulation 23 to determine the depth of and parameters of the investigation, which needs to be proportionate to the severity of the concern notified. All concerns must be graded in terms of severity. The depth of the investigation will then vary according to the issues under consideration. It will not be appropriate to conduct in-depth investigations for all concerns and so it is important to determine as accurately as possible from the

outset what will be proportionate in the circumstances. It is also essential that the assessment of a concern is kept under review throughout its investigation in case the nature of the investigation needs to change.

- 6.62 The number of people participating in an investigation is dependent on the severity and complexity of the concern. For a low grade concern (grade 1 or 2) it may be sufficient for one person to undertake the investigation, whereas a higher grade concern (grades 3-5) may require a multidisciplinary team approach supported by the concerns team. In these cases, it is likely that a comprehensive or concise Root Cause Analysis will be required. It is important that the investigator(s) are appropriately selected according to their knowledge and experience and the nature of the concern. They should also be independent of, and played no part in the actual issue(s) under investigation.
- 6.63 Concerns need to be investigated by people who have completed the relevant training, are competent, objective, have recognised authority and are credible and respected. If a member of staff is involved at any level with a concern that involves a family member, they must declare a conflict of interest. Any investigating officer or person signing off a concern must not have any family relationship with either the person who raised the concern or the person about who the concern is about. This ensures that the integrity of the process is assured without compromising the rights of any individual involved.
- 6.64 By accurately grading a concern, choosing the investigator(s) appropriately, agreeing the terms of reference so they are clear and the use of appropriate tools (e.g. chronologies, “5 Whys”, etc), the investigation can be carried out thoroughly, speedily and efficiently. The intention is to “*investigate once, investigate well*” and this should remain at the heart of the investigation as it progresses.
- 6.65 Information on grading of concerns can be accessed at [Appendix I](#). A variety of investigative tools can be accessed via the [Patient Safety Wales](#) website, including guidance on [how to learn lessons from concerns](#).

Communication with the person or representative who raised the concern

- 6.66 Responsible bodies must ensure that the person who notified the concern is kept updated in a timely manner about the investigation in a format that meets any needs that have already been identified. Consideration should also be given to inviting them to attend meetings with staff and at what stage in the investigation those should most usefully be arranged. It can do more harm for clinical staff to meet a patient too early; neither should things be left so long that the person raising the concern feels they have been forgotten about. Timing should be carefully considered to allow everyone to prepare and for any meeting to be as useful as possible.
- 6.67 Regulation 12(7) of the Regulations also requires that the Responsible Body involves the patient or his or her representative in the investigation of the concern unless Regulation 12(8) applies, and it is not in the interests of the patient to involve them in the investigation. This may be the case for example, if involving them could cause deterioration in their physical and/or mental health.
- 6.68 Where the duty of candour is triggered in relation to the concern, the patient (or their representative) should be informed of the actions (such as the investigation) that the Responsible Body will undertake, including the outcome of such investigations, in accordance with the candour regulations.

Support for staff involved in concerns

- 6.69 Being the subject of a concern or even reporting a concern as a member of staff can be very stressful. In terms of being the subject of a concern, when an issue is raised, whether by a patient or through a report from a member of staff, the details should be shared with the staff member involved wherever appropriate. This should be done supportively. NHS Bodies will have mechanisms in place and local support services available to pro-actively offer the appropriate provision of support and assistance to staff members through their Employee Wellbeing Service/Occupational Health/Employee Assistance Programmes.

6.70 In addition there are several national support services available via the Health Education & Improvement Wales (HEIW) website⁹, such as Health for Health Professionals (Canopi)¹⁰, SilverCloud¹¹ and Samaritans¹². Local Line Managers, Clinical Supervisors, Workforce and OD professionals (including employee wellbeing and occupational health colleagues) and Trade Union representatives will also be able to signpost staff to appropriate support services.

6.71 Staff may need to prepare reports or evidence during the investigation of the concern and assistance may be required from their local concerns team in completing these tasks. Above all, it is important that staff are kept informed about the progress of the investigation of any concern that they raised, or which directly involved them, and the final outcome.

The assist me model¹³ - supporting staff following patient safety incidents may be of value in these circumstances.

Obtaining independent clinical or other advice

6.72 There may be occasions when it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. This may include:

- obtaining a second opinion to aid a patient's understanding of their own care, or to see whether there are any other issues which need to be explored in terms of the provision of care and treatment, as part of the investigation of a concern by a Responsible Body;
- in instances when an allegation of harm has been made by the patient, and where a Welsh NHS body is unable to come to a determination itself as to whether there is a qualifying liability in tort, the securing of an expert opinion to answer questions in relation to the tests relating to breach of duty of care and/or causation, as part of an investigation under Part 5 of the Regulations; and

⁹ [HEIW \(2023\) Workforce support. https://heiw.nhs.wales/support/](https://heiw.nhs.wales/support/)

¹⁰ Canopi (formally Health for health professionals) <https://hhpwales.nhs.wales/about-us/>

¹¹ SilvercloudWales. <https://nhswales.silvercloudhealth.com/signup/>

¹² The Samaritans 2023 <https://www.samaritans.org/>

¹³ HSE 2021 national open disclosure programme “assist me” a model of staff support following patient safety incidents in healthcare. <https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/open-disclosure/assist-me-a-model-of-staff-support-following-patient-safety-incidents-in-healthcare-january-2021-.pdf>

- where the Redress arrangements in Part 6 of the Regulations are triggered any instruction of medical experts must, in accordance with Regulation 32(1)(b), be carried out jointly by the person who notified the concern and the Welsh NHS body. Experts may be instructed to advise in relation to issues relating to causation, condition and prognosis and/or quantum to establish whether there is a qualifying liability in respect of which an offer of Redress should be made. A template letter is at [Appendix J](#).

6.73 A database has been set up containing the names and details of potential independent expert advisers who may be commissioned by a Welsh NHS body to provide advice in the circumstances set out above. The database contains experts from across the health professions, disciplines and specialities/sub-specialties. The database is held by Legal & Risk Services and it will continue to be revised and updated as the Putting Things Right process matures.

6.74 Independent expert advisers have to comply with a set of general terms and conditions if they wish to provide advice to a Welsh NHS body in accordance with the Regulations. These can be found at [Appendix K](#). Whilst these general terms and conditions will apply in all cases, it will also be the case that when an expert adviser is engaged by a Welsh NHS body, they will be asked to agree additionally any terms and conditions in relation to the specific case, in relation to timescales for the production of reports, their format, payment arrangements, or any other requirements that may be determined locally.

6.75 Contact [Legal & Risk Services](#) for further advice on how to engage an independent expert adviser at redress@wales.nhs.uk. A template letter of instruction is at [Appendix J](#). So that people can be assured that the advice being sought is independent, it is essential, and a matter of course, that the patient or their representative is shown or provided with a copy of the letter of instruction and copies of the information which it is proposed will be sent to the independent expert to consider. In terms of the information to be provided to the independent expert, these are likely to include the relevant clinical notes; GP records; statements provided by treating clinicians containing their recollection of

the patient, events and their treatment plans, as well as a list of the specific questions the expert is being asked to address.

6.76 In cases where the Redress arrangements are engaged, the instruction is formally a joint one between the Welsh NHS body and the patient, or their representative. This is mentioned in more detail at Section 7 below.

Alternative Dispute Resolution

6.77 Responsible bodies need to consider whether a concern can be resolved by using alternative dispute resolution (ADR), such as mediation, facilitation or conciliation. This approach is often useful when the person who raised the concern is upset or there is unease between the Responsible Body and the person raising the concern.

6.78 The independence afforded with ADR can help to bring about a resolution of the concern and prevent it escalating further. ADR may help:

- where staff or practitioners are having difficulty in dealing with the concern;
- when the person who raised the concern feels anxious that the approach of the concerns team/lead person is not impartial;
- when there are misunderstandings with relatives, during the treatment of a patient. ADR can lead to a 'shared view' of the situation including their differences.

6.79 To progress ADR, both parties need to provide signed agreement to their involvement in the process and patients need to give consent to their personal records being viewed by an independent party. All meetings, telephone calls, other exchanges and information provided must be carefully documented.

6.80 Responsible bodies may already have arrangements in existence for accessing independent facilitators and mediators. Where this does not exist, then local Llais (Citizen Voice Body)s or NHS Legal and Risk teams may be able to assist. Contact the Board of Llais (Citizen Voice Body)s in Wales for further advice:

Tel: 02920235558
Website: llaiswales.org
Email: enquiries@llaiswales.org

Dealing with people who make unreasonable demands

- 6.81 People raising concerns have the right to be heard, understood and respected and every effort should be made to assure individuals that their concern will be investigated thoroughly. However, there may be times when the distress of a situation leads to the person raising a concern, acting out of character and becoming determined, forceful, angry, make unreasonable demands of staff or even resort to violence.
- 6.82 People who are unhappy about the process or outcome of the investigation of their concern, despite being advised on other avenues available for them, may also show aggression towards staff or continue to persistently pursue their concern by phoning, writing or in person. Although staff understand that a person's anger and aggression may be as a result of the distress that has been caused to them or to their loved ones, behaviour that escalates into actual or potential aggression towards staff is not acceptable.
- 6.83 Further information on how to deal with people who make unreasonable demands can be accessed at [Appendix L](#).

Where a concern needs additional consideration

- 6.84 When a concern first comes to light, or at any stage during an investigation, the Responsible Body must consider whether further actions are required, for example, referral of any matter to other processes such as HR conduct or capability policies or to other bodies such as:
- Welsh Government (for serious incidents);
 - Professional Bodies, e.g. General Medical Council, Nursing and Midwifery Council;
 - Healthcare Inspectorate Wales;
 - Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK - MBRRACE - UK;

- Health & Safety Executive - Reporting of injuries diseases and dangerous occurrences regulations 1995 (RIDDOR);
- Medicines Healthcare and Regulatory Agency (MHRA);
- Information Commissioner's Office;
- Police;
- HM Coroner;
- Human Tissue Authority (HTA);
- Human Fertilisation Embryology Authority;
- Welsh Health Specialised Services (WHSSC);
- Local Children's Safeguarding Boards
- Local Safeguarding Adults Boards.

6.85 These referrals can happen at the same time as an investigation being carried out under the Regulations. Local policies and procedures will detail processes and arrangements within organisations for communicating concerns to other bodies.

Some Useful Links:

[National Reporting and Learning System](#)

[Healthcare Inspectorate Wales](#)

[Health and Safety Executive-RIDDOR: Report an incident](#)

[Medicines Healthcare and Regulatory Agency \(MHRA\)](#)

[Information Commissioner's Office](#)

[All Wales Child Protection Procedures 2008](#)

[In Safe Hands 2000](#)

[Child Practice Reviews](#)

Welsh NHS body's duty to consider whether there may be a qualifying liability in tort

6.86 As set out in paragraph 6.48, in addition to the requirements set out above which apply to all responsible bodies, there is an additional duty placed on Welsh NHS bodies (i.e. local health boards and NHS trusts in Wales, but **not** primary care providers or independent providers), where there has been an allegation of harm, to consider the likelihood of any qualifying liability in tort arising.

6.87 In many concerns it will be obvious that liability for actual harm is not an issue and there may be no requirement to pursue

independent expert advice or consider this aspect any further. Alternatively, the Welsh NHS body may have sought independent expert advice and concluded that there is no liability in tort. At that stage the Welsh NHS body can respond to the concern indicating there is no liability and issue a final response report in accordance with Regulation 24.

- 6.88 Equally, as set out in paragraph 6.47, there will be concerns that alleged harm has been caused where, if that allegation were to be proven, the damages that would be awarded would clearly exceed the financial limits for Redress set out in Regulation 29 (currently £25,000). In these circumstances it is also appropriate to issue a final response under Regulation 24 explaining that the quantum of any potential claim arising out of the concern exceeds the financial threshold in the Regulations and so the Redress arrangements under Part 6 of the Regulations will not be entered into.
- 6.89 Where a qualifying liability in tort exists or may exist, then the concern is subject to further investigation by the Welsh NHS body, which is under a duty to consider Redress under Part 6 of the Regulations. The limit for the financial compensation element of redress is £25,000. At this stage of the handling and investigation of the concern, the Welsh NHS body must issue an interim response in accordance with Regulation 26.

Responding to a concern

- 6.90 A Responsible Body should attempt to issue a final response under Regulation 24 within 30 working days beginning with the day upon which it received notification of the concern. Where the duty of candour applies, 'the day upon which it received notification of the concern' equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

Final response under Regulation 24

- 6.91 The response to a concern from a Responsible body should be issued in line with regulations 24. The final response report must include the following:
- An apology (where appropriate)

- A summary of what the concern was about
- An explanation of how the concern was investigated
- Copies of any expert opinion obtained as part of the investigation
- Copies of relevant medical records, where appropriate
- an explanation of any actions will be taken
- an offer to discuss the response to the concern with the responsible officer or their nominated representative and
- details of the person's right to raise their concern with the Public Services Ombudsman for Wales.

and in the case of a Welsh NHS body:

- in respect of a concern that alleges harm has or may have been caused, an explanation of the reasons why there is no qualifying liability; and
- an explanation of why the Redress arrangements under Part 6 will not be triggered in response to concerns alleging harm has been caused where the financial value of the claim would, if proven, exceed the financial threshold set out in Regulation 29.

6.92 The response must be signed off by the responsible officer or their designated deputy. A draft template response report is attached at [Appendix M](#).

6.93 In terms of responding to concerns which were reported by staff members relating to patient safety incidents, then in cases where the patient is not involved, a similar response report should be prepared and sent to the appropriate committee for their consideration. In reported incidents where there has been moderate or severe harm or death, the patient or representative will have been informed and involved in the investigation and so they will need to be sent a response either under Regulation 24 or 26 as appropriate.

Final responses which exceed 30 working days

6.94 Final responses under Regulation 24 should be issued within working 30 days of first receipt of the concern, but if this is not

possible the person raising the concern must be informed of the reason for delay. The response must then be sent as soon as possible and within 6 months of the date the concern was received. Where the duty of candour applies, 'the day upon which it received notification of the concern' equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

- 6.95 If, in very exceptional circumstances, the response cannot be issued within 6 months, then the person raising the concern must be informed of the reason for delay and given an expected date for response.

Interim response under Regulation 26

- 6.96 Where a Welsh NHS body considers there is or may be a qualifying liability which, in accordance with Regulation 29, would attract financial compensation of £25,000 or less, an interim report under Regulation 26 needs to be issued within 30 working days beginning the day upon which it received notification of the concern. Where the duty of candour applies, 'the day upon which it received notification of the concern' equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

Interim Report

- 6.97 The interim report must include the following:
- a summary of the nature and substance of the issues contained in the concern;
 - a description of the investigation undertaken so far;
 - a description of why in the opinion of the Welsh NHS body there is or may be a qualifying liability;
 - a copy of any relevant medical records;
 - an explanation of how to access legal advice without charge;
 - an explanation of advocacy and support services which may be of assistance;
 - an explanation of the process for considering liability and Redress;

- confirmation that the full investigation report will be made available to the person seeking Redress;
- details of the right of the person to take their concern to the Public Services Ombudsman of Wales;
- an offer of an opportunity to discuss the contents of the interim report with the responsible officer or person acting on their behalf.

6.98 The interim report should be signed off by the responsible officer or person acting on their behalf. A template for an interim report can be accessed at [Appendix N](#).

Interim responses which exceed 30 working days

6.99 The interim report should be issued within 30 working days of first receipt of a concern. If this is not possible, the person raising the concern must be informed of the reason for delay and the interim report should be sent within 6 months of first receipt of the concern. Where the duty of candour applies, 'the day upon which it received notification of the concern' equates to the day upon which the NHS Body first became aware that the duty of candour has come into effect.

6.100 If, in exceptional circumstances, the interim report cannot be issued within 6 months, then the person raising the concern must be informed of the reason for delay and given an expected date for receipt of the interim report.

Section 7 - Redress

7.1 Regulations 25 to 33 cover the arrangements that apply when Redress is to be considered by a Welsh NHS body. If at anytime during the management and investigation of a concern it is considered that a qualifying liability exists, then the Welsh NHS Body must determine whether or not an offer of redress should be made. A Welsh NHS Body may only make an offer of redress for a qualifying liability by way of financial compensation in which the sum does not exceed £25,000.

7.2 Redress is applicable to care and treatment provided by Welsh NHS bodies. Regulations 34 to 48 allow for Redress to

be considered also in relation to care commissioned from NHS providers in other parts of the UK.

7.3 Redress relates to situations where the patient may have been harmed and that harm was caused by a Welsh NHS body. Redress comprises of either one or a combination of all of the following:

- the offer of financial compensation and/or remedial treatment, on the proviso that the person will not seek to pursue the same through further civil proceedings;
- the giving of an explanation;
- a written apology; and
- a report on the action which has or will be taken to prevent similar concerns arising.

7.4 Remedial treatment is treatment which is offered to the patient with a view to trying to improve their condition and to restore them, as far as possible, to the position that they would have been in had the treatment complained of or negligent care not occurred.

Qualifying Liability in Tort

7.5 Redress can only be considered if there is a proven qualifying liability in tort. Investigations will therefore be seeking to prove that the Welsh NHS body has **both** failed in its duty of care to a patient **and** that the breach of duty of care has been causative of the harm that the person has suffered. It is only when both these tests are satisfied that a payment of compensation should be considered.

7.6 This must be made very clear to patients and their representatives as often people believe that there only needs to have been poor care for the test of negligence to be satisfied and for compensation to be owed. However, it is the case that the person also needs to have suffered harm as a consequence (known as “causation of damage”). Determining causation can be very difficult, particularly if the patient was very ill anyway, or might have expected some pain or complications during their period of recovery as a result of treatment. This is the stage at which it will almost certainly be necessary to commission independent expert advice.

7.7 Qualifying Liability - the Law

Standard of Care:

In the leading case of ***Bolam v Friern Hospital Management Committee***, it was agreed that negligence means “failure to act in accordance with the standards of reasonably competent medical men at the time”. It was accepted that there may be one or more perfectly proper standards. The court said:

“A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art... Putting it the other way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view”.

In the case of ***Bolitho v City and Hackney Health Authority***, the court said that it must be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis. The Judge, before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter. If it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, a Judge is entitled to hold that the body of opinion is not reasonable or responsible.

The standard of care expected of healthcare professionals is objective and is tailored to the task which is undertaken. It does not take account of an individual’s inexperience.

In determining what was reasonable care, the court will take account of the particular situation as it presented itself as part and parcel of all the circumstances of the case.

Standard and Burden of Proof:

The standard of proof in cases of medical negligence is “on the balance of probabilities” (i.e. 51% likely).

It is the Claimant's burden to prove that, 'on the balance of probabilities' the Defendant's care fell below the reasonable and accepted standard.

Causation:

If the patient did not sustain injury as a result of the breach of duty, there is no qualifying liability. There must be a causal link between the breach of duty and the damage complained of by the patient. This is essentially an explanatory inquiry: how in fact did the damage occur? The question is normally dealt with by the "but for" test.

The general rule is that if the harm to the patient would not have occurred "but for" the negligence, then the negligence is the cause of the damage. If the harm would have occurred in any event, the negligence is not the cause of the damage.

This is a brief and basic explanation of some of the leading case law in this area and should not be relied upon as a complete account of the law or as a substitute for legal advice. Legal advice can be sought from Legal & Risk Services.

When Redress does not apply

- 7.8 Redress cannot be offered where there is no qualifying liability in tort. Nor can it be offered if the concern is or has been subject to civil proceedings. If the person or their representative raising the concern wishes to pursue their claim through the courts and has issued civil proceedings, any consideration of Redress under these Regulations must cease and the person informed.
- 7.9 Redress under these Regulations does not extend to primary care providers or independent providers.
- 7.10 The Redress arrangements should not be engaged where it is considered at the investigation stage that the amount of financial compensation that would be awarded would exceed the limit set out in Regulation 29, currently £25,000.

Suspension of the limitation period

- 7.11 Regulation 30 governs the position regarding the suspension of the limitation period. If a case may be subject to the Redress provisions, then Regulation 30 allows for the suspension of the limitation period, which is the time normally allowed for a person to bring a legal claim – usually three years from the date of the treatment or incident complained about or three years from the date that the person became aware of the matter which is the subject of their claim.
- 7.12 During the time that Redress is being considered the limitation period is suspended, that is, the “clock is stopped”. This applies from the date on which the concern was first received by the Welsh NHS body. The suspension of the limitation period will also continue once a Welsh NHS body has made an offer of Redress under Part 6 or refused to make an offer under Part 6. The reason for this is to ensure that no person is disadvantaged, or prevented from bringing legal action, should they be unhappy with the outcome of the Redress investigation.
- 7.13 The person and their legal representative have up to 9 months to accept an offer of financial compensation from the date of the offer (in accordance with Regulations 30(3) and 33). After 9 months the limitation clock will start to run again. If the offer is accepted the person or their representative has to sign a formal agreement and legal waiver, that they will not pursue the concern through civil proceedings. The 9 month time period for suspension of limitation also applies if they choose to reject the offer.
- 7.14 It is important that the person or their representative understand that where a financial offer of Redress is made, that they only have 9 months to consider the offer. After that time, the Redress arrangements will no longer apply.
- 7.15 There may be cases where a concern is notified just before the limitation period would expire and it has not been possible for an investigation to be concluded. The Welsh NHS body may wish to give consideration to agreeing an extension of the limitation period in order to allow it to complete its investigation and provide a response whilst avoiding the need for the patient/potential Claimant to issue court proceedings.

- 7.16 In circumstances where it is admitted that there may be a qualifying liability and it subsequently transpires that financial compensation in respect of any qualifying liability will exceed £25,000 it will be necessary for the Welsh NHS body to write to the patient or the patient's representative indicating that it will not make an offer of redress under the regulations. The patient will benefit from the 9 month extension of limitation from the date on which the Welsh NHS body communicated its decision, in accordance with regulation 30 (5).
- 7.17 In cases where a settlement offer requires court approval, such as for a child or somebody who lacks capacity under the Mental Capacity Act, the limitation period is suspended until a settlement is reached which receives the approval of the court.
- 7.18 In cases where there is no liability and it has been decided not to make an offer of Redress, this will be communicated to the person raising the concern. It is important that the person or their representative understand that where a Welsh NHS body has determined, following an investigation undertaken in accordance with Part 6, that no liability exists, that they only have 9 months before the limitation clock starts to run again. This 9 month period is intended to give the person who notified the concern and his or her legal adviser time to prepare to issue civil proceedings if they do not agree with the decision reached by the Welsh NHS body.

Legal advice

- 7.19 In accordance with Regulation 32, where the Redress arrangements are engaged, legal advice **without charge** to the person who notified the concern will be available, should the person or his representative want it, in relation to:
- the joint instruction of clinical experts including clarification of issues arising from their reports;
 - any offer of Redress made in accordance with Part 6 of the Regulations;
 - any refusal to make an offer; or
 - any settlement agreement that is proposed.

7.20 Legal advice may only be sought from a recognised firm of solicitors with known expertise in clinical negligence and who are accredited by the Law Society or from the Action against Medical Accidents Clinical Negligence Panel. NHS organisations are able to obtain contact details from these organisations' websites and share with the person who raised the concern. The cost of such legal and clinical advice must be funded by the Welsh NHS body and not the person who raised the concern.

7.21 Guidance to Welsh NHS bodies on the cost of legal fees is provided at Appendix O.

Redress investigation

7.22 In order to determine whether an offer of Redress can be made under the Regulations, it is necessary to undertake a certain amount of additional investigation, which may include the need to address the following matters:

Whether there is a qualifying liability

7.23 A determination will be needed on whether the breach of duty of care caused or materially contributed to the symptoms or condition the patient currently complains of. The checklist attached at Appendix P will assist in all investigations but in particular with determining the issues around causation. This may require additional external expert evidence.

An up to date assessment of condition and prognosis

7.24 This can be obtained from the patient's treating clinician with agreement of both parties, or from an independent expert, or from up to date general practitioner records.

Compensation Recovery Certificate (CRC)

7.25 A CRC showing any state benefits paid or payable to the patient must be obtained at the outset. Any loss of earnings which may form part of compensation payable under the Regulations may be reduced if the person has been in receipt of certain benefits.

Quantification of any financial loss

- 7.26 Any damages that may be payable under the Regulations within the £25,000 limit will be made up of **general damages** (i.e. payable for pain, suffering and loss of amenity) and **special damages** (i.e. monetary loss which can be calculated with a degree of accuracy such as loss of earnings, costs of care and assistance, etc.). Details of expenditure in respect of additional treatment, care, prescriptions, clothing must be obtained with invoices and receipts where available.
- 7.27 Where loss of earnings is claimed, then wage slips, letters from employer, P60, etc. must be obtained. If the patient is unable to provide details, they must be asked for appropriate addresses to enable the investigator to obtain the necessary details. Proof of loss of earnings is mandatory.
- 7.28 If a future loss of earnings is anticipated by the patient the evidence above is required and information regarding future job prospects should be addressed in the medical evidence or the expert advice commissioned. The evidence of actual financial loss should be set out clearly in the offer of financial Redress, separate from the offer of compensation for the injury/harm.
- 7.29 Should the patient accept the offer of free legal advice, all the evidence referred to above should be provided with the report.
- 7.30 Welsh NHS bodies can contact Legal & Risk Services for advice to ensure they have covered all matters at this stage.

Instruction of independent expert advisers

- 7.31 As can be seen above, there may be a number of issues on which expert advice may be required, including those relating to causation, condition and prognosis and/or quantum to establish whether there is a qualifying liability in respect of which an offer of Redress should be made. Under the Redress arrangements, any expert required to provide advice under the Regulations should be instructed **jointly** by the person raising the concern and the Welsh NHS body. Contact Legal & Risk Services to access the list of advisers at

redress@wales.nhs.uk. The template letter at [Appendix J](#) should assist with the joint instruction of experts.

- 7.32 If the person has accepted the offer of free legal advice then their legal adviser should also be allowed input to the instruction of the expert(s).

Redress - Financial

- 7.33 Where liability in tort is accepted, a Welsh NHS body can make an offer of financial compensation that does not exceed £25,000.

- 7.34 Where it is acknowledged that any financial compensation will exceed £25,000 then the concern **must not** be considered under the Redress arrangements and financial compensation may not be offered under Part 6 of the Regulations.

- 7.35 However, it is recognised that it is difficult at the outset of an investigation under Regulation 23 to be certain about the financial value of a claim and it is inevitable that some cases that were entered into the Redress arrangements because it was considered that financial compensation, should liability be proven, would be worth less than £25,000 transpire, on investigation, to be worth more. In these cases, Regulation 29(3) provides that Welsh NHS bodies may give consideration to making an offer of settlement outside of the provisions of the Regulations, for example, an out of court settlement. Welsh NHS bodies might at this stage, and in the spirit of the Regulations, consider offering to pay the patient's legal costs associated with obtaining advice on any such out of court settlement. However, there is no obligation for them to do so.

Tariff

- 7.36 . The assessment of general damages for pain, suffering and loss of amenity is calculated solely on a common law basis. Welsh NHS bodies are advised to consult Legal & Risk Services for support when determining the amount of damages a concern attracts.

7.37 Any offer of Redress must give consideration to any claim for special damages. If an offer is to be made, the matter should be registered with the Compensation Recovery Unit to establish whether the Welsh NHS body will be liable for any benefits paid and whether they can be offset against any claim for special damages.

Redress - Communicating the decision

7.38 In accordance with Regulation 33, the Welsh NHS body must communicate its decision to either offer Redress in the form of financial compensation, treatment or combination of both or, if no liability could be established as a result of investigations carried out in accordance with Part 6 of the Regulations, not to make an offer.

7.39 The offer of Redress or decision not to make an offer must be communicated to the person raising the concern, or their representative, within 12 months of the date on which the concern was notified to the Welsh NHS body. Where the duty of candour applies, that date equates to the date upon which the NHS body first became aware that the duty of candour has come into effect.

7.40 In exceptional circumstances, if the Welsh NHS body is unable to make a decision within the 12-month period then the reason for delay and an expected date for the decision should be explained in writing to the person who notified the concern.

7.41 The person raising the concern or their representative must be advised that they have 6 months to respond to the offer of Redress or to the decision not to make an offer.

7.42 If the person or their representative, who raised the concern is unable to respond to the decision within 6 months, they must contact the Welsh NHS body and provide an explanation for the delay in responding. The time limit for response to the decision can then be extended to 9 months. However, if no response is received within 9 months the limitation period will start again.

7.43 If an offer of Redress is made this offer will be by way of a formal agreement. By accepting the offer of Redress the person or their representative must sign a waiver to any right to take the same concern, for which they have accepted Redress, to court.

7.44 There may be cases where a proposed Redress settlement will require approval by a court, for example, where a liability relates to a child or person lacking capacity under the Mental Health Act 2005 (1).

7.45 Where a Redress settlement requires approval by a court, the Welsh NHS body must pay all reasonable legal costs to obtain the approval of the court.

Redress - Investigation Report

7.46 Where a person is seeking Redress, the findings of the investigation must be recorded in an investigation report. The investigation report, in accordance with Regulation 26, must be provided to the person who raised the concern and is seeking Redress as soon as reasonably practicable and within 12 months of the date that the body received notification of the concern. Where the duty of candour applies, that date equates to the date upon which the NHS Body first became aware that the duty of candour has come into effect.

7.47 The investigation report must contain:

- copies of any independent expert advice used to determine whether or not there is a liability;
- a statement by the Welsh NHS body confirming whether or not there is a liability; and
- the rationale for their decision.

7.48 A template investigation report can be found at Appendix Q.

7.49 However, it is not necessary for a Welsh NHS body to provide a copy of the investigation report:

- before an offer of Redress is made;
- before a decision not to make an offer of Redress is communicated;
- if the investigation of Redress is terminated for any reason; or if

- the report contains information which is likely to cause the person or other applicant for Redress significant harm or distress.

Investigation reports which exceed the 12 month time limit

7.50 Where an investigation report cannot be provided within the set 12 month timescale, then the person raising the concern must be informed of the reason for the delay and given an expected date for response.

Section 8 - Payment of Financial Compensation

Part 1: Summary

8.1 This section of the guidance replaces Welsh Health Circular (97)17. It is designed to achieve:

- Clarification of the conditions upon which Responsible Bodies may manage and settle concerns (i.e. claims for financial compensation) brought against them arising out of any episode of negligence.
- Promotion of good and economic practice in the management of concerns against the NHS;
- Assurances that learning from events with the objective of improving standards in patient safety are foremost.

8.2 The delegated limit which enables Responsible Bodies to manage and settle concerns for financial compensation in relation to all episodes of clinical negligence and personal injury is £1 million. Up to this limit, proposed settlements do not need to be submitted to the Welsh Government for approval, provided that this section is followed and the conditions are satisfied for the exercise of the delegated authority.

8.3 All payments of financial compensation arising out of any episode of negligence must satisfy the requirements of the Welsh Government's delegated authority to Responsible Bodies.

8.4 For the purpose of this section, the following will be collectively referred to as ‘compensation claims’;

- Concerns involving a qualifying liability in tort resolved by the settlement of damages to a maximum of £25,000 under Redress;
- Concerns (i.e. claims for negligence) exceeding £25,000 and formal claims for negligence below £25,000 resolved in accordance with the relevant Pre-Action Protocols and Civil Procedure Rules.

8.5 To ensure compliance with the delegated authority, the Chief Executives of Responsible Bodies should ensure:

- that their organisations concerns policy and procedure also includes the handling of compensation claims approved by the Board or duly authorised sub-group or committee, which conforms to the standards and conditions set out in this section. This will include adopting a systematic approach to claims handling in line with best current practice and, in particular for clinical negligence cases, any guidance issued by the Welsh Government or Welsh Risk Pool Services (WRPS);
- all compensation claims are reviewed when either failings are identified or at the very latest when liability is conceded and reviewed again upon closure, and that the Responsible Body has in place a suitable detailed procedure for learning from events into which such failings can be channelled to ensure that appropriate action plans are developed, monitored, evaluated and audited to ensure that any necessary remedial action is taken and any general lessons disseminated. The learning from events process should include a governance review process to provide reassurance to the Board that learning has been undertaken and is effective. In addition, the relevant checklist at [Appendix S](#) is completed by the responsible director or manager for each settlement authorised by the Responsible Body and actions taken are monitored for implementation purposes through their learning from events procedures;
- the Board sees regular reports on the number and aggregate value of compensation claims in progress, on

their eventual outcome and on any remedial action taken or proposed;

- that these policies and procedures are subject to regular scrutiny by the WRPS through the relevant WRPS Standard and as appropriate by Internal Audit under the supervision of the Responsible Body's Audit Committee.

8.6 This delegation is conditional on Responsible Bodies meeting the minimum standards of claims handling currently required of members under the relevant WRPS Standard. Minimum standards for the basic claims handling are set out in Part 2 below.

8.7 The Welsh Government will seek assurance from the WRPS that Responsible Bodies are conforming to these conditions and standards. Where the WRPS reviews any cases which are deemed not to comply with this guidance, the Welsh Government will be notified and such cases will be treated as losses requiring either retrospective approval from the Welsh Government (if appropriate) or recovery/write-off action.

8.8 Welsh Government approval will still be required for any compensation claims raising novel, contentious or repercussive features and in case of doubt, Responsible Bodies should consult the Welsh Government for advice.

8.9 The WRPS is a voluntary scheme enabling Responsible Bodies to pool the costs of clinical negligence settlements each year subject to the Welsh Government's top slicing arrangements. Responsible Bodies whether or not they are seeking financial assistance from the WRPS, remain fully accountable for the handling of the compensation claim and have **full authority to settle** any compensation claim subject to the delegated limit and the conditions set out in this guidance. However, reimbursement under the scheme may be refused, delayed or withheld where the Responsible Body has failed:

- to not notify the WRPS of the compensation claim and its projected settlement quantum and date at the earliest possible opportunity;
- to meet with the relevant minimum standard issued by the WRPS;

- to comply with the requirements of the WRPS Procedures for submitting compensation claims for reimbursement;
- to comply with the various Technical and Briefing Notes published by the WRPS.

Part 2: Delegated Authority Conditions

General

8.10 Any Responsible Body wishing to make a compensatory payment to resolve a qualifying liability in tort or to make use of the delegated limits must adopt the minimum standards set out below. If these standards are not followed, all proposed settlements above the general delegated limit of £50,000 for other **ex gratia** payments must be submitted to the Welsh Government for approval.

Policy statements

8.11 Responsible Bodies must have a written policy on the handling of clinical negligence and personal injury compensation claims, approved by the Board or duly authorised committee. This may be a stand-alone policy or incorporated into the Responsible Body's policy on Putting Things Right. The policy as a minimum must cover the points set out below.

Board level responsibility

8.12 Whilst the Chief Executive of each Responsible Body retains ultimate responsibility for compensation claims, the day to day management functions and responsibilities may be delegated to a board member at Director level with clear responsibility for these issues and who will keep the Board informed of major developments.

Compensation claims Specialists

8.13 Whilst Responsible Bodies use different titles to describe their 'claims specialist', the Responsible Body must have access to designated members of staff who have specialised knowledge, expertise, qualifications, experience and on-going

training in the management of negligence compensation claims. Such members of staff should be able demonstrate the ability to report directly or through an appropriate structure to the responsible Board member and either have sufficient seniority to carry influence within the organisation and are given the status to do so or the organisational structure is sufficient to ensure that this occurs.

Qualified legal advice

8.14 The Responsible Body will have a clear policy on the circumstances in which qualified legal advice will be obtained. Whatever the locally determined policy, qualified legal advice **must** always be obtained at an appropriate stage for all compensation claims involving potential expenditure above the standard delegated limit for financial payments of £50,000, and in any case before making any firm offer to settle the compensation claim. This should cover an assessment and advice on:

- liability and causation;
- the strength of the defence and the balance of probabilities;
- the likely quantum of damages, including best and worst case;
- the likely costs of defending the compensation claim.

8.15 The final decision to seek to negotiate a settlement or to continue defending a compensation claim should be taken by the Board or others within the delegated limits.

8.16 Responsible Bodies will wish to bear in mind that those who advise them in any capacity should be regarded as owing a duty of care to them. They may wish therefore, to ensure that their advisers are in a position to meet any potential liability.

Involvement of front-line staff

8.17 There should be clear procedures for involving front-line staff, in particular healthcare professional staff including those involved in the patient's treatment and care, whose co-operation is essential if compensation claims are to be successfully defended or lessons learned effectively.

Procedure for handling compensation claims

8.18 The concept behind Putting Things Right is to ensure a single integrated proportionate investigation process which links incidents, complaints and compensation claims.

8.19 The documented procedure for handling compensation claims should cover the following aspects:

- Setting up a record of the compensation claim and maintaining a review system;
- establishing an objective account of the original incident, giving appropriate weight to the recollection of the staff involved;
- identifying and maintaining all records related to the incident;
- establishing and maintaining contact with all staff involved in the original incident;
- obtaining an in-house “expert view” of the compensation claim and, if appropriate, securing suitable external expert witnesses;
- initial valuation of the compensation claim;
- instruction of solicitors, briefing counsel and monitoring their costs;
- negotiation of out-of-court settlements and the delegated limits which apply;
- for personal injury cases, liaison with the insurers and their solicitors;
- for larger settlements, considering whether periodical payments are an appropriate option;
- liaising with the WRP and complying with the current Reimbursement Procedure;
- processes to identify at an early stage, any procedures or aspects of clinical practice requiring remedial action, including systematic review of all cases after closure;
- clear allocation of responsibility for carrying through any remedial action required in accordance with a defined procedure for learning from events and for disseminating any wider lessons, both within the health board or trust and where appropriate more widely;

- arrangements for analysis of compensation claims against the Responsible Body, in particular of trends and emerging patterns with implications for patient safety and risk management;
- arrangements for regular reporting to the Board or to a duly authorised sub-group or committee of the Board, both in aggregate and on individual compensation claims; and in particular for securing Board agreement to proposals for settlement outside the delegated limits.

Compensation claims database

8.20 The Responsible Body will maintain a database with relevant information on all compensation claims. Care should be taken to maintain patient and staff confidentiality.

Delegated limits

8.21 The Board will agree the circumstances, including delegated financial limits, in which settlements may be approved (a) by the responsible director, (b) by relevant staff, (c) a sub-group of the board. For compensation claims outside the delegated limits, the Board should agree, case by case, a range of possible settlement values within which the director and/or relevant staff have discretion to negotiate. It should be remembered that, in the nature of the legal process, decisions on whether or not to accept an offered settlement may sometimes have to be taken at very short notice.

“Nuisance” compensation claims

8.22 Responsible bodies should avoid settling cases of doubtful merit, however small, purely on a “nuisance value” basis. The decision to settle a case or contest it should always be based on an assessment of the risk of losing and the cost in legal fees of continuing.

Reports to the Board

8.23 The Board or duly authorised sub-group or committee will receive regular reports on:

- the number and aggregate value of compensation claims, and details of any major individual compensation claims;
- the progress and likely outcome of these compensation claims, including the expected settlement date;
- the final outcome of the compensation claim; and
- any proposed remedial action arising out of particular compensation claims.

8.24 These reports will need to be analysed at a level of detail to enable the Board to form a view on emerging trends.

Novel, contentious or repercussive payments

8.25 Despite the general approach to delegation taken in this guidance, all compensation claims involving “novel, contentious or repercussive” expenditure should still be referred to the Welsh Government for approval. The most likely instances are compensation claims:

- involving some unusual and new feature which, if not correctly handled, might set an unfortunate precedent for other NHS litigation;
- which appear to represent test cases for a potential class action, or cases which although not formally part of a class action appear to be very similar in kind to concurrent compensation claims against other Responsible Bodies.

8.26 Responsible Bodies faced with a compensation claim which could fall under either of these categories should contact the Welsh Government for advice.

Reporting Responsibilities

8.27 All payments in settlement of compensation claims should be entered into the Responsible Body’s register of losses and special payments. Where the payment has been partially funded from the WRPS this should be noted in the register.

8.28 Where a Responsible Body decides to settle a compensation claim under the delegated authority set out in this guidance, the following actions should be undertaken:

- Where the total expenditure does not exceed £25,000, the checklist at [Appendix S](#) should be completed and reported to the WRPS within 56 days of conclusion. The Responsible Body as part of the WRPS assessment process may be required to evidence its review of the compensation claim on closure and how it has identified and actioned any lessons arising from the compensation claim;
- Where total expenditure exceeds £25,000, the checklist at [Appendix T](#) should be completed in accordance with the WRPS Claims Reimbursement Procedure;

8.29 Internal audit should annually audit an appropriate random sample of compensation claims submitted to the WRPS.

8.30 In addition, the WRPS will arrange to examine a sample of compensation claims as part of its review of the relevant WRPS Standard.

Section 9 - Serious Incident Reporting and Investigation

Introduction

9.1 This section of the guidance is aimed specifically at the reporting arrangements of concerns which are patient safety serious incidents (referred to as serious incidents in the remainder of this section) and supersedes previous letters and guidance issued by Welsh Government on the reporting of patient related serious adverse incidents. This section is also meant to be read in conjunction with [Section 6 of the guidance, handling and investigating concerns](#).

Definition of a serious incident

9.2 A serious incident is defined¹⁴ as an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following;

- unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
- a never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death (see *Never Events Framework*);
- a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
- allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
- loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

9.3 Examples of serious incidents that must be reported to Welsh Government include but are not limited to:

- Deaths where a healthcare associated infection (including *Clostridium difficile* and methicillin resistant *Staphylococcus aureus*) is mentioned on the death certificate as either the underlying cause of death or contributory factor;
- Outbreak of a healthcare associated infection in a hospital that results in significant disruption (Note: see also No Surprises);
- Healthcare associated pressure ulcers graded as 3 or 4 under the *European Pressure Ulcer Advisory Panel Classification System*. This includes incidents where a patient develops a pressure ulcer(s) within a NHS funded healthcare setting; admitted with a pressure ulcer(s) from another NHS funded healthcare setting or from the community and in receipt of NHS funded healthcare;
- Suspected suicide/unexpected death of mental health patient (including community and in-patient services);
- Self-Harm incidents categorised as 'severe' under the *Grading Framework for dealing with Concerns*;

¹⁴ *National Framework for Reporting and Learning from Serious Incidents Requiring Investigation NPSA 2010*

- Admission of a child under the age of 18 years to an adult mental health ward;
- Absence without leave of a patient subject to the Mental Health Act (please ensure you update the Welsh Government once the patient has been found);
- Intrauterine Foetal deaths if there is early indication that the death it is linked to midwifery/obstetric practice;
- Maternal deaths;
- Patient falls that result in death or severe harm;
- Radiation incidents resulting in patients receiving a radiation dose that is much greater than intended (Note: these incidents need to be reported to Healthcare Inspectorate Wales and Welsh Government using the Notification of IR(ME)R Incident Form (see [Appendix V](#))).

Never Events

- 9.4 All Never Events are defined as serious incidents and must be reported to Welsh Government as per the process described below under 'Serious incident reporting arrangements'.
- 9.5 NHS organisations should ensure that all NHS staff are aware of serious incidents classed as Never Events and the need to report these in line with local incident reporting policies. Never Events should therefore be reported through local reporting systems to the National Reporting and Learning System (NRLS) and the Welsh Government's serious incident reporting system. Nationally this information will be collated to identify shared learning and any action required. Never Events and action taken should already be discussed at Board level. It will be a requirement for this information to be included in Annual Quality Statements from 2012/13.

Serious incident reporting arrangements

- 9.6 Welsh NHS bodies must ensure that staff and contractors are aware of local policies/processes for reporting incidents. All serious incidents that require reporting to Welsh Government must be reported to PatientSafety.Wales@wales.nhs.uk using **Form SI 1** (see [Appendix W](#)). Where possible Welsh Government should be notified within 24 hours of the incident taking place.

- 9.7 When completing the form please ensure:
- All boxes on the form are completed with as much information and detail as possible (but do not include patient or staff identifiable details);
 - An explanation as to why there has been a delay in reporting the incident, if applicable;
 - It is clearly noted if another HB or Trust/ Welsh Health Specialised Services (WHSSC) is involved and which NHS organisations will lead the investigation;
 - Acronyms or abbreviations are not used;
 - All forms are password protected;
 - All forms are signed by the Chief Executive or Executive Director.
- 9.8 If the serious incident may attract significant media attention do not delay in submitting the form. However, if this occurs 'out of hours. (i.e. weekdays before 8am and after 5pm or at weekends) please contact the Welsh Government press office on 029 2089 8099.
- 9.9 Within one working day of receipt of a serious incident form, the Welsh Government will issue an e-mail acknowledgement to the organisation including a Welsh Government reference number. Please use this in all correspondence.
- 9.10 The email will include an initial incident grading together with a timescale to submit a completed investigation. The incident grade is for Welsh Government use only and must not be confused with the Putting Things Right grading.
- 9.11 In addition to the Welsh Government Serious Incident arrangements, Welsh NHS Bodies are required to report all patient safety incidents (irrespective of seriousness and degree of harm) to the National Reporting and Learning System (NRLS). This is to inform the prioritisation and development of safety solutions, including alerts and guidance.
- 9.12 The arrangements for the reporting of serious incidents to Welsh Government and NRLS do not replace the requirement to report to other bodies as required such as:

- Healthcare Inspectorate Wales;
- Mothers and Babies - Reducing Risk through Audits and Confidential Enquiries (MBRRACE-UK);
- Health & Safety Executive;
- Medicines and Healthcare Products Regulatory Agency (MHRA);
- Human Tissue Authority;
- Human Fertilisation Embryology Authority;
- Information Commissioner's Office;
- Police;
- HM Coroner.

If appropriate, individual Welsh NHS Bodies will need to be mindful of the need to inform other Welsh NHS Bodies and/or WHSSC if it is a specialist commissioned service).

No surprises reporting arrangements

9.13 In some cases incidents may not result in direct harm to a patient(s) but may impact on service provision or organisational reputation including adverse media coverage. In such cases a no surprise notification should be submitted in accordance with the process for reporting serious incidents but using **Form SI 2** (see Appendix W).

Serious incident investigation and updates

9.14 All serious incidents should be subject to a root cause analysis investigation. Once this is completed and approved by the relevant organisational committee an incident closure summary must be sent to PatientSafety.Wales@wales.nhs.uk using **Form SI 3** (see Appendix X). This must include findings, recommendations and learning identified for the organisation. In exceptional circumstances we may request a copy of the investigation report in addition to the incident closure summary form. We expect to receive closure forms within a timescale of 3 or 6 months as specified. Particular attention should be afforded to ensuring “never events” are investigated in a timely manner.

9.15 It is important that suitable arrangements are agreed and in place for the lead organisation to update and share information with all relevant bodies, including Welsh Government. In the case of a joint investigation and when the investigation is completed, Welsh Government requires the lead organisation to submit a consolidated incident closure summary form (i.e. including the findings from other organisations) in accordance with the arrangements set out in 9.14 above.

Learning from serious incidents

9.16 The outcome of any investigation must be used to maximise opportunities for learning, quality improvement and improving patient safety. This should be a key element in our overall attempts to reduce adverse events and avoidable harm to patients/service users in line with the aims set out in 1000 Lives Plus programme and organisations' local priorities. As well as local learning, organisations are expected to contribute to the wider opportunities for shared learning. This should be identified when completing the incident closure form.

9.17 Issues and learning arising from incidents will be considered at the National Quality and Safety Forum in order to determine any action required, particularly at a national level. Regular reports will also be compiled for the Director General/Chief Executive NHS Wales and the executive team to help inform policy development and priorities.

Monitoring Arrangements

9.18 Compliance with the serious incident reporting process will be considered as part of the [NHS Delivery Framework monitoring arrangements](#).

9.19 Continued failure to comply with the serious incident reporting and investigation process may result in escalation within the delivery framework. Therefore it is vital that there is pro-active contact between the Welsh NHS body and the Welsh Government, around all aspects of the reporting process.

Public Services Ombudsman for Wales reports

- 9.20 All Public Services Ombudsman for Wales (PSOW) reports are copied to the Improving Patient Safety Team at the same time they are sent to the Welsh NHS body concerned.
- 9.21 **Section 21 Reports:** There is no need for NHS organisations to routinely inform us of the action they have taken to meet the recommendations made by the Ombudsman within section 21 reports. However, depending on the issues identified we may request this information.
- 9.22 **Section 16 Reports:** We will always require confirmation of the actions taken to meet the recommendations made by the Ombudsman within section 16 reports.

Coroner Schedule 5 Report

- 9.23 All Coroner Schedule 5 reports are copied to the Improving Patient Safety Team at the same time they are sent to the Welsh NHS body concerned.
- 9.24 Within three working days of receipt of a Schedule 5 report, the Improving Patient Safety Team will issue an e mail to the organisation confirming receipt.
- 9.25 NHS organisations will need to submit a copy of the response to the Coroner to PatientSafety.Wales@wales.nhs.uk . The covering email must include a reference to the serious incident reference number if applicable.

Section 10 - Cross Border Arrangements for considering redress

Part 7 of the regulations came into force from 1 April 2012.

- 10.1 In general, concerns (and complaints) about care and treatment provided on behalf of the NHS in Wales by organisations outside Wales should be dealt with in accordance with the relevant concerns procedure which applies to that organisation. People are still able to ask for

advocacy assistance from Llais (Citizen Voice Body) to help them take forward their complaints in such circumstances.

- 10.2 However, if during an investigation of a concern under the relevant procedure by the organisation outside of Wales, it becomes apparent that there may be a qualifying liability to which the redress arrangements may apply, then the provisions in Part 7 of the Regulations may be engaged.
- 10.3 Regulation 34 of the Regulations sets out the definitions of terms used in this part of the Regulations. It includes definitions of the terms “English NHS body”, “Scottish NHS body” and “Northern Irish NHS body”.
- 10.4 It should be noted that care is not routinely commissioned by Welsh NHS bodies from NHS bodies in Scotland and Northern Ireland and so it is anticipated that there will not be many instances where a Welsh NHS body will be required to consider redress in respect of a concern that has been notified to it by a Scottish or a Northern Irish NHS body. Nevertheless paragraphs 10.25 below set out guidance in relation to such arrangements.
- 10.5 However arrangements are routinely entered into with English NHS bodies for the provision of services and so the likelihood of the cross border provisions being engaged is greater.

Qualifying Liability in England

- 10.6 Regulation 35 provides that where an English NHS body receives notification of a concern under a relevant complaints procedure in respect of a service which it has provided, or arranged for the provision of, under an arrangement with a Welsh NHS body it **must** consider whether or not the concern is one to which the redress arrangements could apply. A relevant complaints procedure would, in relation to English bodies, currently be the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 (“the 2009 Regulations”).

- 10.7 In practical terms, in order to comply with its obligations under its indemnity arrangements with the NHS Litigation Authority (NHSLA) when an English NHS body receives notification of a concern where qualifying liability exists or may exist, the NHS body is required to notify the NHSLA of such a concern and provide them with the appropriate documents.
- 10.8 If an English NHS body receives notification of a concern which includes an allegation that harm has or may have been caused that relates to services which it has provided or arranged for the provision of, under arrangements with a Welsh NHS body, then regulations 36-37 will apply.
- 10.9 Regulation 36(2) provides that the English NHS body must notify the Welsh NHS body with which it has entered into a contract if it is of the view that a qualifying liability exists or may exist and, after obtaining any necessary consents, provide the Welsh NHS body with:
- A copy of the response to any concern;
 - A copy of the relevant medical records;
 - A copy of any expert opinion that was obtained during the investigation;
 - A written account of why it believes that there is or may be a qualifying liability;
 - The date that it received the concern and
 - Any such information or assistance as the Welsh NHS body may require.
- 10.10 Regulation 37 provides that within 5 working days of the above information being received, a Welsh NHS body must acknowledge to the English NHS body (or in practical terms the English NHS body and the NHSLA) receipt of the notification. In addition within 5 working days of receipt of the notification, the Welsh NHS body must advise the person who notified the concern to the English NHS body that the concern has been passed to the Welsh NHS body to consider whether or not a qualifying liability exists. Regulation 37(3) places an obligation upon the Welsh NHS body that has received the notification to determine whether or not a qualifying liability exists and it must determine whether or not an offer of redress should be made to the patient.

10.11 The Welsh NHS body must:

- Consider the appropriate method and timing of communication with the person who notified the concern as well as the most appropriate method of involving the person who notified the concern;
- Offer to meet with the person who notified the concern;
- Carry out an initial assessment of the concern – taking into account information received from the NHSLA and the notifying English NHS body and
- Whether any further independent medical or other advice is needed.

10.12 Regulation 39(2) provides that the Welsh NHS body and the English NHS body must co-operate, in a way which satisfies the arrangements in Part 7 of the Regulations, to determine whether or not a qualifying liability exists and, if it is determined that a qualifying liability does exist, to make an offer of redress.

Interim Report

10.13 Regulation 40 provides that where a Welsh NHS body is of the opinion that there is, or there may be a qualifying liability, it must produce an interim report (paragraph 6.82 outlines the content for the interim report) to the person who raised the concern (and their legal representative if they have one) within 50 working days of receiving notification of the concern. A copy of the interim report should also be sent to the NHSLA and English NHS body. If the Welsh NHS body is not able to provide an interim report within that time, it must notify the person who notified the concern (and their legal representative if they have one) and the NHSLA and English NHS Body the reasons why and provide the report as soon as reasonable and within 6 months of receiving notification of the concern.

10.14 If, in exceptional circumstances the interim report cannot be issued within 6 months, the Welsh NHS body must advise the person who raised the concern (and their legal representative if they have one) of the reasons for the delay and when the interim report may be expected. The NHSLA

and English NHS Body should also be kept informed. Note that the investigation report outlined at paragraph 10.20 must be provided to the person who raised the concern or their legal representative as soon as reasonably practicable and no later than 12 months from the date the Welsh NHS body received notification of the concern.

- 10.15 Regulation 41 sets out what will happen if the Welsh NHS body concludes, following the investigation taken in accordance with regulation 39, that there is no qualifying liability on the part of the provider of the services.
- 10.16 The forms of redress are the same as those set out in regulation 27 as referred to in paragraph 7.3.
- 10.17 Redress will not be available if the matter is or has been the subject of civil proceedings and if civil proceedings are issued during the course of the Welsh NHS body's consideration of redress the redress process must be stopped and all relevant parties advised.
- 10.18 Regulation 44 is similar to Regulation 29 (which is considered at paragraph 7.10) and sets a global limit of £25,000 for the financial element of redress. This encompasses general and special damages. If on investigation it transpires that the financial quantum of the claim exceeds £25,000, redress, in accordance with the Provisions of Part 7 must not be offered. The regulation provides that the compensation that will be awarded will be assessed on the common law basis. The Welsh Ministers also have the power to issue a compensation tariff. If, in the case of a matter referred from an NHS body in England (or Scotland or Northern Ireland) the amount is likely to exceed the limit shown then the Welsh NHS body will not proceed to consider an offer outside the Regulations.
- 10.19 Regulation 45 is similar to Regulation 30. It deals with the suspension of the relevant limitation periods during the period in which a liability is the subject of an application for redress under Part 7 of the Regulations. Regulation 45(2)(a) provides that the relevant limitation period will be suspended from the date on which the initial concern was received by the English NHS body (or Scottish NHS body or Northern Irish NHS body).

Investigation Report

10.20 In accordance with Regulation 46, a Welsh NHS body must issue an investigation report (as outlined in paragraph 7.49) to the person who is seeking redress or their legal representative, as well as the NHSLA and English NHS body. This investigation report must be provided as soon as reasonably practicable and not later than 12 months from the date the Welsh NHS Body received notification of the concern. If exceptional circumstances mean that 12 months cannot be adhered to, the Welsh NHS body must advise the person who notified the concern or their legal representatives as well as the NHSLA and English NHS body of the reasons for the delay and when the investigation report may be expected. As with paragraph 7.51 there are some circumstances where it is not necessary to provide a copy of the investigation report and these are set out in regulation 46(4).

Legal and Medical Advice

10.21 As with paragraphs 6.57-6.61, 7.19-7.21 and 7.31-7.32, medical and legal advice without charge is to be made available to the person who notified the concern. The costs for such medical and legal advice must be borne initially by the Welsh NHS Body and not the English NHS body.

10.22 In accordance with the law of England and Wales, any successful application for redress will be settled on the basis of the English provider's liability in tort. It is considered that this is appropriate as the law of tort is the same in England and Wales. This would mean that the waiver that a patient is required to sign in accordance with regulation 48(e) would be in respect of the provider body's liability in tort (i.e. the English NHS body's liability). It is anticipated that the Welsh NHS body would pay any settlement costs up front and the legal fees and fees for clinical reports as it is responsible for running the redress arrangement. However, as the claim is being settled on the basis of the English NHS body's liability in tort towards the patient, it is intended to require LHBs and Trusts in Wales to ensure that any commissioning contract

with English NHS provider bodies contains provision allowing for the recovery of such costs (this was agreed when the NHS Redress bill was progressing through Parliament). This includes the cost of legal fees and any associated clinical fees where an investigation by a Welsh NHS body reveals that there is no qualifying liability in tort.

Communicating the decision

- 10.23 As with paragraphs 7.40-7.47, a Welsh NHS Body must communicate its decision to offer or not to offer redress. The NHSLA and the English NHS body should also be sent a copy.
- 10.24 Where a Welsh NHS body decides that there is no qualifying liability they must advise in writing to the person who notified the concern, the decision and the reasons for the decision. At the same time there must be an offer to the person who notified the concern to meet to discuss the decision and provide them with their right to raise concerns, regarding actions of the Welsh NHS body, with the Public Services Ombudsman for Wales. Any decision letter must also be copied to the NHSLA and the English NHS body.

Qualifying liability in Scotland and Northern Ireland

- 10.25 Due to the difference in Welsh Ministers' legal powers, the regulations do not place any obligations on NHS providers in Scotland and Northern Ireland to consider whether or not there may be qualifying liability in respect of services they have provided on behalf of Welsh NHS Bodies. Instead Welsh NHS bodies who enter into commissioning arrangements with NHS bodies in Scotland or Northern Ireland should place obligations on Scottish and Northern Irish bodies as part of the commissioning contracts.
- 10.26 If a Welsh NHS body enters into a commissioning agreement with a Scottish NHS body or a Northern Irish NHS body for the provision of services to Welsh patients, it must insert provisions in the commissioning contract which require the provider to (a) consider, if it receives a complaint about such services which it has provided or arranged for the provision of under the terms of the complaints procedure that it is

required to operate, whether there is or there may be a qualifying liability in tort; and (b) if the provider is of the view that there is or there may be such a liability then, in accordance with the terms of the commissioning contract, it must refer the case to the Welsh NHS body to deal with in accordance with the provisions in regulation 38 and the rest of Part 7.

- 10.27 The commissioning contract should also place an obligation on Scottish and Northern Irish providers to provide the Welsh NHS body with the same information that an English provider is required to provide to Welsh NHS bodies under regulation 36.
- 10.28 In view of the differences in the law and legal systems in Scotland and Northern Ireland, a policy decision has been made which means that any successful application for redress in respect of the services provided by NHS bodies in Scotland or Northern Ireland would be paid for by Welsh NHS bodies. This means that the compensation and associated legal costs would be met by the Welsh body and the waiver that a patient would be required to sign in accordance with regulation 48(e) would be in respect of any liability that the Welsh body may have towards the patient.
- 10.29 The arrangements for Welsh NHS bodies investigating a concern where qualifying liability exists or may exist in relation to services they have commissioned from a Scottish or Northern Irish NHS body are very similar (although not identical) to the arrangements for investigating such a concern notified by an English NHS body.
- 10.30 Regulation 38 prescribes the action that a Welsh NHS body must take if it receives notification from a Scottish or a Northern Irish NHS body that there is or there may be a qualifying liability in tort in respect of services which it has provided, or arranged for the provision of, under arrangements with a Welsh NHS body. Upon notification by a Scottish or Northern Irish NHS body, of a concern where a qualifying liability exists or may exist, the Welsh NHS body must as per paragraph 10.10, acknowledge receipt of the notification within 5 working days. In addition, within 5 working days of receipt of the notification, the Welsh NHS body must advise the person who notified the concern to the

Scottish or Northern Irish NHS body that the concern has been passed to the Welsh NHS body to consider whether or not a qualifying liability exists. The action described at paragraph 10.11 will also apply to Welsh NHS bodies. However, there is no need to co-operate with Scottish and Northern Irish NHS bodies as indicated in 10.12. Para's 10.13-10.24 also applies and references to English NHS body should be substituted to Scottish or Northern Irish NHS bodies accordingly.

Section 11 - Learning from Concerns

- 11.1 In accordance Regulation 49, the outcomes of any investigation must be used to maximise opportunities for learning and quality improvement. This should be a key element in the overall attempt to reduce adverse events and avoidable harm to patients, service users, carers and staff in line with the aims set out in 1000 Lives Plus programme and individual responsible bodies local priorities. As well as local learning, responsible bodies are expected to contribute to the wider opportunities for shared learning.
- 11.2 Responsible bodies must ensure they have arrangements in place to review the outcome of any concerns which are managed and investigated under the Regulations. This will allow responsible bodies to identify areas for improvement and learn from concerns.
- 11.3 All organisations (NHS Trusts, Local Health Boards, primary care practitioners and independent providers) must put in place practical, but proportionate arrangements to enable the regular and ongoing review of concerns to ensure that service improvements are identified and acted upon. This is likely to be through organisations' existing Quality and Safety Committee structures. When learning from concerns, organisations must:
- Act upon issues raised and
 - Monitor improvements and changes made.
- 11.4 Lessons learnt must be shared within the organisation to improve services provided and avoid the recurrence of similar concerns. Local policies and procedures must specify

processes and mechanisms for communicating internally lessons learnt, across all activities and to all staff.

- 11.5 Furthermore, responsible bodies must share lessons learnt outside of their organisations to improve the wider provision of services and avoid the recurrence of similar concerns in other areas. Local policies and procedures must specify processes and mechanisms for communicating externally lessons learnt bearing in mind the principles of patient confidentiality.

Section 12 - Monitoring the process for dealing with concerns

- 12.1 Responsible bodies are required to monitor their processes for dealing with concerns and maintain records to support this activity.

Data collection for concerns dealt with under the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

- 12.2 Regulation 50 sets out the records that responsible bodies are required to maintain. These are:

- Each concern notified to it;
- The outcome of the concerns and whether they were well founded and;
- The timescales within which responses were sent and whether the timescales for response had been extended.

- 12.3 Each year Health Boards and NHS Trusts will be required to submit a completed data collection form to the Improving Patient Safety and Experience Team. This will become an annual statistical publication.

- 12.4 All **Health Boards** will be required to collect information in respect of concerns raised about:

- Services provided by the Health Board;

- Services provided by primary care practitioners in the Health Board area where the concern has been dealt with by the Health Board in accordance with Regulations 18-21; and
- Services provided by primary care practitioners in the Health Board area where the concern has been dealt with by the practice in accordance with the Regulations.

12.5 All **NHS Trusts** will be required to collect information in respect of concerns raised about:

- Services provided by the NHS Trust.

12.6 Regarding timescales for responding to concerns, these are set out within the regulations and are also referred in sections 6 and 7 of this guidance. Health Boards and Trusts will be required to submit information on timescales as part of the annual data collection process.

12.7 Under the NHS Delivery Framework, within tier 1, compliance with the Putting Things Right arrangements is monitored. This includes timescales for providing summary closure reports in respect of serious incident investigations.

When considering their compliance with response times, organisations will need to be mindful of the different timescales afforded within the regulations depending on the type of concern investigation.

In summary:

- All concerns must be acknowledged within 2 days of being received.
- For concerns considered under regulation 24 the expectation is that a **final** response will be issued within 30 working days of receiving the concern. However if the investigation identifies there is or may be a qualifying liability, an **interim** report should be issued within 30 days and a final response then becomes due within 12 months of receiving the concern.

The regulations allow for extensions to the above timescales but delays must be communicated to the person raising the

concern together with an expected timescale by which the response will be available.

Regarding the response times for Health Boards and Trusts to provide closure report summaries following serious incident investigations. The improving Patient Safety Team will provide the timescale by which these are to be received as outlined in [section 9](#).

- 12.8 In practice Responsible Bodies will be a need to collect considerably more data than this minimum, to ensure that the information from concerns is being interrogated and used effectively to learn lessons and improve patient safety and experience.

Section 13 - Annual Report

- 13.1 Regulation 51 provides that each Responsible Body must prepare an annual report for each year. The report must contain, as a minimum:

- Number of concerns received (including, in the case of Welsh NHS bodies, concerns reported under Part 7 of the Regulations related to cross border services);
- The number of concerns deemed well founded; and
- Number of concerns referred to the Public Services Ombudsman for Wales.

- 13.2 In accordance with regulation 51(1)(d) the annual report should also summarise:

- The nature and substance of concerns received;
- Any matters of general importance arising out of these concerns or the way that they were handled including areas of concern within particular departments, staff groups, treatments or services provided, that is reporting on trends; and
- Actions taken to improve services as a result of a concern/s being notified

- 13.3 Where a Welsh NHS Trust, Primary Care provider or Independent provider has entered into an agreement or arrangement with a Local Health Board for the provision of services, they must send a copy of their annual report on the handling and investigating of concerns to the Local Health Board with which they entered into such agreement or arrangement.
- 13.4 An annual report template is available at Appendix Y. This will need to be completed on an annual basis. For Local Health Boards and NHS Trusts this should be published in support of the organisations Annual Quality Statement.
- 13.5 The report is aimed at providing **assurance** and **evidence** to the Public, Welsh Government, Regulators and other stakeholders that your body is dealing and learning from concerns in accordance with the Regulations and that concerns are being *‘investigated once and investigated well’*.
- 13.6 **It is important that bodies say what they have done about concerns received and the lessons learnt.**
- 13.7 At all times the organisation must ensure that the annual report does not identify individuals or any related sensitive information.

Section 14 - Useful Information

- 14.1 This section contains guidance on dealing with concerns that are not notified through the normal routes described in the main guidance.

Action to take when a request for access to health records is received by a Responsible Body

- 14.2 On occasions, the first notification of a concern might be through a request to access health records by a solicitor acting on behalf of a patient or their representative. In this instance, the Responsible Body may not be clear as to the reason why the records have been requested, and whether a concern is in fact being notified under the Regulations. In these instances, the template letter at Appendix Z can be used, which provides

information about the new arrangements that can be passed on to the individual by their solicitor.

Action to take when a concern is notified indicating a conditional fee agreement or insurance premium

14.3 In this instance, as soon as the Responsible Body receives notification of a concern from a solicitor and where it appears that the patient has entered into a conditional fee agreement or insurance premium, they must liaise with Legal & Risk Services immediately, who will support them in dealing with this type of concern. The concern can be handled and investigated in line with the principles of the Regulations.

Section 15 - Glossary

Term	Explanation
Access to Health Records Act 1990	Access to the health records of a deceased person is governed by the <u>Access to Health Records Act 1990</u> .
Alternative dispute resolution	Means mediation, conciliation or facilitation.
Being Open	Being Open involves acknowledging, apologising and explaining when things go wrong. The National Patient Safety Agency policy on 'Being Open' was re-launched in the Autumn of 2009. Where the duty of candour comes into effect, the procedure in the Duty of Candour Procedure Wales 2023 should be followed.
British Dental Association	The <u>British Dental Association</u> (BDA) is the professional association and trade union for dentists in the United Kingdom and was founded in 1880. Membership, which is voluntary, stands at around 23,000. The majority of members are in general practice, or "High Street" practices.

Caldicott Principles	The Caldicott principles support safe and appropriate sharing of personal identifiable information.
Child	A person who has not attained the age of eighteen years.
Civil Proceedings	Civil proceedings are commenced by lodging a completed claim form at a county or High Court.
Claim	A claim is the basis for demanding or getting something, e.g. a patient who has been harmed makes a claim for compensation.
Compensation	A financial payment or remedial treatment or a combination of both financial and remedial treatment (see definition below).
Complaint	Any expression of dissatisfaction.
Concern	Means any complaint, claim or reported patient safety incident to be handled under the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.
Confidentiality	Ensuring that information is accessible only to those authorised to have access.
Consent	As part of an investigation of a concern, permission (consent) is required from the patient to access their clinical record. Consent can be implied, such as in a case of a mother with a small child or explicit e.g. carer acting on behalf of a patient.
Disciplinary Proceedings	Means any procedure for disciplining employees adopted by a NHS organisation for disciplining employees.
Executive Director	Means a member of the Board of a National Health Service Trust who is an employee of that organisation.
General Medical Council	The purpose of the General Medical Council (GMC) is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.
Governance	A system of accountability to citizens, service users, stakeholders and the wider community within which healthcare organisations work, take decisions and lead their people to achieve their objectives.

Healthcare Inspectorate Wales (HIW)	HIW provides independent and objective assurance on the quality, safety and effectiveness of healthcare services, making recommendations to healthcare organisations to promote improvement.
Independent Complaints Facilitation	An independent person (a Facilitator) will listen to the person's concerns, talk to the people involved with the concern and to try to help resolve the concern.
Independent Provider	Provider of health care under arrangements made with a Welsh NHS organisation which is not an NHS body or primary care provider, e.g. Private Hospital or Care Home.
Individual Patient Funding request	A request made to a Local Health Board or Welsh Health Specialised Services to fund health care for an individual patient that falls outside the range of services and treatments that the Health Board has agreed to provide, e.g. high cost drugs, rare conditions, new surgical procedures.
Limitation	In accordance with the <u>Limitation Act 1980</u> a concern may not be notified three or more years from the date of the incident complained about or three or more years from the date that the patient became aware of the matter which is the subject of the concern.
Local resolution	Means to resolve the concern locally in the first instance.
Medical records	A medical record can consist of any information related to an individual, e.g. clinical letters, reports, test results, X-rays, observation charts, nursing notes, doctors notes, Multi-Disciplinary Team meeting records, microfiche, photos, etc.
Mental Capacity Act 2005	The Mental Capacity Act is a law that empowers and protects people who may lack capacity to make some decisions for them.
National Reporting and Learning System (NRLS)	NRLS receive confidential reports of patient safety incidents from healthcare staff across England and Wales. Clinicians and safety experts analyse these reports to identify common risks to patients and opportunities to improve patient safety.

Non-Executive Director	Means a member of the Board of a National Health Service Trust who is not an employee of that organisation. They are often referred to as Independent Board Members.
Non-Officer Member	Means a member of the Board of a Local Health Board who is not an employee of that organisation. They are often referred to as Independent Board Members.
Notification	Reporting or telling someone about a concern.
Notifiable adverse outcome	Occurs when the duty of candour comes into effect in accordance with section 3 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020
Office Member	Means a member of a Local Health Board who is an employee of that organisation.
Patient	A person who has received or will receive services from a responsible body.
Primary Care Provider	A person or organisation (body) that has entered into a contract with a Local Health Board to provide primary care services e.g. General Practitioner, Dentist, Community Pharmacist or ophthalmic medical practitioners.
Patient Safety Incident	Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare.
Public Services Ombudsman for Wales	If a person raising a concern remains dissatisfied they can request an independent review by the Public Services Ombudsman for Wales (PSOW). However, the PSOW expects the responsible body to respond to the person raising a concern before agreeing to review.
Qualifying liability	There is proven personal injury or loss arising out of, or in connection with the care or treatment of a patient due to the service provided by the responsible body.

Redress	<p>Redress relates to situations where the patient may have been harmed and that harm was caused by the NHS in Wales. Redress can comprise of:</p> <ul style="list-style-type: none"> • a written apology; • a report on the action which has or will be taken to prevent similar concerns arising; • the giving of an explanation, and • the offer of financial compensation and/or remedial treatment, on the proviso that the person will not seek to pursue the same through further civil proceedings.
Remedial treatment	<p>Remedial treatment is offered to the patient with a view to trying to improve their condition and to restore them, as far as possible, to the position that they would have been in had the treatment complained of or negligent care not occurred.</p>
Resolution	<p>Resolution is the satisfactory outcome of a concern.</p>
Responsible Body	<p>Means a Welsh NHS body, a primary care provider or an independent provider.</p>
Responsible Officer	<p>In the case of a Welsh NHS organisation, is a person who is an office member or an executive director of that body and who has overall responsibility for the effective day to day operations for dealing with concerns.</p>
Root Cause Analysis	<p>Root Cause Analysis (RCA) is a systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context on which the incident happened. (<i>Seven Steps to Patient Safety, NPSA 2004</i>)</p>
Tariff	<p>A tariff in respect of compensation is a fixed amount of money paid according to the level of harm a patient has suffered. This can assist staff involved in the process of appropriately and consistently determining the level of financial compensation to be awarded to patients where this is an appropriate remedy.</p>

UK GDPR	General Data Protection Regulation ((EU) 2016/679)
Tort	A tort is a "wrong" that involves a breach of a civil duty owed to someone else, which is dealt with through civil proceedings.
Upheld / Well-founded	The number of concerns that were upheld, that is, supported or approved.

Section 16 - Useful Addresses

<p>Action against Medical Accidents (AvMA)</p>	<p>AvMA is an independent charity which promotes better patient safety and justice for people who have been affected by a medical accident.</p> <p>Further information can be found at: www.avma.org.uk/</p> <p>Contact: AvMA 44 High Street Croydon Surrey CR0 1YB Telephone: 020 8688 9555 Fax: 020 8667 9065 Helpline: 0845 123 23 52</p>
<p>Action Hearing Loss</p>	<p>Action Hearing Loss supports deaf and hard of hearing people in Wales.</p> <p>Further information can be found at: www.actionhearingloss.org.uk</p> <p>Contact: South Wales 16 Cathedral Road Cardiff CF11 9LJ Telephone: 029 2033 3034 Textphone: 029 2033 3036 Fax: 029 2033 3035 Email: wales@hearingloss.org.uk</p>

<p>Age UK</p>	<p>Age UK combines the previous support provided by Age Concern and Help the Aged.</p> <p>Further information can be found at: www.ageuk.org.uk/cymru</p> <p>Contact: AGE UK (Wales) Tŷ John Pathy 13/14 Neptune Court Vanguard Way Cardiff CF24 5PJ Advice line: 0800 223 444 Telephone: 029 2043 1555 Email: enquiries@agecymru.org.uk</p>
<p>Care and Social Services Inspectorate Wales (CSSIW)</p>	<p>CSSIW inspects and reviews local authority social services and regulate and inspect social care and early years settings and agencies.</p> <p>Further information can be found at: www.cssiw.org.uk</p> <p>Contact: Care and Social Services Inspectorate Wales Welsh Government Offices Rhydycar Business Park Merthyr Tydfil CF48 1UZ Telephone: 0300 062 8800 E-mail: CIW@gov.wales</p>

<p>Children's commissioner for Wales</p>	<p>Information on children and their rights and the responsibility and authority of the Children's Commissioner Office. The office works to make sure that children and young people are kept safe and that they know about and can access their rights.</p> <p>Further information can be found at: www.childcom.org.uk</p> <p>Contact: Children's Commissioner for Wales Oystermouth House Phoenix Way Llansamlet Swansea SA7 9FS Telephone: 01792 765600 Fax: 01792 765601 Email: post@childcomwales.org.uk</p>
<p>Citizens Advice</p>	<p>The Citizens Advice service helps people resolve their legal, money and other problems by providing free, independent and confidential advice, and by influencing policymakers.</p> <p>Further information including local offices can be found at: www.citizensadvice.org.uk/</p>

<p>Llais (Citizen Voice Body)s (LLAISs)</p>	<p>LLAISs work to enhance and improve the quality of local health services. They are a statutory and independent voice in health services and are able to provide concerns advocacy services.</p> <p>Further information on services provided and how to contact Llais (Citizen Voice Body) in Wales www.llais.org</p> <p>Contact: Board of Llais (Citizen Voice Body) 2nd Floor 33 - 35 Cathedral Road Cardiff CF11 9HB Telephone: 029 2023 5558 Email: enquiries@llaiswales.org</p>
<p>Disability Wales</p>	<p>Disability Wales is the national association of disabled people's organisations, striving to achieve the rights, equality and independence of disabled people in Wales.</p> <p>Further information can be found at: www.disabilitywales.org/</p> <p>Contact: Disability Wales Bridge House Caerphilly Business Park Van Road Caerphilly CF83 3GW Telephone: 029 20887325 Fax: 029 20888702 Email: info@disabilitywales.org</p>

<p>Equality and Human Rights Commission</p>	<p>The Equality and Human Rights Commission provide information and guidance on discrimination and human rights issues.</p> <p>Further information can be found at: www.equalityhumanrights.com/wales/</p> <p>Contact: Equality and Human Rights Commission Wales Freepost RRLR-UEYB-UYZL 3rd Floor 3 Callaghan Square Cardiff CF10 5BT Telephone: 029 20447710 Textphone: 029 20447713 Fax: 029 20 447712 Email: wales@equalityhumanrights.com</p>
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<p>General Dental Council (GDC)</p>	<p>The GDC regulates dental professionals in the United Kingdom. All dentists, dental nurses, dental technicians, clinical dental technicians, dental hygienists, dental therapists and orthodontic therapists must be registered with the GDC to work in the UK. The GDC protects the public by registering qualified professionals setting standards of dental practice and conduct, assuring the quality of dental education, ensuring professionals keep up-to-date, helping patients with <u>complaints</u> about a dentist or dental care professional, and working to strengthen patient protection.</p> <p>Further information can be found at: www.gdc-uk.org</p> <p>Contact: General Dental Council 37 Wimpole Street London W1G 8DQ Telephone: 020 7887 3800 Fax: 020 7224 3294 E-mail: concerns@gdc-uk.org</p>
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<p>General Medical Council (GMC)</p>	<p>The GMC registers doctors to practice medicine in the UK. Their purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine.</p> <p>Further information, including how to raise a concern about a doctor can be found at: www.gmc-uk.org/</p> <p>Contact details for the Regional GMC office in Wales are: General Medical Council (Wales) Regus House Falcon Drive Cardiff Bay CF10 4RU Telephone: 029 2050 4060 Email: gmcwales@gmc-uk.org</p>
<p>General Optical Council (GOC)</p>	<p>The GOC is the regulatory authority responsible for the registration of optometrists and dispensing opticians in the UK and overseeing continuing professional education.</p> <p>Further information, including how to raise a concern about an optician or optometrist can be found at: www.optical.org</p> <p>Contact: General Optical Council 41 Harley Street London W1G 8DJ Telephone: 020 7580 3898 Fax: 02743 63525 Email: goc@optical.org</p>

<p>Health Boards</p>	<p>The reorganisation of NHS Wales, which came into effect on October 1st 2009 created seven integrated Local Health Boards, responsible for all health care services. These have replaced the former 22 Local Health Boards and 7 NHS Trusts.</p> <p>Contact details of the local Health Boards can be found at: www.wales.nhs.uk/ourservices/directory</p>
<p>Healthcare Inspectorate Wales (HIW)</p>	<p>HIW is the independent inspectorate and regulator of all healthcare in Wales. HIW's primary focus is on improving the safety and quality of healthcare services in Wales; Improving citizens' experience of healthcare in Wales; Strengthening the voice of patients and the public in the way health services are reviewed and ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.</p> <p>Further information can be found at: www.hiw.org.uk/</p> <p>Contact: Healthcare Inspectorate Wales Bevan House Caerphilly Business Park Van Road Caerphilly CF83 3ED Telephone: 029 2092 8850 Email: hiw@gov.wales</p>

<p>Health & Professions Council (HPC)</p>	<p>HPC is a new independent, UK-wide regulatory body responsible for the regulation of therapists, biomedical scientists, chiropodists / podiatrists, clinical scientists, dieticians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists / orthotists, radiographers, and speech and language therapists.</p> <p>For further information, including how to raise a concern about any of the above professionals, can be found at: www.hpc-uk.org</p> <p>Contact: Health & Care Professions Council Park House 184 Kennington Park Road London SE11 4BU Telephone: 08453 006184 Fax: 020 7820 9684</p>
<p>Information Commissioners Office (Wales)</p>	<p>The Information Commissioner's Office is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.</p> <p>Further information can be found at: www.ico.gov.uk</p> <p>Contact: Information Commissioners Office (Wales) 2nd Floor Churchill House Churchill Way Cardiff CF10 2HH Telephone: 029 2067 8400 Fax: 029 2067 8399 Email: wales@ico.org.uk</p>

<p>Learning Disability Wales</p>	<p>Learning Disability Wales is the umbrella body for all voluntary organisations in Wales that are active in the field of learning disabilities.</p> <p>Further information can be found at: www.learningdisabilitywales.org.uk</p> <p>Contact : Learning Disability Wales 41 Lambourne Crescent Cardiff Business Park Llanishen Cardiff CF14 5GG Telephone: 029 2068 1160 Fax: 029 2075 2149 Email: enquiries@learningdisabilitywales.org.uk</p>
<p>Legal & Risk Services (L&RS)</p>	<p>L&RS is an NHS Body that acts for all the Trusts and Local Health Boards in Wales. Their core work is advice regarding clinical negligence.</p> <p>Further information can be found at: www.wales.nhs.uk/sites3/home.cfm?orgid=255</p> <p>Telephone: 029 2031 5500 Fax: 029 2031 5555</p> <p>Advice can be obtained by NHS Wales organisations by emailing: redress@wales.nhs.uk</p>

MIND	<p>MIND is a charity which provides information and advice to promote and protect good mental health for all, and ensures that people with experience of mental distress are treated fairly, positively and with respect.</p> <p>Mental health advocates can be located by contacting MIND (see below) or through local Llais (Citizen Voice Body) (see above).</p> <p>Further information can be found at: www.mind.org.uk</p> <p>Contact: MIND Cymru 3rd Floor Quebec House Castlebridge, 5-19 Cowbridge Road East Cardiff CF11 9AB Telephone: 029 2039 5123 Fax: 029 2034 6585 Email: contactwales@mind.org.uk</p>
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<p>NHS Centre for Equality and Human Rights (NHS CEHR)</p>	<p>NHS CEHR is a national, strategic resource for NHS Wales in building capacity and capability to ensure that patients and staff are treated fairly and in accordance with their needs and to support the delivery of the equality and human rights dimensions embedded within Designed for Life and Designed to Work.</p> <p>Further information can be found at: www.wales.nhs.uk/sites3/home.cfm?orgid=256</p> <p>Contact: NHS Centre for Equality and Human Rights Innovation House Bridgend Road Llanharan CF72 9RP Telephone: 01443 233450 Fax: 01443 233362</p>
<p>NHS Direct Wales</p>	<p>For health advice 24 hours a day/7 days a week</p> <p>Further information can be found at: www.nhsdirect.wales.nhs.uk</p> <p>Contact: NHS Direct Wales Thanet House 10 Phoenix Way Enterprise Park Swansea SA7 9EH Telephone: 0845 46 47</p>

<p>Nursing and Midwifery Council</p>	<p>The Nursing and Midwifery Council regulates nurses and midwives in England, Wales, Scotland, Northern Ireland and the Islands.</p> <p>For further information, including how to raise a concern about a nurse or midwife, can be found at: www.nmc-uk.org</p> <p>Contact: 23 Portland Place London W1B 1PZ Telephone: 020 7637 7181</p>
<p>Older People's Commissioner for Wales</p>	<p>The Commissioners role is to ensure that the interests of older people in Wales, who are aged 60 or more, are safeguarded and promoted. She also provides strategic leadership and acts as an ambassador and authority on older people's issues and speaks on their behalf.</p> <p>Further information can be found at: www.olderpeoplewales.com</p> <p>Contact: Older People's Commissioner for Wales Cambrian Buildings Mount Stuart Square Butetown Cardiff C10 5FL Telephone: 08442 640670 / 029 2044 5030 Fax: 08442 640680 Email: ask@olderpeoplewales.com</p>

<p>Public Services Ombudsman For Wales (PSOW)</p>	<p>The PSOW looks to see whether people have been treated unfairly or inconsiderately, or have received a bad service through some fault on the part of the public body providing that service.</p> <p>Further information can be found at: www.ombudsman-wales.org.uk/</p> <p>Contact: Public Services Ombudsman For Wales 1 Ffordd yr Hen Gae Pencoed CF35 5LJ Telephone: 01656 641 150 Fax: 01656 641 199 Email: ask@ombudsman-wales.org.uk</p>
<p>Race Council Cymru (RCC)</p>	<p>The RCC is the overarching/umbrella body established in Wales to bring together key organisations which work to combat prejudice, race discrimination, harassment, abuse and violence.</p> <p>Further information can be found at: www.racecouncilcymru.org.uk</p> <p>Contact: Race Council Cymru 2 Humphrey Street Swansea SA1 6BG Email: info@racecouncilcymru.org.uk</p>

<p>Refugee Voice Wales (RVW)</p>	<p>RVW is an umbrella organisation that represents Refugee Community Organisations (RCOs) in Wales. The organisation was established to empower refugees and asylum seekers, creating a platform for the voices.</p> <p>Further information can be found at: www.refugeevoicewales.org/</p> <p>Contact: Refugee Voice Wales 389 Newport Road Cardiff CF24 1TP Telephone: 029 2043 2987 (direct) Telephone: 029 2048 9800 ext 117 (indirect) Fax: 029 2043 2980 Email: info@refugeevoicewales.org</p>
<p>Royal National Institute for the Blind (RNIB)</p>	<p>RNIB is the UK's leading charity offering information, support and advice to almost two million people with sight loss.</p> <p>Further information can be found at: www.rnib.org.uk</p> <p>Contact: RNIB Cymru Trident Court East Moors Road Cardiff CF24 5TD Telephone: 029 2045 0440 Fax: 029 2044 9550 Email: cymruevents@rnib.org.uk</p>

<p>The General Pharmaceutical Council (GPhC)</p>	<p>GPhC is the regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. They are able to investigate complaints and concerns that indicate that a pharmacy professional's fitness to practice may be impaired.</p> <p>Further information, including how to raise a concern about a pharmacy professional can be found at: www.pharmacyregulation.org</p> <p>Contact: The General Pharmaceutical Council 129 Lambeth Rd London SE1 7BT Telephone: 020 3365 3400 Email: info@pharmacyregulation.org</p>
<p>Welsh Language Commissioner</p>	<p>The role of the Commissioner is to promote the use of the Welsh language; Facilitate the use of the Welsh language and promote equality between the Welsh and English languages.</p> <p>Further information can be found at: www.comisiynyddygybraeg.org/english/Pages/Home.aspx</p> <p>Contact: Welsh Language Commissioner Market Chambers 5/7 St Mary Street Cardiff CF10 1AT Telephone: 029 2087 8000 Fax: 029 2087 8001</p> <p>Email: post@welshlanguagecommissioner.org</p>

Appendix A - Template for recording a verbal concern
“early resolution” - This form can be used at ward level to assist NHS staff with the recording of a concern dealt with immediately.

Details of person who raised concern:

Title - Mr/Mrs/Miss/Ms/ State other:	
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
NHS number (if known):	

If above is not the patient, please provide the patients details:

Title - Mr/Mrs/Miss/Ms/ State other:	
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
NHS number (if known):	

Details of the concern:

1.	Date concern brought to your attention
2.	Date concern occurred if different to above
3.	If person raising the concern is not the patient, what is their relationship to the patient
4.	Name of Ward/Dept/Hospital/individual/Service/Section the concern relates to
5.	Other persons involved in the concern
6.	Outline of concerns - what went wrong, description of the affect this has had, how they have suffered
7.	What patient/third party thinks should be done to put things right
8.	Action taken (to include how this was communicated to patient/third party who raised the concern)
9.	Is person satisfied that their concern has now been dealt with?

Staff name:	
Signature:	
Date:	

Appendix B - Senior Investigation Manager Job Description

NHS Wales
(Insert name) Local Health Board / NHS Trust

JOB DESCRIPTION

Post Title:	Senior Investigations Manager <i>(working title – job title to be determined by NHS body)</i>
Accountable to:	Responsible Officer <i>(insert title of relevant Executive Director)</i>
Responsible for:	‘Dealing with Concerns’ Team
Key Relationships:	Designated Independent Board Member LHB/Trust Board Senior Management Team Divisional/ Locality Management Teams Relevant Committee/Sub-Committee/Joint Committee Members Clinicians, Staff, Independent Contractors Patients, Service Users & Carers Public Service Ombudsman for Wales Police and HM Coroners Health & Safety Executive Healthcare Inspectorate Wales and other regulators Llais (Citizen Voice Body) Advocacy and other support services Legal & Risk Services Patient Safety Wales Welsh Risk Pool Other Responsible Bodies and Local Authorities Welsh Government
Remuneration & Terms & Conditions of Service:	<i>to be determined locally</i>
Location:	<i>to be determined locally</i>

JOB PURPOSE / SUMMARY

The post holder will have responsibility and accountability through the Executive Responsible Officer to the Board for the strategic development and management of the organisation's arrangements for responding to complaints, claims and incidents, to be known collectively as 'concerns,' in line with the requirements set out by the Welsh Government. The post holder will be responsible for developing and implementing a long term strategic approach for the introduction and maintenance of systems which recognise the need to learn from concerns as well as seeking effective remedies for patients, including where appropriate the provision of Redress for anyone harmed by the services it provides.

DUTIES & RESPONSIBILITIES

1. *Dealing With Concerns Framework*

- Design, develop and implement policies and processes to ensure that the NHS body meets the requirements of the *Putting Things Right* framework including the arrangements and procedures governing the management, investigation, seeking remedies, provision of Redress and the learning from concerns which are patient centred and dealt with in an open and transparent way.
- Ensure that a range of techniques are used to aid the timely resolution of concerns, including obtaining independent clinical advice, legal advice, promoting the use of advocacy and facilitation, being open, Duty of Candour, providing apologies and where appropriate the offer of compensation, further treatment and rehabilitation.
- Develop an integrated investigation framework for the organisation in partnership with key stakeholders to consider best practice in investigation techniques to deliver a full and meaningful investigation and proportionate to the range and severity of issues involved.
- Develop a process whereby the investigations undertaken identify the contributory factors and root causes and where appropriate any qualifying liability and that required action is identified, implemented, monitored and evaluated to determine efficacy. Systems should be in place to ensure that, where appropriate, this information is shared across the whole organisation and beyond.
- Ensure systems are in place to evaluate both the quality and timeliness of the investigation and that remedial action necessary

to prevent a recurrence is appropriately implemented, monitored and evaluated.

- Develop, in conjunction with other organisations and through networks of similar post holders, consistent methodologies for implementing best practice dealing with concerns.
- Develop robust arrangements for undertaking joint investigations with other bodies as appropriate.
- Manage the resources allocated to the 'dealing with concerns' function.
- Ensure that the organisation complies with the Welsh Government performance management and monitoring requirements in respect of concerns.

2. Communication & Relationships

- Provide leadership and advice to Board Executives and Independent Members, clinicians and managers on patient safety and on the handling and management of concerns.
- Work with communications staff to manage any media and handling issues arising from concerns.
- Ensure that any concerns, including any serious untoward or patient safety incidents are reported to external bodies or regulators as appropriate and in a timely manner and are handled effectively thereafter.
- Develop proactive relationships with all key stakeholders and interested parties as listed above.
- Play a key role in protecting and enhancing the reputation of the organisation and NHS Wales.

3. Team Management & Development

- Develop a team structure which meets the requirements set out in the Welsh Government's recent interim guidance on the handling of concerns (Sep 2009) and any subsequent versions or additions to this guidance.
- Introduce a departmental structure to ensure that roles are defined and that there are clear lines of authority and responsibility. Ensure an adequate staffing and skill mix to achieve the requirements of the guidance, identifying the appropriate experience, competencies and seniority required to

carry out effective investigations, quantify any qualifying liability, where appropriate offer appropriate resolution, adequately support staff and ensure that lessons are being learned.

- Develop the team to provide professional support to divisional/directorate and primary care teams in undertaking the investigation of concerns ensuring that the investigations are undertaken in a timely manner and to a consistent level of quality.

4. Training, Education & Support

- Ensure that there is an organisation wide competency based training programme in place in relation to the management and investigation of concerns, including *Being Open and the Duty of Candour*. This role will include ensuring that there are systems in place to ensure that the training delivered meets the required standards and that staff are able to maintain competence.
- To work with Workforce and Organisational Development colleagues to lead and support staff to develop an open and fair culture so that staff are supported and managed fairly, staff feel able to be open when things go wrong.
- Ensure that the organisation has effective systems in place to support staff. When a member of staff is implicated support mechanisms are available through the Investigations Manager and the Workforce and Organisational Development department.
- Work closely with the *Being Open* leads to promote an open culture with patients and their carers.

5. Quality Improvement & Assurance

- Ensure that management of concerns and any actions arising from them meet the requirements of *Doing Well, Doing Better – Standards for Health Services in Wales*.
- Ensure that the learning from concerns is aligned with the organisation's quality improvement activities, processes and priorities.
- Contribute to the board assurance framework and work with the Executive Director to develop and agree the required level of information to be reported to the Board and any nominated committee thereof. Assurance should extend to both the investigation of issues, the lessons learned to reduce the risk of recurrence to improve standards in patient safety and care.

- Develop an evaluation and assessment framework to ensure that investigations and the identification of remedial action are carried out to the required standard.

6. General –as required by organisation e.g. health and safety, appraisal etc.

PERSON SPECIFICATION

Qualifications

- Educated to Masters degree level (or equivalent post graduate level)
- Management qualification
- Experience of managing projects
- Evidence of commitment to on-going continual professional development

Experience and Knowledge

- Significant experience of working with senior management and board members
- Experience of working and engaging with senior clinical staff
- Experience of leading/ managing services and teams
- Demonstrable evidence of successful multi-disciplinary team working
- Extensive experience in dealing with patients and the public
- Demonstrable experience of internal and external partnership working
- Trained and experienced in investigation techniques, patient safety concerns management and risk & risk management, using a range of complementary tools, e.g. Being Open, Duty of Candour, Root Cause Analysis, and Incident Decision Tree
- Demonstrable evidence of effective management of internal / external investigation of concerns
- Demonstrable and consistent evidence of organisational and personal learning and change from patient safety concerns, patient experience concerns or improvement programmes
- Demonstrable evidence of facilitation skills in managing/ handling difficult, contentious or sensitive issues as well as handling conflict
- Facilitation/Mediation experience
- Knowledge of the patient safety and quality agenda and policy direction for the NHS

Abilities and Personal Qualities

- Proven leadership, coaching and management skills
- Self-motivated, pro-active and innovative
- Ability to motivate others and work on own initiative
- Effective interpersonal, influencing and negotiating skills
- Resilient and flexible
- Ability to deal with diverse demands and expectations

- Strong communicator
- Effective written and verbal presentation skills
- Analytical skills - ability to make judgements about highly complex facts or situations
- Ability to analyse information, prepare reports and utilise information to inform decision making
- Ability to learn from experience and adapt to changes and new challenges
- Committed to the continuous development of staff and self
- Basic computer skills

Appendix D - Advocacy contacts

Llais (Citizen Voice Body)s in Wales

To access advocacy services for taking forward a concern about NHS Wales, please contact the Llais (Citizen Voice Body) in Wales

Web: www.llaiswales.org

Email: enquiries@llaiswales.org

Children and Young People

Contact Meic on **080880 23456** or visit their website www.meiccymru.org. Meic will listen and support and signpost to someone who can help sort out their complaint. Although Meic is a helpline aimed at children and young people we recognise that sometimes children and young people will ask an adult that they trust to support them or find out information on their behalf. The professionals section on the Meic website contains relevant news articles and a comprehensive database of advocacy services for children and young people, up to age 25, in Wales.

Appendix E - Template for recording verbal concerns to be handled under the Regulations

This form should be completed by NHS staff on behalf of a person who wishes to raise their concerns verbally and when the concern will go on to be handled under the Regulations. A copy of the completed form should be given to the person raising the concern – this form can also be adapted and included when specifically asked for the leaflet, to aid the person raising a concern as to what they need to let the NHS organisation know

SECTION A: Details of person raising the concern

Title - Mr/Mrs/Miss/Ms/ State other:	
Name in full and date of birth:	
Address and postcode:	
E-mail address:	
Daytime contact number: Mobile number:	
NHS number:	

Please indicate the method you prefer to be contacted by:

English or Welsh

Written: Post
 Email

Or

Verbal: Phone
 Face to face

If you have any special requirements, for example English/Welsh is not your first language or you have a sensory impairment, please tell us:

SECTION B: Details of the person who the concern is about if different to section A

Patient's name in full and date of birth:	
Patient's Address and postcode:	
What is your relationship to this patient? i.e. friend/relative/next of kin/advocate/carer etc	

SECTION C: Details about the concern
(NHS Staff should seek answers to the following questions - continue on a separate sheet(s) if necessary).

1. Name of the hospital/GP Practice/department/section/service you have concerns with.
2. What do you think they did wrong, or failed to do?
3. Describe how you personally and or the patient have suffered or have been affected.
4. What do you think should be done to put things right?
5. Date concern occurred or when did you first become aware of the concern.
6. If it is more than 12 months since you became aware of the concern, please give the reason why you have not raised this concern before now.
7. Please attach any documents to support your concern.

SECTION D: If the person raising the concern is the patient please ask them to read the statement and sign below.

I hereby agree that my health records (e.g. Hospital, GP etc) and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited to what is relevant to the investigation of the concern and will only be disclosed to people who need to know it in order to investigate my concern.

Signature of patient:	
Date:	

SECTION E: If person raising the concern is not the patient please complete this section:

I hereby authorise

Name of person raising the concern:	
Address (if different from above):	

to act on my behalf and to receive any and all information that may be relevant to the concern.

I hereby agree that my health my health records (e.g. Hospital, GP etc) and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited to what is relevant to the investigation of the concern and will only be disclosed to people who need to know it in order to investigate my concern.

Signature of patient:	
Date:	

Appendix F - Template to use when there is more than one responsible body

Regulations 17 and 19

Acknowledgement Letter (should be issued in 2 working days) to patient/third party which either:

- raises a concern which involves more than one responsible body or
- raises a concern with a LHB regarding a primary care practitioner

Dear *[patient's name or third party]*

Re: *[patient's name if third party and summarise your understanding of the concern]*

Thank you for your *letter/email/fax/telephone* enquiry of *[00.00.00]* which was received on *[00.00.00]* and for taking the time to contact us with your concern/s about *[insert name of responsible bodies or practice/primary care practitioner]*. Please accept our sincere apologies for the distress and inconvenience that this has clearly caused *you* or that this has clearly caused *[insert patient's name]* as well as to yourself and the rest of the family *[to be used as appropriate]*.

Then either, for concerns which involve more than one responsible body use the following:

For patients: It appears that your concern covers services provided by ourselves and *[insert name of other responsible body]*. With your permission, I would like to contact the other organisation so that we can agree to investigate this matter jointly, and to let you have a single response which covers all of your concerns. To investigate the matters efficiently, we may need to share information with *[other organisation]* and I should be grateful if you would contact me as soon as possible to let me know if you are happy for me to go ahead.

For third parties: It appears that the concern you raised about *[insert patient's name]* covers services provided by ourselves and *[insert name of other responsible body]*. With *[insert patient's name]* permission, I would like to contact the other organisation so that we can agree to investigate this matter jointly, and to let you have a single response which covers all of your concerns. To investigate the matters efficiently, we may need to share information with *[other organisation]*. As you are not the patient, I will need their written consent that they are happy for me to go ahead.

Or, for concerns which have been raised with a Local Health Board about a primary care practitioner use the following:

Before deciding the best way to deal with your concern, we need confirmation from you as to whether you have already raised your concern direct with the

[name of primary care provider] and if you have received a reply. If this is the case, then we are unable to investigate your concern again. If this matter has not been raised previously with *[name of primary care provider]*, we will need to decide who is best placed to investigate.

Consent to obtain medical records from primary care practice

Suitable for the patient or a third party: We take confidentiality seriously, and it is important for you to know that if we do decide to investigate your concern we will/may need to access your/*[insert patient's name]* medical records (e.g. Hospital, GP etc.), so that we can see what they say about the situation you have told us about. In order to do this we will need to obtain these from the primary care practitioner concerned *[and or other NHS Organisation]* and so we will need your/*[the patient's name]* consent for this and to discuss your concern with *[insert name of primary care provider]* on your/their behalf. Please complete/arrange for *[insert name of patient]* to complete the enclosed consent form and return to me as soon as possible.

Please note that if we do not have consent to discuss your concern with *[name of primary care provider]* and in doing so obtain a copy of your or *[insert name of patient]* medical records, a decision will be made as to whether we can investigate the concern ourselves.

For third parties also add: As you are not the patient, we will also need their consent to release information to you in any reply. This is all covered in the consent form.

Investigation of concerns about primary care practitioners by Local Health Boards

Once the decision is made as to who is based place to investigate your concern, we will let you know within 5 working days. If we are going to investigate then we will tell you at that stage what the investigation may involve. If you have any queries about this letter, the investigation process or the concern you have raised, please contact me.

Yours sincerely

[Insert staff name of concerns team]

Enc Consent form to approach primary care practitioner and access
 medical records
 Putting Things Right Leaflet

Suggested additional paragraphs for use in acknowledgments when it is alleged that harm has been caused/there has been a breach of duty of

care by a primary care practitioner and the LHB has been asked to investigate

I will first of all set out my understanding of your concern about *[insert name of patient]*:

- x
- x

The Health Board is able to investigate the following aspects of your concern:

- x
- x

I note that you have alleged that you have been caused harm by the care and treatment provided by *[insert name of primary care practitioner]*. However, we should point out that we cannot make any decisions about whether *[insert name of primary care practitioner]* was legally at fault in relation to your care and treatment – we call this a breach in duty of care which may have caused you harm. This is because the Redress elements of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 do not apply to primary care providers and so whilst the Health Board is able to look into what happened, we cannot come to any view on whether *[insert name of primary care practitioner]* was *legally at fault*. This means that we cannot consider providing you with any form of financial compensation.

If you are willing to consent to me referring your concern to *[insert name of primary care practitioner]*, then I will forward your letter dated *[insert date]* to *[insert name of primary care practitioner]* to advise them that we will be investigating the concerns outlined above. As you have also alleged harm has been caused to you, I will also advise *them/him/her* to notify their medical defence organisation of your concern.

Alternatively, in light of what I have explained above, if you would prefer the Health Board not to become involved, you may wish to provide *[insert name of primary care practitioner]* with details of your concern directly and request that they contact their medical defence organisation with a view to investigating the issues you have raised.

You may wish to consider seeking legal advice from an independent legal adviser to enable you to pursue your concern regarding *[insert name of primary care practitioner]* further.

Please could you confirm in writing or contact me by telephone on *[insert contact details]* to confirm how you would like to proceed.

Should you have any queries regarding the content of this letter, please do not hesitate to contact me.

Consent form

SECTION A: Details of who the concern relates to

Full name of patient:	
Address:	
Date of Birth:	
Has the primary care practitioner already responded to the concern:	
Relationship to person raising the concern:	

SECTION B: Details of the third party raising the concern - complete if applicable

I hereby authorise:

Name of person raising the concern:	
Address (if different from above):	

To act on my behalf and to receive any and all information that may be relevant to the concern.

SECTION C: To be completed by patient

I hereby agree that my concern can be discussed with the primary care practitioner concerned and that my health records (e.g. Hospital, GP etc) and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited only to those who need to see them in order to investigate my concern and only those sections of my health records relevant to the investigation of the concern and will be used.

Signature of patient:	
Date:	

Appendix G - Template acknowledgement letters

Regulation 22 - Letter Template 1

Acknowledgement Letter to Patient raising a Concern (should be issued in 5 working days)

Dear *[Insert patient's name]*

Re: *[Summarise your understanding of the concern]*

Thank you for your *letter/email/fax/telephone* enquiry of *[00.00.00]* which was received on *[00.00.00]* and for taking the time to contact us about your concern/s. Please accept our sincere apologies for the distress and inconvenience that this has clearly already caused you.

Contact point

I will be your named contact at the *Health Board/Trust* whilst your concern is being looked into. I am available to discuss with you any aspect of how your concern will be taken forward. Additionally, if you have any special requirements, such as language, hearing or sight needs, please let me know. My telephone number and e-mail details are shown below. The following information explains the additional support available to you and the overall investigation process.

Help and assistance

If you require independent help in taking forward your concern, then advocacy and support services are available to you through your local Llais (Citizen Voice Body), as outlined in the enclosed leaflet.

Medical records

We take confidentiality seriously, and it is important for you to know that in order to investigate your concern we will/may need to access your medical records (e.g. Hospital, GP etc.), so that we can see what they say about the situation you have told us about. If you are not happy with this, then you must inform us immediately. If we do not hear from you with the next few days then we will assume that you are happy for the investigation to continue and for your notes to be looked at. Please be assured that only people immediately dealing with the investigation will be able to look at your notes.

Investigation

We will now look at your concern, which may involve looking at relevant documents, speaking to staff and seeking clinical opinion. We may also need to speak to you during the investigation, or ask you to attend a meeting. After this time we will respond to you outlining our findings and actions taken.

We will normally let you have a reply within 30 working days of receiving your concern. This means that you should expect a reply from us by [00.00.00]. If we are unable to respond within this time or if further investigation is required, we will let you know.

I hope you have found this helpful and I look forward to hearing from you if you wish to discuss any aspect of this letter.

Yours sincerely

[Insert staff name of concerns team]
Enc Putting Things Right leaflet

Regulation 22 - Letter Template 2
Acknowledgement Letter to Third Party raising a Concern on behalf of a patient (should be issued in 5 working days)

Dear *[Insert Third Party name]*

Re: *[Insert patient's name and summarise your understanding of the concern]*

Thank you for your *letter/email/fax/telephone* enquiry of [00.00.00] which was received on [00.00.00] and for taking the time to contact us about *[insert patient's name]* concern/s. Please accept our sincere apologies for the distress and inconvenience that this has clearly caused *[insert patient's name]* as well as to yourself and the rest of the family *[to be used as appropriate]*

Contact point

I will be your named contact at the *Health Board/Trust* whilst your concern is being looked into. I am available to discuss with you any aspect of how your concern will be taken forward. Additionally if you have any special requirements, such as language, hearing or sight needs, please let me know. My telephone number and e-mail details are shown below. The following information explains the additional support available to you and the overall investigation process.

Help and assistance

If you require independent help in taking forward your concern, then advocacy and support services are available to you through your local Llais (Citizen Voice Body), as outlined in the enclosed leaflet.

Medical Records

We take confidentiality seriously, and it is important for you to know that in order to investigate a concern we will/may need to access *[insert patient's name]* medical records (e.g. Hospital, GP etc) so that we can see what they say about the situation you have told us about. Enclosed with this letter is a consent form, which *[insert patient's name]* must sign to show that they understand that we may need to do this, and that they give their permission for information about their treatment and care to be released to you.

Investigation

Once we have received *[insert patient's name]* consent, we will then look at your concern, which may involve looking at relevant documents, speaking to staff and seeking clinical opinion. We may also need to speak to *[insert patient's name]*, or ask you both to attend a meeting. After this time we will respond to you outlining our findings and actions taken.

We will normally let you have a reply within 30 working days of receiving your concern. This means that you should expect a reply from us by *[00.00.00]*. If we are unable to respond within this time or if further investigation is required, we will let you know.

I hope you have found this helpful and I look forward to hearing from you if you wish to discuss any aspect of this letter.

Yours sincerely

[Insert staff name of concerns team]

Enc Consent form
 Putting Things Right leaflet

Consent form

To be issued with Letter 2

Please provide the following details:

Full name of patient:	
Address:	
Date of Birth:	
Relationship to person raising the concern:	

I hereby authorise

Name of person raising the concern:	
Address (if different from above):	

to act on my behalf and to receive any and all information that may be relevant to the concern.

I hereby agree that my health records (e.g. Hospital, GP etc) and any personal information can be used in the investigation of my concern. I understand that access to my records and personal information will be limited only to those who need to see them in order to investigate my concern and only those sections of my health records relevant to the investigation of the concern and will be used.

Signature of patient:	
Date:	

Appendix H - Paper on consent

PUTTING THINGS RIGHT: CONSENT TO INVESTIGATION OF CONCERNS

This note sets out when explicit consent needs to be obtained from the patient or, if deceased, the next of kin, in order to carry out an investigation of a concern.

1. Concern raised by a patient or their personal representative

If, as in the majority of cases, the patient him/herself raises the concern, then in doing so, they can be deemed to have given implied consent to an investigation. This will also apply if the person has a representative who is entitled to act for them legally (e.g. Power of Attorney) and for MPs/AMs who do not need to provide explicit consent. However, in order for individuals to be clear in the knowledge that their medical records may need to be accessed, this should be explained, as well as indicating what medical records is being accessed e.g. Hospital, GP etc.

This scenario is set out at appendix H - letter “1” under the heading *Medical Records* contained in the letter.

In the event that the patient/personal representative contacts the NHS organisation after raising the concern to say that they are not happy for consent to be inferred and they do not want their records to be accessed, then the NHS organisation must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. Organisations should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

2. Concern raised by a carer/family member/other individual (e.g. person visiting someone else)/casual observer

Where a concern is raised on behalf of a patient, then written consent to investigate the matter should be obtained from the patient, unless the person raising the concern is already legally entitled to represent the patient (e.g. through a Power of Attorney – see section 1 above).

This scenario is set out at Appendix H - letter “2” under the heading *Medical Records* contained in the letter. A consent form should be enclosed with this letter.

Again, if it is not possible to obtain written consent for whatever reason, the NHS organisation must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. Organisations should evaluate the issue to determine whether it

would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

3. Concern raised about a deceased person by their next of kin/personal representative

In this instance, then the same situation applies as set out at section 1 above, whereby implied consent is assumed. The investigating officer should be satisfied that the person is entitled to act on behalf of the deceased. The same consideration is required in terms of the continuation of the investigation as in section 1 above, if the next of kin/personal representative indicates that they are not happy for records to be accessed.

4. Concern raised about a deceased person by someone other than their next of kin/personal representative

In this instance, the same situation applies as in section 2 above, where the written consent of the next of kin or personal representative should be obtained. The same consideration is required in terms of the continuation of the investigation as in section 2 if it is not possible to obtain this written consent.

5. Concern raised in behalf of a child or person who lacks mental capacity

It is acceptable for people to raise concerns on behalf of a child (e.g. by a parent/guardian) or someone who lacks mental capacity (e.g. an advocate/carer). In these instances, consent to access medical records is not required, but if the patient is a child, the NHS body needs to decide whether it is reasonable for another person to represent the child, or if they are able to take forward the concern themselves, with support if necessary. The key issue is the involvement of the child in the handling of the matter.

Because someone else has raised a concern on behalf of a child, this does not remove the right of the child to take the concern forward themselves, with support. The Responsible Body should therefore satisfy itself as to whether the child wishes to raise a concern themselves, with assistance or if they are happy for the person who raised the concern to represent them. If the child is not willing to allow the concern to be investigated then a decision will need to be taken about proceeding and specialist advice sought if appropriate. Particular regard needs to be given to safeguarding issues, and it may be necessary to proceed with an investigation, even if a child appears unhappy to do so. The Responsible Body is under no obligation to provide a response to the person who raised the concern in the first place.

For both children and people who lack mental capacity, the NHS organisation must assure itself that the representative is a suitable person (i.e. that they are entitled to represent the patient).

If difficulties arise and it is not possible to establish who is entitled to bring forward a concern on behalf of a patient, the same consideration as set out in

sections 1 and 2 in relation to the continuation of the investigation is required, and this must be recorded.

6. Concern raised by a staff member

Concerns about something having gone wrong during treatment can be raised by staff members. An initial investigation into the circumstances should proceed immediately in the interests of patient safety, in order to determine the extent of harm or otherwise that may have been caused. The patient's consent is not required to undertake this initial investigation.

However, if the initial investigation reveals that moderate or severe harm or death has resulted from the situation, then the patient or their representative must be contacted. They should be advised that initial investigations have given rise to concerns, and that further, more detailed investigations are required. In these situations, the written consent of the individual in question is required.

If this consent is withheld, once again, the NHS organisation must take a view on whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. It is not necessarily the case that there will be no investigation of the concern. Organisations should evaluate the issue to determine whether it would be in the interests of the health service to continue to look into the matter. This decision must be recorded before proceeding with or closing the matter.

Appendix I - Grading of Concerns

GRADING FRAMEWORK FOR DEALING WITH ALL CONCERNS

The All Wales grading framework is based on a risk matrix developed by the National Patient Safety Agency ¹⁵ and has been used to assess and manage risks and incidents. This approach has been built on to develop a framework for determining the level of investigation required in dealing with all types of concerns in order to promote a consistent approach across NHS Wales. The impact or harm experienced by the patient is always the overriding factor for grading concerns. The harm grading is dynamic in nature and must be considered throughout the investigation. Due consideration should also be given to the potential for litigation, regardless of the harm grading. However there may be situations where the grading of harm is low i.e. a grade 2, but there is indication there they will be pursuing a claim. **The examples listed are meant only to be a guide and not an exhaustive list.**

Grade	Harm	Examples of concerns	Consider potential for qualifying liability / Redress
1	None	<ul style="list-style-type: none"> a) Concerns which normally involve issues that can be easily / speedily addressed; b) Potential to cause harm but impact resulted in no harm having arisen; c) Outpatient appointment delayed, but no consequences in terms of health,; d) Difficulty in car parking; e) Patient fall – no harm or time of work; f) Concerns which have impacted on a positive patient experience. 	Highly unlikely
2	Low	<ul style="list-style-type: none"> a) Concerns regarding care and treatment which span a number of different aspects/specialities; b) Increase in length of stay by 1 - 3 days; c) Patient fall - requiring treatment; d) Requiring time off work - 3 days; e) Concern involves a single failure to meet internal standards but with minor implications for patient safety; f) Return for minor treatment, e.g. local anaesthetic or extra investigations. 	Unlikely

¹⁵ National Patient Safety Agency (2008) A risk matrix for risk managers, NPSA, London

3	Moderate	<ul style="list-style-type: none"> a) Clinical / process issues that have resulted in avoidable, semi permanent injury or impairment of health or damage that require intervention; b) Additional interventions required or treatment / appointments needed to be cancelled; c) Readmission or return to surgery, e.g. general anaesthetic; d) Necessity for transfer to another centre for treatment / care; e) Increase in length of stay by 4 -15 days; f) RIDDOR Reportable Incident; g) Requiring time off work 4 -14 days; h) Concerns that outline more than one failure to meet internal standards; i) Moderate patient safety implications; j) Concerns that involve more than one organisation; 	Possible in some cases
4	Severe	<ul style="list-style-type: none"> a) Clinical process issues that have resulted in avoidable, permanent harm or impairment of health or damage leading to incapacity or disability; b) Additional interventions required or treatment needed to be cancelled; c) Unexpected readmission or unplanned return to surgery; d) Increase in length of stay by >15 days; e) Necessity for transfer to another centre for treatment / care; f) Requiring time of work >14 days; g) A concern, outlining non compliance with national standards with significant risk to patient safety; h) RIDDOR Reportable Incident; 	Likely in many cases
5	Death	<ul style="list-style-type: none"> a) Concern leading to unexpected death, multiple harm or irreversible health effects; b) Concern outlining gross failure to meet national standards; c) Normally clinical/process issues that have resulted in avoidable, irrecoverable injury or impairment of health, having a lifelong adverse effect on lifestyle, quality of life, physical and mental well-being; d) Clinical or process issues that have resulted in avoidable loss of life; e) RIDDOR Reportable Incident; 	Very likely

Appendix J - Template letter for instruction of expert adviser

STANDARD DOCUMENT – JOINT LETTER OF INSTRUCTION TO EXPERT ADVISER ON CAUSATION / REDRESS

(Address)

Dear *(Name)*

[*date*]

(Name of patient) and *(Name of Healthcare provider)*

Thank you for confirming that you are willing to prepare a report in this matter upon the issue of causation.

Your instruction is a joint one between *(insert name of healthcare provider)* and *(insert name of patient)* and we are writing to provide you with detailed instructions. The terms of this letter are agreed by *the Health Board/Trust* and *(insert name of patient)*.

NHS Redress in Wales

The *Health Board/ Trust* is investigating a concern raised by *(insert name of patient)* or on behalf of *(insert name of patient)*, pursuant to the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

The Regulations introduced new arrangements for the handling and investigation of ‘concerns’ (including complaints, claims for compensation and incidents concerning patient safety) about NHS Services in Wales, within the NHS in Wales. The Regulations also introduced the concept of ‘Redress’. They place an obligation on Welsh NHS

bodies to consider, when it is notified of a concern that alleges harm has or may have been caused, whether or not there is a **qualifying liability**.

A 'qualifying liability' is defined within the Regulations as "a liability in tort owed in respect of, or consequent upon, personal injury or loss arising out of or in connection with breach of a duty of care owed to any person in connection with the diagnosis of illness, or in the care or treatment of any patient, in consequence of any act or omission by a health care professional; and which arises from services provided as part of the health service in Wales.

The Law

In order to establish a qualifying liability, the patient must prove that there was negligence in the treatment he/she received and that, as a result of that negligence, he/she suffered injury.

In order to prove that there has been negligence in the treatment that the patient has received, the patient must prove that the standard of that treatment fell below the standard of a reasonably competent medical practitioner in the relevant field at the relevant time.

Importantly, it is a defence to an allegation of negligence if the healthcare provider is able to prove that a reasonable and responsible body of reputable practitioners in the relevant field would have carried out the investigations and treatment in the same way as the prospective healthcare provider did. This is the so-called Bolam defence.

The patient must also prove that the allegedly negligent medical treatment has caused or materially contributed to the injuries he/she has suffered.

If the patient proves that the standard of the treatment he/she received fell below an acceptable standard of care, the patient is entitled to compensation to reflect the difference between (i) the condition which he/she would have been in if the standard of the treatment he/she received had been of an acceptable standard and (ii) the patient's actual condition.

The test for assessing any criticisms of the treatment in question and the issue of causation is whether the patient's case can be proved on the so-called 'balance of probabilities' (i.e. 51% likely or "more likely than not").

Your Report

Please find enclosed the following documentation for your consideration:

1. Hospital records - (name of hospital/trust).
2. GP records.

(Additional documentation might include complaints documentation, adverse incident reports, x-ray/scan films etc.)

Please let us know if there is any further information or documentation you require from the *Health Board/Trust* or from (*insert name of patient*) before preparing your report.

Although we do not require a report in the form and detail of a report prepared for the purposes of disclosure during litigation, it is important that your report is sufficiently detailed to enable the recipients to understand the medical issues which this case raises and the reasons why you have reached your opinion on the standard of medical treatment in question.

In relation to the issue of causation, please analyse the consequences of the shortcomings (if any) in the treatment which the patient received. Please set out what treatment the patient would have required and what the patient's condition and prognosis is likely to have been if the treatment which he/she received had been of an acceptable standard.

In addition to these broad questions, please consider the following, more specific issues in your report:

(Insert agreed list of specific issues)

Please do not confine yourself to these specific issues as we are sure there are others which will be of relevance and significance which you will wish to consider in your report.

Please send your report and all correspondence for the attention of *(insert name of case handler)* at *(insert address)* and to *(insert name of patient)* at *(insert patient's address)*.

We would be grateful if you would ensure that your report is written in layman's terms and that any references to medical terminology are explained clearly.

Fees

The amount which an expert is entitled to charge for preparing a report is *[insert fee previously agreed]*.

We confirm that the *Health Board/Trust* will be responsible for your fee. We would be grateful if you would provide a copy of your invoice to the *Health Board/Trust* with your report.

Timescale

We look forward to receiving your report on or before *(insert date)* or

We look forward to receiving your report as soon as possible.

Yours sincerely

(Name of Investigation Officer)

Appendix K - General terms and conditions for independent expert advisers for use by Responsible Bodies in Wales

Introduction

In accordance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 (referred to in this document as “the Regulations”), there may be occasions when it is necessary to secure an independent opinion on a matter relating to a concern, with a view to resolving it. This may include:

- obtaining a second opinion to aid a patient’s understanding of their own care, or to see whether there are any other issues which need to be explored in terms of the provision of care and treatment, as part of an investigation by a Responsible Body¹⁶ under Part 5 of the Regulations;
- in instances when an allegation of harm has been made by the patient, and where a Welsh NHS body¹⁷ is unable to come to a determination itself as to whether there is a qualifying liability in tort, the securing of an expert opinion to answer questions in relation to the tests relating to breach of duty of care and/or causation, as part of an investigation under Part 5 of the Regulations;
- where qualifying liability in tort is accepted, or subject to further investigation under Part 6 of the Regulations, may be conceded, the securing of expert opinion jointly between the Welsh NHS body and the patient/patient’s legal adviser to determine issues relating to breach of duty, causation, condition and prognosis and/or quantum.

Following a recent exercise, the Welsh Government set up a database containing the names and details of potential independent expert advisers who may be commissioned by Responsible Bodies in Wales to provide advice in the circumstances set out above. The database contains experts from across the health professions, disciplines and specialities/sub-specialties. It will continue to be revised and updated as part of the Putting Things Right process.

The following general terms and conditions are applicable to all independent expert advisers who agree to provide advice to the NHS in

¹⁶ A responsible body means a Welsh NHS body, a primary care provider or an independent provider

¹⁷ A Welsh NHS body is a Local Health Board or NHS Trust in Wales

Wales in accordance with the Regulations. Whilst these general terms and conditions will apply in all cases, it will also be the case that when an expert adviser is engaged by a Responsible Body in Wales, they will be asked to agree additionally any terms and conditions in relation to the specific case, in relation to timescales for the production of reports, their format, payment arrangements, or any other requirements that may be determined locally.

General Terms and Conditions

A person should not act as an independent expert adviser if he or she would have, or might be perceived to have, any conflict of interest in advising on a particular case.

In particular, a person should also not act as an independent expert adviser if they:

- Have had any prior involvement in the matters which are subject to investigation;
- Are employed by, provide services for, or have any other professional association with, the Responsible Body which is the subject of the concern;
- Have any close personal knowledge of, or association with, the person who raised the concern or any person whose actions are the subject of the concern;
- Are not currently on the register of the relevant statutory professional body;
- Are currently the subject of any investigation of their professional work (e.g. under a relevant complaints procedure, through an Ombudsman's investigation in any part of the UK, by a professional or regulatory body or by the courts or if, in the, past, have been severely criticised as a result of such an investigation;
- Feel that the case in question is beyond their area of expertise or experience or that they will not be able to provide advice in a reasonably timely manner;
- Know of any other reason why they are unable to provide independent expert advice for a particular case.

If any of the above are applicable or if there is any doubt about your suitability to act as an independent expert adviser in a particular case, you should inform immediately the person at the Responsible Body who has asked for your advice, with the reasons why you cannot comply.

Indemnity

All potential independent expert advisers should ensure that they are adequately indemnified to provide advice to the bodies which request it in accordance with the Regulations. It is important that you contact the Responsible Body requesting your advice if you have any problems in this regard.

Remuneration

Expert advisers who undertake this role will be paid fee to be agreed with the Responsible Body.

Data Protection/Confidentiality

Following their engagement on a case, expert advisers will receive, by recorded delivery, copies of relevant correspondence and clinical notes relating to the particular concern. The following requirements are made of all expert advisers:

- All information must be stored securely;
- Information sent on a Compact Disc (CD) or Memory Stick must not be saved to any networks or any computer's hard drive;
- Copies of all information received, unless otherwise instructed by the Responsible Body, must be destroyed under confidential conditions within 1 month after notification that the case has been resolved; and
- Any information to be returned to the Responsible Body be done via a secure method of delivery.

The expert adviser's report will be sent to the person who raised the concern and the person/s who are the subject of the concern. It is anticipated that the name and professional qualifications of the expert adviser will remain in the report, in order to provide assurance to the person raising the concern. However, other personal details, such as address and

telephone number of the expert adviser, will be removed prior to distributing the report.

Independent expert advisers must not disclose to any other source the content of any report they produce for a Responsible Body in Wales.

Appendix L - Dealing with people who make unreasonable demands

This section aims to provide a summary of how to manage a concern where the person raising the concern starts to behave unreasonably, becomes abusive, threatening or violent towards NHS staff.

This summary must be read in conjunction with your local Zero Tolerance policies and procedures and in line with the mandatory training provided by your NHS organisation

People raising concerns have the right to be heard, understood and respected. However, there may be times when the distress of a situation leads to the person raising a concern acting out of character and becoming determined, forceful, angry, make unreasonable demands of staff or (rarely) even resort to violence.

People who are unhappy about the outcome of the investigation of their concern, despite being advised on other avenues available for them, may also show aggression towards staff or continue to persistently pursue their concern by phoning, writing or in person.

Although NHS staff understand that a person's anger and aggression may be as a result of the distress that has been caused to them or to their loved ones, behaviour that escalates into actual or potential aggression towards NHS staff is not acceptable.

Examples of unacceptable aggressive or abusive behaviour include:

- Verbal threats e.g. personal abusive comments, rudeness or derogatory remarks. Unsubstantiated allegations or offensive statements can also be termed as abusive behaviour;
- Physically violent behaviour;
- Threatening remarks e.g. both written and oral which result in staff being afraid or left feeling abused;
- Unreasonable demands e.g. the demand for responses within unrealistic timescales, repeatedly phoning, writing or insisting on speaking to particular members of staff.

Dealing with unacceptable actions or behaviour

When people behave in an unacceptable manner towards staff, appropriate action should be taken in line with your NHS organisational policy and procedures.

Where a person raising a concern becomes aggressive or abusive you should consider the following:

- If there are threats or use of physical violence then the incident should be reported to the police;
- If correspondence (letter, electronic or fax) is abusive and contains threats to staff or the organisation this must be reported to Senior Managers/ police;
- If written unsubstantiated allegations are received then the person should be told that the language used is unnecessary and unhelpful. It should be made clear to them that if the behaviour and use of language continues all forms of communication will stop;
- If person is aggressive, abusive or offensive whilst on the telephone then they should be told that their behaviour is unacceptable and if it continues the call will be ended.

Managing persistent behaviour

If a person repeatedly telephones, visits or writes raising a concern which has already been investigated and a response sent then you should consider:

- Seeking support from line management or escalate matter to senior staff as per your local Zero Tolerance policies and procedures;
- Putting an arrangement in place whereby calls can only be received from them at set times on set days;
- One member of staff to be allocated as a contact point for written or verbal communication;
- Restricting contact to written correspondence only;

- Only making appointments to meet with the person if there is no other way of communicating with them – **Never meet them alone**;
- Communicating a decision that no further correspondence or telephone calls will be accepted unless a new issue is raised and any correspondence will only be acknowledged;
- In extreme circumstances consider seeking legal advice to determine if more formal action is required;

At each stage, it should be made clear to the person what actions are being taken and why.

Reporting Violent or Aggressive Behaviour

Incidents where violence and/or aggression occur must be reported and recorded via local reporting mechanisms.

Recording incidents where a person raising a concern has become violent or aggressive will identify trends and ‘hot-spots’ where incidents of aggressive behaviour occur. The organisation can then learn lessons to protect staff and prevent similar incidents of aggression.

Supporting Staff

If you find yourself in a threatening or violent situation, remember the 3 R’s:

- **R**etreat
- **R**aise the alarm
- **R**e-assess

You should never put yourself in a risky situation, if this should happen your first duty is to protect yourself by getting out, staying out, and obtaining support.

Many NHS organisations have dedicated “prevention of violence and aggression teams” that are able to provide additional advice and guidance to staff on recognising and dealing with aggression.

Appendix M - Template final response under Regulation 24

Written response to patient/third party responding to a concern where there is no liability in tort (should be issued in 30 working days)

Dear *[Insert patient's name or third party name]*

Re: *[Insert patient's name if third party and summarise your understanding of the concern as outlined in acknowledgement letter]*

I am writing further to my letter of *[00.00.00]* to provide you with a full response to your concern.

Give details of investigation, outcome and actions taken such as:

- *Summarise nature and substance of the concern/s*
- *Describe the investigation undertaken*
- *Include copies of expert opinions (if received during investigation)*
- *Include copies of any relevant medical records where appropriate (e.g. Hospital, GP etc)*
- *Where appropriate, include an apology*
- *Identify what action, if any, will be taken, including where services have been improved as a result of the concern*
- *Offer the opportunity to discuss the content of the response*
- *If no liability, give reasons for decision as to why*

Thank you for raising your concern with us. I hope this response has addressed all the questions you had and provided some assurance that lessons will be learned from your experiences.

If you are not satisfied with the outcome of our investigation, you can take your concerns to the Public Services Ombudsman for Wales. His contact details are 1 Ffordd yr Hen Gae, Pencoed, CF35 5LJ, telephone 0845 601 0987 or email ask@ombudsman-wales.org.uk.

I have also enclosed a short evaluation form which should you choose to complete is to be returned to the Welsh Government, in order to help them see how the Putting Things Right arrangements are working and whether they need to make any further improvements.

Yours sincerely

Signed by the responsible officer or a person acting on his or her behalf

Enc
Evaluation Form

Appendix N - Template interim response under Regulation 26

Where there is or there may be qualifying liability (to be issued within 30 working days of whichever is the later, either

- the day upon notification of the concern was received; or
- where the duty of candour is triggered, the day upon which the 'in-person' notification under Regulation 4(1) of the Duty of Candour Regulations was given.

[Insert name of NHS Organisation]

[Insert name of person who raised the concern – and name of the person concern is about if this is different]

[Insert date of report]

An Interim Report must contain the following:

- Summary of the nature and substance of the concern
- Description of the investigation undertaken
- Describes why there is or there may be a qualifying liability
- Contains copies of relevant medical records (e.g. Hospital, GP etc)
- Explains the availability of access to legal advice without charge
- Explains the availability of advocacy and support of services
- Explains the procedure which will be followed to determine whether or not qualifying liability exists and the procedure for making an offer of redress if such qualifying liability is found to exist
- Confirms that a copy of the final investigation report will be made available
- Contains details of the right to notify the concern to the Public Services Ombudsman for Wales
- Offers opportunity to discuss content of the interim response with the responsible officer or a person acting on his or her behalf

[Signed by responsible officer or a person acting on his or her behalf]

Enclosures:

Copies of expert opinions

Copies of medical record

Appendix O - Legal fees framework

Disclaimer: The boxes below are mutually exclusive and should not be simply added together at every stage of the matter. The fees allowed regarding an Infant Approval settlement would however be separate. Please note that these figures are accurate as of April 2012. All fees payable are subject to VAT and will change on an annual basis – please contact the Legal & Risk Services for the most recent figures.

STAGE OF PROCESS	TYPE OF FEE PAYABLE TO LEGAL ADVISER
<p>If in interim report produced under Regulation 26, the LHB/Trust admits breach of duty and causation and make offer of settlement to patient, legal advice will be available to:</p> <ul style="list-style-type: none"> • review of appropriateness of the offer • to commission joint report on condition and prognosis if considered necessary to advise on quantum 	<p>Fixed costs of £1,600)</p> <p>Fixed fee of £430 where agreed by both the LHB/Trust and patient legal adviser</p>

<p>If in interim report produced under Regulation 26, the LHB/Trust indicates there may be a qualifying liability but this needs further investigation to determine, then legal advice will be available to:</p> <ul style="list-style-type: none"> • consider breach of duty and investigate causation, allowing for up to 2 expert reports • instruct additional experts if necessary and where agreed by both the LHB/Trust and patient legal adviser 	<p>Fixed fee of £1,600</p> <p>Fixed fee of £434 where agreed by both the LHB/Trust and patient legal adviser</p>
<p>If a qualifying liability is admitted, then legal advice will be available to:</p> <ul style="list-style-type: none"> • commission joint report on condition and prognosis if considered necessary to advise on quantum, allowing for 2 expert reports • Instruct additional experts in relation to the quantum if necessary and where agreed by both the LHB/Trust and patient legal adviser 	<p>Fixed fee of £1,600</p> <p>Fixed fee of £430 where agreed by both the LHB/Trust and patient legal adviser</p>
<p>If a qualifying liability is admitted but no financial offer made, then legal advice will be available:</p> <ul style="list-style-type: none"> • In relation to refusal to make an offer of redress 	<p>Fixed fee of £868)</p>

<p>When there is a need for representation at an Infant Settlement approval hearing, legal adviser will be paid for:</p> <ul style="list-style-type: none"> • Preparation and attendance at Court hearing 	Fixed fee of £1085)
<p>LHB/Trust would also pay:</p> <ul style="list-style-type: none"> • Court fee • Counsel's fee 	<p>Unknown Fixed fee of £450</p>

Appendix P - Investigation checklist

1. Review the PAS System. Identify any radiology relevant to the treatment which is the subject of the concern.
2. Check the patient's medical records (e.g. Hospital, GP etc) and copy only those records which are relevant to the concern including clinical notes, correspondence, operation note(s), consent form(s), anaesthetic records, pre-operation check-list(s), post-operative notes, discharge summary, test results, temperature and blood pressure chart(s), medication charts (if any) and nursing care plans/Kardex.
3. Check whether there are any incident forms and/or policies/protocols in existence of relevance to the concern.
4. Identify the Healthcare professionals involved in providing the care and/or treatment to the patient which is the subject of the concern and the Consultant in charge of the patient's care at the relevant time.
5. Provide the relevant healthcare professionals and Consultant(s) with details of the concern raised and request that they provide you with a detailed factual account of their involvement with the patient, and their comments upon the concern(s) raised. Ask the Consultant(s) in charge of the patient's care at the relevant time if they are able to comment upon whether they consider any aspect of the patient's care and/or treatment to have fallen below a reasonable standard of care (Bolam test) and if so, whether they feel able to comment upon any

affect that any failings have had upon the patient's treatment and/or outcome (causation). You may need to approach a Consultant in an alternative specialty for comments upon causation. N.B. Any comments will be disclosable should legal proceedings be brought against the Health Board in relation to the subject matter of the concern.

6. Consider whether there would be merit in requesting a face to face meeting with any of the healthcare professionals involved if the comments you have received do not serve to address the patient's concern(s) or assist your investigations.
7. Consider whether there would be merit in obtaining a report upon breach of duty and/or causation and condition and prognosis (patient's long term outcome) from an independent clinical expert and the field of expert it will be necessary to instruct.

N.B. Any expert evidence will be obtained on a joint basis between the healthcare provider and the person who raised the concern.

8. Provide a copy of any independent clinical reports to the relevant Consultant(s) and request that they provide you with any comments they have upon the content of the report(s).
9. Review clinician comments and/or independent clinician reports and consider whether there is a qualifying liability, on the balance of probabilities.
10. If you have any queries at any stage of the investigation process, contact Legal and Risk Services.

Appendix Q - Template Redress investigation report

Regulation 31 and 33 - Investigation Report template

[Insert name of NHS Organisation]

[Insert name of person who raised the concern – and name of the person concern is about if this is different]

[Insert date of report]

Investigation report to contain the following:

- Copies of any medical evidence that has been commissioned
- Confirmation as to whether or not there is qualifying liability
- An explanation as to the decision as to whether or not there is qualifying liability

If Redress is offered

- Advise the person who raised the concern that they have 6-months to respond to the offer made and only in exceptional circumstances if they cannot respond to the offer, the person needs to let the Welsh NHS body know why there is a reason for the delay and when the response will be submitted
- Advise that if the settlement proposed is accepted that the person will be required to waive any right to bring civil proceedings
- Advise that in certain circumstances that the settlement agreement will need to be approved by the court, and where approval is required the Welsh NHS body must pay the reasonable legal costs associated with obtaining such approval.

I have also enclosed a short evaluation form which should you choose to complete is to be returned to the Welsh Government, in order to help them see how the Putting Things Right arrangements are working and whether they need to make any further improvements.

Enclosures:

Copies of medical evidence

Evaluation form

Appendix R - Checklist for reimbursement following payment of financial compensation exceeding £25,000

FOR COMPLETION BY RESPONSIBLE BODIES MAKING A CLAIM

Checklist to be used when compiling the summary of a case – clinical negligence and personal injury cases whether settled by ex-gratia payments or by court order.

<p>Responsible Body Name:</p> <p>Responsible Body Code:</p> <p>Case Reference:</p> <p>Laspar Ref:</p> <p>If relates to a SI – WG SI Reference No:</p>
<p>PART (1) INVESTIGATION, MANAGEMENT AND RESOLUTION</p>
<p>1.1 What were the circumstances of the originating incident?</p> <p>1.2 What were the substantive allegations?</p>
<p>2.1 With reference to the allegations above, please give details or summarise the witness evidence of relevant witnesses/staff</p>
<p>3.1 What views (if any) have been obtained from any 'in-house' experts or non-treating clinicians? Please summarise</p> <p>3.2 What external independent expert evidence has been secured? Please summarise</p>
<p>4.1 What were the failings or root causes identified?</p> <p>4.2 What made the Responsible Body decide to dispose of the claim at this time?</p>
<p>5.1 What was the date and/or manner of acknowledgement that there was qualifying liability in tort?</p>
<p>6.1 Has appropriate legal advice been sought? Yes/No</p> <p>6.2 If yes, from whom?</p> <p>6.3 If no, why not?</p> <p>6.4 If advice has been sought, what recommendations were made?</p> <p>6.5 How were these recommendations followed?</p>

<p>7.1 By what means did the Responsible Body become aware of the concern/claim and/or how and on what date did the incident first come to the attention of the Responsible Body and what actions were taken?</p> <p>7.2 Was the incident reported to the appropriate national organisation at the time (for example the NRLS or RIDDOR)</p> <p>7.3 What was the date on which the concern was received?</p> <p>7.4 Please confirm how the concern was investigated and managed pursuant to the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011? explain how the Responsible Body undertook its investigation and summarise the allegations made under Putting Things Right and include a copy of the root cause analysis undertaken under the Regulations</p> <p>7.5 What was the date of Interim Report acknowledging qualifying liability?</p> <p>7.6 What was the date of Final Report?</p>
<p>8.1 How was the value of the damages claim determined?</p> <p>8.2 Have any factors appertaining to the handling of the claim or the course of the claim had any effect on either the damages or legal costs awarded in this claim?</p> <p>8.3 Has any other insurer, third party or contributor been involved in making any payments in settlement of this case? Yes/No</p> <p>8.4 If the answer is yes, please give details including any recommendations made, or apportionments agreed or any special conditions set by any third party.</p> <p>8.5 Has the option of periodical payments been considered or have periodical payments been ordered? Yes/No</p> <p>8.6 If not, why not?</p> <p>8.7 If either, what was the outcome and why?</p> <p>8.8 When did the NHS Wales Department of the Welsh Government approve the periodical payments settlement?</p>
<p>9.1 At what level within the Responsible Body has the proposed settlement been approved?</p> <p>9.2 When was it approved?</p> <p>9.3 Is this within delegated limits formally approved by the Board? Yes/No</p>

<p>9.4 If not, has the approval of the Welsh Government been obtained? Yes/No</p> <p>9.5 If yes, on what date was approval obtained?</p>
<p>10.1 Does the case involve any novel, contentious or repercussive issues (e.g. could it set a precedent for other NHS litigation, or as part of a class action)? Yes/No</p> <p>10.2 If it does, when was the NHS Wales Department of the Welsh Government informed and when?</p> <p>10.3 Where applicable please give the details of the name and position of the person who forwarded this case for Welsh Government approval?</p>
<p>CLAIMS SPECIALIST'S DECLARATION</p> <p>I have considered fully points 1 – 10 on this checklist and my findings are recorded. I confirm that the details recorded in each relevant section are complete and accurate and that these aspects of the checklist have been properly considered and actioned.</p> <p>Signed by –</p> <p>Print Name –</p> <p>Position –</p> <p>Date –</p>
<p>PART (2) RISK ISSUES AND LEARNING FROM EVENTS</p> <p>11 Provide details of actions taken by the Responsible Body to learn lessons from any identified failings(Clinical, Health and Safety, Administrative or other) with a view to minimising or mitigating the risk or preventing the occurrence of this type of incident</p>
<p>12 What monitoring or audit measures have been introduced to ensure any improvements that have been implemented are working effectively? Please note that you may be requested to forward detailed monitoring reports relating to this claim at a later date to ensure all proposed improvements have been implemented completely and effectively and are reviewed on a regular basis.</p>
<p>13 What lessons can be learnt from this incident which would be of value to other Responsible Bodies or to the NHS as a whole?</p>
<p>GOVERNANCE DECLARATION</p> <p>I have considered fully points 11-13 above inclusive on this checklist and my findings are recorded. I confirm that the details recorded above are complete, accurate and reasonable</p>

response to the failings identified. These aspects of the checklist have been properly considered and actioned.

Signed by –

Print Name –

Position –

Date –

PART (3) – RESPONSIBLE BODY DECLARATION AND AUTHORISATION

I confirm that the above details are complete and accurate and all aspects of the checklist have been properly considered and actioned. I agree that this payment offers the best value for money. I also confirm that:

Delete as appropriate

- This case is within the delegated authority of this Responsible Body and is not novel, contentious or repercussive. I, therefore, agree to this special payment.
- The Responsible Body has complied with its obligations and the conditions set out in Welsh Government Guidance to enable it to exercise its delegated authority to settle claims valued below £1 million
- The Responsible Body confirms that there have no material changes relevant to the exercise of the delegated authority since the date of the last WRPS Assessment
- This case is above the delegated authority of this Responsible Body/is novel, contentious or repercussive (*delete as appropriate*) and we have obtained advance formal approval to make this special payment from the Welsh Government

Signed by –

Print Name –

Position – CHIEF EXECUTIVE

Date –

Countersigned signed by –

Print Name –

Position –

Date –

Please note that this section must be signed by 2 senior officers of the Responsible Body both of whom must be authorised signatories and one of whom must be the Chief Executive in accordance with the delegated limits set by the Board

Send to: Head of WRP Services, Alder House, Alder Court, St Asaph Business Park, Denbighshire, LL17 0JL

Appendix S - Checklist where total expenditure does not exceed £25,000

Name and address of Health Board/Trust		
Health Board Reference		
LASPAR Reference		
If relates to a SI – WG SI Reference No:		
Name and contact number of person dealing with the concern		
Name of Patient		
Index date of incident		
Type of incident	Clinical	
	Personal Injury	
Brief description of incident		
Settlement under Redress	Yes/No If yes please complete as follows:	
	Date concern received	
	Date of interim report acknowledging qualifying liability	
	Date of final report	
Breach of duty identified		
Description of injury/injuries sustained		
Damages/Compensation paid £	General Damages	
	Special Damages	Amount
		Type
	CRU	
Details of rehabilitation agreed		
Claimants Costs/Independent Legal Advice	Source of Costs Claim	
	Total Sum paid £	
	Conditional Fee Agreement	Yes/No
	Insurance Premium Paid	
Defence Costs/Expert's Fees paid	Amount	
	Type	
Lessons Learned including monitoring auditing measures		

Lessons of value to other Responsible Bodies or NHS	
I confirm that to the best of my knowledge the above information is true and accurate.	
Signed.....	Date.....
Authorised signatory	

For completion by WRPS

WRPS Reference	
Date inputted on Database	
Actioned by	

Please return the completed form within 70 days of conclusion to:

Head of WRP Services, Alder House, Alder Court, St Asaph Business Park, Denbighshire, LL17 0JL
and send a copy to redress@wales.nhs.uk

Guidance Notes

As a payment under Losses and Special Payments, all Responsible Bodies are required to notify the Welsh Risk Pool Services of all compensatory payments made under £25,000 or excess.

- (1) This form should be completed and forwarded to the Welsh Risk Pool Services within 70 days of the conclusion of relevant concern/claim
- (2) This form should be used to notify the Welsh Risk Pool Services of any compensatory payment made below £25,000 or excess following an allegation of negligence. This will include all redress concerns under Regulation 6 of the NHS (Concerns, Complaints and Redress Arrangements)(Wales) Regulations 2011 and any settlement of claims under the Civil Procedure Rules whether of a clinical, personal injury or other nature
- (3) In the section, 'Breach of Duty' please set out the nature of the breach of duty identified which resulted in the settlement being agreed
- (4) In the section, 'Description of injury/injuries sustained', please set out what injury or damage was caused to the individual concerned and in respect of which the compensation paid was valued
- (5) In the section, 'Damages/Compensation paid', please break down the settlement into general and special damages/CRU. This is extremely important to inform the database on valuing general damages. Please also indicate the type of special damages paid i.e. loss of earnings, care, private treatment, etc
- (6) In the section, 'Details of rehabilitation agreed', please indicate what if any rehabilitation measures have been agreed
- (7) In the section, 'Claimant's costs/Independent Legal Advice paid', please clarify on what basis the fees were paid i.e. fixed fees under Redress/fixed fees under Speedy Resolution/Predictable Costs Regime/Civil Procedure Rules. Please set out payments made for insurance premiums under conditional fee agreements
- (8) In the section, 'Defence Costs/Expert's Fees paid', please clarify on what basis the fees were paid i.e. fixed fees under Redress, Civil Procedure Rules etc
- (9) In the section, 'Lessons Learned', please briefly set out the action taken to minimise or prevent reoccurrence
- (10) Please set out details of any general lessons learned for dissemination across NHS Wales

Appendix T - Checklist where total expenditure does exceed £25,000

Section A			
Trust/Local Health Board		Claims Manager	Name: Tel:
Location of incident, (hospital, clinic etc)		Name of lead clinician	
Patient Surname		Claimant solicitor	
Patient Forename		Defence Solicitor	
Patient Date of Birth		References	WHLS: LASPAR:
Settlement under Redress	Yes/No		

Section B - Details of payments made, EXCL VAT, ADJUSTED FOR INTEREST RECEIVED ON PAYMENTS INTO COURT AND COSTS AWARDED		Section C - Key Dates	
General Damages	£	Incident occurred	/ /
Special Damages	£	Claim made	/ /
CRU	£	Claim settled	/ /
Claimant costs	£	Costs settled	/ /
Defence costs	£	Structured	To be Advised/Yes/No
Total payments	£		

Section D – Previous Reimbursements		Section E – Reimbursement	
Date reimbursed	Amount	Type of Reimbursement (delete as appropriate)	Interim/Final
/ /	£	Total Payments (section B)	£
/ /	£	Less total previous payments (section D)	- £
/ /	£	Less trust/LHB liability	- £
Total previous reimbursements	£	WRP Claim	£

Section F – Checklist and Declaration							
WRP claim form		(tick)	Schedule of costs		(tick)	Annex B Checklist	(tick)
I declare that the information in support of this claim is correct and complies with WRP procedures							
Signature <i>(Authorised signatory)</i>	Print Name	Designation	Date				

Official Use Only	WRP Reference:
--------------------------	-----------------------

Original authorised form		(tick)		
Annex B Checklist		(tick)	Date Stamp:	
Correct excess applied		(tick)		
Schedule of costs		(tick)		
Previous payment check		(tick)		
WRP Manager confirmation				
Delegated Officer Approval				
Signature	Name/Title	Minute No	Date passed to C&D Finance Dept / /	

Send to: Head of WRP Services, Alder House, Alder Court, St Asaph Business Park, Denbighshire, LL17 0JL and send a copy to redress@wales.nhs.uk

Appendix U - Notification of IR(ME)R Serious Incident form



DRIVING
IMPROVEMENT
THROUGH
INDEPENDENT AND
OBJECTIVE REVIEW

SICRHAU
GWELLIANT
TRWY
AROLYGU ANNIBYNNOL
A GWRTHRYCHOL

Please complete all fields (* where applicable) - Guidance on completing and submitting IR(ME)R notification form is available on the [HIW Website](#) and the [Welsh Government Putting Things Right Website](#).

Your Reference:		Our Ref:	Our Grading:
Healthcare Organisation:			
*Hospital Name:			
*Department:			
Modality: (Please highlight the appropriate)	Diagnostic Imaging	Radiotherapy	Nuclear Medicine
Speciality:			
Date Incident Occurred:			
Brief Description of Incident:			
Date Incident Reported to Risk Management			
How many 'MGTI' ¹⁸ were affected? (Please anonymise; use Patient A, Patient B)			
Age of 'MGTI' Patient(s)		Gender of 'MGTI' Patient(s)	
*Intended Site of Treatment e.g. Chest, Abdomen etc		*Actual Site of Treatment	
*Intended Dosage		*Actual Dosage	

¹⁸ 'Much Greater Than Intended'

Brief Description of Immediate Action Taken			
Media Interest <i>(Actual or Potential)</i>			
What other external agencies have been informed about this incident? ¹⁹			
Any other relevant information			
Form Completed by: <i>(Name, Designation and e-mail)</i>			
Incident Officer and contact details			
Date:			
Employer: ²⁰ <i>(Name, Designation, e-mail and Authorisation of form)</i>			
Date:			

Please be aware that information collated through these forms will be used to enable HIW to evaluate healthcare organisations in line with the IR(ME)R regulatory requirements. We may also share this data set (anonymised) when we consider the need to do so to ensure patient safety or improve IR(ME)R services. Please note that the completed form is to be **sent to both** HIW and the Improving Patient Safety Team.

¹⁹ E.g. other Health Boards, WHSSC, NRLS

²⁰ Chief Executive

Please send completed forms to HIW by:

a) e-mail;
HIW.IRMERIncidents@gov.wales

b) post; or
IR(ME)R Incidents
Healthcare Inspectorate Wales
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ

c) portal;
The NWIS Secure File Sharing Portal is a website through which documents can be exchanged safely. To join the portal, the registered person must provide HIW with a list of names and e-mail addresses of individuals who are authorised to use the portal.
[User Guide for Secure File Sharing Portal](#)

Please send completed forms to WG by:

a) e-mail
PatientSafety.Wales@wales.nhs.uk

Appendix V - Notification of Serious Incident form



RESTRICTED WHEN COMPLETED

NOTIFICATION OF SERIOUS INCIDENT
(FORM SI 1)

Llywodraeth Cymru
Welsh Government

WG Reference	WG Grading	
Internal Ref or Datix No.	Date reported to Risk Management	
Organisation		
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:	
Date of making this report		
When did the incident occur?	Date:	Time (24 hours):
Category of Incident (as per NRLS Incident Type Coding List)		
Is this a <i>never event</i> ?		
Where did the incident occur, including site and speciality where relevant?	Local Authority Area	
Who did it affect and how many? (personal details must not be included)	Age of patient(s) if known (Do not provide DOB)	

Brief description of what happened	
Brief description of immediate action taken	
Brief description of action taken if this SI involves another HB/Trust or WHSSC?	
Details of Media interest	
Has this SI been reported to the NRLS?	
What other external agencies have been informed about this incident e.g. HIW/WHSSC?	
Any other relevant information (include No Surprise ref no or Serious Incident ref no if applicable)	
Chief Executive / Executive Sign off (This section must be completed)	Signature: _____ Title: _____ Date: _____ Print Name: _____
For WG use only:	

Appendix W - No Surprise / Sensitive Issue form



RESTRICTED WHEN COMPLETED

Llywodraeth Cymru
Welsh Government

NOTIFICATION OF NO SURPRISE/SENSITIVE ISSUE (FORM SI 2)

WG Reference			
Organisation			
Reporters Name, Designation and contact details	Name: Job title: Contact details: E- mail:		
Date of making this report			
Brief description of issue			
Brief description of any action and media handling			
Any other relevant information (include SI ref no if applicable / age of patient(s) if known, schedule 5)			
Chief Executive / Executive Sign off (This section must be completed)	Signature:	Print Name:	
	Title:		
	Date:		
For WG use only:			

Appendix X - Closure Summary for Serious Incidents



RESTRICTED WHEN COMPLETED

CLOSURE SUMMARY (FORM SI 3)

Llywodraeth Cymru
Welsh Government

WG Ref		NHS Grading	
NHS Ref			
Organisation		Date of incident	
Summary of incident (only complete if there is additional information to the original notification form)			
Please provide the following: Issues/problems identified Contributory factors Root causes			
Cause of death (if applicable)			
Confirmation of actions implemented and arrangements for completing outstanding actions		Timescale (s)	
Please indicate if the incident is associated with			

Appendix Y - Annual Report Template

TITLE OF REPORT

Purpose

To provide information on the progress and performance of (*name of responsible body*) in dealing with concerns.

Background

This report outlines how (*name of responsible body*) has dealt with concerns for the period xxxxx – xxxxxx.

Executive Summary

- 1. Overview of arrangements in place for dealing with concerns**

Describe current approach to dealing with concerns and any planned developments. Include reference to working with other responsible bodies. How effective the new arrangements have been, the approach to 'investigating once and investigating well' and how this has impacted on both the staff and patient experience. Give an indication of the services used, for example, expert advice, legal advice, and alternate dispute resolution and advocacy services.

- 2. Concerns Statistics (as per data collection form)**

In addition responsible bodies should attempt to give an indication of the number of concerns that were not well founded.

- 3. Themes, trends and any key issues emerging from Concerns**

- 4. Lessons Learnt**

- 5. Conclusion and priorities for improvement**

Appendix Z - Template letter re: request for access to health records from a solicitor

Letter template 7

Letter from concerns teams to a solicitor who has request medical records

NB In some cases Solicitors will contact the NHS organisation direct requesting a copy of a patient's medical record and in some cases the reason for this may be an early indication that there is a claim but the reason behind the request may not always be entirely clear

Dear *[name]*

Re: *[patient's names]*

Thank you for your *letter/email/fax* of *[00.00.00]* which was received on *[00.00.00]* requesting a copy of *[patient's name]* medical records.

As you enclosed a consent form from the patient/power of attorney, the request will be dealt with and you should receive a copy by *[insert date]*. **Or** In order to deal with the request we require the *[patient's/power of attorney's consent]* and I would be grateful if the enclosed form could be completed and returned.

We assume that in contacting us, your client has a concern about the care and treatment *he/she* has received from the *Health Board/NHS Trust*.

We would be grateful if you would confirm whether you have discussed your client's right to an investigation of his/her concerns under the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 which are now in place in the NHS in Wales for the handling of concerns about care and treatment. I have therefore enclosed a leaflet about this which you may wish to consider passing on. We would also appreciate receiving clarification of whether your client wishes the Health Board/NHS Trust to investigate his/her concern(s) in accordance with the Regulations on or before *[insert date]*.

Alternatively, should your client wish to pursue this matter outside of the regulations via yourselves, we will provide details of this matter to NWSSP- Legal & Risk Services.

Yours sincerely

[Insert staff name of concerns team]

Enc Consent form if applicable
Putting Things Right leaflet

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F4921011
WAG11- 10803
ISBN 978 1 4734 0087 0