



# Putting Things Right- Handling Concerns Procedure

## Procedure Statement

This procedure sets out the arrangements under Putting Things Right by which Public Health Wales will manage and respond to concerns to meet the requirements of the NHS (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011. This should be read in conjunction with the Public Health Wales Putting Things Right - Handling Concerns Policy and the Welsh Government's Putting Things Right guidance.

It does not replace policies such as, the Incident Reporting Policy and Procedure, Claims Management Policy or the [All Wales Procedure for NHS Staff to Raise a Concern](#) etc. If members of staff are unsure whether to report a concern under the Putting Things Right policy, they should contact the Governance and General Manager, Quality, Nursing and Allie Health Professions for advice.

## Policy Commitment

The Welsh Government legislation the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011), sets out the arrangements that Trusts and Health Boards must undertake for the handling and investigation of concerns.

Public Health Wales is therefore committed to ensuring that the process for managing concerns is open, accessible and fair. To support this Public Health Wales will adopt a common and standardised approach to deal with concerns in line with the requirements of the [NHS \(Concerns, Complaints and Redress Arrangements\) \(Wales\) Regulations 2011](#).

The Putting Things Right Policy provides clear assurance to the Board and external bodies about the commitment of Public Health Wales to implement the legislation in line with the being open principles.

This policy also helps to ensure that Public Health Wales fulfils the requirements of Health and Care Standards 2015.

## Supporting Procedures and Written Control Documents

- Claims Management Policy and Procedure
- Incident Reporting Policy and Procedure (including Serious Incidents)
- Consent Policy
- Standards for Health and Care:
  - Governance, Leadership and Accountability
  - 6.3: Listening and Learning from Feedback

### Other related documents are:

This procedure links and may need to be considered in conjunction with the following policy documents:

- National Patient Safety Policy on Being Open (2009)
- All Wales Protection of Vulnerable Adults (POVA) Procedures
- All Wales Child Protection Procedure
- Access to Health Records Act 1990
- Public Service Ombudsman for Wales Act
- The Code of Openness (1995),
- Human Rights Act 1998,
- Freedom of Information Act (2000)
- Welsh Language Act 1993
- Equality Act 2010

### Scope

The procedure has been produced for the management of concerns and is applicable to all staff who may be involved in investigation of a concern.

### Equality and Health Impact Assessment

Please refer to the completed EHIA

**Approved by** Public Health Wales Board

**Approval Date** 27 September 2018

**Review Date** 27 September 2021

**Date of Publication:** 26 October 2018

**Group with authority to approve supporting procedures** Business Executive Team

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# 1 Introduction

The aim of Putting Things Right - Handling Concerns Procedure is to give guidance on how concerns that are received as complaints should be investigated and responded to in order to promptly and fairly facilitate resolution of issues at a local level for both users of the service, their carers and staff, recognising the individual needs (e.g. language, support, disabilities, etc). This process should be used in conjunction with the Putting Things Right Policy and the [Welsh Government's Putting Things Right – Guidance on Dealing with Concerns about the NHS from 1 April 2011](#) (version 3 November 2013).

Public Health Wales is required to have in place operational procedures for the handling and investigation of concerns, (complaints, patient safety incidents or claims) received in relation to patient safety. This document details the specific process by which Public Health Wales operates the main requirements of Putting Things Right in practice.

The policy and procedure applies to all staff, both permanent and temporary.

The procedure is supported by the

- Putting Things Right – Handling Concerns Policy
- Incident Reporting Policy and Procedure
- Claims Management Policy and Procedure.
- Safeguarding Policy and Procedures.

## **Concerns which are excluded for consideration under these arrangements (Regulation 14)**

The following are matters which do not fall within the remit of this policy:

- A concern notified by a member of staff relating to their contract of employment
- A concern that has been investigated by the Public Services Ombudsman for Wales
- A concern which arises out of an alleged failure of the Organisation to respond to a Freedom of Information request
- Disciplinary action that the Organisation intends to take as a result of the investigation of a concern (in line with this policy)
- An informal concern (made verbally) which is resolved within 48 hours
- A concern that has previously been investigated which the Organisation does not consider reasonable to reopen.

## **2 On the Spot - Informal Concerns (Concerns that can be dealt with at the point of service delivery)**

Some concerns will not be handled under the Putting Things Right regulations and these include concerns that can be dealt with no later than 48 hours after the concern has been raised, or when the person raises the concern has specifically requested that it should be dealt with informally (chart 1). These will usually be issues that are relatively easy to address and those that can normally be dealt with 'on the spot' or within a short period of time.

Staff must ensure that the person raising the concern is happy with the outcome and if they are not they should be advised to raise a concern formally under the Putting Things Right regulations.

Verbal concerns that can be dealt as they arise (informally) should be captured using the form for verbal complaints ([appendix 8](#)) and uploaded and recorded on Datix.

All informal concerns should be recorded on Datix.

## **3 Formal Concerns (chart 2)**

Public Health Wales has a single point of entry for the receipt of concerns. However, it is acknowledged that concerns are also sent directly to Divisional Directors and service area managers.

Where concerns are received directly by a Divisional Director or Programme, Service or Function Manager he/she must acknowledge receipt of the concern and open the concern on DATIX.

### **3.1 Receipt of Concern**

Concerns relating to the services received can be raised in the following ways:

- In writing by letter
- By email using the Putting Things Right website [publichealthwales.handlingconcerns@wales.nhs.uk](mailto:publichealthwales.handlingconcerns@wales.nhs.uk)
- Verbally (these can be received by telephone or in person anywhere within the organisation.). The caller should be asked whether they wish to receive a service in Welsh, and transfer the call to a Welsh speaker if the caller accepts the offer. A written record of concerns raised verbally ([appendix 8](#)) must be made and include
  - Name
  - Landline or mobile telephone number
  - Times when available / not available
  - Time call received

The verbal concern details must be passed to the relevant service area manager immediately and logged on Datix. The receipt of the concern must be acknowledged within **2** working days and the person raising the concern must be provided with a copy of the form if raised verbally.

However, a concern cannot 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

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

### **3.2 Recording of Concerns**

All concerns must be recorded on Datix. This allows data from concerns to be analysed centrally and within Divisions and the submission of reports to the Service User Experience and Learning Panel, the Executive Team and the Quality, Safety and Improvement Committee.

### **3.3 Grading of Concerns**

All concerns should be graded on receipt in terms of severity, from 1 (No Harm) to 5 (Catastrophic Harm) in accordance with the All Wales Grading Framework ([appendix 1](#)). This will determine the level of investigation required in dealing with the issue(s) raised.

The grading of a concern should be kept under review throughout the investigation in case the level of investigation needs to change. For example, the seriousness of a concern may only become evident once an investigation has commenced or has been completed. The grading of a concern may therefore be upgraded or downgraded by the Investigation Lead / Divisional Director during the course of the investigation.

### **3.4 Serious Concerns (graded 4 or 5)**

A serious concern (graded 4 or 5) which is raised as a complaint may already have been raised internally as a serious incident and an investigation may already be underway.

The investigation into the incident should continue to ensure that action is taken to reduce the risk of recurrence and improve service user / patient safety.

The Putting Things Right concerns investigation should run in parallel with the serious incident investigation, and the person raising the concern must be kept informed, particularly of any delays to the final response.

Where a letter raising a concern is received and it becomes apparent that there has been a serious incident that the organisation was previously unaware of, the on-line incident form should be submitted via Datix, and the Putting Things Right Senior Investigation Manager (Governance and General Manager, Quality, Nursing and Allied Health Professionals) should be made aware of the issue. The serious incident/concerns process will commence and again the person raising the concern will be informed that this is the case and of the likelihood that the 30 day target will not be achieved.

Responses to concerns linked with a serious incident will be based on the findings from the serious incident/concerns report and will use the same statements from the staff.

### **3.5 Acknowledgement of Concerns**

All formal concerns must be acknowledged in writing or, electronically if the concern has been received electronically, within **2** working days of receipt.

Where a concern is received in Welsh, it must be acknowledged in Welsh, and the complainant must be offered an opportunity to discuss the matter in Welsh. The complainant's language preference must be recorded on Datix and all communication with them thereafter must be in Welsh unless the complainant indicates otherwise. This requirement also applies to verbal concerns.

The template acknowledgement letter ([appendix 6](#)) is available on Datix and includes:

- An outline of the concerns to be investigated
- Name and telephone number of a named contact (usually the Investigation Lead) for use throughout the handling of the concern
- The offer of an opportunity to discuss with the named contact, either in a meeting or over the telephone, any specific needs and the way in which the investigation will be handled
- When a response from the Chief Executive is likely to be received
- The availability of advocacy and support, i.e. Community Health Council
- If appropriate information outlining that their clinical records will need to be accessed as part of the investigation
- A copy of the Putting Things Right leaflet

### **3.6 Concerns raised by a third party**

If the concern is from a third party who is not the service user, consent must be sought from the service user for the representative to act on their behalf (please see [Section 4](#) regarding the issue of consent).



### **3.7 Concerns received from AM/MPs**

A Member of Parliament (MP) or an Assembly Member (AM) can raise a concern on behalf of a constituent. Explicit consent does not need to be given where a service user has raised a concern with their elected representative but any response should only include information specific to the concern and only if it is necessary in order to respond to the concern. (Please refer to [Section 4](#))

### **3.8 Concerns relation to children and young people**

Any child under the age of 16 is able to raise a concern on their own behalf if they are judged to have sufficient competence and maturity to fully understand what is involved.

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. This should be arranged in accordance with the Welsh Government's 'Model for Delivery Advocacy Services to Children and Young People in Wales'.

In many cases, someone else (parent/carer/guardian) will raise 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 organisation should 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. 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. Public Health Wales is under no obligation to provide a response to the person who raised the concern in the first place.

Concerns involving a child will, in all cases, be copied to the Safeguarding Lead for their additional consideration of any relevant child health issues. In all instances where a child protection issue arises, staff involved should seek advice from the Safeguarding Lead and the Responsible Officer (Executive Director for Quality, Nursing and Allied Health Professionals).

### **3.9 Concerns in respect of service user who lack capacity or who are vulnerable adults**

All concerns must be treated seriously, including those expressed by service user who lack capacity or who are adults at risk. All such concerns should be processed with due reference to the Mental Capacity Act.

In such instances, and where doubts exist about the reasonableness of the concern, discussion should take place with a relative, friend or other

advocate, and with medical and nursing staff, and a decision made about whether the concern should be formally investigated.

Investigation Leads must remain alert to any possibility of abuse of adults at risk, and if there is doubt immediate advice should be obtained from the relevant senior professional staff, or the Safeguarding Lead.

Where it is deemed appropriate for the issues raised in the concern to be dealt with via the Safeguarding Policy, the person raising the concern should be informed and the necessary steps taken.

### **3.10 Concerns from Solicitors / Intention to litigate /Requests for Compensation**

People have a right to convey their concern through a solicitor which should include a signed consent form for the solicitor to act on their behalf. Provided that the solicitor has not served a formal letter of proceedings (an actual letter of claim), the Putting Things Right process should proceed as normal.

The Claims Manager must be notified immediately of any concern which has the potential to be considered under Redress or develop into a legal claim over £25,000.

If and when formal legal proceedings are instigated, the Putting Things Right process is brought to an end with the person raising the concern being appropriately advised in writing.

Where the organisation accepts, in the absence of legal proceedings, that there is a qualifying liability in tort, then the Redress process, as outlined in [Section 8](#), must be considered.

### **3.11 Concerns containing allegations against staff**

Public Health Wales is committed to providing support and advice for the member of staff during the investigation process, as appropriate.

Where concerns raised contain allegations against a staff member, the staff member should receive a copy of the correspondence at the beginning of the investigation to enable them to comment on the concerns raised against them. However, this is not the same as reporting concerns about another member of staff in terms of suspected wrongdoing, criminal activity or unprofessional behaviour which need to be dealt with under the [All Wales Procedure for NHS Staff to Raise a Concern](#).

Any staff member identified personally in the response letter should have a chance to see the draft response letter before issue.

Copies of final response letters will be sent to the relevant Divisional Director who will ensure that identified staff receives a copy.

### 3.12 People Acting Beyond Reasonable Limits

All people who raise concerns have a right to be heard, understood and respected. However, it is also considered that Public Health Wales staff should have the same rights.

A small number of people can either take up a disproportionate amount of time in dealing with their concern or be abusive or threaten violence towards the staff dealing with their concern. These complainants will be deemed habitual or vexatious.

Habitual or vexatious people typically:

- Persist in pursuing a concern where the organisations process has been fully and properly implemented and exhausted
- Seek to prolong contact by changing the substance of a concern or continually raise new issues and questions whilst the concern is being addressed
- Are unwilling to accept documented evidence as being factual e.g. screening notes
- Deny receipt of an adequate response despite evidence of correspondence specifically answering their questions
- Do not accept that facts can sometimes be difficult to verify when a long period of time has elapsed
- Have, in the course of addressing a registered concern, had an excessive number of contacts with staff dealing with their concern and make unreasonable demands on them
- In contravention of the Data Protection Act (or any subsequent legislation such as the General Data Protection Regulation), are known to have recorded face to face meetings and/or telephone conversations without the prior knowledge and consent of the other parties involved
- Have threatened or used actual physical violence towards staff or their families or associates at any time. Where this has happened, personal contact with the person raising the concern and their representative should be stopped and, thereafter, the concern will only be pursued through written communication
- Have harassed or been personally abusive or verbally aggressive on more than one occasion towards staff dealing with their concern or their families or associates. (Staff must recognise that people raising concerns may sometimes act out of character at times of stress, anxiety or distress and should make reasonable allowances for this).

As a last resort and only after all reasonable measures have been taken to try to resolve concerns in line with the concerns policy and procedure, the above criteria will be deemed habitual and/or vexatious.

Support and advice should be readily available for staff when a complainant's actions go beyond acceptable limits. Staff should not be expected to tolerate rude, aggressive and threatening behaviour over the telephone and they

should inform the complainant that if their unacceptable behaviour continues they will terminate the phone call.

Staff should be advised to contact their manager where they believe a person's behaviour is unacceptably challenging. Any such case should be discussed between the Divisional Director, Investigation Lead and Senior Investigation Manager with reference to the Public Health Wales Violence and Aggression to Staff Policy

Provided that any legitimate cause for concern has been appropriately investigated and dealt with, and there is documentary evidence of the person's habitual or vexatious behaviour, the Divisional Director and Responsible Officer has the authority to stand down the investigation process.

Where an investigation is still on-going the Chief Executive should write to the person raising the concern setting parameters for a code of behaviour and the lines of communication.

Where the investigation is complete, a letter will be sent from the Chief Executive to inform them that correspondence is at an end.

It is recognised that persons persistently raising concerns should be protected by ensuring that they receive a response to all genuine grievances.

### **3.13 Withdrawal of concerns**

A concern may be withdrawn at any time by the person who notified the concern. This can be made:

- In writing
- Electronically
- Verbally in person or by telephone

If the concern is withdrawn verbally Public Health Wales will write to the person as soon as possible to confirm their decision. However, even if the concern has been withdrawn but it is felt that the investigation of the concern is still appropriate, the investigation can continue.

### **3.14 Concerns and Disciplinary Process**

The Putting Things Right – Handling Concerns Policy and Procedure has a different purpose to the All Wales Procedure for NHS Staff to raise a Concern (Whistle Blowing) and Disciplinary Procedures. The Putting Things Right – Handling Concerns Policy and Procedure carries no authority to identify or take remedial action in respect of individual staff

If an investigation into a concern indicates the need for a disciplinary investigation, the Investigation Lead must discuss these issues with the staff member's line manager and notify the Divisional Director.

A decision to initiate a Disciplinary Investigation rests with the relevant line manager with advice from the relevant professional Lead, HR and Divisional Director.

If a disciplinary investigation begins before the investigation into the concerns raised has been completed, consideration will need to be given to how far the investigation under the Putting Things Right – Handling Concerns Policy and Procedure can continue and whether other investigations can run alongside it.

The person raising the concern should be informed in general terms of disciplinary sanctions imposed on any staff member. A judgement will need to be made between reassuring the complainant that the matter they raised has been taken seriously and dealt with satisfactorily, while protecting the confidentiality of the staff member.

### **3.15 People who cannot raise a concern under these arrangements**

Not all concerns can be dealt with under the arrangements for dealing with concerns. Matters excluded 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 People and Organisational Development (POD) policies and procedures
- Where the concern is being or has been investigated by the Public Services Ombudsman for Wales
- Where the Trust has not complied with the [Freedom of Information \(FOI\) Act 2000](#). Such concerns will be dealt with by the Information Commissioner's Office
- Where the Trust has not complied with the [Welsh Language Act](#). Such concerns will be dealt with by the Welsh Language Commissioner.
- Disciplinary proceedings identified as a result of the investigation. These would be looked at under local People and OD processes
- Concerns which are raised and resolved on the same day or within 48 hours, that is, "on-the-spot"
- Where someone tries to re-open the same concern that they have already agreed was dealt with satisfactorily "on the spot", unless it is considered that the issues raised needs to be looked at again and then it must follow the procedure 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, in respect of which court proceedings have already been issued. 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

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 also not excluded. If the concern is excluded under the Regulations then the person must be advised that the matter cannot be dealt with.

## **4 Consent to Investigate Concerns**

In the some cases, the investigation of a concern requires access to medical records and so the issue of consent will need to be considered. The following provides information on when consent is required.

### **4.1 Consent where a service user raises a concern themselves about service they have received.**

For concerns raised about Public Health Wales services, there is no need to expressly seek the service users consent to investigate their concern as they can be deemed to have given implied consent. However, the service user should be informed in the acknowledgement letter that their medical records may need to be examined so that they have the opportunity to indicate if they do not want their health records accessed.

For concerns of a non clinical nature, the possibility of access to medical records should be removed from acknowledgement letter.

In the event that the service user is not happy for their records to be accessed, then Divisional Director and the Responsible Officer must make a decision on whether the issue raised is of sufficient seriousness to merit an investigation without access to the medical records and whether it would be in the interests of the organisation to continue to look into the matter. If not, there will be no investigation of the concern. This decision must be recorded before closing the matter.

### **4.2 Consent where a third party raises a concern on behalf of a service user**

A representative may raise a concern on behalf of a service user but this should be with the service user explicit knowledge and with written consent, unless the person raising the concern is legally entitled to act for the service user (e.g. has Lasting Power of Attorney).

Where the service user lacks capacity, consent should be obtained from the next of kin who is legally entitled to represent the service user / legal representative, if they are not the person raising the concern.

In the interests of the service user's confidentiality and in accordance with Caldicott Principles, it is appropriate to request confirmation of the service user's authorisation that the person raising the concern may act on their behalf.

If the Community Health Council acts on behalf of the service user consent should be provided. Correspondence relating to the concern will be sent to the person raising the concern with copies of all correspondence being sent to the appropriate Complaints Advocate at the Community Health Council.

Explicit consent does not need to be given where a service user has raised a concern with their elected representative (MP / AM) but any response should only include any information specific to the concern and only if it is necessary in order to respond to the concern. Where it is necessary to give detailed personal information in order to respond to the concern, consideration should be given to seek explicit consent from the service user. Consent should always be sought from the service user if the AM/MP has received a concern from a third party.

If it is not possible to obtain written consent for whatever reason, the organisation must consider whether the issue in question is of sufficient seriousness to merit an investigation without access to the medical records. This decision must be recorded before closing the matter.

#### **4.3 Consent when the service user has died**

Investigation into a concern can proceed where a service user has died. If the person raising the concern is not the service user personal representative (a service user personal representative is a person who would have a claim arising out of the service user death) then consent to investigate the concern must be obtained from the appropriate person(s) for example the named next of kin.

If the personal representative refuses to give consent, this is not necessarily a reason for refusing to investigate a legitimate concern, but it will be necessary to respond in general terms without divulging personal or clinical details.

#### **4.4 Consent for concerns raised on behalf of a child or person who lacks capacity**

It is acceptable for people to raise concerns on behalf of a child or someone who lacks mental capacity. In these instances, consent to access medical records is not required, but if the service user is a child, the organisation needs to consider 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. Please refer to [Section 3.8](#) above for more information relating to concerns raised in relation to children.

#### **4.5 [Consent](#) to investigate serious incidents**

When an incident occurs that has been reported to the Welsh Government as a serious incident the Divisional Director will, in accordance with the Regulation advise the service user to whom the concern relates or his or her representative of the incident and involve them in the investigation. The exception to this is if informing them would not be in their best interest, for example involving them could cause deterioration in their physical or mental health. For such incidents the investigation will commence straightaway and as part of discussion, consent will be sought to access medical records.

In any investigation and in line with data protection legislation and the Caldicott Principles, only information relevant to the investigation of the concern will be accessed and then only by those people that have demonstrable need to have access

## **5. Process for Investigating Concerns**

### **5.1 Investigating concerns about Trust Services and Staff**

Most concerns are likely to be about services provided solely by Public Health Wales and the following process applies.

Following receipt and grading of a concern, the Divisional Director for the service area, programme or function will appoint the Head of Programme, Service Area or Function as investigation lead. It is important that the Investigator(s) are appropriately selected according to their knowledge and experience and the nature of the concern.

The Head of Programme, Service Area or Function as investigation lead will be responsible for:

- Carrying out the initial assessment and grading of the concern to assist in determining the depths and parameters of the investigation and keeping this under review
- Whether the concern should be considered a Serious Incident as defined in the Guidance on the Reporting and Handling of Serious Incidents and notified to the Chief Risk Officer to report to the Welsh Government or other external regulatory bodies
- The most appropriate method of involving the complainant with the investigation, including discussion about how the investigation is conducted
- The level and type of support required by any member or members of staff involved in the matters raised by the concern
- Whether the person investigating the matters raised in the concern requires independent medical or other advice



- Whether the concern may be capable of resolution by making use of alternative dispute resolution
- The making of decisions about the root cause of the matters giving rise to the notification of the concern
- Where the concern notified includes an allegation that harm has or may have been caused; the likelihood of any qualifying liability arising and the duty to consider redress. Redress may consist of any one or a combination of the following:
  - A full explanation of what happened
  - An apology
  - An offer to provide care or treatment (where appropriate); and
  - A report on the action that has or will be taken to prevent similar cases arising; and / or
  - financial compensation where appropriate.

(See [Sections 8](#) for further information.)

However, the Head of Programme, Service Area or Function as investigation lead may not necessarily undertake the investigation but will have responsibility of overseeing the process and, if necessary, will appoint an Investigation Officer.

In no circumstances should the Head of Programme, Service Area or Function as investigation lead or the Investigation Officer be the subject of the concern or directly involved in the incident

It is essential that the investigation addresses the concerns and underlying causes of the issue. Therefore, on receipt of the concern, the Head of Programme, Service Area or Function as investigation lead (or the Investigating Officer) should, where possible, telephone the person raising the concern to seek:

- A clear understanding of the nature of the concern
- The expectations of the person raising the concern
- To offer a meeting
- To confirm that the investigation is underway and
- To explain the investigation process.

If the person raising the concern has engaged with an advocate then they should be kept informed of any decision made about how the concern will be handled.

On occasions, a meeting may be sufficient to resolve a concern. If the offer of a meeting is accepted and is able to resolve the concern, no further investigation is required. However, the meeting must be followed up by a full written response based on the discussions and should 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. If a meeting is

agreed, the person raising the concern should always be informed of their right to be accompanied by a relative/friend/ advocate and/or a representative of the Community Health Council.

An apology, where this is appropriate, should be conveyed at the earliest opportunity, and recorded on the Datix file. This may be by telephone and should not await the formal response letter.

The level of investigation should be proportionate to the severity of the concern notified and will be determined by the initial assessment of the concern and the grading allocated to it.

For concerns graded 1-2, the investigation should be completed within 20 days. For concerns of a more serious or complex nature, where possible the investigation should be undertaken within the 30 days response timescales.

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 will normally be sufficient for one person to undertake the investigation, whereas a higher grade concern (grades 3 to 5) may require a multidisciplinary team approach.

The grading of a concern should be kept under review throughout the investigation in case the level of investigation needs to change. For example, the seriousness of a concern may only become evident once an investigation has commenced or has been completed. The grading of a concern may therefore be upgraded or downgraded by Head of Programme, Service Area or Function as investigation lead or Investigating Officer. At the end of the investigation the Head of Programme, Service Area or Function as investigation lead should confirm the final grading to be recorded on Datix.

The Head of Programme, Service Area or Function as investigation lead will ensure that any staff who are the subject of the concern receive a copy of the concern raised, and that any investigative interview is carried out impartially and fairly with due consideration of the potentially stressful nature of such interviews.

The Head of Programme, Service Area or Function as investigation lead or the investigating officer will interview relevant staff as necessary, and record key points from the discussion. Relevant written records and documentation will be used in the investigation to confirm and expand on the information obtained from staff.

The Head of Programme, Service Area or Function as investigation lead or the Investigation Officer should consider whether independent clinical or other advice will need to be sought in order to address the concern.

The person who raised the concern should be kept updated in a timely manner about progress of the investigation in a format that meets any needs that have already been identified.

All contacts with the person raising the concern should be noted and recorded on the Datix file with date and time.

Where appropriate, the resolution of the concern through mediation or alternative dispute resolution should be considered. The Community Health Council is able to offer a mediation service.

If the investigation has identified that there is no qualifying liability, then a final response (under Regulation 24) will be drafted by the Head of Programme, Service Area or Function as investigation lead. For concerns graded 1-2, this should be achieved within 20 days and signed off by Chief Executive. For concerns of a more serious or complex nature, then this should be within 30 days. (see [Section 6](#) for further information).

If the investigation has identified that there is or may be a qualifying liability in tort worth less than £25,000, then an interim report (under Regulation 26) must be issued within 30 days. (see [Section 7](#) for further information).

If the investigation has identified that there is or may be a qualifying liability in tort worth more than £25,000 then a Regulation 24 letter should be drafted.

Redress can only be considered if there is a proven qualifying liability in tort (a civil wrong). For investigation to establish if there is a qualifying liability the following must be considered:

- Firstly it must be established that there has been a breach of the organisation's duty of care. This means that the care or treatment was below the standard which would have been provided by a responsible body of similar professionals carrying out similar treatment to that complained of.
- Secondly it must be established that the breach of duty caused the harm the service user suffered

It is only when these tests are satisfied that a payment of compensation can be considered.

If a final response, or in cases where there may be or is a qualifying liability, an interim report cannot be sent within 30 days, the person raising the concern must be notified via a holding letter.

As soon as this is known, and before the agreed timescale has passed, the Head of Programme, Service Area or Function as investigation lead must arrange, via the Divisional Director, to issue a holding letter to the person

raising the concern and, if appropriate, their advocate, explaining the reason for the delay and suggesting a revised timescale.

All correspondence relating to the investigation, e.g. written statements, emails, action plans, investigation reports etc should be uploaded to Datix. It should be noted that this information will be disclosed in the event of a concern progressing to litigation. Therefore, staff should be advised that their statements may be disclosed if the concern progresses to litigation.

The Head of Programme, Service Area or Function is responsible for ensuring that lessons are identified, loaded to DATIX and are responsible for putting in place measures to ensure that any lessons identified are implemented.

## **5.2 Investigating concerns which involve more than one organisation**

There will be situations where services provided by more than one organisation form part of the concerns raised. In practice it is likely that the person has only raised the concern with one organisation, however it is possible that they might have raised the concern with both. This must be checked carefully to ensure that there is no duplication of effort of the part of any organisation.

If the concern is received by Public Health Wales and it seems clear that the matters also involve another organisation, then the Divisional Director / Head of Programme, Service Area or Function must, within 2 working days of receipt of the concern:

- Inform the person raising the concern that another organisation is or may be involved in their concern;
- Seek consent from the person raising the concern to contact and notify the other organisation that they are involved in the concern raised.

Once consent has been received, the second organisation must be informed within 2 working days of receiving 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;
- Who will directly communicate with the person raising 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.

Where a concern is received by another NHS organisation but include questions to be answered by Public Health Wales then an investigation will be

undertaken and the reply sent to the other responsible body involved. In such instances the Public Health Wales Responsible Officer and relevant Divisional Director will request sight of the final response letter prior to it being sent to the complainant.

## **6. Final Response - where it has been identified there is no qualifying liability (Regulation 24)**

Where it has been identified during the course of an investigation that no qualifying liability exists then a final response needs to be issued under Regulation 24. Regulation 24 states that final responses should be issued within 30 working days, but wherever possible Head of Programme, Service Area or Function as investigation lead should aim for a 20 day response.

The Head of Programme, Service Area or Function as investigation lead will either compile or approve the draft response which should include:

- An apology where appropriate;
- A summary of what the concern was about;
- An explanation of how the concern was investigated;
- Copies of any relevant medical records and expert reports, where appropriate;
- An explanation of any actions taken;
- An offer to discuss the response to the concern or any further issues with the Head of Programme, Service Area or Function as investigation lead;
- Where appropriate, the offer of a meeting should be given.
- Details of the person's right to raise their concern with the Public Services Ombudsman for Wales.

If the final response has not been able to be prepared within the agreed timescale, an apology and reason for the delay should be provided in the response.

The letter should be written in a language that the person raising the concern will easily understand, avoiding medical or technical jargon. When such information needs to be included in the response a simpler explanation will also be given as to its meaning. Where there may be difficulties in understanding the response, Public Health Wales will make every effort to provide the appropriate support. Where the preferred language of the complainant is Welsh, the response letter must be provided in Welsh.

Where necessary, people raising concerns should be given the opportunity to receive their response in an appropriately accessible format, e.g. large print, electronically or on audio cassette.

In respect of a concern that alleges that harm has or may have been caused and this has been found not to be the case, the letter must also contain an explicit explanation of the reasons why there is no qualifying liability.

The response must be agreed both with the relevant senior professionals involved in the investigation and the Divisional Director. Following approval by the Divisional Director, the draft response letter and a copy of the original concern will be forwarded via the Responsible Officer to the Chief Executive for signature. As a matter of good practice, it must also be shared with any staff involved in investigating the concern.

The signed Chief Executive's letter should be scanned onto Datix and the Divisional Directors PA will, on behalf of the Divisional Director, ensure that copies are distributed to staff directly involved in the investigation, and where appropriate to the Community Health Council and / or AM / MP.

The final response from the Chief Executive theoretically closes the Putting Things Right process. However, further correspondence may be received when the person raising the concern does not feel that all the issues in the original correspondence have been addressed. Every effort will be made to address these further issues satisfactory including, where appropriate, the setting up of a meeting between the person raising the concern and relevant staff where this has not yet happened. Notes should be taken at meetings and these will be shared with the person raising the concern.

Further letters received from the person raising the concern and dissatisfied with their final response will be acknowledged within **2** working days.

Any outstanding issues will need to be investigated and a response prepared, which will also be signed by the Chief Executive, within a further 20 day or, if this is not possible, 30 day timescale.

## **7. Interim Report - where it has been identified there is or may be a qualifying liability valued at less than £25,000 (Regulation 26)**

Where following an investigation the Lead Investigator needs to issue an interim report if they are of the opinion that there may be a qualifying liability i.e.

- that we owe the person raising a concern a duty of care and that duty has or may have been breached and
- that it is possible that but for the negligence the service user would not have suffered harm,

The matter also needs to be identified to the Divisional Director, Claims Manager, SIM and Responsible Officer. A draft interim response needs to be prepared and a SBAR form ([appendix 11](#)) needs to be completed) for consideration by the Redress Panel. It should be noted that the Executive Team acts as the Redress Panel.

Under the regulations an interim report needs to be issued within 30 working days of first receipt of a concern from the person or their representative. Divisions should, where possible, allow time for the concern to be considered by the Redress Panel. Where the preferred language of the complainant or his or her legal representative is Welsh, the interim report must be provided in Welsh. The interim report must include:

- 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 Public Health Wales 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 for Wales;
- An offer of an opportunity to discuss the contents of the interim report with the Investigation Lead and/or staff involved in English or Welsh.

The interim report should be signed off by the Divisional Director.

If it is not possible to issue the interim report within 30 working days of first receipt of a concern, the person raising the concern must be informed of the reason for the delay and the interim report should be sent within 6 months of first receipt of the concern.

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 the delay and given an expected date for receipt of the interim report.

## **8. Redress and Redress Panel**

If during the course of an investigation it is identified that there is a possibility of a qualifying liability, then the matter must be presented to the Divisional Director, Claims Manager, SIM and Responsible Officer.

Redress cannot be offered where there is no qualifying liability in tort nor can it be offered if the matter is or has been subject to civil proceedings.

If it is determined that there is no qualifying liability a response under Regulation 24 will be issued identifying the reasons why no qualifying liability exists.

### **Where it is not possible to confirm breach of duty**

In some instances it may not be possible to determine whether there has been a breach of duty and it may be considered appropriate for an independent expert opinion to be sought. This will be commissioned by the Claims Manager with the appropriate Divisional Director informing the person raising the concern of the delay in their response.

### **Where it is not possible to confirm causation**

When it is not possible to determine whether there is causation an independent expert should be consulted to determine causation. The choice of independent expert is to be instructed jointly by the person raising the concern and Public Health Wales. If the person raising the concern also accepts the offer of free legal advice then their legal adviser should also be allowed input to the instruction of the expert.

Where breach of duty and causation has been confirmed it is the duty of the Redress Panel to consider whether Redress should be offered and which form of Redress is appropriate (see paragraph 5.2 for types of Redress which can be offered). Where it is deemed appropriate to make an offer of financial compensation the Claims Managers will seek advice from Legal and Risk Services.

Damages that may be payable under the Regulations should not exceed £25,000 (i.e. general damages plus special damages plus any repayments of benefits payable to the Department of Works and Pensions arising from the breach of duty of care i.e. CRU). If it is known that financial compensation would exceed £25,000 then the Redress regulations should not be engaged.

Once quantum has been assessed approval for the making of such an offer should be sought from the Redress Panel (Executive Team)

Following confirmation of the above by the Redress Panel, the Divisional Director will finalise the draft response, and forwards it to the SIM, Responsible Office and relevant Executive Director for review prior to it being sent to the Chief Executive for signing.

The decision to either offer Redress or not to make an offer of Redress if no liability could be established must be communicated within 12 months of the first receipt of the concern. The response should include

- the investigation report which outlines the findings of the investigation
- copies of any independent expert advice used to determine whether or not there is a liability;
- a statement confirming whether there is a liability and the rationale for that decision
- evidence of the assessment of quantum
- the offer of free legal advice

Where the preferred language of the complainant or his or her legal representative is Welsh, the response must be provided in Welsh.



The offer to accept Redress will be made by 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.

The person and/or legal representatives have up to 6 months in which to accept an offer of financial compensation from the date of the offer. After that time the Redress arrangements will no longer apply.

## **9 Process for Learning and Promoting Improvements**

A key requirement of the follow-up/closing the loop process and, in order to bring about real improvements, is the sharing of lessons learned arising from concerns with the staff involved and, where relevant, the wider organisation and external stakeholders.

The Board Committees support organisational learning, which is then shared locally through Divisions and throughout Public Health Wales. Action plans and risk reduction measures should be managed and followed up locally within Divisions by the Divisional Director and Programme, Service Area and Function Managers. Following the conclusion of a concern, an analysis will be undertaken to extract the lessons learnt, to prevent recurrence. The Divisions are responsible for ensuring that lessons learned from analysis of concerns result in a change of practice as appropriate. This information must be captured on Datix

Within Public Health Wales, lessons learned arising from concerns will be shared via the following routes:

### **Individual**

- Reflective practice and discussions as part of staff supervision
- Policies and procedures to be made available to staff

### **Team / Laboratory / Programme**

- Reviewing concerns that have occurred within the Team / Laboratory / Programme area
- Discussed at team meetings and briefings on lessons learnt.

### **Divisional**

- Management Meetings to review concerns, along with reports from individual teams, laboratories, programmes
- Monitoring of progress against action plans
- Promotion of learning and best practice through Divisional structures and staff

### **Trust Wide**

- Staff e-bulletin
- Service users / staff stories

- Mandatory training – incorporating learning concerns into relevant training courses.
- Review of reports and external investigations by the following Committees and Groups
  - Quality, Safety and Improvement Committee
  - Executive Team
  - Quality Management Group
  - Service User Experience and Learning Panel
  - Infection Prevention Control Group
  - Safeguarding Group
  - Information Governance Working Group
  - Welsh Language Committee
  - Health and Safety Group

Where appropriate the Public Health Wales will share learning from concerns with the host organisations, stakeholders and partners.

## **10. Training**

Please refer to Section 12 of the Policy for Putting Things Right, The Management of Concerns (Complaints, Claims and Service user / patient Safety Incidents)

## **11. Management and Storage of Concerns Files**

The Datix system should contain all information concerning the investigation and correspondence with the person raising the concern.

The Datix and any paper files relating to the concern must be kept for a period of 10 years. Records relating children should be retained until they attain the age of 25 (with the minimum 10 year provision).

This Datix and paper file is the responsibility of the Lead Investigator for the complaint / investigation and must be provided if requested by the SIM / Claims Manager. It is the responsibility of the Head of Programme, Service or Function to ensure that when closing the concern the file is complete, accurate and holds no contentious remarks as the information is disclosable.

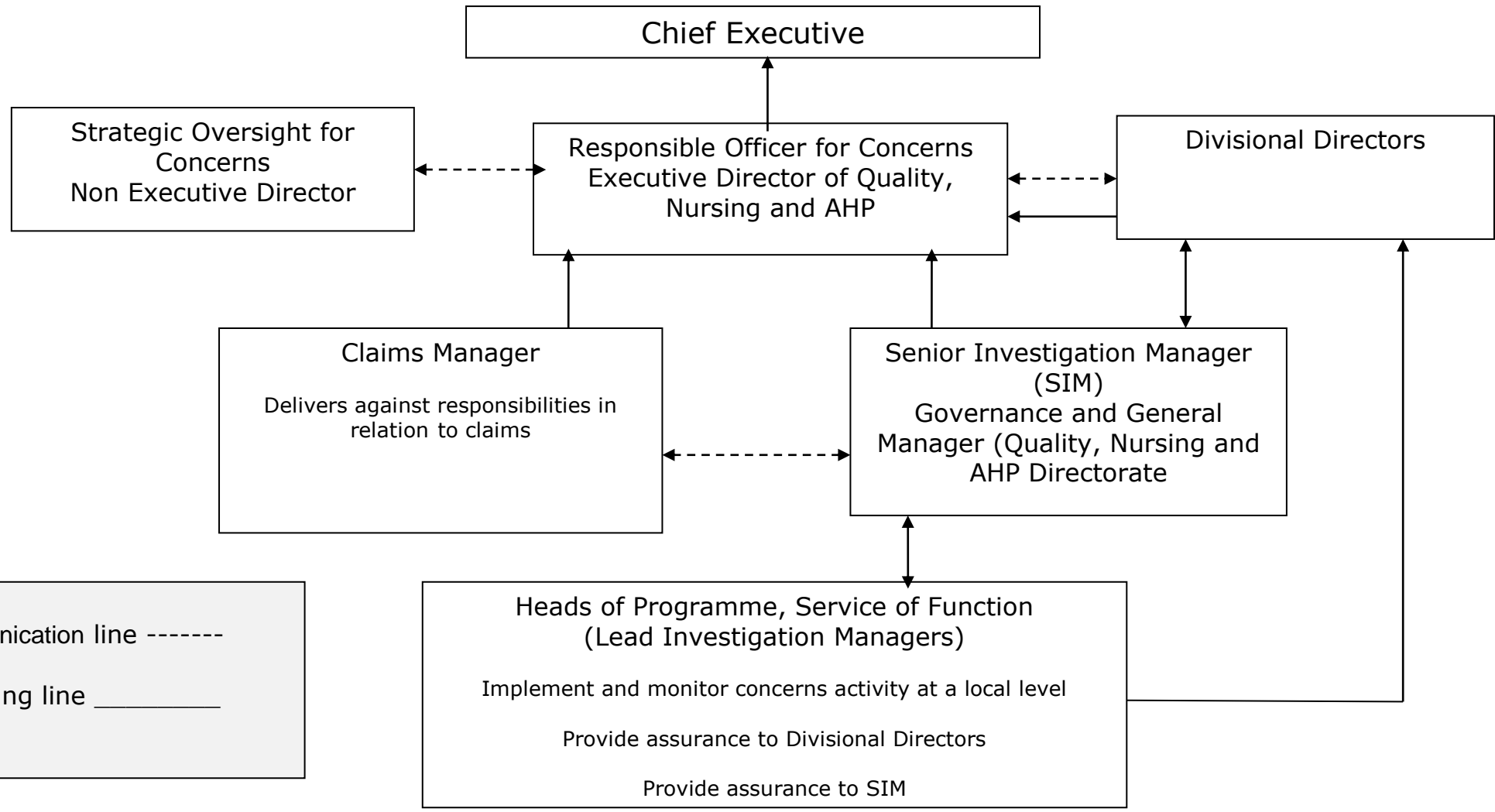
If a concern becomes a claim then the file is combined into the litigation File.

## Appendix 1: All Wales Grading Framework

Grading Criteria for Concerns Status:	Examples of concerns	Potential for qualifying liability / Redress
<p style="text-align: center;"><b>1</b></p> <p style="text-align: center;">No Harm</p>	<p>Concerns which normally involve issues that can be easily/speedily addressed, with no harm having arisen (e.g. appointment delayed, but no consequences in terms of health, difficulty in car parking, etc) but have impacted on a positive service user / patient experience</p>	<p style="text-align: center;">Highly unlikely</p>
<p style="text-align: center;"><b>2</b></p> <p style="text-align: center;">Low Harm</p>	<ul style="list-style-type: none"> <li>• Concerns regarding care and treatment which span a number of different aspects/specialties</li> <li>• Increase in length of stay by 1 – 3 days</li> <li>• Service user / patient fall – requiring minor treatment</li> <li>• Requiring time off work – 3 days</li> <li>• Concern involves a single failure to meet internal standards but with minor implications for service user / patient safety</li> <li>• Return for minor treatment, e.g. requiring local anaesthetic</li> </ul>	<p style="text-align: center;">Unlikely</p>
<p style="text-align: center;"><b>3</b></p> <p style="text-align: center;">Moderate Harm</p>	<ul style="list-style-type: none"> <li>• Clinical / process issues that have resulted in avoidable, semi permanent injury or impairment of health or damage that requires intervention</li> <li>• Additional interventions required or treatment / appointments needed to be cancelled</li> <li>• Readmission or return to surgery, e.g. requiring general anaesthetic</li> <li>• Necessity for transfer to another centre for treatment / care</li> <li>• Increase in length of stay by 4 – 15 days</li> <li>• RIDDOR reportable incident (moderate harm)</li> <li>• Requiring time off work 4 – 14 days</li> <li>• Concerns that outline more than one failure to meet</li> </ul>	<p style="text-align: center;">Possible in some cases</p>

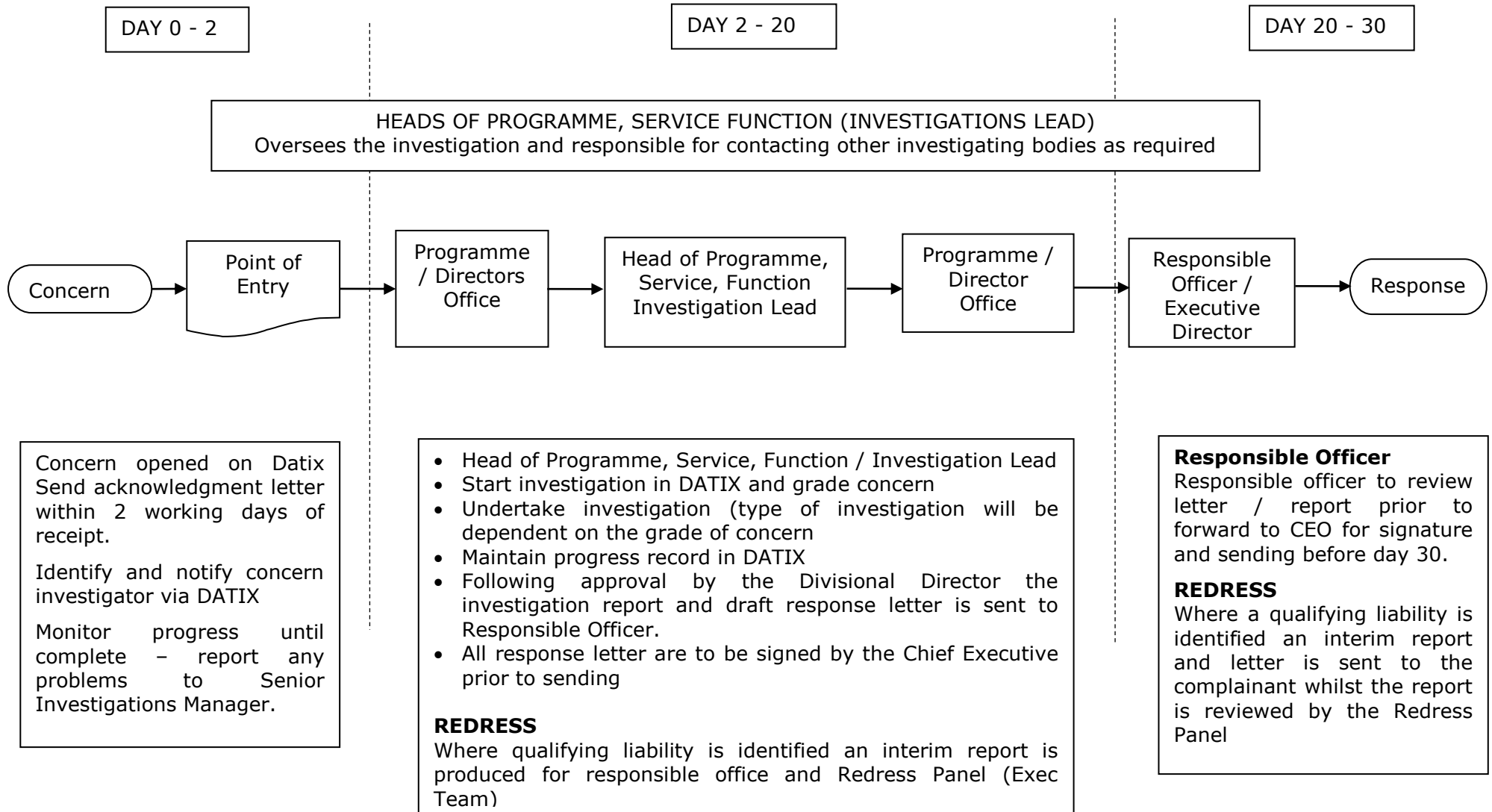
	<ul style="list-style-type: none"> <li>internal standards</li> <li>Moderate service user / patient safety implication</li> <li>Concerns that involve more than one organization</li> </ul>	
4 Severe Harm	<ul style="list-style-type: none"> <li>Clinical process issues that have resulted in avoidable, semi permanent harm or impairment of health or damage leading to incapacity or disability</li> <li>Additional interventions required or treatment needed to be cancelled</li> <li>Unexpected readmission or unplanned return to surgery</li> <li>Increase in length of stay by &gt;15 days</li> <li>Necessity for transfer to another centre for treatment / care</li> <li>Requiring time off work &gt;14 days</li> <li>A concern outlining non compliance with national standards with significant risk to patient safety</li> <li>RIDDOR reportable incident (significant harm)</li> </ul>	Likely in most cases
5 Catastrophic Harm	<ul style="list-style-type: none"> <li>Concern leading to unexpected death, multiple harm or irreversible health effects</li> <li>Concern outlining gross failure to meet national standards</li> <li>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.</li> <li>Clinical or process issues that have resulted in avoidable loss of life</li> <li>RIDDOR reportable incident (catastrophic harm)</li> </ul>	Very likely

### Appendix 2: Public Health Wales Handling Concerns Structure



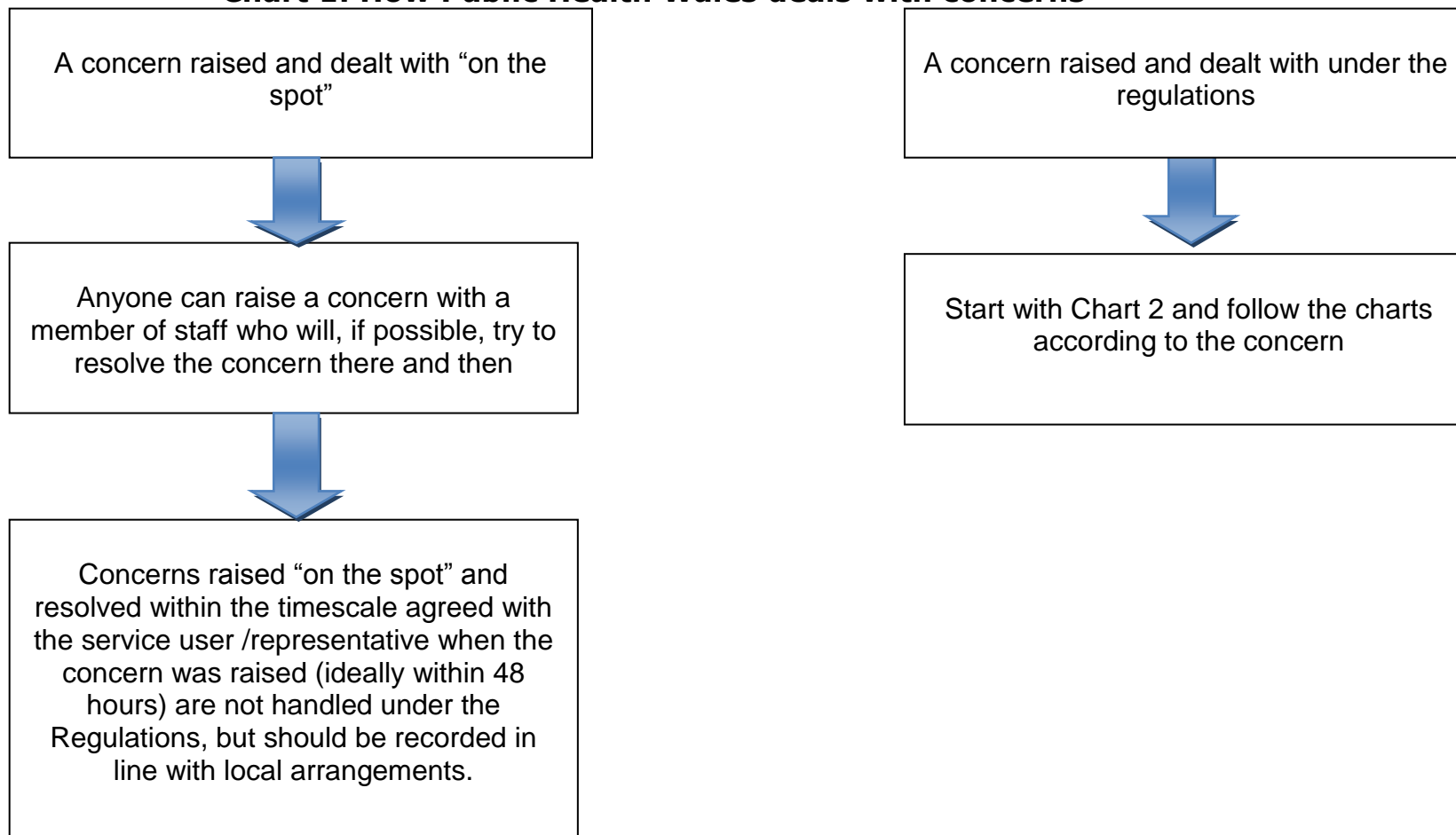
Key:  
Communication line -----  
Reporting line \_\_\_\_\_

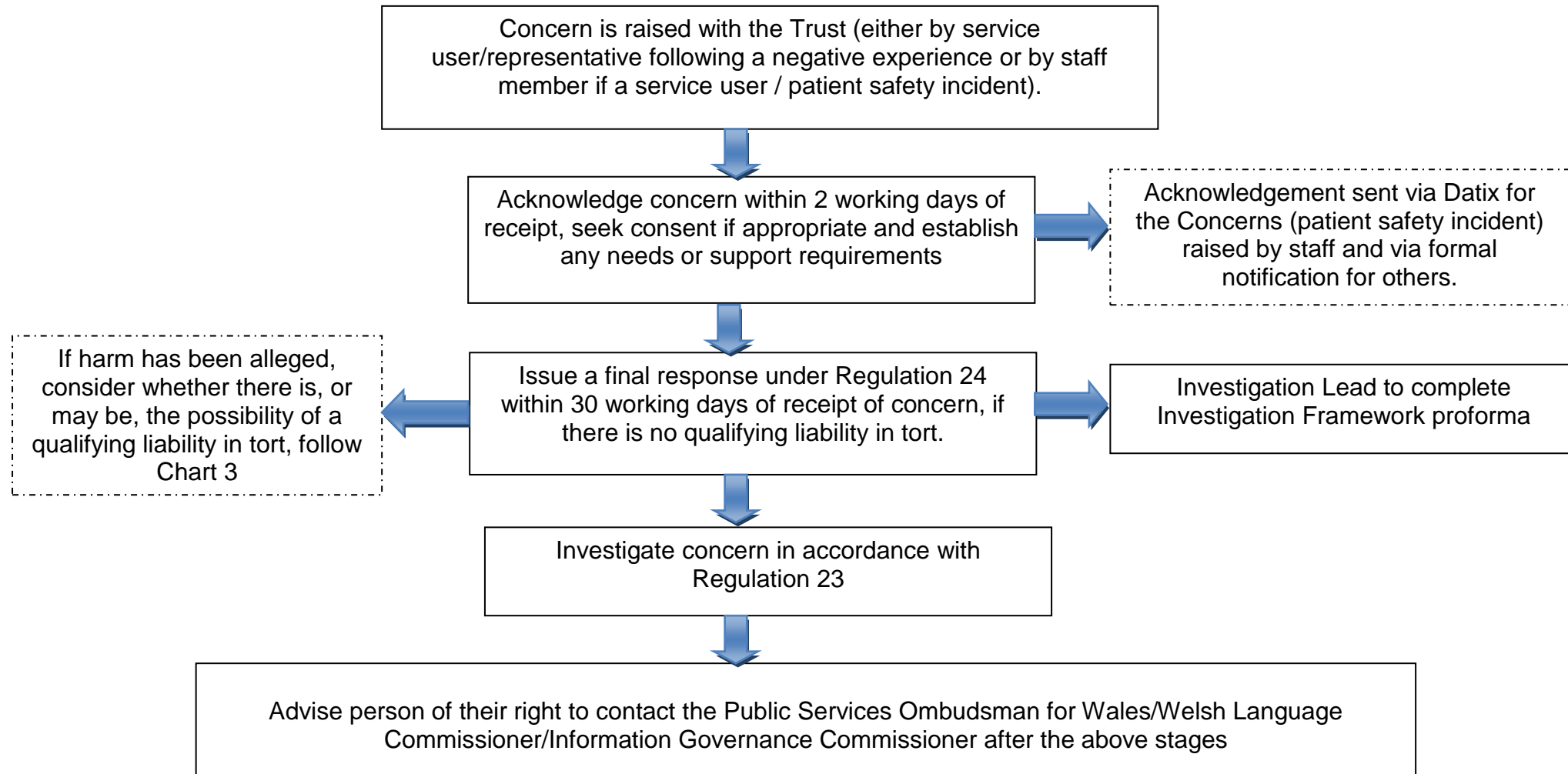
### Appendix 3 Flowchart for Dealing with Concerns (excluding 'On the Spot Concerns')



## Appendix 4: Concerns Flow Charts

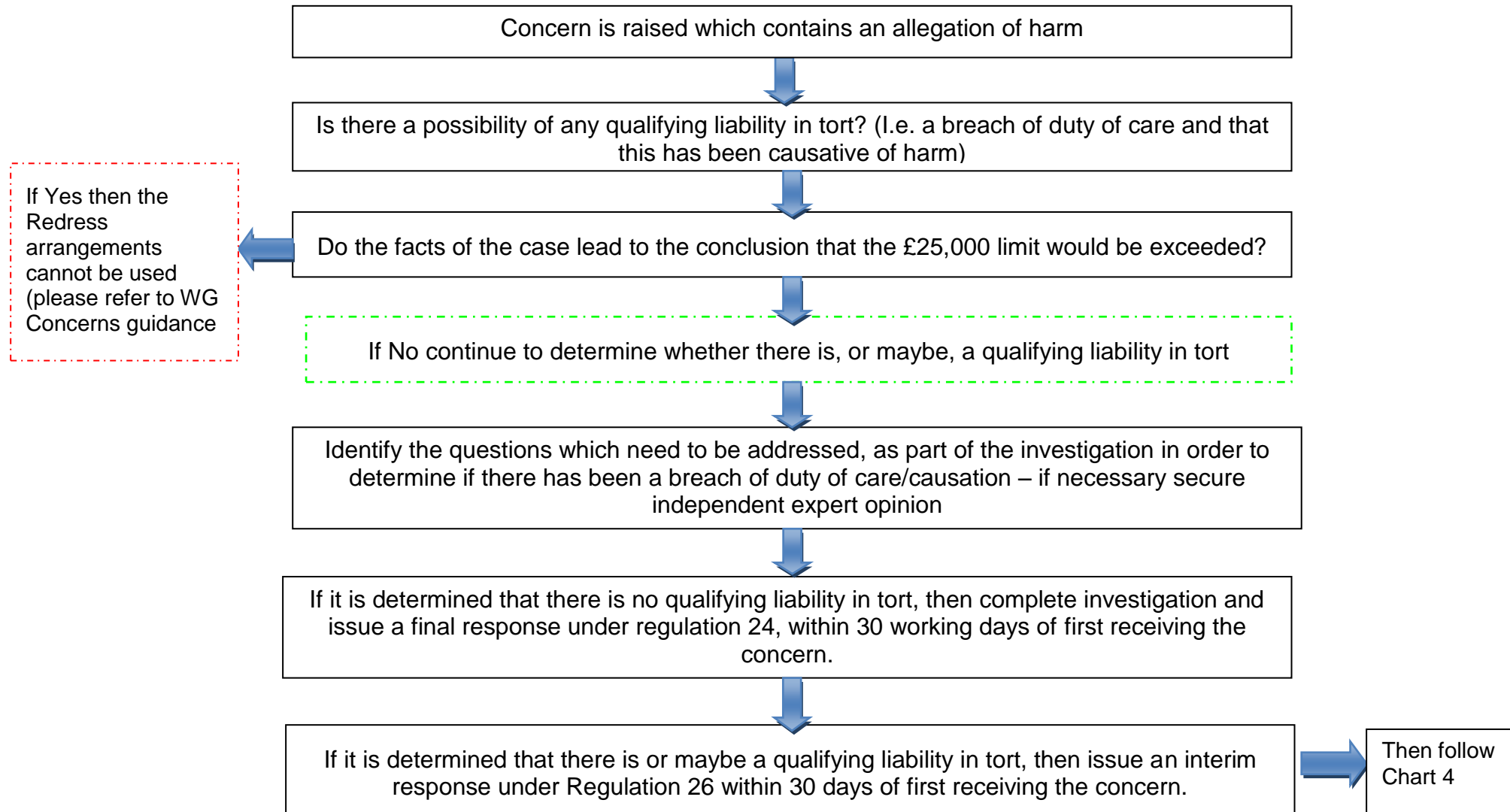
### Chart 1: How Public Health Wales deals with concerns



**Chart 2: How the Trust deals with a concern raised and dealt with under the Regulations**



### Chart 3: Welsh NHS body considering the possibility of a qualifying liability in tort as part of investigation under Regulation 23



### Chart 4: Welsh NHS body undertaking an investigation under the NHS Redress arrangements

Welsh NHS body has determined that there is or maybe a qualifying liability in tort and issued an interim response under Regulation 26.



Investigation commences under Part 6 of the regulations (Redress), advise person they are entitled to free legal advice. The limitation period is suspended from the date the concern was first received by the Trust. Redress might include an apology, report, explanation, financial compensation and/or remedial treatment – Remember £25,000 financial limit cannot be exceeded.



Obtain Compensation recovery Certificate in respect of any state benefits claimed and obtain evidence of any mandatory loss the person may be claiming (e.g. lose of earnings, sots of care and assistance).



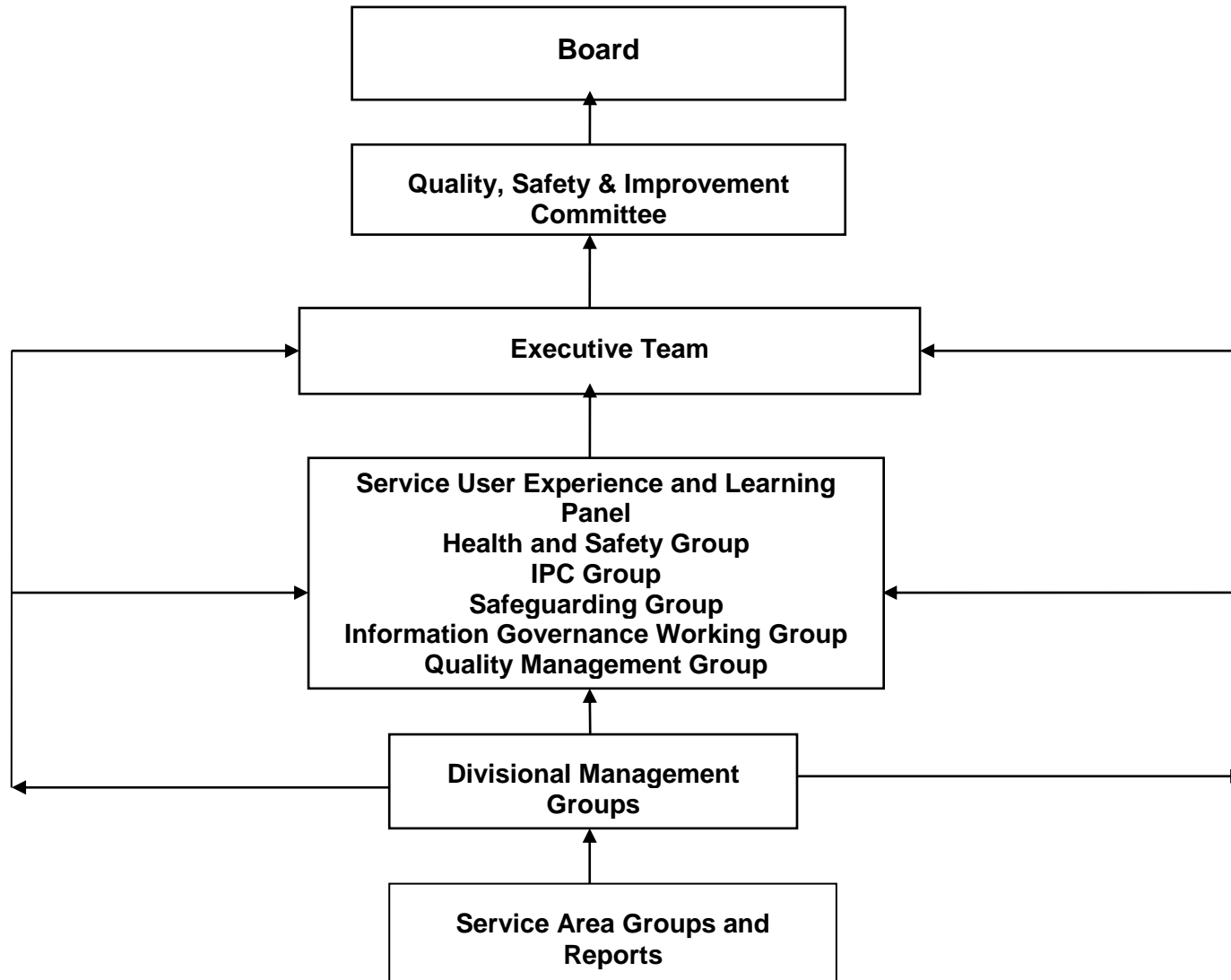
If qualifying liability in tort is admitted, the Redress panel will proceed to quantifying claim and drawing up an offer – use tariff and/or commission independent advice on quantum. Communicate decision to person, if they have accepted offer of free legal advice, send copies of offer and all evidence to their legal adviser



If qualifying liability in tort is not admitted, communicate decision to person, and if they have accepted offer of free legal advice send copies of offer and all evidence to their legal adviser.

For both options: Decision to be issued within twelve months of the first receipt of the concern.  
Person has nine months to respond to the offer.

## Appendix 5: Monitoring of Concerns and Learning



## **Appendix 6: Template Acknowledgement Letter**

### **Acknowledgement letter to service user / patient raising a concern (to be issued within two working days of receipt)**

Dear *[Insert service user / patient's name]*

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

Thank you for your *letter/email/fax/telephone call* 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*

*(Insert Public Health Wales contact name\*)* will be your named contact at Public Health Wales whilst your concern is being looked into and if you would like to talk or meet to discuss any aspect of your concern or the investigation, or if you have any special requirements, such as language, hearing or sight needs please do not hesitate to contact *(insert contact name)* using the following contact details:

*Insert address, telephone number and email address*

#### *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 Community Health Council, 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, 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.

If you have any queries about this letter, the investigation process or the concern you have raised, please contact me.

Yours sincerely

*(Divisional Director or Responsible Officer)*  
*Public Health Wales*

\*Public Health Wales contact name can be Director of Service or Lead Investigator

Enc Putting Things Right leaflet

## Appendix 7

### Acknowledgement letter to third party raising a concern on behalf of a service user / patient (to be issued within two working days)

Dear *[Insert Third Party name]*

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

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

#### *Contact point*

*(Insert Public Health Wales contact name\*)* will be your named contact at Public Health Wales whilst your concern is being looked into and if you would like to talk about any aspect of your concern, or if you have any special requirements, such as language, hearing or sight needs please do not hesitate to contact *(insert name)* using the following contact details:

*Insert address, telephone number and email address*

#### *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 Community Health Council, 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 service user / patient's name]* medical records 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 service user / 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 service user / 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 service user / 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.

If you have any queries about this letter, the investigation process or the concern you have raised, please contact me.

Yours sincerely

*Responsible Officer*  
*Public Health Wales*

Enc Consent form

Putting Things Right leaflet

\*Public Health Wales contact name can be Director of Service or Lead Investigator

## Appendix 8: Recording verbal concerns to be dealt with under the regulations

This form should be used by Public Health Wales staff when someone wishes to raise their concern 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 and uploaded to Datix.

### Client/Service user / patient Details

Title - Mr/Mrs/Miss/Ms Other - please state	
Name in full	
Date of birth	
Hospital no. (if known)	
Address (inc. post code)	
e-mail address	
Daytime contact number	
Mobile telephone number	
Preferred contact time/ Problem contact time	
Preferred Language - Welsh / English	

### Details of person raising the concern (if different from above)

Title - Mr/Mrs/Miss/Ms Other - please state	
Name	
Relationship to service user / patient	
Address (inc. post code)	
e-mail address	
Daytime contact number	
Mobile telephone number	
Preferred contact time/ Problem contact time	
Preferred Language - Welsh / English	



**Details of the concern**

Date concern occurred

Date concern brought to your attention (if different from above)

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.

Name of department/individual/service area etc. concern relates to

Any other person(s) involved?

Outline of concern – what went wrong, what effect has this had?

What can be done to put things right?

Other relevant information

Please attach any documents to support your concern

## Appendix 9: Consent Form

### Access to medical records

I hereby agree that my health records 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 Client/Service user / patient	
Date	

### If the person raising the concern is not the client/service user / patient

I hereby authorise \_\_\_\_\_  
to act on my behalf and to receive any and all information that may be relevant to the concern.

Signature of client/service user / patient	
Signature of complainant	

I hereby agree that my health records 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 Client/Service user / patient	
Date	

## Appendix 10: Investigation of Concerns Template

### Concern Information:

**Datix Reference**

**Division**

**Participant No. and Initials:**

**NHS Number:**

**Date complaint received:**

**Date investigation commenced:**

**Investigator name and Designation:**

**Does the complaint involve more than one responsible body?**

### Summary of Concern:

Is this an SI that requires reporting to Welsh Government? If yes please notify the Chief Risk Officer

Does this Concern relate to a SUI? (If so please give reference number)

### Investigation Details:

**Concern Grading:****Grading framework for dealing with all concerns (please tick) (guidelines attached)**

Concerns Grading  
framework for dealing

Grade 1 – Highly unlikely

- Grade 2 – Unlikely
- Grade 3 - Possible in some cases
- Grade 4 – Likely in many cases
- Grade 5 – Very Likely

**Risk Grading: Does the risk need to be raised on the Divisional / Directorate risk register**

Likelihood of reoccurrence	Consequence				
	Negligible	Minor	Moderate	Major	Catastrophic
Almost certain	○	○	○	○	○
Likely	○	○	○	○	○
Possible	○	○	○	○	○
Unlikely	○	○	○	○	○
Rare	○	○	○	○	○

Further investigation needed? Yes  No

Follow-up information needed? Yes  No

Person Responsible For Follow Up:

Timescale For Follow Up: .....

**Timescales must be strictly adhered to where possible as Public Health Wales are required to report these to Welsh Government.**

Date Investigation Completed And Response Sent To Head Of Programme / Service / Function:

..... / ..... / 20.....

Was the investigation completed within 20 working days? If not provide reasons why?

**Key Factors Leading to the Concern/Root Cause(s):**

**Outcome of Investigation:**

**Lessons Learned to Prevent Future Occurrences:**

**How will the lessons learnt be monitored:**

**Draft Response to Complainant:**

[Empty text area for drafting a response to a complainant]

**Completed concerns form should be uploaded to Datix**

## Appendix 11: SBAR Form

**Situation**

(Briefly state the issues raised within the concern)

**Background**

(Information relating to the concern)

**Assessment**

(Assessment of the findings following investigation)

**Recommendations**

**Author:** ..... **Date:** .....

**Date Reviewed by Executive Team:** .....

## Appendix 12: Type of Responses and the Regulation that Applies

Type of response and the regulation that applies	Type of Case	Within 2 working days	Within 30 working days of first receipt	Within 6 months of first receipt (reasons must be provided)	Within 12 months of first receipt (reasons must be provided)	Longer than 12 months ( <b>exceptional</b> ) (reasons must be provided)
Acknowledgement letter (Regulation 22)	All cases	√				
Final response (Regulation 24)	Cases that do <b>not</b> involve issues of liability		√	√		
Interim response (Regulation 26)	Cases that do or may involve issues of liability		√	√		
Investigation Report and Communication of Decision (Regulations 31 and 33)	Cases that do or may involve issues of liability				√	√

Note: The 2 working day acknowledgment period falls within the overall 30 working days for response.