NHS Wales national framework – Management of patient safety incidents following nosocomial transmission of COVID-19

Background

Within the NHS there can be occasions when a patient safety incident or concern occurs that can affect yourself or a member of your family. If this occurs then NHS organisations in Wales are required to follow the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Regulations"). This is further supported by a Welsh Government guidance document which is known as Putting Things Right ("PTR," v3, 2013).

There is a responsibility for the NHS to be open with patients if an incident has potentially caused harm and to undertake a reasonable level of investigation to determine what has happened, what has been learned and what needs to happen next to minimise the likelihood of the incident happening to anyone else.

During the COVID-19 pandemic, there have been many people who have sadly acquired COVID-19. The circumstances surrounding the reasons that they have acquired COVID are varied. Some people have required hospital admission for either COVID or other serious illnesses. It is possible that during this hospital stay they may have acquired COVID-19. This is known as "nosocomial" or "healthcare acquired" COVID. The pandemic has been unprecedented and something that the NHS and society has never encountered. However, it is important for members of the public or families who may have concerns regarding the circumstances surrounding the manner that they or their family member acquired COVID in hospital, understand the details surrounding their specific case as well as any information that can be taken as we learn more about this virus.

Framework document

In early 2021, the NHS Wales Delivery Unit worked with NHS bodies across Wales to co-produce a Framework document that set out a consistent national approach to the management of nosocomial COVID-19 cases.

There are many factors and complexities that will need to be considered as we implement the framework into practice. Should the initial assessment of an incident identify that the incident was preventable, the harm that was concerned avoidable then patients or their families will be contacted directly.

NHS Wales National Framework - Management of Patient Safety Incidents following Nosocomial Transmission of COVID-19

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1. Summary of Changes since version 1.2

- Scope of guidance updated to align more closely with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 – Putting Things Right (PTR)
- **Section 4.1** - Clarification that that when harm is discussed, especially in increased length of stay – this is directly related to a COVID-19 infection, and not where a patient may require increased length of stay because a care home was closed, for instance.
- **Section 4.2** - Further clarification that timescales HCAI (Healthcare Associated Infections) categories are for surveillance purposes only. However, they provide organisations with a starting point.
- **Section 6.2** - Update on outbreak reporting to recognise the removal of daily outbreak reporting to Welsh Government and reverting to 'No Surprises' communication
- **Section 9.1** - Added information on the National Nosocomial COVID-19 Programme learning collaborative Purpose
- **Appendix A** – Inclusion of Nosocomial COVID-19 Proportionality Investigation Decision Tool
- **Appendix B** – Flow chart indicating the requirements for private providers & NHS organisations to conduct investigations, where a patient's care is funded by the NHS

2. Purpose

Hospitals and care settings are high-risk environments for potential COVID-19 transmission. Hospital transmission of COVID-19 is a significant risk to patient safety, as it can result in severe harm or death. Surveillance and monitoring of COVID-19 infections acquired within hospitals (nosocomial transmission) is essential to identify sources and minimise risk of further transmission.

This Framework provides a consistent approach for NHS Wales organisations to identify, review and report patient safety incidents following nosocomial transmission of COVID-19 in compliance with the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 – Putting Things Right (PTR).

3. Scope

- All NHS Health Board and Trust premises where NHS services are provided
- All premises where NHS services are provided through contractual arrangements with NHS health boards and trusts in Wales
- Other premises, in situations where incidents or outbreaks of infection arise directly from NHS health board or trust staff providing healthcare services in out of hospital settings, such as care and residential homes, and private dwellings (Primary and Community Care settings).

Incidents outside of this scope, including other incidents relating to COVID-19, should be managed in line with current organisational incident management processes.

4. Definitions

4.1. Harm

Putting Things Right guidance (PTR guidance, v3, 2013) provides guidance on the definitions of harm in relation to patient safety incidents. The following definitions of moderate and severe harm have been summarised from the PTR guidance for ease of reference, however organisations should refer to the PTR guidance for full details.

It is important to remember that in the context of this Framework, 'harm' relates to the harm occurring because of nosocomial transmitted COVID-19. Where harm mentions a length of stay, this is associated with an increased length of stay as a direct result of a COVID-19 infection, not because of a delayed discharged, where a patients care home is closed due to an outbreak, for instance. PTR is concerned not only with harm that has occurred as the result of a patient safety incident, but also harm that *could have* occurred because of that incident.

Moderate Harm:

- Resulted in avoidable, semi-permanent injury or impairment of health or damage that requires intervention
- Additional interventions, required in addition to any baseline treatments for original hospitalisation treatment plan i.e., planned surgery/procedure
- Intended treatment is cancelled or significantly delayed
- Increase in length of stay by 4 – 15 days (directly related to COVID-19 infection)

Severe Harm:

- Issues that have resulted in avoidable, permanent harm or impairment of health, or damage leading to incapacity or disability
- Additional interventions required such as ITU care
- Cancellation or significant delay in urgent treatment
- Increase in length of stay by >15 days (directly related to COVID-19 infection)
- A concern outlining noncompliance with national standards with significant risk to patient safety

Recognising Harm:

There is recognition that harm can be difficult to apply in the context of COVID-19. However, National Institute for Health and Care Excellence (NICE) describe the long-term effects of COVID as *ongoing symptoms for 4 weeks or more after the acute start of COVID-19.*

- **Acute COVID-19:** signs and symptoms of COVID-19 for up to 4 weeks.
- **Ongoing symptomatic COVID-19**: signs and symptoms of COVID-19 from 4 to 12 weeks
- **Post-COVID-19 syndrome**: signs and symptoms that develop during or after an infection consistent with COVID-19, continue for more than 12 weeks and are not explained by an alternative diagnosis.

Death:

COVID-19 can lead to death soon after diagnosis, but it may also cause death many weeks later. Someone who tests positive can of course die from another cause such as cancer or heart disease at any time.

A death in someone who has tested positive becomes progressively less likely to be directly due to COVID-19 as time passes, and more likely to be due to another cause. However, there is no agreed cut-off after which COVID-19 can be excluded as a probable cause and sadly, some people die from their infection many weeks later.

Coronavirus can also contribute to a death without being the main or underlying cause. The World Health Organisation (WHO) recognises this complexity and states that: "*A COVID-19 death is defined for surveillance purposes as a death resulting from a clinically compatible illness in a probable or confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID-19 disease (e.g., trauma). There should be no period of complete recovery between illness and death."* This definition therefore requires a clinical assessment of each case.

4.2 Categories

Definitions* for the surveillance of Healthcare Associated COVID-19 infections have been agreed by the 4-Nations HCAI Surveillance group and are shown below.

It should be noted that these are definitions for **surveillance** purposes. However, they provide organisations with a starting point when investigating nosocomial COVID-19. There is a recognition that following an investigation/review a patient could fall into a different surveillance category.

Four nation surveillance categories

HCAI category	Criteria
Community onset	Positive specimen date ≤2 days after admission
Indeterminate healthcare-associated	Positive specimen date 3-7 days after admission
Probable healthcare-associated	Positive specimen date 8-14 days after admission
Definite healthcare-associated	Positive specimen date 15 or more days after admission
Community onset **Possible** healthcare-associated	Positive specimen date ≤14 days' post-discharge, or within 2 days after hospital admission, with discharge from hospital in 14 days before specimen date.

*Definitions taken from **SAGE (Scientific Advisory Group for Emergencies) paper** on nosocomial cases of COVID-19 in England

5. Investigation Process

5.1. General Principles

The purpose of undertaking investigations into cases of nosocomial transmission of COVID-19 is to determine instances of actual or potential patient harm**,** and to learn lessons to improve communicable disease control for the future. Investigations should be proportionate to the degree of actual or potential harm identified.

There are multiple pathways within an organisation that could trigger an investigation, and this Framework intends to clarify and support how those processes can work together in practice. The overarching principle is to ensure organisations investigate once and investigate well.

To achieve this, organisations should ensure internal processes support the following:

- rapid detection of cases reaching threshold for investigation (as set out in section 4.3)
- appropriate initial assessment to determine if harm has been caused, including the degree of harm caused
- proportionate and timely investigations are undertaken where appropriate to determine any issues in care where harm (including death) has, or could have, occurred.

In all cases, a proportionate investigation must be undertaken in line with PTR.

To minimise hindsight bias, investigations should ensure care and treatment is benchmarked against the specific guidelines and policies in place at the time of infection transmission. Consideration must be given to all relevant facts at the time including infection prevalence and staffing levels.

The depth of the investigation will vary according to the issues under consideration and the degree of harm caused. Organisations should therefore ensure they have access to a range of suitable investigation approaches/tools to support a proportionate approach across a range of outcomes. It will not be appropriate to conduct in-depth investigations for all cases 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 an incident is kept under review throughout its investigation in case the nature of the investigation needs to change.

Organisations must ensure appropriately trained people undertake investigations, with clear guidelines explaining the requirements of the investigation and the process to be followed.

5.2. Process Flow

To support a consistent approach to investigations, a flow chart (Appendix A) has been designed to help organisations manage the process, ensuring appropriate interfaces with other processes such as Medical Examiners and mortality reviews.

5.3. Identification of Incidents Requiring Investigation

(a) **Identify COVID-19 Positive Cases:** in the case of patient deaths, identification will be triggered by hospital procedures, including Medical Examiner review. For other cases, several other sources will exist, including but not limited to:

- findings from mortality reviews (Stage 1 or Stage 2)
- suspected or confirmed outbreaks or Period of Increased Incidence (PIIs)
- surveillance data from ICNet
- concerns processes, including patient safety incidents reported in Datix

Cases meeting the criteria for investigation are likely to include current and previous inpatients. Organisations therefore need to ensure there are processes to capture both inpatients and discharged patients.

(b) **Identify HCAI:** Organisations must have processes in place to determine if a patient has acquired nosocomial COVID-19.

(c) **Identify Harm:** Organisations must have processes in place to undertake an initial clinical review of all nosocomial transmission cases to determine the level of harm, or potential harm, caused (if any) by the nosocomial transmission. Clinical review can be incorporated into infection prevention & control procedures in the initial stages of outbreak/identification.

(d) **Undertake Investigation**: Organisations must have processes in place to identify which cases require investigation, and to undertake investigations proportionate to the level of harm/potential harm caused by the nosocomial transmission of COVID-19. A proportionality decision tool has been developed to assist organisations, which is included in Appendix A.

5.4. Investigation Methodology

Where an investigation is indicated and to ensure consistency of approach, it is expected that organisations will use an appropriate systematic approach to investigating cases. Organisations may use established investigation methods (such as Post-Infection Reviews, Root Cause Analysis), or can utilise specific COVID-19 toolkits that support a proportionate approach determined by the level of harm in line with PTR. The methodologies to use for these cases are a decision for each organisation, although it is expected that the organisation will ensure it is clear to staff which methodologies have been agreed for use and how investigations using those methodologies should be appropriately carried out.

Organisations must ensure records are kept of who has carried out investigations in relation to nosocomial transmission of COVID-19.

Organisations must ensure that investigation methods, including the use of investigation tools, does not narrow the focus of any investigation as to exclude any other issues in care,

besides the HCAI. All issues in care identified must be managed appropriately in keeping with PTR.

Aggregate / Cluster Investigation

In the case of outbreaks, where several patients are infected through the same source, initial investigations to determine the cause of the transmission can be part of normal infection prevention & control processes and combined using aggregate/cluster-based methodologies to reduce duplication. Organisations should ensure that any aggregate or cluster investigation methodologies also allow a proportionate individual investigation of individual patients, based on the level of harm caused.

5.5. Medical Examiners

The independent role of the Medical Examiner (ME) is to provide scrutiny to hospital deaths not otherwise referred to the coroner, by reviewing the relevant episode of care. In this regard, MEs (Medical Examiner) can support the initial assessment of nosocomial COVID-19 deaths in the following ways:

- confirmation regarding timing of infection transmission
- provide opinion on where COVID-19 should feature on a death certificate, and how contributory to the death the infection was
- family contact regarding the cause of death
- liaison with Her Majesty's Coroner
- referral for further review under the mortality process
- independent review

Where it is available, ME review should therefore be considered as an integral part of reviewing inpatient deaths, in keeping with the principle of investigate once, investigate well.

As of the date of publication, the ME process is actively being rolled out across NHS Wales. For organisations where the ME service is not yet active, organisations should ensure that their current mortality review processes link in with the investigation processes in line with the principle of investigate once, investigate well.

5.6. Mortality Reviews

For cases of nosocomial transmission of COVID-19, following ME scrutiny the case may be referred to the Health Board/Trust for a stage 2 mortality review and potential further investigation. A stage 2 mortality review may also be required following a stage 1 mortality review in an organisation where the ME service is not yet operating. As a mortality review does not constitute an investigation under PTR, organisations will need to ensure they have processes in place for proportionate investigation of these deaths if something more than stage 2 mortality review process is considered necessary.

5.7. Breach of Duty

Where Qualifying Liability (QL) has been decided to be admitted in relation to a PTR matter relating to COVID-19, or an admission of breach of duty only, advice **must** be sought from Legal & Risk Services before the decision is communicated. The costs of advice in relation to the decision on QL will be reimbursed by Welsh Risk Pool Services. A copy of the advice should be submitted with the request for reimbursement.

6. Reporting Arrangements

6.1. Local Reporting

Health boards and Trusts are required to ensure accurate and timely internal reporting of all incidents of nosocomial transmission of COVID-19 using established reporting mechanisms.

Incidents should be reported and appropriately graded depending on any level of harm determined at the time of reporting. Affected patients should be linked and easily identifiable within organisational incident records and appropriately linked to all corresponding processes such as inquests, claims or concerns (complaints). This is particularly important for incidents where severe harm or death has occurred.

6.2. National Reporting – Outbreak Monitoring

The requirement for daily outbreak reporting to Welsh Government ceased from 31 May 2022. Instead, organisations should revert to 'No Surprises' communications with Welsh Government

6.3. National Reporting of Individual Cases of significant harm from nosocomial COVID (Nationally Reportable Incidents)

In line with WG (Welsh Government) advice, at the time of publication of this Framework document incidents of nosocomial transmission of COVID-19 are not required to be nationally reported. This position is actively under review and any changes to this requirement will be communicated through an updated version of this Framework document.

Cases of nosocomial COVID-19 continue to be managed, recorded, and reported via the National Nosocomial COVID-19 Programme, until such time a decision to revert to business as usual has been agreed in-line with national incident report policy.

7. Patient & Family Engagement

7.1. Timing of Patient & Family Contact

Ward / Hospital Level Contact

Contact with patients and families will occur in several ways through the natural course of a patient's journey. Patients and families should have regular contact with nursing and medical staff to discuss treatment plans, and these contacts should be used to address informal queries raised by patients or their families. Escalation through the appropriate local nursing / medical structures should be used to quickly address queries. Where queries or concerns cannot be resolved, engagement of Patient Advisory Services (or similar) should be considered. Patients and families should also be advised of the organisation's concerns processes in the event they remain dissatisfied.

Concerns Process

More formal contact may occur if patients and/or their families raise concerns either formally or informally. All concerns will be managed in keeping with PTR requirements including timescales. Where organisations are unable to meet agreed timeframes, patients and families must be updated accordingly.

Identification of nosocomial transmission of COVID-19

Concerns raised internally via incident reporting, or through the processes for identifying and investigating incidents of nosocomial transmission of COVID-19, as set out in this Framework, will be managed in line with PTR requirements. On the timing of patient / family contact in this context, PTR states, "*where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern and involve the patient, or his or her representative, in the investigation of the concern*." Organisations should therefore make contact in keeping with PTR requirements when harm is first identified. Initial contact should set out what the organisation has, is, or is intending to do next, taking into account patient and family concerns and wishes. Organisations should be clear and realistic about the anticipated timeframes.

Death

In addition to the above, please refer to section 4.5 and 4.6 in relation to the role of the Medical Examiner Service who have established processes for liaising with families in the event of patient death, and family engagement as part of the mortality review process.

7.2. Single Point of Contact

As part of patient and family engagement, and the requirements of the National Nosocomial COVID-19 programme organisations should have a dedicated single point of contact (SPOC) to assist patient and families affected by nosocomial COVID-19. Provisions should be made to ensure access to the service is available five days a week, ideally Monday – Friday,

within core business hours i.e. 9:00 – 17:00. Outside of these hours, there should be consideration of a voicemail facility with a clear message managing expectations in relation to how further communication will take place.

7.3. Duty of Candour

On 1 June 2020, The Health, and Social Care (Quality and Engagement) (Wales) Act became law. Welsh Government is currently preparing to implement the Act. As part of this work, establishment of an organisational Duty of Candour on providers of NHS services, will require organisations to be open and honest with patients and service users when things go wrong. In anticipation of this work, organisations are asked to undertake their work in this area, fully in keeping with those principles.

8. Governance

8.1. Board Reporting

Health Boards and Trusts must have systems and processes in place to ensure their Executives and Boards are kept appraised of incidents of nosocomial transmission of COVID-19, in line with their internal reporting mechanisms for all Serious Incidents. Particular attention should be given to those incidents where significant harm or death has occurred because of nosocomial transmission of COVID-19. Reporting should include the number of incidents identified requiring a degree of investigation, and any specific organisational risks / challenges to undertaking this work, so that they are managed at the appropriate level. This would ordinarily be undertaken through the existing Board governance structures.

8.2. Executive Level Oversight & Sign-off

Organisations must ensure their Standing Operating Procedure (SOP) to manage this process includes a descriptive section as to how local level directorates and divisions will sign off investigations as part of the scrutiny process. The SOP will also need to describe how corporate oversight and monitoring will be managed, and how this is reported to Quality and Safety Committees and Board. Organisations should be able to produce their SOPs (Standing Operating Procedure) upon request.

9. Sharing Learning

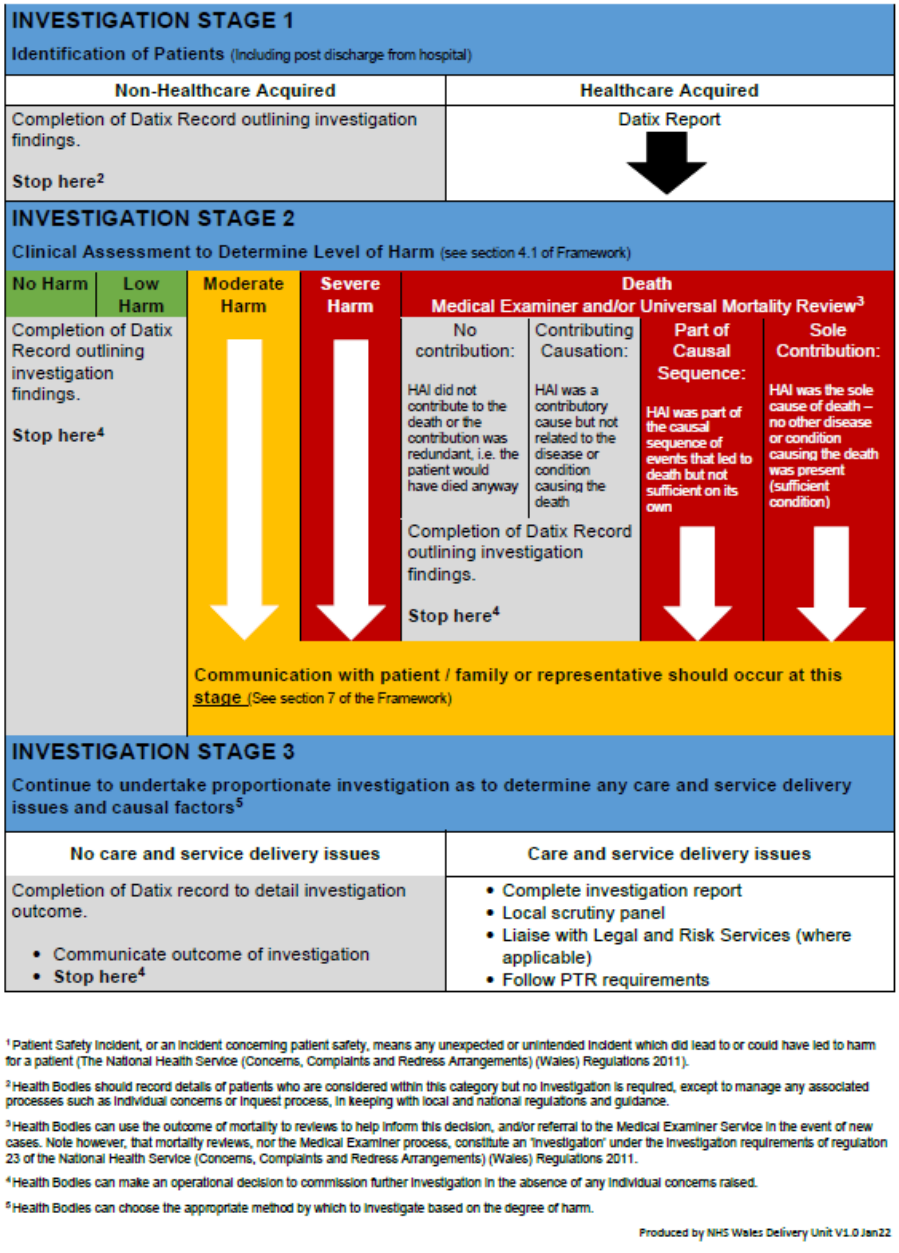
9.1. Local Sharing of Learning

Organisations must have systems and processes in place to rapidly share and embed learning identified through investigations and reviews of nosocomial infections and outbreaks of COVID-19. Internal processes to support learning should be clearly defined within the organisation's SOP.

The NNCP (National Nosocomial COVID 19 Programme) programme has developed a national Systems Learning & Implementation Cycle which is supported by a programme specific learning plan. The key principles of the learning model are to Identify, Collate, Analyse, and Implement learning, ensuring information is validated at each stage. All learning will be supported by an MDT (multidisciplinary team) learning collaborative which will ensure all validated learning is directed to the appropriate system level i.e., Policy, clinical practice, or new improvement initiatives

Appendix A – Nosocomial COVID-19 Investigation Proportionality Decision Tool

Nosocomial COVID-19 Patient Safety Incident[1]
Investigation Proportionality Decision Tool



[1] Patient Safety Incident, or an incident concerning patient safety, means any unexpected or unintended incident which did lead to or could have led to harm for a patient (The National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011).

[2] Health Bodies should record details of patients who are considered within this category but no investigation is required, except to manage any associated processes such as individual concerns or inquest process, in keeping with local and national regulations and guidance.

[3] Health Bodies can use the outcome of mortality to reviews to help inform this decision, and/or referral to the Medical Examiner Service in the event of new cases. Note however, that mortality reviews, nor the Medical Examiner process, constitute an 'investigation' under the investigation requirements of regulation 23 of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011.

[4] Health Bodies can make an operational decision to commission further investigation in the absence of any individual concerns raised.

[5] Health Bodies can choose the appropriate method by which to investigate based on the degree of harm.

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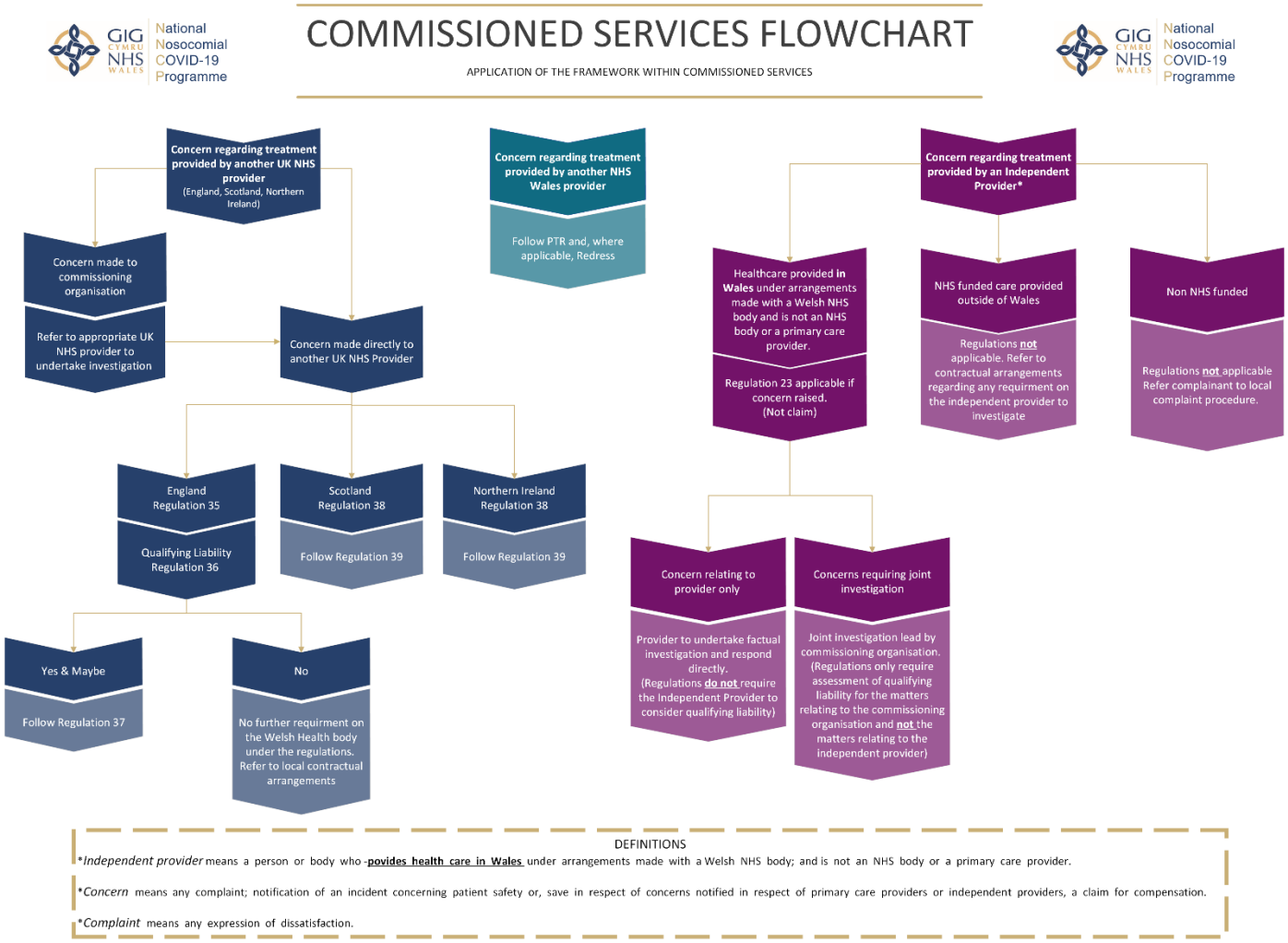
Appendix B – Commissioned Services Flow Chart – Application of the Framework



DEFINITIONS

Independent provider* means a person or body who -povides health care in Wales** under arrangements made with a Welsh NHS body; and is not an NHS body or a primary care provider.

**Concern* means any complaint; notification of an incident concerning patient safety or, save in respect of concerns notified in respect of primary care providers or independent providers, a claim for compensation.

**Complaint* means any expression of dissatisfaction.

Appendix C – Operational Delivery Considerations

Operational delivery issue	Considerations
Appropriate hospital admission	Was there an alternative? Would harm have occurred if the patient were not admitted into hospital?
Following the correct pathway into hospital	Was the patient admitted following the appropriate Red, Purple, Amber & Green route into hospital?
Hospital capacity at the time of admission	Was there limited bed capacity at the time of admission due to patient demand or ward closures due to outbreaks?
Diagnostic factors (*recognising this was updated as evidence emerged*)	Were diagnostic factors identified at the time of admission such as temp >37.8, cough
Context of waves	Recognise knowledge gained as evidence emerged (*more was known during wave 2*)
Community prevalence	Higher community transmission rates are likely to have an impact on hospitals
Staffing levels & experience	Recognising staff sickness levels due to isolation & redeployed staff (including skill mix)
Circulating variants	The Delta variant has been shown to increase transmissibility by approximately 60% compared to the Alpha variant
Guidance	The guidance in place at the time of transmission (national & local guidance)
Testing	Access to testing (staff & patient) including national and local guidance at the time of transmission. Access to consumables