National Nosocomial COVID-19 Programme: patient and family frequently asked questions

Answers to common questions on the national nosocomial COVID-19 programme.

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Contents

Introduction

The National Nosocomial COVID-19 Programme (NNCP) was established in direct response to the COVID-19 Pandemic. NHS Wales has legislation known as National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 – Putting Things Right (PTR), that sets out the requirements of what a Health Board/Trust must do when a patient safety incident occurs, and/or a complaint regarding NHS funded care is made. 'Nosocomial' means - any infection, including COVID-19, which is caught through the delivery of healthcare. An infection caught in hospital or through a healthcare setting is considered a patient safety incident, meaning the provisions of the Putting Things Right (PTR) process apply.

There is now an agreed National Framework and programme of work to support a consistent national approach towards investigations following patient safety incidents of nosocomial COVID-19, this programme of work has ministerial support.

The key outcomes of the programme are to provide high-level assurance that all patient safety incidents of healthcare acquired COVID-19 are investigated in line with the requirements of PTR, and to ensure concerns raised by patients and their families are fully addressed. The programme will collect learning from investigations and cross reference this with patient and staff experience, which will be captured as part of the programme.

This document aims to provide answers to some of the common questions asked regarding the programme. We acknowledge however that patients and families will have more detailed queries. At the end of this document, readers will find contact details for each Health Board and Trust, where individual queries can be raised and responded to directly by the appropriate organisation. Details of independent advocacy and bereavement support are also provided.

General

What does Nosocomial COVID-19 mean?

In this instance, 'Nosocomial COVID-19' means - COVID-19 infections that were caught in hospital or other healthcare setting.

Nosocomial infections, also referred to as 'healthcare-associated infections' (HAI), are infection(s) caught during the process of receiving health care, and where that infection was not present during the time of a person's admission to hospital or healthcare setting. They may occur in different areas of healthcare delivery, such as in hospitals, long-term care facilities, and ambulatory settings. The infection may also appear after discharge from a healthcare setting, but are attributed to the time a person was in contact with the healthcare setting.

How do you determine if a COVID-19 infection was caught in a health care setting?

The NHS uses established national (UK) definitions, which are endorsed by Public Health Wales. These definitions set out how likely it is that an infection is healthcare caught by the number of days following admission to hospital/ healthcare environment and when testing positive for COVID-19 was confirmed. Generally, a person is said to have probable nosocomial COVID-19 if they test positive for COVID-19 after 8 days of receiving care. However, this is not a concrete rule and there will be occasions where organisations will need to consider the likelihood of infection transmission between 3-7 days, which is classified as indeterminate acquisition, this is due to the incubation period of COVID-19 and other risk factors, such as exposure to the virus.

What is Putting Things Right (PTR)?

PTR is a guidance document which describes how National Health Service (NHS) providers in Wales, Health Boards and Trusts should handle 'concerns' based upon the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 ("the Regulations").

Putting Things Right (PTR), is the guidance document produced by Welsh Government, to help health bodies in Wales interpret the legal requirements of the Regulations and how to put these regulations into practice when dealing with a concern. PTR includes guidance on investigating complaints and patient safety incidents, which are slightly different.

What is a 'concern'?

The term 'concern' is used to mean any complaint, claim or patient safety incident (about NHS treatment or services).

What is a patient safety incident (PSI)?

A PSI is an unintended or unexpected incident, which either led to harm or could have harmed one or more patients.

Harm does not need to have occurred in order for an incident to be reported. PSI's are generally incidents reported internally by staff working in NHS organisations.

All cases of nosocomial COVID-19 in NHS Wales are considered to be patient safety incidents.

Can a patient safety incident also be a complaint?

Yes. PSI's are generally reported by staff within the organisation. In some cases, the patient, family or their representative may choose to complain or make a claim about the same incident. Health bodies are required to join up all concerns processes, past or present, and assess whether further investigation is required. This will also include working with the coroner where appropriate. Health bodies should work with complainants (person or people who raised the complaint) where concerns remain unresolved, to ensure their wishes and views are taken into consideration during any investigation.

However, individuals only need to make a formal complaint should they so wish, the investigation process places the same requirement on health bodies to respond to patients and families.

What are nationally reportable incidents?

Some PSI's are considered to be "nationally reportable incidents", which is usually based on the level of harm caused by the incident. These incidents are reported to the NHS Wales Delivery Unit, who oversee the functions for learning from national incidents.

To reduce administration, nosocomial COVID-19 PSI's are not nationally reported, and are instead managed separately through the national programme where learning is captured and coordinated.

More detail on Nationally Reportable Incidents can be found in the **National Patient Safety Incident Reporting Policy**.

Why is nosocomial COVID-19 a patient safety incident?

Any hospital caught infection, including COVID-19, is classed as a PSI because the infection is unexpected and/or unintended, regardless of whether the patient comes to harm or not.

If nosocomial COVID-19 is a patient safety incident, why is there a separate framework for managing these incidents?

Whilst investigations into healthcare caught infections are standard practice across the NHS, there are many factors and complexities that need to be considered in relation to COVID-19. Little was known about COVID-19 at the beginning of the pandemic, including modes of transmission, infectivity and disease severity. We continue to learn about how the infection spreads, and the size and scale of the pandemic. The separate framework is designed to support Health Boards and Trusts practically apply PTR within the context of COVID-19. The legal duty on organisations to investigate in keeping with the Regulations is, however, unchanged.

How is harm defined?

Putting Things Right provides guidance to the NHS on the definitions of harm in relation to PSI's. There are 5 categories of harm within the guidance:

1. no harm
2. low harm
3. moderate harm
4. severe harm

5. death

Establishing the exact degree of harm caused by the incident will often require patient and/or family input into the assessment. In broad terms harm is described as something that was caused by the COVID-19 infection.

Low harm:

- Increase in length of stay (in hospital or healthcare setting) by up to 3 days
- Minor implications for patient safety
- Return for minor treatment, or extra investigations

Moderate:

- Avoidable injury/damage that requires clinical intervention
- Additional clinical intervention for patients already receiving healthcare prior to acquiring COVID-19
- Increase in length of stay (in hospital or healthcare setting) as an In-patient by at least 4 days

Severe harm:

- Permanent harm that could have been avoided
- Additional interventions such as ITU (Intensive Therapy Unit) care, that could have been avoided
- Cancellation or significant delay in urgent care
- At least 15 days increase in hospital stay

Death:

The death of 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 likely cause and sadly, some people die from their infection many weeks later.

The framework provides reference to World Health Organisation guidance to help determine how responsible COVID-19 was to a patient's sad death, particularly when other health issues existed before the COVID-19 infection was caught. Where death has occurred, investigations will consider the findings of mortality reviews and medical examiners reviews to determine to what extent COVID-19 caused the death.

What is an investigation?

All concerns, including patient safety incidents, must be managed and investigated in keeping with the Regulations. The investigation must review what happened, why it happened and identify any learning that might improve patient safety, their experiences or outcomes in the future. Organisations are free to decide on the most appropriate way to undertake an investigation. The framework helps organisations determine the level of investigation that would be appropriate based upon the patient outcome i.e. no harm – death, with higher impact outcomes receiving more detailed investigations. The Regulations set out the minimum standards for NHS Wales PSI investigations.

Does the Framework cover harm or deaths of people in care homes from nosocomial COVID-19?

The Framework applies to all cases of healthcare caught COVID-19 infections, which occurred during NHS funded care. This includes individuals who were transferred from hospital into a social care or private setting and subsequently test positive for COVID-19 within 14 days of leaving hospital.

The Regulations, which apply to the healthcare sector, are not however applicable to the social care sector where COVID-19 infections were caught in social care or private care home. The social care sector does not have an equivalent law that requires investigations into cases of social care caught COVID-19, in the way that the healthcare sector are required to. Application of the framework becomes more complex when people in receipt of commissioned NHS funded care, contract COVID-19 in other non NHS Wales care settings, such as care homes, private facilities, and other non-NHS providers outside of Wales. There is work underway with the social care sector to help gather learning from the pandemic, particularly in relation to the Social Care incident management responses to outbreaks of COVID-19.

The national framework is currently being updated to provide further clarity in relation to how patients who caught COVID-19 through the provision of commissioned care, including social care settings are to be handled. However, below is a list of examples which would be within scope of the framework if it is assessed the patient caught COVID-19 through the delivery of NHS funded care, regardless of where their death subsequently occurred:

- caught COVID-19 through provision of healthcare in hospital and died in hospital
- caught COVID-19 through the provision of NHS healthcare in the community and died in hospital
- caught COVID-19 in hospital but died at home or care home following

discharge/transfer
- caught COVID-19 in hospital and discharged but died of healthcare acquired COVID-19 following readmission to hospital
- COVID-19 listed on any part of the death certificate if considered healthcare caught

What are 'mortality reviews' and 'medical examiner reviews' and why are they different to PTR or PSI investigations?

Mortality reviews form part of a standard process when someone dies in hospital. The reviews are designed to assess the care and treatment provided to a person and to identify any opportunities for learning and improvement. As part of the process, the reviews consider if there was anything that occurred during the person's care that might have caused or contributed to their sad death.

Medical examiner (ME) reviews were introduced recently in England and Wales. The Medical Examiner Service provides independent scrutiny of all deaths not investigated by the coroner. The ME service ensures that an accurate cause of death is recorded, and identifies any concerns surrounding the death itself, which can then be further investigated if required. The ME also takes on board the views of the family and friends of the person who has died.

The ME service was not fully implemented in Wales at the start of the pandemic, meaning some people who died earlier in the COVID-19 pandemic will not have been subject to an ME review.

Importantly though, mortality reviews or reviews undertaken by the independent Medical Examiner service, cannot be considered as an investigation according to the Regulations. These reviews seek to answer different questions to an investigation, which aims to understand what happened, why it happened and what actions can be taken to improve future patient safety, experience and outcomes.

However, a patient safety incident (PSI) review will be started where mortality or medical examiner reviews identify anything unintended or unexpected. This would then trigger an investigation in keeping with the requirements of the Regulations. Therefore these processes compliment and inform each other.

When will families hear the outcomes of the investigations?

When a patient safety incident is reported internally by NHS staff, there will be occasions when patients and families are initially unaware that an incident has occurred. In these instances, the Regulations and PTR requires organisations to assess the incident, and inform families of those incidents that have caused 'moderate harm' or above. Patients and/or their families should be invited to contribute to investigations in these instances. There is no requirement for organisations to contact patients or families when 'no or low harm' has occurred. This does not affect the rights of any person to raise a concern about care and treatment, which will be investigated in accordance with NHS Wales' complaint handling arrangements.

PTR guides organisations on what to do depending on the outcome of the investigation. Some investigations will inevitably result in offers of redress (financial compensation) under the PTR process, and/or legal claims for compensation, which will be managed in line with long standing NHS Wales arrangements.

Are investigations completed independently?

The vast majority of investigations in the NHS are conducted internally by the organisations where the incident occurred. This is because staff within those organisations are best placed to understand the unique situation and context that the incident occurred in. However, Investigations will always be undertaken

independently, that is to say, by people not involved or connected to an incident. Organisations are required to ensure investigations are open and transparent for both staff and patients/families.

PTR does not require independent investigation from the organisation that is the subject of a complaint. PTR advises that investigations should be undertaken by persons not connected with the incident, and with appropriate investigation training and knowledge. The Regulations also allow independent expert reviews to be commissioned by health bodies in certain circumstances, and involving the complainants in the appointment of any independent expert where needed.

To support independence, the National Nosocomial Review Programme requires organisations to establish local scrutiny panels, which are independent of the investigation. The scrutiny panel has responsibility for ensuring regulatory standards of investigations are met, and will make the final assessment on a case by case basis as to whether care was reasonable. The NHS Wales Delivery Unit will be responsible for assuring the overall standard of investigation and scrutiny panels from a national perspective.

Have all health boards started their investigations?

Yes. All health board and Trust organisations have started the process of identifying COVID-19 PSI's that meet the definition, and started to conduct investigations. The number of incidents varies greatly between the different NHS organisations in Wales due to population size and different community transmission rates. Given the significant number of investigations required to be carried out, the whole programme is anticipated to run over two years, with investigations being undertaken throughout this whole period. As a result, some investigations will not be able to be started for some time.

Have all the investigations to date only been triggered by

PTR complaints?

No. There are many investigations underway which resulted from a combination of both internally reported PSI's and complaints received from patients and family members. Cases that have been identified because of a patient or family member/representative raising a complaint, have been prioritised in keeping with the NHS Wales complaint procedures.

What if complaints have been referred to the Public Services Ombudsman for Wales (PSOW)?

A complaint is normally made to the PSOW in circumstances where a complainant remains dissatisfied with a response from NHS organisations, either in regard to the internal investigation finding, and/or the handling of the complaint. When a complaint is made directly to the PSOW, the usual process is that the Ombudsman's office will ask the NHS organisation to explain what investigations have been conducted to date and whether a 'final response' has been issued. This is primarily because the Ombudsman will require NHS organisations to have had the opportunity to investigate and respond before they consider a case and whether to intervene.

Where the PSOW has already decided to investigate a complaint, NHS organisations will stop internally led investigations, and instead provide all required information to the PSOW.

However, the person raising the complaint will need to decide whether they want the PSOW to continue their investigation. Patients and or families/ representatives can also discuss directly with the relevant NHS organisation using the contact details below.

Where NHS organisations are already mid- investigation under the relevant PTR process, do these now move to the new investigation framework?

The framework is fully compliant with PTR and will not require organisations to reinvestigate where the required standards of investigation have been met. There will however be a requirement for any previous investigations to be considered by the newly created local scrutiny panels. Panel members can request further investigation should this be necessary.

What is the timeline for the investigations under the new framework?

Investigations will start at different times through the two-year process as organisations incrementally work through the incidents. Organisations will progress at different rates because the number of incidents varies. It is important to stress that this process is not an alternative to the PTR process, rather a formalised way to work through the significant volume of investigations. This means that investigations should be completed in keeping with PTR timescales but there is recognition this will be variable. Organisations will communicate anticipated investigation timeframes with patients and families on an individual basis as part of the process.

Communication

How will health boards and trusts contact affected patients and families?

Organisations will use different methods to contact patients and families. Some organisations will write, whilst others may make telephone contact first, before following up with letters.

Once initial contact has been made, patients and families will be given a single point of contact who will remain their contact throughout the process. All patients and/or families/representatives will receive a final outcome letter explaining the investigation undertaken and the outcome of that investigation.

Who do I contact to ask if I or a relative are part of the programme?

You can contact the relevant organisation at any time using the contact details below.

When will patients and families who have not previously had contact, be made aware they are subject to an investigation?

Organisations are actively identifying all cases which require investigation in order to communicate with that person using last known contact details. Where a patient is known to be deceased, the process includes the identification of family members or other appropriate contacts. Organisations will use information held on their systems regarding next of kin or other nominated contacts from the last

episode of care to support this.

What happens if the next of kin details have changed since the incident?

Health bodies will make all reasonable enquiries to establish the next of kin (NOK) or nominated point of contact, often using details recorded during the last episode of care. Organisations will triangulate information held through different services they provide to be able to make contact.

Advocacy support

What advocacy support is there to raise concerns?

If you cannot resolve your concern informally with the relevant organisation, or you would prefer to raise your concern formally, the Community Health Council (CHC) offers an independent complaints advocacy service that can help you.

The CHC can also support you with **making a complaint to the Public Services Ombudsman for Wales**.

Bereavement support

What bereavement support is available?

All organisations have bereavement support available to families. Anybody wishing to seek further information or request referral for bereavement support should contact their local organisation on the below contact details.

Health board and Trust contact details

Contact details

Health boards

Aneurin Bevan University Health Board	0300 373 0652 - **abb.covidinvestigationteam@wales.nhs.uk**
Betsi Cadwaladr University Health Board	03000 846992 - **BCU.HCAICovid19@wales.nhs.uk**
Cwm Taf Morgannwg University Health Board	01443 443084
Cardiff & Vale University Health Board	02921 836407 - **Cav.Covidsupport@wales.nhs.uk**
Hywel Dda University Health Board	0300 303 8322 - **covidenquiries.hdd@wales.nhs.uk**
Swansea Bay University Health Board	01639 684440 - **SBU.NosocomialReviewTeam@wales.nhs.uk**
Powys Teaching Health Board	01874 442918
Velindre University NHS Trust	02920 196161 - **HandlingConcernsVelindre@wales.nhs.uk**