

May 15 2024

Dear

ATISN 19514 – Midazolam patient safety incident reporting

Thank you for your request which I received on 29 April 2024. You asked for:

In relation to the details of Patient Safety Incidents across Wales provided by Welsh Government to Health Inspectorate Wales. Please answer the following:

1. If a patient is given a ‘therapeutic’ dose of morphine and Midazolam for pain relief, which, the treating doctor says, he is expecting to wear off in two hours, but the patient loses consciousness and never regains it, is this a notifiable Patient Safety incident?

2. If the answer to 1 is yes, what steps to report the matter:

a) should be taken by the Health Authority?

b) can be taken by the patient’s family?

3. Is it mandatory for the Health Authority to make a report?

4. In the absence of a report by the Health Authority, what support, if any, does the Welsh Government provide to the family of the deceased to make a report independently of the Health Authority, and to whom should the report be made?

Response

The Welsh Government is unable to respond to individual cases as these are matters which must be dealt with by the medical providers responsible. NHS bodies should determine patient safety incidents and near misses and report them locally. They have systems and processes in place to investigate incidents, analyse data, identify risks, themes, and trends to extract learning and disseminate throughout their organisation. It is important that incidents are investigated locally so NHS bodies can learn from what may have gone wrong and make improvements to prevent reoccurrence.

Some patient safety incidents must be reported nationally to the NHS Wales Executive to inform national learning, as set out in their National Policy on Patient Safety Incident Reporting and Management [Patient Safety Incidents - Delivery Unit \(nhs.wales\)](#). These are called Nationally Reportable Incidents (NRIs) and are defined as ‘patient safety incidents which cause or contribute to *unexpected or avoidable death, or severe harm*, of one or more patients, staff or members of the public, experienced during NHS funded healthcare’.

All NRIs are subject to investigation by health bodies in accordance with the principles set out in the Putting Things Right process, [NHS Wales complaints and concerns: Putting Things Right | GOV.WALES](#). NRI investigation outcomes, actions and learning must be submitted to the NHS Wales Executive to inform national learning.

If you have concerns about the care or treatment provided by an NHS body you may raise them directly through the Putting Things Right process by contacting the relevant NHS body.

If you are not happy with the final response from the health board, you may wish to contact the Public Services Ombudsman for Wales who has legal powers to look into complaints about public services in Wales. The Ombudsman is independent of all government bodies and the service provided is impartial and free of charge. The Ombudsman's office may be contacted at:

Public Services Ombudsman for Wales
1 Ffordd yr Hen Gae
Pencoed
CF35 5LJ

Tel: 0300 790 0203

Email: ask@ombudsman.wales

[Public Services Ombudsman for Wales](https://www.ombudsman.wales/)

You may also wish to know that a new national citizen voice body (operating name Llais) has been established from 1 April 2023. Llais replaces the network of Community Health Councils and reflects the views and represent the interests of the people of Wales in respect of health and social care services. It is independent of government, the NHS and local authorities but works with them and others, to support the continuous improvement of person-centred services. Llais also offers a free, independent complaints advocacy service to support anyone wishing to make a complaint about health or social services they have received. Contact details can be found in this link: [Your voice in health and social care | Llais \(llaiswales.org\)](https://www.llaiswales.org/)

Website: [llaiswales.org](https://www.llaiswales.org)

Email: enquiries@llaiswales.org

Telephone: 02920 235558

Or write to:

Llais

Third Floor

33-35 Cathedral Road,

Cardiff

CF11 9HB

Next steps

If you are dissatisfied with the Welsh Government's handling of your request, you can ask for an internal review within 40 working days of the date of this response. Requests for an internal review should be addressed to the Welsh Government's Freedom of Information Officer at:

Information Rights Unit,
Welsh Government,
Cathays Park,
Cardiff,
CF10 3NQ

or Email: Freedom.ofinformation@gov.wales

Please remember to quote the ATISN reference number above.

You also have the right to complain to the Information Commissioner. The Information Commissioner can be contacted at: Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF.

However, please note that the Commissioner will not normally investigate a complaint until it has been through our own internal review process.

Yours sincerely,