



Memorandum of Understanding (MoU) between Healthcare Inspectorate Wales (HIW) and National Institute for Health and Care Excellence (NICE)

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Revision history and approval

Version	1.0
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Authors	HIW: Joseph Wilton NICE: Julie Vile
Date agreed	14/05/2020
Formally agreed by	HIW: Alun Jones NICE: Professor Gillian Leng
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Introduction

- 1. The purpose of this Memorandum of Understanding (MoU) is to set out a framework to support the working relationship between Healthcare Inspectorate Wales (HIW) and National Institute for Health and Care Excellence (NICE).
- 2. This working relationship is part of the maintenance of an effective regulatory system for health in Wales which promotes patient safety and high quality care.
- 3. This MoU relates only to the regulation of healthcare in Wales. It does not override the statutory responsibilities and functions of HIW and NICE. It does not create legally binding rights or obligations; nor does it imply any transfer of responsibility from one to the other, nor sharing of statutory functions or accountabilities.
- 4. The purpose of the MoU is to define the joint agreement between the two organisations and to describe how HIW and NICE will work in partnership to support improvement in the quality of care. It covers the guidance, advice and other products that NICE provides for the healthcare system, the support HIW provides assurance and monitoring of the implementation of NICE guidance, quality standards and indicators, and the support NICE provides to HIW in order for HIW to fulfil its role in the regulation of healthcare services.
- 5. As part of the activities undertaken as a result of this MoU, other agreements (for example, information sharing agreements, or joint working protocols) may be established. Such agreements will exist separately to this MoU.

Roles and responsibilities

Healthcare Inspectorate Wales

- 6. HIW is the independent inspectorate and regulator of healthcare in Wales. HIW carries out its functions on behalf of Welsh Ministers and, although part of the Welsh Government, protocols have been established to safeguard its operational autonomy. HIW's main functions and responsibilities are drawn from the following legislation:
 - Health and Social Care (Community Health and Standards) Act 2003;
 - Care Standards Act 2000 (and associated regulations);
 - Mental Health Act 1983 and 2007, Mental Health (Wales) Measure 2010;
 - Independent Health Care (Wales) Regulations 2011;
 - Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008; and
 - Ionising Radiation (Medical Exposure) Regulations 2017 and Amendment Regulations 2018.

7. HIW aims to:

- Provide assurance: Provide an independent view on the quality of care.
- Promote improvement: Encourage improvement through reporting and sharing of good practice
- Influence policy and standards: Use what we find to influence policy, standards and practice
- 8. HIW's core role is to review and inspect NHS and independent healthcare organisations in Wales to check that patients, the public, and others are receiving safe and effective care which meets recognised standards. Health services are reviewed against a range of published standards, policies, guidance and regulations. As part of this work HIW will seek to identify and support improvements in services and the actions required to achieve this. If necessary, HIW will undertake special reviews and investigations where there appears to be systematic failures in delivering healthcare services to ensure that rapid improvement and learning takes place.
- 9. HIW is also responsible for the registration and regulation of independent healthcare providers under the Care Standards Act 2000. The regulation of such establishments is governed by the Independent Health Care (Wales) Regulations 2011.

National Institute for Health and Care Excellence

10. NICE is an English executive non-departmental public body operating within the wider health, public health and social care system. Its role and responsibilities in Wales are defined primarily by a service-level agreement with Welsh Government under section 83 of the government of Wales Act (2006). The latest agreement

- approved in 2018 gives all NICE guidance, including health, public health and social care guidelines, equal status in Wales as England although Welsh users may need to take into account the different legislative framework that sometimes applies.
- 11. NICE provides guidance to support practitioners and managers in making sure that the care commissioned and provided is of the best possible quality and offers the best value for money. NICE's guidance is not mandatory, with the exception of NICE technology appraisals, where regulations require NHS bodies in Wales to comply with the technology appraisal recommendations within 60 days from the Final Appraisal Determination.
- 12. NICE also supports the adoption and implementation of guidance and quality standards through a dedicated programme that includes providing online resources, wider influencing and joint working. NICE uses its guidance, as well as accredited guidance, within an indicator development programme to develop indicators to support measurement in general practice (including the Quality and Outcomes Framework (QOF)) and indicators to measure care and outcomes.
- 13. NICE also produces a range of other products, including evidence summaries on new medicines, guidance on best practice in prescribing, and an on-line evidence portal for health and social care (NICE Evidence Services) that includes books and journals purchased on behalf of the NHS. NICE holds the contract for the British National Formulary (BNF) and supports online access through the NICE website. It also provides information on new drugs in development through a restricted database for horizon-scanners (UK Pharmascan).

Principles of co-operation

- 14. HIW and NICE acknowledge their respective statutory and non-statutory responsibilities and functions, and will take account of these when working together.
- 15. The working relationship between HIW and NICE will be mutually supportive, valued at the highest levels of both organisations, with visible leadership, clear lines of accountability and a coherent corporate approach.
- 16. In implementing this agreement, HIW and NICE intend that their working relationship will be characterised by the following principles:
 - the need to make decisions that promote high quality healthcare and which protect and promote patient health, safety and welfare;
 - full openness and transparency between the two organisations as to when cooperation is, and is not, considered necessary or appropriate;
 - respect of each other's independent status;
 - the need to use resources and intelligence effectively and efficiently through appropriate coordination and information sharing;
 - the need to be efficient, with business processes designed to deliver outputs quickly, facilitate rapid communication between the partners and to enable the partnership to change and develop

- the need to maintain public confidence in the two organisations; and
- a commitment to address any identified overlaps or gaps in the regulatory framework and responsibilities to promote the delivery of high quality care.
- 17. HIW and NICE are also committed to transparent, accountable, proportionate, consistent, and targeted regulation (the principles of better regulation).

Joint Priorities and Areas of Work

18. There are several areas of work where HIW and NICE need to work closely together to support high quality healthcare. The areas listed below represent core areas of ongoing work that will be assumed to continue, unless agreed otherwise (see section below on agreeing priorities).

Exchange of Information

- 19. HIW and NICE will work together to ensure, where appropriate, NICE guidelines and NICE quality standards and HIW's inspection methodology align, to ensure standards of care that are aspirational and achievable. Co-operation between HIW and NICE will often require the exchange of information. Exchange of information will be expected, but not limited, to cases where:
 - either HIW or NICE identifies concerns or opportunities to collaborate on matters relating to the health and wellbeing of the public, particularly in relation to care quality standards and the following of best practice principles
 - a resolution to a concern would benefit from a coordinated multi-agency response
- 20. In such cases, all exchanges of information will be lawful and proportionate and shared in confidence with the named contact in the other organisation at the earliest possible opportunity. The contact details in Annex B will be used for the raising and sharing of concerns. The receiving organisation will provide feedback on any action that was taken to improve how HIW and NICE work together to improve the quality of care.
- 21. All arrangements for co-operation and exchange of information set out in this MoU and any joint working protocol that may be developed will take account of and comply with the General Data Protection Regulation (GDPR), Data Protection Act 2018, Freedom of Information Act 2000, Health and Social Care (Community Health and Standards) Act 2003, section 76 of the Health and Social Care Act 2008, Care Standards Act 2000 and all relevant HIW and NICE legislation relating to these matters, and respective Codes of Practice, frameworks or other policies relating to confidential personal information and information issues.
- 22. Both HIW and NICE are subject to the Freedom of Information Act 2000. If one organisation receives a request for information that originated from the other the receiving organisation will discuss the request with the other before responding.

23. Where HIW or NICE encounters a serious concern which it believes falls within the remit of the other, they will promptly convey the concern and relevant information to a named individual with relevant responsibility within the other organisation.

Media and Publications

- 24. HIW and NICE will seek to give each other adequate warning of, and sufficient information about, any planned announcements to the public on issues relevant to both organisations, including the sharing of draft proposals and publications.
- 25. HIW and NICE commit to work together, where appropriate, to produce joint statements or communications highlighting collaboration or activities relevant to both organisations.
- 26. HIW and NICE respect confidentiality of any documents shared in advance of publication and will not act in any way that would cause the content of those documents to be made public ahead of the planned publication date.

Governance

- 27. The effectiveness of the working relationship between HIW and NICE will be supported by regular contact, either formally or informally. This contact and any partnership working is described in Annex A.
- 28. Meetings to discuss intelligence, policy and operational issues of interest to both organisations should take place between relevant colleagues at both organisations when appropriate; at least twice a year. Contact details of relevant operational level contacts in each organisation are shown at Annex B. From this meeting specific areas of joint work may be identified and taken forward by task and finish groups, convened of members from one or both organisations.
- 29. Any disagreement between HIW and NICE will normally be resolved at working level. If this is not possible, it must be brought to the attention of the MoU managers identified at Annex B, who may then escalate it as appropriate within the two organisations to reach a mutually satisfactory resolution. Both organisations should aim to resolve disagreements in a reasonable time.

Duration and review of this MoU

- 30. Both organisations have identified a person responsible for the management of this MoU in Annex B. They will liaise as required to ensure this MoU is kept up to date, identify any emerging issues and resolve any questions that arise in the working relationship between the two organisations.
- 31. This MoU is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. This MoU will be reviewed

annually by the MoU managers identified at Annex B, but may also be reviewed more urgently at any time at the request of either organisation.

Signed

Alun Jones

Interim Chief Executive
Healthcare Inspectorate Wales

Date: 07.05.2020

Professor Gillian Leng

Gul Leg

Chief Executive

National Institute for Health and Care Excellence

Date: 14.05.2020

Annex A - Partnership Working

While this MoU sets out the guiding principle of information and incident sharing, there are also some specific activities which will facilitate the partnership between HIW and NICE:

Regular Engagement

HIW and NICE will aim to meet on a regular basis for the sharing of inspection findings, outcomes of reviews and methodology developments; at least twice a year. The aim of this engagement will be for HIW to inform NICE of any areas and settings which may benefit from more targeted attention from NICE. It will also be to aid HIW in the development of inspection and review tools, and making sure they are informed by best practices.

In addition to the core ongoing areas of work described above, NICE and HIW will also build in an annual discussion as part of the business planning cycle to review priorities. Any new areas of work will be considered, and whether the resources are available to take them forward.

Both organisations will identify and share developments which may impact on existing areas of joint working as listed above. As part of the monitoring and arrangements for engagement described below, both organisations will also discuss and identify new potential areas of joint working that may emerge from associated initiatives.

NICE and HIW will take into account the work of other arm's length bodies and key national organisations, in setting priorities and areas of joint work.

Training and Support

NICE can, when required, provide training to HIW inspectors and reviewers, to inform them of the work of NICE and what they should be aware of when on inspection. This training will be hosted by HIW and facilitated by NICE, who will provide the content and speaker.

In return, HIW can provide training and support to any NICE staff who have an interest in HIW and the methodology used. HIW is willing to discuss and describe the different methodologies used by HIW when out on inspection, and what evidence and intelligence is collected from settings.

Supporting the development of NICE guidance and quality standards

NICE's guidance development process includes a number of stages of stakeholder consultation (stakeholder workshop, scope and guidance consultation). HIW are eligible to register as stakeholders and can provide comments at these stages as appropriate.

NICE's quality standard development process includes two consultation stages. Where appropriate, HIW will provide comments during the topic overview stage and on draft quality standards, indicating potential links with fundamental standards of care.

Particular attention will be paid to ensure that there is liaison between NICE and HIW on the development of guidance and standards for healthcare and that HIW's findings inform the NICE health care programme. HIW and NICE will work together to ensure, where appropriate, there is alignment.

Annex B - Contact Details

Healthcare Inspectorate Wales	National Institute for Health and Care Excellence
Welsh Government Rhydycar Business Park Merthyr Tydfil CF48 1UZ	Level 1A City Tower Piccadilly Plaza Manchester M1 4BT
Tel: 0300 062 8163	Tel: 0300 323 0140

There will be named contacts between HIW and NICE as follows:

Chief Executives	
Alun Jones	Professor Gillian Leng
Interim Chief Executive	Chief Executive
alun.jones39@Gov.Wales	gillian.leng@nice.org.uk
MoU managers	
Joseph Wilton	Julie Vile
Head of Partnerships, Intelligence and	Implementation Facilitator
Methodology	julie.vile@nice.org.uk
joseph.wilton@gov.wales	Tel: 07973 970466

Concerns Mailbox

Tel: 0300 025 2663

concerns.hiw@gov.wales

Tel: 0300 062 8163