

# Landscape overview of UK healthcare decision-making structures

Authors: Dr Pauline Addis and Sonia Garcia Gonzalez-Moral

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T: +44(0) 191 208 2259 E: info@io.nihr.ac.uk www.io.nihr.ac.uk

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### Contents

| Acronym list   | 3  |
|--|----|
| Background   | 4  |
| Aim  | 4  |
| Methods  | 5  |
| Search strategy  | 5  |
| Selection criteria                                       | 5  |
| Data extraction and charting                             | 5  |
| Results  | 6  |
| Government bodies, advisory and leadership agencies      | 12 |
| Certification/health technology appraisal (HTA) agencies |    |
| Clinical guidelines (CGs)                                | 13 |
| Regulators   | 14 |
| Health delivery  | 14 |
| Accelerators and pathways                                | 15 |
| Discussion   | 16 |
| Conclusion   |    |
| Appendix A   |    |
| Appendix B   |    |
| List of UK structures excluded                           |    |
| Acknowledgements and Disclaimers                         |    |





### Acronym list

| AAC<br>AWTTC<br>CG<br>CQC<br>DHSC<br>DoH<br>HFEA<br>HSC<br>HTA<br>HTAU<br>HTC<br>HTW<br>ICBs<br>IDAP<br>ILAP<br>IO<br>LSHW<br>MHRA<br>NHS<br>NI<br>NIA<br>NIA<br>NIA<br>NICE<br>NIHR<br>ODH | Accelerated Access Collaborative<br>All Wales Therapeutics and Toxicology Centre<br>Clinical Guidelines<br>Care Quality Commission<br>Department for Health and Social Care<br>Department of Health<br>Human Fertilisation and Embryology Authority<br>Health and Social Care<br>Health Technology Assessment<br>Human Tissue Authority<br>Healthcare Technology Centre<br>Health Technology Wales<br>Integrated Care Boards<br>Innovative Devices Access Pathway<br>Innovative Licensing and Access Pathway<br>Innovative Licensing and Access Pathway<br>Innovation Observatory<br>Life Sciences Hub Wales<br>Medicines and Healthcare products Regulatory Agency<br>National Health Service<br>Northern Ireland<br>NHS Innovation Accelerator<br>National Institute for Health and Care Excellence<br>National Institute for Health and Care Research<br>Office for Digital Health (part of NICE) |
|---|--|
|   |  |
| OHID  | Office for Health Improvement and Disparities  |
| SCOG  | Specialised Commissioning Oversight Group  |
| SIGN  | Scottish Intercollegiate Network   |
| SMC   | Scottish Medicines Consortium  |
| SPPG  | Strategic Planning and Performance Group   |
| UKHSA   | UK Health Security Agency  |



### Background

Across the UK there are many organisations, agencies, bodies with agency and initiatives associated with making decisions around the provision of healthcare. For clarity, we will refer to these entities as "structures" throughout this report. Although the priorities and remits of such structures are publicly available, their involvement, role and capacity in national decision-making processes is more difficult to ascertain. While some structures may have statutory decision-making capacity, others may act in a more facilitatory or advisory capacity or focus on the adoption and delivery of healthcare. Given the ever-changing landscape of structures, there is value in providing an up-to-date overview of the current state of play of UK health and care decision-makers. In this report, we aim to provide a comprehensive overview of structures and their remit in healthcare decision-making.

The NIHR Innovation Observatory (IO) is a publicly, National Institute for Health & Care Research-funded, horizon scanning and research intelligence centre with a national remit. One of the IO's main objectives is the provision of timely intelligence, identified and analysed using advanced horizon scanning processes to support decisions on new and emerging innovative healthcare technologies ("devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life"1). Horizon scanning is an analytical method that belongs to a broader family or methods usually referred to as Futures or Foresight methodologies.<sup>2</sup> Intelligence gathered and analysed using horizon scanning methods has several potential benefits and applications for the life sciences and health services sector: 1) it may aid decisions on which innovative healthcare technologies to consider for national health technology appraisal (HTA) processes, 2) help identify areas of unmet need in which to stimulate further innovation, and 3) help the health delivery system to understand the needs for adoption of innovative healthcare technologies to avoid unnecessary delays in patient access, for example, through early preparation of any allied systems/services needed to support healthcare technology use. One aspect of note is that the timing of horizon scanning is becoming earlier, meaning that structures are better able to identify and understand new innovations with the potential to improve patient care.

### Aim

The aim of this project is to identify all structures across the UK who are involved in making decisions about the provision of new and emerging innovative healthcare technologies, to identify their remit and additional functions highlighting any overlaps or gaps in these.

<sup>&</sup>lt;sup>1</sup> https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices

<sup>&</sup>lt;sup>2</sup> https://www.oecd.org/strategic-foresight/whatisforesight/



### Methods

#### Search strategy

To identify a list of all the structures that could be involved in the process of healthcare decision-making in the UK, we used a number of search approaches. First, we collated a list of national stakeholders with whom the IO regularly interacts. Secondly, we undertook free-text searches in Google (detailed search strategies provided in Appendix A) and thirdly we hand searched links found in the relevant websites identified.

To complement the above, we undertook a focussed bibliographic literature search in PubMed for published reports that included UK-based decision-making structures in healthcare, published since 2019 (publication date of the NHS Long Term Review). Additionally, we hand searched the websites of relevant independent UK institutions working to improve health and care such as:

- The Health Foundation
- The King's Fund
- Health Services Management Centre (at Birmingham University)

#### **Selection criteria**

The compiled list of structures was screened by two authors (SG and PA) independently with disagreements resolved through discussion. The inclusion criteria were as follows: 1) an existing structure, 2) based in the UK, 3) whose remit and additional functions could be obtained, either through website searching or via direct approach, and 4) whose remit included making decisions about UK healthcare provision at a national level. The following types of structures were excluded: 1) a scheme, programme or collaborative 2) a funding agency 3) an education provider or 4) a structure who makes decisions at a local or regional level. For pragmatic reasons, we excluded from the scope of this report a membership regulator or representation organisation such as the General Medical Council or the Association of British Pharmaceutical Industry, as their decision-making is relevant mostly to their members although we acknowledge that some of these organisations' decisions may feed into governance structures.

#### Data extraction and charting

Data extraction was completed by authors (SG and PA) independently with any disagreements resolved through discussion. Structures identified were charted against the following seven categories in a non-mutually exclusive manner.

- Advisory/leadership: any organisation that provides advice or expertise and/or may issue policy. Example: The Department for Health and Social Care.
- **Certification/health technology appraisal:** organisations involved in certification of quality and safety of a healthcare product or making recommendations for the use of technologies in clinical practice. Example: The Scottish Medicines Consortium.



- **Clinical guidelines:** organisations that use evidence to produce recommendations, including guidelines. Example: The National Institute for Health and Care Excellence.
- **Regulator:** organisations involved in regulation, licencing and/or monitoring of agencies and processes. Example: The Care Quality Commission.
- **Health delivery:** organisations involved in the delivery of a therapy or a treatment to patients. Examples: The Specialist Commissioning Oversight Group.
- Accelerator: organisations involved in accelerating access to market of an innovation and/or facilitating collaboration. Example: The Accelerated Access Collaborative (NHS England).
- **Pathway:** initiative to facilitate or accelerate the access to certain therapy or treatment or for a new technology to access the market. Example: The Innovative Licensing and Access Pathway.

In addition, each structure was given a brief descriptor, such as "Independent appraisal organisation" and self-ascribed information on their remit and additional functions was extracted from their webpages and stored in an Excel document.

### Results

A total of 118 structures were identified through the searches described above. Of these, 63 were deemed out of scope as per our inclusion criteria outlined in section above. Examples of excluded structures are funding organisations such as UK Research and Innovation, professional colleges or associations such as the General Medical Council, Government advisory bodies like the Office for Life Sciences or NHS commercial or supply chain departments. A further group made up of 20 heterogeneous initiatives, schemes, collaborations, teams or groups were not assessed for inclusion, as they did not fulfil the criterion of being a "structure" understood as "organisations, agencies, and bodies with agency and initiatives associated with making decisions". A complete list of excluded structures is provided in Appendix A. A total of 32 different structures fulfilled all the inclusion criteria.

Table 1 presents the characteristics of the 32 structures included in relation to the seven categories defined in the methods section. Furthermore, column 11 includes whether the structure has a statutory mandate for decision-making or not as reported in their "about us" information section.





#### Table 1. Characteristics of included structures.

| Structure name  | Webpage  | Coverage | Cert<br>HTA | Advisor<br>Leader<br>Expert | CG | Health<br>delivery | Reg | Acc | Path | Mndt |
|---|--|----------|-------------|-----------------------------|----|--------------------|-----|-----|------|------|
| Department for<br>Health and Social<br>Care (DHSC)                    | https://www.gov.uk/government/organ<br>isations/department-of-health-and-<br>social-care/about | England  |             | •                           |    |                    |     |     |      | •    |
| Health and Social<br>Care Directorates<br>(Scotland)                  | https://www.sehd.scot.nhs.uk/aboutus.<br>html  | Scotland |             | •                           |    |                    |     |     |      | •    |
| Department for<br>Health and Social<br>Services (Wales)               | https://www.wales.nhs.uk/nhswalesabo<br>utus   | Wales    |             | •                           |    |                    |     |     |      | •    |
| Department of<br>Health, Social<br>Services and<br>Public Safety (NI) | https://www.health-ni.gov.uk/  | NI       |             | •                           |    |                    |     |     |      | •    |
| NHS England   | https://www.england.nhs.uk/about/wh<br>at-we-do/   | England  |             | •                           |    | •                  |     |     |      | •    |
| NHS Scotland  | https://www.nss.nhs.scot/  | Scotland |             | •                           |    | •                  |     |     |      | •    |
| NHS Wales   | http://www.wales.nhs.uk/   | Wales    |             | •                           |    | •                  |     |     |      | •    |





| Structure name   | Webpage   | Coverage                     | Cert<br>HTA | Advisor<br>Leader<br>Expert | CG | Health<br>delivery | Reg | Acc | Path | Mndt |
|--|---|------------------------------|-------------|-----------------------------|----|--------------------|-----|-----|------|------|
| Health and Social<br>Care (HSC) NI                                   | http://www.northerntrust.hscni.net/abo<br>ut-the-trust/trust-overview-2/health-<br>and-social-care-in-northern-ireland/                             | NI                           |             | •                           |    | •                  |     |     |      | •    |
| UK Health<br>Security Agency<br>(UKHSA)                              | https://www.gov.uk/government/organ<br>isations/uk-health-security-agency<br>https://www.gov.uk/guidance/contacts<br>-phe-regions-and-local-centres | England                      |             | •                           |    |                    |     |     |      | •    |
| Office for Health<br>Improvement and<br>Disparities (OHID)           | https://www.gov.uk/government/organ<br>isations/office-for-health-improvement-<br>and-disparities/about   | England                      |             | •                           |    |                    |     |     |      |      |
| Public Health<br>Agency NI   | https://www.publichealth.hscni.net/abo<br>ut-us   | NI                           |             | •                           |    | •                  |     |     |      | •    |
| Public Health<br>Scotland  | http://www.healthscotland.scot/   | Scotland                     |             | •                           |    | •                  |     |     |      | •    |
| Public Health<br>Wales   | https://phw.nhs.wales/about-us/   | Wales                        |             | •                           |    | •                  |     |     |      | •    |
| Medicines &<br>Healthcare<br>products<br>Regulatory Agency<br>(MHRA) | https://www.gov.uk/guidance/contact-<br>mhra  | England<br>Scotland<br>Wales | •           |                             |    |                    |     |     |      | •    |





| Structure name  | Webpage  | Coverage                           | Cert<br>HTA | Advisor<br>Leader<br>Expert | CG | Health<br>delivery | Reg | Acc | Path | Mndt |
|---|--|------------------------------------|-------------|-----------------------------|----|--------------------|-----|-----|------|------|
| The National<br>Institute for<br>Health and Care<br>Excellence (NICE) | https://www.nice.org.uk/   | England<br>Wales<br>NI*            | •           | •                           | •  |                    |     |     |      | •    |
| NICE Office for<br>Digital Health<br>(ODH)                            | https://www.nice.org.uk/about/what-<br>we-do/digital-health/office-for-digital-<br>health              | England,<br>Wales, NI              | •           |                             |    |                    |     | •   |      |      |
| Scottish Medicines<br>Consortium (SMC)                                | https://www.scottishmedicines.org.uk/<br>https://www.scottishmedicines.org.uk/a<br>bout-us/contact-us/ | Scotland                           | •           | •                           |    |                    |     |     |      |      |
| Healthcare<br>Technology<br>Centre (HTC)                              | https://lshubwales.com/healthcare-<br>technology-centre-htc  | Wales                              | •           |                             |    |                    |     | •   |      |      |
| Health Technology<br>Wales (HTW)                                      | https://healthtechnology.wales/about/  | Wales                              | •           | •                           | •  | •                  |     |     |      |      |
| All Wales<br>Therapeutics and<br>Toxicology Centre<br>(AWTTC)         | https://awttc.nhs.wa es/   | Wales                              |             | •                           | •  |                    |     |     |      |      |
| Innovative<br>Licensing and<br>Access Pathway<br>(ILAP)               | https://www.gov.uk/guidance/innovati<br>ve-licensing-and-access-pathway                                | England<br>Wales<br>NI<br>Scotland |             |                             |    |                    |     |     | •    |      |





| Structure name   | Webpage   | Coverage | Cert<br>HTA | Advisor<br>Leader<br>Expert | CG | Health<br>delivery | Reg | Acc | Path | Mndt |
|--|---|----------|-------------|-----------------------------|----|--------------------|-----|-----|------|------|
| Scottish<br>Intercollegiate<br>Guidelines<br>Network (SIGN)  | https://www.sign.ac.uk/   | Scotland |             |                             | •  |                    |     |     |      |      |
| Care Quality<br>Commission (CQC)                             | https://www.cqc.org.uk/   | England  |             | •                           |    |                    | •   |     |      | •    |
| Human<br>Fertilisation and<br>Embryology<br>Authority (HFEA) | https://www.hfea.gov.uk/about-us/   | UK       |             |                             |    |                    | •   |     |      | •    |
| Human Tissue<br>Authority (HTAu)                             | <u>https://www.hta.gov.uk/about-</u><br><u>hta/who-are-hta</u>            | England  | •           |                             |    |                    | •   |     |      | •    |
| Specialised<br>Commissioning<br>Oversight Group<br>(SCOG)    | https://www.england.nhs.uk/commissio<br>ning/spec-services/key-docs/#scog | England  |             | •                           |    | •                  |     |     |      |      |
| Strategic Planning<br>and Performance<br>Group (SPPG) NI     | https://online.hscni.net/about-us/  | NI       |             | •                           |    | •                  |     |     |      |      |
| NHS Wales health boards and trusts                           | <u>https://gov.wales/nhs-wales-health-</u><br><u>boards-and-trusts</u>    | Wales    |             | •                           |    | •                  |     |     |      | •    |
| National Services<br>Division                                | https://www.nss.nhs.scot/departments/<br>national-services-division/      | Scotland |             | •                           |    | •                  |     |     |      |      |





| Structure name                                  | Webpage   | Coverage | Cert<br>HTA | Advisor<br>Leader<br>Expert | CG | Health<br>delivery | Reg | Acc | Path | Mndt |
|---|---|----------|-------------|-----------------------------|----|--------------------|-----|-----|------|------|
| Accelerated<br>Access<br>Collaborative<br>(AAC) | https://www.england.nhs.uk/aac/what-<br>we-do/how-do-we-do-this/                                      | England  |             | •                           |    |                    |     | •   |      |      |
| NHS Innovation<br>Accelerator (NIA)             | https://www.england.nhs.uk/aac/what-<br>we-do/how-can-the-aac-help-me/nhs-<br>innovation-accelerator/ | England  |             |                             |    |                    |     | •   |      |      |
| Life Sciences Hub<br>Wales (LSHW)               | https://lshubwales.com/welcome-life-<br>sciences-hub-wales  | Wales    |             |                             |    |                    |     | •   | •    |      |

Cert/HTA: organisation involved in certification of quality and safety of a product or makes recommendations for use of a healthcare technology in clinical practice. Advisor/leader/expert: Provides advice/expertise, may issue policy.

CG: Producing clinical guidelines.

Health delivery: Organisation or group of organisations involved in the delivery of a therapy or a treatment to patients.

Reg: Regulation, licencing and monitoring of agencies and processes.

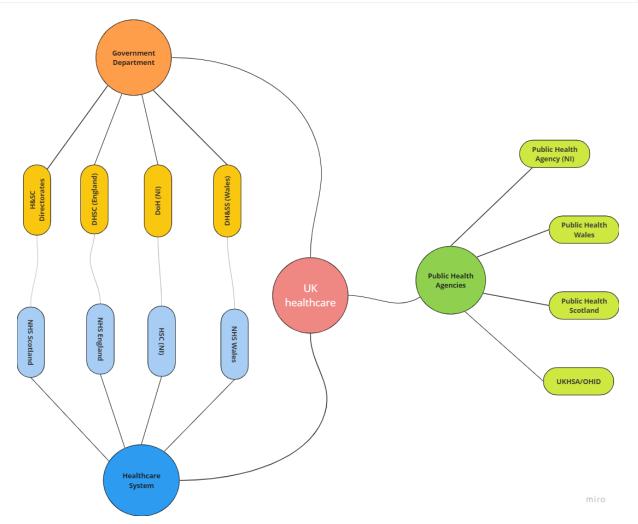
Acc: agency involved in accelerating access to market of an innovation and/or facilitating collaboration.

Path: Facilitates access to certain therapy or treatment or for a new technology to access the market.

\*NICE guidance published after 2006 is reviewed locally for its applicability to NI and, where applicable, is endorsed by the DoH for implementation.

Mndt: whether the structure has a statutory mandate or not.







#### Government bodies, advisory and leadership agencies

Of the structures in this group (Fig. 1), those with the widest remits are the relevant Government departments: the DHSC for England, several Health and Social Care Directorates for Scotland, the Department for Health and Social Services for Wales and the Department of Health, Social Services and Public Safety (DoH) for NI. Each of these provides leadership and direction, sets healthcare policy and allocates top level resources. While each devolved nation is responsible for its own health policy, some issues are overseen by the DHSC, such as genetics and xenotransplantation. These structures act as the parent departments for the publicly funded healthcare systems in each devolved nation: NHS England, NHS Scotland, NHS Wales and the separately created equivalent in NI, Health and Social Care (HSC) which provides social as well as health care. These publicly funded systems all provide primary, secondary, specialist care as well as community care. Each nation also has a public health agency: the UK Health Security Agency (HSA) and the Office for Health Improvement and Disparities (OHID) in England, the Public Health Agency in NI as well as Public Health Scotland and Public Health Wales. The remit of these is to improve health and wellbeing, protect and secure the



population's health and reduce inequalities and poverty; as well as to collect population-level surveillance data and provide statistics. All the bodies found have a statutory mandate, with the exception of OHID.

#### Certification/health technology appraisal (HTA) agencies

Seven structures were found with responsibility for certification, assessment and appraisal of new medicinal products and other new health technologies such as devices, diagnostics and digital applications. Of these, the MHRA has a remit across England, Scotland and Wales; NICE and the Office for Digital Health (ODH) with remit across England and Wales (by agreement with the Welsh government). In NI, NICE guidelines are reviewed locally for applicability to NI and, where found to be applicable, are endorsed by the NI DoH for implementation in the HSC. There is one structure with a remit for England (the HTAu), one has a remit across Scotland (SMC) and three have a remit across Wales (the Healthcare Technology Centre (HTC), Health Technology Wales (HTW) and the All Wales Therapeutics and Toxicology Centre (AWTTC)).

These structures' decision-making roles apply to some but not all stages of the product development pipeline which usually comprises stages from ideation, prototyping, early testing to clinical trials, licencing and post-launch surveillance.

#### Clinical guidelines (CGs)

Four structures are involved in CG development: NICE, SIGN, the HTW and the AWTTC. NICE has an operational remit in England and Wales. In NI, NICE guidance published after 2006 is reviewed and, where applicable, is endorsed by the DoH for implementation. NICE is an independent non-departmental government agency with the following remits:

- Producing evidence-based guidance and advice for health, public health and social care practitioners.
- Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
- Providing a range of information services for commissioners, practitioners and managers across health and social care.

The Scottish Intercollegiate Guidelines Network (SIGN), with operational remit in Scotland, is part of the Evidence Directorate of Healthcare Improvement Scotland. SIGN is independent from both Healthcare Improvement Scotland and the Scottish Government that funds Healthcare Improvement Scotland. SIGN's focus of work is the development and dissemination of national CGs containing recommendations for effective practice based on current evidence to reduce variation in practice and health outcomes.

HTW has the greatest number of roles including certification, providing advice, leadership and expertise, CG development and health delivery for Wales. The AWTTC advises on new medicines and ensures medicines are used effectively and appropriately in Wales.



Besides CG development, NICE also retains certification and advisory/leadership roles for England and Wales for medicines only. For NI, the Department of Health issued a Circular in 2022 describing the new process for endorsement, implementation, monitoring and assurance of NICE CG. This process establishes that the Department will review NICE CG in line with legal, policy or financial related consequences of the implementation of such CG which may result in endorsed guidelines with specific caveat highlighted for the local health and care system.<sup>3</sup> SIGN's sole role is CG development for the Scottish nation and health care system. Of these four structures, only NICE has a statutory mandate.

#### Regulators

Three structures were found with a remit for regulation: the Care Quality Commission (CQC), the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTAu). The CQC covers just England, the HFEA covers the UK and the HTAu covers England, Wales and NI as well as carrying out some activities relating to approvals for living organ donations on behalf of the Scottish Government. The CQC ensures that people are provided with safe, effective, compassionate, high-quality care by monitoring, inspecting and regulating services. To improve poor care, this agency takes action including notices, fines or prosecution. The HFEA licenses, monitors and inspecting fertility clinics including taking action regarding a clinic's licence where necessary. The HTAu regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. They also give approval for organ and bone marrow donations from living people. All three structures have statutory mandates.

#### Health delivery

Eleven structures were identified as health delivery organisations involved in health improvement through the delivery of treatments or therapies to patients or by promoting greater health prevention and protection measures. These include:

- The healthcare systems for all UK nations (NHS Wales, NHS England, NHS Scotland and Health and Social Care NI), all of which have statutory mandates.
- Commissioning groups such as the Specialised Commissioning Oversight Group (SCOG) with responsibility to deliver the key priority of creating sustainable, clinically effective and affordable specialised services for England; the Strategic Planning and Performance Group (SPPG) in charge of commissioning health and social services, performance management of Health and Social Care Trusts and supporting service improvements, and deploying and managing annual funding from the Northern Ireland Executive; and the seven NHS Wales health boards and three trusts who are responsible for planning and delivering NHS services in their areas across Wales. The National Services Division commission and coordinate services across Scotland including specialist services and population screening. Healthcare is delivered in each area by the appropriate group: for

<sup>&</sup>lt;sup>3</sup> NICE Clinical Guidelines – Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland. Prof Sir Michael McBride. Circular Reference: HSC (SQSD) 13/22. Belfast: Department of Health, 1<sup>st</sup> April 2022. Available at: https://www.health-

ni.gov.uk/sites/default/files/publications/health/doh-hsc-sqsd-13-22.pdf



example, in England these are the Integrated Care Boards, which were formed in 2022.<sup>4</sup> Of these structures, only the NHS Wales health boards and trusts have statutory mandates.

- National public health agencies for health improvement and protection, such as Public Health Scotland and Public Health Wales, whose remits are described above. All of these have statutory mandates.
- HTW is a national agency working to improve the quality of care in Wales with several competences, of which health delivery is one, but it does not have a statutory mandate.

#### Accelerators and pathways

A total of six structures were identified as accelerators: the NICE Office for Digital Health (ODH), the NHS England Accelerated Access Collaborative (AAC), the NHS Innovation Accelerator (NIA), the Healthcare Technology Centre (HTC), Life Sciences Hub Wales (LSHW) and the Innovative Licensing and Access Pathway (ILAP). None has a statutory mandate. Often these accelerators work in close tandem with a decision-making structure that houses them, for example the AAC works closely with NHS England to accelerate the introduction of new innovations.

With a remit covering England Wales and NI, the ODH aims to accelerate NICE efforts to deliver digital innovation to the health and care system, and has four priority areas:

- Identify digital technologies that offer the greatest potential to improve health and wellbeing.
- Establish universal data and evidence standards for digital health technologies.
- Monitor evaluation methods and processes to accommodate the evolution of technologies.
- Work with strategic partners to improve digital health approval pathways and reimbursement policy.

The AAC is an NHS England-led accelerator that aims to bring together DHSC, NICE, industry associations, research organisations, patient representatives and other health and care partners. Overall, it aims to accelerate the introduction of ground-breaking new treatments and diagnostics which can transform care, and its broad remit includes supporting innovators, demand signalling, horizon scanning, testing infrastructure and promoting adoption and spread.

The NIA is another NHS England initiative, delivered in partnership with the 15 Academic Health Science Networks (renamed Health Innovation Network in Sept 2023). It has a similar remit to the ACC, but it helps innovators and their innovations, which have already demonstrated positive impact in the NHS, to scale through the system. The NIA does not offer a guaranteed route to widespread adoption across the NHS.

<sup>&</sup>lt;sup>4</sup> <u>https://digital.nhs.uk/services/organisation-data-service/upcoming-code-changes,</u> <u>https://www.england.nhs.uk/integratedcare/what-is-integrated-care/</u>



As previously described, the HTC supports the translation of promising ideas from the Life Science and Health sectors in Wales into new products, processes and services, aiming to create long lasting economic value alongside broader societal benefits. This structure works closely with LSHW, an arm's length integration body of the Welsh Government that acts across the innovation pathway. LSHW has a broad remit including identifying innovations, market analytics, business case support and project management.

The ILAP is the only pathway organisation identified in this mapping exercise. A relatively new enterprise initiated in 2021, the ILAP aims to accelerate the time to market, facilitating patient access to medicines. The ILAP is permanently supported by member organisations such as the AWTTC; the MHRA; NICE and the SMC.

Another pathway identified, although not yet fully established and therefore not included in the scope of this report, is the Innovative Devices Access Pathway (IDAP) which aims to enable and improve patient access to innovative and transformative medical devices by providing an integrated and enhanced regulatory and access pathway to developers. In its current pilot form the IDAP is an initiative to bring new technologies and solutions to the NHS to help with medical needs that are not currently being met.

### Discussion

This project aimed to identify and collate the structures across the UK involved in the process of making decisions in healthcare. This report provides a snapshot of structures as at the time of publication: we acknowledge the changing landscape of structures as new emerge rapidly (e.g., IDAP) whilst others change in name, funding or purpose (e.g., AHSN nowadays known as NHS England Health Innovation Network). Keeping this list up to date will require regular revision and updates. However, at the time of publication it provides a fair representation of the structures and they roles in the ever-changing healthcare decision-making landscape.

Of the 118 structures found, 32 met the inclusion criteria and were classified into seven categories. Additionally, we indicated whether the structure had mandatory decision-making powers, independently of their classification. Overall, there were more structures across the UK with leadership, expertise or advisory functions (24 in total) than there were for health delivery (12 structures), HTA/certification (seven), accelerated access (five), clinical guidelines (four), regulatory (two) and pathways (one). The structure that retained the greatest number of functions the HTW, with responsibilities was across certification/HTA, advisory/leadership/expertise, clinical guidelines and health delivery for Wales. By coverage, England had more structures involved in healthcare decision-making with eight, and a further four that span across more than one nation. The bodies with a statutory mandate included all Government bodies, advisory and leadership agencies.

**Government bodies, advisory and leadership agencies:** the structures in this class all have broadly similar remits and aims, except in NI where both social and health care are provided, However, all have distinct geographic jurisdictions.



**Certification/health technology appraisal agencies:** although the overall aim of these structures is to recommend cost-effective innovations into practice safely, each have different remits since they occupy different places within the decision-making pipeline. Each plays their own role, but also links to the others to ensure the seamless translation of innovations. NICE, the SMC and HTW/AWTTC have parallel remits with the difference that each one has statutory mandates for different geographical areas.

**Clinical guidelines:** of the structures identified, HTW has the broadest remit, followed by NICE and then SIGN. The aspects of HTW's remit not covered by NICE and SIGN are picked up by other structures, such as licencing by the MHRA.

**Regulators:** the three regulators found both aim to improve standards but are responsible for very different areas, making comparison irrelevant.

**Health delivery:** For England, NHS England is the main health delivery organisation with the majority of NHS planned and arranged locally by integrated care boards (ICBs). However, there are currently over 140 specialised services, covering a diverse range of disparate and complex services. These include services for uncommon conditions such as rare cancers, long-term conditions such as renal (kidney) and specific mental health problems. In addition to these, highly specialised services are typically best delivered nationally through a very small number of centres of excellence due to the small size of the population they serve. In contrast, healthcare services in Wales are delivered by local health boards and specialised trusts, and in Scotland the National Services Division provides specialised services. Commissioning of healthcare services in NI is the responsibility of the SPPG.

**Accelerators:** there are two structures with a similar remit in England, although the NIA supports innovations with proven impact. The HTC has a similar remit in Wales, and no equivalent structures were found in NI or Scotland.

### Conclusion

There are a number of structures across the UK with a remit to aid decision making in healthcare. These are very heterogenous and have diverse remits: some perform different functions at different points in the decision-making pathway whilst others are focussed on a specific area. The structures with wider remits tended to be those with statutory mandates. This report is the first to analyse UK decision-making structures across the whole health technology innovation pathway, rather than focusing on one particular aspect of the healthcare system. The results will inform the IO's strategic priority setting.





### Appendix A

Terms used for searches performed using Google. The first two pages of results were scanned to identify any further agencies.

- a. Google search 1: "England body decision healthcare"
  - <u>https://www.england.nhs.uk/shared-decision-making/why-is-shared-decision-making-important/shared-decision-making-to-comply-with-national-legislation-and-policy/</u> General Medical Council
  - NHS Confederation
  - Professional Standards Authority
  - Academy of Medical Royal Colleges
  - Integrated Care Systems
- b. Google search 2: "UK body decision healthcare"
  - All structures found here were added: <u>https://www.gov.uk/government/consultations/healthcare-regulation-deciding-when-statutory-regulation-is-appropriate/healthcare-regulation-deciding-when-statutory-regulation-is-appropriate#annex-a-list-of-regulatory-bodies-and-the-professions-they-regulate</u>
  - British Medical Association
- c. Google search 3 "UK agency decision healthcare"
  - No new results
- d. Google search 4 "UK agency remit healthcare"
  - All agencies found here were added: <u>https://senedd.wales/research%20documents/15-020%20-</u> %20the%20organisation%20of%20the%20nhs%20in%20the%20uk%20comparing%20structures%20in%20the%20four %20countries/15-020.pdf
  - <u>https://www.ombudsman.org.uk/</u>
- e. Google search 5: "Scotland body decision healthcare"
  - No new results





- f. Google search 6: "Northern Ireland body decision healthcare"
  - No new results
- g. Google search 7: "Northern Ireland healthcare"
  - Health Service Executive
- h. Google search 8: "Welsh body decision healthcare"
  - Healthcare Inspectorate Wales (HIW)
  - Social Care Wales
  - Health Education and Improvement Wales (HEIW)
- i. Google search 9: "Wales body decision healthcare"
  - No new results
- j. Google search 10: "healthcare system in the UK"
  - National Centre for Rural Health and Care
  - Rural Health and Care Alliance

### Appendix B

List of UK structures excluded.

| Organisation                 | Webpage  | Description (what they are)  |
|------------------------------|--|--|
| Innovative<br>Devices Access | https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2022/03/Innovative- | A pathway that allows manufacturers to<br>provide their innovative device to<br>healthcare professionals and patients at |
| Pathway (IDAP)               | devices-access-pathway-IDAP.pdf  | the earliest, safe, opportunity  |



| UK Research<br>and Innovation                                   | https://www.ukri.org/about-us/strategy-plans-and-data/             | A non-departmental Government body<br>that directs research and innovation<br>funding  |
|---|--|--|
| Innovate UK   | https://www.ukri.org/about-us/innovate-uk/                         | Provides money and support to<br>organisations to make new products<br>and service   |
| Specialist<br>Pharmacy<br>Service (SPS)                         | https://www.sps.nhs.uk/home/about-sps/who-we-are/                  | Provides professional advice on<br>medicines, commissioned and funded<br>by NHS England  |
| NHS<br>Commercial<br>Solutions                                  | https://www.commercialsolutions-sec.nhs.uk/pages/what-we-do        | We are a not-for-profit procurement<br>shared services hub that works to<br>unlock collaborative solutions across<br>the NHS and the wider public sector.            |
| Association of<br>British<br>Pharmaceutical<br>Industry (ABPI)  | https://www.abpi.org.uk/about-the-abpi/                            | Represents British Pharmaceutical<br>Industry  |
| ABPI Northern<br>Ireland  | https://www.abpi.org.uk/about-the-abpi/abpi-northern-ireland/      | Represents NI Pharmaceutical industry  |
| Association of<br>British<br>Healthtech<br>Industries<br>(ABHI) | https://www.abhi.org.uk/who-we-are/                                | We represent the HealthTech industry<br>to key stakeholders, such as<br>governments, healthcare systems and<br>regulators.   |
| NHS Supply<br>Chain   | https://www.supplychain.nhs.uk/                                    | It manages the sourcing, delivery and<br>supply of healthcare products, services<br>and food for NHS trusts and healthcare<br>organisations across England and Wales |
| Academic<br>Health Science                                      | https://www.ahsnnetwork.com/about-academic-health-science-networks | There are 15 Academic Health Science<br>Networks (AHSNs, now renamed)  |





| Network         |   | across England to spread innovation at      |
|-----------------|---|---|
| (AHSNs), now    |   | pace and scale – improving health and       |
| NHS England     |   | generating economic growth.                 |
| Health          |   |   |
| Innovation      |   |   |
| Network,        |   |   |
| including       |   |   |
| Pipeline tool   |   |   |
| NHS             |   |   |
| Transformation  |   |   |
| Directorate     |   | To drive the digital transformation of      |
| (was NHSX)      | https://transform.england.nhs.uk/   | the NHS and social care                     |
| DHCNI (NI)      | https://dhcni.hscni.net/  |   |
| DHCW (Wales)    | https://dhcw.nhs.wales/   |   |
| NHS             |   |   |
| Improvement     | https://www.gov.uk/government/organisations/nhs-improvement                         | Now part of NHS England                     |
| Government      |   |   |
| Office for      |   |   |
| Science (GO-    |   |   |
| Science)        | https://www.gov.uk/government/organisations/government-office-for-science/about     | Government Science Advisory group           |
| Advanced        |   |   |
| Research and    | https://www.gov.uk/government/publications/advanced-research-and-invention-agency-  | Independent funding organisation, set       |
| Invention       | aria-statement-of-policy-intent/advanced-research-and-invention-agency-aria-policy- | outside UKRI to fund innovations. NB        |
| Agency (ARIA)   | statement#relationship-with-ukri  | not functional as at November 2022          |
| NHS             |   | The NHS Innovation Service will act as      |
| Innovation      |   | an 'information gateway' to support         |
| Service (moving |   | people developing new innovative            |
| from            | https://www.supplychain.nhs.uk/programmes/product-innovation/healthtech-connect/    | products, services or initiatives in health |





| HealthTech<br>Connect)  |   |  |
|---|---|--|
| The Catapult<br>Network   | https://catapult.org.uk/  | Catapults provide businesses with<br>access to their expertise and facilities,<br>enabling them to test, demonstrate and<br>improve their ideas  |
| NIHR MedTech<br>and In vitro<br>diagnostics Co-<br>operatives<br>(MICs) | https://www.nihr.ac.uk/partners-and-industry/industry/access-to-<br>expertise/medtech.htm#two                       | Centres of expertise and bring together<br>patients, clinicians, researchers,<br>commissioners and industry.   |
| NHS Clinical<br>Entrepreneurs<br>Programmes                             | https://nhscep.com/   | Aims to develop the commercial skills,<br>knowledge and experience of individual<br>clinical and non-clinical healthcare staff.  |
| Office for<br>Market Access   | https://www.nice.org.uk/about/what-we-do/life-sciences/office-for-market-access                                     | They provide NICE-independent help to<br>companies at all stages of product<br>development and commercialisation to<br>get expert advice   |
| Early Access to<br>Medicines<br>Scheme (EAMS)                           | https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/eams/   | EAMS helps to give people with life<br>threatening or seriously debilitating<br>conditions early access to new<br>medicines that do not yet have a<br>marketing authorisation but where<br>there is a clear unmet medical need |
| Rapid Uptake<br>Product<br>Schemes<br>(RUPS)                            | https://www.england.nhs.uk/aac/what-we-do/introducing-revolutionary-medicines-to-the-<br>nhs/rapid-uptake-products/ | It identifies and supports products with<br>NICE approval that support the NHS<br>Long Term Plan's key clinical priorities<br>but have lower than expected uptake to<br>date.  |



| MedTech         | https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-       | This is a policy emerging form the NHS  |
|-----------------|--|---|
| Funding         | funding-mandate/   | Long Term Plan commitment to            |
| Mandate         |  | accelerate the uptake of selected       |
| (MTFM)          |  | innovative medical devices, diagnostics |
|                 |  | and digital products.                   |
|                 |  | An initiative to improve the quality of |
|                 |  | research in surgery and complex         |
|                 |  | interventions to build up a robust      |
| IDEAL           |  | evidence base about new procedures      |
| Collaboration   | https://www.ideal-collaboration.net/about/   | and devices                             |
|                 |  | Provides funding through a competitive  |
| Biomedical      |  | process for pre-market R&D for          |
| Catalysts       | https://apply-for-innovation-funding.service.gov.uk/competition/1107/overview        | businesses                              |
|                 |  | This multi-agency initiative identifies |
| Medicines       |  | and develops opportunities to use       |
| Repurposing     |  | existing medicines in new ways, outside |
| Programme       | https://www.england.nhs.uk/medicines-2/medicines-repurposing-programme/              | the current marketing authorisation     |
|                 |  | A topic intelligence database currently |
| NICE Early      |  | being created; it aims to support the   |
| Value           | https://www.nice.org.uk/news/blog/nice-s-early-value-assessment-for-medtech-panning- | production of digital health outputs in |
| Assessment      | for-nuggets-of-innovation-gold   | priority clinical areas.                |
| Organisation    |  |   |
| for Review of   |  |   |
| Digital Health  |  |   |
| Applications    |  | Providers of a digital health quality   |
| (ORCHA)         | https://orchahealth.com/about-us/unique-approach/                                    | management platform                     |
|                 |  | Champions research, innovation and      |
| Office for Life |  | the use of technology to transform      |
| Sciences        | https://www.gov.uk/government/organisations/office-for-life-sciences/about           | health and care service                 |



| NHS Blood &   |   | Responsible for the supply of blood,  |
|---|---|---|
| Transplant  | https://www.nhsbt.nhs.uk/   | organs, tissues and stem cells  |
| RAPID C-19  | https://www.nice.org.uk/covid-19/rapid-c19  | Service ending as COVID-19<br>treatments being moved back to<br>routine commissioning   |
| NHSE<br>Specialised<br>Commissioning                  | https://www.england.nhs.uk/commissioning/spec-services/   | New treatments assessed by Clinical<br>Priorities Advisory Group on<br>cost/benefit, recommends to<br>Specialised Services Commissioning<br>Committee who make final decision |
| Clinical<br>Priorities<br>Advisory Group<br>(CPAG)    | https://www.england.nhs.uk/commissioning/cpag/  | CPAG assesses drugs, medical devices<br>and treatments according to their<br>clinical effectiveness, benefit for<br>patients and value for money.                             |
| Specialised<br>Services<br>Commissioning<br>Committee | https://www.england.nhs.uk/wp-content/uploads/2018/06/10iii-pb-04-07-2018-spec-<br>comm-committee-annual-report.pdf | Disbanded   |
| Innovation and<br>Technology<br>Payment (ITP)         | https://www.ahsnnetwork.com/accelerated-access-collaborative/innovation-technology-<br>payment-itp                  | No longer provided  |
| NHSE/I<br>Commercial<br>Medicines Unit<br>(CMU)       | https://www.england.nhs.uk/medicines-2/commercial-medicines/commercial-medicines-<br>unit/                          | Responsible for buying and securing the<br>supply of medicines prescribed in NHS<br>hospitals in England  |
| National<br>Screening<br>Committee<br>(NSC)           | https://www.gov.uk/government/organisations/uk-national-screening-committee/about                                   | Advises ministers and the NHS in the 4<br>UK countries about all aspects of<br>screening and supports implementation<br>of screening programmes.                              |



| Scottish Health<br>Technologies         |  | We provide advice to NHS Scotland on<br>the use of new and existing health<br>technologies (excluding medicines),<br>likely to have significant implications for |
|---|--|--|
| Group (SHTG)                            | https://shtg.scot/about-us/  | people's care  |
| Health<br>Education<br>England (HEE)    | https://www.hee.nhs.uk/  | Education agency   |
| National                                |  |  |
| Services<br>Scotland                    | https://www.nss.nhs.scot/  | Provide services and advice to the NHS and wider public sector   |
| Scottish Patient<br>Safety<br>Programme | https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/ | Aims to improve the safety and reliability of care and reduce harm.  |
| Healthcare<br>Improvement<br>Scotland   | https://www.scottishmedicines.org.uk/  | The national source of advice on the clinical and cost-effectiveness of all new medicines for NHS Scotland   |
| General<br>Medical<br>Council           | https://www.gmc-uk.org/about/what-we-do-and-why/our-mandate                      | We work to protect patient safety and<br>improve medical education and practice<br>across the UK   |
| Health and<br>Safety<br>Executive       | https://www.hse.gov.uk/aboutus/our-mission-and-priorities.htm                    | UK government agency: national regulator   |
| The Health<br>Foundation                | https://www.health.org.uk/about-the-health-foundation                            | Independent charity committed to<br>bringing about better health and health<br>care for people in the UK   |
| Nuffield Trust                          | https://www.nuffieldtrust.org.uk/about   | Independent think tank; provide research and analysis  |
| The King's<br>Fund                      | https://www.kingsfund.org.uk/about-us  | Independent charitable organisation  |



| External<br>Assessment                                   |  |   |
|--|--|---|
| Centres/Group<br>s                                       | (example) https://www.newcastle-hospitals.nhs.uk/services/medical-physics/nice-external-<br>assessment-centre/ | Seven national bodies: health technology assessment   |
| Professional<br>Standards<br>Authority                   | https://www.professionalstandards.org.uk/what-we-do/our-work-with-<br>regulators/decisions-about-practitioners | Independent body, accountable to the<br>UK Parliament   |
| Academy of<br>Medical Royal<br>Colleges                  | https://www.aomrc.org.uk/  | Membership body for the UK and<br>Ireland's 24 medical royal colleges and<br>faculties.   |
| Integrated Care<br>Systems                               | https://www.england.nhs.uk/integratedcare/what-is-integrated-care/   | Statutory partnerships, act at local level  |
| NHS<br>Confederation                                     | https://www.nhsconfed.org/publications/governing-health-and-care-system-england                                | Membership body for organisations<br>that commission and provide NHS<br>services  |
| Joint<br>Committee on<br>vaccination and<br>Immunisation | https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation                           | Independent expert advisory committee<br>that advises United Kingdom health<br>departments on immunisation, making<br>recommendations concerning<br>vaccination schedules and vaccine<br>safety |
| Health<br>Research<br>Authority                          | https://www.hra.nhs.uk/about-us/what-we-do/  | Executive non-departmental body;<br>provides a unified national system for<br>the governance of health research   |
| NHS Business<br>Services<br>Authority                    | https://www.nhsbsa.nhs.uk/   | Executive non-departmental public<br>body of the DHSC; administration and<br>infrastructure   |
| Advisory<br>Committee on<br>the Safety of                | https://www.gov.uk/government/groups/advisory-committee-on-the-safety-of-blood-<br>tissues-and-organs          | Advises UK ministers and health<br>departments on the most appropriate<br>ways to ensure the safety of blood,   |



| Blood, Tissues            |  | cells, tissues and organs for   |
|---------------------------|--|---|
| and Organs                |  | transfusion/transplantation   |
| Advisory                  |  |   |
| Committee on              |  |   |
| Dangerous                 |  | Provides scientific advice on the risks of                                      |
| Pathogens                 | https://www.gov.uk/government/groups/advisory-committee-on-dangerous-pathogens                   | exposure to various pathogens   |
| NHS Pay                   |  |   |
| Review Body               | https://www.gov.uk/government/organisations/nhs-pay-review-body                                  | Advises on the pay of NHS staff   |
| Review Body               |  |   |
| on Doctors' and           |  |   |
| Dentists'<br>Remuneration | https://www.gov.uk/government/organisations/review-body-on-doctors-and-dentists-<br>remuneration | Advises government on rates of pay for doctors and dentists.                    |
| Health and                |  |   |
| Social Care               |  | It is our responsibility to scrutinise the work of the Department of Health and |
| Select                    |  | Social Care and its associated public   |
| Committee                 | https://committees.parliament.uk/committee/81/health-and-social-care-committee/                  | bodies  |
| Patient and               |  | Provides a voice for patients, clients,   |
| Client Council            |  | carers, and communities on health and   |
| (NI)                      | https://pcc-ni.net/  | social care issues  |
| Northern                  |  |   |
| Ireland Blood             |  |   |
| Transfusion               |  | Responsible for the collection, testing   |
| Service                   | https://nibts.hscni.net/   | and distribution of blood donations   |
| Northern                  | https://niscc.info/  | We regulate standards of social care  |
| Ireland Social            |  | conduct and practice, and we promote  |
| Care Council              |  | work force training and development   |
| Northern                  |  | Supports the development of nurses  |
| Ireland Practice          |  | and midwives by promoting high  |
| & Education               |  | standards of practice, education and  |
| Council for               | https://nipec.hscni.net/   | professional development  |





| Nursing and<br>Midwifery  |  |  |
|---|--|--|
| The<br>Pharmaceutical<br>Society of<br>Northern<br>Ireland (PSNI) | https://www.psni.org.uk/   | Regulates Pharmacists and Pharmacy<br>Premises in NI   |
| Scottish<br>Ambulance   |  |  |
| Service   | https://www.scottishambulance.com/                                   | Emergency medical provider   |
| Parliamentary<br>and Health<br>Service<br>Ombudsman               | https://www.ombudsman.org.uk/  | The Ombudsman is responsible for<br>considering complaints by the public<br>that UK Government departments,<br>public authorities and the National<br>Health Service in England have not<br>acted properly or fairly or have<br>provided a poor service. |
| British Medical<br>Association                                    | https://www.bma.org.uk/what-we-do                                    | The BMA represents, supports and<br>negotiates on behalf of all UK doctors<br>and medical students   |
| Social Work<br>England  | https://www.socialworkengland.org.uk/about/our-role-and-legislation/ | Our purpose is to regulate social<br>workers in England so that people<br>receive the best possible support; also,<br>education and training standards   |
| The General<br>Chiropractic<br>Council (GCC)                      | https://www.gcc-uk.org/about-us/what-we-do                           | Registers chiropractors; publishes Code;<br>sets educational standards   |
| The General<br>Dental Council<br>(GDC)                            | https://www.gdc-uk.org/about-us/what-we-do                           | Register qualified dental professionals,<br>set standards for the dental team,<br>investigate complaints about dental  |



|   |   | professionals' fitness to practise, and<br>work to ensure the quality of dental<br>education   |
|---|---|--|
| The General<br>Optical Council<br>(GOC)                 | https://optical.org/en/about-us/who-we-are/introduction-to-the-general-optical-council/ | Setting standards; approval<br>qualifications leading to registration;<br>maintaining register; investigating and<br>action  |
| The General<br>Osteopathic<br>Council (GOsC)            | https://www.osteopathy.org.uk/home/   | Setting, maintaining and developing<br>standards of osteopathic practice and<br>conduct  |
| The General<br>Pharmaceutical<br>Council (GPhC)         | https://www.pharmacyregulation.org/about-us/what-we-do                                  | Set standards for education and<br>training, also guidelines; register<br>pharmacy professionals; inspection;<br>revalidation activities; investigating<br>concerns                          |
| The Health and<br>Care<br>Professions<br>Council (HCPC) | https://www.hcpc-uk.org/about-us/what-we-do/  | Set standards; approve programmes;<br>keep a register; act if professionals do<br>not meet standards   |
| The Nursing<br>and Midwifery<br>Council (NMC)           | https://www.nmc.org.uk/about-us/our-role/   | High education and professional standards; maintain register; investigate concerns   |
| Health Service<br>Executive                             | https://www.hse.ie/eng/   | Healthcare system in Ireland   |
| Healthcare<br>Inspectorate<br>Wales (HIW)               | https://www.hiw.org.uk/   | We inspect NHS services, and regulate<br>independent healthcare providers<br>against a range of standards, policies,<br>guidance and regulations to highlight<br>areas requiring improvement |



| Social Care<br>Wales                                   | https://socialcare.wales/                        | We are the national leadership<br>organisation in Wales for social care<br>workforce regulation, supporting<br>service improvement through research<br>and data, and delivering workforce<br>development for the social care and<br>early years sectors                         |
|--|--|---|
| Health<br>Education and<br>Improvement<br>Wales (HEIW) | https://heiw.nhs.wales/                          | Our purpose is to integrate, and grow<br>expertise and capability in planning,<br>developing, shaping, and supporting the<br>health workforce -ensuring we have the<br>right staff, with the right skills, to<br>deliver world-class health and care to<br>the people of Wales. |
| National Centre<br>for Rural Health<br>and Care        | https://www.ncrhc.org/about                      | It acts as a governance vehicle for<br>formal collaboration amongst partners<br>interested in the four key drivers of<br>impact in rural health and care, as well<br>as influencing policy and strategy.  |
| Rural Health<br>and Care<br>Alliance                   | https://rsnonline.org.uk/ruralhca-about-the-rhca | This is an organisation dedicated to<br>providing news, information, innovation<br>and best practice to those delivering<br>and interested in rural health and care.  |





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