Document 3 - Community Diagnostic Hub (CDH) Draft Qualification Specification

Context:

This service specification has been derived from the CDH Key Considerations Guidance document version 1.2 and subject matter expert review and input.

Purpose:

The purpose of this service specification is to set out the high-level, minimum requirements for a CDH.

Action:

Please review and confirm that this service specification covers all key elements relating to the vision, design and deliver for CDH.

Service Specification for NHS Community Diagnostic Hub Framework

Service Specification No.	1.11
Service	NHS Community Diagnostic Hub Framework
Period	September 2021 – August 2024
Date of Review	September 2022

1. National Context

1.1. Diagnostic activity forms part of over 85% of clinical pathways. The NHS spends over £6bn a year on over 100 diagnostic services and with this carries out an estimated 1.5 billion diagnostic tests.

1.2. Over the past five years, demand for diagnostic services in England has risen at a greater rate than increases in diagnostic capacity. Diagnostics is recognised as a priority in the Long-Term Plan and is a key enabler to delivering a number of related commitments, including cancer, cardiovascular disease and stroke. The COVID-19 pandemic has exacerbated pre-existing challenges in diagnostics, resulting in substantial increases to waiting lists and waiting times for some diagnostic modalities. The need for enhanced infection prevention and control measures has also reduced capacity of existing services and slowed patient flow through diagnostics.

1.3. Professor Sir Mike Richards' independent review of NHS diagnostic services, published in October 2020, Diagnostics: Recovery and Renewal, sets out the case for increasing diagnostic capacity in England and for a new model of diagnostic service provision. One of the key recommendations of the report is for the rapid establishment of Community Diagnostic Hubs (CDHs). NHS England and NHS Improvement is committed to supporting the roll out of CDHs, as part of a broader strategy to expand capacity and transform diagnostic provision in England, as recommended in the independent review.

1.4. CDHs will provide a broad range of elective diagnostic services away from acute facilities, providing easier and quicker access to tests and greater convenience to patients, as well as relieving pressure on acute sites by reducing outpatient referrals and attendances. CDHs also provide an opportunity to re-design clinical pathways that require diagnostic services included in a CDH plan. CDHs need to provide additional capacity to enable the totality of diagnostic service provision to meet the needs of local populations.

1.5. There are three 'CDH facility' archetypes identified, see annex A, which may help inform regions and systems what range of CDH facilities they may need to consider for their locality. There is no need to limit design of facilities to one of the archetypes – a blend can be considered as long as the minimum requirements of a CDH are me

2. Outcomes

2.1. NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2. CDHs will deliver additional, digitally connected, diagnostic capacity in England, providing all patients with a coordinated set of diagnostic tests in the community, in as few visits as possible, enabling an accurate and fast diagnosis on a range of a clinical pathways.

2.3. CDHs in England must be a freestanding, digitally connected, multi-diagnostic facility that can be, as an option where appropriate, combined with mobile / temporary units.

2.4. CDH provision should be located separately from the main acute hospital facilities and accessible from patients' homes

3. Service Aims

3.1. All CDHs must contribute to the following primary aims:

- To improve population health outcomes by reaching earlier, faster and more accurate diagnoses of health conditions.
- To increase diagnostic capacity by investing in new facilities, equipment and training new and existing staff, contributing to recovery from COVID-19 and reducing pressure on acute sites.
- To improve productivity and efficiency of diagnostic activity by streaming provision of acute and elective diagnostic services where it makes sense to do so; redesigning clinical pathways to reduce unnecessary steps, tests or duplication.
- To contribute to reducing health inequalities driven by unwarranted variation in referral, access, uptake, experience and outcomes of diagnostic provision.
- To deliver a better and more personalised diagnostic experience for patients by providing a single point of access to a range of safe, quality diagnostic services in the community.
- To support integration of care across primary, community and secondary care and the wider diagnostics transformation programme.

3.2. CDHs also have several cross-cutting aims:

- To improve staff development and satisfaction by offering new roles, development opportunities, training excellence and an opportunity to work in flexible and innovative ways

- To Make Every Contact Count and deliver health promotion and/or signpost to other services where it is meaningful and impactful to do so

- To utilise CDHs as test sites for quality improvement, research, innovations and service evaluations

- To contribute to NHS Net Zero ambitions, by enabling fewer outpatient attendances and reducing patient journeys to acute hospital sites

- To act as anchor institutions, consciously supporting positive social, economic and environmental impacts locally, through workforce and training and wider local regeneration to advance the welfare of the populations they serve.

4. Scope – Minimum Requirements

4.1. The Community Diagnostic Hub must, as a minimum:

- Receive and process referrals for straight to test from primary, community and secondary care.

  Referrers that should be considered include but are not limited to: primary care professionals, NHS screening services, paramedics, specific community services e.g. rapid response teams, urgent treatment centres, NHS 111 if triaged by the Integrated Urgent Care Clinical Assessment Service, A&E departments and specialist secondary care providers and diagnostic services, appropriately trained First Contact Practitioners (e.g. for musculoskeletal conditions) and Allied Health Professionals. Referrals can cover both tests for new diagnoses and follow up tests.

- Book patients in for a coordinated set of tests and inform patients of the preparation they require before coming in for their test(s), taking into account all applicable quality standards (i.e. MRI). Multiple methods for booking appointments must be considered to improve accessibility.

- CDHs must collaborate with the local NHS pathology network to ensure the minimum requirements for laboratory tests are in place.

- CDHs must be able to manage multiple referral routes into the service and minimise test duplication.

- CDHs must provide the necessary preparatory materials to help patients understand the diagnostic tests they are booked in for, what they must do in preparation for undergoing the diagnostic tests including ensuring advanced prescriptions are taken appropriately and providing informed consent if required.

- CDHs must carry out the range of diagnostic tests required for a patient in as few visits and in as few locations as possible with consideration of reasonable adjustments required for patients. As a minimum, the following tests should be provided in a CDH:

  - Imaging: CT, MRI, Ultrasound, Plain X-Ray
  - Physiological measurement: Electrocardiogram (ECG), including 24 hour and longer tape recordings of heart rhythm monitoring, ambulatory

blood pressure monitoring, echocardiography (ECHO), oximetry, spirometry including reversibility testing for inhaled bronchodilators, Fractional exhaled nitric oxide (FeNO), exhaled carbon monoxide, full lung function tests, blood gas analysis via Point of Care Testing (POCT),simple field tests (e.g. six min walk test), issuing of multichannel equipment for recording home 'limited' sleep studies.

- Pathology: phlebotomy, Point of Care Testing, simple biopsies, NT-Pro BNP, urine testing and D-dimer testing. Point of Care Testing to be used to enhance the decision-making during patient consultation and operated in conjunction with the pathology network
    - Phlebotomy: -
      The collection of venous blood samples using approved collection devices and processes by trained and competent staff. This must align with the defined requirements of the contracted, accredited provider pathology network laboratory for each requested test in terms of any pre collection requirements, correct sample container, storage and transport to the laboratory

    - Simple Biopsies and fine needle aspirates: -
      Any tissue collected for investigation to be carried out by the contracted, accredited provider pathology network laboratory. These will be collected as part of the surgical process and processed according to the agreed protocol on the partner pathology network laboratory with written procedures for safe handling of tissue and reagents

    - Point of Care Testing: -
      Any pathology investigation carried out on analysers or equipment operated on the CDH premises by competency assessed CDH staff. All such tests must be of an appropriate sensitivity and specificity for the required purpose as agreed clinically with the partner network pathology laboratory, staff competency must be completed and recorded, quality control must be performed according to an agreed schedule and recorded and results must be integrated into the patient record. Examples may include, urine dipstick meters, NT-Pro BNP, D-Dimers, blood gases and other valid tests where immediate access to the result would enhance decision making and or shorten the patient pathway

    - For larger CDHs only - Endoscopy services including gastroscopy, colonoscopy and flexi sigmoidoscopy.

- The following tests have been identified by advising clinicians as being clinically unsuitable for delivery in this community setting. This list of exclusions is not currently exhaustive and can be expanded according to local clinical advice: -

    - Endoscopic retrograde cholangiopancreatography (ERCP)
    - Complex interventional procedures including biopsies of internal organs
    - Trans-oesophageal and stress ECHO
    - Bronchoscopy and endobronchial ultrasound (EBUS)
    - Cardiopulmonary exercise tests (CPET)
    - Some challenge tests
    - Complex sleep studies that include monitoring of EEG

- Report the results in a timely way to the referrer.

  CDHs must have the appropriate digital infrastructure and connectivity (see section 6) to share data outcomes of procedures (e.g. traces, images) and any other relevant information for interpretation elsewhere or where interpretation can be done by CDH staff to share the report for onward clinical care. Patients should be kept informed of how they may escalate any worsening of symptoms in between receiving a test at a CDH and discussing their results with a healthcare professional.

  Where a follow-up appointment with the CDH is required, for example in several months' time, CDH staff may create this booking providing the referring clinician is made aware and can confirm or amend the booking depending on ongoing clinical needs of the patient.

- Be available to all adults with appropriate reasonable adjustments e.g. people with learning disability who require a longer appointment or need a quiet area to wait should be accommodated. If the service is made available for children and young people, then appropriate design and safeguarding processes must be demonstrated.

5. Scope – Optional Requirements

5.1. CDHs may consider accepting self-referrals, for patients with an ongoing care need where presentation to a CDH for a defined test is an agreed part of their clinical pathway as pre-determined by their ongoing care clinician. If enabling this feature, systems should carefully identify which clinical pathways are best suited to self-referral. This may include consideration of pathways that utilise home monitoring equipment. Systems should ensure that patients, GPs and/or other relevant clinicians are always kept informed of any self-referral test results. Self-referral is not considered a minimum requirement for a CDH.

5.2. When designing CDHs, planners should check with their Children and Young People (CYP) teams to determine whether children's diagnostic services should be provided by a CDH. If needed, CDHs may help deliver priorities to increase CYP's access to simple tests such as phlebotomy, radiography, and pulmonary function tests to diagnose asthma. Regions and systems should consider that CYP diagnostic tests are lower in volume, more complex, and require specific safeguarding measures and estates requirements. Many CYP diagnostic tests including MRI and ECG may be more appropriately delivered in paediatric specialist facilities (such as in acute hospitals).

5.3. Annex B lists other possible diagnostic tests, which may want including in a CDH, depending on local need. This list is not exhaustive. Consideration of tests / screening (excluding pathology) with the highest backlog of need from the pandemic is also required.

5.4. CDHs may also provide:

- Proactive outreach to patients - leading health promotion activities, providing information sharing events and carrying out symptom awareness events.

- Consultation services with a consultant specialist – pre- or post-diagnostic testing, virtual or face-to-face where it can provide efficient patient pathways.

- Communication of a diagnosis and/or treatment plan to the patient. Inclusion of consultations, minor procedures and/or prescription will require appropriate rooms, staff skill mix, training and facilities in a CDH to carry out these activities. If CDH staff are expected to make a diagnosis, systems will need to ensure that the appropriate wraparound patient support is available in person or virtually. Where appropriate, CDHs may also choose to provide condition management advice.

- Onward referral if needed. Clinical responsibility for the patient journey remains with the original referring clinician. Where a clear need for onwards referral is identified for pre-agreed pathways or cases with urgent findings, CDH staff should refer the patient on behalf of the referring clinician that could include for further diagnostic tests within secondary/tertiary care or to community or voluntary services. The referring clinician is informed and receives results for all tests that they have ordered, and clinical responsibility remains with them. Any staff that refer from a CDH will need to have the appropriate license and training to refer. CHDs should also consider straight to test and how this are integrated with pathways.

5.5. Any additional, optional services provided by CDHs would need to be supported with appropriate digital connectivity and IT requirements.

6. Digital Connectivity – see Annex C for digital standards

6.1. Data and information flows (including clinical data) are anticipated to initially be local and regional, but in the longer-term systems should aim for wider sharing to enable collaboration across regional boundaries and nationally.

6.2. CDH providers will need to record and share information for clinical, operational and assurance purposes, including in anonymised or aggregated form where appropriate. To ensure appropriate access to and sharing of data: -

- Patient identification using the validated NHS number must be used including for all (clinical) data transfers and communications. This is critical to accurately link the patient to their record ensuring safe care, integration of patient data and images, referrals using the NHS e-Referral Services, and electronic prescribing. The NHS number should be validated using Personal Demographics Service (PDS) look-up. An Application Programming Interface (API) is available through NHSX to support this

- Existing digital and IT services should be used where appropriate (e.g. e-Referral Service); CDHs must evolve towards use of common digital solutions across a system, region or nationally to maximise integration across CDHs and with NHS services, for example image sharing within the East Midlands Radiology Network (EMRAD)

- The relevant NHS standards (e.g. DICOM, HL7, National Interim Clinical Imaging Procedures code-set) should be used where information is transferred between the CDH and local provider (e.g. trust, primary care provider), to move towards standard naming conventions and categorisation for services to ensure they link in with local networks

- CDHs should be able to receive procedure requests and issue results and reports electronically, to a variety of referrers in primary and secondary care via existing order communications and e-referral service

- The appropriate mechanism and responsibility for long-term storage of patient information, including making results and images available to authorised persons on demand, should be developed considering the likely integration of multiple IT systems, care settings and providers (including NHS and independent sector providers)

6.3. To use digital technology to deliver CDH aims: -

- CDH providers need to be able to adapt digital connectivity during the lifetime of the contract to ensure use of the optimum available technology given the fast-moving nature of the IT landscape and CDH service model

- CDHs should have facilities to deliver workforce training through a variety of digital means, which could include a range of interventions such as virtual procedures and supervision, simulation or online training

- Digitally enabled diagnostic equipment should be prioritised to facilitate efficiency and reduce the demand on staff

- CDH should consider how best to make use of digital and technological innovation to manage and improve patient care to contribute to the cross-cutting aim of CDH being test sites for quality improvement and innovations. This could include emerging use of Artificial Intelligence (AI) to understand patient risk, prioritise waiting lists to aid elective recovery, or to aid results interpretation to identify results of particular significance. Over a period of time, CDHs could work with, but not limited to Academic Health Science Networks (AHSN) and NHS Accelerated Access Collaboratives (AAC) to identify appropriate medical technology which could be introduced to manage and improve patient care

6.4. To receive and process referrals: -

- CDHs should have the IT (and related workforce) capabilities to receive requests and referrals and to manage/respond to these, in a timely manner, according to the prioritisation needs determined by the local system including vetting, protocolling and pre-procedure checks as appropriate

- Requests/referrals should be received electronically, although capability to receive paper requests/referrals may be required as a back-up system only and to provide for patients that do not use digital booking channels. Systems should be fully digital for the request/referral process by April 2022 but still have provision for patients who digitally opt out.

6.5. To receive and report on cancer referrals, all diagnostic referrals will need to be tracked and reported via diagnostic returns DID and DM01, CDHs will need to: -

- Be connected to NHS e-referral system (ERS)

- Have systems in place to book the referrals as well as receive them

- Have cancer tracking systems in place so that they can record and submit data on Cancer Waiting Times

6.6. To book in patients and help them prepare for their tests: -

- Comprehensive single access point booking service(s) which avoid digital exclusion and support patient choice is required as default. This may mean offering alternative booking routes such as by phone, primary care teams to directly book slots, or through an administrative assistant. By April 2022, the default booking service must be digital

- IT solutions to identify missed appointments and take appropriate action, or to facilitate the pre-appointment process must be explored (e.g. automated distribution of instructions the patient must follow prior to a test, and appointment reminders)

- Staff must have access to existing patient record information including previous images and test results and details of reasonable adjustments to care, including the Reasonable Adjustment flag. New digital systems should use the new NHS Digital API within their development to help ensure these flags are easily visible

- IT solutions must support two-way communication between the patient and CDH, in case a patient needs to get further information on their test and change or cancel their appointment

- Systems may wish to consider use of electronic check-in services at CDHs as one method of enabling patient-led, data collection

6.7. To enable coordinated testing: -

- CDHs must explore how to maximise efficiency through use of scheduling optimisation software to appropriately coordinate multiple tests to minimise the number of locations and appointments a patient must attend. This should reflect the reality that requests and referrals may come directly from primary care, and/or through local triage or vetting services, and in some cases patients may require a series of diagnostic tests, of which some are not provided within the CDH. Co-ordination with existing diagnostic services may be required to ensure patient safety is maintained

6.8. To enable reporting and completion of certain tests: -

- Mechanisms need to be in place to access the results of tests and associated data products conducted in NHS and independent sector settings

- IT systems will need to consider how result information is integrated into the patient medical record, how diagnostic reports are shared with the relevant stakeholders, and how relevant results are shared with the patient

- Mechanisms should be in place to flag urgent or unexpected results/reports to ensure timely follow-up by the responsible clinician and must be partnered with closed-loop systems to ensure delivery of results/reports are acknowledged

7. Clinical Governance

7.1. Any person (individual, partnership or organisation) who provides a regulated activity in England must be registered with the Care Quality Commission (CQC). Providers of care that are already registered must keep their statement of purpose up to date and notify the CQC of any changes.

7.2. The need for registration (opposed to the need to update a statement of purpose) with the CQC will depend on changes to any of the following: -

- the provider
- the regulated activity
- the "location" at which, or from which, the activity will be provided. Where regulated activities are provided and managed as one service but are carried out in a number of different premises the place from which the regulated activities are 'carried out on' or managed is known as the location. For example, mobile or visiting services, can have a location as a condition of their registration as either the head office or a regional office from which day-to-day management of the regulated activities is directed.

7.3. CQC registration is required for diagnostic and screening procedures, so all CDH providers will need to demonstrate they can meet the CQC regulations under the Health and Social Care Act 2008, fundamental standards, and associated guidance.

8. NHS/UK applicable standards

8.1. All services should be working towards accredited standards for their respective pathways and will be required to have those standards and have gone through relevant accreditation processes within two years of operation as a CDH. Table 3 below sets out the key accreditation considerations (not an exhaustive list):

Table 3: Key CDH accreditation

Area	Standard
Imaging	Quality Standards for Imaging (QSI) imaging-services-accreditation
Pathology	Demonstrates compliance to the Medical Laboratory Accreditation (ISO 15189) in conjunction with the local network Aspire to Point of Care Testing (ISO 22870)
Physiological Measurement Services	Improving Quality in Physiology Services (IQIPS) iqips-standards Other societal standards e.g., British Society of Echocardiology (BSE) accreditation Spirometry certification ARTP
Endoscopy	Joint Advisory Group in GI (JAG) accreditation

Infection prevention control

8.2. Good infection prevention (including cleanliness) is essential to ensure that CDH users receive safe and effective care. All CDHs are expected to demonstrate

compliance with the Code of Practice on the prevention and control of infections, under The Health and Social Care Act 2008.

8.3. Comply with any future ventilation standards as set out by the Chartered Institution of Building Services Engineers (CIBSE)

Patient Safety

8.4. The CDH must have safe management of patients for medicines, resuscitation, and pathways for escalation to support emergencies and therefore linked with an acute Trust. Safety experts need to be appointed within the facility for eg Radiation protection and MRI safety in imaging

8.5. The implementation of the NHS patient safety strategy must form an integral component of the development of CDHs. CDHs must develop clear processes for reporting incidents and responding to complaints, so that staff, patients and the public understand how to do this. System-based patient safety incident investigations and prompt escalation of significant patient safety issues must also be undertaken when appropriate.

8.6. The CDH must have safe systems for patient identification and consider technological solutions to support this (Patient identification in outpatient settings, Wrong site surgery, wrong patient report - Healthcare Safety Investigation Branch 2021).

Information Governance

8.7. CDHs must comply with all relevant legal and regulatory frameworks, NHS policy and procedural elements in relation to data security and data handling, including data governance requirements detailed with the NHS Standard Contract.

9. Patient Experience

9.1. CDHs should ensure equitable access, excellent experience, and optimal outcomes for all patients.

9.2. Table 1 below sets out a draft set of 'I statements' to illustrate the patient experience all CDHs should be aiming for.

Table 1: Patient experience

Service Component	Requirements
Receive and Process Referrals	• My clinician will consider a range of information about me and discuss this with me, and/or my caregiver, to determine which diagnostic tests are needed and in which order. • The choice about which tests to have will be a shared decision between me, and/or my caregiver, and the clinician I speak to. • I am offered the opportunity to receive diagnostic tests in a Community Diagnostic Hub when appropriate and available. • I and/or a caregiver understand what a community diagnostic hub is and what I can expect from the service. • I understand and am comfortable with relevant information about myself and my health being shared with the CDH service team. This may include results from tests carried out by my referrer.

Booking & Preparation	• I and/or a caregiver can book my appointments easily through an accessible range of channels. • I and/or a caregiver can answer necessary pre-appointment questions easily and accessibly. • I am asked about the support and reasonable adjustments I may need, including those in my health passport if I have one, so that the CDH team can help to prepare any additional support I may need. • I and/or a caregiver know what to expect during my visit to a CDH, my diagnostic tests, diagnostic journey, who will be involved, and how to prepare. I and/or a caregiver understand the risk associated with any tests that I am undergoing. • If I and/or a caregiver have questions or concerns, I and/or a caregiver know who to contact and receive an answer quickly.
Coordinated Testing	• I am able to and feel comfortable to travel to the Community Diagnostic Hub and feel safe when I am there. If I and/or a caregiver have questions or concerns, we can easily raise these with CDH staff members. • I have access to the extra support, such as physical assistance, and/or reasonable adjustments I need to ensure I have as positive experience as possible during testing. • I have the range of diagnostic tests I need in as a few visits and locations as possible. • My diagnostic tests are carried out in sensible order – if further tests are needed on the day, the reason for this is explained clearly to me and/or my caregiver.
Reporting	• I and/or my caregiver are clearly communicated with about when and from whom I will hear back about the results of my tests. • If I receive a diagnosis at the CDH, I and/or my caregiver are supported to understand what my diagnosis means for me through clear explanation and discussion about my treatment plan. • I and/or my caregiver are clear about my choices, onward referral and any other next steps, including changes I need to make to my lifestyle or where I can go to for extra support. • I can expect my diagnostics report to be comprehensive, explaining all my tests and results in a simple and jargon-free way so that I can understand the results and what it means for me. I can expect that any language used within my report will respect my preferred pronoun and that my gender is not presumed. • I can expect my results to be shared with any healthcare professionals involved in my care wherever I am seeing them, so that tests are not unnecessarily repeated. • I and/or my caregiver know who to contact if we have further questions or if my symptoms change.

9.3. All communications with patients, communities and staff need to take account of healthcare disparities and the impact of socio-cultural factors on health. CDH providers should be proactive in seeking to overcome cultural and communication barriers such as not having English as a first language, limited access to translation services, perceived lack of culturally competent care, and experiences of feeling stigmatised or discriminated against. Steps to address such barriers include:

- Ensuring information is provided both verbally and in writing and providing written information in accessible formats such as EasyRead

- Tailoring messages to reflect local communities and explicitly consider cultural norms

- Allowing for longer appointment time to accommodate communication needs and welcoming follow up contact where patients or carers have further questions

- Easy access to in person interpretation services whenever possible

10. Interdependencies within the system

10.1. CDH's must collaborate with local Trusts in relation to: -
- Patient Safety
- Test coordination
- Eliminating test duplication

10.2. CDHs must ensure that any pathology requests are carried out in conjunction with the pathology network

10.3. CDHs must adopt the principles set out in the NHS People Promise

11. Estates

11.1. CDH locations should meet primary considerations:
- Be separately located from emergency diagnostic facilities preferably away from an acute site where elective diagnostic tests can be done safely. If located on an acute campus, the CDH should be located in, a separate building and accessed without passing through emergency facilities. Where this is not possible, the CDH should be accessible through a separate entrance.
- Be configurable to meet specifications of the required diagnostic services (e.g. negative pressure in areas doing pulmonary function testing) and support functions (e.g. waste management), in line with the minimum requirements for CDHs and reflecting local priorities
- Provide sufficient capability to manage infection and ensure a COVID-19-minimum environment, such as through implementing one-way systems to aid social distancing.
- Be located in areas which:
    1. Are easily accessible through good public transport and private vehicles, particularly for specific population groups experiencing health inequalities (see section 8).
    2. Have sufficient car parking facilities for patients, carers and staff
    3. Facilitate activities needed by the CDH (e.g. for transport of phlebotomy or pathology samples).
- Be enabled with network connectivity, internet access and sufficient devices to allow staff to access relevant information to carry out their duties
- Be accessible for extended hours (e.g. 12-14 hours a day, 7 days a week).
- Contribute to CDH cross-cutting aims, including
    1. Improving staff development and satisfaction through support for local diagnostic workforce strategy (e.g. facilities for training and on- or off-site clinical supervision)
    2. Delivery of NHS Net Zero ambitions across the system.

3. Support the role of the CDH as an anchor institution, consciously supporting positive social, economic and environmental impacts locally.

- Support the Equalities and Health Inequalities agenda (including reasonable adjustments under the Equality Act 2010) and be aligned to the service Equalities and Health Inequalities Impact Assessment (EHIA) (see section 8), with particular consideration for those groups whose health inequalities have been exacerbated by COVID-19.
- Provide secure, safe clinical and flexible facilities that are Health Technical Memorandum (HTM) including but not limited to HTM 03-01 (Specialised Ventilation for healthcare premises), Health Building Note (HBN) and National Patient Safety Alert compliant. CDH buildings should meet health and safety and accessibility guidance, including any reasonable adjustments likely to be required by patients and staff.

12. Equipment

12.1. CDH providers must ensure that all equipment used in the delivery of CDH services complies with the relevant CE marking (or equivalent UKCA scheme), safe installation and equipment management policy and be appropriate for the clinical case mix.

12.2. CDH providers must ensure that MHRA guidance, Managing Medical Devices (updated 2021) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf is followed for all equipment /medical devices.

12.3. CDH providers who include endoscopy within their services must consider turnaround times for sterilisation (as there is strict guidance within JAG and HTM 01-06), as well as appropriate storage which has to be monitored and managed.

12.4. Equipment will need to be quality controlled, be well maintained with governance and oversight with emerging networks.

12.5. All equipment should be refreshed to ensure it avoids being outdated.

13. Workforce

13.1. CDH providers should embed the values of the NHS People Plan, ensuring an appropriately skilled, well supported workforce who can work effectively in new and different ways. CDH should contribute to skill development, training and workforce deployment including through:

13.2. Skills in CDH

- Staffing skill mix should be optimised to drive the effective use of multi skilled roles to ensure clinically competent staff to deliver the service, within a clear clinical governance framework and practitioners scope aligned to service and patient need.
- CDHs should act as “incubators” of workforce innovation, supporting staff to work differently, testing out innovative models of care which are clinically led, with the right backing and support to the workforce to make it happen
- Collaboration across providers, system, regional and national partners to develop competency-based roles.

- All staff should be appropriately trained and accredited by their professional body.

13.3. Training

- All CDHs need to provide staff training and continuous development opportunities for their workforce.
- CDH providers should support coordinated training at regional or system level and evolve to support multidisciplinary working, guided by engagement with professional bodies and regulators where appropriate
- Training should flexible and easily accessible to support development at all career points.
- All staff working in a CDH must: -
    - hold appropriate relevant professional registration for their CDH role
    - attend an appropriate induction for their CDH role
    - complete all mandatory training / PDP at the required intervals according to their CDH role
    - have an active personal development plan that is reviewed and refreshed appropriately

13.4. Workforce deployment:

- CDH should participate in staff rotation between CDHs, acute, and primary care where appropriate, to further develop skills and coordinate service continuity.
- Flexible working should be considered for clinical and non-clinical roles
- Effective staff management and support should be in place for all staff, in line with the NHS People Promise.
- Any changes to deployment and workforce model should be co-produced with staff, so that staff feel empowered to make changes, innovate and adapt to meet patient and staff needs
- The Provider must ensure that each CDH is staffed with a sufficient number of trained, qualified and capable Staff who are able to deliver the Services as agreed and scheduled locally.
- The Provider will act flexibly with respect to deployment of Staff including potentially interchanging staff between the Provider's facilities to ensure service continuity.
- The Provider will ensure that the staffing model safely delivers the full range of diagnostics services required including clinical and non-clinical support staff.
- The provider will ensure that temporary staff provisioned via bank or agency have appropriate training competency and induction training.
- The provider will clearly identify the management structure and the leadership of the service supported by a facility organogram.
- The provider will set out a business continuity plan and should detail how the service will respond to issues of reduced staffing availability. This should include contingency and escalation plans.

14. Reporting

14.1. Principles of Data Reporting for CDHs:

The following data reporting principles should be adhered to by all CDHs:

- Recording and monitoring all activity undertaken at a CDH is required to track progress against key metrics of success relating to the primary aims of CDHs.

- All activity undertaken at a CDH needs to be distinguishable from other diagnostic activity undertaken in a system and CDH-delivered activity needs to be visible at a system, regional and national level. To do so, it is expected that CDHs have their own code that can uniquely identify them and report activity separately from other sites.
- Data collection and reporting will be required at regular intervals, these intervals and/or reporting requirements may vary due to the reporting need and/or modality

14.2. Data coding and reporting requirements: -

- Patient attendances at a CDH should be coded as an outpatient attendance and activity data must be recorded from the first day of operation. This data should be incorporated into the existing outpatient Commissioning Data Set (CDS).
- OPCS4 codes should be used to record every test undertaken at a CDH, even if the test does not currently feed into a nationally held dataset or is not needed to translate to a Healthcare Resource Group (HRG) for payment purposes (noting that work is ongoing to find a longer-term solution as OPCS4 codes do not currently provide the level of granularity required to identify all tests).
- In addition to CDS data flows, CDH waiting list and activity data must be submitted for a subset of diagnostic tests via Diagnostics Waiting Times and Activity dataset (DM01) and imaging activity from radiological information systems must be submitted to the Diagnostic Imaging Dataset (DID).
- CDHs will be required to work with their regional Directory of Services (DoS) leads on an ongoing basis to provide data and information on site, location and services available to ensure the national DoS reflects the specific capabilities of each CDH and can signpost appropriately.

14.3. Data monitoring

- Table 2 sets out a set of indicative metrics that will be monitored at national level through a CDH impact dashboard
- Some of this data relates to activity in a CDH and some related to wider diagnostic activity across the system. CDH providers must collect and report data against metrics 4 and 5 that relate to CDH activity.
- In the immediate term, this dashboard will draw from existing data flows, such as DM01, and will therefore be dependent on those reporting submission timelines.
- The availability of data collection against the proposed metrics is variable, with limited data for physiological measurements and pathology against the stated metrics in Table 2. As outlined above, CDHs should code patient attendances as outpatient appointments and use OPCS4 codes to record diagnostic tests where current data collection is poor as an interim solution.
- Where indicated on the Health Inequality (HI) column, the data will also need to be broken down by protected characteristics and demographic groups.

Table 2: CDH Day 1 Metrics

#	Draft Metric	Rationale	HI
1	% change in total waiting list size from pre-pandemic baseline and pandemic baseline (for all minimum required tests)	Understanding whether CDHs have created additional elective capacity across system.	×

2	% change in elective diagnostic activity from pre-pandemic baseline and pandemic baseline (for all minimum required tests)	Understanding whether CDHs have created additional elective capacity across system.	×
3	% change in emergency diagnostic activity from pre-pandemic baseline and pandemic baseline (for all minimum required tests)	Understanding whether CDHs have caused downstream effect on emergency capacity across system.	×
4	% of elective activity across system being delivered by CDHs (for all minimum required tests)	Understanding to what extent CDHs are contributing to the capacity metrics above.	×
5	Total activity delivered by a CDH (for all minimum required tests).	Building a full picture of the activity being delivered across CDHs without comparison to previous points in time.	✓

14.4. Future data collection CDHs must work towards: -

- Systems must work with providers, including CDHs to continue to improve the collection and recording of staff training & development, ethnicity, deprivation, disability and age data and consider how further data could be captured to inform ongoing efforts to tackle health inequalities.
- Work is ongoing nationally to understand the feasibility of a set of outcome metrics that monitor health outcomes in CDHs as well as the service's impact on the wider system. Further information on requirements to report these metrics will follow for e.g. Pathology Quality Assurance Dashboard (PQAD) and annual pathology data collection positioning.

Annex A: CDH Facility Archetype

Archetype	Description
 **Standard Model**	A CDH that provides the minimum diagnostic tests, except for endoscopy, and any other diagnostic test deemed a priority locally. Only diagnostic testing is required to be carried out in this archetype; however, provision of consulting rooms should be considered if there is an opportunity for streamlining and providing more efficient overall patient pathways.
 **Large Model**	A large CDH that offers all minimum services and endoscopy, and potentially provides some of the optional components in the diagnostic pathway e.g. consultation**.** Delivery of endoscopy needs to be embedded within a Regional Network and be aligned to any local endoscopy training academies.
 **Hub and Spoke Model**	The central hub must include all minimum diagnostic tests to support a coordinated service for patients that requires multiple tests. CDH 'spokes' provide further capacity to 'hubs' for specific tests through a satellite location, mobile unit or pop-up. Spokes can be used to meet specific service needs (e.g.to reach certain populations or increase local capacity for specific tests). The spokes can help integrate CDH models with other community diagnostic expansion (e.g. primary care diagnostic services) or to deliver care at home where this helps to progress the intended aims of the programme. Spokes should also be considered in areas that can support local recovery from COVID-19. There must be digital connectivity and interoperability between the different facilities comprising the hub and spoke model.

Annex B: Optional diagnostic tests

Further to the national minimum requirements the below provides, by diagnostic modality, additional services to include in a local CDH model.

Endoscopy

The following endoscopy procedures may also be considered suitable for delivery in a CDH: screening colonoscopy, colon capsule endoscopy, and trans-nasal endoscopy (also other non-GI procedures e.g. cystoscopy, hysteroscopy and colposcopy). Novel diagnostic technology such as capsule endoscopy and trans nasal endoscopy (TNE) may be highly suited to delivery through a CDH model. These services may be used to identify whether a patient should be referred on for a gastroscopy, though robust evaluation would be required before widespread implementation.

Planning for local endoscopy provision must consider how services can be configured to maximise training opportunities both locally and across the region.

Imaging

In planning their CDH imaging provision, systems may wish to consider a range of imaging procedures have been identified as suitable for delivery in a CDH but will not be considered mandatory. Systems should consider providing the following tests if they align to pathway decisions and with local population needs mammography (particularly considering recovery from COVID-19 needs), elastography (e.g. fibroscan) and DEXA scan, CT colonography.

Physiological measurement

Some physiological measurement tests have been identified as suitable for delivery in a CDH but are not considered mandatory. In planning physiological measurement (also known as physiological science) within CDH provision, systems may wish to consider the following:

- Systems should consider providing the following tests if they align with pathway decisions and with local population needs: urodynamics and audiology/hearing services, simple pH monitoring and non-complex neurophysiology services of high volumes (e.g. for carpal tunnel syndrome), electrophysiological tests
- There are opportunities for hearing screening and provision of hearing aids to be included which do not require a soundproof or treated room
- With appropriate planning CDHs in supporting clearing any spirometry backlogs
- Complex sleep studies that involve monitoring of electroencephalography (EEG) are not considered applicable to a CDH, while more simple sleep equipment can be issues and returned to a CDH for off-site analysis which can form part of a local sleep pathway
- Other physiological measurements tests in the following science areas may be added to the scope of a CDH during the framework period: -
    - Ophthalmology /Vision
    - Vascular
    - Audiology
    - Cardiology
    - Urology
    - Gastro Intestinal
    - Neurology
    - Teledermatology

Pathology

Phlebotomy and POCT should be provided in all CDHs. However, samples other than POCT should be processed through pathology networks and not on CDH sites. Point of Care Testing to be used to enhance the decision-making during patient consultation and operated in conjunction with the pathology network

Annex C – Digital Standards

Digital Standards

The Provider(s) shall be required to comply with the following Standards where relevant and where a Standard is accessed via a URL, the version of the Standard set out on that web page shall be the version of the Standard that shall apply to a Call-Off Contract or Statement of Work upon execution of the same:

1.	**General**	**Evidence /Metric/test**
Note on Section 1: All Providers must have the requirements listed in section 1 in place in at the start of this Framework.		
1.1	ISO 9000; ISO 9001:2015 Quality Management	
2.	**IG and Security**	
Note on Section 2: All Providers must have the requirements in place that are listed in points 2.1 – 2.4		
2.1	10 Steps to Cyber Security' guidance: https://www.ncsc.gov.uk/guidance/10-steps-cyber-security	Statement
2.2	BS ISO 22301:2012 Societal security – Business Continuity management systems – Requirements	Statement
2.3	BS ISO 27001:2013 Information and Data Security	Statement
2.4	BS ISO/IEC 27002:2013 Information technology — Security techniques — Code of practice for information security controls	Statement
3.	**Development and System Design Services**	
Note on Section 3: All providers must have the following		
3.1	BS ISO/IEC 12207:2017 Systems and software engineering.	
3.2	BS 8878:2010 Web accessibility. Code of Practice.	
3.3	Open Standards: "Open Standards Principles 2018: For software interoperability, data and document formats in government IT specifications" (which can be found at https://www.gov.uk/government/publications/open-standards-	

	principles) and any supplementary or replacement government guidance.	
3.4	Adopted Open Standards as detailed on the Standards Hub https://www.gov.uk/government/publications/open-standards-for-government	
3.5	Web Content Accessibility Guidelines (WCAG) 2.0 to level AA; or WCAG 2.1, (as updated pursuant to the Public Sector Bodies (Websites and Mobile Applications) Accessibility Regulations 2018).	

3a	**Specific Data storage and transfer standards**	
Note on Section 3a: All Providers must have points of Section 3a in place by commencement of the Framework. Points 3a.7 and 3a.8 are required to be implemented by all Providers within the initial 2 years of the Framework.		
3a.1	Existing digital and IT services eg e-referral service should be used where appropriate and capable of meeting local performance requirements.	Local agreement
3a.2	CDHs must be capable of secure storage of all clinical data received and generated by the diagnostic procedures until such time as it can be safely transferred to an agreed longer term storage.	
3a.3	The CDH (staff and IT systems) must be capable of receiving and processing requests and referrals electronically using HL7 v2 as a minimum. Increasing use of HL7 FHIR is expected in the future and the CDH must adapt to include these as needed.	Witnessed deployment testing.
3a.4	The CDH must be capable of issuing test results electronically to referrers (and other local systems if required) using Hl7 v2 or other format determined locally. Increasing use of HL7 FHIR is expected in the future and the CDH must adapt to include these as needed.	Witnessed deployment testing.
3a.5	The CDH must be capable of receiving, managing and making referrals using the e-Referral Service NHS e-Referral Service - NHS Digital	Witnessed deployment testing.
3a.6	CDH providers will need to store and share information for operational and assurance purposes, in an aggregated form where appropriate	
3a.7	The CDH must support the co-ordinated scheduling of appointments across diagnostic disciplines to minimise patient trips to the hub, whilst supporting patient choice..	Witnessed deployment testing.
3a.8	The CDH must support the co-ordinated scheduling of appointments in collaboration with NHS Diagnostic services being provided on other premises by other NHS organisations if needed, whi8lst supporting patient choice.	Witnessed deployment testing.
3a.9	IT solutions must support two-way communications with patients to provide further information, allow for changes or cancellations.	Witnessed deployment testing
3a.10	The CDH must include a (machine readable) validated NHS Number in all communications about patients. Personal Demographics Service - FHIR API - NHS Digital	Witnessed deployment testing.

3a.11	Radiological and echocardiographic images must be transferred using DICOM.	Witnessed deployment testing.
3a.12	Radiological imaging procedures must be coded according to the NICIP standard National Interim Clinical Imaging Procedure (NICIP) Code Set - NHS Digital	System configuration testing
3a.13	Pathology tests must be coded according the Unified test List standard where possible or otherwise to the standards in use in local pathology services. BETA - Clinical Information Standards - NHS Digital	System configuration testing
3a.14	Images & traces produced during testing must be transferred to an agreed point (probably local acute Trust) for interpretation and storage within a locally agreed timescale (maximum 24 hours)	Contract monitoring/service management meeting
3a.15	Pathological specimens acquired in the CDH must be transferred to the organisation where they are to be analysed, in accordance with local IT and operating procedures.	Detailed written agreement or process.
3a.16	Interim data products from diagnostic procedures – eg images, ECG traces must be provided to requester/referrer as required.	Witnessed deployment testing
3a.17	It must be possible for authorised personnel to view clinical data about specific patients held on CDH systems in a timeframe appropriate to their ongoing clinical care.	Witnessed deployment testing
3a.18	CDHs must consider the deployment of innovative technological approaches including Artificial Intelligence	By agreement with local contract holder.
3a.19	Although CDHs are expected to be fully digital with respect to requests, referrals and results by 2022, in the interim, paper processes must be supported.	By agreement with local contract holder.
3a.20	CDHs must ensure that processes are in place to support potentially digitally excluded communities and individuals	By agreement with local contract holder.
3a.21	Missed appointments must be identified and appropriate action taken in line with local agreements.	By agreement with local contract holder.
3a.22	CDHs must enter into agreements with local NHS acute Trust to ensure access to the clinical data held on their systems to support staff in carrying out procedures eg access to local PACS to view previous images.	By agreement with local contract holder.
3a.23	Mechanisms must be in place to flag urgent results/reports to ensure timely follow-up by the responsible clinician.	
3a.24	Closed loop systems must be in place to ensure delivery of results & reports is acknowledged.	

4.	**DHSC and NHS Standards**
4.1	NHS Service Standards (and references therein): http://service-manual.nhs.uk/service-standard
4.2	The NHS digital, data and technology standards and clinical information standards as set out in this link and associated pages (as updated from time to time):

	http://digital.nhs.uk/about-nhs-digital/our-work/nhs-digital-data-and-technology-standards
5.	**Buyer Standards**
5.1	Such other standards and requirements as notified by the Buyer to the Supplier (including successor standards and requirements).