SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	170082S
Service	High Consequence Infectious Diseases, Special Isolation Unit (Airborne) Children aged 16 years and under
Commissioner Lead	*For local completion*
Provider Lead	*For local completion*

1. Scope

1.1 Prescribed Specialised Service

This interim service specification covers the provision of Special Isolation Unit (Airborne) for managing sporadic cases of confirmed airborne High Consequence Infectious Diseases for children aged 16 years and under Patients aged 16-18 years can be considered to be treated in either a paediatric or an adult unit taking into account their clinical presentation, any particular specialist needs and dependencies of the individual and any risks to public health.

1.2 Description

The purpose of a Special Isolation Unit (Airborne) is the safe and effective treatment of High Consequence Infectious Diseases that are known or suspected to be transmissible from person to person via the airborne route (airborne HCIDs).

High consequence infectious diseases are characterised by:

a) acute infectious illness;
b) an ability for illness to spread in the community and within healthcare settings including staff if not properly protected;
c) high case-fatality rate;
d) difficulty in rapid recognition and detection;
e) effective treatments often lacking; and
f) coordination is required at a national level to ensure an effective and consistent response.

1.3 Airborne HCIDs are capable of being transmitted person-to-person by the airborne route; this may be in addition to other routes of transmission e.g. contact, droplet.

1.4 Current known pathogens within that are within scope (HCID Programme, April 2017)

a) Middle East respiratory syndrome (MERS) coronavirus infection
b) Avian influenza A(H7N9) infection
c) Avian influenza A(H5N1) infection
d) Monkeypox virus infection
e) Nipah virus infection

f) Yersinia pestis infection(pneumonic plague only)
g) Severe acute respiratory syndrome (SARS) coronavirus infection*
h) Any new and novel pathogens that may arise

*no suspected or confirmed SARS cases globally since 2004, but SARS remains a notifiable disease under WHO International Health Regulations.

1.5 The unit must be able to admit a patient (aged 16 years and younger) and start treatment within 6 hours of a confirmed diagnosis. The unit is expected to be able to care for up to two patients at any one time. This interim service specification excludes the management of patients with suspected airborne HCIDs; only patients with laboratory-confirmed airborne HCIDs are within scope. The interim service specification excludes the provision of surge capacity for when the stated, collective number of beds for managing sporadic confirmed cases has been exceeded e.g. during an epidemic. Surge capacity is managed through a different set of arrangements.

1.6 It is preferable that the service is co-located with an adult high consequence airborne service, especially where families are affected. Co-location in the context of this service specification means on the same hospital site.

1.7 All planned children's care in the NHS should be delivered by trained paediatric staff.

1.8 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

NHS England commissions highly specialised services for adults with infectious diseases. Airborne HCIDs are very rare diseases with a high case-fatality rate and high risk of transmission in healthcare facilities and the community. This service requires national commissioning and coordination.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

2.1.1 Service Configuration is based on published literature and the work of NHS England HCID Programme.

2.1.2 A Special Isolation Unit (Airborne) is a definitive facility for treatment of confirmed cases of airborne HCID. Prior assessment and diagnosis will have occurred in other healthcare facilities, but once confirmed, cases will be transferred to a Special Isolation Unit (Airborne). This specification relates to maintaining readiness of a Special Isolation Unit (Airborne): to be able to admit and start treatment of any patient with a confirmed diagnosis of airborne HCID within 6 hours (maximum) of notification.

2.1.3 The purpose of a Special Isolation Unit is the complete containment of any airborne HCID. In order to control and contain the possible spread of airborne HCID to healthcare staff, other patients, visitors and the general public, there are a number of structural and operational requirements that the Special Isolation Unit must fulfil as described below.

2.2 Special Isolation Unit structural requirements

2.2.1 The unit will be part of a paediatric Critical Care unit,
sited in an area away from general circulation of staff, patients and visitors such that

patients are not admitted through Accident and Emergency department.
The objectives are to:

a) Achieve complete physical separation of HCID patients to mitigate against disease spread;
b) Provide direct access for HCID patients to specialist infectious diseases and critical care clinical expertise;
c) Ensure security against disruption and crime with appropriate lock down procedures and access and egress records in place to allow for any epidemiological follow up of potential contacts;
d) Allow for secure and direct transfer of patients from ambulance to unit;

2.2.2 There must be clear segregation of clean and potentially contaminated areas of the Special Isolation Unit. Clearly delineated pathways through the unit for staff, patients, visitors, supplies and waste must be integrated into the structural design.

2.2.3 Changing rooms for staff are required within the unit.

2.2.4 All surfaces within the unit must be easy to clean. Floor, walls and other surfaces must be impervious to water and resistant to damage from disinfectants.

2.2.5 Patient isolation suites within the unit must be at negative pressure relative to the rest of the unit. Facilities should comply with Health Building Note 04-01 Supplement 1 for isolation facilities for infectious patients in acute settings. Air should be HEPA (or equivalent) filtered before discharge into the atmosphere.

2.2.6 Validation for performance and against technical specification should be carried out by an appropriate external organisation annually; ongoing monitoring must be in line with Health Building Note 04-01 Supplement 1, Isolation facilities for infectious patients in acute settings (Department of Health 2013); Heating and ventilation systems Health Technical Memorandum,03-01: Specialised ventilation for healthcare premises (Department of Health 2007).

2.2.7 Environmental monitoring should be built-in to monitor the performance of negative pressure ventilation systems.

2.2.8 The provider must be able to deliver level 3 critical care in an appropriate facility as above, within the Critical Care Unit.

2.3 Operational requirements

The unit will have in place detailed written operational policies and standard operating procedures covering all activities in the unit. These must include:

a) Unit activation and deactivation;
b) Roles and responsibilities of staff;
c) Patient admission and discharge;
d) Staff entry and exit;
e) Personal Protective Equipment (PPE) and Respiratory Protective Equipment (RPE) maintenance, use, disposal and storage; the Trust must have a designated storage area for additional equipment including (Personal Protective Equipment) PPE which needs to be available in the event that a suspected case is admitted;
f) A designated member of the ID team must be responsible for liaising with the Trust supplies department to agree the list of emergency stock and amounts to be kept;
g) Management of spillages;
h) Routine cleaning of the unit and equipment;

i) Taking of clinical specimens and subsequent handling;
j) Ambulance and ambulance crew decontamination;
k) Disinfection, decontamination and terminal cleaning of the unit and equipment;
l) Special arrangements for waste handling and disposal;
m) Special arrangements for laundry;
n) Emergencies, for example fire or flooding, including evacuation;
o) Maintenance and repair.

2.3.1 Where possible, all procedures and investigations must be carried out in the single room with a minimal number of staff present. Only if clinical need dictates, and in agreement with the infection control team, should patients be transferred to other departments.

2.3.2 The unit must be staffed by individuals trained in the management of airborne HCID. All staff must receive regular appropriate training and instruction in the whole safe system of work in the facility and including the use of PPE.

2.3.3 Access must be restricted to authorised personnel only. The general public, including patients, relatives and visitors, must be excluded from the area when the unit is in use except when if in the view of the clinical team it is essential for clinical care that a visitor enters the patient room (for example in the case of a child or vulnerable adult), then visits must adhere to national guidance including infection prevention and control guidance (and relevant guidance such as PHE MERS guidance) A register of all personnel including clinical, non-clinical and maintenance staff entering the unit must be kept as a means of tracking potential exposure to infection.

2.4 Other requirements

Providers of an Special Isolation Unit will also be required to ensure detailed written operational policies are in place for:

a) Laboratory procedures, including transport of specimens to the laboratory
b) After death care
c) Contingency plans that have been tested and that this occurs on an annual basis
d) Provide assurance in relation to the delivery of these plans
e) A local escalation plan, agreed with commissioners must be in place which details how the provider and the health economy, local, regional and national will manage the impact of managing one or more cases of HCID (Airborne)
f) Provide a plan for the logistical management of children and families

2.5 The trained Special Isolation Unit staff will include the following staff groups:

a) Consultants in Paediatric Critical Care and Anaesthetics
b) Support from consultants in paediatric infectious diseases and paediatric respiratory medicine
c) Doctors in training
d) Nurses, including critical care nurses
e) Physiotherapists
f) Pharmacists
g) Radiographers
h) Essential support staff, including cleaners

Surgical and other specialised input will be developed in a network approach, not every unit will be expected to train all staff groups.

2.6 First–line personnel allocated to the unit will usually be employed substantively by the provider and work in other related departments such as ICU. First-line personnel must be trained and ready and able to open the unit within 6 hours (maximum) of notification of a confirmed case.

2.7 It is recognised in this specification that the pool of staff required to provide this service may exceed the capacity of a single unit to provide care over a prolonged period. Commissioned providers are expected to make appropriate sustainable arrangements with other trusts to provide staff to support operational demands and enable the unit to function continuously for a period of at least three weeks. These arrangements will include the release of staff for training and for exercises. The agreements between trusts in relation to staffing will be explicitly agreed in a subcontract between the parties which can be made available to commissioners on request. All funding requirements relating to the training and participation in exercises will be met from the 'readiness allocation.

2.8 Training requirements

2.8.1 Staff will be trained in the whole safe system of work within the high hazard environment.
This training must include emergency procedures in event of fire, power failure etc. Comprehensive electronic training records that demonstrate that individual staff have met specific competencies must be maintained.

2.8.2 All Special Isolation Units will be required to undertake regular training exercises to simulate 'real life' situations. All the units commissioned through this service specification must be able to provide simulation training. At least one exercise per annum is required. The outcome of these exercises must be reported to NHS England as the commissioner in line with EPRR Core Standards. These exercises must include rehearsal of national and local escalation plans (see below) and joint training with other relevant organisations such as Ambulance Trusts and neighbouring NHS Trusts.

2.9 Interdependence with other Services

Respiratory services, diagnostic radiology must be co-located. Providers will have the infrastructure and mechanisms in place to be able to refer samples to testing laboratories 24/7 (including PHE specialist and reference laboratories). In practical terms it is expected that units will be able to ensure that the samples are appropriately packaged and have access to urgent sample couriers 24/7 There must be a microbiology laboratory on site.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification
This service specification covers children aged 16 years or under in or entering England diagnosed with a confirmed airborne HCID. Devolved nations may also have access to this service and this activity will be funded as agreed by the Highly Specialised Commissioning team and the devolved administrations. This is a new service and as such is not covered by existing arrangements.

3.2 Population Needs: the need for this service is rare but readiness is vital. It is anticipated that there will be up to four units in England for children with capacity to care for two children.

3.3 **Expected Significant Future Demographic Changes:** increased international travel will increase the risk of importation of an HCID to England.

3.4 **Evidence Base**

Service Configuration is based on published literature and the work of NHS England High Consequence Infectious Diseases Programme. Details of the most relevant guidance are set out below;

a) Avian influenza collection (PHE) https://www.gov.uk/government/collections/avian-influenza-guidance-data-and-analysis

b) MERS collection (PHE) https://www.gov.uk/government/collections/middle-east-respiratory-syndrome-coronavirus-mers-cov-clinical-management-and-guidance

c) HPA SARS collection (historical) http://webarchive.nationalarchives.gov.uk/20140629102627/http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/SevereAcuteRespiratorySyndrome

3.4.1 Specialist facilities known as High Level Isolation Units (HLIUs) manage patients with HCID that are spread by contact ((viral haemorrhagic fevers such as Ebola) and not the airborne route; these are **not** in the scope of this service specification and are commissioned separately. Individual providers may be separately commissioned for both the Specialist Isolation Unit defined here and an HLIU if they meet the requirements for both specifications.

3.4.2 Examples of airborne HCID include avian influenza (e.g. H7N9) and Middle East Respiratory Syndrome (MERS) coronavirus. Although the likelihood of any particular known or new HCID spreading to the UK is low, it is highly likely that sporadic cases will be imported by international travel. The impact on the NHS and wider society could be substantial if the NHS is unable to deliver safe and effective care, and the ability to do so is an essential component of public confidence in the NHS. More than 1000 cases of MERS, which was first identified in Saudi Arabia in 2012, have been reported with a high case-fatality rate (up to 40%). In 2015 in South Korea, a large outbreak (>180 cases) of MERS occurred from a single imported case, and most of the secondary cases acquired the infection in healthcare facilities. Approximately 35% of the cases required critical care. More than 17000 individuals required quarantine, each for 14 days, in order to control the outbreak. A similar scenario in the UK was the focus for a Chief Medical Officer led exercise (Alice) in 2016. The incidents of MERS in the UK were: 1 case in 2012, and 3 cases in 2013 (including two secondary transmission cases that occurred in the UK).

3.4.3 Early case identification is crucial to prevent spread of an airborne HCID. Processes to support this and protect health care staff prior to confirmed diagnosis are being addressed in a wider NHS England HCID Programme. This service specification specifies the requirements for a Special Isolation Unit to maintain preparedness to manage confirmed cases, and it is expected that confirmed cases would be transferred to one of these units as soon as practicable except in exceptional circumstances.

4. Outcomes and Applicable Quality Standards

4.1 **Quality Statement – Aim of Service**

Airborne HCIDs are very rare diseases with a high case-fatality rate and high risk of

transmission in healthcare facilities and the community. This service specification sets out the requirements for a national programme of service readiness. The quality standards required to ensure this readiness are set out below.

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	**x**
Domain 2	**Enhancing quality of life for people with long-term conditions**	
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**

4.2 Indicators are set out in Table 2 below:
Detailed definitions of indicators, setting out how they will be measured, are included in schedule 6.

4.3 This is a Highly Specialised Service and providers will work as part of a clinical network in relation to this service and share training and clinical expertise as appropriate. This will include training on how to meet the needs of pregnant women and newly delivered mothers. Providers are required to share rapidly any important information that may improve understanding of the disease, including clinical features and transmission. As part of the network providers will agree lead responsibility for the research portfolio of the network (e.g. which trials the centres will sign up to) and agree which experimental therapies should be considered for treatment of any cases. One provider will lead the clinical network. The clinical lead will be part of the dynamic clinical decision making process when providers have to make complex decisions. Learning will be shared with non-airborne isolation facilities. Providers will set up and participate in annual audit days to which commissioners and other stakeholders will be invited. The details of the audit programme are included in the standard NHS England acute contract for specialised services, set out in Schedule 4A-C.

4.4 Applicable CQUIN goals are set out in Schedule 4D

Table 2

Number	**Indicator**	**Data source**	**Outcome framework domain**	**CQC key question**
Clinical outcomes				
101	Number of occasions	Provider	1, 3, 4, 5	responsive,

	where unit is unable to commence treatment on a patient within six hours			effective, caring
102	Number of cases where HCID infection has spread from the Specialist Isolation Unit	Provider	1,5	effective, safe
Patient experience				
201	Patient and carer feedback included in formal debrief	Self-declaration	1, 3, 4, 5	responsive, effective, caring
Structure and process				
301	Infectious Diseases team	Self-declaration	1, 3, 4, 5	well led, effective, caring, responsive, safe
302	Infrastructure and facilities	Self-declaration	1, 3, 4, 5	safe, effective
303	Isolation unit	Self-declaration	1, 3, 4, 5	safe, effective
304	System preparedness - annual readiness exercise	Self-declaration	1, 3, 4, 5	safe, effective
305	System preparedness - staff training	Self-declaration	1, 3, 4, 5	safe, effective
306	Local escalation plan	Self-declaration	1, 3, 4, 5	safe, effective, caring, responsive

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

a) The provider must comply with the following national standards: Health Building Note 04-01 Supplement 1,Isolation facilities for infectious patients in acute settings (Department of Health 2013)

b) Heating and ventilation systems Health Technical Memorandum,03-01: Specialised ventilation for healthcare premises (Department of Health 2007)

5.2 Other Applicable National Standards to be met by Commissioned Providers

a) Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010 defines the standards and evidence required from providers in this regard).

b) All hospital settings should meet the standards for Children and Young People in emergency settings http://www.rcpch.ac.uk/emergencycare

c) All hospital settings should meet the Standards for the Care of Critically Ill

Children (Paediatric Intensive Care Society, London 2010).

d) There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010.

5.3 Other Applicable Local Standards

Not applicable

6. Designated Providers (if applicable)

(Not applicable, providers will be selected through a procurement process)

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:
HCID - High Consequence Infectious Diseases
HLIU - High Level Isolation Unit
EPRR - Emergency Prevention, Resilience and Response
MERS - Middle East Respiratory System
PPE - Personal Protection Equipment

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Appendix 1

Quality Schedule detail

Number	Indicator	Descriptor	Notes	Evidence documents	Data Source	Alert	Domain	CQC Key Question
	Clinical Outcomes - quantitative data where possible using national data need to minimise the burden							
101	Number of occasions where unit is unable to commence treatment on a patient within six hours	Number of occasions where unit is unable to admit and start treatment of any patient with a confirmed diagnosis of airborne HCID within 6 hours (maximum) of notification.		Annual Report	Provider	> 0	1, 3, 4, 5	responsive, effective, caring
102	Number of cases where HCID infection has spread from the Specialist Isolation Unit	Number of cases where HCID infection has spread from the Specialist Isolation Unit		Annual Report	Provider	> 0	1, 5	effective, safe
	Patient Experience - PROMS PREMS							
201	Patient and carer feedback included in formal debrief	The review of the patient pathway and clinical practice by the HCID team includes patient feedback.			Self-declaration	No	1, 3, 4, 5	responsive, effective, caring
	Structure and Process - infrastructure requirements, staffing, facilities etc							
301	Infectious Diseases team	The Infectious Diseases specialist clinicians include: The trained Specialist Isolation Unit staff will include the following staff groups: Consultants in Paediatric Critical Care; Consultant in Paediatric Anaesthesia; Doctors in training; Nurses, including critical care nurses with an expertise in HCID; Physiotherapists with an expertise in HCID; Pharmacists with an expertise in HCID; Radiographers with an expertise in HCID.		Operational Policy	Self declaration	No	1, 3, 4, 5	well led, effective, caring, responsive, safe

		Paediatric Surgeons First-line personnel must be trained and ready and able to open the unit within 6 hours (maximum) of notification of a confirmed case. Any planned children's care should be delivered by trained paediatric staff.						
302	Infrastructure and facilities	The HCID unit will be sited in an area away from general circulation of staff, patients and visitors and meet the requirements as per the service specification.		Operational Policy	Self declaration	No	1, 3, 4, 5	safe, effective
303	Isolation unit	The Specialist Isolation Units undertakes at least one training exercise per annum to simulate 'real life' situations, and reports the outcome of these exercises to NHS England.	Based on compliance with Health Building Note 04-01 Supplement 1 Isolation facilities for infectious patients in acute settings, (DoH 2013)	Operational Policy	Self declaration	No	1, 3, 4, 5	safe, effective
304	System preparedness - annual readiness exercise	The HCID unit reviews its level of preparedness annually, undertaking at least one 'readiness exercise'.		Operational Policy	Self declaration	No	1, 3, 4, 5	safe, effective
305	System preparedness - staff training	All staff are trained in the whole safe system of work within the high hazard environment. This training must include emergency procedures in event of fire, power failure etc. Comprehensive training records that demonstrate that individual staff have met specific		Operational Policy	Self declaration	No	1, 3, 4, 5	safe, effective

		competencies must be maintained.						
306	Local escalation plan	The provider of the service will have a local escalation plan that has been agreed with their neighbouring NHS Trusts and organisations, commissioning CCGs, NHS England EPRR and commissioner and include the elements outlined in the service specification.		Operational Policy	Self declaration	No	1, 3, 4, 5	safe, effective, caring, responsive

Appendix 2

Department of Health - Heating and ventilation systems; Health technical memorandum 03-01: Specialised ventilation for healthcare premises

Appendix 3

Department of Health - Health Building Note 04-0; Supplement: Isolation facilities for infectious patients in acute settings