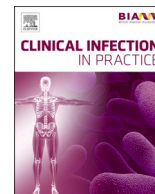




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Practical clinical reviews

Best practice standards for the delivery of NHS infection services in the United Kingdom

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ABSTRACT

Infection expertise in the NHS has historically been provided predominantly by hospital-based medical microbiologists responsible for provision of diagnostic services and advice to front-line clinicians. While most hospitals had consultant-led microbiology departments, infectious diseases departments were based in a small number of specialist centres. The demand for infection expertise is growing in the NHS, driven by advances in medical care, increasing awareness of the impact of antibiotic resistant and healthcare associated infections and threats from emerging infectious diseases. At the same time diagnostic services are being reorganised into pathology networks. The Combined Infection Training (CIT) is delivering a consultant workforce with expertise both in laboratory diagnostic practice and delivery of direct patient care. These changes create challenges for delivery of high quality infection expertise equitably across the NHS. They also offer an opportunity to shape infection services to meet clinical and laboratory demands.

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To date there has not been an attempt to bring together a single set of best practice guidelines for the requirements of an infection service. This document sets out seven standards. These are written to be practical and flexible according to the diverse ways in which infection expertise may be required across the NHS. It has been prepared by the Clinical Services Committee of the British Infection Association drawing on published evidence and guidance where they exist and on the group's extensive experience of delivering infection services in hospitals across the NHS. It was then refined with input from the RCP Joint Specialist committee (JSC) and the RCPATH Specialist Advisory Committee (SAC) and through consultation with the RCPATH membership. It has been endorsed by the Royal College of Pathologists and the Royal College of Physicians. It will be reviewed annually by the CSC and updated as additional evidence becomes available.

Introduction

Infection expertise in the NHS has historically been provided predominantly by hospital-based medical microbiologists responsible for provision of diagnostic services and advice to front-line clinicians. While most hospitals had consultant-led microbiology departments, infectious diseases departments were based in a small number of specialist centres. The demand for infection expertise is growing in the NHS, driven by advances in medical care, increasing awareness of the impact of antibiotic resistant and healthcare associated infections and threats from emerging infectious diseases. At the same time diagnostic services are being reorganised into pathology networks. Previous documents prepared by the Association of Medical Microbiologists (now incorporated in the British Infection Association (BIA)) and Royal College of Pathologists for configuration of microbiology and infectious diseases services (e.g. "Blue Skies Agenda for Microbiology: How do we deliver Microbiology services for the next decade and beyond?", (2006) and "Getting ahead of the curve – a strategy for infectious diseases", (2002) have lost relevance with the advent of Combined Infection Training (CIT). CIT is delivering a consultant workforce with expertise both in laboratory diagnostic practice and delivery of direct patient care. These changes create challenges for delivery of high quality infection expertise equitably across the NHS. They also offer an opportunity to shape infection services to meet clinical and laboratory demands.

Organisations looking at provision of infection services to their patients have access to a range of existing standards for laboratory services and certain clinical services. Of note, although infection expertise remains based predominantly in secondary care this expertise is also needed by primary care providers and public health bodies. To date there has not been an attempt to bring together a single set of best practice guidelines for the requirements of an infection service. This document sets out seven standards. These are written to be practical and flexible according to the diverse ways in which infection expertise may be required across the NHS. It has been prepared by the Clinical Services Committee of the British Infection Association drawing on published evidence and guidance where they exist and on the group's extensive experience of delivering infection services in hospitals across the NHS. It is endorsed by The Royal College of Physicians Joint Specialist Committee and the Royal College of Pathologists. It will be reviewed annually by the CSC and updated as additional evidence becomes available.

Background

The demand for high quality infection expertise in the NHS is increasing, driven by advances in medical care which put patients at greater risk of more complex infections. More patients are at risk of infection because of the treatments they receive including cancer chemotherapy, immunotherapies, organ transplantation and insertion of surgical or medical devices (vascular access lines, orthopaedic devices, prosthetic heart valves). Improvements in care for premature babies, increasing life expectancy and burden of comorbidities such as diabetes and obesity are increasing the number of people at risk of infection throughout life. There are new treatment options especially in virology (e.g. in HIV, viral hepatitis, CMV, SARS-CoV-2). The threat of

antibiotic resistant and healthcare associated infections is now very clear, as is the importance of robust infection control and antibiotic stewardship practice to counter these threats. There is a public expectation that the NHS and public health services can protect the population from emerging infections including viral haemorrhagic fevers, pandemic influenza and novel coronaviruses which require immediate diagnostic and clinical input from infection services.

The last decade has seen considerable reorganisation of diagnostic infection services in the NHS with many microbiology/virology laboratories being consolidated into pathology networks. One consequence of this has been de-coupling of clinical and laboratory staff due to lack of co-location of clinical and laboratory services. This places additional difficulties providing an integrated bench to bedside service. It can impact on the continuity of care and the multidisciplinary working which is a cornerstone of good medical practice (GMC, "Good Medical Practice", 2018). The evolution of the laboratory diagnostics service to include more advanced techniques, in the molecular and genomic fields in particular, heralds an exciting time for the service, but which also places new cost and time demands on it.

Changes in infection specialist training structure in 2014, with the introduction of Combined Infection Training (and entry after core medical training with MRCP) increased the breadth of training and therefore the flexibility of the consultant workforce (in line with the recommendations of the later "Shape of Training" review (published 2013) so services may be variably delivered depending on local staffing. The introduction of new curricula in the infection specialities in 2021/2022 will continue to train a flexible broad-based workforce in infection.

As infection services in the NHS move from a situation where every hospital has access to onsite diagnostic microbiology to the 29 networks outlined by NHSI (for England only) it is critical that the role of the infection specialist at the interface of laboratory in ward is maintained so that developments within networks are clinically driven and all patients across the NHS receive excellent infection advice on the interpretation of Microbiology tests and consequent patient management. A number of significant changes across the NHS present both challenges and opportunities in this regard:

- Diagnostic services being increasingly centralised,
- New diagnostic technologies, including for point of care testing are being introduced,
- A new cadre of consultants trained in infectious diseases and either acute medicine and/or medical microbiology increasingly deliver direct patient care,
- The nature and burden of infectious diseases which affect NHS patients are in flux.

Strong clinical leadership at both hospital and network level is essential to ensure that patient care is optimised in this changing landscape.

Aims of this document

This document aims to set out best practice standards that Infection Services can use to ensure that they can deliver a high quality service to

suit their population.

Where existing standards cover the provision of diagnostic services (UKAS) handling of diagnostic samples (SMI) and clinical practice (e.g. NICE, PHE, on behalf of specialist advisory panels), and by specialist societies (e.g. BHIVA, BTS, BIA) these are highlighted.

Whether laboratories are in networks (either as a “hub” or “spoke”) or standalone, a complementary set of quality standards are described for managing a full integrated Infection Service (of which a UKAS accredited laboratory forms one part).

These standards are intended as a benchmark for a consistent, high quality infection service. It is envisaged that as more evidence and data is acquired, so these standards will evolve.

Please note: this document is intended for UK infection services. In some cases, organisations and bodies referred to apply to England; devolved nations will usually have differently named organisations and bodies with similar remits.

The majority of infection diagnostic laboratories will process samples for a neonatal and/or paediatric population. Specialist paediatric laboratories and infection services, as well as other specialist centres may have different requirements in addition to these core standards. However, these are outwith of the scope of this document.

Definition of an infection specialist

An infection specialist is defined for the purposes of this document as a medical or clinical scientist consultant in the infection disciplines with an appropriate postgraduate qualification (e.g. FRCPath and/or MRCP).

Standards for NHS infection services

Standard 1. NHS infection service general specification

A high-quality clinical and laboratory infection service should be consultant led (medical or clinical scientist) and:

- Integrate laboratory diagnostics with clinical diagnosis, advice and patient management
- Deliver leadership and expertise in infection control and antimicrobial stewardship.
- Provide expertise to primary care, public health services including infection surveillance, outbreak management and vaccination programmes.
- Work in close collaboration with clinical colleagues in other specialities and also occupational health, facilities, estates, domestic services, environmental health and catering.
- Incorporate multidisciplinary expertise as locally appropriate in
 - o Medical microbiology (including mycology, parasitology and other sub-specialisms as appropriate)
 - o Medical virology
 - o Molecular diagnostics
 - o Infectious diseases
 - o Clinical scientists and biomedical scientists
- Be supported as locally appropriate by
 - o Specialist nurses (e.g. infection control, TB (tuberculosis), OPAT (outpatient antimicrobial therapy), sepsis),
 - o Specialist pharmacists (antimicrobial, departmental and community),
 - o Physician associates, non-infection trained physicians and trainees in infection specialities
 - o adiology
 - o IT and data analysts

[Level of evidence GPP]

Standard 2. Minimum standards for an infection service

Infection services are constantly evolving, and should have the ability to respond to local requirements, which may vary. All laboratory, estates and clinical aspects need to be considered. There is increasing frequency and complexity of the clinical service via bacteraemia ward round services, requested bedside consults, multidisciplinary team meetings (MDTs), intensive care ward rounds and involvement in development and implementation of patient pathways and care bundles.

In some centres there are clinics staffed by infection specialists (outpatient parenteral antibiotic therapy, HIV and hepatitis clinics, general infectious diseases, joint clinics with surgeons (e.g. bone and joint infections) and chronic fatigue clinics. Larger centres also have infectious diseases in-patients with isolation facilities and regional referrals led by infectious diseases physicians (who may be dually training with medical microbiology, medical virology or general internal medicine). Centres without ID in-patients may have clinical services predominantly provided by medical microbiology or medical virology specialists with or without dual accreditation with ID.

The remit of the service’s clinicians includes providing an interface between the laboratory and users, in addition with Public Health services, clinical commissioning groups, local authorities and the Department of Health.

Standard 2.1 laboratory service

All laboratories must have clear guidance on specimen transport times. Integrity of samples is paramount; the UK SMI (Standards for Microbiological Investigations) provides guidance where relevant on timeframes for processing important clinical specimens.

KAIs (Key Assurance Indicators) must be in accordance with those defined by RCPATH (2018) and must be made available to all users, which must include turnaround times (TATs). Any changes to these must be risk assessed and made available to all users. Within Pathology networks, any proposed changes must be made available to all network partners prior to initiating in order to get consensus agreement. For standalone laboratories, it is acknowledged that these KAIs will be different to networked laboratories according to their testing repertoire and capabilities.

The following are requirements of all laboratories:

- Robust and reliable transport system that meets the needs of the local service
- Robust and reliable IT system with a shared LIMS system
- All laboratories must participate in nationally recognised External Quality Assurance (EQA) schemes for all tests provided where available.
- A competency framework must be available outlining necessary competencies and persons deemed competent to undertake each task.
- All laboratories must clearly demonstrate that they are compliant with UKAS ISO15189 standards for competencies and training.

All laboratories must declare if they have the ability to receive and handle category 4 specimens and arrangements for receiving them or referring to another laboratory if appropriate.

[Level of evidence: D]

Routine diagnostic practice

Standards for the processing of routine microbiological standards are well established and maintained by

United Kingdom Accreditation Service (UKAS). UKAS has recognised standards for the diagnostic element of the Infection Service (ISO 15189:2012), which laboratories are assessed against for accreditation. These are supported by the Royal College of Pathologists (RCPATH) Key Performance Indicators for laboratories ([RCPATH, 2013](#)).

Public Health England (PHE). PHE has published Standards for

Table 1
Standards for maximum times for processing and availability of results for time critical samples (from the time of collection).

Standards for maximum times for processing of URGENT and CRITICAL samples (from the time of collection) as defined by RCPATH (2013)	
Sample	Ideal maximum time between collection and laboratory processing – dependent on the laboratory being notified of urgent tests in advance.
CSF (acute non-shunt/shunt samples only)	2 h (SMI B27)
Blood cultures	4 h (SMI B37)
Sterile tissues and biopsies from deep seated organs and sites (operative samples)	2 h (IDSA 2018) Miller et al., 2018
Sterile joint aspirate	2 h (IDSA 2018)- processing out of normal working hours is by local agreement (Miller et al., 2018)
Sterile aspirate (e.g. from pleural/peritoneal/CAPD fluids)	2 h (or refrigerated within this timeframe if not available out of hours) (IDSA 2013) (Miller et al., 2018)
Bronchoalveolar lavages	2 h (or refrigerated within this timeframe if not available out of hours) (IDSA 2013) (Miller et al., 2018)
Corneal scrapes/vitreous taps/aqueous taps	In theatre or within 2 h (8 h for acanthamoeba if testing via culture) (IDSA 2018) (Miller et al., 2018)
Brain abscesses	2 h (IDSA 2018) (Miller et al., 2018)
Liver abscess	2 h (IDSA 2018) (Miller et al., 2018)
Blood borne virus (BBV) screening for un-booked women in labour or just post-delivery	4 h from receipt in laboratory (BHIVA 2018: Management of HIV in pregnancy; section 6.5.5) (Public Health England, 2016)
Blood borne virus screening for patients requiring urgent haemodialysis	48 h from receipt in laboratory (DoH guidelines: Addendum for Guidelines for dialysis away from base [DAFB])
Blood borne virus screening for sharps/splash injuries	48 h from sample collection; 24 h from receipt in laboratory (BHIVA/BASHH 2015: HIV post exposure prophylaxis guidelines)

Minimum standards for availability of time critical results

Test	Recommended availability/access	Guidance Source(s)
BBV (HBV(hepatitis B), HIV (human immunodeficiency virus)) testing for un-booked women in labour or just post-delivery patients	24 h a day, 7 days a week (Public Health England, IDPS Infectious Diseases in Pregnancy Screening, 2016) [HBV vaccination +/- immunoglobulin within 24 h; HIV confirmed results within 8 working days] (Public Health England, 2016)	
Syphilis for un-booked women in labour or just post-delivery patients	Within normal working hours and normal working week (BASHH guidance 2015)	
Molecular testing for routine viral respiratory pathogens (e.g. influenza, RSV (respiratory syncytial virus))	Within normal working hours, 7 days a week; within 24 h of collection during winter season for effective infection control and patient management. Trust contingencies must be in place to manage patients with suspected influenza).	
Molecular testing for SARS-CoV-2	Within normal working hours, 7 days a week; within 24 h of collection	
Molecular testing for category 4 viral respiratory pathogens (e.g. MERS CoV)	7 days a week, results within 24 h of collection. (Public Health England, 2017a, 2017b)	
Molecular testing for norovirus (where available within a network and according to local protocols)	Within normal working hours, 7 days a week, within 24 h of collection. Trust contingencies must be in place to manage patients with suspected norovirus.	
Testing for routine faecal pathogens (e.g. salmonella)- using culture OR molecular testing methods	Within normal working hours, 6–7 days a week according to local protocols	
Stool testing for Clostridioides difficile (C. difficile)	Within normal working hours, 7 days a week (Public Health England, 2013)	

Table 1 (continued)

Standards for maximum times for processing of URGENT and CRITICAL samples (from the time of collection) as defined by RCPATH (2013)	
Sample	Ideal maximum time between collection and laboratory processing – dependent on the laboratory being notified of urgent tests in advance.
Smear microscopy for acid fast bacilli	Within normal working hours and within one working day of receipt of the specimen, 6 day service (NHS England, 2007)*

*Consideration must be given to the availability of appropriately trained staff to perform this test. If this is not practical, then consideration should be given to the use of molecular testing to provide a rapid diagnosis.

Microbiological Investigations (SMIs) on behalf of a multi-agency working group. They act as technical standard operating procedures for laboratories and can be used as measurable standards for laboratories.

[Level of evidence: D]

Non-routine diagnostic practice

All hospitals with an accident and emergency department and/or acute assessment unit and/or acute inpatients must have access to a 24 h diagnostic microbiology service. This may be within the hospital itself, or as part of a network.

This is to allow for urgent CSF (cerebrospinal fluid) and other sterile samples (e.g. corneal scrapes, samples for suspected necrotising fasciitis, samples obtained from interventional radiology and theatre etc.) to be processed urgently. Not processing these samples in real time can result in degradation of sample and/or inappropriate antimicrobial use. It can also lead to a delay in organism work up which can result in inappropriate or ineffective antimicrobial prescription.

The definition of an acute sample is one where the result is likely to affect management of a patient before the time when a routine sample would be reported. An example of this would be a CSF sample to confirm the diagnosis of infective meningitis or encephalitis.

The SMI for cerebrospinal fluid B27 states:

“Time between collection to microscopy and culture should occur within a maximum of 2 h. Cells disintegrate and a delay may produce a cell count that does not reflect the clinical situation of the patient”.

In addition, provision must be made for the rapid handling (including packaging and forwarding) of samples containing suspected highly communicable pathogens e.g. viral haemorrhagic viruses and other hazard group 4 organisms. Failure to provide adequate provision for handling these samples could have serious adverse consequences.

Choice of site of 24 hr diagnostic service must take into account the transit time and transit conditions for samples at all times of the day from the point of collection until the time the specimen is received in the laboratory. This should be determined via a vertical audit and a risk assessment undertaken. *Significant consideration must also be given to end-to-end connectivity of IT systems in place.*

The use of molecular platforms to provide rapid diagnostic services can be considered for example, CSFs; however it must be recognised that whilst these can provide an identification of an organism, it cannot provide a cell count and differential. Therefore consideration must be given as to whether the SMI B27 recommendations can be met using molecular diagnostic methods alone.

Availability of testing repertoire

Ideally, as hospitals run a 24/7 service, so should laboratories. However, this is not always practical or even necessary depending on the service provided. These *minimum* standards for availability of time critical results may be provided locally or by outsourcing to a linked or

Table 2
Delivery of core Infection Service activities.

Service	Frequency	Compulsory attendance for infection service member	Comments/relevant standards
Core infection service activities (expected to be available in all acute NHS Trusts and/or acute hospital sites)			
Significant bacteraemia service e.g. <i>Staphylococcus aureus</i>, multidrug resistant organisms	Physical review within 24 h during working week and follow up as indicated clinically.	Infection specialist	Type of service may depend on practicalities such as geography eg. telephone consultation may be more appropriate
Intensive care/high dependency unit ward rounds	Ward round three times a week with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> intensive care team	Faculty of Intensive Care Medicine recommendation for 7 day microbiology input to consultant intensivist-led ward rounds may be impractical given the development of Pathology networks especially on weekends; hence it is felt that three times a week is a pragmatic approach <i>provided a 24 h, 7 day telephone advice service is available</i> (The Faculty of Intensive Care Medicine, 2016) https://www.ficm.ac.uk/sites/default/files/gpics_v2-public-consultation-draft-october-2018_0.pdf (Draft version updated guidance, 2018)
Review of patients with complicated infections	As indicated clinically. RCP recommends minimum 0.5–2.0 PAs which may include MDTs.	Infection specialist	
Antimicrobial stewardship ward round	Ideally on acute medical assessment units daily during normal working week; minimum 3 ward rounds per week on acute medical assessments.	Infection specialist <i>and</i> antimicrobial pharmacist	Department of Health, 2003 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/784894/UK_AMR_5_year_national_action_plan.pdf , (The UK's five-year national action plan, xxxx Public Health England 2015). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/417032/Start_Smart_Then_Focus_FINAL.PDF (Department of Health, 2019) Public Health England 2013. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/321891/Clostridium_difficile_management_and_treatment.pdf
<i>Clostridioides difficile</i> ward round	Weekly.	Infection specialist <i>and</i> infection prevention and control advisor <i>and</i> gastroenterologist/surgeon <i>and</i> pharmacist <i>and</i> dietician	Public Health England 2013. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/321891/Clostridium_difficile_management_and_treatment.pdf
Sepsis team MDT and advice	MDT Twice monthly. Senior microbiology input (ST4 and above; the form of advice) into management of all sepsis patients on 24/7 basis.	Infection specialist <i>and</i> sepsis team	https://www.ncepod.org.uk/2015report2/downloads/JustSaySepsis_FullReport.pdf NCEPOD, 2015 No national guidance for MDTs
Diagnostic laboratory duties (incorporating microbiology, virology, mycology, molecular diagnostics and parasitology)	Daily including on weekends. Authorisation of laboratory results, remote clinical advice (via telephone or email), laboratory liaison, quality assurance and troubleshooting (where a laboratory is on site).	Infection specialist with appropriate laboratory expertise	UKAS ISO15189
Primary care consultation, liaison and education	Daily as required (may vary according to Trust/hospital).	Infection specialist	
Liaison with Public Health team	Daily as required (may vary according to Trust/hospital).	Infection specialist	
Trust/Site specific services			
Inpatient ward rounds	Consultant review of all inpatients with infections requiring specialist input twice weekly, with more complex patients seen every day and new patients seen within 24 h of referral.	Infection specialist	If applicable to the Trust https://www.rcpmedicalcare.org.uk/designing-services/overview
Inpatient referrals	As required.	Infection specialist	If applicable to the Trust https://www.rcpmedicalcare.org.uk/designing-services/overview
Outpatient clinics	Weekly for both general infectious diseases referrals, and follow-up of discharged in-patients. Where there is a suitable expertise and support,	infection Specialist	If applicable to the Trust https://www.rcpmedicalcare.org.uk/designing-services/overview

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Table 2 (continued)

Service	Frequency	Compulsory attendance for infection service member	Comments/relevant standards
Infection inpatient MDTs	other outpatient services may also be delivered e.g. returning traveller, rapid access. Weekly.	Infection specialist <i>and</i> radiologist	If applicable to the Trust
Speciality specific services (if available in the Trust)			
Cardiothoracic/transplant/specialist intensive care/high dependency units	Ward round three times a week with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> cardiothoracic team	The Faculty of Intensive Care Medicine 2018 draft guidance recommends 7 day microbiology input
Level 3 neonatal unit ward round	Weekly with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> neonatal team	According to local protocols No national guidance available; however we consider it appropriate to have a weekly ward round to oversee control of infection in addition to 24/7 availability of clinical advice for level 3 units.
Infective Endocarditis ward rounds/MDT	Weekly with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> Cardiologist <i>and</i> antimicrobial pharmacist	European Society for Cardiology 2015 guidelines for the management of infective endocarditis recommend a multidisciplinary approach to the management of patients with Infective Endocarditis https://academic.oup.com/eurheartj/article/36/44/3075/2293384#108779571
Transplant MDTs	Weekly with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> transplant team	NHS England service specifications for solid organ transplant services: https://www.england.nhs.uk/wp-content/uploads/2017/04/liver-transplantation-service-adults.pdf https://www.england.nhs.uk/wp-content/uploads/2017/05/service-spec-adult-kidney-transplant-service.pdf (NHS England, 2017b; NHS England, 2017)
Haematology level 3 MDT	Weekly. For other levels of haematology service attendance should be determined locally according to need.	Infection specialist <i>and</i> haematology team	NICE guidance does not give guidance on frequency of attendance for infection specialist https://www.nice.org.uk/guidance/ng47/chapter/recommendations#multidisciplinary-teams (National Institute for Clinical Excellence, 2016a)
TB MDT	Monthly.	Infection Specialist <i>and</i> TB nurse <i>and</i> TB doctor (if different to infection specialist)	NICE 2016. https://www.nice.org.uk/guidance/ng33/resources/tuberculosis-pdf-1837390683589 (National Institute for Clinical Excellence, 2016b; NHS England, 2007)
Burns ward rounds/MDTs	Weekly.	infection specialist <i>and</i> burns team	
Paediatric infections MDTs	Monthly.	Infection specialist <i>and</i> paediatric team	
Oncology MDTs	Monthly.	Infection specialist <i>and</i> oncology team	
Bone and Joint MDT	Weekly with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> orthopaedic team	NHS England service specification 2013 https://www.england.nhs.uk/wp-content/uploads/2017/04/b07-bone-joint-infec.pdf (NHS England, 2013)
Neurosurgical MDT	Weekly with telephone and bedside consults as needed for urgent cases.	Infection specialist <i>and</i> neurosurgical team	
Outpatient clinics and community (including speciality and Trust specific services)			
Outpatient Antimicrobial Therapy (OPAT) Service	Daily for clinical advice, MDT once a week. OPAT clinic recommended.	Infection specialist <i>and</i> OPAT nurse	BSAC/BIA guidance BSAC OPAT guidance (Chapman et al., 2019) RCP recommend allocation of 2 PAs https://www.diabetes.org.uk/resources-s3/2017-09/030416%20DiabeticFoot%20FINAL%20pdf.pdf https://www.boa.ac.uk/wp-content/uploads/2016/08/DiabeticFoot-FINAL.pdf (British Orthopaedic Association, 2016)
Diabetic foot rounds	Weekly virtual or physical MDTs.	Infection specialist. Ideally within a MDT clinic with podiatry, diabetes, vascular <i>and</i> foot and ankle surgeons.	
Cystic Fibrosis (CF) MDT	Minimum fortnightly.	Infection specialist <i>and</i> CF team	NICE 2017: https://www.nice.org.uk/guidance/ng78/chapter/Recommendations#multidisciplinary-team (National Institute for Clinical Excellence, 2017) ECFS 2014: https://www.cysticfibrosisjournal.com/article/S1569-1993(14)00084-8/pdf (ECFS, 2014)
Genitourinary medicine (GUM) MDT	Quarterly laboratory service users meeting. MDTs as agreed locally.	Infection specialist <i>and</i> clinician in genitourinary medicine	
HIV MDT			https://www.england.nhs.uk/wp-content/uploads/2013/06/b06-spec-hiv-serv.pdf (NHS England, 2013)

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Table 2 (continued)

Service	Frequency	Compulsory attendance for infection service member	Comments/relevant standards
Hepatitis MDT	Quarterly laboratory service users meeting. MDTs as agreed locally Monthly.	Infection specialist and/or clinician in HIV medicine	If applicable to the Trust
Hepatitis clinic	Weekly.	Infection specialist and/or gastroenterologist	If applicable to the Trust
TB clinic	Weekly.	Gastroenterologist and/or infection specialist and/or respiratory clinician	As above: https://www.nice.org.uk/guidance/ng33/resources/tuberculosis-pdf-1837390688389

NB Some infection specialists sub-specialise in particular areas, for example mycology. Where required an infection specialist will call upon a colleague with specific expertise e.g. virology, mycology and parasitology. In certain specialist centres, other specialist MDTs may be appropriate e.g. oral maxillary – facial complicated infections.

nominated laboratory (see Table 1).

Priority may be given to inpatient samples over outpatient and primary care samples, given the difference in urgency for results and availability of someone to act on a result.

[Level of evidence: D]

Point of care (POCT) testing

POCT can be used by different staff grades, which allows for greater skill mix. They can also provide a fast turnaround time (TAT) for results, which can impact on patient care and/or infection prevention and control (IPC) measures. Currently available technologies which can impact on IPC include:

- Influenza/RSV/SARS-CoV-2
- *C. difficile*
- MRSA (methicillin resistant *Staphylococcus aureus*)
- Viral gastroenteritis
- CPE/CPO (Carbapenemase producing Enterobacterales/organisms)

The ever growing demand and perceived advantages of POCT needs to be balanced with potential disadvantages around costs and maintenance, quality control of technology being used, the limitations of what the POCT target repertoire, lack of quality assurance and potential adverse events attached to over reliance on one test.

Certain factors need to be considered when implementing POCT in trusts:

- Basing the platform at the “bedside” e.g. in the Emergency Department
- Training staff in other departments
- Governance, responsibility and accountability via a POCT governance team of which microbiology/virology must be part.
 - o There has to be diagnostic quality assurance of all microbiology and virology POCT tests, from pre-analytical through to post-analytical stages similar to standard microbiology/virology tests.
 - o The POCT service should be linked with local laboratory for IQC (internal quality control and assurance).
 - o The linked microbiology/virology laboratory should assist the POCT service team regarding EQA (external quality assurance) and fall within the local NHS Trust Pathology quality structure
- Maintenance and troubleshooting
- Funding
- IT integration with microbiology LIMS (Laboratory Information Management System) needs to be considered to fool-proof test results to patient care pathways and for Public Health reporting purposes
- Laboratory based “POCT”/molecular testing (molecular tests that could be used as POCT but might be better based within a 24 h and/or on-call laboratory setting)
- Availability of trained staff 24/7 - consider training blood science staff
- Need for culture for susceptibility testing, typing in outbreaks etc.
- Networks: Consider if POCT should be in every spoke laboratory or Trust
- Cost of platform (and ongoing costs)
- The utility of a laboratory diagnosis versus clinical diagnosis in emergency and outbreak situations

All POCT for respiratory viruses must be in line with Department of Health guidance: “Point of Care Tests for Influenza and other Respiratory Viruses” (Public Health England, 2018a, 2018b)

[Level of evidence: D]

Standard 2.2 delivery of an infection service to patients

The Royal College of Physicians provides overarching framework

guidance for the design of high-quality, coordinated and joined up clinical services (<https://www.rcpmedicalcare.org.uk/designing-services/overview>) and within these makes specific recommendations for infectious diseases service delivery and quality assurance.

Infection services vary in their scope of practice depending on availability of local resources such as workforce and isolation facilities as well as the demographics and needs of the population served. However, there are overarching standards which every infection service should meet.

- For England, every infection service must be demonstrably safe in accordance with the Care Quality Commission (CQC, 2019a, 2019b).
- Local services should interact with relevant regional and national referral/support networks.
- General standards for care should be aligned with the Trust quality and safety agenda.
- Where there are infectious diseases physicians with admission rights, an infection service should provide both in-patient and clinic-based services, ideally with designated beds or ward, and provision of isolation and negative pressure rooms.
- Outreach care should be provided through ward-based consults across all other specialties, which may result in joint care for some patients. In centres that have no inpatient bed-base, this outreach consult service will provide the only in-patient infection service.
- Early identification of patients that require specialist infectious disease support (e.g. HIV, hepatitis B, hepatitis C, TB returning travellers, those with previous drug resistant organisms, bone and joint infection, fungal infections in transplant and other immunocompromised patients) can be aided by regular input of the infection specialist to the medical admission units
- Inpatients should be cared for on a ward appropriate to their admitting condition. For example, an HIV positive patient presenting with a hip fracture should be admitted to an orthopaedic ward, with HIV specialists (infectious diseases or GU medicine) providing input on any aspect of HIV care, such as management of antiretroviral therapy.
- All patients, irrespective of the hospital they present to should be able to access the same standard of care, in particular those with more unusual or complex infections.
- Where infection services are disseminated across networks, access to services should be available via primary care urgent referral pathways, other primary care referral pathways (for clinically stable patients), and inter- and intra-hospital referral pathways.

Table 2 sets out how the main different activities which an NHS Infection Service may provide should be delivered. It is not an exhaustive list and services will vary between NHS organisations.

A major implication of these service specifications is that achieving the core service standards demands on-site infection specialist expertise at all acute NHS Trusts. They are not always feasible and may need to be delivered remotely in a hub and spoke model.

[Level of evidence: D]

Standard 3: Infection prevention and control

The input of an infection specialist in the control and prevention of healthcare associated infections is essential to the optimal functioning of a hospital and some community services. This contribution is usually provided as a specialist role, either “Infection Prevention and Control Doctor (IPCD)” and/or “Director of Infection Prevention and Control (DIPC)” (Department of Health, 2003). The nature and time allocated to the role vary across organisations depending on Trust size, number of sites covered, specialist sites within the organisation and available infection prevention and control resources in terms of nurses, antimicrobial pharmacists and clinical scientists. Although no specific

guidance exists for time allocated, it is accepted that this is a demanding and time-consuming clinical role. Sufficient dedicated time must be allocated to allow for the infection prevention and control role to be adequately covered.

Time must be allocated for infection prevention and control, including IPCD and DIPC roles. This is in addition to an Antimicrobial Stewardship Lead. The PA (programmed activities) allocations for these are detailed in Standard 5. These time allowances are to be considered as part of direct clinical care (DCC) and NOT supporting professional activities (SPA).

In general, this specialist role involves providing advice on policies for infection prevention and control, risk assessment and management of exposures to infection. It involves working with infection control teams, DIPC or IPCD on a local or regional basis, including liaison with the relevant health protection staff in the investigation and prevention of communicable diseases in the community. It may also involve assisting in the investigation and control of community outbreaks. Those working within public health laboratories will contribute to surveillance in local and regional departments of epidemiology and health protection.

Duties usually include:

- Oversight of alert pathogens e.g. *Clostridioides difficile*, MRSA, carbapenemase reducing Enterobacterales (CPE)/carbapenem resistant organisms (CPOs), vancomycin resistant *Enterococci* (VRE), influenza, norovirus, SARS-CoV2 etc with regards to provision of advice when appropriate, identifying and advising on outbreaks and transmission and prevention of infection, and escalation to local health protection teams and NHSE/1 as appropriate.
- Oversight of healthcare associated infection surveillance, including ensuring data submission via health-care associated infections (HCAI) databases.
- Detection, investigation and management of healthcare associated infection outbreaks
- Provide technical microbiological expertise in relation to:
 - o Water management e.g. attending water safety group
 - o Specialist ventilation systems
 - o Decontamination
 - o Personal protective equipment
- Contribute and support surgical site surveillance systems
- Overview of local control of infection policies and their implementation;
- Working with the infection prevention and control team within the healthcare organisation and if DIPC, responsibility for this team;
- Challenging inappropriate clinical hygiene practice as well as antibiotic prescribing decisions;
- Becoming an integral member of the organisation’s clinical governance and patient safety teams and structures;
- Becoming an integral member of the organisation’s infection control committee (ICC) and reporting as locally agreed
- Contributing to or producing the DIPC annual report on the state of healthcare associated infection in the organisation for which he/she is responsible and involved in its public release.

It must be recognised that the above work is *in addition* to the daily operational infection prevention and control service provided by other members of the infection service.

Standard 4: Workforce configuration

Skills-based workforce planning

The workforce contributing to each infection service must have the capacity and expertise to deliver its service commitments. A gap analysis approach could be used to map expertise and capacity of the workforce against service requirements.

Given changes in specialist training in medical microbiology,

Table 3
Specific roles and recommended PA time allowance (DCC and not SPA).
 Ideally the workforce will involve a skill mix of infection specialists to meet the needs of the local service.

	PA required & comments
Baseline (universal) roles	
Infection Prevention & Control Doctor	6.0–10.0 (depending on size of hospital/Trust and clinical case mix). Works with the DIPC on the oversight and management of communicable infections. Responds to infection prevention and control incidents and outbreaks and contributes to Trust level initiatives and investigations of these.
Antimicrobial stewardship lead	4.0–6.0* Works with pharmacy and infection specialists as well as the wards to ensure that prescribing is in line with local guidance. Oversees the development of local antimicrobial guidelines, often with other specialities.
Microbiology/Infection service clinical lead	2.0–4.0 (where required and dependent on shared duties between network lead and local lead). Responsible for developing the service including the laboratory and the team. Often assists in managing budgets and cost improvement programmes (CIP). Dependant on size of network and scope of the diagnostic service.
Primary care laboratory authorisation, liaison and collaborative working	2.0–4.0 Works with primary care to provide clinical advice and response to telephone enquiries, as well as collaborate on initiatives in the community e.g. screening, contribution to Protected Learning Time (PLT) events. Depends on number of GP practices served.
Liaison with Public Health team/CCDC	1.0–2.0 (variable depending on frequency incidents and outbreaks, Trust demographics etc.)
Liaison with ward doctors, telephone enquiries about antibiotics, clinical advice and laboratory authorisation	6.0–10.0
Speciality MDT ward rounds/meetings e.g. C. difficile, infective endocarditis	0.25–0.75*per weekly MDT commitment
Infection referrals (RCP recommendations for Infectious Diseases Workforce (RCP, 2019a, 2019b))	0.5–2.0 PAs per consultant depending on roles and in context with speciality MDT ward rounds/meetings. This may include attendance at other MDTs (e.g. haematology, bone infection), and other specialty ward rounds e.g. intensive care. Increasingly, patients with a confirmed bloodstream infection are seen without formal referral during infection consultation rounds.
Ward rounds (where relevant) (RCP recommendations for Infectious Diseases Workforce (RCP, 2019a, 2019b))	2.0–3.0 On average, consultants undertake two to three specialty-based ward rounds per week. Daily ward visits have become necessary to ensure that patients are reviewed daily by consultants and to facilitate timely review and discharge from hospital. This involves each consultant in an additional 0.5–1.0 PA per week. Each consultant team should have no more than 20 inpatients under their care at any one time, including when cross-cover is needed for leave.
Additional roles	
Director of Infection Prevention and Control (DIPC)	2.0 Directly reportable to the Trust

virology, and infectious diseases when considering workforce configuration for an infection service which integrate laboratory diagnostics with clinical diagnosis, advice and patient management it is important consider the expertise and competence of staff rather than traditional professional labels.

It is important that skills-based workforce planning does not neglect expertise which historically has been linked exclusively with traditional professional roles for example provision of clinical and strategic laboratory oversight by medical microbiologists.

The drive for increasing the roles of non-medically qualified professions such as biomedical and clinical scientists, nurses and pharmacists, as well as the recognition of other infection-related professionals such as infectious diseases (ID) physicians, public health doctors and epidemiologists has helped develop the notion of the infection team.

Extended roles for non-medically qualified professions increase efficiency and are to be welcomed; however where non-medical posts replace medical posts there should be a documented risk assessment of any gaps in capacity created by doing this.

Development of scientist roles

This aspect of the clinical service model is of the upmost importance. Scientists (both biomedical [BMS] and clinical [CS]) must be able to shoulder more of the responsibility within the laboratory.

This will also attract and retain key members of staff, by offering high quality training programmes and career opportunities as incentives. This must be developed in conjunction with best training models, with differing paths for biomedical and clinical scientists, and must be placed high in terms of priority.

The training programme to acquire HCPC registration as a clinical scientist (Scientist Training Programme) is common to both microbiology and virology, which fits well with the common part 1 FRCPath examination. Clinical scientists can attain consultant scientist status via completion of the Higher Specialist Scientist Training (HSST) programme and attainment of part 2 FRCPath. As HSST trainees they will specialise in either microbiology or virology. The HSST programme allows for CSs to garner more clinical experience and ultimately provide a consultant level service at the end of training. More detailed information on clinical scientist career pathways can be obtained from the National School of Healthcare Science <https://nshcs.hee.nhs.uk/>.

Consultant clinical scientists perform roles analogous to those of consultant microbiologists and virologists and therefore should be considered as part of the core consultant body. Currently clinical scientists in microbiology are in the minority. This should change as more trainees complete STP and HSST programmes, or by demonstrating equivalence to the Academy for Healthcare Science (AHCS). Consultant clinical scientists are well placed to lead innovative service improvements and laboratory quality assurance, usually in a well-defined area e.g. infection prevention and control.

In contrast, clinical scientists are found in many more clinical virology laboratories/teams. Their roles vary from being mainly laboratory orientated, (focusing on R&D and quality, for example) through to clinical roles which are largely indistinguishable from those of medically qualified consultants.

Previously for biomedical scientists to progress, they would follow managerial roles. Whilst a formal unified clinical training pathway does not currently exist for BMSs, the eligibility criteria for HSST has recently been widened to include appropriately experienced and skilled senior BMS to directly apply. Hopefully this will make it easier for BMSs to pursue a more clinical progression route. Departments may wish to encourage such development with obvious benefits from having knowledgeable, enthusiastic and experienced BMSs in particular areas, for example orthopaedics or renal medicine. Training should be delivered with appropriate governance.

Table 3 (continued)

	PA required & comments
Sepsis lead	<p>executive board with responsibility for the Trust Infection Prevention and Control team (including nursing) and the oversight and surveillance of communicable infections within the organisation.</p> <p>1.0</p> <p>Champions best practice and takes responsibility for the clinical governance of patients with sepsis. Also works closely with those responsible for antimicrobial stewardship in their hospital(s).</p>
OPAT lead	<p>1.0–4.0*</p> <p>RCP: Ad hoc OPAT patient reviews together with the weekly OPAT MDT (with nursing, pharmacy and microbiology colleagues) require 1–2 PAs per week</p>
Network laboratory lead	<p>3.0–4.0*</p> <p>Responsible for the development and operational management of the diagnostic laboratory service and workforce across a Pathology network. Accountable to Pathology management and in turn to the Trust executive board. A local laboratory lead may be required dependant on size of the network and scope of the diagnostic service.</p>

* PA allocation will depend on acuity and size of Trust, complexity of work. Some MDTs e.g. neurosurgery, may require more discussion than others and require more time. Diary exercises may be helpful in deciding what PA allocations are appropriate.

NB: Where Pathology networks exist involving different hospitals and trusts it is likely that some of these core roles will be shared across the network and PAs allocated accordingly.

[Level of evidence: GPP].

Development of physician assistants and advanced nurse practitioners/clinical nurse specialists

Clinical work may be also supported by Physician's Assistants (PAs) and Advanced Nurse Practitioners/Clinical Nurse Specialists. (ANPs/CNS). PAs can provide valuable support for review and management of infection in-patients, and ANPs may have a central role in delivering services such as OPAT/OAT and antimicrobial stewardship.

Salaried associate specialist (SAS) doctors

This term includes staff grade, associate specialist and speciality doctors. These are medical doctors whose experience and qualifications within their speciality varies but who have at least four years of post-graduate training, of which 2 are in their relevant speciality. Often these are doctors who have qualified and specialised overseas. Some may be working towards College registration within the UK.

They can make a valuable contribution to the infection service workforce.

Specialist dental NHS consultants and oral microbiology

These are clinical specialists possessing the same FRCPATH qualification as medical microbiologists and registered on the General Dental Council (GDC) microbiology specialist list. Although currently a small speciality, these individuals contribute to the management and delivery of infection services within both medical and dental contexts in some centres. Further information can be found in the GDC oral microbiology curriculum [GDC oral microbiology curriculum](#) (General Dental Council

Oral Microbiology, 2013).

[Level of evidence: GPP]

Standard 5: Maintenance of CPD and service governance

Maintenance of CPD to cover the full scope of work must be in accordance with the respective professional bodies of each member of the infection service.

RCPATH KAI 5 states:

“All senior medical and scientific staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level shall be compliant with regulatory requirements for continuing professional development (CPD)”.

Suggested evidence includes:

- Registration for CPD with appropriate organisation (e.g. RCPATH, Institute of Biomedical Science [IBMS], RCP or other equivalent schemes).
- Record of satisfactory performance
- Other evidence of appropriate CPD relevant to the whole scope of each individual's practice.
- Review of CPD at appraisal

Infection specialists are required to ensure they prove ongoing competencies in the areas in their scope of practice. This may be via documented peer review, MDTs and audits, in keeping with guidance from GMC and specialist accreditation bodies (e.g. RCPATH, RCP, CQC and UKAS).

The advent of the Shape of Training means that many new consultants will be trained in laboratory diagnostics and clinical medicine. A single integrated and co-ordinated infection service delivering the relevant elements of Table 3 provides better patient care and a better training environment than the more traditional separation of infectious diseases and microbiology. Co-ordination of this service should take into account the skills and interests of all available infection consultants, preferably on a rotational basis to ensure on-going CPD in broad based skills, knowledge and experience.

Standard 6: Training and teaching

All consultants have a responsibility to train specialist trainees, overseas medical training initiative (MTI) doctors, locums for service, junior doctors and other health care professionals working in their local healthcare network. Each trainee must have a named clinical supervisor for each module. Consultants need allocated time in their job plan to deliver training and supervision.

Consultants who are designated educational supervisors also need allocated time in their job plan to deliver this role. There is no national standard tariff for the time that should be allocated to perform the role of educational supervisors but the role will be discussed and formalised at job planning with the Clinical Director and designated SPA time provided. 0.25 SPA is recommended per trainee for direct supervision; dependent on the model of supervision/programme this may be shared between named educational supervisor and named clinical supervisor. Time allocation for educational supervisions may vary within the devolved nations.

<http://www.nact.org.uk/documents/job-descriptions/>

Additionally it is becoming increasingly recognised that medical infection specialists need to become more involved with training for both biomedical and clinical scientists. Clinical mentors are required for Higher Specialist Scientist Trainees (HSSTs), and the direction of travel within the workforce dictates further training involvement throughout the laboratory, with opportunities to shape (and even integrate some elements of) both medical and scientific training.

Likewise, the increasing involvement of PAs, ANPs and CNSs in clinical practice requires them to receive appropriate support and training in line with standards set out by the Faculty of Physicians Associates at RCP.

<https://www.rcplondon.ac.uk/news/faculty-physician-associates>

Teaching must ensure that standards of laboratory practice and patient care are in line with current national and international standards and evolving literature.

[Level of evidence: D]

Standard 7: Service research and development (R&D)

The 2006 Review of Pathology Services by Lord Carter of Coles (Lord Carter of Coles, 2016), plus the NHS improvement initiative to consolidate diagnostic services in Pathology networks actively encourage a programme of development of service change and development. Research at all levels is required in order to develop services, especially in the field of molecular testing and point of care testing. Virology in particular is a speciality which greatly benefits from partnership with academic institutions, has been evident with the SARS-CoV2 pandemic.

In accordance with the RCPATH KAIs (2018) all infection services must seek to maintain a programme of service development (clinical and diagnostic) and where possible, clinical and diagnostic research programmes. This is documented in KAI 8 which states:

“Laboratories shall demonstrate commitment to sustained innovation of their services through continuous quality improvement (CQI), which may include the conduct of formal academic research and the evaluation of novel approaches aimed at improving the health of patients and the wellbeing of the wider population”.

All infection service departments must have a programme of audit, at a clinical and laboratory programme to demonstrate effectiveness of any service improvements as well as the routine service.

Appropriate evidence of service development and research could include, but is not limited to:

- A documented approach to pursuing CQI using a systematic and rigorous methodology, with examples demonstrating the application of this in practice.
- Evidence that audit is being used to inform CQI rather than as a ‘standalone’ activity, mapping services against pre-existing standards.
- Research outputs relevant to improving patient experiences or outcomes.
- Records of systematic approaches to identifying, validating and adopting new technologies.

In addition to service development, formal research partnership with academic institutions wherever possible is to be encouraged.

[Level of evidence: D]

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A

See Table A1.

Table A1

Summary table – Explanation of grades of evidence (modified from Palmer K et al. BMJ 2008; 337:1832) (Palmer and Nairn, 2008).

Grade (level) of evidence	Nature of evidence
Grade A	At least one high-quality <i>meta</i> -analysis, systematic review of randomised controlled trials or a randomised controlled trial with a very low risk of bias and directly attributable to the target population or A body of evidence demonstrating consistency of results and comprising mainly well-conducted <i>meta</i> -analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias, directly applicable to the target population.
Grade B	A body of evidence demonstrating consistency of results and comprising mainly high-quality systematic reviews of case-control or cohort studies and high-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relation is causal and which are directly applicable to the target population or Extrapolation evidence from studies described in A.
Grade C	A body of evidence demonstrating consistency of results and including well-conducted case-control or cohort studies and high-quality case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relation is causal and which are directly applicable to the target population or Extrapolation evidence from studies described in B.
Grade D	Non-analytic studies such as case reports, case series or expert opinion or Extrapolation evidence from studies described in C.
Good practice point (GPP)	Recommended best practice based on the clinical experience of the authors of the writing group.

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Glossary of definitions and abbreviations

- BHIVA:** British HIV Association
BASHH: British Association for Sexual Health and HIV
BIA: British Infection Association
BMS: Biomedical Scientist
BSAC: British Society for Antimicrobial Chemotherapy
BTS: British Thoracic Society
CDR: Communicable diseases reporting
CQC: Care Quality Commission
DoH: Department of Health
FRCPath: Fellowship of the Royal College of Pathologists
GMC: General Medical Council
HBV: Hepatitis B
HCV: Hepatitis C
HIV: Human Immunodeficiency Virus
IDSA: Infectious Diseases Society of America
IPC: Infection Prevention and Control
MERS-CoV: Middle Eastern respiratory syndrome corona virus
MRCP: Membership of the Royal College of Physicians
NHS: National Health Service
NICE: National Institute for Clinical Excellence
OPAT: Outpatient antimicrobial therapy
PHE: Public Health England
RCPath: Royal College of Pathologists
RCP: Royal College of Physicians
SMI: Standards for microbiology investigations
TB: Tuberculosis
UKAS: United Kingdom Accreditation Service