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DOCUMENT CONTROL PAGE

Title:	Antibiotic and Antifungal **Treatment** Guidelines in Haematology/Oncology patients (Children's)
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Supersedes:	Antibiotic and Antifungal **Treatment** Guidelines in Haematology/Oncology patients (Children's) V4
Application:	RMCH/MCS

Originated / Modified By:	Originated by: Paediatric haematology/oncology, microbiology and pharmacy departments **Version 5** - Modified by: Heather McGrath Wilkinson, Bernadette Brennan, Zoie Aitken
Designation:	Paediatric haematology and oncology pharmacist, consultant paediatric oncology, consultant microbiologist
Ratified by:	RMC Policies and Guidelines Group AMSC Guideline Group
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Responsibility of:	Paediatric haematology/oncology, microbiology and pharmacy departments

Amendments:	Changes from V4 to V5 - Addition of isavuconazole - Updated posaconazole dosing and suggested dosing based on halving tablets - Updated guidance on risk stratification - Removal of rifampicin in addition to flucloxacillin for positive culture for staph aureus - Updated TDM information in line with mycology handbook - Removal of amphotericin liposomal test dose requirement

EqIA Registration Number:	27/17R

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1 Introduction

The Department of Health recommend that Trust have antibiotic prescribing guidelines to aid decisions relating to treatment of infection and minimise unnecessary / inappropriate antibiotic use.

Haematology / oncology patients are vulnerable to severe life-threatening infections that require prompt treatment with antimicrobials targeting the likely causative organisms.

2 Purpose

This document is a prescribing guideline to provide recommendations to guide empiric choice of therapy for treatment of paediatric haematology / oncology patients with suspected bacterial and/or fungal infection.

3 Roles and Responsibilities

The roles and responsibilities of named individuals within the organisation, regarding their duty to comply with this policy and protect patients from the risks of acquiring healthcare associated infection, are identified in the **Trust Infection Control Strategy 01** in accordance with The Health Act, Code of Practice, 2006 section 2.

The roles and responsibilities of named individuals within the organisation, regarding prescribing responsibilities are identified in the **Trust Medicines Policy.**

4 ANTIBIOTIC AND ANTIFUNGAL GUIDELINES for Paediatric Haematology / oncology patients

This antibiotic guideline should be used in conjunction with the “Guidance for risk stratification of febrile non-neutropenia in haemato-oncology patients”. This guidance is available on the Policy Hub on the Trust intranet and is contained within the Junior Doctor’s Handbook. The guidance provides advice on ‘risk stratification’ of patients, and the recommended clinical management pathway for the first 48-72 hours based on this risk. ‘Low risk patients with non-neutropenic fever will not require admission for intravenous antibiotics. All other patients require a minimum of 48 hours IV antibiotics as outlined below.

- All neutropenic (or suspected) patients (ANC $<0.5 \times 10^9$/L) will require admission for empirical IV antibiotics.
- **“Febrile” is defined as a SINGLE temperature of 38°C or above**

4.1 MANAGEMENT OF SUSPECTED SEPSIS

The first dose of antibiotics MUST be administered within ONE hour of presentation in neutropenic patients.

- Take blood cultures and full blood count and CRP
- Administer antibiotics **within ONE hour of presentation**
- Confirm if previous suspected/proven hypersensitivity reaction (HSR) to penicillin.
- Commence empirical treatment, as below.

4.2 - IF PATIENT IS FEBRILE (TEMP ≥38°C):

	Drug	Dose	Frequency	Notes
1st line No known penicillin allergy **AND** Not receiving **methotrexate** >500mg/m^2	**PIPERACILLIN/ TAZOBACTAM**	*<2kg or <1 month age: see neonatal formulary on EOLAS* *1 month – 18 yrs*: **90mg/kg IV** Max single dose 4.5 gram	Every SIX hours	IV bolus over 5 min.
Penicillin allergy (Suspected delayed non-severe (DNS) or unable to classify) **OR** Receiving **methotrexate** >500mg/m^2	**MEROPENEM**	*<2kg or <1 month age: see neonatal formulary on EOLAS* *1 month – < 12 yrs AND < 50kg*: **20mg/kg IV** *≥50kg and/OR 12 – 18 yrs*: **1 gram IV**	Every EIGHT hours	IV bolus over 5 min.

4.3 - IF PATIENT IS FEBRILE AND ALSO NEUTROPENIC (ANC <0.5x10^9/L) OR CLNICALLY UNWELL:

	Drug	Dose	Frequency	Notes
ANC <0.5x10^9/L **OR** **Clinically unwell** **OR** **New diagnosis leukaemia**	***ADD*** **AMIKACIN** **to antibiotics as per febrile above**	*<2kg or <1 month age: see neonatal formulary on EOLAS* *1 month (and >2kg) – 18 yrs*: **20mg/kg IV** Max single dose 1500mg	Every TWENTY-FOUR hours	Caution in renal impairment TDM mandatory Dosing differs from BNFc this is recognised practice in neutropenic sepsis AKI not requiring CVVHF: give 15mg/kg (max 1.5gram) then HOLD subsequent dose until level <5mg/L AKI requiring CVVHF: 10mg/kg for initial dose then discuss management with PICU Pharmacist Chronic renal dysfunction: give single dose 10mg/kg (max 1.5gram) HOLD subsequent doses until level <5mg/L Obesity: Dose using IDEAL body weight. Follow STAMP assessment. For further advice contact Pharmacy

4.4 PATIENTS WITH KNOWN SEVERE ALLERGY TO PENICILLIN – INITIAL THERAPY

- **Determine the severity/type of hypersensitivity reaction (HSR) as outlined in the paediatric antibiotic guidelines accessed via EOLAS**
- **Prescribe empirical antibiotic treatment with AMIKACIN AND SEEK URGENT ADVICE from microbiology, as detailed below.**
- **First dose of amikacin MUST be administered within ONE hour of presentation.**

For further guidance on empirical treatment refer to Trust Antimicrobial Guidelines "Prescribing for Patients with Penicillin Allergy". Where guidance refers to "penicillin/beta-lactam" as the drug of choice, this should be piperacillin/tazobactam, and where this refers to "Beta-lactam (non-penicillin)" this should be meropenem. Where a "non-beta-lactam" is recommended this must be discussed URGENTLY with microbiology.

	Abbrev	Description	Treatment	Notes
Suspected type 1 HSR	T1	Anaphylaxis: a severe multi-system reaction characterised by erythema, urticaria or angioedema and hypotension and/or bronchospasm OR Urticaria or angioedema without systemic features	**AMIKACIN 20mg/kg IV over 30 mins** **AND** **URGENT CONTACT MICROBIOLOGY**	Consider allergy testing. ALL beta-lactam antibiotics must be avoided until allergy testing.
Suspected delayed severe drug HSR	DS	DRESS TEN SJS AGEP		AVOID beta-lactam antibiotics.
Suspected delayed non-severe (DNS) drug HSR	DNS	Morbilliform: Generally benign Non-pruritic Unsightly Spares palms/soles Spares mucosa Systemically well *Onset 4 – 9 days post exposure*	**AMIKACIN 20mg/kg IV over 30 mins** **AND** **MEROPENEM* 20mg/kg (max 1g) IV over 5 minutes**	CONSIDER RE-EXPOSURE *In suspected DNS HSR the potential risk for re-exposure to beta-lactam antibiotics should be assessed against clinical need.
Unable to classify – drug HSR cannot be excluded	U		**AMIKACIN 20mg/kg IV over 30 mins** **AND** **MEROPENEM* 20mg/kg**	AVOID beta-lactam antibiotics where possible. *Discuss with Consultant and Microbiology.

			(max 1g) IV over 5 minutes	

4.5 FURTHER ACTION: (*refer to "Guidance for risk stratification of febrile neutropenia and non-neutropenia"*)

- If positive blood cultures change/rationalise therapy based on microbiology advice, cultures and sensitivities. Additional empirical treatment options may be required whilst cultures and sensitivities confirmed. Refer to guidance on page 8.
- **If organism reported as gentamicin sensitive, switch amikacin to gentamicin.**

Review at 48 hours of continuing fever	• In neutropenic patients with continuing fever, who are deemed clinically 'high risk': • STOP amikacin if blood cultures negative, irrespective of on-going fever AND in the absence of other signs of sepsis • Continue IV empirical broad-spectrum antibiotics until apyrexial for 48 hours • Repeat blood cultures at least every 48 hours. • Continue to investigate for clinical focus. For clinically 'low risk' patients with negative blood cultures at 48 hours, IV antibiotics may be stopped and the patient discharged home FOLLOWING DISCUSSION WITH A CONSULTANT. If there is persistence of organisms on repeat blood cultures at 48 hours, especially if Gram negative bacteria or CPE+, then consideration should be given to remove the line – REFER decision to attending Haematology/Oncology Consultant
At 96 hours	**If patient remains febrile at 96 hours INVESTIGATE FOR SUSPECTED FUNGAL INFECTION:** 1) Arrange imaging – CT chest, Consider CT/USS of other regions including the abdomen and CNS

For treatment options refer to:	2) Serum beta-D-glucan and galactomannan (caution – false positive beta-D-glucan with piperacillin/tazobactam) 3) Change prophylaxis to/ add empirical treatment in the unwell patient whilst investigations are being undertaken or where investigations are delayed. 4) If results of imaging are negative, change back to primary prophylaxis in high risk patients. 5) Where there is continuing neutropenic fever, continue to look for definitive evidence of invasive fungal infection. This should be guided by symptoms and signs. Consider repeat CT chest where there are no signs and symptoms but continuing fever. 6) If imaging reveals probable or proven fungal illness manage as invasive fungal infection. Every attempt should be made to make a positive microbiological diagnosis. BAL or biopsy is necessary to identify species and guide antifungal management.

4.6 ADDITIONAL MANAGEMENT OF PROVEN OR SUSPECTED INFECTION:

- Where blood cultures are positive seek advice from microbiology on cultures and sensitivities.
- The following additional empirical antibiotic cover may be considered:

Infection	Drug	Dose	Frequency	Notes
Positive blood culture for Gram positive organism	Add Teicoplanin (IV)	*1 month – 18 years:* **10mg/kg IV** Max. single dose 1200mg	Every 12 hours for THREE doses Then Every 24 hours	IV bolus over 5 min. Duration dependent on organism isolated If previous teicoplanin resistant coagulase-negative staph isolated give vancomycin with TDM (see Trust Antimicrobial Guidelines available on EOLAS)
Positive blood culture for *Staph aureus* infection	Flucloxacillin (IV)	*1 month – 18 years:* **50mg/kg IV** Max.single dose 2g	Every SIX hours	Flucloxacillin: IV bolus over 3-5 min. For penicillin allergic patients discuss management with a Consultant Microbiologist.

				Continue for at least 14 days from the date of the first negative blood culture, longer if a deep source is identified.
	MRSA or penicillin allergy Teicoplanin (IV)	*1 month – 18 years:* **10mg/kg IV** Max. single dose 1200mg	Every 12 hours for THREE doses Then Every 24 hours	IV bolus over 5 min. Continue for at least 14 days from the date of the first negative blood culture, longer if a deep source is identified.
	Line site swab Flucloxacillin (PO)	*1 month – 1 year:* 125mg *2-9 years:* 250mg *10-18 years:* 500mg	Every SIX hours	Check history for previous MRSA For penicillin allergic patients discuss management with a Consultant Microbiologist.
Positive blood culture for *coagulase negative staphylococcus*	*Teicoplanin*	*1 month – 18 years:* **10mg/kg IV** Max. single dose 1200mg	Every 12 hours for THREE doses Then Every 24 hours	IV bolus over 5 min. **If previous teicoplanin resistant coagulase-negative staphylococcus isolated give vancomycin with TDM (see Trust Antimicrobial Guidelines available on EOLAS)**

4.7 ANTIFUNGAL – TREATMENT OF INVASIVE FUNGAL INFECTION

ASPERGILLUS

- Targeted towards Aspergillus, as the most likely cause of fungal infection in neutropenic patients.
- A **switch in class** of antifungal therapy should be considered where breakthrough infection has occurred in patients on prophylactic or empirical antifungals.

Antifungal	Route	Loading dose	Maintenance dose		Frequency	Duration	Comments
Voriconazole	IV or PO	*Children < 2 years* 6mg/kg BD every 12 hours for two doses *Children ≥ 2 years* See BNFc	*For children under the age of 2 years* 4mg/kg *Children ≥ 2 years* See BNFc		TWICE DAILY	Discuss with Consultant	Oral bioavailability is approx. 96% **Care – drug interactions, see BNFC** For children **2-12 years loading** doses are ALWAYS given via the **IV route.** Use in combination with micafungin until therapeutic voriconazole levels are achieved. Monitor voriconazole levels (see section 4.7) Continue voriconazole as secondary prophylaxis.
PLUS Micafungin	IV	None	< 40kg	2mg/kg	ONCE DAILY	7-14 days in total	Start with Voriconazole. Continue until voriconazole levels within therapeutic range then de-escalate therapy accordingly. Monitor liver function.
			≥ 40 kg	100mg			

ASPERGILLUS (continued)

- For patient on prophylactic azole antifungals, where a switch in class is considered appropriate
- First line in patients receiving regular vinca alkaloids.

Antifungal	Route	Dose	Frequency	Duration	Comments
Liposomal amphotericin	IV	3mg/kg Dose may be escalated to 5mg/kg in severe infection	ONCE DAILY	Discuss with Consultant	Test dose no longer recommended Monitor the patient carefully for signs of hypersensitivity EVERY TIME amphotericin liposomal is administered Give over 30-60 minutes

CANDIDA BACTERAEMIA

- Lines should be removed where possible
- Liposomal amphotericin can be added in the unwell patient – discuss with Microbiology

	Antifungal	Route	Age	Dose	Frequency	Duration	Comments
Initial treatment	Micafungin	IV	< 40Kg	2mg/kg	ONCE DAILY	14 days from the date of the first negative blood culture, if no deep source identified	Monitor liver function.
			≥ 40 kg	100mg	ONCE DAILY		
If sensitive, switch to	Fluconazole	IV / PO		12mg/Kg (max 400mg)	ONCE DAILY		Pharmacy stocks 50mg and 200mg capsules, plus 50mg/5ml suspension

TREATMENT OF INVASIVE FUNGAL INFECTION – continued.

There are other rare invasive fungal infections (e.g mucormycoses) which will require treatment with alternative therapies. Refractory invasive fungal infections (IFI)/patients with IFI intolerant to 1st line therapy may require more intensive treatment. These individual cases should be discussed with a consultant microbiologist and mycology lab. Dosing information for therapies are provided below however should be used only as a guide. For further information discuss with pharmacy.

Antifungal	Route	Age/weight	Loading dose	Maintenance dose	Frequency	Duration	Comments
Posaconazole	PO using 40mg/ml oral solution	< 18 years	None	6mg/kg (max 200mg initially)	FOUR TIMES A DAY	Discuss with Consultant	**UNLICENSED IN CHILDREN <18 years old** Give with or immediately after a meal/nutritional supplement to ensure adequate absorption. For patients tolerating food/nutritional supplements the total daily dose may be given in two divided doses, 12 hours apart.
Posaconazole (cont.)	PO using 100mg tablets	>2 years AND >40kg	300mg TWICE A DAY-on-day 1	300mg	ONCE DAILY	Discuss with Consultant	**UNLICENSED IN CHILDREN <2 YEARS OLD AND <40KG** **Suggested dosing – discuss with pharmacy for advice** **≥ 15 kg to < 22 kg** 100 mg 12 hourly on day one, followed by 100 mg once daily thereafter **≥ 22 kg to < 31 kg** 150 mg 12 hourly on day one, followed by 150 mg once daily thereafter

							≥ 31 kg to < 36 kg 200 mg 12 hourly on day one, followed by 200 mg once daily thereafter **≥ 36 kg to < 40 kg** 250 mg 12 hourly on day one, followed by 250 mg once daily thereafter
	IV	< 18 years	6 mg/kg (max 300 mg) TWICE A DAY-on-day 1	6mg/kg (max 300mg initially)	ONCE DAILY	Discuss with Consultant	Unlicensed in children under 2 years of age Duration of therapy should be based on the severity of the underlying disease, recovery from immunosuppression, and clinical response.
Isavuconazole Doses are expressed as isavuconazole. 372 mg of isavuconazonium sulfate is equivalent to 200	IV/PO	>6 months to 2 years	3mg/kg THREE TIMES A DAY for 2 days (equivalent to 6mg/kg isavuconazonium sulfate)	3mg/kg	ONCE DAILY	Discuss with Consultant	UNLICENSED IN CHILDREN <18 years old Patients with one of the following features: • Has had an incomplete response to treatment* • Unable to achieve therapeutic drug levels with initial treatments

mg of isavuconazole.	IV/PO	>2 years	5.5mg/kg THREE TIMES A DAY for 2 days (equivalent to 10mg/kg isavuconazoium sulfate)	5mg/kg	ONCE DAILY		• Has had significant adverse effects ** with voriconazole • Initial treatment options are contraindicated*** *Must include voriconazole **a significant associated adverse effect includes development of photosensitivity, squamous cell carcinoma, visual disturbances, periostitis, cardiotoxicity and peripheral neuropathy ***due to significant drug interactions (not manageable by therapeutic drug monitoring and/or dose alteration) or pre-existing co-morbidities (e.g. renal impairment with liposomal amphotericin).

4.8 THERAPEUTIC DRUG MONITORING (TDM) of ANTI-INFECTIVES TREATMENT

- TDM is mandatory in all patients on amikacin and gentamicin (see EOLAS for guidance on gentamicin TDM)
- TDM is mandatory in all patients on treatment dose voriconazole and posaconazole.
- Blood samples are sent Clinical Biochemistry at MFT –Oxford Road Campus (ORC). Amikacin and gentamicin TDM will be processed at ORC. Anti-fungal TDM will be processed at the Regional Mycology Laboratory at MFT- Wythenshawe Campus.
- Results should be reported on HIVE. Please note that results for antifungals may take 3-5 days to be processed and reported. If a result is not available after 5 days, the Regional Mycology Lab can be contacted directly on 0161 2912124
- For more information on monitoring of blood levels of antifungals visit https://mrcm.org.uk/

Antibiotic drug	Route	Timing of level	Level & Action/Dose adjustment advice		Additional prescribing notes
AMIKACIN	IV	Trough – 24 hours after first dose	<5mg/L	Continue current dose and repeat levels every THREE days.	Check renal function before giving. AKI not requiring CVVHF: give 15mg/kg (max 1.5gram) then HOLD subsequent dose until level <5mg/L AKI requiring CVVHF: 10mg/kg for initial dose then discuss management with PICU Pharmacist Chronic renal dysfunction: give single dose 10mg/kg (max 1.5gram) HOLD subsequent doses until level <5mg/L Obesity: Dose using IDEAL body weight. Follow STAMP assessment. For further advice contact Pharmacy
			>5mg/L	HOLD next dose. Repeat level at 36 hours and until <5mg/L Increase dose frequency accordingly	
GENTAMICIN	IV	Trough – 18-24 hours post dose.	For monitoring and further information – see paediatric antibiotic guidelines on EOLAS		

Antifungal drug	Route	Indication	Level	On going Monitoring	Target range	Dose adjustment advice
VORICONAZOLE	IV	Treatment	Trough – 10-12 hours post dose. Day 3 after loading dose and each dose change	Repeat at day 5, then weekly until therapeutic. Then weeks 2,4,8 and 12.	1.3-5.7mg/L	Non-linear kinetics. Informed clinical judgement regarding target range is only possible on pre-dose sample as indicated. Levels <1.3mg/L – increase dose by 20% Levels >5.7-7mg/L – decrease dose by 20% Levels >7mg/L – omit dose then decrease by 30% Monitor LFTs. If bilirubin >50 consider omitting dose/review therapy. Discuss with Consultant/Pharmacy
	PO	Treatment	Trough – 10-12 hours post dose. Day 3 after loading dose and 2 weeks after each dose change	Fortnightly until therapeutic then at weeks 2,4,8 and 12. Every 1-3 months		
POSACONAZOLE	IV/PO	Treatment	Steady state (random level) - 10-14 days after 1st dose and each dose change.	Monthly for 3 months then every 3 months.	>1.0 mg/L	Levels <1.0 mg/L – increase dose by 20% Level >3mg/L – decrease dose by 10-20%. Monitor LFTs. If bilirubin >50 consider omitting dose/review therapy. Discuss with Consultant/Pharmacy.
ISAVUCONAZOLE	IV/PO	Treatment	IV: Trough 3 days after 1st dose and each dose change.	Repeat at day 5, then weekly until therapeutic. Then weeks 2,4,8 and 12. Every	2-4mg/L	Non-linear kinetics. Informed clinical judgement regarding target range and dose adjustments is only possible on pre-dose sample as indicated. Consult Mycology Reference Centre for advice.

			PO: 10-24 hours post dose window	three months thereafter.		Monitor LFTs. If bilirubin >50 consider omitting dose/review therapy. Discuss with Consultant/Pharmacy Levels above 5.0 mg/L have been associated with an increase in GI side effects.

- Where there is impairment of hepatic or renal function consult Pharmacy for advice/dose modifications. Caution with IV formulations of azole antifungals in renal impairment as the vehicle may accumulate causing adverse neurological effects

5 Equality Impact Assessment

The Trust is committed to promoting Equality, Diversity and Human Rights in all areas of its activities.

This policy has been equality impact assessed by the author using the Trust's **Equality Impact Assessment (EqIA) framework**.

The completed Equality Impact Assessment has been completed and submitted to the Equality and Diversity Department for 'Service Equality Team Sign Off'

There are no significant issues in relation to equality, diversity, gender, colour,

race or religion are identified as raising a concern.

6 Consultation, Approval and Ratification Process

The original guideline and any updates / amendments are sent out for consultation via:
Paediatric Haematology / Oncology Consultants
Specialist paediatric pharmacists
Antimicrobial Stewardship Subgroup

7 Dissemination and Implementation

Email copy for information: Antimicrobial Stewardship Subgroup

Haematology / Oncology Department

Medical staff Children's division via Clinical effectiveness Lead

Children's A&E

Lead nurses and Ward Managers RMCH

Publication in a web page format on the intranet via the policy hub. All previous versions are removed from the website at the time of update.

All previous versions are removed from the website at the time of update

Implementation of Trust approved procedural documents.

Process for Monitoring Compliance and Effectiveness

Compliance and Effectiveness is assessed by an annual Trust wide point prevalence audit. Results are reported to the Trust Infection Control Committee and Divisional Clinical Governance Committees.

The Lead Pharmacist – Antibiotics is responsible for monitoring compliance with the Paediatric Anti-Infective Prescribing Guidelines at Division and Corporate Level.

This will be completed on an annual basis and reported to the Trust Infection Control Committee and Divisional Clinical Governance Committees

The following audit standards will be monitored for compliance:

Criteria	Target
Antibiotics should only be prescribed for treatment of an infection or for prophylaxis of infection for indications outlined in the guidelines	95%
The choice if empiric antibiotic therapy should be in accordance with the Trust Anti-infective guidelines unless specific clinical factors prevent this. NB for the purpose of the audit prescribing according to culture and sensitivity results or according to microbiology advice is not considered empiric	Non-compliance < 12%
Allergy status should be documented on all medication charts and prescriptions in accordance with the Trust Medicine's Policy	100%
Patients should not be prescribed antibiotics that they have a documented allergy to	100%
The indication for antibiotic therapy should be documented on the medication chart	50%
Doses and dose frequency should be appropriate for age, weight, renal and hepatic function	95%
All prescriptions should have the review date or intended duration prescribed in accordance with the Trust Medicine's Policy	50%
IV antibiotics should only be continued beyond 48 hours if clinically justified due to clinical status of the patient or no suitable oral switch	95%

Any shortfalls identified will have an action plan put in place to address which will have timescales included for re-audit / monitoring. The action plans are monitored by the Antibiotic subgroup of the Trust Infection Control Committee.

8 References and Bibliography

Paediatric Formulary Committee. BNF for children [online] Available from www.medicinescomplete.com [accessed: 17/05/2024].

Summary of Product Characteristics available from www.medicines.org.uk/emc

"Guidelines for the diagnosis, prevention and treatment of invasive fungal diseases in paediatric patients undergoing allogeneic Haematopoietic Stem Cell Transplantation" UK Working Group; Version 1.0; 10th Oct 2017

Wythenshawe Pathology Handbook. Manchester University NHS Foundation Trust - Division of Laboratory Medicine. Available from: https://mft.nhs.uk/app/uploads/2023/09/Pathology-Handbook.pdf [accessed 17/05/2024]

9 Associated Trust Documents

Trust Medicines Policy.

Trust Infection Control Strategy

10 Appendices

"Guidance for risk stratification of febrile neutropenia and non-neutropenia in Haematology and Oncology" Version 2.0; Professor Bernadette Brennan; February 2024 access via MFT intranet Policy Hub"