One + all | we care

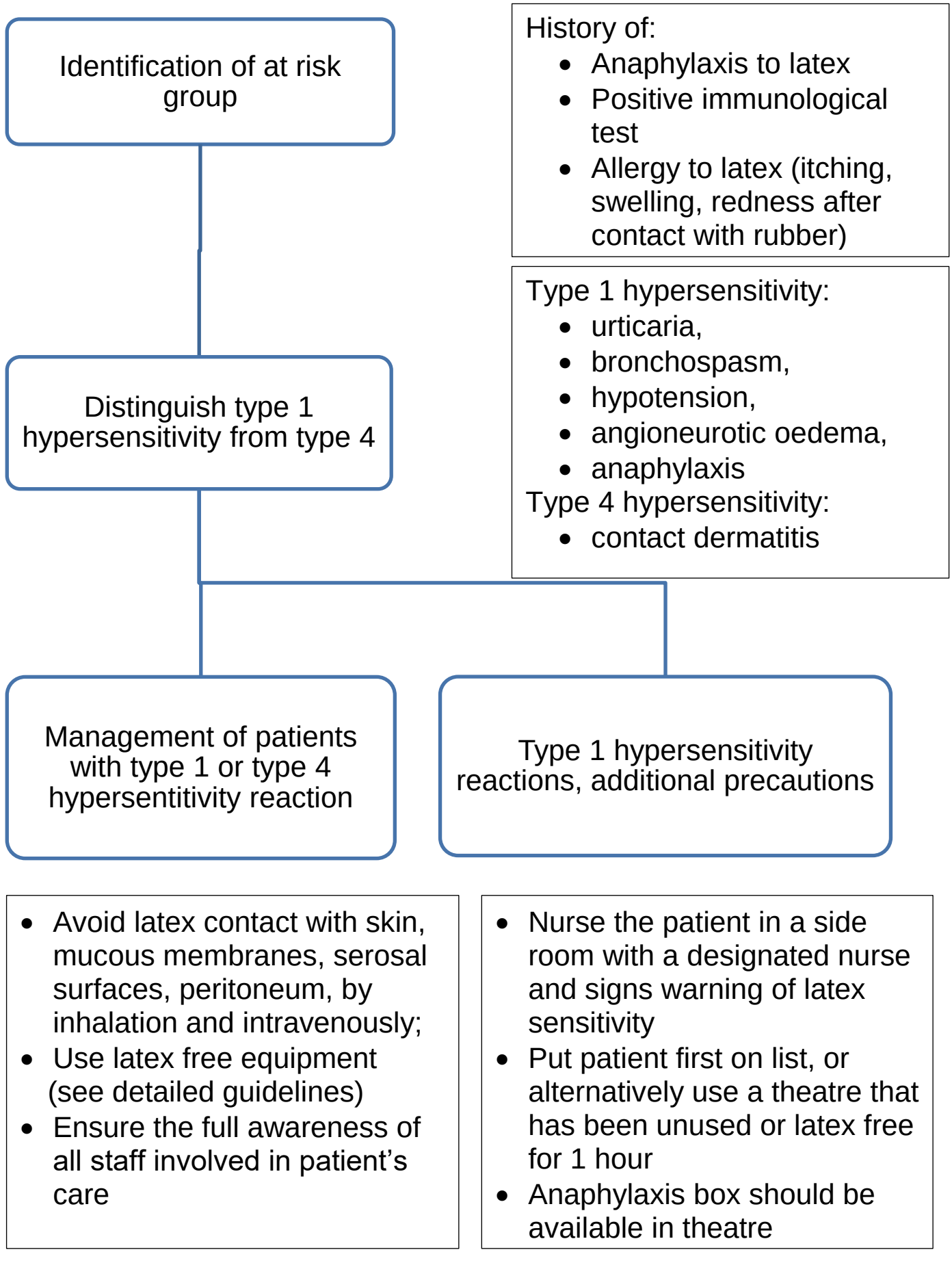
Royal Cornwall Hospitals NHS Trust

Anaesthetic Management of Patients with Latex Allergy Clinical Guideline

V10.0

August 2019

Summary: Anaesthetic management of patients with latex allergy



1. Aim/Purpose of this Guideline

1.1. This document provides guidelines for the safe management, within the theatre environment, of patients with an allergy to latex, with the aim of preventing an allergic reaction.

1.2. This guideline does not cover:

1.2.1 The recognition, treatment or investigation of latex induced anaphylaxis under anaesthesia. This is covered by the relevant AAGBI national guideline.

1.2.2 The precautions for avoiding latex sensitization in RCHT employees. This is covered by the RCHT guideline – Prevention and Management of Occupational Dermatitis and Latex Allergy in a Healthcare Setting.

1.3 This version supersedes any previous versions of this document.

1.4. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can't rely on Opt out, it must be Opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1 Background

2.1.1 In the largest series of anaesthesia-associated IgE-mediated hypersensitivity reactions published (from France), latex was the second-commonest cause of anaesthetic related anaphylaxis after muscle relaxants, accounting for 20% of cases. [1]

2.1.1.1 In contrast, in a more recent UK study latex was the fifth commonest cause of IgE-mediated hypersensitivity reactions accounting for only 5.8% of all anaesthesia associated reactions, with no cases diagnosed in the last two years of the study [2]. This decreasing trend has also been noted in other studies [1, 3]. This is commonly thought to be due to the use of powder-free and low- allergen latex gloves , and to the decreasing use of latex products in general, leading to decreased sensitisation.

2.1.1.2. There were also no reports of latex-induced anaphylaxis in the 6th

National Audit Project on perioperative anaphylaxis which was conducted by the Royal College of Anaesthetists and published in May 2018.

2.1.1.3 But perioperative anaphylaxis may vary over time and between different patients' populations. Fortunately most reactions to latex are not anaphylactic, but are Type 4 hypersensitivity reactions or simple irritant dermatitis

2.2 Identification of at Risk Groups

2.2.1 The following groups will need to have precautions taken as described in this guideline.

2.2.2 History of anaphylaxis to latex or a positive immunological test to latex (N.B. false negatives can occur to tests – see below).

2.2.2.1. History of allergy to latex:

- Itching swelling or redness after contact with rubber products or latex gloves.
- Swelling of tongue or lips after dental examination or blowing up balloons.
- Allergic reaction to rectal or vaginal examination, or to condoms.

2.2.3 Try to distinguish Type 1 hypersensitivity from Type 4 hypersensitivity. This will influence the level of precautions you need to take.

TYPE 1 HYPERSENSITIVITY	**TYPE 4 HYPERSENSITIVITY**
Urticaria (local or generalised), bronchospasm, hypotension, rhinoconjunctivitis, angioneurotic oedema, anaphylaxis and death	Contact dermatitis
Usually 20-60 minutes after induction	12-48 hours after contact
Confirmed by positive skin prick test OR blood test for specific IgE antibodies against latex (overall 75-90% sensitivity)	Patch testing confirms
Due to latex proteins Genetic predisposition	Minority due to latex proteins, majority due to other compounds used in rubber manufacture
First report in 1979	Recognised since 1929
Rare	Common
HIGH RISK OF ANAPHYLAXIS ON EXPOSURE TO LATEX	**VERY LOW RISK OF ANAPHYLAXIS ON EXPOSURE TO LATEX**

2.2.4 The following groups without a history of latex allergy should be treated with a high index of suspicion:

- Repeated catheterisation e.g. child with spina bifida (risk 500 – 1000 times greater than normal child), urogenital abnormalities.
- Health care workers / occupational exposure to latex.
- Multiple surgical procedures.
- Atopic nature / multiple allergies, especially allergy to avocado, kiwi fruits, chestnuts and bananas.
- Sensitivity to gloves, condoms and balloons
- Patients with severe dermatitis of their hands.
- Previous unexplained anaphylaxis.

2.3 Management – This section applies to all latex allergic patients (Type 1 and Type 4).

2.3.1 The key precaution is to avoid contact with latex on the skin, intravenously, by inhalation and particularly by contact with mucous membranes, peritoneum and serosal surfaces.

2.3.2 Use latex free equipment. Check that equipment is latex free either on its packaging or in the table below. For items not included in the table, and with unmarked packaging, the manufacturer should be contacted, although frequently the information can be found on the Internet. The single most important precaution is to avoid using latex gloves.

2.3.3 Ensure the full awareness of all staff involved with the patient, including surgeons, theatre and recovery staff, ward medical and nursing staff, and porters. A latex-free environment must be maintained not only in theatre but in recovery, on the ward and in transit.

2.3.4 Drugs in glass or plastic ampoules are safe. For vials and pre-filled syringes – see later in this guideline, as a few contain latex in the stopper or plunger. Avoid using latex containing vials if possible. If the patient needs a drug and there is no latex free alternative available, then use clinical judgement. Latex can leach into the drug from a vial stopper. This can cause an allergic reaction, although case reports are few and are mainly of local reactions rather than anaphylaxis. However in this situation, remove the stopper from vial first, and then mix and draw up the drug. This avoids getting a core of latex in your needle by puncturing the stopper.

2.3.5 Latex injection ports on intravenous fluids are safe provided they are not pierced. Most are latex free anyway – see list.

2.3.6 Use an HME filter at the patient end of the circuit. This will provide protection from the latex present within some anaesthetic machines and circuits.

2.4 Additional Precautions – This section describes additional precautions required only for patients suspected of having a type 1 hypersensitivity to latex.

2.4.1 Ideally, if there are no reasons not to, nurse the patient in a side room with a designated nurse and signs warning of latex sensitivity. Keep staff traffic to a minimum.

2.4.2 Put patient first on list, or alternatively use a theatre that has been unused or latex free for 1 hour. This time will reduce the level of latex particles in the atmosphere, although evidence is limited regarding the need for this degree of caution in operating theatres where all latex gloves are of the non-powdered type, as at RCH. Latex gloves are the main source of airborne latex in theatre and they can contaminate equipment. Therefore, do not use latex gloves when preparing theatre and remove all latex products from the theatre. A laminar flow theatre is ideal. Wash hands after touching latex objects. Change theatre scrubs if you have used latex containing items earlier. Put 'Latex Allergy' warning signs on theatre doors.

2.4.3 Consider recovering the patient in theatre in severe cases.

2.4.4 Have resuscitation drugs available. 'Anaphylaxis box', which contains all drugs needed in case of anaphylactic reaction, should be available in theatre.

2.4.5 Prophylaxis with antihistamine or steroid premedication lacks an evidence base and will not reliably prevent an allergic reaction. It may however make the reaction harder to recognise, and mask the early signs

2.5 Safe and Unsafe Equipment

ITEM	SAFE	SAFE WITH MODIFICATION	UNSAFE
Airway			
LMA	Fannin Integral Silicone Laryseal by Flexicare I-gel by Intersurgical LMA Unique Intavent Orthofix		
ET tubes	Portex Mallinckrodt single lumen Sheridan double lumen Mallinckrodt double lumen		Red rubber double lumen tubes
Guedel airways	Intersurgical		
Nasopharyn-geal airways	Portex Rusch		
Face masks	Intersurgical King systems from Armstrong medical 'Bubblegum mask' in various colours Vital signs Laerdal		Black Rusch masks
Circuit bags and tubing	Green bags safe Tubing safe		
Catheter mounts	Portex Intersurgical		
Gum elastic bougie	Brown - safe provided silicone coat intact Blue Sunmed – latex free Blue Meditech – latex free		
HME filters	Intersurgical Teleflex Humid-vent (paediatric)		
Oxygen masks	Intersurgical (including mask with integral rebreathing bag) Teleflex Hudson RCI Flexicare Ventimask		
Self inflating bag	Laerdal		

ITEM	SAFE	SAFE WITH MODIFICATION	UNSAFE
Intravenous			
Syringes	Becton Dickinson Plastipack Braun Becton Dickinson Discardit 2 component syringe Terumo		
Needles	Microlance Terumo		Butterfly needles with rubber ends – check packaging
Cannulae	Abbocath Veneflon Hydrocath Arrow Quickflash arterial cannula Vygon Arterial Leadercath ref 115.090		
Giving sets	Baxter giving sets EMC4042, MMC2071B, RMC2071B, RMC 9614, EMC9608 and BMC2236 Braun - Sangofix ES. Mediplus 5850 Medex (Code MX822-S).		
Extension sets / Drug infusion lines	Vygon V-Green Associated hospital supplies BL120		
Fluid warmers	3M Ranger warmer insert		
Paediatric giving set	Braun – Dosifix Baxter VMC9694		
PCA system	Vygon V-green PL160Y Vygon Protect-A- Line 2 Abbot Medical Baxter		
Taps, valves and 2/3 way connectors	Swan-Lock 16.5267 Intavent TIVA double lumen set code 7200A Mediplus 6510 3 way Coventry connector Codan R-lock one-way valve Vygon Infusafe Protect-dual lumen 0831.201		Cardiff valve – Vygon 284.00

ITEM	SAFE	SAFE WITH MODIFICATION	UNSAFE
Drugs			
Drugs	Anything in glass or plastic ampoules. Instillagel. Astra Zeneca xylocaine spray.	For vials and pre-filled syringes see advice elsewhere in this guideline.	??Syntocinon – 1 case report suggests that 'artificial oxytocin' may cross react with latex BJA 2007 98;845-6
Colloids and crystalloids	Gelofusine or bicarb in polyfusor bags or Ecobag		
Monitoring			
BP cuffs	Safe if marked latex free (should be all cuffs).	Other cuffs can be used if arm wrapped in cotton bandage. Avoid tubing touching patient	
ECG leads	Philips M1672A Datex-Ohmeda S/5 monitor leads. Hewlett Packard leads with codes M1510A, M1590A, M1611A and M1613A (codes only on packet not lead itself).	Cover other leads in latex free tape	
ECG stickers	Skintact 3M Medicotest		
Oximeter	Philips Intellivue Datex-Ohmeda S/5 monitor Ohmeda	If unsure cover finger with Tegaderm or latex free glove	
Temperature	Covidien Genius 2 tympanic probe and covers		
Pressure transducers	Medex MX9605 Ohmeda		
Oesophageal stethoscope	Hewlett Packard Vital signs		
CVP line	Vygon – Multicath 155.196 Vygon – Multicath 3 155.207 Vygon – Multicath 3 155.167 Vygon – Multicath 4 8158.167 Vygon – Leadercath 120.202		
CardioQ monitor	CardioQ oesophageal probe		

ITEM	SAFE	SAFE WITH MODIFICATION	UNSAFE
Other			
Operating tables, trolleys and operating table accessories	Foam padding Trolleys/tables marked latex free	If unsure, cover tables/trolleys with cotton sheet. Cover table attachments with cotton sheets or stockinette.	
Gloves	**Check for latex free symbol on packaging as many gloves do contain latex.**		**Latex gloves!**
Suction catheters	Yankauer/Unoplast/Pennine Sherwood/Coviden		
Epidural sets	Portex CSE Minipack Portex epidural minipack and RCH pre-packed epidural kits Ref 922/016/0509 Graesby Flo-safer epidural extension set Perifix by B-Braun		
Spinal sets	Vygon basic spinal set REF 199.30		
Ethyl-chloride	Cryogesic ethyl chloride direct stream		
Linb exanguin-ators		Anetic Aid Rhys – Davies exanguinator contains very small quantities of latex. Manufacturer considers it safe, but could cover limb in stockinette or velband in a Type 1 latex allergic patient before use.	
Tourniquets	Zimmer limb torniquet Anetic Aid limb tourniquet	If unsure, wrap limb in cotton bandage and put tube in stockinette. Cover tourniquet as it may touch other leg.	
Defib pads	Skintact DF27N		

ITEM	SAFE	SAFE WITH MODIFICATION	UNSAFE
Cell salvage	Electa, Orthopat and Haemonetics cell saver disposables Pall LeukoGuard leucodepletion filter		
Diathermy plates	Skintact plate		
Theatre cap	Theatre cap without elastic Universal elasticated theatre cap		
Tapes and dressings	Blue Dot elastic adhesive bandage Vecafix Tegaderm Hydrofilm Transpore Micropore Cosmopor Mepore (but may have latex in packaging) Durapore Smith and Nephew IV3000	Sleek. New version is latex free but old not. Check box.	Elastoplast Band Aid
Flowtrons	No problem		
TEDS	Urgo Preventex anti-embolism stockings		
Nasogastric tube	Rusch		
Urinary catheters	**Check for latex free symbol on packaging as some catheters do contain latex.**		**Latex catheters**
Warming devices	Bair hugger Warmtouch		
Defib pads	Skintact DF27N 3M (2346N)		
Stethoscope		Avoid tubing touching patient if unsure	

2.6 Drug Vials and Pre-Filled Syringes

Drugs in glass or plastic ampoules are safe, but those in vials and pre-filled syringes may not be. The latex content of intravenous drugs in vials and pre-filled syringes can be checked in the guideline on the RCH Intranet Pharmacy page. Some commonly used drugs in vials are also shown below. Different formulations of a given drug made by different manufacturers may differ in their latex content, so the information below ONLY applies to drugs made by the stated manufacturer.

Drug	Manufacturer	Latex content
Ceftriaxone	Stravencon	Latex free
Ketamine	Pfizer	Latex free
Paracetamol infusion	B Braun	Latex free
Propofol 50ml vial	Fresenius kabi	Latex free
Propofol 20ml vial	Norameda	Latex free
Remifentanil	Wockhardt	Latex free
Rocuronium	Hameln	Latex free
Thiopentone	Archimedes Pharma	**Contains Latex**
Vecuronium	Merck Sharp & Dohme	Latex free

3. Monitoring compliance and effectiveness

Element to be monitored	Adherence to published AAGBI and RCHT guidelines
Lead	Lead anesthesia consultant for each case
Tool	Audit and review of suspected cases of latex hypersensitivity and their management will take place in monthly anesthesia governance meetings.
Frequency	Will be determined by the incidence of cases.
Reporting arrangements	The committee reviewing the cases will be the anesthesia directorate. Cases will be discussed at audit meetings and the details will be recorded in the minutes.
Acting on recommendations and Lead(s)	See above.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within a month. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Anaesthetic Management of Patients with Latex Allergy Clinical Guideline V10.0					
Date Issued/Approved:	July 2019					
Date Valid From:	August 2019					
Date Valid To:	August 2022					
Directorate / Department responsible (author/owner):	Dr Anna Malik, Consultant Anaesthetist					
Contact details:	01872 258195					
Brief summary of contents	This document provides guidelines for the safe management, within the theatre environment, of patients with an allergy to latex, with the aim of preventing an allergic reaction.					
Suggested Keywords:	Anaesthesia, surgery, allergy, latex, hypersensitivity					
Target Audience	RCHT	CFT	KCCG			
	✓					
Executive Director responsible for Policy:	Medical Director					
Date revised:	January 2019					
This document replaces (exact title of previous version):	Clinical Guideline for the Anaesthetic Management of Patients with Latex Allergy. V9					
Approval route (names of committees)/consultation:	Anaesthetic and Theatres business group Governance Lead Anaesthetics					
Divisional Manager confirming approval processes	Roberta Fuller					
Name and Post Title of additional signatories	Not Required					
Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings	{Original Copy Signed}					
	Name: Matthew Body					
Signature of Executive Director giving approval	{Original Copy Signed}					
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only			
Document Library Folder/Sub Folder	Clinical / Anaesthetics					

Links to key external standards	The Association of Anaesthetists of Great Britain and Ireland **References:** • Dong, SW, Mertes, PM, Petitpain, N, et al. GERAP. Hypersensitivity reactions during anesthesia. Results from the ninth French survey (2005–2007). Minerva Anestesiologica 2012; 78: 868–78. • Low, A.E., McEwan, J.C., Karanam, S., North, J., and Kong, K.L. Anaesthesia-associated hypersensitivity reactions: seven years' data from a British bi-specialty clinic. Anaesthesia. 2016; 71: 76–84 • Carle, C, Harper, NJN. Anaphylactic reactions associated with anaesthesia. Anaesthesia and Intensive Care Medicine 2010; 11: 391– 3.
Related Documents:	• Procedure for Allergies or Idiosyncrasies to Medicines and Food • Standard infection prevention and control precautions policy • Pathology User Guide See also reference and bibliography: **Bibliography:** • 6th National Audit Project on perioperative anaphylaxis, Royal College of Anaesthetists, May 2018**.** • Association of Anaesthetists of Great Britain and Ireland. • Suspected anaphylactic reactions associated with anaesthesia. • Anaesthesia 2009; 64: pages 199-211
Training Need Identified?	No

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
01 Mar 12	V6.0	Now on current hospital template and headings. Amended; Page 6 Intralipid rescue box available from theatres, or Poldark ward if General Theatre is closed at night/weekends.	Sharon Dunstan Senior Pain Specialist Nurse.
23 Jul 12	V7.0	Amended; Page 2. No's 14 and 15 Monitoring should be documented on RCHT Trust MEWS Chart [Modified Early Warning System] and Analgesic Assessment chart. An Epidural Care Plan must be implemented	Sharon Dunstan Senior Pain Specialist Nurse.
3 Mar 14	V8.0	General rewording and reorganisation of contents. 2.1.5 – Wording changed as all prescribing now on EPMA. 2.3.3 – Clarification re occlusion. 2.7.2 – Treatment of hypotension now reads 250ml bolus in IV fluid rather than colloid. 2.7.4 – Algorithm for leg weakness added. 2.7.10 – Signs of local anaesthetic toxicity added. 2.7.11 – List management of local anaesthetic toxicity added. Intralipid rescue box is now situated on Tolgus ward and **not** Poldark ward. 2.7.12 – Reference for anticoagulation abnormalities.	Jayne Thomas. Pain Specialist Nurse.
July 2015	V.90	Reformatted to new template	John Gowenlock
April 2019	V.10	• .Update to formatting, EIA compliance sheet • Summary sheet added on page 2. • 1.2.2 Changed to: Prevention and Management of Occupational Dermatitis and Latex Allergy in a Healthcare Setting. • 2.1.1 Revised • 2.2.5 Added: Sensitivity to gloves, condoms and balloons • 2.4.6 Added: 'Anaphylaxis box', which contains all drugs needed in case of anaphylactic reaction, should be available in theatre. • 3. References added • 4.Bibliography: NAP6 added	Anna Malik

Appendix 2. Initial Equality Impact Assessment Form

Name of the strategy / policy /proposal / service function to be assessed **Anaesthetic Management of Patients with Latex Allergy Clinical Guideline for the V10.0**					
Directorate and service area: Anaesthetics, Critical Care and Theatres			**Is this a new or existing Policy:** Existing		
Name of individual completing assessment: Dr Anna Malik			**Telephone:** 01872 258195		
1. *Policy* Aim* *Who is the strategy / policy / proposal / Service function aimed at?*	This document contains guidelines for the safe management of patients with a known or suspected allergy to latex within the theatre environment				
2. *Policy* Objectives*	Ensure appropriate precautions are taken when caring for a patient with a known or suspected latex allergy within the theatre environment				
3. *Policy* – intended Outcomes*	Safe management of patients with known or suspected latex allergy				
4. *How will you measure the outcome?	Monitoring through incident reporting and case discussion at governance meetings				
5. Who is intended to benefit from the *policy*?	Patients.				
6a Who did you consult with	Workforce	Patients	Local groups	External organisations	Other
	X				
b). Please identify the groups who have been consulted about this procedure.	Anaesthetic and Theatres business group Governance Lead Anaesthetics				
What was the outcome of the consultation?	**Agreed.**				

7. The Impact
Please complete the following table. **If you are unsure/don't know if there is a negative impact you need to repeat the consultation step**.

Are there concerns that the policy **could** have differential impact on:				
Equality Strands:	Yes	No	Unsure	Rationale for Assessment / Existing Evidence

Age		**X**		
Sex (male, female, trans-gender / gender reassignment)		**X**		
Race / Ethnic communities /groups		**X**		
Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.		**X**		
Religion / other beliefs		**X**		
Marriage and Civil partnership		**X**		
Pregnancy and maternity		**X**		
Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian		**X**		

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:

- You have ticked "Yes" in any column above and
- No consultation or evidence of there being consultation- this excludes any *policies* which have been identified as not requiring consultation**. or**
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended.	**Yes**		**No**	**X**

9. If you are **not** recommending a Full Impact assessment please explain why.

No negative impact.

Date of completion and submission	April 2019	Members approving screening assessment	Policy Review Group (PRG) **APPROVED**

This EIA will not be uploaded to the Trust website without the signature of the Human Rights, Equality & Inclusion Lead.

A summary of the results will be published on the Trust's web site.