

Document Type:	Standard Operating Procedure	
Reference Number : 1992	Version Number: 4	Next Review Date: 31 December 2022
Title:	Hepatitis B Immunisation Procedure SOP	
Document Author:	Targeted Case Worker / Adult Nurse	
Applicability:	As defined in document	

1. **Purpose of this document** - This procedure states the method and process for administering Hepatitis B immunisation
2. **Scope of this SOP:** - Applicable to all registered nursing and medical staff working within the Torbay Drug & Alcohol Service, Torbay and South Devon NHS Foundation Trust
3. **Competencies required** - All nursing and medical staff working to this SOP will undergo training in administration of vaccination as well as how to manage anaphylaxis and resuscitation. All nursing staff will receive an annual update on immunisation, anaphylaxis and resuscitation.

All nurses will have knowledge of the 'Immunisation against infectious disease' manual (DOH 2006) available online at www.dh.gov.uk (last accessed 10.10.18)
<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>

The nurse will have knowledge of Torbay and South Devon NHS Foundation Trusts protocol on anaphylaxis/ anaphylactic shock, available via the intranet
<http://documents.torbayandsouthdevon.nhs.uk/TSDFT/G0337.pdf?web=1>

4. **Procedure / Steps: Patients covered** – all service users assessed as being at risk, presenting to the Torbay Drug & Alcohol Service will be offered vaccination
 - 4.1 The Torbay Drug & Alcohol Service Manager will ensure that all nursing and medical staff are fully aware and up-to date with this Standard Operating Procedure (SOP), including recording that the staff member has read and understood this SOP.
 - 4.2 A reference copy of this SOP will be kept in a designated easily accessible policy file within the Torbay Drug & Alcohol Service and also stored electronically on the Trusts public website.
 - 4.3 Prior to receiving any vaccination all service users must be provided with information relating to the benefits and risks associated with immunisation.

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- 4.4 A written assessment will be carried out and verbal consent will be obtained from the service user as a necessary pre condition to any vaccination being administered.
 - 4.5 The assessment will include information giving re: hepatitis B, assessment of risk taking behaviour which may lead to exposure to the virus and advice and information on reduction of risk in the future.
 - 4.6 The assessment must also include identification of any allergies or sensitivities, past or current hepatitis symptomology, pregnancy or recent febrile illness, all of which may postpone the commencement of a vaccination programme whilst medical advice is sought.
 - 4.7 The consent will include verification that the details of the vaccination will be forwarded to the clients GP.
 - 4.8 In order to receive a Hepatitis B Vaccination there needs to be a prescription. A standard prescription sheet is available for signing by the prescribing doctor / non-medical prescriber and must be in place prior to administration of any vaccine (P-MAR). – Appendix 1
 - 4.9 The vaccination administration must be carried out in a suitable environment, in a clinically equipped room with the appropriate privacy for discussion and with all the necessary equipment at hand (hand washing facilities, cotton wool, kidney dish, plasters, vaccines in fridge, sharps bin, clinical waste bin, anaphylaxis pack and resuscitation equipment).
 - 4.10 Universal precaution will be followed without exception due to the risk of cross infection and exposure to body fluids (blood).
 - 4.11 The staff member will explain the appropriate vaccine schedule (based on the vaccination policy and assessment) to the service user in preparation for the vaccine administration.
 - 4.12 The vaccine is removed from the fridge and placed in a kidney dish with a dry swab and plaster. Ensure a sharps bin is close to hand before administering the injection and make a note of the batch number and expiry date in the designated space on the prescription form.
 - 4.13 The service user needs to expose their upper arm/ deltoid muscle to receive the injection. The staff member should ensure that the service user is as comfortable and relaxed as possible in this position.
 - 4.14 The vaccine is administered by intramuscular (IM) injection into the relaxed deltoid muscle. Safety Needle should be used for administration of vaccine.
 - 4.15 Withdraw the needle and advise the service user to hold the swab for up to thirty seconds prior to applying a plaster to the area.
 - 4.16 Dispose of the needle in a sharps container and the swab in a clinical waste bin.

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- 4.17 Sign and date the prescription form to be uploaded onto HALO case notes when course completed.
 - 4.18 Ensure that the service user is aware of future dates and arrangements for their next vaccination or follow up blood test if required.

Management of reactions:

- 4.20 Advise the service user that they may experience some aching of the limb which has been injected, and to report with any other adverse effect immediately. Advise the service user to wait on the premises for twenty minutes post vaccination in order that they can be closely monitored for this initial period.
- 4.21 Although documented reactions are rare, adrenaline must be available at every immunisation session.
- 4.22 In the event of an anaphylactic reaction to immunisation adrenaline should be administered (as per the anaphylactic shock protocol) and 9999 calls made for emergency assistance.
- 4.23 First aid measures will be taken, priority being given to maintaining the service user's airway and breathing and circulation.
- 4.24 Verbal information of vaccination given and action taken should be given to the emergency services and the incident recorded in the service users notes.
- 4.25 Any reaction should be reported on the clinical incident recording form and via the Trusts incident reporting system Datix.

Storage:

- 4.26 The Cold chain will be monitored and maintained at all times. Daily fridge checks when service open. If cold chain broken – Datix and escalate to manufacturers for further advice.

5. Monitoring tool:

Standards:

Item	%	Exceptions
Safety – this document serves as a summary / checklist / reminder of the main points for nurses immunising		
Governance – Nurses immunising should ensure they follow this protocol	100	Nil
Offered vaccination	100	Nil
Uptake for vaccination		Refusals and medical indications
How will monitoring be carried out?		Via NTDMS returns, internal and external service audit and supervision
When will monitoring be carried out?		Quarterly
Who will monitor compliance with the guideline?	Service Manager, TDAS	
<p>Equality Statement. The Trust is committed to preventing discrimination, valuing diversity and achieving equality of opportunity. No person (staff, patient or public) will receive less favourable treatment on the grounds of the nine protected characteristics (as governed by the Equality Act 2010): Sexual Orientation; Gender; Age; Gender Reassignment; Pregnancy and Maternity; Disability; Religion or Belief; Race; Marriage and Civil Partnership. In addition to these nine, the Trust will not discriminate on the grounds of domestic circumstances, social-economic status, political affiliation or trade union membership.</p> <p>The Trust is committed to ensuring all services, policies, projects and strategies undergo equality analysis. For more information about equality analysis and Equality Impact Assessments please refer to the Equality and Diversity Policy</p>		

6. References:

National Treatment Agency (2006) Models of Care for adult drug misusers: Update 2006. London: NTA

Immunisation against infectious diseases –

<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>

Guidance for the prevention, testing and management of hepatitis C in primary care (appendices on hepatitis A and B vaccination guidance) RCGP (2007)

Drug Misuse and Dependence: UK Guidelines on clinical management (2007) London, Department of Health (England), the Scottish Government, Welsh Assembly Government and Northern Ireland Executive

7. Appendix

[Appendix 1. Prescription and Medication Administration Record](#)

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	1992		
Document title:	Hepatitis B Immunisation Procedure SOP		
Purpose of document:	This procedure states the method and process for administering Hepatitis B immunisation		
Date of issue:	31 December 2019	Next review date:	31 December 2022
Version:	4	Last review date:	
Author:	Targeted Case Worker / Adult Nurse		
Directorate:	Community		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Care and Clinical Polices Group Meeting Clinical Director of Pharmacy		
Date approved:	10 December 2019		
Links or overlaps with other policies:	Hepatitis B immunisation policy (substance misuse) 1920 BBV testing policy (substance misuse) 1847 Anaphylaxis and Anaphylactic shock protocol 0337 -Version 3 Cold chain policy 1913 Injectable Medicines Policy 1923		

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes <input type="checkbox"/>	
	Please select Yes No	
Does this document have implications regarding the Care Act? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
Does this document have training implications? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>

Does this document have financial implications? <i>If yes please state:</i>	<input type="checkbox"/>	<input type="checkbox"/>
Is this document a direct replacement for another? <i>If yes please state which documents are being replaced:</i>	<input type="checkbox"/>	<input type="checkbox"/>

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
July 2012	1	New	Care and Clinical Policies Group
Oct/Nov 2014	2	Revised	Care and Clinical Policies Group
02 December 2016	3	Revised	Care and Clinical Policies Group
31 December 2019	4	Revised	Care and Clinical Policies Group Clinical Director of Pharmacy

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

“The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves”. (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Quality Impact Assessment (QIA)

<i>Please select</i>				
Who may be affected by this document?	Patient / Service Users	<input checked="" type="checkbox"/>	Visitors / Relatives	<input type="checkbox"/>
	General Public	<input type="checkbox"/>	Voluntary / Community Groups	<input type="checkbox"/>
	Trade Unions	<input type="checkbox"/>	GPs	<input type="checkbox"/>
	NHS Organisations	<input checked="" type="checkbox"/>	Police	<input type="checkbox"/>
	Councils	<input type="checkbox"/>	Carers	<input type="checkbox"/>
	Staff	<input type="checkbox"/>	Other Statutory Agencies	<input type="checkbox"/>
	Others (<i>please state</i>):			

Does this document require a service redesign, or substantial amendments to an existing process? No	<input type="checkbox"/>
<i>If you answer yes to this question, please complete a full Quality Impact Assessment.</i>	

Are there concerns that the document could adversely impact on people and aspects of the Trust under one of the nine strands of diversity?	Age	<input type="checkbox"/>	Disability	<input type="checkbox"/>
	Gender re-assignment	<input type="checkbox"/>	Marriage and Civil Partnership	<input type="checkbox"/>
	Pregnancy and maternity	<input type="checkbox"/>	Race, including nationality and ethnicity	<input type="checkbox"/>
	Religion or Belief	<input type="checkbox"/>	Sex	<input type="checkbox"/>
	Sexual orientation	<input type="checkbox"/>	None	
<i>If you answer yes to any of these strands, please complete a full Quality Impact Assessment.</i>				
If applicable, what action has been taken to mitigate any concerns?				

Who have you consulted with in the creation of this document? <i>Note - It may not be sufficient to just speak to other health & social care professionals.</i>	Patients / Service Users	<input checked="" type="checkbox"/>	Visitors / Relatives	<input type="checkbox"/>
	General Public	<input type="checkbox"/>	Voluntary / Community Groups	<input type="checkbox"/>
	Trade Unions	<input type="checkbox"/>	GPs	<input type="checkbox"/>
	NHS Organisations	<input checked="" type="checkbox"/>	Police	<input type="checkbox"/>
	Councils	<input type="checkbox"/>	Carers	<input type="checkbox"/>
	Staff	<input checked="" type="checkbox"/>	Other Statutory Agencies	<input checked="" type="checkbox"/>
	Details (<i>please state</i>):			

Rapid Equality Impact Assessment *(for use when writing policies and procedures)*

Policy Title (and number)	SOP Hepatitis B Immunisation Procedure :1992		Version and Date	November 2016	
Policy Author	NMP/Clinical Lead				
An equality impact assessment (EIA) is a process designed to ensure that a policy, project or scheme does not discriminate or disadvantage people. EIAs also improve and promote equality. Consider the nature and extent of the impact, not the number of people affected.					
EQUALITY ANALYSIS: How well do people from protected groups fare in relation to the general population? <i>PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below</i>					
Is it likely that the policy/procedure could treat people from protected groups less favorably than the general population? (see below)					
Age	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Disability	Yes <input type="checkbox"/> No <input type="checkbox"/>	Sexual Orientation	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Race	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Gender	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Religion/Belief (non)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Gender Reassignment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Pregnancy/ Maternity	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Marriage/ Civil Partnership	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is it likely that the policy/procedure could affect particular 'Inclusion Health' groups less favorably than the general population? (substance misuse; teenage mums; carers ¹ ; travellers ² ; homeless ³ ; convictions; social isolation ⁴ ; refugees)					Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Please provide details for each protected group where you have indicated 'Yes'.					
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion					
Is inclusive language ⁵ used throughout?					Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Are the services outlined in the policy/procedure fully accessible ⁶ ?					Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Does the policy/procedure encourage individualised and person-centered care?					Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Could there be an adverse impact on an individual's independence or autonomy ⁷ ?					Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If 'Yes', how will you mitigate this risk to ensure fair and equal access?					
EXTERNAL FACTORS					
Is the policy/procedure a result of national legislation which cannot be modified in any way?					Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)					
Review of existing SOP.					
Who was consulted when drafting this policy/procedure? What were the recommendations/suggestions?					
ACTION PLAN: Please list all actions identified to address any impacts					
Action	Person responsible		Completion date		
AUTHORISATION:					
By signing below, I confirm that the named person responsible above is aware of the actions assigned to them					
Name of person completing the form	NMP/Clinical Lead		Signature		
Validated by (line manager)	Manager		Signature		

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes No

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our [GDPR](#) page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdf@nhs.net,
- See TSDFT's [Data Protection & Access Policy](#),
- Visit our [Data Protection](#) site on the public internet.