ר) 2023 may be Health gov.au	Queensland		(Affix identification label here)	
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			name(s):	
of Que <i>ight Ac</i> thout p ission i		Addre		
e State e <i>Copy</i> pted wi st perm	Facility:	Date o	of birth: Sex: M F I	
© The under the ed or ada To reque:	A. Does the patient have capacity to provide consent?		C. Patient <i>OR</i> substitute decision-maker <i>OR</i> parent/ legal guardian/other person confirms the following	
Except as permitted unde reproduced, communicated or To re	Consent? Complete for ADULT patient only		procedure(s)	
	Yes → GO TO section B		I confirm that the referring doctor/clinician has explained that I	
cept as ced, c	□ No → COMPLETE section A		have been referred for the following procedure:	
eprodu	You must adhere to the Advance Health Directive (AHD)		Sclerotherapy:	
L	or if there is no AHD, the consent obtained from a substi decision-maker in the following order: Category 1. Tribur			
	appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.			
	Name of substitute decision-maker:			
	Category of substitute decision-maker:			
-			Name of referring doctor/clinician:	
gu	Complete for CHILD/YOUNG PERSON patient only			
RITE IN THIS BINDING MARGIN	Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the		D. Risks specific to the patient in having sclerotherapy (Doctor/clinician to document additional risks not included in	
THIS BIN	proposed procedure and the consequences of non-tre – 'Gillick competence' (<i>Gillick v West Norfolk and Wist</i> <i>Area Health Authority</i> [1986] AC 112) → GO TO section B		the patient information sheet):	
/RITE IN	 No Parent/legal guardian/other person* with parental right responsibilities to provide consent and complete this for → COMPLETE section A 			SCL
	*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to th Queensland Health 'Guide to Informed Decision-making in Health Care and local policy and procedures. Complete the source of decision-maki authority as applicable below.	,		ERUTHERAPY CONSENT
	If applicable, source of decision-making authority (tick of	ne):		計
	$\Box \text{ Court order } \rightarrow \bigcirc \text{ Court order verified}$		E. Risks specific to the patient in <i>not</i> having sclerotherapy	रू
	□ Legal guardian → ○ Documentation verified		(Doctor/clinician to document specific risks in not having	ſτ
<i>с</i> о	Other person → ○ Documentation verified Name of parent/legal guardian/other person:		sclerotherapy):	
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view: 2023 3	Relationship to child/young person:			
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onte heck d: 08	B. Is an interpreter required?			-
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Clinical content review: 2023 Clinical check: 08/2023 Published: 08/2023	If yes, the interpreter has:			
	provided a sight translation of the informed consent for	orm		
	in person I translated the informed consent form over the telepho	ne	F. Alternative procedure options	
	It is acknowledged that a verbal translation is usually a		(Doctor/clinician to document alternative procedure not	
	summary of the text on the form, rather than word-by-wo	ord	included in the patient information sheet):	
317	translation.			
M96	Name of interpreter:			
SW9617				
	Interpreter code: Language:			

Government	URN:	(Affix identification label here) URN: Family name: Given name(s):			
	Family				
Sclerotherapy Consent	Given				
	Addres	ddress:			
	Date of	of birth: Sex: M F I			
G. Information for the doctor/clinician		I/substitute decision-maker/parent/legal guardian/other			
Information for the doctor/clinician The information in this consent form is not intended to b a substitute for direct communication between the doctor arent/legal guardian/other person. have explained to the patient <i>OR</i> substitute decision-maker <i>OR</i> parent/legal guardian/other person the contents of t orm and am of the opinion that the information has bee inderstood. Wame of doctor/clinician: Designation: Date: Date:	arent/ arent/ arent/ arent/ dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure: dure:	person have received the following consent and patient information sheet(s): □ 'Sclerotherapy' □ 'About Your Anaesthetic' (Adult patient only) □ 'About Your Child's Anaesthetic' (Child/young person patient only) □ 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)' (Adult patient only) □ 'Transfusion Consent: Fresh and/or Manufactured Blood Products (Full/Limited Consent)' (Child/young person patient only) On the basis of the above statements, 1) I/substitute decision-maker/parent/legal guardian/other person consent to having sclerotherapy. Name of patient/substitute decision-maker/parent/legal guardian/other person: □ I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person is Gillick competent and signs this form). 2) Student examination/procedure for professional training purposes: For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient OR substitute decision-maker OR parent/legal guardian/other person consent, assist with/ conduct an examination or procedure on a patient while the patient is under anaesthetic. I/substitute decision-maker/parent/legal guardian/other person consent to a clinical student(s) undergoing training to: • observe examination(s)/procedure(s) □ Yes Not eassist with examination(s)/procedure(s)			

Sclerotherapy

Adult and Child/Young Person | Informed consent: patient information



A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.

1. What is sclerotherapy and how will it help me?

Sclerotherapy is a procedure used to treat malformations of blood and lymph vessels. Vessels are tubular-shaped structures that carry fluids, such as blood or lymph throughout the body. A medication (called a sclerosant) is injected into a malformed vessel during sclerotherapy and causes the vessel to close, which in turn shrinks the malformation. Malformations may consist of many vessels, therefore you may need to have several treatments.



Image: Ultrasound guided injection into a vessel. ID: 14633959994. <u>www.shutterstock.com</u>

Malformations of blood and lymph vessels may occur in an unborn baby or during the first few years of a child's life. These malformations can be found anywhere in the body.

A blood vessel malformation is a cluster of abnormal veins.

A lymph vessel malformation is a region of abnormal lymph vessels, which appear as cysts filled with fluid. The cysts can be small or large, or a combination of different sizes.

The decision to treat malformations in veins or lymph vessels is often based on signs and symptoms including pain, deformity, appearance and functional limitations and is made following consultation with, and discussion between, the patient, their carers, and the team of clinicians associated with the care and treatment of the patient. Imaging with ultrasound, and sometimes Magnetic Resonance Imaging (MRI), is usually needed to fully assess the malformation and assist in deciding on the best treatment plan.

Sclerotherapy aims to reduce the size of the malformation and ease any associated pain. It can also improve the appearance and function of the affected area. Sclerotherapy will not 'cure' the malformation.

Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. Children will likely receive a general anaesthetic. If you received sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the sedation anaesthetic. If you have a drug or medication dependence, please tell your doctor/clinician.

Please tell the doctor/clinician if you are breastfeeding or pregnant, or suspect that you may be pregnant.

On the day of the procedure

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
 - your doctor/clinician will provide specific instructions about your medicines
 - take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show your doctor/ nurse what you are taking.
- If you feel unwell, telephone the medical imaging department for advice
- Tell your doctor/clinician if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
 - had previous problems and/or known family problems with anaesthesia
 - been taking prescribed and/or over the counter medicines, herbal remedies and supplements; this may include and is not limited to blood thinning medicines, the

contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin)

- allergies/intolerances of any type and their side effects
- You may be required to change into a hospital gown and remove some of your jewellery.

If you are booked to have the procedure with sedation or general anaesthetic as a day procedure, arrange for an adult to escort you home and stay with you overnight.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath when instructed by the doctor/clinician.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

For a parent/legal guardian/adult of a patient having sclerotherapy

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

 if the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/ adult.

During the procedure

An intravenous (I.V.) cannula is a small plastic tube that will be inserted into a vein, usually in your hand or arm. This is for any medication or fluids required during the procedure, including sedation.

Routine observations, for example blood pressure and heart rate, will be taken before the start of the procedure.

The skin around the malformation will be cleaned and a sterile drape will cover your body.

The doctor/clinician will use local anaesthetic to numb the skin near the malformation before inserting a small needle. If the malformation is close to the skin, it may be possible for the needle to directly reach the malformed vessel. If the malformation cannot be reached directly through the skin, a catheter (a long, very thin tube) will be passed through the normal vessels of the body until it reaches the malformed vessel(s).

X-rays or ultrasound will be used to guide the doctor/clinician to the target vessel, regardless of whether a needle or catheter is used to deliver the medication.

The doctor/clinician will also monitor the injection of the medication using x-rays or ultrasound.

The sclerosant medication is injected into a malformed vessel and causes the vessel to close, which in turn shrinks the malformation. You may need to have several treatments. It is considered better to have multiple smaller treatments, as this limits the amount of pain and swelling caused by each treatment. Each treatment is usually completed in 1 hour.

There are a number of sclerosant medications available. The treating doctor/ clinician (a radiologist) will choose the most suitable medication based on the type, size and location of the abnormality. At the end of the procedure the doctor/ clinician will remove the needle and/or catheter and a clear, dry dressing is applied.

After the procedure is complete, you will be transferred from the procedure room to a recovery area.

Your observations and puncture site will be monitored regularly. You may be required to rest in bed for up to 2 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

If the I.V. cannula is no longer required, it will be removed after you have recovered.

2. What are the risks?

In recommending the procedure, the doctor/ clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- pain and swelling, which often require medication
- the malformation doesn't respond as well as expected to the treatment, and further treatment is required.

Uncommon risks and complications

- skin breakdown around the injection site requiring antibiotics and possible surgery
- infection, requiring antibiotics and further treatment
- temporary nerve damage that improves over time. Permanent nerve damage is rare
- if the lesion is in the head and neck region, the patient's airway may become blocked and this may require prolonged breathing support and admission to the Intensive Care Unit

- blood in the urine if large doses of sclerosant medications (typically alcohol or Fibrovein) are used. This will require the patient to receive fluids via an I.V. cannula, and may continue for some time
- damage to the lungs if large doses of a sclerosant medication called bleomycin are used
- skin discolouration if bleomycin is used as the sclerosant medication
- damage to surrounding structures, such as blood vessels, organs and muscles, requiring further treatment
- excessive bleeding from the puncture site. This may require additional treatment and/ or corrective surgery
- bleeding is more common if you have been taking blood thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- an allergic reaction to injected medications, requiring further treatment
- the procedure may not be possible due to medical and/or technical reasons
- skin burns or damage from exposure to x-rays
- intoxication if alcohol is used as the sclerosant medication.

Rare risks and complications

- seizures and/or cardiac arrest due to local anaesthetic toxicity or if alcohol is used
- death because of this procedure is very rare.

If general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems such as heart attack or pneumonia
- stroke resulting in brain damage.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure¹.

If ultrasound alone is used, there is no radiation.

What are the risks of not having sclerotherapy?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure. Please contact the referring doctor/clinician to discuss.

3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.

4. What should I expect after the procedure?

Due to the action of the medication, the treated area will usually be swollen, tender and may appear bruised following treatment. Peak pain and swelling is expected around 12–24 hours following the injection. Swelling, tenderness and any bruising is expected to gradually improve over 1–2 weeks after the procedure.

During this time, if you are able to take them, pain relief medications such as paracetamol and ibuprofen may be used at recommended doses. If a compression bandage or garment is applied after the procedure, you will be advised on the care of this at the time of application.

The maximum effect of treatment is usually seen 2–3 months after the procedure. At this point in time a decision is made regarding the need for any further treatment. Several treatment sessions over a year or more are often required.

Following sclerotherapy, normal activity is encouraged, however, contact sports and heavy lifting should be avoided for 2 weeks after the procedure.

What are the safety issues when you leave hospital?

If you had sedation, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.

Contact your nurse or treating doctor immediately or go to your nearest Emergency department or GP (your local doctor) if you develop any of the following:

- pain unrelieved by over-the-counter pain relief medication
- signs of infection such as redness, inflammation at the puncture site or fever.

5. Who will be performing the procedure?

Doctors, radiographers, nurses, nuclear medicine technologists, sonographers and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your procedure. A doctor/clinician other than the consultant/ specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/ clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/ conduct an examination or procedure on a patient while the patient is under anaesthetic.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit <u>www.health.qld.gov.au/consent/students</u>.

6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website <u>www.qld.gov.au/health/services/hospital-</u> <u>care/before-after</u> where you can read about your healthcare rights.

You can also see a list of blood thinning medications at <u>www.health.qld.gov.au/</u> <u>consent/bloodthinner</u>.

Further information about informed consent can be found on the Informed Consent website <u>www.health.qld.gov.au/</u> <u>consent</u>. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.



Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.



In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:

1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au

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