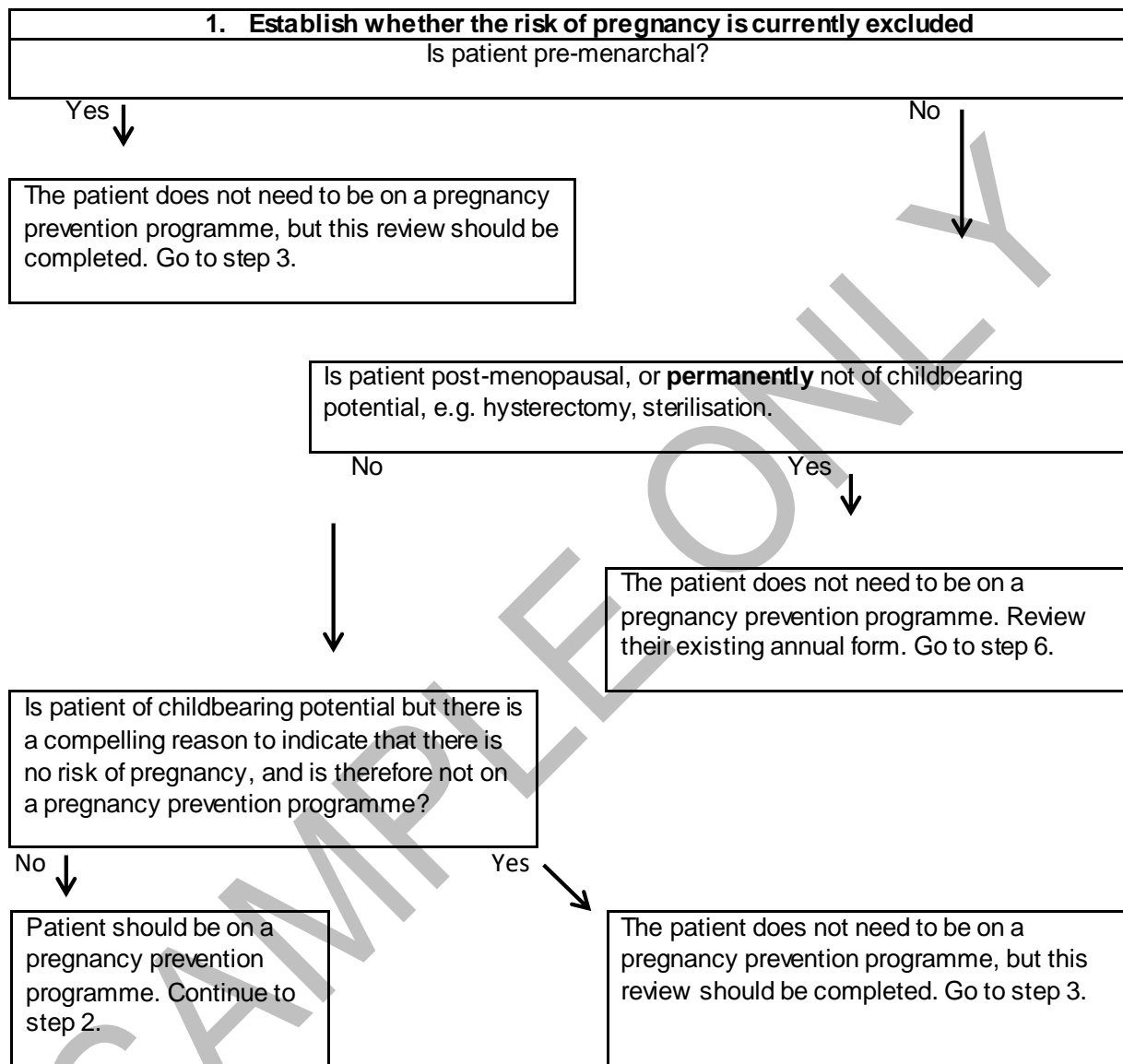


Procedure for management of female inpatients, already prescribed valproate, admitted to inpatient ward

Prescribing valproate to a woman of childbearing potential without the pregnancy prevention programme (PPP) conditions being fulfilled is contraindicated and represents an unlicensed use of the drug.^{1, 4}



2. A review of the patient's Pregnancy Prevention Programme (PPP) should be undertaken	
When is this review taking place?	
MONDAY TO FRIDAY 9am – 4pm	OUT OF HOURS, OR WEEKEND



Seek pharmacy support (if available)
Contact local ward pharmacy team, or duty pharmacist in main pharmacy dispensary.

Admitting prescriber to commence data gathering, see below.
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Pharmacy to commence data gathering
<ul style="list-style-type: none"> • Why is she using valproate (is it for bipolar / epilepsy / other)? • Ask if she is aware of the need for highly effective contraception, and the need to be on a Pregnancy Prevention Programme while taking valproate. • Is she on a PPP? • What type of contraception is she using for the PPP? • Has this contraception been used uninterrupted, with full compliance and full effectiveness? • Has she recently had unprotected sex that might have resulted in pregnancy? • Inform her of the known risks of valproate in pregnancy, and ensure that she understands she must not get pregnant whilst taking valproate. • Ask when her last annual valproate review was with her specialist (psychiatrist/ neurologist/ paediatrician). • Look for her Annual Risk Valproate form in electronic patient record (print if found).
Pharmacy: On completion, give a handover to the admitting prescriber immediately
Pharmacy staff: now continue to step 6.

Admitting prescriber to commence data gathering
<ul style="list-style-type: none"> • Why is she using valproate (is it for bipolar / epilepsy / other)? • Ask if she is aware of the need for highly effective contraception, and the need to be on a Pregnancy Prevention Programme while taking valproate. • Is she on a PPP? • What type of contraception is she using for the PPP? • Has this contraception been used uninterrupted, with full compliance and full effectiveness? • Has she recently had unprotected sex that might have resulted in pregnancy? • Inform her of the known risks of valproate in pregnancy, and ensure that she understands she must not get pregnant whilst taking valproate. • Ask when her last annual valproate review was with her specialist (psychiatrist/ neurologist/ paediatrician). • Look for her Annual Risk Valproate form in electronic patient record (print if found).
Prescriber: now continue to step 3.

3. Establish reason for using valproate	
Is valproate being used for a licensed indication (i.e. bipolar or epilepsy) or unlicensed-but-approved* indication (i.e. valproate in bipolar)?	No → Review reasons for unlicensed /off-label prescribing of valproate, and refer to the original prescriber, e.g. neurologist.

Yes/ Unknown

Licensed/ unlicensed-but-approved* indications are:

*Treatment of epilepsy (with **valproate**); Treatment (with **valproate*** or '**Depakote**') of manic episode in bipolar disorder when lithium is contraindicated or not tolerated / continuation of treatment after manic episode in patients who have responded to valproate* or 'Depakote' for acute mania.*

"Off-label" uses might include compulsive & aggressive behaviour, depression, neuropathic pain, dementia, migraine, as mood stabiliser, or to prevent clozapine-induced seizures.

4. Review the treatment	
VALPROATE USED FOR BIPOLAR	VALPROATE USED FOR EPILEPSY
<i>Only continue if valproate represents the best treatment option for bipolar after assessing the risks/benefits, and/or other treatments are ineffective or not tolerated. If necessary discuss with specialist who regularly manages her bipolar.</i>	<i>Continue treatment. Do not stop treatment without discussion with specialist who regularly manages her epilepsy.</i>
Is valproate treatment to continue?	

Yes

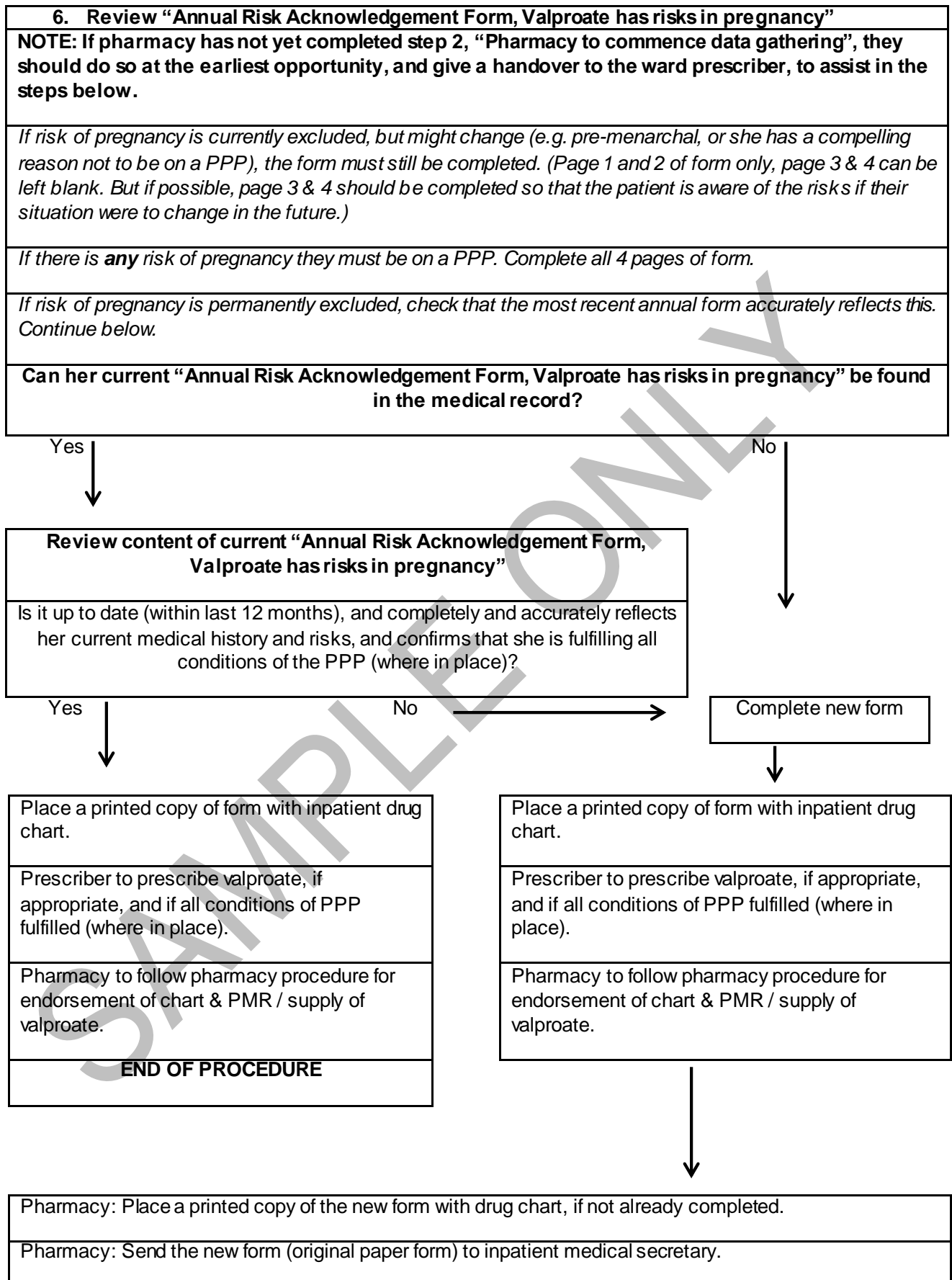
No

The conditions of the pregnancy prevention programme (PPP) continue to apply until the switch from valproate is complete. Refer to guidelines¹ on "Switching or discontinuing valproate".

5. Establish current risk of pregnancy
<i>Review information gathered so far, about possibility of pregnancy:</i>
<ul style="list-style-type: none"> ○ <i>Establish whether there is any possibility that she has recently had unprotected sex;</i> ○ <i>Establish whether there is possible non-compliance or non-effectiveness of contraception, e.g. use was interrupted;</i>
<i>Where necessary, refer her for highly effective contraception.</i>
<i>Pregnancy tests may not detect an early pregnancy that has occurred after unprotected sex in the preceding 3 weeks. Therefore, women should have a repeat pregnancy test 3 weeks after starting a new contraceptive method if there was any risk of pregnancy at the start of the contraceptive method, even if the first test was negative. ¹</i>
<i>Unplanned pregnancy: Refer to guidelines ¹ and SPC⁴.</i>

Could patient be pregnant?			
No	Yes, could be pregnant	No	Yes, could be pregnant
VALPROATE USED FOR BIPOLAR		VALPROATE USED FOR EPILEPSY	
Continue valproate treatment for bipolar.	Pause valproate treatment for bipolar. If possible risk of pregnancy, or is pregnant, valproate should be switched to another treatment, and the patient's treatment reviewed immediately. If clinically appropriate, the drug can be restarted provided that a negative serum hCG pregnancy test has been obtained a minimum of 14 days after the last possible day on which she could have had unprotected sex.	Continue valproate treatment for epilepsy.	If possible risk of pregnancy, or is pregnant, valproate should not be stopped for epilepsy. Her neurology team must be consulted. This consultation should be considered extremely urgent (within days) and should occur at the earliest possible opportunity after she is admitted. The consultation should involve a thorough discussion about the risks posed by either continuing the valproate or stopping it.
Now continue to step 6.			

SAMPLE ONLY



Inpatient medical secretary: Scan the new form to medical record (see Appendix 4). For CHS patients contact your pharmacy team for advice.

Inpatient medical secretary: Write to GP, including the new form (original paper form or scan). Scan copy to medical record (see Appendix 4). For CHS patients contact your pharmacy team for advice.

END OF PROCEDURE

SAMPLE ONLY