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National PATHOLOGY ACCREDITATION Advisory Council

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Consultation Phase Response Form for draft NPAAC Documents

Please complete and return this NPAAC Consultation Phase Response Form to the Secretariat by the requested date.

It would be appreciated if you could indicate whether the draft document is acceptable in its current form or not, and any potential regulatory costs associated with compliance to the proposed requirements.

Please note:

- The NPAAC Consultation Phase Response Form is in Word format to assist you in providing comments on the draft NPAAC document. To assist the Secretariat in collating responses, it would be appreciated if the template was not structurally modified.
- Adding extra table rows or pages is acceptable as required
- Responses can be forwarded to the NPAAC Secretariat via Email – npaac@health.gov.au and by post to NPAAC Secretariat, GPO Box 9848 (MDP 951), CANBERRA ACT 2601

FROM:

	Ms	**Date**	14 Dec 2018
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RESPONSE:

Draft Document Name: Requirements for Transfusion Laboratory Practice Fourth Edition 2018	
I consider the draft document acceptable in its present form	☐
I consider the draft document acceptable "as is" but I have proposed minor suggestions for improvement* **Please refer to my suggestion/responses overleaf*	☒
I do NOT consider the draft NPAAC document acceptable in its present form, and I have proposed various responses for consideration* **Please refer to my suggestion/responses overleaf*	☐

SUGGESTION/RESPONSE OVERLEAF:

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
4	C2.3 (iii)	The specimen label **must** include the date and time of collection and the collector identifier.	The specimen label **must** include the collector identifier. The date and time of collection should be on the specimen label. The sample can be accepted if the date and time of collection are recorded on the request and the collector's details on the request match the specimen label. *if the sample collector identifier can be matched to the request collector identifier and the request has the date and time of collection recorded, then the sample could be accepted. Neonatal samples have limited space for recording all information required. Time is not considered crucial as the validity of the sample can be set to midnight of the third day (C4.13)*
11	S.4.12(b)	A valid pretransfusion specimen that has been tested in accordance with the requirements of S4.1 and S4.5.	Replace with Standard 3.1 and 3.5.
14	S7.4 (d)	The potential for the maternal alloantibody to limit the availability of compatible red cell transfusion	*Remove from standard. This is difficult for a state wide service as there are a wide number of variables . What information would be expected to be added to the report?*
15	S8.2 (c)	Women presenting at delivery without prior pretransfusion testing during the pregnancy.	*Remove from standard. Many antenatal patients are ' shared care'. What difference in testing is expected to be performed compared to other patients who have previously presented during the pregnancy?*
20	S10.7	Laboratories must have written protocols on the pre-, intra and post transplant selection of blood components with respect to ABO and RhD groups of recipient and donor for transfusion, haemopoietic progenitor cell transplants (HPCT) patients who are to undergo or have undergone HPCT	Laboratories must have written protocols on selection of blood components with respect to ABO and RhD groups of recipient and donor for transfusion, haemopoietic progenitor cell transplants (HPCT) patients who are to undergo or have undergone HPCT *Why do the protocols need to be divided into pre-, intra and post transplant? Definition of each of these could be difficult and lead to more confusion.*
21	C10.11 (iv)	Most alloimmunised women have a high likelihood of further sensitisation. It is recommended that red cells	Most alloimmunised women have a high likelihood of further sensitisation. It is recommended that patients with high risk pregnancies (eg placenta acreta) are provided

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		matching the maternal C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^bS and s types are selected.	with red cells matching the maternal C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^bS and s types. *Most alloimmunised women are not transfused either during the pregnancy or post partum. Units are routinely provided to cover delivery for all alloimmunised patients. This would create a lot of extra testing, delays in blood supply and increase in the number of phenotyped units required from the Blood Service*
22	S10.13	ABO/RhD compatible with both the mother and fetus; if the fetal blood group is not known group O RhD negative red cells should be used	ABO/RhD compatible with both the mother and fetus; if the fetal blood group is not known group O RhD negative red cells should be used, providing the mother does not have an anti c or anti e. *Ambiguous - O Rh D Negative is not appropriate if the mother has a high titre anti c.*
23	S10.14	Laboratories must have a written protocol on the selection of blood components for chronically transfused patients.	*Definition of 'chronically transfused' is required*
23	C10.14(ii)	Red cells matched to the patient's ABO group and red cell phenotype may be provided where readily available.	Red cells matched to the patient's ABO group and red cell Rhesus and Kell phenotype should be provided. *Is there a definition of long term transfusion regimen as C9.2 (v) recommends 'Patients that may require long-term transfusion regimens should have an extended phenotype performed (for example C, c, E, ee, Jk^a, Jk^b, Fy^a, Fy^b, K, S and s) at the earliest practical time ideally before their initial transfusion. Consideration should be given to providing red cells of the patient's Rh and K types where readily available. If the phenotype cannot be identified, genotyping by the Blood Service should be considered.* *The blanket recommendation for matching C, c, E, e, K, Fy^a, Fy^b, Jk^a, Jk^b, S and s means when other patients present with antibodies to these antigens, there can be difficulty in sourcing required units. This recommendation seems to have resulted in little chance of*

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
			finding a unit with an extended phenotype in a large inventory. This also results in a lot of extra work when the patient may never have formed an antibody. Recent literature seems to indicate Rh K match is sufficient initially
24	S11.4	Pretransfusion testing, labelling and documentation must be performed in accordance with Standard 2, Standard 4 and Standard 5.	Should be Standard 2, Standard 3, and Standard 4.
28	C14.1 (ii)	Where laboratories are deploying manual and automated techniques they must submit QAP results for both methods	Where laboratories are deploying manual and automated techniques they must analyze QAP samples using both methods. *This is unclear and requires clarification.* *Is the intention the same sample is tested both manually and via automation? If this is the case, further RCPA enrolments would be required.* *Is use of a Banjo or Saxo reader considered 'manual'? Would the results need to be manually read by the Scientist in addition to the Banjo/Saxo reader and reported to QAP?* *Does this apply to transfusion surveys? When performing these investigations is it usual to use a combination of both automated and manual techniques in order to arrive at a final result. The actual combination would be dependent on the result obtained. This would vary from sample to sample as the result from each state of testing determines the next step. E.g. RCPA General Transfusion Survey.*
** Standard or Commentary*			

POTENTIAL REGULATORY IMPACT INCLUDING COSTS, ASSOCIATED WITH COMPLYING WITH PROPOSED REQUIREMENTS

1. Do you expect that additional activities will be required in order for your laboratory to comply with the revised Requirements?

☒ Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required to carry out the additional activities?

215 antenatal patients would require full phenotype performed in 2017. Time taken for full phenotype estimated to be 30min. Additional time to order phenotyped units and for the Blood Service to source and supply would be 30min for patient at delivery. These cases rarely use the units, as the crossmatch is to ensure product can be provided quickly if there is a post partum bleed. More complicated pregnancies, where patients are requiring transfusion during the pregnancy may need multiple allocations (these are the patients where the phenotyped units would be more likely to be used). It is estimated each order would take around 30min.

NB This assessment is based one statewide pathology service as an example.

Additional time to enter results into QAP and review outcomes

(b) What additional staff to you estimate will be required to carry out the additional activities?

No additional staff would be required.

(c) What costs to you estimate will be incurred as a result of the additional activities?

$15,000 for phenotypes (approx. cost would be $70/ patient). Genotyping could be performed at blood service (unknown cost). Additional labour costs managing blood orders.

Extra enrolments for RCPA : Depending on interpretation, each site (34) to purchase data management (Up to $ 10,880)

(d) Will these costs be one-off or ongoing?

Every year similar numbers of antenatal patients would be expected. (some repeat patients) .

Extra RCPA enrolment costs would be ongoing.

2. Do you expect that changes to existing processes/procedures or infrastructure will be required in order to comply with the revised Requirements?

☒ Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required as a result of these changes?

Updating procedures: 30min

(b) What additional staff to you estimate will be required as a result of these changes?

Nil

(c) What costs to you estimate will be incurred as a result of these changes?

Minimal

(d) Will these costs be one-off or ongoing?

One off

Any additional general comments including any potential costs associated with compliance to the proposed requirements (please provide specific examples):