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Comments on:

Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies

General.

This document duplicates what is in the NPAAC document. What purpose does this serve? Testing for overseas products will be done by overseas laboratories which are outside Australian jurisdiction.

Schedule 2
Who is going to accept the responsibility (and expense) of being labelled as the manufacturer of the multiple different products we use? The collecting centre? The Laboratory? The transplant centre?

Schedule 2 policy (1) (b) An approved quality system in place. This will be almost impossible for most centres to achieve as the availability of quality managers is very limited.
Schedule 2 policy (1) (b) is taken from Blood and indicates the lack of consultation with experts in the field of human transplantation. This is completely nonsensical for BMT. One would question which experts had been consulted if the ID standard immediately excludes one of our most important sources of HPC products – 10% of our overseas donors are from the UK.

(4) Acceptance and release of each product? Each type from each donor centre? Are we talking about one product (HPCs), or 3 (HPC-BM, HPC-cord, HPC-A) , or 5? (HPC-A related, HPC-A, unrelated, manipulated; HPC-A, related, manipulated; HPC-BM; HPC-cord.)

Schedule 3 (2) qualified interviewer. Definition of qualified interviewer.

Table 2
Under item J, including Hep C, the term ineligible suddenly appears, but is not defined anywhere in the document.
Item (q) relates to the exclusion for UK ACJD and is not a contraindication to BMT donation.

Schedule 4 Item (6) (b) define regulatory approval. Do any PCR tests have regulatory approval? There is no appropriate Medicare rebate to cover the large number of tests that are required within a short period of time for HPC donation, Is this planned as part of this and/or the NPAAC process?

Schedule 5

(1) (a) requirement for NAAT where available will increase considerably the expense of testing. Who will pay for this additional testing? This is not just the cost of the lab test; it is the procurement, transport, testing and rapid result return that is required fo rthese time critical samples and scenarios.

(1) © (ii) again illustrates the lack of understanding of human transplantation by whoever wrote this document. What is critical is that the donor is evaluated before the patient starts conditioning. We evaluate our donor 30 days prior to collection, to ensure they are medically fit, willing and safe to donate; then within 7 days of the patient starting conditioning therapy, then again within 7 days of donation. It is no good finding out within 5 days of donation that the donor is unfit.

(2) (5) again comes down to issues of what is approved, specified and acceptable.

Table 4

Incorrect- donors do not have to negative for Hep B and Hep C; they may be ineligible, but this does not mean that they may not be used.

General

This document sets out in a complicated and inaccurate way, processes which are already in place, but adds complexity and considerable cost.

It is of no value for international collections which accounts for just under half of our unrelated donors. And thus we are better served by complying with an international standard, like FACT, rather than a local one.

With kind regards,

Peter Shaw

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