

02/05/2022

Re: MED-A review by JACIE inspectors

To whom it may concern

Context

Until recently, JACIE Clinical inspectors have been tasked with reviewing a sample of MED-A forms at a centre against the original patient file(s) to check the degree of accuracy of data collected. This has been part of the inspection process since the very first inspections and was introduced in place of the EBMT audits that had previously been operating as a confirmation of data accuracy.

Issues

1. The inspection process has become increasingly lengthy and complex compared to the earlier inspections while the time available remains approximately the same. The MED-A review is a very time-consuming part of the inspection for the Clinical inspector, often consuming several hours for just 2 items on the Checklist (B9.1 and B9.1.3, 8th edition).

Inspectors will continue to check that centres have performed their own audit of accuracy at a minimum annually as per B4.8.3.2 *Audit of the accuracy of the data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Med-A Forms of the EBMT*

Therefore, the responsibility for providing evidence of an annual data audit will fall to the centre and inspectors will check that this has been performed. Failure to perform data audits or poorly completed audits will result in the centre being non-compliant against the standard.

2. Inspectors note significant variability in how well centres organise their patient files which can aid or handicap this process
3. GDPR requirements raise concerns among centres on how they can share this data with external reviewers
4. The need to move to remote inspections already led to removing the MED-A review from the process due to the difficulties in accessing patient data via remote means.
5. There is no connection from the JACIE inspections to the Registry in terms of feedback nor is this information used in any other meaningful way.

For the above reasons, the Committee agreed that JACIE will no longer include the MED-A review as part of the inspection process from 1 May 2022.

Yours faithfully,



Dr. Kim Orchard,

Chair JACIE Committee