“How do you find out when your centre is due for reaccreditation now that everything is postponed due to Covid-19 pandemic “

JACIE encourages you to submit reaccreditation applications well in advance of the expiry date of your current accreditation, taking as expiry date any extension of your accreditation granted because of the Covid19 pandemic. JACIE will not contact centres that are due for reaccreditation but instead, centres should send their Application form approximately 1 year prior to Accreditation expiry.

“What are the requirements to become an Inspector? Ways of contact? “

There is a list of qualifications and experience candidates must have to become JACIE inspectors, depending on the area of expertise (Clinical inspector (pediatric/adult), hematopoietic progenitor cell collection facility Inspector, cell processing laboratory inspectors and quality management inspector). The full list of requirements can be found on the EBMT website here: https://www.ebmt.org/inspectors/how-become-inspector
For further information and submitting applications please contact inspectors@ebmt.org.

“Tuula: As a QM inspector the scope during the on-site inspection might involve visiting/interviewing professionals from all parts of the B, C, D and CM. How do you manage this in a practical way during the inspection days? “

I find that prior to going onsite it is really important to understand the structure of the quality system so that you can go through all common standards with one person (document control, audits, training, Adverse Incidents etc.) as number of standards are replicated across the sections. I would then look at a few sample documents for each area to confirm that the document control, formatting is applied consistently (if part of the same QMS).
In C, CM, D I would then focus on the Standards that are specific, or which would be challenging for those areas. It’s often things like validation & qualification.
I think its also very important to work closely with your other inspector colleagues. So, I often tend to sit in together interviews with programme/medical directors but also might ask fellow inspectors to ask specific questions in their interviews. The shared time with the other inspectors can be really valuable in comparing how embedded the quality system is in all the areas.
Lastly, this obviously becomes a lot harder if there’s 2 quality systems to inspect. In my experience it’s really important to prepare as much as possible in advance in order to get it all done.
Hope this is of some help. Preparation and planning helps and the more complex the programme, the more preparation needed. Completing as much of the checklist as possible before going on site also helps as then you are mainly checking whether the systems are in fact in use as part of the day to day working.

“We have an upcoming inspection for IEC (CART). We have all relevant documents, and protocols etc ready. My concern is how we will demonstrate this process to the inspector without any actual data of CART or examples. Is the planned documentation enough? “

Depending on the country, this is a normal situation and should not constitute any problem. The inspection will focus on the readiness of the centre to start administering IEC, so planned documentation should be enough. As an example, it is important that outcomes measures for IEC therapies and subsequent audits of these outcomes are defined and planned. If the centre has administered other kinds of IEC, examples of documentation for these other therapies should also be provided.

“Iris: Is it necessary to get written consent of the key personnel for being listed in the application to JACIE? “

No, requesting consent is not necessary since the lawful basis for processing the key personnel data is Article 6(1)(b) - contract: *processing is necessary for the performance of a contract to which the data subject is party.* The data subjects are part of the institution that wishes to receive the accreditation and in order to be able to achieve the objective, the key personnel minimal information shall be assessed according to the standards. However, they shall be informed that their data is shared with JACIE, in the JACIE Application form this information is provided.

“I have a question on outcome data of patients after transplant. CCs are supposed to present outcome data during (re)accreditation but reporting is often very poor (or not including engraftment data). The need of those data for AC/CCs is one of the important arguments of Donor Centers/Registries why a limited set of patient outcome data are important to receive. How is this issue addressed during inspection? Are there plans of JACIE inspectors to increase importance to request these quality data? “

Indeed this is a very important question. As an inspector I -of course- take carefully in account the results of the annual quality meeting of the center with the mandatory indicators on follow up.
But I agree it is not enough. Maybe we should think about a follow up of patients on the long term. Including survival but also quality of life. A 1 year to 5 years post-transplant ?
And of course, improve and forward on a regular way these results to donor centers or registries

“Our centre applied for JACIE reaccreditation and first time IEC assessment in November 2021. Due to covid, we are still in the backlog waiting to be inspected. Would it be beneficial to separate the 2 inspections in order to progress with IEC assessment much quicker or do we need to be reaccredited first in order to deliver IECs? “

Unfortunately, not. In order to get the IEC accreditation, the Clinical unit, collection and process unit need to also be accredited.

“For countries with a rare language, what is the planning for future inspections in these countries?“

Currently, the solution for centres that speak a language for which there is no Inspector pool is to have an on-site inspection in English with the help of a facilitator. In these cases, the Centre needs to translate documentation into English and perform the inspection not in the native language, and there is a discount applied to the accreditation fees. To move forward, and considering that remote inspections are probably here to stay, we are looking at the possibilities of performing remote inspections with facilitation/translation, too.

“Anna: How long should you work with JACIE and EBMT before becoming an inspector?“

It depends on the area of expertise. We require clinical, collection and processing inspectors 5 years prior professional experience. For quality management inspectors the requirement is 3 years prior experience,
There is a list of qualifications and experience candidates must have to become JACIE inspectors, depending on the area of expertise (Clinical inspector (pediatric/adult), hematopoietic progenitor cell collection facility Inspector, cell processing laboratory inspectors and quality management inspector). The full list of requirements can be found on the EBMT website here: https://www.ebmt.org/inspectors/how-become-inspector
For further information and submitting applications please contact inspectors@ebmt.org.

“When do you expect inspector training will resume? There are no dates on the website at present. “

The next inspector course is expected to take place in 2022 autumn. The dates and format of the course are still to be confirmed. All the information will be posted on the EBMT website at https://www.ebmt.org/events

“What subject matter would Inspectors like to see in videos that are sent as pre inspection evidence? “

Please see the video requirements on the EBMT website at https://www.ebmt.org/ebmt/documents/jacie-video-requirements-centers

“I have been on the inspectors list for some time, and was due to take part in an inspection in 2020 and 2021, however cancelled due to COVID. Are these now being reinstated as I have not heard anything from JACIE to enable me to attend as a trainee. “

We are continuously inviting trainees for onsite inspections whenever it’s possible. As JACIE has started different inspection formats as well, at the moment we are not offering trainee opportunities for full remote and short process inspections, which limits the possibility for trainee involvement. As soon as possible we will be in touch with a trainee opportunity.

“Really useful presentations thank you. The video required for a virtual inspection - is this a tour of the different aspects of the programme such as inpatient unit, laboratory? “

Please see the video requirements on the EBMT website at https://www.ebmt.org/ebmt/documents/jacie-video-requirements-centers

“Do you anticipate hybrid inspections being the way forward? “

It is certainly a potential way of moving forward but the process needs to be developed. Current formats of inspection are onsite and remote.