Hematol Oncol Stem Cell Ther (2017) 10, 195–197

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ORIGINAL RESEARCH REPORT

Considerations in setting up and planning a graft processing facility

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Received 23 March 2016; accepted 30 March 2017
Available online 13 December 2017

Abstract
The graft processing facility forms one of the core components of a clinical haematopoietic stem cell transplant program. The quality of a graft is instrumental in leading to consistent and reproducible outcomes of engraftment and other parameters. As such, meticulous planning and consideration is required and will include core elements including physical design and clinical correlates. The successful running of such a facility depends on an overarching quality program and adherence to local and international regulatory guidelines.

Introduction

One of the key elements in performing a successful stem cell transplant, whether autologous or allogeneic is to ensure that a high quality graft is infused into the patient. As such, any consideration for starting a stem cell transplant program needs to include the setting up of a reliable graft processing facility. Reliability implies not only producing a high quality graft but ensuring that this is done consistently with minimal unnecessary variation between grafts. It also means putting safety considerations as one of its key priorities.

Main functions of a graft processing facility

The critical processes are:

- Overseeing the safe receipt/handling of donor stem cells
- Defining the product: its quality and characteristics
- Determining what if any manipulation is required for the transplant

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https://doi.org/10.1016/j.hemonc.2017.12.001

— Ensuring product safety including testing for infectious diseases as well as safe transport and delivery of the cells back to the hospital/patient.
— Maintaining full traceability of the graft product [1,2]

Building a graft processing facility

The facility, at its core, has to be able to provide minimally manipulated products in support of a transplant program. These stem cell grafts are usually obtained from either apheresed peripheral blood, bone marrow or cord blood and knowledge of the varying principles in processing each different donor source is required.

Crucial to this planning which will require practical financial considerations, there has to be an understanding of the anticipated clinical workload and the projected future transplant activity of the program. This would then influence the determination of physical space required and allow for growth. Ensure that the processing costs are factored into the final calculation of the cost or revenue of a transplant episode as this will inform all financial calculations. Manpower can start small but should expand appropriately with any substantial increase in transplant activity. It is however recommended that even with a small startup program, there should be a quality-focused individual in place who may not necessarily be full time but should have a certain independence from the routine processing and be familiar with basic principles of stem cell processing. If the facility is sited in a blood bank, access to a quality manager is usually made easier [3,4].

Ideally, one should not only factor in physical growth of the program but also an expansion into more complex cell processing: for example Haplo-identical transplants with CD34 selection or protocols of T cell depletion.

Additional resources can become available as a result of this increased activity allowing for purchase of laboratory equipment. As complexity and volume increases, the facility may look into automation like cell washers and controlled rate freezing as well as cell selection devices like the CliniMACS.

The increased stem cell processing activity also facilitates the development of a robust training program for the facility staff and exposure to more hands on training. Improved familiarity with larger volumes of activity and greater standardization via standard operating procedures (SOPs) will also allow for better consistency and quality of the product.

Prior to the planning of a new graft processing facility, it is useful to take a strategic view and some of the relevant questions to be asked are:

- Does every transplant program require a processing lab?
- Does centralising reduce costs and make best use of manpower?
- How many transplant centres are there and what is the overall current and future projected transplant activity?
- Should the facility be hospital based or should there be involvement of the Transfusion Services.

Some countries/transplant programs have taken the view that graft processing has many parallels with blood component processing and have therefore leveraged on this. Some examples include the NHS Blood and Transplant which provides graft processing and cell therapy services for numerous clinical transplant programs across the UK and the national Blood service of Singapore which supports the smaller clinical programs including paediatrics and private hospitals.

Strengths of transfusion laboratories and blood banks

- Harvesting and handling of apheresis and cellular products
- Quality systems with a focus on ''processes"
- Product safety focus including stringent donor testing
- Product labelling and release criteria including infectious disease testing
- Multidisciplinary: technologists, similar staff training; microbiologists
- Back-up power supplies

Required equipment

The list of required and desired equipment necessary for graft processing has been detailed elsewhere [5]

General considerations for any equipment:

- Reliable maintenance and availability
- Qualification/validation and monitoring of equipment/reagents
- Back up/contingency.

Clinical considerations

The quality and content of the graft is an essential parameter in determining engraftment and immune reconstitution as well as the incidence of graft versus host disease and relapse.

It is important therefore to have a close relationship with the clinical transplant program and be viewed as an integral part of the transplant team. The laboratory should be represented at clinical transplant planning meetings so that expected collection dates and transplant dates are clearly communicated, and the laboratory staff has access to engraftment data that can, and must be correlated with the stem cell collection data (CD34 count, total nucleated dose, & viability). This will give an assurance that the clinical outcomes match the reliability of processing and can also serve as an indicator if processing standards are suboptimal.

The graft processing facility should also be aware of the types of transplants being performed. An autologous program will normally require expertise in cryopreservation and thawing while supporting an allogeneic program may only need capabilities in handling fresh cells although some graft manipulation (red cell depletion) may be required if marrow grafts are used for ABO mismatched allogeneic transplants. Having said this, some graft processing