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Handling, processing and disposal of stem cell products in Europe: A survey by the cellular therapy and immunobiology working party of the European Society for Blood and Marrow Transplantation

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Abstract

Background. There is considerable heterogeneity in processing of stem cells for hematopoietic stem cell transplantation across Europe. The Foundation for the Accreditation of Cellular Therapy (FACT)–Joint Accreditation Committee International Society for Cellular Therapy and European Society for Blood and Marrow Transplantation (EBMT) (JACIE) standards provide minimum guidelines that, however, leave room for significant variations in practices at the individual transplantation center (TC). *Methods.* To better understand the extent of heterogeneity in storage conditions, quality controls (QCs), graft processing and disposal, a questionnaire was developed, reviewed by the Cellular Therapy and Immunobiology Working Party (CTIWP) and sent to all EBMT TCs. *Results.* In this study, 288 TCs from 46 countries (32 European, 14 associated) responded to the survey. Long-term storage is performed mainly either in liquid nitrogen or in the vapor phase of liquid nitrogen with 10% dimethyl sulfoxide (DMSO; 58% of centers). In case of microbiological contamination, most TCs make a case-by-case decision in collaboration with the clinicians. CD34+ counts are performed routinely either before and/or after thawing. Some centers perform additional QCs. DMSO is generally not removed (83%) and the graft is thawed at the bedside (68%) in a water bath (78%). There is heterogeneity between the centers regarding duration of storage and graft disposal. *Discussion.* Overall, this survey demonstrates that the majority of responding TCs uses standardized procedures (intracenter standardization). However, significant intercenter variations persist, which warrant further standardization and investigations on clinical and financial consequences. Additionally, efforts should be undertaken to provide more specific international guidelines on storage duration and graft disposal, which may also have an important impact on health care services worldwide.

Key Words: *dimethyl sulfoxide, quality control, stem cells*

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Introduction

Autologous and allogeneic stem cell transplantation (HSCT) is a potentially curative therapeutic option for many nonmalignant and malignant diseases [1]. Patient factors (including age, gender, underlying disease, remission at transplantation, previous therapies), mobilization schedules, collection techniques, graft processing and storage conditions all have–besides others–an influence on the success and outcome of HSCT. Stem cell dose is recognized as an essential factor for engraftment and patient survival [2,3]. Essential requirements for a processing laboratory have been published [4].

The Foundation for the Accreditation of Cellular Therapy (FACT)–Joint Accreditation Committee International Society for Cellular Therapy and European Society for Blood and Marrow Transplantation (EBMT) (JACIE) International Standards have been developed to provide some guidelines and support for facilities performing HSCT and cellular therapy and eventually also improve the quality of HSCT [5]. At the same time, their goal is standardization and quality assurance within transplantation centers (TCs) but they leave some practices to the discretion of the individual center and facility. Additional national regulations and/or governmental laws apply and supersede the FACT-JACIE Standards.

Furthermore, different practices have a considerable impact on the overall costs of HSCT and patient care and burden our health care services.

This survey aimed to better understand the extent of heterogeneity in storage conditions, routine quality controls (QCs), graft processing and disposal. At the same time, we aimed to identify fields of uncertainty to improve graft quality, which may affect transplant outcome. In addition, more knowledge on policies can help to better coordinate multicenter studies within the different EBMT centers and try to harmonize practices.

Materials and methods

A questionnaire regarding graft storage conditions, QCs, graft processing and disposal was developed by some of the authors and reviewed by the Cellular Therapy and Immunobiology Working Party (CTIWP) of the EBMT (Supplementary online material). We focused on peripheral blood stem cells (human progenitor cells, hematopoietic progenitor cells, apheresis [HPC(A)]) and bone marrow (hematopoietic progenitor cells [HPC(M)]), as handling and processing of cord blood remains restricted to a minority of TCs and is subject to particular guidelines. All EBMT TCs were invited to participate in this survey. The questionnaire was provided in electronic form through Survey Monkey and was accessible through a link on the invitation e-mail sent to all EBMT centers.

The survey included 39 questions. Five hundred forty-three active centers were invited, of these 288 centers responded. Two hundred thirty-one (82%) questionnaires were complete. Several incomplete responses were present for some centers; in some cases the question did not apply to their facility, in others the reason was not provided. For the purpose of this analysis all completed questions were evaluated.

Results

Between June and October 2015, 288/543 (53%) registered active centers in 46 (of 55) countries (32 European, 14 associated) responded to the survey (Figure 1). The survey was completed by processing facility directors (n = 142), other laboratory scientists (n = 23), quality managers (n = 27) or other staff members (including the program director, data managers, nurses or physicians). Some surveys were incomplete and thus evaluable only for the completed question.

Storage conditions

Most centers (199/272; 73%) store grafts overnight if necessary to be infused or processed the next day. Both HPC(M) and HPC(A) are stored mainly at 4 ± 2°C (Figure 2). Many centers never store bone marrow overnight, but infuse it immediately. Some centers do not have a storage facility for long-term storage. The majority of centers store products below –150°C (n = 175). Only 14 centers store their grafts at –80°C using mechanical freezers. Long-term storage is done in liquid nitrogen and/or liquid nitrogen in vapor phase: 81 centers store in liquid nitrogen, 94 centers in liquid nitrogen in vapor phase and 67 centers in both liquid nitrogen and liquid nitrogen in vapor phase.

Storage of potentially infectious grafts (i.e., positivity for human immunodeficiency virus [HIV], hepatitis B virus [HBV] and/or hepatitis C virus [HCV]) concerns mainly autologous grafts. Potentially infectious autologous grafts are stored in various ways, including storage in a separate tank (n = 148), in the same tank as noninfectious grafts but in an additional bag (n = 54) or in a separate tank in an additional bag (n = 38).

Seventy-one centers systematically dispose of collected cell products that positively test for microbiological contamination. Most centers (n = 178) proceed on a case-by-case basis. Usually the issue is discussed with the clinicians and a decision is made on a risk-benefit basis (as suggested by FACT-JACIE Standards). In addition, antibiotic prophylaxis and/or

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