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The role of pharmacies in haematopoietic stem cell transplantation process: A nationwide survey by Gruppo Italiano Trapianto di Midollo Osseo

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Abstract

What is known and objective: The aim of this survey, conducted by the Gruppo Italiano per il Trapianto di Midollo Osseo (GITMO), was to evaluate the involvement of pharmacists in the haematopoietic stem cell transplant (HSCT) program in Italian adult and paediatric centres.

Methods: A 63-item online questionnaire was developed and sent to the Italian Transplant Programs on behalf of GITMO.

Results and discussion: Overall, 54.7% of the Italian HSCT centres participated in the survey (88.5% adult, 7.7% paediatric, 3.8% mixed), of which 50% were in public hospitals and 50% affiliated with public universities. Just over 80% declared that a pharmacist is involved in the HSCT centre, and 86.5% reported the presence of a documentation system to signal of adverse events, accessible by physicians, nurses and pharmacists in 57.7%. Chemotherapy drugs were centralized in the pharmacy in 98.1% of HSCT centres, while parenteral nutrition was centralized in 55.8%. The use of off-label drugs was authorized by an internal committee and by the regional health authorities in 88.5% of the centres. On univariate analysis, few statistically significant differences were found on response frequencies between public hospitals and university centres or between HSCT centres performing only autologous stem cell transplantation versus other centres performing autologous and allogeneic stem cell transplantation.

What is new and conclusion: This survey suggests that there is good collaboration between pharmacists and physicians and nurses in Italian HSCT transplantation centres. The enhancement of pharmacists dedicated to HSCT programs could improve some problems, for example, the centralization of parenteral nutrition.

KEYWORDS
GITMO, haematopoietic stem cell transplantation, pharmacist, pharmacy, side effects

1 | WHAT IS KNOWN AND OBJECTIVE

Haematopoietic stem cell transplantation (HSCT) is a standard therapy for a number of malignant and non-malignant haematologic diseases.[1,2]

Haematopoietic stem cell transplantation consists of the administration of one's own (autologous) or a donor's (allogeneic) previously collected stem cells, preceded by a myelo-ablative or reduced intensity chemotherapy and/or radiotherapy-based conditioning regimen.[3] Patients undergoing HSCT require numerous drug administrations, including conditioning regimen medications, supportive care and drugs to prevent or treat HSCT-related complications, especially while hospitalized.[4–6] Pharmacists should ensure both the patients' and the healthcare professionals' (HCPs) safety during the drug preparation process by preventing mistakes and by providing information on drug management and manipulation, solution conservations, side effects, drug interactions and costs.[7,8] Furthermore, the pharmacist is involved in patients' nutritional support and the management of HSCT-related complications such as graft versus host disease (GvHD). The pharmacist is also responsible for recording AEs and for alerting the competent authorities.[9] The burden of medication costs on pharmacoeconomics is well recognized in oncology and haematology settings, and the pharmacist is fundamental to optimizing drug use and to limiting mistake-related costs.[10,11]The role of the pharmacist in a haematopoietic stem cell transplant (HSCT) program has been better defined by the Eighth Edition of the Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee ISCT and EBMT (FACT-JACIE) standards,[12] which considers the pharmacist a fundamental part of the HSCT multi-professional team. However, although Italian laws are valid throughout the country, the Italian National Health Service is managed at the regional level. There are many organizational and economic differences between regional hospitals that could impact the relationship between transplant programs and their pharmacies and that generate different organizational issues, various communication dynamics, and a variability in cost management and available resources (eg hospitals with or without a university affiliation).[13]On behalf of the Gruppo Italiano Trapianto Midollo Osseo (GITMO), a survey was designed to explore the role of the pharmacist in the adult and paediatric HSCT process so as to highlight any differences between centres in public hospitals and in university hospitals, between autologous and allogeneic transplant programs, between adult and paediatric centres, and between pooled regions.

2 | METHODS

2.1 | The questionnaire

A 63-item questionnaire was developed based on a literature search and in light of legislation. The questionnaire was then tested for its readability and understandability on the transplant team (pharmacists, physicians and nurses) in 2 transplant programs of the GITMO network and further refined until its final form was reached. The questionnaire was divided into the following sections: (1) 3 questions on describing the centre, (2) 9 questions on the interaction between the pharmacist and the transplant team (physicians and nurses); (3) 18 questions on the chemotherapy preparation process; (4) 8 questions on the preparation of monoclonal antibodies; (5) 4 on advanced dressings management; (6) 2 on galenic preparation; (7) 6 on parenteral nutrition; (8) 8 on off-label drugs; (9) 4 on biosimilar drugs; (10) 1 on vaccine management; (11) 3 on gene therapies.

The questionnaire was emailed as a Word document to the medical director of all GITMO centres. A single completed questionnaire per centre was requested; a pharmacist, physician and nurse were involved in answering the questions.

2.2 | Statistical analysis

Statistical analysis was performed using the Matrix Laboratory (MATLAB) Statistical toolbox version 2008 (MathWorks). Data are presented as numbers and percentages for categorical variables. Continuous data are expressed as the mean ±standard deviation (SD) or median with interquartile range (IQR). The χ^2 test and Fisher's exact test were performed to evaluate significant differences in proportions or percentages between two groups. Particularly, Fisher's exact test was used where the χ^2 test was not appropriate. All tests with p value $(p) < 0.05$ were considered significant.

3 | RESULTS AND DISCUSSION

3.1 | Results

Ninety-five GITMO centres were invited between December 2020 and February 2021 to complete the survey; 52 centres (54.7%) returned the completed survey, of which 46 (88.5%) were adult HSCT centres, 4 (7.7%) were paediatric and 2 (3.8%) were mixed adult-paediatric centres. Less than half of the sample (25; 48.1%) was in a public hospital facility, and 26 (50.0%) were university hospitals. Both allogeneic and autologous transplant procedures were performed by 39 (75%) centres, while 11 (21.2%) centres performed autologous transplant only and 2 (3.8%) allogeneic transplant only.

The survey highlighted very good collaboration between haematologists and pharmacists in 42 (80.8%) of the participating HSCT centres, while optimal collaboration between pharmacists and nurses was less frequent in 26 (50.0%). In particular, while almost all participants described the interaction between haematologists and pharmacists as very frequent (48; 92.3%), the interaction between nurses and pharmacists was far less frequent (31; 59.7%). The pharmacists in 45 (86.5%) centres were invited to the department meetings, where drug-related issues were discussed. Updated documents on side effects, toxicities and drug interactions were available in 34 (65.4%) centres and an AE signalling system was present in 45 (86.5).

The chemotherapy solutions were prepared in a centralized pharmacy in almost all HSCT centres, and this service was guaranteed 24 h a day and 7 days a week in 30 (57.7%) and in 34 (65.4%) centres, respectively. In 43 (82.7%) centres, chemotherapy prescription was computerized; in all cases, it was validated by the pharmacist and was double-checked before preparation in almost all centres (50; 96.2%). Specific operating procedures for the extravasation of chemotherapy drugs and their accidental spreading were available everywhere. Monoclonal antibodies were prepared by the centralized pharmacy in 50 (96.2%) of HSCT centres, while parenteral nutrition was centralized in 29 (55.8%).

Almost all participants (48; 92.3%) said that advanced dressings were sufficiently available, and a product availability review was done by the pharmacist at least once yearly in most of the centres (41; 78.9%).

Galenic laboratories were present in 42 (80.8%) hospital pharmacies, where the main formulas produced were ointments (31; 77.5%), eye drops (17; 42.5%) and mouthwashes (21; 52.5%). In 46 (88.5%) centres off-label drugs use had to be authorized by a hospital committee, which referred such use to the regional health authorities. Regarding the post-transplant vaccination pathway, most of the hospital pharmacies (42; 80.8%) did not manage it directly. Further detailed results of the survey are available in Table 1.

Missing answers were excluded from the univariate analysis. Few significant differences emerged between public and university hospitals. A documentation system to maintain and update knowledge of side effects, AEs and drug interactions was available to all HCPs (physicians, pharmacists, nurses), more in university hospital centres than in public hospitals (73.1 vs. 44.0, respectively; $p = 0.03$), as were registration and alerting systems for AEs (96.1% vs. 76.0%; $p = 0.05$). In addition, university hospitals more frequently had a galenic laboratory than did public hospitals (92.3% vs. 68.0%; $p = 0.02$); consequently, more university hospital centres used galenic formulas in daily practice (96.1% vs. 56.0%; $p < 0.01$). CAR T-cell therapy was performed mostly in university hospital centres ($p = 0.01$).

Comparing data from centres that perform autologous HSCT only ($n = 12$) with those that perform allogeneic HSCT as well ($n = 40$), the analysis showed that documentation systems for HCP knowledge maintenance were more frequently available for all professionals in centres that performed both autologous and allogeneic transplant than in those that performed only autologous transplants (67.5% vs. 25.0%, respectively; $p = 0.01$). Also, there were more cleaning rooms were present in the pharmacies of these centres (72.5% vs. 33.3%, respectively; $p < 0.01$). No significant differences were seen between the regions, and comparisons between paediatric and adult centres were not possible due to the low number of participating paediatric centres.

4 | DISCUSSION

The hospital pharmacist should be an active member of the multidisciplinary team managing the patient pathway. Their complex journey makes it possible to provide services and information that ensure the effectiveness and appropriateness of treatment, patient safety and cost optimization.[14] As mistake-related AEs during the medication management process were the most frequent cause of harm to patients during hospitalization,[15,16] the impact of pharmacists' proximity to HCPs on reducing these events is well recognized by the literature[17] and by the Italian Ministry of Health.[18]Our survey showed a good level of collaboration between HSCT HCPs and pharmacists, who seemed to be actively involved in transplant activities. The involvement of pharmacists in clinical care is well recognized in the literature,[19,20] and they are fundamental to medication safety management; they ensure that the correct steps are taken in the preparation process to guarantee patients' safety, and that authorities are alerted of AEs and side effects. Further, they manage off-label drugs, especially in paediatric settings, where many drugs are used off-label because of patient age.[14] In addition, pharmacists play an irreplaceable role in increasing and maintaining HCPs' knowledge of the effects of medications.[21–23] Galenic medications and advanced dressing preparations are important to the care of HSCT patients, who can develop complications, including cutaneous, mucosal or ocular side effects, which are not easy to cure.[24] As highlighted by the results of this survey, galenic pharmacies should be present in public hospitals as well, given the reported wide use of these formulas in those HSCT centres where they were available. In our survey, few data were available on paediatric centres, suggesting further specific investigations. However, considering the complexity of these patients' care, the importance of a multidisciplinary relationship between the oncology-haematology units and the hospital pharmacy should be stressed in order to reduce collaborative barriers.[25] Nutritional support solutions should be prepared following aseptic measures strictly, as for galenic preparations, or managed as medications when commercial formulas are available.[26] Our results highlighted that cleaning rooms for sterile preparations were not available everywhere, nor were galenic laboratories, especially in public hospitals. Pharmacist should be considered a key member of the nutritional support team, with responsibility for procuring, preparing and distributing solutions as well as for providing education and information on their management and conservation.[27,28] However, as our survey shows, the involvement of pharmacists in the nutritional support process remains partial in many hospitals.

5 | WHAT IS NEW AND CONCLUSION

Our study has some limitations. As the sample represents just over half of the invited centres, the results cannot be said to represent all HSCT centres in Italy. Some specific issues were not investigated, and the adopted research methodology does not provide an in-depth understanding of qualitative issues. Furthermore, our findings may not be reproducible outside Italy due to different laws and healthcare system organization.

Pharmacists play an important role in the care of HSCT patients: they address the information and educational needs of staff, patients,

TABLE 1 Results of the survey

	Total $N = 52$	Public Hospital $N = 25$	University hospital $N = 26$		Autologous only $N = 12$	Autologous + Allogeneic $N = 40$	
GITMO HSCT centres	**% (N)**	**% (N)**		***p* value**	**% (N)**		***p***
Centres description							
Type of healthcare facility							
(a) Public Hospital	48.1 (25)				66.7 (8)	42.5 (17)	0.28
(b) University Hospital	50.0 (26)				33.3 (4)	55.0 (22)	(C)
(c) Missed	1.9 (1)				0.0 (0)	2.5 (1)	
Type of patients cared for							
(a) Adult	88.5 (46)	96.0 (24)	80.8 (21)	0.20 (C)	100.0 (12)	85.0 (34)	0.36(C)
(b) Paediatric	7.7 (4)	4.0 (1)	11.5 (3)		0.0 (0)	10.0 (4)	
(c) Both	3.8 (2)	0.0 (0)	7.7 (2)		0.0 (0)	5.0 (2)	
Type of transplant performed							
(a) Autologous only	21.2 (11)	32.0 (8)	15.4 (4)	0.20 (C)			
(b) Allogeneic only	3.8 (2)	4.0 (1)	0.0 (0)				
(c) Both	75.0 (39)	64.0 (16)	84.6 (22)				
Interaction between pharmacist and the transplant team							
Quality of the collaboration between pharmacists and physicians (5-point Likert scale)							
(a) Very good	80.8 (42)	84.0 (21)	76.9 (20)	0.37 (C)	75.0 (9)	82.5 (33)	1.0 (F)
(b) Good	17.3 (9)	12.0 (3)	23.1 (6)		16.7 (2)	17.5 (7)	
(c) Poor	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
(d) None	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
(e) Missing	1.9 (1)	4.0 (1)	0.0 (0)		8.3 (1)	0.0 (0)	
Quality of the collaboration between pharmacists and nurses (5-point Likert scale)							
(a) Very good	50.0 (26)	52.0 (13)	50.0 (13)	0.36 (C)	50.0 (6)	50.0 (20)	0.72 (C)
(b) Good	46.2 (24)	48.0 (12)	42.3 (11)		50.0 (6)	45.0 (18)	
(c) Poor	3.8 (2)	0.0 (0)	7.7 (2)		0.0 (0)	5.0 (2)	
(d) None	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Frequency of interaction between pharmacists and physicians							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
(a) Very frequent	92.3 (48)	92.0 (23)	92.3 (24)	0.38 (C)	83.3 (10)	95.0 (38)	0.53 (F)
(b) Frequent	5.8 (3)	4.0 (1)	7.7 (2)		8.3 (1)	5.0 (2)	
(c) Occasional	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
(d) None	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
(e) Missing	1.9 (1)	4.0 (1)	0.0 (0)		8.3 (1)	0.0 (0)	
Frequency of interaction between pharmacists and nurses							
(a) Very frequent	59.6 (31)	64.0 (16)	53.8 (14)	0.52 (C)	50.0 (6)	62.5 (25)	0.58 (C)
(b) Frequent	38.5 (20)	36.0 (9)	42.3 (11)		50.0 (6)	35.0 (14)	
(c) Occasional	1.9 (1)	0.0 (0)	3.9 (1)		0.0 (0)	2.5 (1)	
(d) None	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Are the pharmacists involved during the HSCT unit meetings where medication-related problems are discussed?							
(a) Yes	86.5 (45)	92.0 (23)	80.8 (21)	0.42 (F)	91.7(11)	85.0 (34)	1.0 (F)
(b) No	13.5 (7)	8.0 (2)	19.2 (5)		8.3 (1)	15.0 (6)	
Availability of a documentation system for the HCP knowledge updating on medication side effects, toxicities or interactions							
(a) Yes	65.4 (34)	60.0 (15)	73.1 (19)	0.32 (C)	41.7 (5)	72.5 (29)	0.08 (F)
(b) No	34.6 (18)	40.0 (10)	26.9 (7)		58.3 (7)	27.5 (11)	
If so, is it accessible by all professionals (physicians, pharmacists and nurses)?							
(a) Yes	57.7 (30)	44.0 (11)	73.1 (19)	**0.03 (F)**	25.0 (3)	67.5 (27)	**0.01 (F)**
(b) No	19.2 (10)	32.0 (8)	7.7 (2)		41.7 (5)	12.5 (5)	
(c) Missing	23.1 (12)	24.0 (6)	19.2 (5)		33.3 (4)	20.0 (8)	
Availability of a local registration and warning system for AEs							
(a) Yes	86.5 (45)	76.0 (19)	96.1 (25)	**0.05 (F)**	91.7 (11)	85.0 (34)	1.0 (F)
(b) No	13.5 (7)	24.0 (6)	3.9 (1)		8.3 (1)	15.0 (6)	
Availability of a reporting system of AEs to competent authority							
(a) Yes	88.5 (46)	80.0 (20)	96.1 (25)	0.10 (F)	91.7 (11)	87.5 (35)	1.0 (F)
(b) No	11.5 (6)	20.0 (5)	3.9 (1)		8.3 (1)	12.5 (5)	

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
Chemotherapy preparation process							
Availability of a centralized pharmacy for chemotherapy preparation							
(a) Yes	98.1 (51)	100.0 (25)	96.1 (25)	1.0 (F)	100.0 (12)	97.5 (39)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
(c) Missing	1.9 (1)	0.0 (0)	3.9 (1)		0.0 (0)	2.5 (1)	
Chemotherapy preparations guaranteed 24 hours a day							
(a) Yes	57.7 (30)	60.0 (15)	57.7 (15)	0.87 (C)	50.0 (6)	60.0 (24)	0.54 (C)
(b) No	42.3 (22)	40.0 (10)	42.3 (11)		50.0 (6)	40.0 (16)	
Chemotherapy preparations guaranteed 7 days a week							
(a) Yes	65.4 (34)	64.0 (16)	65.4 (17)	0.92 (C)	58.3 (7)	67.5 (27)	0.73 (F)
(b) No	34.6 (18)	36.0 (9)	34.6 (9)		41.7 (5)	32.5 (13)	
Type of chemotherapy prescription support							
(a) Paper	7.7 (4)	12.0 (3)	3.8 (1)	0.25 (C)	0.0 (0)	10.0 (4)	0.20 (C)
(b) Digital	82.7 (43)	84.0 (21)	80.8 (21)		100.0 (12)	77.5 (31)	
(c) Both	9.6 (5)	4.0 (1)	15.4 (4)		0.0 (0)	12.5 (5)	
Is the prescription validated by the pharmacist before preparation?							
(a) Yes	100.0 (52)	100.0 (25)	100.0 (26)	1.0 (F)	100.0 (12)	100.0 (40)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Is there a direct link between the pharmacist dedicated to the chemotherapy preparation and HSCT HCPs?							
(a) Yes	100.0 (52)	100.0 (25)	100.0 (26)	1.0 (F)	100.0 (12)	100.0 (40)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Is a direct phone line guaranteed?							
(a) Yes	84.6 (44)	88.0 (22)	80.8 (21)	0.70 (F)	83.3 (10)	85.0 (34)	1.0 (F)
(b) No	15.4 (8)	12.0 (3)	19.2 (5)		16.7 (2)	15.0 (6)	
During the chemotherapy preparation process, is a double-check performed?							
(a) Yes	96.2 (50)	96.0 (24)	96.1 (25)	1.0 (F)	91.7 (11)	97.5 (39)	1.0 (F)
(b) No	1.9 (1)	0.0 (0)	3.9 (1)		0.0 (0)	2.5 (1)	
(c) Missing	1.9 (1)	4.0 (1)	0.0 (0)		8.3 (1)	0.0 (0)	

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
Does the pharmacy provide information on the interactions between different antineoplastic agents?							
(a) Yes	92.3 (48)	96.0 (24)	88.5 (23)	0.61 (F)	91.7 (11)	92.5 (37)	1.0 (F)
(b) No	7.7 (4)	4.0 (1)	11.5 (3)		8.3 (1)	7.5 (3)	
Does the pharmacy provide information on the interactions between chemotherapy and ancillary medications?							
(a) Yes	53.8 (28)	44.0 (11)	61.5 (16)	0.21 (C)	50.0 (6)	55.0 (22)	0.76 (C)
(b) No	46.2 (24)	56.0 (14)	38.5 (10)		50.0 (6)	45.0 (18)	
Is there a standard procedure for chemotherapy preparation outside pharmacy hours?							
(a) Yes	65.4 (34)	64.0 (16)	69.2 (18)	0.69 (C)	58.3 (7)	67.5 (27)	0.73 (F)
(b) No	34.6 (18)	36.0 (9)	30.8 (8)		41.7 (5)	32.5 (13)	
Is the pharmacy able to provide adequate information on drug storage, handling, and administration when a medication comes from foreign countries?							
(a) Yes	98.1 (51)	100.0 (25)	96.15 (25)	1.0 (F)	100.0 (12)	97.5 (39)	1.0 (F)
(b) No	1.9 (1)	0.0%(0)	3.9 (1)		0.0 (0)	2.5 (1)	
After the implementation of a new antineoplastic medication, does the pharmacy provide adequate information to haematology HCPs?							
(a) Yes	100.0 (52)	100.0 (25)	100.0 (26)	1.0 (F)	100.0 (12)	100.0 (40)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Are the variations in the standard conditioning protocol discussed and shared with the pharmacist and nurses?							
(a) Yes	100.0 (52)	100.0 (25)	100.0 (26)	1.0 (F)	100.0 (12)	100.0 (40)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Is the transplantation program discussed with the pharmacist to facilitate medication provision?							
(a) Yes	76.9 (40)	84.0 (21)	69.2 (18)	0.21 (C)	66.7 (8)	80.0 (32)	0.44 (F)
(b) No	23.1 (12)	16.0 (4)	30.8 (8)		33.3 (4)	20.0 (8)	
Are there databases or texts on the management of medication-related issues available to the pharmacist?							
(a) Yes	92.3 (48)	88.0 (22)	96.1 (25)	0.63 (F)	83.4 (10)	95.0 (38)	0.53 (F)
(b) No	5.8 (3)	8.0 (2)	3.9 (1)		8.3 (1)	5.0 (2)	
(c) Missing	1.9 (1)	4.0 (1)	0.0 (0)		8.3 (1)	0.0 (0)	

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
In your centre, are there SOPs to manage chemotherapy extravasation?							
(a) Yes	100.0 (52)	100.0 (25)	96.1 (25)	1.0 (F)	100.0 (12)	97.5 (39)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0%(0)		0.0 (0)	0.0 (0)	
In your centre, are there SOPs to manage chemotherapy environmental spreading?		0.0 (0)	3.9 (1)		0.0 (0)	2.5 (1)	
(a) Yes	100.0 (52)	100.0 (25)	100.0 (26)	1.0 (F)	100.0 (12)	100.0 (40)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
Monoclonal antibody preparation							
In your centre, are MA medications prepared by the pharmacy?							
(a) Yes	96.2 (50)	100.0 (25)	96.1 (25)	1.0 (F)	100.0 (12)	95.0 (38)	1.0 (F)
(b) No	3.8 (2)	0.0 (0)	3.9 (1)		0.0 (0)	5.0 (2)	
MA preparations guaranteed 24 h a day							
(a) Yes	57.7 (30)	64.0 (16)	53.8 (14)	0.56 (C)	58.3 (7)	57.5 (23)	1.0 (F)
(b) No	38.5 (20)	36.0 (9)	42.4 (11)		41.7 (5)	37.5 (15)	
(c) Missing	3.8 (2)	0.0 (0)	3.8 (1)		0.0 (0)	5.0 (2)	
MA preparations guaranteed 7 days a week							
(a) Yes	65.4 (34)	68.0 (17)	65.4 (17)	0.83 (C)	66.7 (8)	65.0 (26)	1.0 (F)
(b) No	28.8 (15)	28.0 (7)	30.8 (8)		25.0 (3)	30.0 (12)	
(c) Missing	5.8 (3)	4.0 (1)	3.8 (1)		8.33 (1)	5.0 (2)	
Type of prescription support for MA							
(a) Paper	7.7 (4)	12.0 (3)	3.8 (1)	0.51 (C)	0.0 (0)	10.0 (4)	0.48 (C)
(b) Digital	71.2 (37)	68.0 (17)	77.0 (20)		83.3 (10)	67.5 (27)	
(c) Both	17.3 (9)	20.0 (5)	15.4 (4)		16.7 (2)	17.5 (7)	
(d) Missing	3.8 (2)	0.0 (0)	3.8 (1)		0.0 (0)	5.0 (2)	
Is the prescription validated by the pharmacist before drug preparation?							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
(a) Yes	94.2 (49)	96.0 (24)	96.1 (25)	1.0 (F)	91.7 (11)	95.0 (38)	0.28 (F)
(b) No	1.9 (1)	4.0 (1)	0.0 (0)		8.3 (1)	0.0 (0)	
(c) Missing	3.9 (2)	0.0 (0)	3.9 (1)		0.0 (0)	5.0 (2)	
Is there a direct link between the pharmacist dedicated to MA preparation and HSCT HCPs?							
(a) Yes	96.2 (50)	100.0 (25)	96.1 (25)	1.0 (F)	100.0 (12)	95.0 (38)	1.0 (F)
(b) No	3.8 (2)	0.0 (0)	3.9 (1)		0.0 (0)	5.0 (2)	
During the MA preparation process, is a double-check performed?							
(a) Yes	88.5 (46)	92.0 (23)	88.5 (23)	1.0 (F)	83.3 (10)	90.0 (36)	1.0 (F)
(b) No	1.9 (1)	0.0 (0)	3.85 (1)		0.0 (0)	2.5 (1)	
(c) Missing	9.6 (5)	8.0 (2)	7.7 (2)		16.7 (2)	7.5 (3)	
Does the pharmacy perform further preparations of medications dangerous to the HCPs?							
(a) Yes	65.4 (34)	52.0 (13)	76.9 (20)	0.13 (C)	66.7 (8)	65.0 (26)	1.0 (F)
(b) No	30.8 (16)	40.0 (10)	23.1 (6)		25.0 (3)	32.5 (13)	
(c) Missing	3.8 (2)	8.0 (2)	0.0 (0)		8.3 (1)	2.5 (1)	
Advanced dressings management							
Are the advanced dressings available in your pharmacy adequate to your needs?							
(a) Yes	92.3 (48)	88.0 (22)	96.1 (25)	0.26 (F)	91.7 (11)	92.5 (37)	1.0 (F)
(b) No	7.7 (4)	12.0 (3)	3.9 (1)		8.3 (1)	7.5 (3)	
In your centre, do you have a list of ADs that must always be available?							
(a) Yes	73.1 (38)	64.0 (16)	84.6 (22)	0.09 (C)	58.3 (7)	77.5 (31)	0.27 (F)
(b) No	26.9 (14)	36.0 (9)	15.4 (4)		41.7 (5)	22.5 (9)	
Is a review of the medications and dressings available conducted regularly (e.g., yearly)?							
(a) Yes	78.9 (41)	84.0 (21)	76.9 (20)	1.0 (F)	83.3 (10)	77.5 (31)	1.0 (F)
(b) No	19.2 (10)	16.0 (4)	19.2 (5)		16.7 (2)	20.0 (8)	
(c) Missing	1.9 (1)	0.0 (0)	3.9 (1)		0.0 (0)	2.5 (1)	
Is possible to order dressings not available in the hospital handbook?							
(a) Yes	98.1 (51)	96.0 (24)	100.0 (26)	1.0 (F)	100.0 (12)	97.5 (39)	1.0 (F)
(b) No	1.9 (1)	4.0 (1)	0.0 (0)		0.0 (0)	2.5 (1)	
Galenic laboratory							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
In your pharmacy, is there a galenic laboratory?							
(a) Yes	80.8 (42)	68.0 (17)	92.4 (24)	**0.02 (F)**	75.0 (9)	82.5 (33)	0.42 (F)
(b) No	17.3 (9)	32.0 (8)	3.8 (1)		25.0 (3)	15.0 (6)	
(c) Missing	1.9 (1)	0.0 (0)	3.8 (1)		0.0 (0)	2.5 (1)	
In your centre, do you use galenic preparations?							
(a) Yes	76.9 (40)	56.0 (14)	96.1 (25)	**<0.01 (C)**	66.7 (8)	80.0 (32)	0.44 (F)
(b) No	23.1 (12)	44.0 (11)	3.9 (1)		33.3 (4)	20.0 (8)	
Parenteral nutrition							
In your hospital, does the pharmacy prepare PN?							
(a) Yes	55.8 (29)	44.0 (11)	69.2 (18)	0.07 (C)	33.3 (4)	62.5 (25)	0.07 (C)
(b) No	44.2 (23)	56.0 (14)	30.8 (8)		66.7 (8)	37.5 (15)	
PN preparations guaranteed 24 h a day							
(a) Yes	17.3 (9)	16.0 (4)	19.2 (5)	1.0 (F)	8.3 (1)	20.0 (8)	0.66 (F)
(b) No	69.2 (36)	68.0 (17)	73.1 (19)		66.7 (8)	70.0 (28)	
(c) Missing	13.5 (7)	16.0 (4)	7.7 (2)		25.0 (3)	10.0 (4)	
Are the PN solutions made with automatic machine (not manually)?							
(a) Yes	51.9 (27)	40.0 (10)	65.4 (17)	0.07 (C)	25.0 (3)	60.0 (24)	0.068 (F)
(b) No	32.7 (17)	44.0 (11)	23.1 (6)		50.0 (6)	27.5 (11)	
(c) Missing	15.4 (8)	16.0 (4)	11.5 (3)		25.0 (3)	12.5 (5)	
In your pharmacy, is there a clean room?							
(a) Yes	63.5 (33)	60.0 (15)	69.2 (18)	0.33 (C)	33.3 (4)	72.5 (29)	**<0.01 (F)**
(b) No	25.0 (13)	32.0 (8)	19.2 (5)		58.4 (7)	15.0 (6)	
(c) Missing	11.5 (6)	8.0 (2)	11.6 (3)		8.3 (1)	12.5 (5)	
In your pharmacy, are PN solutions for preterm infants prepared?							
(a) Yes	53.9 (28)	48.0 (12)	61.5 (16)	0.40 (C)	33.3 (4)	60.0 (24)	0.08 (F)
(b) No	34.6 (18)	40.0 (10)	30.8 (8)		58.4 (7)	27.5 (11)	
(c) Missing	11.5 (6)	12.0 (3)	7.7 (2)		8.3(1)	12.5 (5)	
Is the pharmacist involved in the nutritional support decision process?							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
(a) Yes	55.8 (29)	48.0 (12)	65.4 (17)	0.13 (C)	41.7 (5)	60.0 (24)	0.28 (F)
(b) No	32.7 (17)	44.0 (11)	23.1 (6)		50.0 (6)	27.5 (11)	
(c) Missing	11.5 (6)	8.0 (2)	11.5 (3)		8.3 (1)	12.5 (5)	
Off-label medications							
In your centre, are the off-label medications managed accurately?							
(a) Yes	94.2 (49)	88.0 (22)	100.0 (26)	0.14 (F)	83.3 (10)	97.5 (39)	0.13 (F)
(b) No	5.8 (3)	12.0 (3)	0.0 (0)		16.7 (2)	2.5 (1)	
Is there a specific committee for prescription validation?							
(a) Yes	88.5 (46)	84.0 (21)	92.3 (24)	0.42 (F)	75.0 (9)	92.5 (37)	0.13 (F)
(b) No	11.5 (6)	16.0 (4)	7.7 (2)		25.0 (3)	7.5 (3)	
Is the committee timing adequate to your needs?							
(a) Yes	88.4 (46)	84.0 (21)	92.4 (24)	0.62 (F)	75.0 (9)	92.5 (37)	0.12 (F)
(b) No	5.8 (3)	8.0 (2)	3.8 (1)		16.7 (2)	2.5 (1)	
Missing	5.8 (3)	8.0 (2)	3.8 (1)		8.3 (1)	5.0 (2)	
Are both the economic and clinical aspects considered by the committee during the prescription validation process?							
(a) Yes	88.4 (46)	84.0 (21)	92.3 (24)		75.0 (9)	92.5 (37)	
(b) No	5.8 (3)	8.0 (2)	3.8 (1)	0.62 (F)	16.7 (2)	2.5 (1)	0.12 (F)
(c) Missing	5.8 (3)	8.0 (2)	3.8 (1)		8.3 (1)	5.0 (2)	
Are the committee meeting minutes available to the HCPs?							
(a) Yes	73.1 (38)	64.0 (16)	80.8 (21)	0.23 (C)	66.7 (8)	75.0 (30)	0.69 (F)
(b) No	21.1 (11)	28.0 (7)	15.4 (4)		25.0 (3)	20.0 (8)	
(c) Missing	5.8 (3)	8.0 (2)	3.8 (1)		8.3 (1)	5.0 (2)	
Is there a specific register for the off-label drug utilizations?							
(a) Yes	67.4 (35)	64.0 (16)	69.3 (18)	0.69 (C)	58.3 (7)	70.0 (28)	0.47 (F)
(b) No	28.8 (15)	32.0 (8)	26.9 (7)		41.7 (5)	25.0 (10)	
(c) Missing	3.8 (2)	4.0 (1)	3.8 (1)		0.0 (0)	5.0 (2)	
Is each authorization updated by the committee?							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52 % (N)	Public Hospital N = 25 % (N)	University hospital N = 26	p value	Autologous only N = 12 % (N)	Autologous + Allogeneic N = 40	p
(a) Yes	69.2 (36)	64.0 (16)	73.1 (19)	0.62 (C)	58.4 (7)	72.5 (29)	0.45 (F)
(b) No	25.0 (13)	28.0 (7)	23.1 (6)		33.3 (4)	22.5 (9)	
(c) Missing	5.8 (3)	8.0 (2)	3.8 (1)		8.3 (1)	5.0 (2)	
Biosimilar drugs							
Is biosimilar drug utilization regulated by regional laws?							
(a) Yes	90.4 (47)	84.0 (21)	96.2 (25)	0.19 (F)	91.7 (11)	90.0 (36)	1.0 (F)
(b) No	9.6 (5)	16.0 (4)	3.8 (1)		8.3 (1)	10.0 (4)	
Does the pharmacy updates the HCPs on recommendations provided by the laws or regional guidelines?							
(a) Yes	92.3 (48)	88.0 (22)	96.2 (25)	0.36 (F)	83.3 (10)	95.0 (38)	0.22 (F)
(b) No	7.7 (4)	12.0 (3)	3.8 (1)		16.7 (2)	5.0 (2)	
Does your pharmacy conduct an economic evaluation on biosimilar medication use?							
(a) Yes	96.2 (50)	92.0 (23)	100.0 (26)	0.32 (F)	91.7 (11)	97.5 (39)	0.42 (F)
(b) No	3.8 (2)	8.0 (2)	0.0 (0)		8.3 (1)	2.5 (1)	
Does the pharmacy provide information to HCPs on new biosimilar medication availability?							
(a) Yes	86.5 (45)	84.0 (21)	88.5 (23)	0.70 (F)	75.0 (9)	90.0 (36)	0.33 (F)
(b) No	13.5 (7)	16.0 (4)	11.5 (3)		25.0 (3)	10.0 (4)	
Vaccine management							
Are the post-transplant vaccines provided directly by the hospital pharmacy to patients?							
(a) Yes	19.2 (10)	24.0 (6)	15.4 (4)	0.50 (F)	16.7 (2)	20.0 (8)	1.0 (F)
(b) No	80.8 (42)	76.0 (19)	84.6 (22)		83.3 (10)	80.0 (32)	
Gene therapies							
In your centre, do you perform CAR T-cell therapy or other gene therapies?							
(a) Yes	34.6 (18)	16.0 (4)	53.8 (14)	**0.01 (C)**	8.3 (1)	42.5 (17)	0.08 (F)
(b) No	65.4 (34)	84.0 (21)	46.2 (12)		91.7 (11)	57.5 (23)	
If so, is the hospital pharmacy involved in the CAR T-cell therapy process?							
(a) Yes	100 (18)	22.2 (4)	77.8 (14)	1.0 (F)	100.0 (1)	42.5 (17)	1.0 (F)
(b) No	0.0 (0)	0.0 (0)	0.0 (0)		0.0 (0)	0.0 (0)	
If so, please describe the pharmacy involvement in the process steps.							

(Continues)

TABLE 1 (Continued)

GITMO HSCT centres	Total N = 52	Public Hospital N = 25	University hospital N = 26		Autologous only N = 12	Autologous + Allogeneic N = 40	
	% (N)	% (N)		p value	% (N)		p
(a) Procurement/Order management/Cell collection	77.8 (14/18)	75.0 (3/4)	78.6 (11/14)	1.0 (F)	100.0 (1/1)	76.5 (13/17)	1.0 (F)
(b) Cell engineering	0.0 (0/18)	0.0 (0/4)	0.0 (0/14)	1.0 (F)	0.0 (0/1)	0.0 (0/17)	1.0 (F)
(c) Chemotherapy	72.2 (13/18)	75.0 (3/4)	71.4 (10/14)	1.0 (F)	100.0 (1/1)	70.6 (12/17)	1.0 (F)
(d) Cells infusion	38.9 (7/18)	50.0 (2/4)	35.7 (5/14)	1.0 (F)	0.0 (0/1)	41.2 (7/17)	1.0 (F)
(e) Follow-up	44.4 (8/18)	75.0 (3/4)	35.7 (5/14)	0.27 (F)	0.0 (0/1)	47.1 (8/17)	1.0 (F)
(f) Process auditing	27.8 (5/18)	25.0 (1/4)	15.4 (4/14)	1.0 (F)	100.0 (1/1)	23.5 (4/17)	0.28 (F)

Abbreviations: ADs, advanced dressings; AEs, adverse events; CAR-T, chimeric antigen receptor T cells; GITMO, Gruppo Italiano Trapianto Midollo Osseo; HCPs, healthcare professionals; HSCT, haematopoietic stem cell transplantation; MA, monoclonal antibody; N, number; PN, parenteral nutrition; SOPs, standard operating procedures. Bold values are statistically significant difference (p value < 0.05).

and their families, clinical issues, patient safety, technical skills and economic problems in a multi-professional care process that requires competences development and maintaining.[12,29] Excluding some particular aspects, this work highlighted the low organizational variability among Italian healthcare facilities. Furthermore, it allowed a better understanding of behavioural issues and their related factors that could be useful to implementing heath technology assessment strategies for developing new projects in this field and for improving the quality of care.

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CONFLICT OF INTERESTS

The authors declare no conflict of interests.

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