



## Cost analysis of a domiciliary program of supportive and palliative care for patients with hematologic malignancies

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### ABSTRACT

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The costs of home care (HC) programs may be tailored to the specific needs of patients with hematological malignancies. The aim of this study was to analyze the use of resources and the costs of a program of HC for four different prognostic groups of patients subdivided according to disease status. Over 2 years, 144 patients with hematological malignancies were assisted at home. Patients were subdivided according to disease status and life expectancy in the following groups: (i) terminal phase, with a life expectancy of 3 months or less; (ii) advanced phase, with a life expectancy of 6 months or less; (iii) chronic phase, with a life expectancy of more than 6 months; (iv) discharged early from the hospital with curable disease, following anticancer chemotherapy. Median mean monthly costs (MMC) in Euro (€) have been compared with the costs of hospitalization (DRG). Among the 4 groups of patients, those discharged early and in terminal phase required the highest mean monthly number of home visits (27.2 and 24.1), transfusions (6.1 and 6.8) and days of care (22.8 and 19.7) respectively. MMC were affected by the following variables: disease status and transfusion requirements. MMC for terminal patients (4,232.50€) and those discharged early (3,986.40€) were higher than those for advanced (2,303.80€) and chronic patients (1,488,30€). The cost of HC was lower than the corresponding DRG charges, but exceeded the district fares for HC of cancer patients. In hematological patients, the costs of HC differ according to disease status and transfusion requirements. For some categories of patients, costs of HC are lower than those of hospitalization, although higher than the current national fares for HC programs.

Key words: home care, supportive care, palliative care, hematological malignancies.

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Home care (HC) for the management of many diseases is considered advantageous, both in terms of quality of care and reduction in costs.<sup>1</sup> Oncology represents a clinical setting where domiciliary assistance very often plays an important role for the care of patients in different phases of their clinical history, during curative treatment, life-prolonging therapies or the terminal period. HC can be limited only to the parenteral administration of therapeutic agents and blood products outside the hospital ward or day care center (home treatment) or can be part of a more complex program of comprehensive care of the patients and their families focusing primarily on comfort and support. Key aspects include controlling symptoms, psychosocial care, a personalized management plan capable of maximizing patients quality of life and the provision of co-ordinated services, especially at home but also in the hospital, day care and specialized units. This type of assistance - called supportive care or palliative care for the terminal phase of the disease - is provided by multidisciplinary teams of physicians, nurses, psychologists and social workers. These operate under the responsibility of the hospital consultant in a hospital-based service or the general practitioner in a district-based service.<sup>2</sup>

A specific program of domiciliary provision of supportive and palliative care for patients with hematological diseases has been developed to respond to the global needs of some categories of frail patients. This program, run by a specialist hematological team, aims to improve the quality of life of patients and their careers, and to reduce the number and costs of inappropriate hospitalization. The home service initially assisted patients with chronic or terminal illnesses. It was later also employed for the supportive care of patients discharged by the hospital wards after chemotherapy or bone marrow/peripheral blood stem cell transplantation programs.<sup>3</sup>

Although the main reason for the HC program is to assist patients and their families – the financial constraints conditioning the national health systems require an accurate evaluation of the economic advantage of the home solution compared with the consolidated hospital-based setting.

Cost and cost-effectiveness studies have suggested that, both for patients in the terminal phase of their cancer disease and for patients during active anti-cancer treatment, HC is an efficient service reducing both the inappropriate use of available hospital beds and the unit cost of provision of care compared with conventional medical beds.<sup>4-6</sup>

To provide HC services tailored to the specific needs of palliative support for patients with hematological malignancies, it is important to perform a detailed analysis of the different cost drivers contributing to final HC costs and how such cost drivers differ in relation to the characteristics of the patients

assisted. In fact patients with hematological diseases display clinical features (use of palliative chemotherapy, transfusion requirements, high frequency of infections and hemorrhages, etc.) which require specialized HC services.

This study has consequently focused its attention upon the use of resources and the direct costs of two years of the HC program carried out at our Institution according to the different phases of disease and life expectancies of the patients assisted. Mean monthly costs of the HC program have also been compared with the national diagnostic related groups (DRG) scale charges for hospitalized patients affected by the corresponding hematologic diseases.

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## Design and Methods

### Home Care Program

The HC program for patients with hematological diseases which started in February 1993 is partially funded by a non-profit organization, the Italian Association against Leukemias, Lymphomas and Myeloma, Rome section (ROMAIL), affiliated to the Department of Biotechnologies and Hematology of the University “La Sapienza” of Rome. At the time of referral to the HC program, doctors are asked to assign the patient to one of the following four prognostic groups according to disease status (curable or not curable) and life expectancy as follows:

- *Terminal phase.* Not curable disease, with a life expectancy of 3 months or less: in need of palliative care.
- *Advanced phase.* Not curable disease, with a life expectancy of 6 months or less: in need of palliative care.
- *Chronic phase.* Not curable disease, with a life expectancy of more than 6 months: in need of supportive therapies.
- *Discharged early with curable disease.* Patients in need of supportive care for anti-cancer treatment-related complications, such as infections or neutropenia/pancytopenia.

A member of the HC program team evaluates the needs of each patient and decides the appropriate setting (home, residential care, out-patients) in which to assist him/her. Patients included in the HC program must show a Karnofsky performance score of 50% or less,<sup>7</sup> be homebound and have a skilled nursing need. The multi-professional home care team is part of the hematology department staff skilled in the palliative care approach. It includes hematologists, nurses, psychologists and social workers. The general practitioner is involved, however the physician of the team is responsible for patients' care and co-ordinates the type and frequency of interventions of the team according to the needs of the patients and of their

families. Patient management is discussed weekly in HC program meetings.

To guarantee continuity of care, a doctor of the HC team is on telephone call 24 hours daily and available for visits and consultations requested by the general practitioner, the team nurse or the patient's family. Direct contact with the hospital blood bank assures the availability of blood products at any time. A surgeon, an infectious disease specialist, a heart specialist, a neurologist and an orthopedic surgeon of the hospital are also available for consultation.

Since patient needs and expectations change over time, patients may be admitted to the day care or to the wards of the Institution during the HC program because of clinical or social situations, such as uncontrollable symptoms, the necessity for diagnostic imaging and a respite program for the caregivers.

One course of HC program is defined as the start to the end of assistance which may be due to death or a return to the out-patient or hospital setting.

### **Treatments**

At home, in addition to visits, patients enrolled in the HC program receive hematological, biochemical and ultrasound evaluations, parenteral administration of fluids, antibiotics and antimycotic drugs, leukocyte and erythrocyte growth factors, analgesics, anti-emetics, anti-fibrinolytics and transfusional support (PEU, packed erythrocyte units; PPU, packed platelets units). During the study period, the standard anti-infectious therapy consisted of intravenous cephalosporine and aminoglycoside for neutropenic patients and oral antibiotics (association amoxicillin and clavulanic acid or ciprofloxacin) for non-neutropenic patients. Oral anti-blastic drugs or intravenous mono-chemotherapy were administered only for palliative purpose or in chronic disease. Only 2 patients with curable disease discharged from the hospital were treated with granulocyte colony stimulating factor (G-CSF).

Patients with curable or chronic disease received PPU transfusions as anti-hemorrhagic prophylaxis when platelets were  $<10 \times 10^9/L$  ( $<20 \times 10^9/L$  in case of fever or when minor hemorrhagic symptoms were present). Patients with advanced or terminal disease received PPU only when a hemorrhage  $>$ grade 1 WHO scale occurred. Usually, PEU were provided when the Hb was below 8 g/dl. The frequency of services such as visits, intravenous administration of fluids and drugs, and transfusional support are expressed in monthly mean activity.

### **Patients and costs**

Analysis of the resources and their related costs required for the HC program during the years 2004 and 2005 was performed by extracting the data from the clinical records and from the database where all home activities were recorded. Therefore, the costs

originate from real life data and not from a theoretical model. The costs of the program have been divided into four categories: 1) health care providers, physicians and nurses, and support and co-ordination team (direct costs and overheads estimated in a 60:40 ratio) calculated by matching the number of home accesses during the study period with the 2004 unit cost of a medical or nurse visit; 2) use of materials and medicines including their preparation; 3) transfusional support; 4) laboratory (hematology, blood chemistry, microbiology) and diagnostic procedures according to the figures published by the Official Gazette of the Italian Republic.

In this program, categories of cost #1, human resources, are reimbursed by the non-profit organization. Categories #2, 3 and 4 are refunded by the district (regional) public health system (hospital and local trust budget). The mean monthly costs (MMC) of the courses of HC, calculated by multiplying the monthly mean use of resources for the unit cost, are expressed in Euros (€). They include: human resource costs, materials and medical transfusion support, drugs, laboratory and diagnostic procedure. Median monthly costs and 25–75% interquartile (IQ) cost ranges were also calculated.

The MMC of the HC program were subsequently compared with the national DRG scale charges according to the 06/30/1997 decree of the Italian Ministry of Health and its modifications to evaluate the costs of hospitalization of the patients with the same hematological diseases and clinical conditions as those assisted under the HC program.

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## **Results**

### **Use of resources**

During the period of study, 144 patients with hematological malignancies were assisted at home (Table 1). Seventeen were managed over two different periods. Therefore, 161 courses of assistance were carried out at home, for a total of 12,345 days of care, with a median duration of care of 77 days (range 1–734). During this period, patients received 1,612 domiciliary medical visits, 3,259 nurse visits, 1,315 PEU and 132 PPU were transfused, 2,104 blood samples were taken, and 882 doses of intravenous antibiotics were administered.

On the whole, patients in chronic phase showed a better Karnofsky performance score (mean 48.6) compared to the other groups (mean 38.5).

All 146 courses of HC for patients in advanced, terminal and chronic phase ended with the patient's death. A hundred and twelve of them died at home (77%) and 34 (33%) died in the hospital. The median duration of survival was respectively 18 days (range 1–83) for terminal patients, 124 days (range 55–266)

**Table 1.** Patients' characteristics

Patients		
No. of patients	144	
Mean Karnofsky Score range (%)	41.4 (20-50)	
Median age, years (range)	73 (10-98)	
Male gender (%)	69 (48)	
Disease characteristics		
Disease characteristics	No.	(%)
<b>Diagnosis</b>		
Acute leukemia	40	(28)
Lymphoma	36	(25)
Myeloma	25	(17)
Chronic myeloproliferative syndrome	8	(6)
Myelodysplastic syndrome	19	(13)
Others	16	(11)
<b>Disease status</b>		
Terminal phase	89	(62)
Advanced phase	31	(21)
Chronic phase	9	(6)
Curable, discharged early	15	(11)

for advanced patients, and 379 days (range 22–734) for chronic patients. All 89 patients (100%) in terminal phase died within the expected limit of 3 months, whereas 25 of the 31 patients in advanced phase (81%) died within 6 months. All 9 patients in chronic phase (100%) died 24 months after the start of the HC program. Seven (78%) died in hospital because of non-hematological disease-related conditions (4 cardiac diseases, 3 neurological-vascular diseases). Eight of the 15 patients (53%) discharged early with curable disease returned to out-patient care. Seven patients (47%), after ending the initial HC management program, started a new course because of disease progression to a terminal phase and died within 3 months.

The intensity of HC provided was strictly related to patient disease status and life expectancy (Table 2). Patients discharged early or at terminal phase had a shorter mean duration of domiciliary assistance compared to patients with advanced and chronic phase (22.8 and 19.7 days versus 143 and 421 days, respectively). However, these patients received a higher

cumulative mean monthly number of transfusions ( $6.1 \pm 3.5$  SD and  $6.8 \pm 4.1$  versus  $2.3 \pm 1.9$  and  $1.6 \pm 1.4$ , respectively) and a higher cumulative mean monthly number of visits (27.2 and 24.1 versus 11.4 and 8.6, respectively). During the last three months of survival, because of their worsening clinical conditions, patients in advanced phase received a mean monthly number of visits (22.4) and of transfusions ( $5.7 \pm 3.4$ ) similar to those of patients in terminal phase.

Age and co-morbidity of the patients did not affect the employment of resources.

### Costs

The combination of the four cost drivers (health care providers, materials and drugs, transfusional support, laboratory) and their relative weight in the cost-building of the MMC of the four groups of the assisted patients are shown in Table 3. Patients in chronic phase of disease required the lowest monthly costs of care (MMC € 1,488.3, range 455.9–4,769.5; median €1,056.0, IQ range 572.4–1,441.2), followed by patients in advanced phase of disease (MMC €2,303.8, range 309.7–10,822.1; median €1,439.5, IQ range 886.2–1,857.1), those discharged early (MMC € 3,986.4, range 241.2–6,285.3; median €2,745.1, IQ range 995.3–3,786.2) and by those in terminal phase (MMC €4,232.5, range 437.0–14,599.6; median €3,106.1, IQ range 1,711.2–5,052.1). When compared to patients who received a cumulative mean number equal or less than 4 transfusions (PEU and/or PPU) per month of care, those receiving more than 4 transfusions had noticeably higher costs, with an additional difference in MMC of €5,563.7 for patients discharged early, €3,353.9 for those in advanced phase and €2,469.5 for those in terminal phase.

In the advanced phase of disease group, no difference in costs was observed between the group of 6 patients who survived more than 6 months and the group of 25 who died within the expected time-frame. However, an analysis of the last three months of care (and survival) for patients in advanced phase revealed similar costs in this time interval (MMC €4,050.3; median 2,983.4) compared to those in terminal phase

**Table 2.** Use of resources during 161 courses of Home Care.

Disease Status	No. of courses	Mean No. of days of HC (range)		Mean No. transfusions/month ( $\pm$ SD)			Mean No. of visits/month		
				PEU	PPU	Total	Doctor	Nurse	Total
Discharged early	15	22.8	(8-62)	2.4 ( $\pm$ 1.8)	3.7 ( $\pm$ 2.6)	6.1 ( $\pm$ 3.5)	6.6	20.6	27.2
Terminal	106	19.7	(1-83)	3.2 ( $\pm$ 2.4)	3.6 ( $\pm$ 2.4)	6.8 ( $\pm$ 4.1)	7.4	16.8	24.2
Advanced	31	143.2	(55-266)	2.1 ( $\pm$ 1)	0.2 ( $\pm$ 0.5)	2.3 ( $\pm$ 1.9)	2.8	8.6	11.4
Chronic	9	421	(22-734)	1.6 ( $\pm$ 1.6)	–	1.6 ( $\pm$ 1.4)	2.2	6.4	8.6
Total	161	152.6	(1-734)	–	–	4.2 ( $\pm$ 2.4)	–	–	16.8

HC: Home care; D: Standard deviation; PEU: Packed erythrocyte units; PPU: Packed platelet units.

(MMC €4,232.5; median 3,106.1).

In patients in terminal and curable phases, costs relating to staff, drugs and transfusional support were equally distributed (nearly 30% for each), whereas in patients with advanced and chronic phases drugs accounted for 50% of the care program. Costs of laboratory tests did not exceed 2% of the global cost of care for each category of patients. In this HC program, 67% of the direct costs were sustained by the public health system (including transfusions, drugs, materials and laboratory) and 33% by the non-profit organization (human resources, costs of home care visits).

Costs of the HC program have been compared to the corresponding DRG, for hospitalized hematological patients during the year 2004 (Figure 1). The MMC of HC for chronic patients was inferior to the lowest DRG (chronic myeloproliferative syndromes, € 3,511.0). The MMC of the other three groups of patients managed at home was inferior to the second DRG (non-acute leukemia: €7,245.0) in the descending order of price, whereas the highest MMC for HC (early discharge, with more than 4 transfusions: €9,550.2) was still lower than the highest DRG (DRG 473, myeloid or lymphoid acute leukemia).

Patients with acute leukemia in terminal phase with more than 4 mean monthly transfusions had the highest MMC of home care (€11,080.0; *data not shown*) compared to patients with other hematological malignancies, but lower than the amount of the corresponding DRG charge. In a palliative care setting, the MMC of HC for hematological patients in terminal phase was higher than the current Italian monthly costs for some HC district programs (€1,500–2,500), and similar or lower than the current monthly costs for residential programs, such as hospices (€5,600–7,000).

## Discussion

Patients with cancer during their disease history display clinical problems that require a sub-acute care rather than hospitalization for acute care. Usually, the palliative care provision is restricted to patients with terminal phase/resistant disease, ineligible for any treatment or with underlying situations contraindicating further chemotherapy or radiotherapy, with a median estimated survival of about 3 months.<sup>8,9</sup> Nevertheless, many patients with refractory diseases

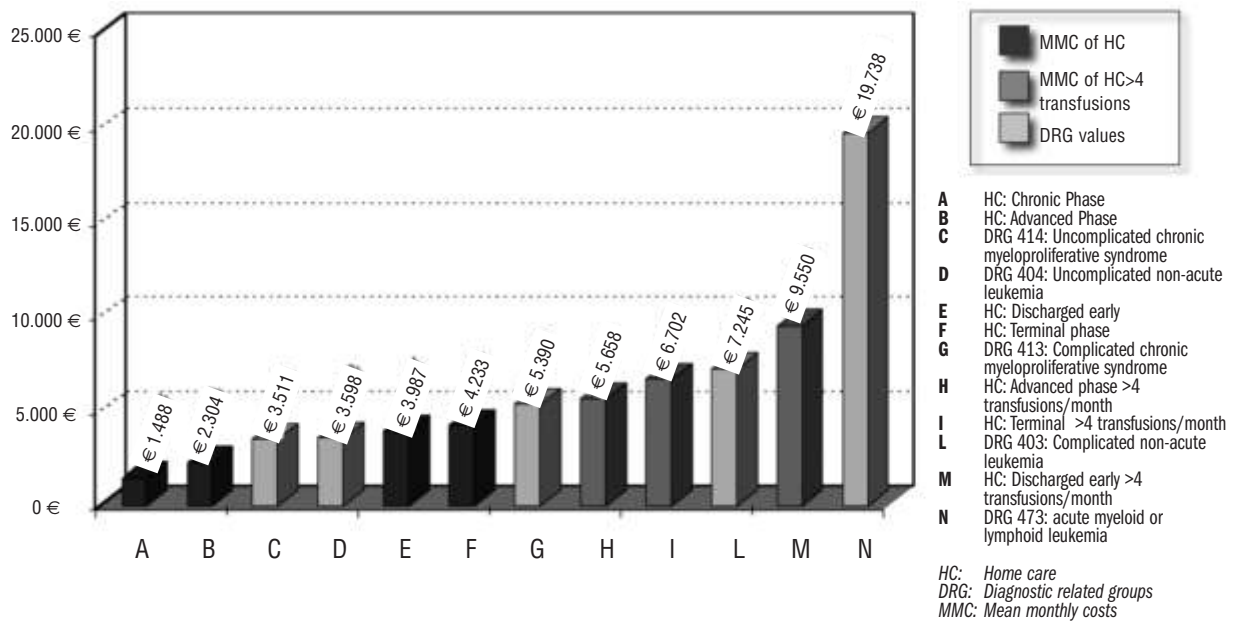
**Table 3.** Analysis of the mean monthly costs of the different patient groups.

Patients	Mean Monthly Cost (MMC) Drivers in Euros								
	Staff		Transfusions		Drugs		Laboratory		Total
	€	(%)	€	(%)	€	(%)	€	(%)	
Discharged early	1,354.9	(34)	1,148.2	(29)	1,432.2	(36)	51.1	(1)	€ 3,986.40
Discharged early > 4 transfusions	1,354.9	(14)	6,711.9	(70)	1,432.2	(15)	51.1	(1)	€ 9,550.10
Terminal	1,513.6	(36)	1,224.3	(29)	1,442.6	(34)	52.0	(1)	€ 4,232.50
Terminal > 4 transfusions	1,513.6	(23)	3,693.7	(55)	1,442.6	(21)	52.0	(1)	€ 6,702.00
Advanced	664.6	(29)	339.8	(15)	1,266.1	(55)	33.3	(1)	€ 2,303.80
Advanced > 4 transfusions	664.6	(12)	3,693.7	(65)	1,266.1	(22)	33.3	(1)	€ 5,657.70
Chronic	507.3	(34)	227.3	(15)	728.3	(49)	25.4	(2)	€ 1,488.33

**Table 4.** Comparison of costs of Home Care for onco-hematological patients.

Study	Disease Phase	Unit cost of home care (range)	Median No. of days of home care
Our study	Post-CHT, chronic, terminal	*MMC €4,845 (1,488 - 9,550)	153 (19.7-421)
Miano M et al. <sup>17</sup>	Post-CHT, post-allo BMT, terminal	§ACP €2,936 (150-20,700)	19 (1-172)
Svahn BM et al. <sup>6</sup>	Post-allo HSCT	°MCP \$25,346 (\$12,000-\$45,400)	16 (0-26)

\*MMC: Mean monthly costs per patient; §ACP: average costs per patient; °MCP: Median costs per patient; CHT: chemotherapy; BMT: bone marrow transplantation; HSCT: hematopoietic stem cell transplantation.



**Figure 1.** Comparison between the mean monthly costs (MMC) of Home Care and the corresponding DRGs.

who undergo life-prolonging anti-cancer therapies suffer from uncontrolled symptoms related to treatment or to disease progression. Although estimated to survive more than 3 months, these patients require a comprehensive approach very similar to palliative care to meet numerous physical, psychological and social needs.<sup>10</sup> The decision to delay the transition from a curative to a palliative strategy until a very late stage of the disease is particularly realistic for the hematological setting, where malignancies are so persistently sensitive to innovative treatment strategies that end-of-life care is ineffectual or not offered at all.<sup>11-13</sup> This is why we have also included in our HC program the group of patients in advanced phase of their disease with an expected median survival of more than 3 months.

In Italy, local or national organizations of the National Health System (NHS) purchase health services, administered by public, non-profit or private providers, by using the DRG system for hospitalized patients. Nevertheless, different studies have indicated that this system does not adequately define costs in the sub-acute areas of care (palliative care, rehabilitation medicine, psychogeriatrics, geriatric management) which aim to modify functional status or improve quality of life of the patients rather than cure their underlying disease.<sup>14</sup> The sub-acute casemix is characterized by complex and expensive care programs that require prolonged periods of hospitalization. Furthermore, the Australian healthcare system has implemented a new casemix classification system for sub-acute and non-acute care based on the concept that phase of care (stage of illness) is the best predictor

of care costs.<sup>15,16</sup>

Our findings agree with those reported by the Italian group in Genova regarding the average cost per patient of HC (2,936€, range 150–20,700€) for pediatric patients with hematological malignancies.<sup>17</sup> In a clinical setting of patients receiving allogeneic hematopoietic stem cell transplantation, Svahn *et al.*<sup>6</sup> reported that the median cost from day 0 to day +76 was \$25,340 for the HC group, compared to \$36,437 for the hospital care control group ( $p < .001$ ). In the multivariate analyses, high costs were associated with late engraftment, acute grade II-IV GVHD and hospital care. A comparison of the overall MMC of the four patient groups in our study with the results of those mentioned studies above is shown in Table 4. In addition, we confirm the findings of the Australian study, demonstrating that the costs of the HC program for patients with hematological diseases differ in relation to the phase of the disease and the transfusion requirement. The intensity of care and the average use of resources over a one month period correlated to the phase of the disease. Patients in the terminal phase of their disease and those discharged early by the hospital had costs (nearly 4,000€ per month) higher than those observed in patients with advanced or chronic phase disease (1,500–2,000 € per month). This difference can be explained by the higher number of medical and nursing visits, and transfusions required by the former two groups of patients. Care requirements were in fact greater both in the case of disease progression, with the appearance of new or more severe symptoms for patients in terminal phase, or when very frail patients (pancytopenic, with infective complications, etc.),

already discharged from the hospital ward, needed to be strictly followed to prevent complications or to administer daily parenteral therapies. Patients with advanced disease, and in particular those with chronic disease, required less frequent home visits because their clinical condition was more stable. Nevertheless, in their last three months of life, patients in advanced phase showed similar care costs to terminal patients due to the increased care required by disease progression. The need for blood product transfusions was a significant cost driver, regardless of disease phase. It raised the MMC of care from a minimum of €2,500 for terminal patients to a maximum of €4,500 for early discharged patients. The high need for transfusions may differentiate the costs and the organizational model of HC for hematological patients compared to patients affected by other forms of cancer.<sup>18</sup>

The MMCs for HC are lower than the average costs that would have been charged to the NHS in the event of hospitalization of the same categories of hematological patients. With this HC organizational model, even the highest mean cost of one month of domiciliary assistance, that of patients with acute leukemia requiring an intensive program of transfusions, was lower than the corresponding DRG in case of hospitalization. Although in this study different economical categories have been compared, namely the costs of HC courses with charges for reimbursement (DRG) of hospitalization, from the perspective of the purchaser of health services (NHS organizations and trusts), assisting these categories of patients at home appears less expensive than hospital care. Furthermore, the mean monthly costs for the reimbursement of HC for palliative care in some Italian districts (€850–2,000) in the years 2004-2005 appear inadequate to cover the costs of HC.

In spite of the significant weight of transfusions in the cost-building and the high standards of HC (continuity of assistance 24 hrs/day, immediate availability of blood products, high frequency of home visits, etc.), in our model staff costs did not exceed 36% of the four cost drivers considered. In fact, payment of the health care providers usually makes up the major part (nearly 70%) of care costs. The availability of doctors and nurses not specifically employed for HC, but paid on single-visit demand may have reduced personnel costs. However, in this care model, transfusion and drug costs may exceed the costs of providers, when compared to care models dedicated to a less intensive medical need.

Sub-acute care can be suitably provided at home satisfying the patient's need for privacy and comfort with professional health assistance available. In our experi-

ence, the majority of patients and their families said they were satisfied with HC program although no detailed study was carried out. The costs of care at home can also be reduced compared to the hospital. In this study, a detailed analysis of the resources used, the different cost-drivers, and a comparison of the mean costs of HC with DRG has confirmed the economic advantage of HC over hospitalization. These results may allow the financial requirements of a HC program based on the specific needs of hematological patients in the different clinical phases of their disease to be defined. This program has been carried out at a single center and the costs of care study were designed in a retrospective observational fashion to define descriptively, from a statistical point of view, the use of resources, without any inferential analysis. These data, therefore, require further validation in other hematological centers providing this model of care as results are strictly related to this structure. Since this is a cost-analysis study, patients' quality of life, an important objective in this setting, has not been investigated by methods such as the European Organization for Research and Treatment of Cancer (EORTC) Quality of life Questionnaire-C30. It is commonly believed that comprehensive home programs meet the needs of cancer patients. However, the limited research conducted so far has not formally demonstrated a significant positive impact on the quality of life of such HC programs over conventional care.<sup>19,20</sup> Further studies are, therefore, required to assess the cost-effectiveness of home interventions directed towards specific symptoms or problems affecting quality of life.

Finally, for the health care system as a whole, the costs of assistance are the sum of those sustained by the health care providers and those by the patients and their families. Therefore, costs of home care sustained by the patients and their families should also be investigated to highlight the economic burden of the disease on the family in terms of caregiving, non-reimbursed drug and medical equipment, and loss in work productivity.

#### **Authors' Contributions**

*CC drafted the paper and designed the study; GAB, GMD, PN gave substantial contributions to conception, design, and acquisition of data; MB and RF revised the manuscript; MGM and AN were responsible for analysis and interpretation of data; GA, FM and and RF gave the final approval of the version to be published.*

#### **Conflict of Interest**

*The authors reported no potential conflicts of interest.*

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