

# Safety and Family Satisfaction of a Home-Delivered Chemotherapy Program for Children with Cancer

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## Research

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# Abstract

**Background.** Home chemotherapy programs for children with cancer are safe and feasible but have hardly worked in Italy, and there is conflicting evidence on their impact on the quality of life. In Friuli Venezia Giulia, Italy, a home chemotherapy program was implemented between 2011 and 2019. This study investigates safety, feasibility and satisfaction of parents.

**Methods.** Patients between 0 and 18 years diagnosed with malignancy were included. Deceased patients and patients whose families moved abroad or interrupted contact with the service were excluded. Adverse effects comprised immediate deterioration of the patient's condition, equipment failure, errors in drug storage, dose or patient identification and personnel safety issues. Parental satisfaction was explored through an email survey of 32 Likert-type and short open questions.

**Results.** Thirty-five patients received 419 doses of intravenous chemotherapy at home (cytarabine, vincristine, vinblastine). No adverse events were reported. Twenty-three families out of 25 eligible completed the survey. Most reported being "very satisfied" with the possibility of maintaining a work/domestic routine and reducing time and financial burden of hospital access. Most were "very satisfied" with the opportunity for their child of being less troubled by the treatment. Besides, most reported being "very satisfied" with the chance for healthy siblings of maintaining their routine and coping with their brother/sister's disease. Most perceived the program as safe. All families recommended extending the program to all children in the region.

**Conclusions.** This study supports home chemotherapy as safe and effective, positively influencing the quality of life for children and families.

## Background

While cancer is still a leading cause of death in childhood and adolescence in high-income countries<sup>1,2</sup>, advances in the survival rates arise interest in the quality of life of children and their families during the treatment<sup>3</sup>. The literature describes home-delivered chemotherapy as safe and feasible for both adults and children. It requires adherence to strict conditions, related to the treatment protocol and phase, home environment and location, caregiver motivation and training, and patient characteristics<sup>4</sup>. However, conflicting evidence exists on the impact of these programs on the quality of life of patients and families and their cost-effectiveness.

Since 2011, a home assistance program run by the Pediatric Home Care Team (PHCT) at the Hospital of Pordenone, Friuli Venezia Giulia, Italy, takes care of children with complex needs, both oncological and not, living in the Pordenone province and the nearby Udine and Venice provinces. The team provides services at home, including blood tests, intravenous chemotherapy, assessment of compliance with oral medications and dose adjustments on behalf of the Hub Oncology Centre, antibiotic therapy, transfusions, pain management and support treatments, psychological support for children and families, end-of-life care. A pediatrician, two pediatric nurses and a psychologist work five days a week from 8.00

am to 4.00 pm, with the reference pediatrician available on call until 8.00 pm. For emergencies, at night and during the weekends, patients can rely on the on-duty staff at the Pediatric Department of the local Hospital. The PHCT visits patients at home and delivers intravenous chemotherapy on behalf of the Hub Oncology Centre. The drugs chosen for home administration are cytarabine, vincristine and vinblastine because they have sufficient stability, do not require prolonged infusions or any specific support therapy (i.e. hyper-hydration) and do not carry a significant risk of immediate adverse reactions (i.e. anaphylaxis or acute toxicity)<sup>5,6</sup>. The Pharmacy Department of the Oncology Centre in Aviano prepares the drugs under sterile conditions and guarantees safe transport and the Medical Board of the Hospital approved a written protocol for their storage, transportation, delivery and disposal. The mean time spent on each home visit is 45 minutes, including physical examination, counselling, and other procedures, i.e. central venous catheter (CVC) care or blood sample drawing.

This research aims to explore the safety and the impact of home-delivered chemotherapy on the quality of life of children and families.

## Methods

We performed a retrospective evaluation on children who received chemotherapy at home by the PHCT in the Local Health Authority of Pordenone (*Azienda Sanitaria Friuli Occidentale*, ASFO) in Friuli Venezia Giulia, Italy.

Inclusion criteria were: age between 0 and 18 years; diagnosis of malignancy; intravenous chemotherapy carried out at home by the Pediatric Department of ASFO on behalf of the Hub Pediatric Oncology and Hematology Centre between 01/06/2011 and 31/05/2019. We excluded deceased patients and patients whose families moved abroad or interrupted their contact with the Pediatric Department.

The primary outcome was the frequency of adverse events; the secondary outcome was family satisfaction measured through questionnaires.

For the research, we focused only on curative intravenous chemotherapy delivered at home, avoiding questions on oral chemotherapy, diagnostic procedures, pain or support therapy (i.e. transfusions) or end-of-life care.

Regarding the primary outcome, we reviewed the clinical records to document adverse effects. Adverse effects include immediate acute deterioration of patient's condition (i.e. anaphylactic reactions, drug extravasation or any other critical condition requiring emergency transport to the hospital), equipment failure (i.e. CVC malfunctioning), errors in drug transport or storage, staff safety issues (i.e. accidental contamination with cytotoxic drugs or needle stick), errors in dosing or patient identification. We did not focus on predictable side effects of chemotherapy (i.e. nausea and vomiting, fever, neutropenia) because we assumed that they occurred at the same rate as the treatment administered in the hospital setting.

Regarding the secondary outcome, we retrospectively collected information on family socio-demographics (including nationality and language, primary caregiver's education and profession, spouse's education and profession), children's age at diagnosis, number of family members, distance from the closest hospital and the Hub Oncology Centre, number of working days lost due to therapies, the possibility of having paid leave for the primary caregiver and obtaining financial support from charities. We then collected qualitative data on the impact of home-delivered chemotherapy on the family routine and the overall quality of life and the perception of safety and effectiveness. We used a 5-item Likert-type scale ranging from "not at all satisfied/completely disagree" to "very satisfied/strongly agree" to assess parental satisfaction on different aspects and short open questions. The full questionnaire is provided in the Supplementary Information files (Supplementary file 1).

We sent an invitation email with the project description and a link to the survey. The Hospital Revisory Board approved the questionnaire. Parents filled a consent form for clinical charts revision for scientific purposes when they were first admitted to the hospital. The email with the link contained a specific consent question for anonymized data collection.

We performed only a descriptive analysis. Continuous data were presented as median and interquartile range (IQR); categorical data (including the Liker-type questions) as number and percentage.

## Results

As for safety, 35 patients met the inclusion criteria, 22 males and 13 females, with a median age at diagnosis of 6 years (IQR 5 years). The most common diagnosis was acute lymphoblastic leukemia (ALL) with 32 cases, followed by Wilms tumor (2 cases) and soft tissue sarcoma (one case). Five patients with ALL experienced disease relapse. We, therefore, considered 40 chemotherapy schedules for a total amount of 419 doses administered at home in the reference time interval. All patients had a central venous catheter.

We did not report any acute deterioration of the patients' condition, nor equipment failure, nor errors in drug transport, storage or disposal, nor errors in dosing or patient identification, nor staff safety issues.

As for the secondary outcomes (satisfaction), we first considered all 35 patients. We excluded three patient for contact problems, three patients who completed their treatment abroad and four deceased patients. In the end, we enrolled 25 families to participate in the questionnaire. The diagnoses were ALL (22 cases), Wilms tumor (two cases) and soft tissue sarcoma (one case). There were 16 males and nine females.

Twenty-three families answered the anonymous questionnaires (dropout rate 8%). Median age at diagnosis of children for the response group was five years (IQR 4). Most children were less than seven years old at the time of diagnosis.

There were 19 Italian and four foreign families, but all use the Italian language to communicate with the team.

The area covered by the PHCT was 900 square kilometers (Supplementary information file 2). Most families lived within 20 kilometers from the nearest hospital (12/23, 52.2%) and more than 100 kilometers far from the Hub Oncology Centre (13/23, 56.5%). All families reached the hospital by car. Most families reported a mean hospital access rate of fewer than five times a month (13/23, 56.5%). Most families (21/23, 91.3%) received financial support from charities or foundations during the therapy. Most caregivers (12/23, 52.2%) reported between 30 and 365 personal days taken from work and most reported to be allowed some paid leave (14/23, 60.9%); a minority of caregivers gave up their job (2/23, 8.7%). The mother was the most frequent primary caregiver (22/23, 91.3%) and also the person who spent the most time with the child during the hospital stay.

Tables 1 and 2 summarize participants' socio-demographics, travel, and job-related issues. Figures 1 summarizes parental satisfaction related to travel, job and financial issues. In Fig. 2, parental satisfaction associated with the psychological impact on the child and healthy siblings is summarized. Figure 3 summarizes parental satisfaction related to the perception of safety and effectiveness and suggestion on program expansion.

Table 1  
Participants' socio-demographics

	<i>N</i>	<i>%</i>
Main caregiver (N = 23)		
Mother	21	91,3%
Father	2	8,7%
Family nationality (N = 23)		
Italian	19	82,6%
Other	4	17,4%
Language adopted with the Service team (N = 23)		
Italian	23	100%
Other	0	0%
Main caregiver's profession (N = 23)		
Housewife	5	21,7%
Workman	4	17,4%
Office worker	8	34,8%
Executive manager	2	8,7%
Self-employed	3	13,0%
Entrepreneur	1	4,3%
Spouse's profession (N = 23)		
Housewife	0	0,0%
Workman	6	26,1%
Office worker	9	39,1%
Executive manager	4	17,4%
Self-employed	2	8,7%
Entrepreneur	2	8,7%
Main caregiver's instruction level (N = 23)		

	<i>N</i>	<i>%</i>
Primary school diploma	1	4,3%
Middle school diploma	2	8,7%
High school diploma	9	39,1%
University degree	9	39,1%
Professional school license	2	8,7%
Spouse's instruction level (N = 23)		
Primary school diploma	1	4,3%
Middle school diploma	3	13,0%
High school diploma	9	39,1%
University degree	2	8,7%
Professional school license	8	34,8%
Total number of family members (N = 23)		
3	8	34,8%
4	8	34,8%
5	6	26,1%
6	1	4,3%
Number of other children (N = 23)		
None	6	26,1%
1	9	39,1%
2	7	30,4%
3	1	4,3%
Age of the child at the diagnosis (N = 23)		
0–3 years	7	30,4%
4–7 years	11	47,8%
8–12 years	2	8,7%
> 12 years	3	13,0%

Table 2  
Means of transport, distance and parental job-related issues

	<i>N</i>	<i>%</i>
Means of transport used during therapy (N = 23)		
On foot	0	0%
Car	23	100%
Taxi	0	0%
Train/bus	0	0%
Average monthly frequency of travels to hospital for visits, procedures and therapies (N = 23)		
Less than 5 times a month	13	56,5%
Between 5 and 10 times a month	5	21,7%
More than 10 times a month	5	21,7%
Distance from the nearest hospital (km) (N = 23)		
Less than 5 km	7	30,4%
Between 5 and 20 km	12	52,2%
More than 20 km	4	17,4%
Distance from the Hub Oncology Centre (km) (N = 23)		
Less than 50 km	2	8,7%
Between 50 and 100 km	8	34,8%
More than 100 km	13	56,5%
Average monthly frequency of absences from work for the main caregiver due to visits, procedures and therapies (N = 23)		
< 30 days	5	21,7%
30–365 days	12	52,2%
> 365 days	4	17,4%
Layoff	2	8,7%
Main caregiver allowed some paid leave from work (N = 23)		
Yes	14	60,9%
No	9	39,1%
Financial support by charities/foundations (N = 23)		

	<i>N</i>	<i>%</i>
Yes	21	91,3%
No	2	8,7%

All families (23/23,100%), although at different levels, suggested expanding of the program for all children with cancer in the region; in particular, 21/23 “strongly agreed” with the expansion of the program (91,3%), one “agreed” (4,3%) and one “moderately agreed” (4,3%).

Table 3 summarizes open comments.

Table 3  
Short open comments

<b>Comment (N = 23)</b>	<i>N</i>	<i>%</i>
Positive references	16	69,6%
Improvement in logistic issues (time schedule, personnel involved)	3	13,0%
Improvement in communication between Centres/personnel	3	13,0%
Improvement in communication with parents	1	4,3%
Other issues (this comment reports on difficulties with oral therapy for this child)	1	4,3%

## Discussion

This retrospective study on safety and family satisfaction of a home-delivered chemotherapy program for children with a diagnosis of malignancy shows an excellent safety profile and high levels of parents’ satisfaction.

No adverse event occurred during the transport, storage, administration or disposal of chemotherapy, nor any acute deterioration of the patient’s condition after administration. Besides, the staff did not experience any safety issues. This finding highlights the safety of an established protocol for chemotherapy transport, storage, administration and disposal and underlines the need for specific training for nurses and clinicians<sup>4,7</sup>. These data are in line with other studies aimed at exploring the safety of home intravenous therapy programs for both adult and pediatric patients with cancer. In 1996, an Australian experience described 1688 visits for the administration of anticancer treatment to 179 adult cancer patients over five years (where “home” included patients’ workplaces, General Practitioners’ offices and daycare centers). They reported rare and minor complications, mainly difficulties with venous accesses, and a single serious complication, with a dystonic reaction to metoclopramide that required hospital evaluation<sup>8</sup>. In 2006, a Canadian experience on 23 children with ALL who received chemotherapy at home and in the hospital did not show any difference in adverse events rate for the two groups<sup>9</sup>. A

more recent Canadian study with 136 children who received various services at home, including chemotherapy (1701 visits between 2013 and 2015, 58% of which for chemotherapy administration) did not report any adverse event<sup>10</sup>. Similarly, a Danish experience with 57 children reported no adverse events for a total 317 chemotherapy doses (vincristine and dactinomycin) administered at home<sup>11</sup>.

The questionnaire used in our study mainly focused on family perception and satisfaction. Most families reported great appreciation for the possibility of reducing the time burden for hospital access with the home chemotherapy program, and for the opportunity of maintaining a daily work/domestic routine. Most families reported a mean hospital access rate of fewer than five times a month. This finding is in line with qualitative data of the Canadian experience of Lippert *et al.*, who showed that a home chemotherapy program helped families maintain their routine, limiting the physical and mental burden of hospital access<sup>10</sup>.

Most families positively regarded the possibility for their child of maintaining a play/study routine and living the moment of therapy with less trauma. Literature offers mixed evidence on this issue. In studies on the adult population, receiving chemotherapy at home helped patients in maintaining their identity and their capacity for making choices<sup>12</sup>. A qualitative focus on the cohort of 57 Danish children who received home chemotherapy pointed out that families perceived that being treated at home helped their child maintain a sense of normality<sup>13</sup>. On the contrary, the findings of Stevens *et al.* on 23 children pointed out that children receiving home chemotherapy tended to experience more distress. These authors suggested that in the long term children may have perceived that home was no longer a safe place, free from medical interventions<sup>9</sup>.

In our survey, families positively evaluated the opportunity for siblings to experience fewer interferences in their routine and to become familiar with their brother/sister's disease and treatment. Literature points out that childhood cancer has a high impact on healthy siblings. They may be overlooked because of their ill brother/sister and may find it hard to cope with their parents' difficulties<sup>14</sup>; moreover, some of them may experience school absenteeism, academic struggles and social restrictions from peers<sup>15</sup>.

We investigated satisfaction issues with a simplified questionnaire with problem-oriented questions to minimize the dropout rate. We did not explicitly direct our questions to children and healthy siblings because there were many pre-school children to avoid interpretation bias.

We did not explore family perception of oral chemotherapy (6-mercaptopurine and oral methotrexate) during the maintenance phase of treatment for ALL. The role of the PHCT during the maintenance phase was that of periodic clinical assessment, blood sample drawing at home and communication with the Hub Oncology Centre of the blood results to plan dose adjustments and retesting. After discussion with the Hub Oncology Centre, the PHCT communicated the adjusted doses of oral medications to the families and scheduled the following blood sample drawing.

In the comment section, some parents underlined the importance of a continual interface between the Oncology Hub Centre and the PHCT to provide consistent communication. This comment leads to a clear improvement point because communication between Hub and Spoke centers is critical for the success of these projects. The Hub Centers must provide the treatment schedule with doses and rate of administration, and they should always be available to help in the safe management of adverse effects (i.e. febrile neutropenia). The PHCT should provide constant feedback on their evaluation of patients.

Home care may help the staff in developing a broader observation of patients and families in their environment. Moreover, as a Spanish study on 87 adult patients with cancer pointed out, patients and families may perceive the staff as more focused and establish a closer relationship with them<sup>16</sup>.

All families suggested expanding the program to all children diagnosed with cancer in the region.

As far as cost analysis is concerned, the essential costs derive from the preparation, storage and transport of the drug, travel and use of hospital resources. Drug-related charges are the same if the therapy is delivered in an in-hospital setting. A pediatrician and a pediatric nurse were always involved in chemotherapy administration, and they used a car purchased explicitly for the program. However, it is impossible to calculate the exact travel costs because, on the same day, they made visits for purposes other than chemotherapy in the same area.

Most families positively evaluated the possibility of reducing the financial burden of hospital access. We could not make a quantitative analysis of the economic impact on families. However, we hypothesize that the project might help reducing expenses for families due to fewer travels and less personal days taken from work for both parents. Financial disruption could have a substantial influence on parental distress during and after treatment of childhood cancer: this issue should be assessed and discussed thoroughly and respectfully during the treatment phases<sup>17,18</sup>.

This study has some limits. We acknowledge its retrospective nature, the limited sample size, and the fact that we did not adopt a validated scale for quality of life measurement. We also recognize that asking families to recall their experience with the home chemotherapy program from as long as nine years ago may cause a recall bias.

The points of strengths are an extended time window (8 years), the inclusion of different diagnostic groups (leukemias and solid tumors) and the analysis of specific issues related to the impact of a childhood cancer diagnosis on family life.

Furthermore, this is the first evaluation of a home chemotherapy program for children with cancer in Italy. The National Health System in Italy ensures full coverage of direct medical expenses for patients with cancer and foundations and charities often provide families with additional financial support. Nevertheless, all families must face other costs, such as those related to parental job disruption, travels to and from the Hub center for exams, therapies or complications, sibling care and missed daycare or school days. Our findings suggest that home-delivered chemotherapy may help reduce this burden.

Ultimately, this is an example of cooperation and integration between Hub Centers and peripheral hospitals, which could result in resource rationalization and cost reduction for both families and the Health System.

Future trends of research should address cost-effectiveness with more specific outcome measures, explore the effect of home-delivered chemotherapy on children and families prospectively by comparing their quality of life with that of children and families who did not receive home-delivered chemotherapy.

## Conclusions

This study shows that a home chemotherapy program is safe, feasible and useful for maintaining a good quality of life for children and families.

## Abbreviations Key

<b>PHCT</b>	Pediatric Home Care Team
<b>ASFO</b>	Azienda Sanitaria Friuli Occidentale
<b>CVC</b>	Central Venous Catheter
<b>IQR</b>	Inter Quartile Range
<b>ALL</b>	Acute Lymphoblastic Leukemia

## Declarations

## Ethics approval and consent to participate

The hospital IRB approved the study. All participants provided their written consent to the use of the retrospectively collected data for the purposes of this study.

## Consent for publication

Not applicable

## Data Availability Statement

Data that support the findings of this study are available on reasonable request from the corresponding author.

## Competing interests

The Authors declare no conflict of interest.

## Funding

The Authors declare no funding for this study.

## Authors' contribution

All the authors have contributed to the manuscript in significant way and agreed upon the manuscript content. In particular, Irene Del Rizzo, Lucia De Zen and Luca Ronfani designed the questionnaire. Lucia De Zen contacted the families for the survey. Irene Del Rizzo collected the data. Irene Del Rizzo and Luca Ronfani analyzed the data. Irene Del Rizzo prepared the initial draft. Lucia De Zen, Luca Ronfani, Margherita Robazza, Francesca Barbieri, Roberto Dall'Amico, Marco Rabusin and Egidio Barbi critically revised the initial draft and provided contribution to the final version. Lucia De Zen and Egidio Barbi ultimately revised the manuscript. All authors approved the final version.

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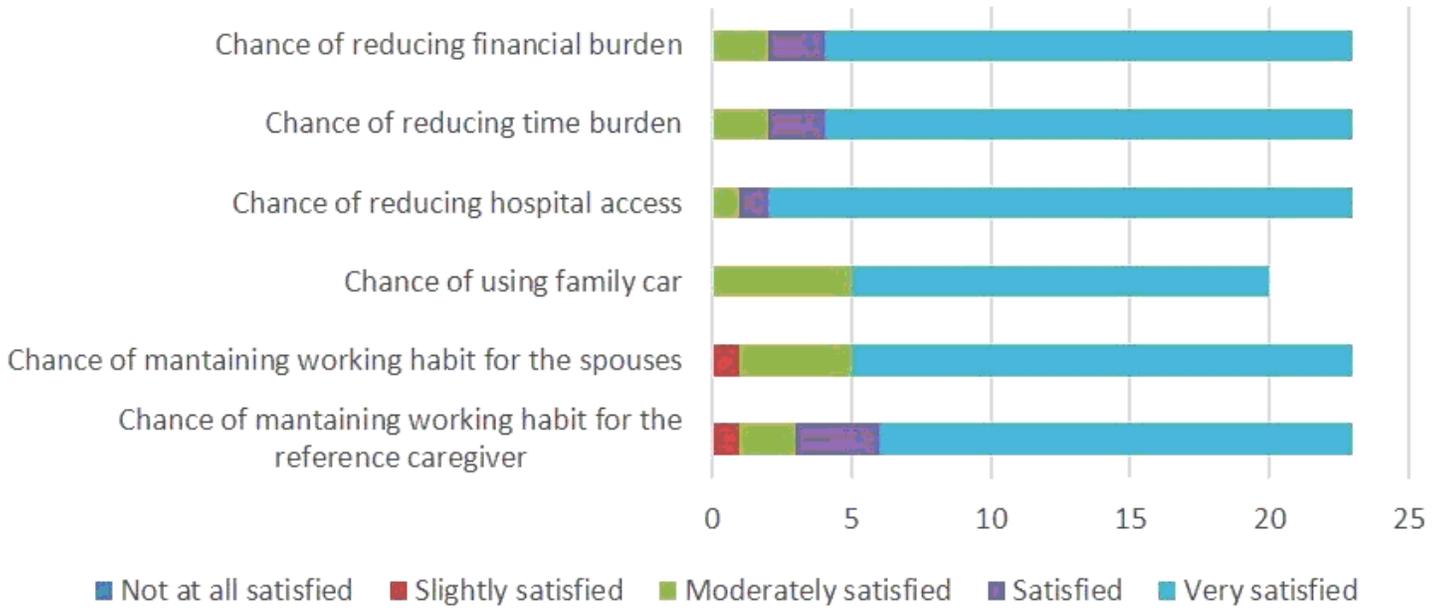
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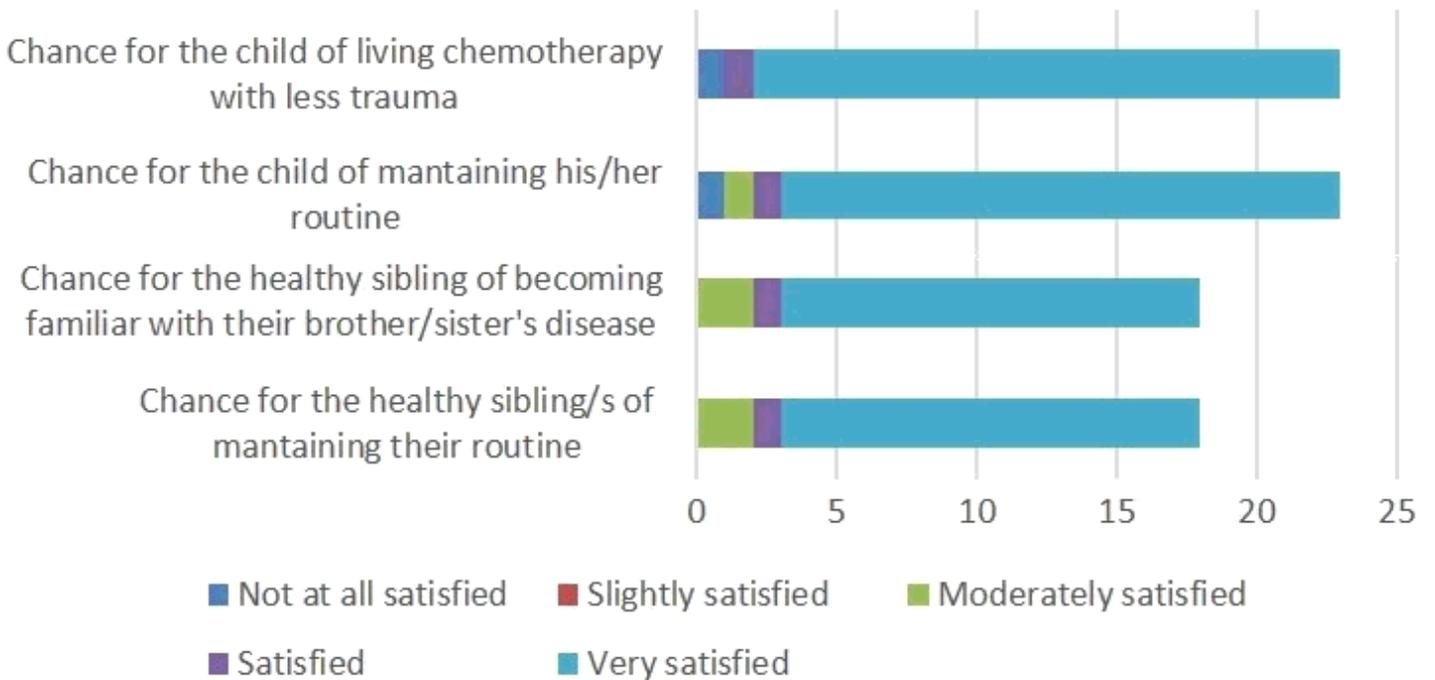
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## Figures



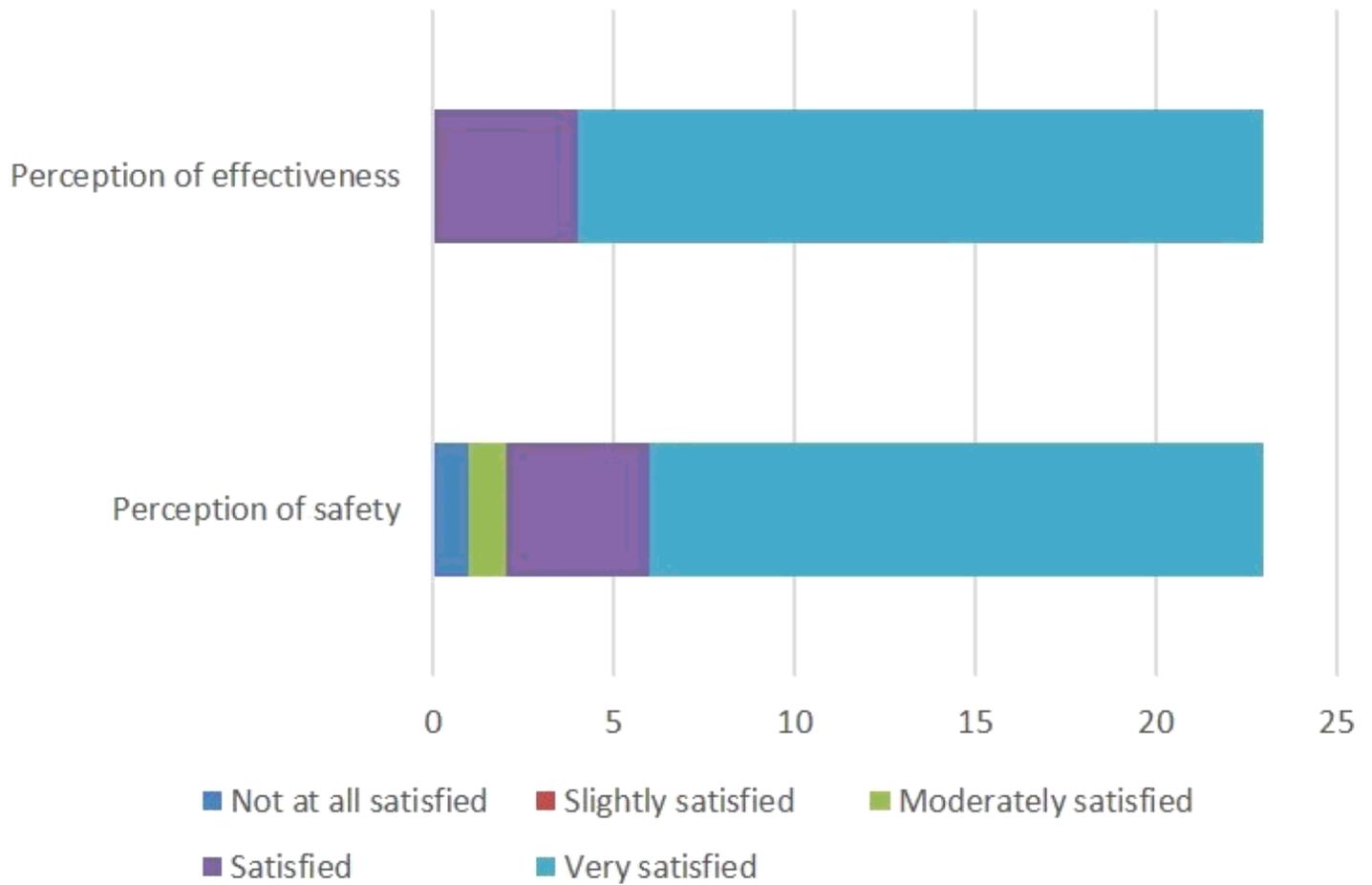
**Figure 1**

Parental satisfaction related to work, travel and financial issues



**Figure 2**

Parental satisfaction related to the psychological impact of the program on the ill child and his/her healthy sibling/siblings



**Figure 3**

Parental satisfaction related to the perception of safety and effectiveness of the program

## Supplementary Files

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