

Research Article

Right to health care and materials required for intermittent catheterization: a comparison between Germany and Brazil

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ABSTRACT

Purpose: This study aimed to conduct a comparative analysis of the effectiveness of the fundamental social right to health in regard to the acquisition of materials for intermittent catheterization (IC) in subjects with spina bifida (SB) in Brazil and Germany.

Design/Methods: This quantitative, descriptive, correlational, multicenter, interdisciplinary study comprised two stages: the first in Brazil (2008/2009) and the second in Germany (2010–2012). The sample comprised 200 individuals (100 in each country) with SB and an experience in performing IC.

Findings: In Germany, the most common type of catheter used contains hydrophilic coating, and all participants reported acquiring IC materials via health insurance and using a new catheter at every procedure. In Brazil, the most common type of catheter used is made of uncoated plastic, with 31%

of participants reporting having acquired IC materials from the health system and 27% reporting financial difficulty in acquiring these.

Conclusions: The treatment of SB related neurogenic bladder should come under the umbrella of the “existential minimum” a concrete means of ensuring human dignity. Thus, the materials necessary to complete IC should be provided by the state, even if necessary under a court order.

Clinical Relevance: In Germany, all individuals can easily access their required IC materials, however, in Brazil, many patients have difficulty in acquiring materials, being forced to either reuse catheters or suspend the procedure, which can lead to health complications and reduced social participation.

Keywords: Spinal Dysraphism, Catheterization, Intermittent Catheterization, Public Health, Catheter.

Introduction

The Constitution of the Brazilian Republic promulgated in 1988 state the right to health as a duty of the state and fundamental social right of all citizens, ratified in the Brazilian legal order rights stipulated by the Universal Declaration of Human Rights as adopted by the United Nations (UN) in 1948.^{1,2}

Specifically, article 198 specifies the Unified Health System (SUS).¹ For implementation of this right established by the constitution, the operation of SUS was defined in 1990 within the Health Organic Act 8080, which regulates the provision of health, as a right to be provided by the state to each and every Brazilian citizen and is based on legal principles including universal access to health services at all levels of care, equity, comprehensive care, and community participation.³

Despite constant arguments involving public managers and the construction of legal theories about the costs of realization of rights, the budget imbalance and compatibility between social demands and the financial capacity of the state, it is noteworthy that, in the Brazilian case, the realization and concretion of fundamental rights, both individual and social, should be a primary concern of society and the state and precede any other type of public spending.

A mere formal guarantee without the direction and prioritization of the state to ensure comprehensive care health for the Brazilian population, with a focus on preventive actions, would prevent many individuals from retaining their dignity and represents an attack against the Federative Republic of Brazil and its democratic state, because human dignity is one of the fundamentals according to the Constitution of the Republic.¹

In this context, despite these constitutional provisions and legal rights to health forcing the state to act in an objective and positive way, the realization of access to services, as well as the acquisition of material resources for self-care at home, are aimed at ensuring support for the entire Brazilian population, as will be discussed in detail in this study, specifically in regard to the acquisition of materials required for intermittent catheterization (IC).

It is noteworthy that IC is the most widely used treatment for neurogenic bladder. This procedure has two main objectives: protection of the urinary system and acquisition of urinary continence. It is known that renal impairment is among the leading causes of death among young individuals with Spina Bifida (SB), and urinary incontinence is included among the causes that undermine the quality of life and social participation.⁴⁻⁷

Few reports in the scientific literature link the theme of the citizen's right to access material resources required in their health care to the inclusion of case studies of individuals with disabilities by comparing the situation among different countries. This is the main reason that we couldn't bring more current studies to argue on the subject, which points to the importance of this research.

Objective

The study aimed to compare the effectiveness of the fundamental social right to health within the perspective of the acquisition of IC materials by individuals with SB in Brazil and Germany.

Methods

This was a quantitative, descriptive, correlational, multicenter, interdisciplinary study. This study was authorized by the SARAHs Rehabilitation Hospital (Belo Horizonte, Brazil) and Dortmund University and by the ASBH (Association of Spina Bifida and Hydrocephalus; Dortmund, Germany). Written informed consent was obtained from all participants before data collection, which was performed between 2008 and 2012, in Brazil and in Germany.

In Brazil, data were collected with a survey questionnaire from a urological follow-up protocol for MMC patients from a large rehabilitation hospital. In Germany, data collection was performed using a translated and validated version with translation and back-translation, to confirm that the original meaning has been preserved. There was pre-testing with persons with MMC and caregivers, with items adapted to fit the German context and culture (the complete questionnaire can be found here: <http://de.surveymonkey.com/s/TUDortmund-spinabifida-brasilien-deutschland>). In Brazil, the data were collected with a printed questionnaire and in Germany with an online questionnaire.

We chose these two countries because they come from different realities, cultures, and there is a scientific partnership between the two study centers in rehab. In addition, we have motivation to achieve understanding, sharing and learning differences, difficulties and facilities for people with disabilities in each country.

Study participants were Brazilian and German patients diagnosed with SB and experienced in IC use. Individuals with urinary ostomy (Mitrofanoff) were excluded. Based on the formula derived from Freeman, the convenience sample was calculated, which comprised 200 individuals with SB (100 in each country) with experience in performing IC. A specific age group was not stipulated so that cross-cultural contextual effects on age differences in status could be examined. Caregivers completed the questionnaire for the younger participants, age 18 years and younger.

The data were analyzed using statistical software, Statistical Package of Social Science, version 19.0. For nominal variables, contingency tables and Yates' chi-square or Fisher's Exact were used. For ordinal and interval variables with few integer values, the Mann-Whitney U-test was used for two independent samples. Two-tailed statistical tests were conducted with probability of minimal significance for decision-making set at 0.05.

The sample age range was 0–55 years, with a mean of 14.5 (11.5); respective data for Brazil and Germany were 0–28 years, mean 9.9 (6.0) and 0–55 years, mean 19.2 (13.7). The Brazilian sample comprised children, youths, and young adults, whereas the German sample comprised children, youths, and adults (i.e., the Brazilian sample was represented by a younger population than the German; t-test, $p < 0.001$; Levine's test, $p < 0.001$).

The total sample comprised 108 females and 92 males, with the respective data for Brazil and Germany being 43/57 and 65/35. Both Brazilian and German samples had a uniform distribution of SB (Fisher's exact test, $p = 0.153$).

It was observed that 42.0% and 41.0% of Brazilian and German individuals, respectively, were "unable to walk," and required a full-time use of a wheelchair (z-test, $p = 0.885$).

To evaluate the level of schooling, we compared German and Brazilian educational levels. According to data from the two samples, the level of schooling showed a heterogeneous distribution, being higher in the German sample (Mann-Whitney U-test, $p < 0.001$). There was a predominance of early childhood education and 1–5 years of schooling in the Brazilian sample and individuals with ≥ 13 years of schooling in the German sample (Mann-Whitney U-test, $p < 0.001$).

From the two samples, we obtained 69 questionnaires completed by patients and responded to by 131 families, most having been answered by mothers (57.5%). In Brazil and Germany, 20.0 and 49.0%, respectively, of questionnaires were completed by patients. In the German sample 51% of questionnaires were answered by another party (z-test, $p = 0.769$). On the other hand, in the Brazilian sample, most questionnaires (72.0%) were answered by mothers (z-test, $p < 0.001$).

Regarding the currently used method of bladder catheterization, 53% and 22% of German and Brazilian participants, respectively, performed self-catheterization ($p < 0.001$), whereas 33% and 63%, respectively, reported performing assisted catheterization (performed by another person; $p < 0.001$).

Brazilian participants used uncoated plastic (78.0%), metal (18.0%), or both metal and plastic catheters (4.0%), whereas German participants used hydrophilic-coated catheters (60.0%), catheter gel (31.0%), uncoated plastic catheters (2.0%), a combination of two catheters and hydrophilic gel (4.0%), or other types of catheter (3.0%) (Figures 1, 2 and 3). It is noteworthy that 100% of German participants used disposable catheters, whereas Brazilian participants reused the same catheter for one week.

Among the reasons for the irregular use of necessary medications and supplemental treatment, 20% reported financial difficulties as the main reason.

The Brazilian participants were inquired about the existence of financial difficulties in regard to the purchase of materials necessary for catheterization, as described in Table 2.

The form of acquisition of IC materials by German patients depended on the practicalities of the national health care system, because they received the necessary IC materials via the German system of health insurance. Thus, participants were inquired whether they had received IC materials from their health insurance program without incurring any difficulties or whether they had experienced inconveniences (Table 3).

It is evident from Tables 2 and 3 that German participants (87.0%) received more financial assistance from the health care system in relation to the acquisition of the IC material than the Brazilian participants (31.0%; Student's t-test, $p < 0.001$). Financial difficulty was also cited by participants as one of the reasons for discontinuation of IC.



Figure 1: Brazilian metal catheter



Figure 2 - Brazilian uncoated plastic catheter

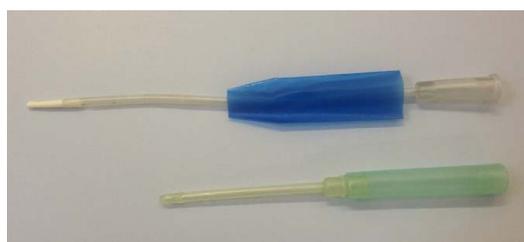


Figure 3: German hydrophilic-coated catheters

Discussion

It was not stipulated that any specific age group participate in the survey; rather, the study aimed to broadly encompass all individuals regularly performing IC and also used the variation in age range to understand the context of IC in both the countries. The difference in mean age between the two countries (i.e., the Brazilian sample being somewhat younger than the German, the latter showing the greater age range) mirrors what occurs in the general population, because the longevity of Germans is greater than that of Brazilians.^{1,8,9}

Furthermore, SB is already present in one generation of adult Germans, unlike that in Brazilians in whom SB is a more recent phenomenon. This difference also suggests that treatments for SB (e.g., surgical repair of myelomeningocele, use of a bypass valve in the treatment of hydrocephalus, intermittent catheterization, and prevention of renal deterioration) were initiated and standardized earlier in Germany than in Brazil and that an increased life expectancy of individuals with SB is consequently found in Germany compared with that in Brazil.

The level of schooling among participants was higher in the German sample because of the age difference between these countries, which may reflect the situation in the general population because Germany has higher rates of education than Brazil.^{8,9}

There was a similarity in the distribution of no ambulatory patients who rely on a wheelchair for locomotion. A study of young people with SB revealed that the full-time use of a wheelchair is associated with reduced quality of life, but psychological stress and self-management problems are prevalent, regardless of individual mobility.¹⁰ Thus, severe physical disability is neither a contraindication nor an insurmountable obstacle to the realization of IC, because many wheelchair-dependent individuals can master the technique of catheterization.¹¹ We also emphasize that this study found no influence of wheelchair use on performing of self-catheterization.

Type of catheter and manner of disposal were found to be at variance in the two countries. In Germany, 100% of participants reported use of single-use disposable catheters, whereas in Brazil, catheter reuse is common particularly when there are difficulties accessing materials, as addressed in other study.^{12,13}

Catheter type proved to be an interesting aspect of the study because it mirrors the economic contrast between the two countries, reflecting differences in the attitudes and policies of the respective authorities in regard to the fundamental social right to health. The average cost of a coated catheter as used by German participants was US\$3.62, and this translates as a monthly expenditure of US\$434.74 for an individual catheterizing four times per day. All individuals in the German sample received catheters via their health insurance, although 13% mentioned problems claiming this refund.

In Brazil, pre-lubricated or hydrophilic catheters are not distributed by SUS.¹⁴ Metallic catheters were donated by the rehabilitation hospital where the study was conducted; however, these can be used only by women. Furthermore, because reuse has generated controversy on account of the difficulties involved in maintaining their cleanliness, this type of catheter was used

Table 1: Distribution of clinical and demographic features by nationality

	Brazilian	German	p-value
Age (mean)	9.9 years	19.2 years	≤0.001
Gender	43 females	65 females	0.003
	57 males	35 males	
School Level	05 (special school)	07 (special school)	0.551
	41 (childhood education)	19 (childhood education)	≤0.001
	26 (1-5 years of schooling)	10 (1-5 years of schooling)	0.002
Unable to walk	28 (6-12 years of schooling)	25 (6-12 years of schooling)	0.630
	0 (≥13 years of schooling)	39 (≥13 years of schooling)	≤0.001
	42.0%	41.0%	0.885

Table 2: Distribution of Brazilian sample according to financial difficulty in the acquisition of IC materials (n = 100)

Financial difficulty	n	%
No	42	42
Receives donation of the material	31	31
Yes	27	27
Total	100	100

less frequently. Plastic catheters (polyvinyl chloride, PVC) are reused for up to 1 week. Every month, in Belo Horizonte, the municipal health authority donates 30 catheters for children up to 5 years of age and 7 years for older children.¹⁵

In Brazil, the donation policy in regard to distribution of catheters varies according to the individual local health policy; in some municipalities, individuals with SB can receive free catheters while others they are forced to reuse theirs for up to 1 week.

The price of a plastic catheter in Brazil, when bought in stores specializing in hospital supplies, is approximately U\$0.22, plus the price of the lubricant tube [30 g; approximately U\$2.23]. The minimum monthly cost of a reusable catheter and replacing it every 7 days would thus be U\$1,56, while by discarding it after each procedure would escalate the cost to U\$26.75; in both cases an additional U\$8.92 would be required for the 4 tubes of lubricating gel. This calculation indicates the great variation in cost dependence on catheter single use or reuse.

In accordance with the Secretary of Planning and Management, the city of Belo Horizonte pays U\$0.13 for each urethral probe (no. 12 type) and U\$0.35 for each tube of lubricant gel (Register of medication prices—Act 4, Process: 04.000516.08.54; Table 4).

According to the table above, when converting these values into percentages equivalent to the Brazilian minimum wage, it appears that the use of hydrophilic catheters as used by Germans participants generates an equivalent monthly cost of approximately 1.5-fold the minimum wage in Brazil, which is unaffordable for most Brazilian families. On the other hand, the cost of single-use, PVC catheters amounts to 11% of the Brazilian minimum wage when funded by the patient and 6.6% of the minimum wage when funded by the municipal government of Belo Horizonte. This fact highlights the need

for prioritization and preventive action by the state, despite budgetary constraints.

Therefore, the disposable PVC catheter may represent an intermediate option between the sterile technique and reuse, more viable economically and more appropriate from the point of view of practicality and support as a prophylactic measure in IC-associated complications; indeed, several companies and international specialists in urological rehabilitation encourage the use of a fresh catheter for each procedure as a measure of support in the prophylaxis of urinary tract infection.¹⁶⁻¹⁹ One should also take into account the comfort and convenience associated with the use of disposable catheters, which makes the procedure easier by eliminating the washing, drying, and storage required otherwise, ensuring a higher level of patient dignity. In previous studies, use of disposable catheters was found to be a facilitating factor in the implementation of IC, as reported by mothers who complained about the time spent on the cleaning of reusable catheters and the fear of contamination following the procedure.¹³

It is important to highlight that there are studies including patients who use these hydrophilic catheters that presented a significantly lower number of inflammatory episodes at scrotal level, lower number of post/intra/inter catheterization bleeding episodes, lower number of urinary tract infections and expressed a significant higher satisfaction level.²⁰ These data imply the quality of care among the materials available in both countries.

In regard to the acquisition of equipment for performing IC, as noted earlier, there are differences between the two countries. In Germany, patients receive IC materials via their health insurance, although some (13%) reported problems in receiving reimbursement. In Brazil, 42% reported no financial difficulty in acquiring materials, 31% reported of receiving materials from the government, and 27% reported financial problems acquiring materials.

Table 3 : Distribution of the sample according to the presence of the German problem for receipt of the materials of the CI by health insurance (n = 100)

Problem	n	%
Yes	13	13
No	87	87
Total	100	100

Table 4: Unit values of catheters and lubricant gel, monthly costs, and minimum monthly Brazilian salary

	PVC Catheter		Pre-lubricated Catheter	Lubricant gel
	Weekly reuse	Single use		
Per unit cost	0,27 U\$ ^a	0,27 U\$ ^a	3,63 U\$ ^b	2,69U\$ ^a
Monthly cost	1,88 U\$ ^a	32,23 U\$ ^a	435,15 U\$	10,74U\$ ^a
Unit cost for the municipality of BH	0,16 U\$	0,16 U\$	-	0,5 U\$
Monthly cost for the city of BH	1,13 U\$	19,34 U\$	-	1,99 U\$
% of Brazilian minimum salary ^c	0.64%	11.0%	148.62%	3.67%

(a) Values in dollar, as found in Belo Horizonte (BH) - 2011 (money conversion: 1,00 U\$= R\$2,24).

(b) Value per catheter paid by German health plans.

(c) Minimum Brazilian salary (per month) valid since 01/03/2011 (R\$545.00 = U\$243,01).

In other studies, the factors influencing the realization of the vision of IC caregivers of Brazilian children with SB and identified the financial aid and IC materials received from the government as facilitating factors for the procedure.^{13,21}

Note that the economic situation of families with individuals with special care needs is often exacerbated when the family caregiver resigns from a paid job to provide care for a relative.¹¹ Thus financial assistance in the purchase of IC materials becomes essential for many low-income families, particularly in Brazil, with respect for human dignity being the foundation of a democratic state itself. As stated above, the right to health is a fundamental social right, and of all constitutional rights, fundamental rights addressing the essential needs and interests of individuals are those with the greatest relevance.

In this context, in contrast to arguments that emerged in Germany in the 1980s about the costs incurred by the state in the fulfillment and realization of rights, the concept of an "existential minimum" was adopted by Brazil, having first been applied by the Supreme Court in 2004.²²⁻²⁴

Existential minimum is considered as one of the pillars of the Republic itself, with the dignity of the human person expresses a set of civilizational values incorporated into the heritage of humanity. Its core consists of elemental material existential minimum, and voiceover that identifies the set of goods and basic utilities for both physical and indispensable to the enjoyment of freedom itself. Below that level, even when there is survival, there is no dignity. The list of benefits that make up the existential minimum includes minimum income, basic health, and basic education.²⁵ Due to its essential character, the existential minimum comprising fundamental rights, both individual and social, have an end immediately payable before the Judiciary, which has generated a rapid growth in litigation,

in particular the right to health, in the Brazilian case.²⁶ In this direction, is included the right to receive the materials to perform the catheterization by persons with disabilities by respecting the principle of the right to existential minimum.

We recommend that, in Brazil, the clean intermittent catheterization technique with single-use catheter be used. This technique can be a mid-range option, between the sterile technique and the clean technique with reusable catheter. It is more viable from an economic perspective and more practical, comfortable and useful as a means of prophylaxis for complications associated with IC. The use of the disposable catheter has various advantages, these include: the possibility of encouraging autonomy, which has immeasurable value for the individual with SB since it facilitates self-catheterization and commitment to the procedure; and because it eliminates steps of the technique such as cleaning, drying and storage of the catheter. Increasing life-long commitment to the procedure can avoid complications related to not using IC, such as hospital admission, urological surgeries and even hemodialysis, resulting in this being a more economical option over the long term. The majority of recent studies in developed countries have also advised against catheter re-use. Reporting that catheter re-use only be used in cases of extreme poverty, which is not the situation in Brazil. It should be noted that a priori, according to the instructions on packaging for probes supplied by manufacturers, all catheters are single-use and no manufacturer is responsible or has a standard protocol for catheter re-use.

We suggest that, when a catheter must be re-used, procedures should be studied, standardized and validated to show the steps for re-use, from cleaning to storage.

This study has a number of limitations that would need to be addressed in future research. The sampling was restricted

to differing sites in the two nations, constituting a potential confound in cross-cultural comparisons and generalizations. Future studies are needed to confirm our findings and to identify other relevant factors that affect the rights of the people with SB and your intermittent catheterization.

Conclusion

This study found marked differences between Brazil and Germany in regard to various health care issues. In Germany, all individuals can easily access their required IC materials (i.e., modern, single-use, pre-lubricated or hydrophilic catheters); however, in Brazil, many patients have difficulty in acquiring materials, being forced to either reuse catheters or suspend the procedure, which can lead to health complications and reduced social participation.

In Brazil, finance is a major problem: the needs of the individual must be balanced against state budget constraints and recognition of the right to the "existential minimum" of its citizens with disability, as the IC materials. In this sense, one should seek to optimize public spending, focusing on prioritizing the fundamental social rights. Therefore, we recommend that, in Brazil, the clean intermittent catheterization technique with single-use catheter be used.

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