Revista Bioética
Print version ISSN 1983-8042 On-line version ISSN 1983-8034
Rev. Bioét. vol.26 no.1 Brasília Jan./Mar. 2018
Doi: 10.1590/1983-80422018261231

RESEARCH

Judicial proceedings for the acquisition of insulin pump in the city of Ribeirão Preto

Raísa Gabrielle dos Santos Andrade[1], *Ellen Cristina Barbosa dos Santos*[2], *Carla Regina de Souza Teixeira*[1], *Jéssica Magalhães Felipe Batista*[1], *Clarissa Cordeiro Alves Arrelias*[1], *Liudmila Miyar Otero*[3], *Plinio Tadeu Istilli*[1]

1. Universidade de São Paulo, Escola de Enfermagem de Ribeirão Preto (EERP/USP), Ribeirão Preto/SP, Brasil. **2.** Universidade Federal de Pernambuco (UFPE), Recife/PE, Brasil. **3.** Universidade Federal de Sergipe, São Cristóvão/SE, Brasil.

Abstract

This exploratory, descriptive, documental and statistical article, with a quantitative approach, aims to analyze individual legal cases for the supply of insulin pump by users of the Sistema Único de Saúde (unified health system) in a municipality in the state of São Paulo, Brazil. We identified 40 (6.2%) cases demanding insulin pumps. Most of the cases were filed by men in the age group of 11 to 20 years. We also identified cases for the acquisition of drugs and other products such as glucometers and infusion sets, and insulin reservoirs. This study promotes discussions about the rights and integral care of people with diabetes *mellitus*. Thus, one hopes that it contributes to the understanding of how the process of judicialization can assist users in the search of new perspectives for the care of diabetes *mellitus*.

Keywords: Nursing. Diabetes *mellitus*. Patient rights. Public policies.

Resumo

Processos judiciais para aquisição de bomba de insulina em Ribeirão Preto

Objetivou-se analisar ações judiciais individuais para a aquisição de bomba de insulina movidas por usuários do Sistema Único de Saúde em município do estado de São Paulo, mediante estudo exploratório-descritivo do tipo documental e estatístico, de caráter quantitativo. Foram identificados 40 (6,2%) processos relacionados a demandas por bombas de insulina do total de 636 processos. A maioria das ações foi impetrada por homens para pacientes na faixa etária entre 11 e 20 anos. Foram também identificadas ações para adquirir medicamentos e outros insumos, como glicosímetros, conjuntos de infusão e reservatórios de insulina. O estudo tem como intuito promover discussões sobre direitos e assistência integral da pessoa com diabetes *mellitus*. Assim, espera-se contribuir para o entendimento de como o processo de judicialização pode auxiliar os usuários a buscar novas perspectivas para o cuidado com a doença.

Palavras-chave: Enfermagem. Diabetes *mellitus*. Direitos do paciente. Políticas públicas.

Resumen

Procesos judiciales para la adquisición de la bomba de insulina en Ribeirão Preto

Se tuvo como objetivo analizar las acciones judiciales individuales para la adquisición de la bomba de insulina por parte de los usuarios del Sistema Único de Salud, en un municipio del estado de São Paulo, mediante un estudio exploratorio-descriptivo, de tipo documental y estadístico, de carácter cuantitativo. Se identificaron 40 (6,2%) procesos relacionados con demandas de bombas de insulina de un total de 636 procesos. La mayoría de las acciones fueron impetradas por varones para pacientes en la franja etaria de entre 11 y 20 años. También se identificaron acciones para adquirir medicamentos y otros insumos, como glucómetros, equipos de infusión y reservorios de insulina. El estudio tiene como objetivo promover discusiones acerca de los derechos y de la asistencia integral de la persona con diabetes *mellitus*. Así, se espera contribuir a la comprensión acerca de cómo el proceso de judicialización puede ayudar a los usuarios en la búsqueda de nuevas perspectivas para el cuidado de la enfermedad.

Palabras clave: Enfermería. Diabetes *mellitus*. Derechos del paciente. Políticas públicas.

Aprovado CEP-EERP/USP CAAE: 52739515.8.0000.5393

Declaram não haver conflito de interesse.

Diabetes mellitus (DM) is a chronic non-communicable disease (NCD) and has become a significant global public health problem. By 2015, 415 million people worldwide had the disease and the number of deaths from diabetes reached five million. Projections for the year 2040 predict 642 million people affected[1].

In Brazil, a multi-center study evaluating the urban population between 30 and 69 years of age in the late 1980s showed that the prevalence of DM was 7.6%[2]. Higher figures were found in studies in Ribeirão Preto, where rates of 12.1%[3] and 15.02%[4] were found. Currently, 10.2 million adult Brazilians with ages between 20 and 79 years, have diabetes, with a national prevalence of 9.3%. The death toll in this age group was above 130 thousand[1].

DM follow-up is based on lifestyle change, encouraging the adoption of healthy habits associated with continuous education. The main goal should be normoglycemia, through the search for strategies for long-term maintenance[5]. Because it is a disease with high chronicity and with the possibility of causing incapacitating complications, it often requires the use of medications[5].

In this sense, oral antidiabetic drugs or insulin, which may or may not be combined, are used for treatment. Oral antidiabetic drugs are substances whose purpose is to reduce glycemia, keeping it within normal limits. According to their mechanisms of action, they are divided into classes and are indicated to treat individuals with type 2 DM. The use of insulin is indicated both for the treatment of type 1 DM and type 2 DM. This hormone influences and controls various physiological processes and is known for its action on glucose homeostasis[5]. Most of the time, these drugs are used on a large scale and for all the patient's life[5].

For effective control of DM, it is necessary to establish public policies related to the creation of mechanisms that minimize the onset and worsening of the disease, reducing costs[6]. In Brazil, the Unified Health System (Sistema Único de Saúde - SUS) aims to manage, organize, systematize and implement health actions in Brazil, having as basic principles the universality of access to services, integral care and equity in the distribution of resources[7]. From a DM perspective, the SUS emerges as a tool for policies that reorganize attention regarding the provision of the necessary inputs to control the disease[8].

With regard to the supply of medicines, many have been the efforts of public entities to provide pharmaceutical assistance. This fact is supported by continuous formulations and reviews of public policies. These began in 1998 with the creation of the National Medicines Policy (Política Nacional de Medicamentos - PNM), which was designed to guarantee access to essential medicines[9]. According to the World Health Organization (WHO), each country should establish its catalog of essential medicines, and this selection must follow criteria that assure the therapeutic needs of a given population[10].

In Brazil, pharmaceutical assistance is governed by the National List of Essential Medicines (Relação Nacional de Medicamentos Essenciais - Rename), for the medicines of exceptional dispensation, besides the medicines made available through programs for specific diseases, such as tuberculosis, malaria, diabetes, among others. The list of medicines offered is formulated according to strict criteria that consider from epidemiological aspects to safety and efficacy[11].

As for DM, in 2007 Law 11,347/2006 came into force, which provides for the free distribution of drugs and supplies necessary for the application of insulin and monitoring of capillary glycemia in users enrolled in education programs aimed at the disease[12]. Currently, the market presents a wide variety of drugs, supplies and devices for DM care; however, even with this availability, the user's difficulties in following the proposed treatment contribute to the poor control of the disease, the appearance of chronic complications and greater dependence on drug treatment[13].

In the late 1970s, Continuous Insulin Infusion Systems (Sistemas de Infusão Contínua de Insulina - Sici), or insulin infusion pumps, began to be studied by the Diabetes Control Complications Trial (DCCT), and from the late 1980s many people with type 1 DM began to use them as a resource to maintain strict control of glycemic levels[14]. SICI or insulin pumps, devices that simulate normal physiology, with continuous (basal) release of insulin and pulses (*bolus*) at mealtimes, or for the correction of hyperglycemia, giving great flexibility to the lifestyle, particularly in relation to meal times. Among the advantages are the more predictable, accurate and safe absorption, with improved glycemic control and less occurrence of hypoglycemia, guaranteeing a better quality of life[15].

For continuous use of the insulin pump, it is necessary to consider the cost of maintenance, since it requires the exchange of catheters, tubes and reservoirs, as well as the acquisition of insulin itself and the strips to monitor blood glucose. Thus, the person with DM often has to resort to alternative means, through lawsuits against public

entities, in order to guarantee access to treatment and their right to health. In Brazil, some studies have shown that the actions against the State to request medicines have been growing in recent years[16,17]. However, little has been verified regarding the supply of other inputs for DM care, such as insulin analogues and insulin pumps.

The purpose of this study was to analyze the individual lawsuits to obtain insulin pumps from SUS users with DM between 2007 and 2013 against the Regional Health Department XIII (Departamento Regional de Saúde XIII - DRS XIII) of the State of São Paulo and the Municipal Health Department of Ribeirão Preto/SP.

Methods

This is an exploratory-descriptive study of documentary and statistical type, and of quantitative character. The study universe was the lawsuits filed against the Division of Pharmacy and Diagnostic Support of the Municipal Health Department of Ribeirão Preto (Divisão de Farmácia e Apoio Diagnóstico da Secretaria Municipal de Saúde de Ribeirão Preto) and the Regional Health Department XIII (DRS XIII) of the State of São Paulo, regarding the issue of insulin pumps for treatment of DM, between January 2007 and December 2013. The study variables were related to procedural elements, such as the case number, the year of commencement, the status of the action (judged, not judged, terminated by the death of the author) and conductor of the action (public defender, model office or private office); and variables related to users, such as age, municipality of origin and origin of the medical prescription (university hospital, federal, state, municipal, clinic accredited by the SUS or private practice), raised by a semistructured data collection instrument.

The data were organized and entered in a database and imported into the Statistical Package for Social Sciences software, version 17.0. For the statistical analysis, a descriptive technique was used through mean, standard deviation and percentage.

Results

It was found that in the period between 2007 and 2013, 636 lawsuits were filed for the acquisition of drugs and supplies related to DM. Of these, 40 (6.2%) were for insulin pumps. The predominant age group was between 11 and 20 years (35.9%), as shown in Table 1, and most of the cases were filed by men (72.5%).

Table 1. Distribution of lawsuits for the supply of insulin pump to people with DM, between 2007 and 2013, by age group, Ribeirão Preto, 2016

Age group	Number	%
0-10	6	15,4
11-20	14	35,9
21-30	10	25,6
31-40	4	10,3
41-50	2	5,1
51-60	3	7,7

The most requested materials were insulin pump (infusion set and insulin reservoir), continuous glucose monitor and MiniLink data transmitter (Table 2). It was also found that all requests for insulin pumps were prescribed in private medical offices. Regarding the year of opening of the judicial proceedings, two cases were identified in 2007, one in 2008, five in 2009, five in 2010, four in 2011, fifteen in 2012 and eight in 2013

Table 2. Distribution of the requests in lawsuits for the supply of insulin pumps and other materials by people with DM, between 2007 and 2013, Ribeirão Preto, 2016

Materials requested	Number	%
Insulin pump	40	100
CIP input	39	98
Continuous glucose monitor	30	75
Minilink Transmitter	30	75
Accu-Chek Performa Strips	2	5
Disposable needles	1	3

In addition to requests for supply of insulin pumps, it was possible to identify the request of other inputs, such as medicines and materials. Among the drugs are the Lispro and Aspart insulins (Table 3).

Table 3. Distribution of the requests in lawsuits for the supply of insulin analogues for people with DM, between 2007 and 2013, Ribeirão Preto, 2016

Inputs requested	Number	%
Lantus Insulin	1	3
Lispro Insulin	11	28
Aspart Insulin	17	43
Detemir Insulin	3	8
Glulisine Insulin	3	8
Aspart + Protamine	1	3

http://dx.doi.org/10.1590/1983-80422018261231

Discussion

Currently, the great advantage of the use of the infusion pump is the flexibility offered to the user, generating a high degree of acceptance and enabling the adherence to the treatment of people with DM. In the literature there are few studies that have verified lawsuits for insulin pumps [18,19].

Most of the listed lawsuits correspond to requests for medicines and other inputs, as shown by 170 lawsuits against the São Paulo State Municipal Department Paulo (os tradutores sugerem alterar para "Secretaria Municpal de Saúde da Cidade de São Paulo" ou "Secretaria Estadual do Estado de São Paulo", visto que não foi localizada a existencia de uma Secretaria Municipal sem especificação da pasta a que pertence, restando uma dúvida, pois a Secretaria Municipal não pode ser do Estado de São Paulo, seria contraditório, se é municipal se refere à cidade de São Paulo, se estadual, ao Estado de São Paulo) to obtain medicines, of which 37% were related to DM [19]. The same study found that most of the actions referred to young people, which corroborates the findings of this study. This reveals that age is compatible with the indication of insulin pumps for people with type 1 DM [20]. Regarding gender, the data diverge, since most of the actions were performed by men (72.5%), whereas other studies have shown that the actions were, in greater number, required by women [19,21].

Previously, it was believed that only diabetic patients in late adolescence, and who were familiar with the treatment and especially motivated, should be put on insulin infusion pump therapy. However, comparisons between the multiple injected dose scheme and infusion pumps are shown to be equivalent for both DM1 and DM2 treatment in terms of improved glycated hemoglobin or total daily insulin dose. The difference in the forms of treatment is more evident in the incidence of hypoglycemia and in the level of patient satisfaction with the treatment adopted, although the pumps perform better in children and adolescents [20].

Intensive treatment with SICI is associated with an increase in the financial cost when compared to traditional treatment. You should also take into account the value of the inputs needed to use the appliance. The initial cost of the device with catheters, syringes, needles, infusers, material for insertion of the catheter and belts of attachment of the device to the body is about 5 thousand dollars [22].

In addition to the initial cost, maintenance of the treatment includes inputs of pump, insulin, battery, and other materials that have an annual cost of US$ 1,500 [23]. However, these costs are justified by studies that have unanimously demonstrated that insulin pump treatment is more cost-effective for patients with DM because it allows and facilitates changes in diet and exercise. In addition, it improves metabolic control, reduces episodes of severe hypoglycemia or diabetic ketoacidosis, thus contributing to a higher quality of life of patients [22].

Consistent with the demands for insulin pumps, it was evidenced that 100% of the processes requested systems for continuous infusion pump (CIP), which are composed by the infusion set and the insulin reservoir. This is justified by the fact that the expenses with the maintenance of the infusion pump are high, since these assemblies require periodic changes to function properly. In addition, 30 trials (75%) sought glucometers for continuous glucose monitoring, characterized as an effective methodology for investigating glycemic oscillations and an important tool for therapeutic adjustment in people with DM [24]. Concerning insulin pumps, the glucometer can provide the user's blood glucose in real time (wireless), making it safer to use the infusion pump [20].

These devices are known to be costly both for acquisition and maintenance. However, a Spanish study comparing continuous insulin infusion and conventional treatment in people with DM1 found that the use of insulin pump decreased the overall cost of patient care, cost-utility and reduction of complications occurrence in the lifetime [25]. Therefore, users with DM, aware of their rights guaranteed by the Brazilian Constitution, which guarantees access to drugs, materials for insulin application and monitoring of capillary glycemia, provided for in current legislation, have judicial system to obtain insulin pumps by clinical indication.

This process is called judicialization and can be generically considered as a phenomenon constituted by the influence of the Judiciary in political and social institutions. The judicialization of health has been growing significantly, with the increase of lawsuits against the State [26]. When the outcome of the actions is favorable to citizens, health systems are required to ensure the cost of treatment.

Some national studies have verified that a great part of the health assets requested to the courts is related to the pharmaceutical assistance [16,21]. In addition to these, others addressed actions that pleaded items such as food, hospital beds,

wheelchairs, disposable gloves, syringes, probes, disposable diapers, glucometers, among other items [16].

It was evidenced in our study that all insulin pumps were prescribed by physicians from private practices. This suggests that patients who resort to the judiciary have better socioeconomic conditions, which could call into question the real impossibility of these users to finance their treatments.

However, this analysis did not correlate aspects of socioeconomic profile, making it difficult, therefore, to advance a more in-depth discussion on the topic. Despite this, it is impossible to ignore the extent to which the right to health is conditioned to the socioeconomic situation of those who demand the receipt of the pumps, which may require legal action, and as this right is denied to other segments of the population that, due to economic or educational reasons, can not get the same treatment.

Another point that deserves discussion is the need to accompany the patient who uses the insulin pump, which makes the work of a multidisciplinary team that has experience with this type of treatment in both the public and private spheres essential. Other important points are the work of the therapeutic education team and adequate family support.

Before prescribing the pump therapy, the treatment should be broadly discussed, realistically, with the family and patient, as the incidence of withdrawal from infusion pump therapy tends to be higher in cases of less informed patients [20]. On the other hand, the causes of withdrawal from therapy are related to the inability to use the equipment, the lack of family support and costs, as well as the distortion of the body image, with feelings of negative factors by the visibility of the insulin pump [20]. Therefore, prospective studies with insulin pump users should be conducted to deepen knowledge about the subject.

Another significant finding of this study is the occurrence of great demands for medications such as Lispro (28%) and Aspart (43%) Insulin, characterized as ultrarapid insulins with increased onset and concentration and shorter duration of action. In a previous study, good glycemic control was verified with the use of these substances, as well as a reduction in hypoglycemic events [27].

These data corroborate the data in the literature that the insulin analogues most commonly used in subcutaneous infusion pump therapy are insulin Aspart, Lispro and Glulisine, since they are the ones with the fastest action and providing the lowest reduction of glucose available for continuous infusion devices. In addition, they are associated with a lower rate of hypoglycemia when compared to regular human insulin [27].

Therefore, it is fundamental that all nursing professionals, regardless of their area of expertise, know the advantages, disadvantages and peculiarities of the infusion pump, since users with DM may need care at any of the levels of care offered by the SUS. In a more specific way, nurses should have scientific data that supports their interventions in relation to the user with DM using SICI, mainly due to their role as health educators [28].

Finally, it should be noted that the 1988 Constitution guarantees health as the right of everyone and the duty of the State, but nonetheless, users of the Unified Health System must resort to legal action to guarantee their right to integral, egalitarian and universal health.

Final considerations

This study identified 636 lawsuits filed against the Division of Pharmacy and Diagnostic Support of the Municipal Health Department of Ribeirão Preto/SP and the Regional Health Department XIII (DRS XIII) of the state of São Paulo that were requesting drugs and supplies to control DM . Of these, forty were related to the acquisition of insulin pumps, which seems still low in relation to the judicial demand in patients with DM. In addition to these, demands were also made for drugs, such as insulins, and supplies, such as infusion sets, insulin reservoirs, and glucometers.

In the national literature few studies have analyzed judicial processes for obtaining insulin pumps, and most published studies refer to the acquisition of drugs. Because it is an innovative technology and still not very widespread in the SUS, due to the high cost, many users end up seeking legal help to obtain it.

Associated with this, it is hoped to contribute to the understanding of how the judicialization can help users to seek new alternatives for DM care. However, in this study we showed that most of the prescriptions of the insulin pump come from private clinics, from a small part of the population with better socioeconomic conditions. That is, this process generates high costs for the SUS, but does not improve the quality of life of most of the people with DM. It should also be emphasized that patients who receive this allowance must be accompanied by teams prepared to meet their demands, which implies meeting other needs.

In order to access new technologies in DM care, access to information is necessary. I this study, we found that the lack of information interferes with the way in which the right to health is understood, as well as in the way it is claimed through the judicialization. Thus, we found the mismatch between users of the public health system who use the private health service and those who use only the SUS, since those sought access to the insulin pump while they are probably unaware of its right and innovations in treatment for this chronic condition.

It is considered that the strategies of qualified information to the patients, together with the recognition by the State of the benefits of insulin pumps, regarding the control of the disease and quality of life of the users, could serve as a basis to adopt the treatment for at least some types of users, such as adolescents and young people. Perhaps the recognition of the effectiveness of the treatment and its consequent adoption by the Brazilian State for the care of adolescents and young people could help to reduce the costs and also the number of legal proceedings to obtain it.

Referências

1. International Diabetes Federation. IDF Diabetes Atlas. 7ª ed. Bruxelas: Internacional Diabetes Federation; 2015.
2. Malerbi DA, Franco LJ. Multicenter study of the prevalence of diabetes *mellitus* and impaired glucose tolerance in the urban Brazilian population aged 30-69 yr. The Brazilian Cooperative Group on the Study of Diabetes Prevalence. Diabetes Care. 1992;15(11):1509-16.
3. Torquato MTCG, Montenegro Junior RM, Viana LAL, Souza RAHG, Lanna CMM, Lucas JCB *et al*. Prevalence of diabetes *mellitus* and impaired glucose tolerance in the urban population aged 30-69 years in Ribeirão Preto (São Paulo), Brazil. São Paulo Med J. 2003;121(6):224-30.
4. Moraes AS, Freitas ICM, Gimeno SGA, Mondini L. Prevalência de diabetes *mellitus* e identificação de fatores associados em adultos residentes em área urbana de Ribeirão Preto, São Paulo, Brasil, 2006: Projeto Obediarp. Cad Saúde Pública. 2010;26(5):929-41.
5. Oliveira JEP, Vencio S, organizadores. Diretrizes da Sociedade Brasileira de Diabetes 2015-2016. São Paulo: AC Farmacêutica; 2016.
6. Organização Mundial da Saúde. Cuidados inovadores para condições crônicas: componentes estruturais de ação: relatório mundial [Internet]. Geneva: OMS; 2003 [acesso 12 mar 2017]. Disponível: https://goo.gl/9gY21C
7. Brasil. Presidência da República. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências [Internet]. Diário Oficial da União. Brasília; 20 set 1990 [acesso 12 mar 2017]. Disponível: https://goo.gl/Y1ndbT
8. Oliveira SLC, Lunardi Filho WD. Aids e diabetes *mellitus versus* justiça distributiva no sistema público de saúde. Rev Bras Enferm. 2004;57(6):750-3.
9. Brasil. Ministério da Saúde. Portaria GM/MS 3.916, de 30 de outubro de 1998. Aprova a Política Nacional de Medicamentos [Internet]. Diário Oficial da União. Brasília; nº 215-E, p. 18-22, 10 nov 1998 [acesso 2 mar 2017]. Seção 1. Disponível: https://goo.gl/UCuS9E
10. Organização Mundial da Saúde. Selección de medicamentos esenciales: perspectivas políticas de la OMS sobre medicamentos [Internet]. Geneva: OMS; 4 jun 2002 [acesso 12 mar 2017]. Disponível: https://goo.gl/KQQ9Tt
11. Pepe VLE, Figueiredo TA, Simas L, Osorio-de-Castro CGS, Ventura M. A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica. Ciênc Saúde Coletiva. 2010;15(5):2405-14.
12. Brasil. Presidência da República. Lei nº 11.347, de 27 de setembro de 2006. Dispõe sobre a distribuição gratuita de medicamentos e materiais necessários à sua aplicação e à monitoração da glicemia capilar aos portadores de diabetes inscritos em programas de educação para diabéticos [Internet]. Diário Oficial da União. Brasília; 28 set 2006 [acesso 10 fev 2017]. Disponível: https://goo.gl/px81nP
13. Santos ECB, Teixeira CRS, Zanetti ML, Santos MA. A efetivação dos direitos dos usuários de saúde com diabetes *mellitus*: co-responsabilidades entre poder público, profissionais de saúde e usuários. Texto Contexto Enferm. 2011;20(3):461-70.
14. American Diabetes Association. Continuous subcutaneous insulin infusion. Diabetes Care. 2004;27(1 Suppl):S110.
15. Boland EA, Grey M, Oesterle A, Fredrickson L, Tamborlane WV. Continuous subcutaneous insulin infusion: a new way to lower risk of severe hypoglycemia, improve metabolic control, and enhance coping in adolescents with type 1 diabetes. Diabetes Care. 1999;22(11):1779-84.
16. Borges DCL, Ugá MAD. Conflitos e impasses da judicialização na obtenção de medicamentos: as decisões de 1ª instância nas ações individuais contra o Estado do Rio de Janeiro, Brasil, em 2005. Cad Saúde Pública. 2010;26(1):59-69.
17. Pereira JR, Santos RI, Nascimento Junior JM, Schenkel EP. Análise das demandas judiciais para o fornecimento de medicamentos pela Secretaria de Estado da Saúde de Santa Catarina nos anos de 2003 e 2004. Ciênc Saúde Coletiva. 2010;15(3 Suppl):3551-60.

18. Silveira D, Angelo T, Pinheiro RM, Gratieri T. Infusão subcutânea contínua de insulina: cenário nacional e internacional. Cad Saúde Colet. 2016;24(4):496-501.
19. Nunes CFO, Ramos Junior AN. Judicialização do direito à saúde na região Nordeste, Brasil: dimensões e desafios [Internet]. Cad Saúde Colet. 2016 [acesso 10 out 2017];24(2):192-9. Disponível: https://goo.gl/LU4pyc
20. Vieira FS, Zucchi P. Distorções causadas pelas ações judiciais à política de medicamentos no Brasil. Rev Saúde Pública. 2007;41(2):214-22.
21. Liberatore Júnior RDR, Damiani D. Bomba de infusão de insulina em diabetes melito tipo 1. J Pediatr. 2006;82(4):249-54.
22. Machado MAA, Acurcio FA, Brandão CMR, Faleiros DR, Guerra Júnior AA, Cherchiglia ML *et al*. Judicialização do acesso a medicamentos no Estado de Minas Gerais, Brasil. Rev Saúde Pública. 2011;45(3):590-8.
23. Heinemann L, Fleming GA, Petrie JR, Holl RW, Bergenstal RM, Peters AL. Insulin pump risks and benefits: a clinical appraisal of pump safety standards, adverse event reporting, and research needs: a joint statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. Diabetes Care. 2015;38(4):716-22.
24. Brorsson AL, Leksell J, Viklund G, Lindholm Olinder A. A multicentre randomized controlled trial of an empowerment-inspired intervention for adolescents starting continuous subcutaneous insulin infusion: a study protocol. BMC Pediatr. 2013;13:212.
25. Gomez AM, Alfonso-Cristancho R, Orozco JJ, Lynch PM, Prieto D, Saunders R *et al*. Beneficios clínicos y económicos de la terapia con bomba de insulina integrada a sistema de monitoreo continuo de glucosa en los pacientes diabéticos tipo 1 en Colombia. Endocrinol Nutr. 2016;63(9):466-74.
26. Marques ORA, Melo MB, Santos APS. Ações judiciais no âmbito do Sistema Único de Saúde do Brasil, bases legais e implicações: um estudo de caso em um tribunal da região Sudeste. Rev Direito Sanit. 2011;12(1):41-66.
27. Luis DA, Romero E. Análogos de insulina: modificaciones en la estructura, consecuencias moleculares y metabólicas. Semergen. 2013;39(1):34-40.
28. Santos ECB, Galindo Neto NM, Santos ITS, Teixeira CRS, Landim CAP. Bomba de infusão contínua em pacientes com diabetes *mellitus*: revisão integrativa. Rev Enferm UFPE on line. 2013;7(Esp):4192-8.

Correspondência
Carla Regina de Souza Teixeira – Av. dos Bandeirantes, 3.900 CEP 14040-902. Ribeirão Preto/SP, Brasil.

Raísa Gabrielle dos Santos Andrade – Graduada – andraderaisa24@gmail.com
Ellen Cristina Barbosa dos Santos – Doutora – ellenbarbosa@usp.br
Carla Regina de Souza Teixeira – Doutora – carlarst@eerp.usp.br
Jéssica Magalhães Felipe Batista – Mestre – jessica.batista@usp.br
Clarissa Cordeiro Alves Arrelias – Mestre – claarrelias@usp.br
Liudmila Miyar Otero – Doutora – lumamiyar@hotmail.com
Plinio Tadeu Istilli – Doutorando – ptistilli@usp.br

Participation of the authors
Raísa Gabrielle dos Santos Andrade, the main drafter of the article, proposed its preliminary structureand articulated the argument. Ellen Cristina Barbosa dos Santos, main critical contributor and of the article. Carla Regina de Souza Teixeira, critically suggested changes and improvements in the reasoning of arguments. Jessica Magalhães Felipe Batista included topics, reviewed the bibliography and recommended improvements in the text. Clarissa Cordeiro Alves Arrelias did the spelling and critical review. Liudmila Miyar Otero did the general review. Plinio Tadeu Istilli recommended inclusions and deletions on formatting and structure.

Recebido: 13. 4.2017
Revisado: 4.10.2017
Aprovado: 21.11.2017