

ORIGINAL ARTICLE

PERFORMANCE OF PEOPLE WITH DIABETES MELLITUS UNDER INSULIN THERAPY*

Pamela dos Reis¹, Sonia Silva Marcon², Evelin Matilde Arcain Nass³, Guilherme Oliveira de Arruda⁴, Ivi Ribeiro Back⁵, Iven Giovanna Trindade Lino⁶, Verônica Francisqueti⁷

ABSTRACT

Objective: to evaluate the performance of people with diabetes mellitus or family member responsible for the storage, preparation, administration and disposal of materials used in insulin therapy.

Method: Descriptive cross-sectional study conducted with users followed in primary care in a municipality in southern Brazil. Data were collected between January and March 2017, through instrument application and systematic observation of the insulin therapy process at home.

Results: 168 users with an average age of 69.9 years old were evaluated. The number of errors regarding the insulin application process ranged from 3 to 22 out of 31 questions. It was found that 96 (56%) participants disposed of material in an inappropriate place and 157 (93.4%) reused syringes/needles.

Conclusion: The performance of a significant portion of people with Diabetes and/or family members responsible for insulin therapy at home is flawed regarding the knowledge and practice of waste storage, preparation, administration and disposal.

DESCRIPTORS: Diabetes Mellitus; Insulin; Nursing; Health education; Self-care.


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¹RN. Nursing Ph.D. student. State University of Maringá. Maringá, PR, Brazil. 


²RN. Ph.D. in Philosophy of Nursing. Professor of Nursing and Graduate Nursing, State University of Maringá. Maringá, PR, Brazil. 

³RN. Nursing Ph.D. student. State University of Maringá. Maringá, PR, Brazil. 

⁴RN. PhD in Nursing. Professor at the Federal University of Mato Grosso do Sul. Campo Grande, MS, Brazil. 

⁵RN. PhD in Health Sciences. Professor at the University Center of Maringá. Maringá, PR, Brazil. 

⁶RN. Nursing Ph.D. student. State University of Maringá. Maringá, PR, Brazil. 

⁷RN. Master's student in Nursing, State University of Maringá, PR, Brazil. 

DESEMPENHO DE PESSOAS COM DIABETES MELLITUS NA INSULINOTERAPIA

RESUMO

Objetivo: avaliar o desempenho de pessoas com Diabetes Mellitus ou familiar responsável no armazenamento, preparo, administração e descarte dos materiais utilizados na insulino terapia.

Método: estudo transversal descritivo, realizado com usuários acompanhados na Atenção Primária de município no Sul do Brasil. Os dados foram coletados entre janeiro e março de 2017, mediante aplicação de instrumento e observação sistematizada do processo de insulino terapia no domicílio.

Resultados: foram avaliados 168 usuários com idade média de 69,9 anos. O número de erros referentes ao processo de aplicação da insulina variou de 3 a 22 de um total de 31 questões. Verificou-se que 96 (56%) participantes faziam o descarte de material em local inadequado e 157 (93,4%) reutilizavam seringas/agulhas.

Conclusão: o desempenho de uma parcela importante das pessoas com Diabetes e/ou familiares responsáveis pela insulino terapia no domicílio é falho em relação ao conhecimento e prática do processo de armazenamento, preparo, administração e descarte de resíduos.

DESCRITORES: Diabetes Mellitus; Insulina; Enfermagem; Educação em Saúde; Autocuidado.

ACTUACIÓN DE PERSONAS CON DIABETES MELLITUS EN INSULINOTERAPIA

RESUMEN

Objetivo: evaluar la actuación de personas con Diabetes Mellitus y/o de familiares a cargo en el almacenamiento, preparación, administración y descarte de los materiales utilizados en la insulino terapia.

Método: estudio transversal descriptivo, realizado con usuarios acompañados en la Atención Primaria municipal en el Sur de Brasil. La recolección de datos se realizó entre enero y marzo de 2017, mediante aplicación de instrumento y observación sistemática del proceso de insulino terapia en el domicilio.

Resultados: se evaluaron 168 usuarios con edad promedio de 69,9 años. El número de errores relativos al proceso de aplicación de la insulina osciló entre 3 y 22 en un cuestionario de 31 puntos. Se verificó que 96 (56%) participantes descartaban el material en lugares inadecuados y 157 (93,4%) reutilizaban jeringas/aguja.

Conclusión: la actuación de una importante franja de personas con Diabetes y/o de familiares a cargo de la insulino terapia en el domicilio es deficitaria en relación al conocimiento y a la realización del proceso de almacenamiento, preparación, administración y descarte de residuos.

DESCRIPTORES: Diabetes Mellitus; Insulina; Enfermería; Educación en salud; Autocuidado.

INTRODUCTION

Diabetes Mellitus (DM), a disease characterized by metabolic disorders that result in hyperglycemia, is one of the Chronic Nontransmittable Diseases that has dramatically increased worldwide⁽¹⁾. It is estimated that by the year 2045 there will be 629 million adults in the world with DM, with 42 million residents in Central and Latin America⁽²⁾. The prevalence in Brazil is 7.5%, being higher in the South (8.9%) and Southeast (8.2%) regions⁽³⁾.

Despite the impact on an individual's life, proper drug therapy and a healthy lifestyle can control the disease, reducing the risk for complications⁽¹⁾. In type 1 DM (DM1), insulin treatment is a classic and indispensable indication and should be started as soon as the diagnosis is established. In cases of type 2 DM (DM2), patients are not insulin dependent, but its use may be necessary in order to achieve metabolic control⁽¹⁾.

Although insulin has a beneficial effect on blood glucose control, misuse can lead to risks⁽⁴⁾. The Institute for Safe Drug Use Practices classifies all types of exogenous insulin as potentially hazardous because of the high risk of damage due to failure in the use process.⁽⁵⁾ The risk for unstable glycaemia is potentiated by inadequate use of insulin, because in addition to uncontrolled hyperglycemia, episodes of hypoglycemia can occur, an acute complication that can be fatal^(1,6).

In Brazil, in the last five years, some studies⁽⁷⁻¹¹⁾ evaluated the insulin delivery technique. However, it is noteworthy that only one evaluated the technique performed by the patients, in the case of elderly septuagenarians,⁽⁷⁾ with observation of the process in their homes. The others were carried out in health service outpatient clinics,⁽⁸⁻¹¹⁾ using self-reported information about the technique, which may be in disagreement with the one performed in the daily life.

It is believed that the observation of the technique in a context closer to the patient's reality, with the inputs themselves and in the usual place of application, may contribute to the knowledge of a real panorama of the phenomenon. In this context, the present study aimed to evaluate the performance of people with diabetes mellitus (or responsible family member) regarding the storage, preparation, administration and disposal of materials used in insulin therapy.

METHOD

This is a descriptive study with a quantitative approach, conducted with people with DM or responsible family members who used insulin and were followed in Primary Health Care (PHC) of a medium-sized municipality in the metropolitan region of Porto Alegre, Rio Grande do Sul. The PHC service of the municipality has eight Basic Health Units (BHU) and ten Family Health Strategy (FHS) teams.

Users aged 18 years old and older were considered eligible for the study. The inclusion criteria adopted were: Make use of insulin and be accompanied within the PHC of the municipality. The only exclusion criterion adopted was the use of injection pens in the administration of insulin, since the instrument used in data collection focuses on syringe application as recommended by the Brazilian Diabetes Society (*Sociedade Brasileira de Diabetes* - SBD).⁽¹⁾

To define the sample size, we used the list of eligible DM patients who were taking insulin at the municipal pharmacy, containing name, address and age. At the time, the drug and the corresponding supplies were dispensed to 286 people, of whom seven were under 18 years old. Thus, considering a population of 279 people, a 3% estimation error ($e = 0.03$), 95% confidence level ($z=1.96$) and prevalence of 10%, plus 20% for possible losses, one obtained a sample of 194 people, who were randomly selected and stratified by age

group (18-59 years and 60 years or older) and reference unit.

At the end, a sample of 168 participants was obtained. Losses and exclusions resulted from refusal (13), death (5), change of municipality of residence (4) and use of pen injectors (4).

The initial approach of the participants was accomplished together with the Community Health Agent (CHA) during home visits. In 54 cases (32.14%) in which there was no FHS coverage, the referral BHU nurse verified the individual's acceptance to receive a telephone call or visit from the researcher.

Data collection at all stages of the study was performed by the first author and occurred in the first quarter of 2017 with the application of two instruments. The first addressed sociodemographic and clinical characteristics, with the following variables: Age, gender, marital status, education, occupation, family income, time since diagnosis of DM, type of DM and time of insulin use. The other instrument was developed based on the SBD Guidelines and addressed knowledge about insulin use/management. This instrument was developed in Brazil for application by telephone and consists of 38 questions that encompass, in addition to insulin treatment, sociodemographic characteristics and instructions for its application by telephone⁽¹²⁾.

In this research, the data were collected face to face at home. Thus, the questions were adapted, with the permission of the authors, for a script of observation of the process of (self) application of insulin (real or simulated) in the format of a checklist. Also, the instructions for applying by phone have been deleted. The applied instrument consisted of 31 questions, 15 that addressed the knowledge about insulin therapy and 16 the administration technique. The definition of right or wrong questions took into account the SBD's recommendations.⁽¹⁾

It is noteworthy that during all stages of the data collection process the participants were reassured by clarifying that the intention was to help them and not to evaluate what they were doing. In addition, at the end of applying the instruments, all participants were instructed on the correct insulin administration technique according to the SBD.

The data were organized in a databank in the program. Microsoft Excel and analyzed in the Statistical Analysis Software (SAS, version 9.4). Descriptive statistics was used with the percentage of hits and misses in each item of the instrument and use of mean and standard deviation. The SPSS version 20 program was also used, in which the Kolmogorov-Smirnov normality test was triggered, from which it was observed that the data followed a far-from-normal distribution, so, for data representation, we opted for the median as a measure for central trend.

The nonparametric Kruskal-Wallis test was also performed to analyze the differences between the median errors committed. For these tests, a significance level of 5% was considered.

The study was approved by the Ethics Committee of the proposing institution (Opinion No. 1.889.132).

RESULTS

A total of 168 people with DM participated in the study, being 159 (94.7%) Type 2 and 108 (64.3%) female. The average age was 59.9 years old. There was a predominance of married participants 111 (66.1%), with incomplete primary education 117 (69.64%) and retired 103 (61.31%). The income per capita of 62 (36.90%) was less than one minimum wage, while for 95 (56.5%) it was one to two wages.

The time since diagnosis ranged from one to 40 years (average 13.44 years) and the average time of insulin use was 6.36 years. Insulin self-application was performed by 129 (76.8%) participants and the others were assisted by family members.

It is noteworthy that 40 (23.2%) participants reported not having been instructed by a professional about the administration of insulin at home. They reported having learned through observation in health services or with relatives who were already using it. Also, according to the reports, the professionals who provided guidance were members of the nursing staff 90 (53.6%), doctors 36 (21.4%) and pharmacists 6 (3.6%).

Table 1 - Knowledge of insulin therapy among patients with DM according to SBD recommendations. Parobé, RS, Brazil, 2017

Question	Right* n=168	%
Application site	168	100
Preparation prior to disposal of sharps	164	97.6
Type of syringe used	163	97
Post-application site observation	154	91.7
Application site rotation	149	88.7
Type of insulin used	113	67.2
Insulin transport	76	45.2
Destination of sharps	74	44
Container in which sharps are stored	62	36.9
Insulin syringe graduation scale	57	33.9
Size of syringe used	47	27.9
Validity of open insulin bottle	28	16.6
Insulin storage location in use	27	16
Needle type	12	7.1
Reuse of syringe and insulin needle	11	6.5

* In the questions about knowledge the referred answers were considered.

Regarding knowledge of insulin therapy, Table 1 shows that higher percentages of correct answers occurred in relation to the places where insulin can be applied, preparation before disposal and observation of the site after application. The worst percentages were regarding reuse of syringe and needle, knowledge of the type of needle used and validity of the bottle after opening.

Regarding the knowledge of the type of insulin used, it was considered the right answer that was in accordance with the medical prescription, verified by the researcher after the answer. Answers in disagreement and "don't know" were considered wrong. Thus, 55 (32.7%) made the mistake and justified using the insulin dispensed in the pharmacy upon presentation of the prescription. Knowledge about the size of the syringe used, graduation scale and needle type were considered after the material was checked.

In the questions regarding the application (location, rotation and observation) the referred to answers were considered. All participants reported applying insulin in appropriate places, but 149 (88.7%) mentioned not performing rotation. The most used site in the applications was the abdomen, having been reported by 152 (90.5%) participants of which 90 (53.7%) used only this site.

Reusing the syringe and needle was reported by 157 (93.4%) participants, and occurred for a period of one to 30 days. It is noteworthy that in the municipality under study the amount of material dispensed induces reuse, since, in general, 10 syringes and needles are dispensed per month for each patient.

Adequate storage locations for insulin in use were considered in the lower shelf of the refrigerator or at room temperature (up to 30 degrees Celsius). Inadequate insulin storage sites were reported by 141 (83.9%) participants, with the refrigerator door being used by 123 (73.2%). Insulin transport was performed on ice Styrofoam by 156 (92.9%) participants, but 83 (49.4%) left it in direct contact with ice.

Table 2 shows data regarding the observation of insulin preparation and application.

Table 2 - Distribution of the correct answers observed in insulin preparation and application (checklist). Parobé, RS, Brazil, 2017

Question	n	Right	%
Positioning the insulin vial for aspiration	168	162	96.43
Needle insertion angle into skin	168	158	94.05
Finger tapping the syringe for air removal	168	157	93.45
Insulin homogenization	168	154	91.67
Checking and adjusting insulin dose after air removal	168	154	91.67
Hand washing	168	128	76.19
Application site massage	168	112	66.67
Subcutaneous fold	168	111	66.07
Observation of insulin characteristics	168	95	56.55
Insulin aspiration sequence	23*	12	52.17
Needle recapping until application	168	74	44.05
Cotton and alcohol 70% skin antiseptis	168	73	43.45
Withdrawal of insulin from refrigeration	167**	24	14.37
Insulin bottle rubber disinfection	168	24	14.29
5 second wait to remove needle from skin	168	21	12.50
Insertion of air into the insulin vial	168	6	3.57

* taking more than one insulin type

** one participant did not keep it refrigerated

Regarding preparation and administration, the steps with the lowest percentage of correct answers were "introduction of air into the insulin vial", "waiting 5 seconds to remove the skin needle" and "disinfection of the rubber vial". It is noteworthy that it was common

during the orientation about the procedure, performed at the end of data collection, the spontaneous report of lack of knowledge about the above mentioned steps.

The number of errors ranged from 3 to 22 out of a total of 31 questions. The overall mean error was 13.16 ± 3.34 and the median 14.00 (IQR = 11-15), data not shown in the table. No significant difference was observed between the medians of errors according to time of insulin use and time of diagnosis, but there was a slight decrease in the median of errors, as the time of insulin use and the time for DM diagnosis increases (Table 3).

Table 3 - Mean errors and standard deviation according to time of insulin use and time since diagnosis. Parobé, RS, Brazil, 2017

Variables	n	Errors Median (IQR*)	p-value**
Insulin usage time			
Up to 1 year	23	14 (12.25-15.75)	p=0.898
1-5 years old	73	14 (11-16)	
5-10 years old	48	14 (10-15)	
>10 years	24	12 (11-14)	
Diagnostic time			
Up to 1 year	4	14 (5.75-14.75)	p=0.245
1-5 years old	31	14 (12-15)	
5-10 years old	45	140 (11-16)	
>10 years	88	13.50 (11-15.75)	

*IQR - Interquartile Range; ** Significance regarding the Kruskal-Wallis test.

DISCUSSION

The sociodemographic characterization of the participants corroborates the results of other studies conducted in the Brazilian context, in which a predominance of insulin use by the elderly, low-educated population, is identified⁽¹³⁻¹⁷⁾.

The support for self-care for people taking insulin is important, as self-application, facilitates treatment independence. However, this independence is sometimes compromised for reasons resulting from complications of the disease, such as low visual acuity, which may lead to doses in disagreement with the prescription⁽¹⁸⁾.

Therefore, in cases of impossibility or even difficulty in self-application, the presence of a family member who takes responsibility for this activity makes the treatment safer. In this study, all people who did not self-apply insulin had the help of a family member for the procedure, which was also pointed out in a study conducted in Fortaleza-CE with 87 people, of whom 37 (42.5%) did not do the self-application⁽⁸⁾.

The report on lack of professional guidance on insulin application by 40 (23.2%) participants is worrisome, although the data are better than the study conducted in Formiga-MG, with 347 patients, in which half said they had not received this kind of information⁽¹⁹⁾.

The lack or deficiency of orientation increases the possibility of errors in the application of insulin at home⁽⁴⁾. The Institute for Safe Practices in the Use of Medicines recommends the adoption of protocols for guidance to patients, family members and/or caregivers clearly on the therapeutic regimen and administration of insulin to reduce errors⁽⁵⁾.

Health professionals play a relevant role in promoting self-care for people with chronic diseases and should guide and raise awareness about the need and implementation of treatment⁽²⁰⁾. The possibility in PHC of establishing a link with the population and monitoring over time make this the most appropriate place for health promotion and prevention of complications, however, very often, this does not occur. A study conducted in Porto Alegre-RS with people who used insulin and who did not have adequate glycemic control found that health education for people with DM, despite being in the city, was fragile and inefficient⁽²¹⁾.

The lack of knowledge by 55 (32.74%) participants about the type of insulin being used also represents a risk to the user, because they should be able to recognize whether or not the type dispensed by the health service meets the prescribed. This is because insulin types have differences in the mode and timing of their action, which can lead to significant changes in blood glucose levels⁽¹⁾.

The number of correct answers regarding the graduation of the syringe was small (33.93%). It should be noted that in the municipality under study, the syringes provided are 100 units without needle attached. This type of syringe does not allow the administration of two types of insulin simultaneously^(18,22) and most patients do not know or do not understand the graduation scale, which is demarcated every two units, which may result in inadequate dose aspiration. In such cases, the use of 30- or 50-unit syringes that have a grading scale demarcated to each unit would facilitate the identification of the correct dose and make the practice safer⁽¹⁾.

Thus, given the possibility of errors and their implications for people's health, in the bidding processes for the acquisition of this type of material in the public service, prequalification as well as qualification in the receipt of articles is necessary, so that the products offered to the population may have acceptable quality and meet the user needs⁽²³⁾.

Hand hygiene before simulating the insulin application was accomplished by 128 (76.19%) participants, a result lower than the one found in a study that analyzed self-reported responses, in which 84 (96.60%) reported hand hygiene before the procedure⁽⁸⁾. It is believed that the discrepancy in values may be related to this step in the above research being based on self-report. Often, upon the repetition of procedures there occurs an automatism, where the behavior happens without the perception of the person in relation to it. In this way, the individual can express their intention about the behavior, instead of the habit itself⁽²⁴⁾. Faced with failures in the procedure, the practice of hand washing needs to be worked with this population, as it represents one of the most important infection prevention measures⁽²⁵⁾.

Participant performance in the steps "Introducing insulin vial air", "Waiting 5 seconds to remove needle from skin" and "Insulin vial rubber disinfection" was poor. The introduction of air into the insulin vial, a practice that prevents the formation of vacuum within the vial,⁽²⁶⁾ was not performed by 162 (96.43%) participants. These results are similar to those found in a survey of 87 people followed at a Family Health Center in Fortaleza-CE, which concluded that care in the administration of insulin is not fully provided⁽⁸⁾.

Keeping the needle in the skin for at least five seconds after administration aims to reduce the return/exit of the drug⁽²⁶⁾ and disinfecting the insulin vial before use reduces the chance for drug contamination by microorganisms⁽¹⁾.

The disposal of sharps was improperly performed by 96 (56.0%) participants, with common waste being the most frequently used place (88 cases - 52.38%). Please note that the disposal of sharps, biological and chemical waste used in homes in inappropriate containers and/or common waste exposes the risk of injury and infection by blood borne

pathogens to large numbers of people. At the homes, these materials should be deposited in appropriate industrialized containers or in rigid and resistant containers and after delivered to the BHU^(8,27).

Reuse of syringes and needles was adopted by the majority (157 - 93.45%) of the participants. The reason was the lack of material, which is not supplied in sufficient quantity by the municipal pharmacy, a fact already reported in another study conducted in Rio Grande do Sul⁽²⁸⁾. Thus, the Ministry of Health considers safe the reuse of the syringe/needle set by the same person for up to eight applications, provided that the storage guidelines are respected⁽²⁷⁾.

In contrast, the SBD stands against needle/syringe reuse and advises practitioners to discourage this practice⁽²⁹⁾. It is noteworthy that some patients reported reusing them for up to 30 days. In the simulations it was observed that the reused syringe/needle was stored in the refrigerator, together with the insulin vial, and some patients performed a needle cleaning at each use by washing in running water or alcohol, a practice without scientific basis.

The problems resulting from reusing syringes and needles in insulin therapy are: Loss of lubrication; loss of sharpening and changes in needle bevel; increased risk for needle breakage; flow blockage due to insulin crystallization and erasure of the graduation scale in the syringe, which increases the chances for dosage error⁽²⁹⁾. The main impairment of these problems for the patient is the increased occurrence of lipodystrophy (alteration in subcutaneous fat distribution). Its presence can make glycemic control difficult, because initially there is a delay in insulin release, triggering hyperglycemia, and later it is released at once, causing hypoglycemia⁽²⁹⁾.

The mistakes in the administration of medication by people with chronic diseases point to the need for greater involvement and action of the health team, in order to equip them for the proper use and maintenance of drug therapy⁽³⁰⁾.

Possible limitations of the study include: The fact that there was not considered as inclusion/exclusion criterion possible cognitive difficulties for understanding and executing the insulin preparation and administration process; not been quantified in performing the checklist if the errors identified were due to lack of knowledge/guidance or negligence in the execution of each of the steps that make up the insulin preparation and administration process; the possibility that the presence of the researcher interfered with the performance of the person responsible for this process.

In any case, it is believed that the obtained results are very close to reality. It is noteworthy that, regardless of the difficulty for understanding, these people are responsible for the administration of insulin at home and health professionals need to be aware of cases that need more frequent monitoring.

CONCLUSION

The results show that, in the municipality under study, the performance of a significant portion of people with DM and/or family members responsible for home insulin therapy is poor in relation to knowledge and practice of the process on waste storage, preparation, administration and disposal. More than half of the participants missed at least half of the knowledge questions and more than half had errors in at least one third of the aspects evaluated in the simulation.

Insulin treatment, even though widely used, has lack of information and guidance to users, which could be noticed by reports of lack of guidance, and evidenced by the frequency of identified errors. There is a need to promote health actions that empower people with DM about their disease and promote empowerment for self-care. In its turn,

the the failure to distribute the inputs needed for insulin therapy requires a commitment to guiding and supervising the procedure in order to minimize the damage resulting from these failures.

Recognition of weaknesses in the insulin therapy technique may contribute to the establishment of diabetes education measures and prevention of complications.

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Corresponding author:

Pamela dos Reis

Universidade Estadual de Maringá

R. Gleba Paiçandu, 80 - 87130-000 – Ivatuba, PR, Brasil

E-mail: pamdosreis@gmail.com

Role of Authors:

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work - PR, SSM, GOA, VF

Drafting the work or revising it critically for important intellectual content - PR, SSM, EMAN, GOA, IRB, IGTL

Final approval of the version to be published - SSM

Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved - PR