


# BMJ Open Medical sharps in Portugal: a cross-sectional survey of disposal practices among the diabetic population

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## ABSTRACT

**Objective** We aim to determine the disposal site for biohazardous materials resulting from diabetes surveillance and therapy.

**Design** Cross-sectional study.

**Setting** Five Portuguese primary care facilities.

**Participants** We randomly sampled diabetic patients representative of five primary care facilities. Inclusion criteria consisted in patients ≥18 years old with an active diagnosis of diabetes mellitus (DM). Patients unable to provide written informed consent were excluded.

**Outcome measure** Sociodemographic variables, diabetes duration, type of treatment, medical sharps disposal practices and whether adequate disposal information were provided.

**Results** A total of 1436 diabetics were included. Overall, 53.8% of diabetics conducted regular capillary glycaemia measurements, although 45.3% of them had no medical indication. Statistically significant predictors of adequate disposal were not having an active professional status ( $p=0.011$ ) and having a DM duration between 5 and 10 years ( $p=0.014$ ). Only being professionally inactive remained an independent predictor after multivariate logistic regression. Less than a fifth of patients on injectable therapy report having been advised by healthcare staff regarding sharps disposal. Over a fifth of the latter report having received wrong advice. The majority of diabetics dispose of biohazardous materials in unsorted household waste (68.1% of needles/devices with needles and 71.6% of lancets). Other incorrect disposal sites identified were recycling bins, toilet and home accumulation. Only 19.1% of the needles/devices with needles and 13.1% of the lancets were disposed of at healthcare facilities.

**Conclusions** Most diabetics have unsafe disposal practices for their biohazardous materials, mostly in unsorted household waste. We identified that being unemployed independently predicts adequate disposal of medical sharps and found evidence of low patient literacy on the topic, as well as poor patient education. Therefore, educating and raising awareness among healthcare professionals is crucial to address this public health issue.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Cross-sectional study concerning a large primary care randomised sample.
- ⇒ Sampling including outpatients from both rural and urban areas, from four different counties in the North of Portugal, which increases external validity towards the Portuguese diabetic population.
- ⇒ There is a non-negligible possibility of memory bias due to self-reported assessments, and of selection bias due to the exclusion of patients unable to go to the primary care unit.
- ⇒ Due to lack of previously validated questionnaires on the topic, the questionnaire applied was designed by the researchers and lacked formal validation.

## INTRODUCTION

About 422 million people around the world have diabetes mellitus (DM), and its prevalence has been increasing over the past decades.<sup>1</sup> DM is also a very common chronic disease in Portugal. In 2018, it was estimated that 13.6% of its population between the ages of 20 and 79 suffered from DM, representing more than 1 million individuals, with roughly 60 000 new diagnoses every year.<sup>2</sup>

Many of these patients, especially those who suffer from DM type 1, require daily use of medical sharps in order to control blood glucose levels and administer insulin, leading to the generation of a considerable amount of sharp waste within the household setting.<sup>3,4</sup> The most commonly used sharps for home treatment of DM are lancets, needles, reusable and disposable insulin or glucagon-like peptide-1 (GLP-1) analogues pens and insulin cartridges.<sup>4,5</sup>

According to the WHO, about 16 billion injections are administered worldwide every year, and many of these needles and syringes are improperly disposed of afterwards.<sup>6</sup> While medical sharps used and discarded in a hospital setting are considered biomedical



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waste, and are strictly regulated, those used in household and community settings are included in municipal solid waste and disposed of accordingly.<sup>7 8</sup>

The undifferentiated elimination of these by-products of DM management at home not only leads to environmental pollution, but also represents a major threat to anyone who inadvertently handles ordinary household waste, such as workers at material recovery facilities, but also for landfill workers and those who collect waste from households.<sup>9 10</sup> Approximately 5.2 million people die every year worldwide due to diseases derived from the inadequate management of healthcare waste.<sup>11 12</sup> Improper disposal of sharps carries potential risk of propagation of some diseases, such as hepatitis B, C and HIV, to anyone who comes in contact with these sharps. This situation may become a serious public health problem as these diseases are chronic infections and often remain undetected for a long period of time.<sup>13</sup>

According to the Portuguese Diabetes Association, 650 000 sharps are used daily by Portuguese diabetic patients at their homes.<sup>14</sup> Although its importance, proper disposal of medical sharps is often neglected as a part of patient education on self-injection techniques, leading to potentially unsafe disposal methods.<sup>15</sup> There is practically no legislation, national guidelines or local municipal rules regarding disposal of home-generated sharps in Portugal. The Portuguese Manual for Children and Young Adults with DM type 1 states that sharps should be disposed of to a proper container, without further specifications.<sup>16</sup>

Some known barriers to safe disposal include lack of information about how and where to dispose, lack of proper advice by healthcare professionals, wrong perception that sharp disposal information is only meant for illegal drug users, and that using community sharp disposal services by patients may reveal their DM status.<sup>11 17 18</sup>

With the predicted increase in the prevalence of DM in the future, its subsequent biological waste will also increase. This issue is not exclusive to Portugal, as many other countries, including the USA and the UK, are also struggling to find solutions to this problem.<sup>10 18 19</sup>

Despite all the risks associated with sharps disposal, little evidence regarding patient education is available on this subject and no characterisation of the Portuguese reality has been conducted. Adequate information is needed to inform policy change and reinforcement.

The main purpose of this study was to determine the disposal site for biohazardous materials resulting from diabetes surveillance and therapy. We also intended to explore sociodemographic differences and identify potential independent predictors of adequate disposal, determine the proportion of non-insulin-treated diabetics who check their blood glucose, ascertain whether adequate education is currently being provided to patients on this topic and determine the occurrence of accidental pricks.

## METHODS

A cross-sectional approach was designed to target primary healthcare users. Eligible population included diabetic patients aged 18 years or over and with an active diagnosis of type 1 or type 2 DM. Physically disabled users or those with chronic pathology that conditioned their visit to the health unit to sign the informed consent were excluded. No further exclusion criteria was established.

We drew a list of all patients attending the five primary care facilities in the North of Portugal that participated in the study, who had an active diagnosis of diabetes, regardless of its type. All patients with an active code of T89 (insulin dependent diabetics) or T90 (non insulin dependent diabetes) from second edition of the International Classification of Primary Care 2 in MIM@UF (information and monitoring module of the functional units) administrative platform, as coded by their general practitioner, in these primary care facilities participating the study, were deemed eligible.

The sample size was defined for each primary care unit, with a 5% margin of error and 95% CI, using the Raosoft Sample Size Calculator program, yielding an overall required sample size of 1424 diabetic individuals. We then randomised the list of diabetic patients per primary care unit using the Microsoft Office Excel 2019 program, and sequentially contacted individuals until the sample size requirements were met. We randomly selected nearly 25% of diabetic patients per healthcare unit.

If contact was not feasible (eg, due to the lack of a telephone number in the national patient register [RNU] or after two unsuccessful contact attempts), the individual immediately following in the list was selected from the global patient list created.

The first five randomised patients per unit, comprising a total of 25 patients, were contacted for a pilot questionnaire application to ensure questions comprehension and adequacy. Changes on the questionnaire were conducted based on patient feedback and consisted mainly of adding options to closed questions on site of disposal. These patients were excluded from the following questionnaire application.

On recruitment, data collection took place between July 2020 and February 2021. A questionnaire (figure 1) was applied to all consenting individuals, either during a scheduled appointment in the primary healthcare unit, or by telephone. The results obtained were structured in a shared spreadsheet (Microsoft Office Excel 2019) between researchers and later exported to IBM SPSS V.26.0. Categorical variables are herein summarised as absolute and relative frequencies, while continuous variables are summarised with both central and dispersion measures according to their distribution type. Logistic regression with stepwise forward methodology was conducted with adequate disposal site as outcome variable and variables deemed by the researchers as potentially relevant as predictive variables.

The protocol for this study is available as a online supplemental file.

## SURVEY "WHAT IS THE DESTINATION OF OUR DIABETIC PATIENTS' NEEDLES AND LANCETS?"

By completing this survey, I declare that I have freely given my informed consent to participate in this research study.

Check the box corresponding to your answers with an X.

Demographic data:

- Gender: ☐ Feminine ☐ Masculine
- Age: \_\_\_\_ Years
- Education (for how many years did you attend school?)
  - ☐ 0 Years
  - ☐ 4 Years or less
  - ☐ 6 Years
  - ☐ 9 Years
  - ☐ 12 Years
  - ☐ More than 12 Years
- Professional situation:
  - ☐ Employed
  - ☐ Unemployed
  - ☐ Student
  - ☐ Retired

1. For how many years have you been a diabetic?

- ☐ Less than 5 Years
- ☐ 5-10 Years
- ☐ More than 10 Years

2. Are you on insulin treatment?

- ☐ Yes
- ☐ No

3. Are you being treated with other injectable diabetes' medications?

- ☐ Yes
- ☐ No

**IF YOU ANSWERED NO TO THE PREVIOUS TWO QUESTIONS GO TO QUESTION 6.**

4. If you are being treated with insulin or other injectable medications for diabetes, for how many years have you been on it?

- ☐ Less than 5 Years
- ☐ 5-10 Years
- ☐ More than 10 Years

5. Where do you usually deposit needles or needle devices after use?

- ☐ Domestic waste
- ☐ Recycling bin
- ☐ Hospital
- ☐ Health Center
- ☐ Pharmacy
- ☐ Toilet
- ☐ Other ☐

Which? \_\_\_\_\_

6. At home, do you usually prick your finger to measure your blood glucose (blood sugar level)?

- ☐ Yes
- ☐ No

**IF YOU ANSWERED NO TO QUESTIONS 2, 3 AND 6 STOP THE SURVEY. THANK YOU FOR YOUR COOPERATION.**

7. Where do you usually deposit lancets (to prick your finger) after use?

- ☐ Domestic waste
- ☐ Recycling bin
- ☐ Hospital
- ☐ Health Center
- ☐ Pharmacy
- ☐ Toilet
- ☐ Other ☐

Which? \_\_\_\_\_

8. Have you been informed of an appropriate place to waste needles, needle devices, or lancets (for finger pricks)?

- ☐ Yes
- ☐ No

**IF YOU ANSWERED NO TO QUESTION 8 GO TO QUESTION 11.**

9. You have been informed by whom?

- ☐ Family/friend
- ☐ Doctor
- ☐ Nurse
- ☐ Pharmacist
- ☐ Television
- ☐ Internet
- ☐ Other? ☐

Which? \_\_\_\_\_

10. Which was the indicated location?

- ☐ Domestic waste
- ☐ Recycling bin
- ☐ Hospital
- ☐ Health Center
- ☐ Pharmacy
- ☐ Toilet
- ☐ Other ☐

Which? \_\_\_\_\_

11. Has anyone accidentally been stung by one of your needles, needle devices, or lancets (to prick your finger) after you threw them away?

- ☐ Yes
- ☐ No

THANK YOU SO MUCH FOR YOUR COOPERATION.

**Figure 1** Questionnaire used in the study (online supplemental file 1).

**Table 1** Sociodemographic characteristics of participants

Variable	Total (n=1436) n (%)
Sex	
Female	692 (48.2)
Male	744 (51.8)
Age	
18–39	18 (1.3)
40–64	534 (37.2)
65–74	486 (33.8)
Over 75	398 (27.7)
Educational level	
Illiterate	2 (4.5)
4 years	903 (62.9)
6 years	171 (11.9)
9 years	148 (10.3)
12 years	90 (6.6)
University	152 (11.1)
Professional status	
Active	406 (28.3)
Unemployed	74 (5.2)
Retired	955 (66.5)
Background	
Urban	829 (57.7)
Rural	607 (42.3)

### Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

### RESULTS

A total of 1436 diabetic patients responded to the questionnaires, either via telephone or in face-to-face appointments at their health unit, between July 2020 and February 2021. Questionnaires were applied by the researchers to 25.6% of the diabetic patients of the included health units. These 5 health units belong to 4 municipalities in the north of Portugal and serve a total of 71 762 patients, of whom 7.8% (5601) had an active diabetes diagnosis.

Sociodemographic variables are presented in [table 1](#). The majority of patients were male (51.8%), completed primary education (62.9%), were retired (66.5%) and belonged to the urban setting (57.7%). Information regarding diabetes characterisation can be found in [table 2](#). The majority of participants (52.5%, n=754) had a diabetes duration longer than 10 years, less than a fifth were insulin dependent (17.1%, n=245) while GLP-1 agonists were administered to a total of 42 (2.9%) diabetics.

Overall, most of the diabetic patients in the study sample conducted regular capillary glycaemia measurements

**Table 2** Disease and treatment characteristics of participants (n=1436)

Variable	Total (n=1436) n (%)
Diabetes duration	
<5 years	292 (20.3)
5–10 years	390 (27.2)
>10 years	754 (52.5)
Under injectable therapy	273 (19.0)
Insulin only	231 (16.1)
GLP-1 analogues only	28 (1.9)
Both GLP-1 analogues and insulin	14 (1.0)
Duration of injectable therapy	
<5 years	114 (8.0)
5–10 years	76 (5.3)
>10 years	83 (5.8)
GLP-1, glucagon-like peptide-1.	

(n=773, 53.8%). Among insulin-treated patients, over 95% complied with the use of blood glucose test strips (non-compliance rate of 4.5%, n=11). Nonetheless, the use of medical sharps among non-insulin-treated patients, who therefore do not require regular glycaemia self monitoring, amount to nearly half of this subpopulation (45.3%, n=539).

Regarding disposal habits ([table 3](#)), the vast majority of diabetics dispose of biohazardous materials in unsorted household waste, more precisely 68.1% (n=186) of needles or devices with needles and 71.6% (n=554) of lancets. Only 19.1% (n=52) of the needles/devices with needles and 13.1% (n=104) of the lancets were disposed of at healthcare facilities, such as primary care, hospital or community pharmacy. Other incorrect disposal sites such as recycling bins (6.6% of needles and 6.5% of lancets), the toilet (0.4% of needles and 1.0% of lancets) or even accumulation at home (4.4% of needles and 2.8% of lancets) should also be mentioned.

Retired and unemployed people ([table 4](#)), as well as individuals with diabetes duration between 5 and 10 years, deliver significantly more needles/devices with needles in healthcare facilities (p=0.011; p=0.014, respectively).

**Table 3** Place where diabetics deposit biohazard materials

Disposal site	Needles	Lancets
	n (%)	n (%)
Primary care	7 (2.6)	8 (1.0)
Recycling deposit	18 (6.6)	50 (6.5)
Pharmacy	27 (9.9)	66 (8.5)
Hospital	18 (6.6)	30 (3.9)
Unsorted household waste	186 (68.1)	554 (71.6)
Toilet	1 (0.4)	8 (1.0)
Other	16 (5.9)	58 (7.5)



**Table 4** Relation of sociodemographic data with the place where biohazard materials are deposited (using the chi-squared test)

Sociodemographic data	Needles	Lancets
Sex	P=0.165	P=0.182
Age	P=0.343	P=0.394
Educational level ( $\geq 12$ years vs $< 12$ years)	P=0.620	P=0.687
Professional status	P=0.011	P=0.061

However, these findings do not stand statistical significance when the analysis is shifted towards lancets disposal ( $p=0.06$ ;  $p=0.195$ ). There is a tendency towards greater correct lancet disposal in rural health units ( $p=0.43$ ), although statistical significance has not been achieved in the case of needles ( $p=0.09$ ). In multivariable logistic regression with needle adequate disposal site as dependent variable, only being unemployed predicted adequate disposal habits, regarding both needles and lancets, (OR 4.98 (1.30–19.05),  $p=0.02$  and OR 3.21 (1.18–8.25),  $p=0.02$ , respectively), after adjusting for sex, age, education level and professional status. Likelihood of adequate disposal did not differ significantly between patients medically treated with insulin or other injectable therapies versus other patients ( $p=0.620$  for needles and  $p=0.620$  for lancets).

Approximately 6.5% of diabetics report having been provided information by a healthcare professional (ie, medical, nurse or pharmacy staff) on adequate medical sharps disposal. Among the diabetic population that has been prescribed either injectable therapy or insulin administration, this percentage rises to one fifth of patients (19.0%). The highest reported information provider was nursing staff (45.9%), followed by community pharmacy services (21.6%) and medical doctors (17.1%). Apart from the healthcare system, family and friends were a relevant reported information source (10.8%), while internet, television and other media were residual sources in this dataset ( $n=2$ ). Additionally, 22.3% of those allegedly informed by healthcare professionals, report have been advised to dispose of them in household waste.

In addition, there were reported a total of six accidental pricks in needles/devices with needles or lancets already used and discarded by diabetic patients (0.8% of medical sharps users).

## DISCUSSION

To the best of our knowledge, there was no data available about home disposal practices of medical sharps in the Portuguese diabetic population, as in many other countries.<sup>20</sup> We found clear evidence of inadequate disposal of medical sharps among these patients, findings that are corroborated by studies in the same scope conducted in other countries, which reported household

bin disposal of medical sharps ranging from 33% to 92%,<sup>3 7 8 10 13 15 17 18 21–28</sup> a common problem worldwide.<sup>9</sup> Our results show that over two-thirds of diabetic patients discard sharps directly into common household bins. Only 19.1% ( $n=52$ ) of needles/devices with needles and 13.1% ( $n=104$ ) of lancets were disposed of at healthcare facilities, that is, primary care, hospital or community pharmacy. Most of them, however, did not use suitable containers to hold their sharps, using plastic bags instead, most likely because these items were readily available and easy to find at their home. Some patients reported the deposit in recycling bins, some by flushing the toilet and others reported the accumulation of such materials at home in undifferentiated containers since they started using needles and lancets.

In addition to environmental concerns, this can be considered a health hazard, considering that accidental needle pricks carry the risk of transmission of infectious diseases among caregivers, healthcare workers during domiciliary appointments, other family members or even strangers. However, the number of accidents implying sharps reported here was low, most likely underestimated, mainly because patients only report accidents which they have knowledge or recall of. Other professionals, for instance waste and sanitation workers, are exposed to such risks daily, which amplifies the possibility of avoidable accidents.

Additionally, we found a clear overuse of medical sharps. We estimate medical sharps use among diabetics with no regular blood monitoring indication to be as high as 45.3% ( $n=539$ ). Besides, this shows that patients and, perhaps, even healthcare staff tend to overvalue glycaemia measurements in non-insulin dependent diabetics, which in these patients does not play an essential role on either treatment goals or prognosis.<sup>29</sup>

Alarming, as few as 6.5% of diabetics report having been provided with any sort of information on adequate disposal by a healthcare professional. When information was provided, the major informant was the nursing staff, probably due to their role on patient education in glucose monitoring. This lack of systematic information about the adequate disposal of these sharps can be explained by the absence of legislation on this matter, which limits health professionals' options regarding advice. The lack of safe disposal options in the community may also contribute to the high rate of erroneous advice by health professionals to dispose of it in the household waste (22.3%). Other studies have revealed rates of non-education of diabetic patients about correct medical sharps deposition practices ranging from 34% to 96.2%.<sup>7 8 10 13 18 22–24 26 27</sup> However, from the beginning of the therapeutic plan, it is necessary to provide education to patients and their families about the importance of proper disposal of sharps, not neglecting the education of healthcare professionals.<sup>20</sup> Even though educating patients might be challenging, a broad and improved knowledge on safe sharps disposal is required, as there is evidence that patients are more likely to dispose of sharps properly if advised by healthcare

providers, especially if there is ongoing support from the healthcare team.<sup>18 21 30</sup>

We identified other factors besides poor patient education that must be considered. Being unemployed was independently associated with having better disposal habits, which may be related to greater physical capability than retired status and having more time available than being professionally active, in order to be able to dislocate to a health facility that manages medical waste. Additionally, a DM duration between 5 and 10 years independently predicted an adequate disposal of medical sharps. The reason for this may be that lower DM duration can be associated with less knowledge of management options while longer DM duration may be associated with older and poorly educated patients. Curiously, we found no independent statistically significant association between degree of education and inadequate disposal practices, after adjusting for the above factors.

Appropriate disposal practices could help reduce the risks associated with community generated sharps. The US Food and Drug Administration recommends placing used needles and other sharps into a sharps disposal container to reduce the risk of needlestick injuries.<sup>20</sup> Options such as special municipal pick-up services for medical sharps, community drop-off centres, exchange or mail-back programmes, or at home needle destruction devices, in which needles are burnt or melt rendering it safe for disposal, are also reported from some countries, as the USA.<sup>22 31–33</sup> In Australia, a website has been created to guide patients in finding the location of safe disposal of sharps services, and smartphone-based applications have even been developed to make the services user-friendly.<sup>34</sup> According to our data, we believe that a system similar to the one implemented in the UK could prove useful. This includes sharps bins designed with a lid, obtained on prescription from the family doctor, general practitioner or pharmacist. When full, the box is collected for disposal by local administration services.<sup>35</sup> This would eliminate the need for the active dislocation by the diabetic patient to the healthcare facility. Another potentially viable system could be a disposal flow similar to that implemented in some Portuguese pharmacies to collect syringes from intravenous drug users, with proper safe containers and disposal circuits. Nonetheless, this would still require dislocation rendering it perhaps less effective.

As the Diabetes Technology Society Green Declaration stated, the solution for the sustainability and waste management of the diabetes devices used at home must integrate a group of stakeholders, including people with diabetes, healthcare professionals, device manufacturers, government and regulatory agencies and regional partnerships. Each one of these must take part in identifying and overcoming barriers that could not be overcome individually. The Diabetes Technology Society Green Declaration presents a group of tasks for said stakeholders, among which we note the need for: standardised methods for medical waste and sharps management established

by government entities, to provide incentives for manufacturers to partake in the initiatives and to promote research on how these materials are disposed of to define the current barriers that prevent proper waste disposal.<sup>36</sup>

Aligned with this last task, we bring new findings on this matter for the Portuguese population that increase the need for reflection among staff in the National Health System. Primary care services can be considered the ideal study setting for these patients as the majority is subject to regular follow-ups and management by their primary care physician and nursing team, and most information on their condition is provided in this setting. Another main strength of this study is the random sampling of patients from several primary care facilities located in both rural and urban areas, from a widespread geographical area (four different counties within North of Portugal), which may be representative of the North of Portugal diabetic population even though the family health units themselves were not randomised. Estimated prevalence of diabetes in the studied healthcare facilities was 7.8%, a mismatch to the previous national estimate of 13.6% diabetes prevalence in 2018.<sup>2</sup> This may be explained either by population differences or underdiagnosis in the North of Portugal. Lack of representativeness due to patient access limitations is unlikely as the Portuguese public health system provides universal health coverage.

Methodological concerns of this study include the possibility of information bias (ie, memory bias) with subsequent under or over-reporting by patients, since data collection relies on self-reported assessments; selection bias derived from the need to have an updated telephone number in the family health unit and the exclusion of dependent patients unable to go to primary care units; the lack of a formal validation of the questionnaire (only a pilot was conducted to ascertain that patients understood the implemented questions and introduced new options on closed questions); participating health units were not sampled as they were the researchers' working units, although they comprised both urban and rural settings which we believe may reduce the impact of the convenience sampling of the studied units in addition to the random sampling of patients. Despite these limitations, this study provided valuable local data on sharp handling and disposal in a community setting. Considering the increasing prevalence of DM, expanded studies with significant samples in broader geographic areas may be needed to more accurately depict sharp disposal practices of patients and its burden.

In conclusion, we found that most diabetics dispose of their biohazardous materials resulting from diabetes surveillance and therapy in unsorted household waste. In the era of the optimisation of household medical waste management and of the public discussion of the environmental effects of waste, management of DM treatment byproducts is mandatory, and deserves the attention of both the scientific community and the health authorities. In fact, with the increasing prevalence of DM, this problem can potentially give origin to an emerging global

crisis, demanding international efforts to be dealt with. The purpose of this investigation was to contribute to the solution, providing hard data on this topic in the current Portuguese reality and call for action for all stakeholders.

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**Contributors** Conceived and designed the protocol: ALC-R, ALT, ACdA, MVC, LLD, CCR, TT-G. Conceived the database: ALC-R. Collected the data: ALC-R, ALT, ACdA, MVC, LLD, CCR, JMP, AF, FM, SS. Performed the statistical analysis: DM-D. Wrote the paper: ALC-R, ALT, ACdA, MVC, LLD, CCR, JMP, AF, FM, SS, DM-D, TT-G. Revising the article: ALC-R, ALT, LLD, JMP, AF, DM-D, MVC, TT-G. Guarantor: ALC-R.

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## RESEARCH PROTOCOL

### WHERE DO OUR DIABETICS DISPOSE OF THEIR ' NEEDLES AND LANCETS?

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9 MARCH 2020

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ABSTRACT

**Introduction:** Diabetes *mellitus* has a prevalence of 13.3% in the Portuguese adult population. Self-monitoring of blood glucose by insulin-treated diabetics is recommended, which is not the case for

non-insulin-treated type 2 diabetics. A large volume of insulin and blood glucose strips are used daily, as well as lancets and transdermal needles. The production of spiked waste or waste containing biological material is very high, but there is no legislation in Portugal to guide the management of such waste. Thus, this study aims to evaluate the use and disposal of needles and lancets by diabetics.

**Methods:** Cross-sectional observational study, carried out in primary health care (PHC), using questionnaires applied to a representative sample of diabetics aged over 18 years, randomly selected from five Family Health Units in the north of Portugal. The selected individuals will be invited to join the project in person, during scheduled appointments at the PHC, or by phone, by scheduling an appointment to apply the questionnaire. The data obtained will be structured in Microsoft Office Excel 2019 ® and analyzed using IBM SPSS 26.0 ®.

## INTRODUCTION

According to the National Diabetes Observatory, in 2015 the estimated prevalence of Diabetes Mellitus in the world population was 415 million people<sup>1</sup>. In Portugal the prevalence reached 13.3% of the population between 20 and 79 years old, which corresponds to about 1 million Portuguese<sup>1</sup>. The outpatient sale of insulins within the National Health System (NHS) in mainland Portugal in 2015 reached about 1.4 million packages. On the other hand, in the same year around 2,895 thousand packages of blood glucose strips were sold<sup>1</sup>.

Self-monitoring of blood glucose by insulin-treated patients has clear evidence of its benefit and is recommended<sup>2</sup>. On the other hand, according to the latest 2019 American Diabetes Association guidelines, its use in non-insulin-treated diabetic patients appears to have limited clinical benefit. Self-monitoring is only beneficial if its results are reviewed by a healthcare professional, or by the patients themselves, and are taken as a basis to modify behaviors and/or adjust therapy<sup>3,4</sup>.

The large volumes of insulin and blood glucose strips sold in Portugal imply that a large number of lancets and transdermal needles are also used every day in our country. In fact, at home, in the context of diabetes surveillance and therapy, the production of spiked waste or waste containing biological material is tremendous, but so far there is no legislation in Portugal to guide the management of such waste<sup>5</sup>.

The gaps in the management of bio-risk products inherent to diabetes surveillance and therapy are not only limited to Portugal. According to a public statement from Diabetes UK in December 2018, although sharps containers are available on prescription or can even be provided by local authorities or pharmacies, the truth is that patients often report difficulty in accessing these containers and there is inconsistency regarding collection services<sup>6</sup>.

However, the American reality seems to be different. The Food and Drug Administration recommends a two-step process for the proper management of needles and other sharp objects, in which the first step consists of placing these objects, at the household level, into an appropriate container that will then, in a second step, be collected according to the standards established by each community, these standards being easily accessible not only on the Internet but also by telephone contact<sup>7</sup>.

Given the epidemiological data on Diabetes, it is clear that we are facing a potential public health problem that urgently needs to be better characterized and the respective corrective measures need to be established accordingly.





## PROBLEM PRESENTATION

### Overview

Currently, a large volume of insulin and blood glucose strips are used daily, as well as lancets and transdermal needles. However, there is no regulation for their disposal after use, which can lead to a potential public health problem. It is, therefore, urgent to evaluate the use and disposal of needles and lancets by diabetics.

### Research Questions

Where are the needles and lancets used by diabetics wasted after use?

Can unregulated waste of needles or lancets lead to accidents?

What percentage of non-insulin-treated diabetics use lancets?

Are there differences in outcomes depending on demographic data?

## OBJECTIVES

### Overall Objective

To evaluate the use and disposal of needles and lancets by diabetics.

### Specific Objectives

To determine what is the final destination that diabetics give to the biohazard materials resulting from the surveillance and therapy of their pathology.

To determine the occurrence of accidents resulting from the non-regulation of needle and lancet waste.

To determine the population of non-insulin-treated diabetics who test their blood glucose levels.

To determine the differences in results according to demographic data.

## STUDY DESIGN AND METHODS

### Study Type

Cross-sectional observational study with use of questionnaires.

### Population and Sample of Study

Population: Diabetics, aged over 18 years old, from USF Famalicão I, Joane, O Basto, Oceanos and Ara de Trajano.

Sample: representative sample of the above-mentioned population.

### Sample Size and Sample Selection and Recruitment Process

The total number of diabetics in each functional unit was obtained by consulting the NHS Information and Monitoring System database, and the most recently available data was consulted: December 2019.

In December 2019, the total number of diabetics at USF Joane was 1189, at USF Famalicão I was 1231, at USF O Basto was 840, at USF Oceanos was 1394 and at USF Ara de Trajano was 947, making a total of 5601 diabetics in all the functional units mentioned.

The sample size was defined for each functional unit mentioned above, based on the dimension of diabetic patients registered in each unit, with a margin of error of 5% and confidence interval of 95%, through the Sample Size Calculator program of Raosoft®.

Thus, the sample size of USF Joane corresponds to 291 diabetics, of USF Famalicão I corresponds to 293 diabetics, of USF O Basto corresponds to 264 diabetics, of USF Oceanos corresponds to 302 diabetics and of USF Ara de Trajano corresponds to 274 diabetics, with a total of 1424 diabetics to be included in this study.

Inclusion criteria:

- a) age 18 years or older;
- b) patients with an active diagnosis of diabetes mellitus with ICPC-2 codes T89 and T90.

Exclusion criteria:

- a) patients who are physically or due to a chronic pathology unable to come to the functional unit.

The selected sample will be obtained based on a simple random technique, through the application of a series of random numbers, generated through the Random.org® program.



The selected individuals will be invited to join the project, at the time of their next scheduled consultation. If this procedure is not possible, the individuals will be contacted by phone and invited to come to the functional unit to participate in the study. Whenever the selected individuals refuse to participate in the project, do not have a telephone number in the administrative record or are uncontactable after two attempts to call at different times, the individual immediately following in the ordered list will be selected.

In person, during a scheduled consultation, or after an invitation, the project will be presented to the patients, who will be asked to sign the informed consent. After signing, the questionnaire will be applied (interview in the case of illiteracy or self-answer in all other cases). The questionnaire to be applied in this study was designed by the researchers and obtained the favorable approval of a Family Medicine specialist, in order to meet the objectives previously described in this document. The questions were written in everyday language in order to be understandable by patients of all levels of education.

To ensure the applicability of this questionnaire, the researchers will conduct a pre-test with the questionnaires, to be applied in a small sample in the five functional units, to assess the responsiveness and any difficulties experienced by users.

## **Information Sources**

Diabetic patients of USF Famalicão I, Joane, O Basto, Ara de Trajano and Oceanos

## **Information Gathering Process**

Information will be collected through the application of a questionnaire.

## **Information Management**

An anonymized database will be created, in a password-protected file. All data will be treated confidentially and only within the scope of this study, and the anonymity of the participants will be guaranteed.

## **Statistical Analysis**

Statistical analysis of results will be performed on the basis of frequency and association using Microsoft Office Excel 2019® and IBM SPSS Statistics 26.0® computer programs.

The following variable associations will be analyzed:

- Relationship between demographic data (gender, age, education, employment status, USF of enrollment) and the place of deposit of needles or lancets;
- Relation between the time of diabetes diagnosis and the place of deposit of needles or lancets;
- Relation of the time of injectable therapy with the place of deposit of needles or lancets;
- Relationship between the user's USF and the information obtained about the appropriate place for depositing needles or lancets;
- Relation of the type of provider of information on the proper place for depositing needles or lancets with the deposit place that was indicated;
- Association between the use of insulin or injectable medication and the use of lancets;
- Relationship between the use of lancets only (no injectable therapy) and the use of injectable therapy and the deposit site of needles or lancets.

Two multinomial and multivariate logistic regressions with fixed and random effects will be performed, 1 for each outcome: Place of deposit and information about the appropriate place of deposit. For each of these models, all the predictors listed in the associations described above will be considered covariables. Variables that proportionally increase or decrease the probability of the outcome will be fixed covariables. The remaining variables will be random covariates. Odds ratio will be obtained, indicating the risk ratio between the two groups evaluated, as well as a reference site to be compared with all the others. Results will be presented as OR with a 95% confidence interval.

Timeline

	t	t+1 month	t + 2 months	t + 3 months	t + 4 months	t + 5 months	t + 6 months	t + 7 months	t + 8 months
--	---	--------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------	-----------------

<b>Sample Size Determination</b>									
<b>Pre-test application</b>									
<b>Data collection, recording and analysis</b>									
<b>Presentation of the results and preparation of the final report</b>									

t: month of approval of the research project by the competent authorities

## STUDY STRENGTHS AND WEAKNESSES

### Strengths

- This disease is highly prevalent in the Portuguese population.
- Diabetics are a risk group requiring regular surveillance in USFs, which has a substantial impact on the use of human, material and economic resources.
- Representativeness of multiple regions of the northern area with user selection through simple random sampling.
- Due to the lack of regulation on the disposal of needles and lancets used by diabetics, this work is of particular importance and innovation for its potential impact on improving the provision of care to this special population and subsequently on improving the health of the community.

### Weaknesses

- Selection bias: included users limited by travel to primary health care; excluded users due to non-updated data in the administrative registry.
- Limited extrapolation to the population of ARS Norte.
- Established questionnaire not previously validated.



## ETHICAL CONSIDERATIONS

Prior to the interview, the study will be explained to the participants who will sign the informed consent form, if they agree to participate. These will be kept in a locker in one of the researchers' USFs, whose access will be limited by a lock, whose key represents a unique copy.

A random number will be assigned to each questionnaire, through the site <https://www.random.org/>, which will be used to enter the data obtained into the computer programs previously defined. The key that establishes the relationship between the random number assigned and the user number will be written in physical format, using A4 lined paper and a blue ballpoint pen, and kept in an unmarked envelope inside a locker of one of the researchers' USFs, whose access will be limited by a lock and whose key represents a unique copy. This document will not be transposed to digital format at any time during the implementation of this protocol.

At the conclusion of the research project, the researchers will destroy the key created, in order to preserve the safety of the users included in this study.

## IMPLICATION FOR THE POPULATION'S HEALTH

- OPTIMIZATION OF THE USE OF HUMAN, MATERIAL AND ECONOMIC RESOURCES.
- IMPROVED DELIVERY OF CARE TO DIABETICS AND SUBSEQUENTLY IMPROVED HEALTH OF THE COMMUNITY.

## BUDGET

The budget for this research will be borne by the researchers. The resources used will be:

- Human Resources
- Computers
- Ink cartridges
- Paper
- Ballpoint Pens
- Staples

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## APPENDICES

### Appendix 1: Questionnaire "WHAT IS THE DESTINATION OF OUR DIABETIC PEOPLE'S NEEDLES AND LANCETS?"

*By completing this questionnaire I declare that I have freely and informally consented to participate in this research study.*

Please mark the box corresponding to your answers with an X.

#### Demographic Data:

- Gender: ☐ Female ☐ Male
- Age: \_\_\_\_ Years
- Schooling (how many years did you go to school?):
  - ☐ 0 years
  - ☐ 4 years or less
  - ☐ 6 years
  - ☐ 9 years
  - ☐ 12 years
  - ☐ More than 12 years
- Employment Status:
  - ☐ Active
  - ☐ Unemployed
  - ☐ Student
  - ☐ Retired

---

#### 1. How many years have you been diabetic?

- ☐ Less than 5 years
- ☐ 5-10 years
- ☐ More than 10 years

#### 2. Do you take insulin treatment?

- ☐ Yes
- ☐ No

3. Do you take treatment with another injectable diabetes medication?

☐ Yes

☐ No

**IF YOU ANSWERED NO TO THE TWO PREVIOUS QUESTIONS GO TO QUESTION 6.**

4. If you have been on insulin or other injectable diabetes medication for how many years have you been on it?

☐ Less than 5 years

☐ 5-10 years

☐ More than 10 years

5. Where do you usually dispose of needles or devices with needles after use?

☐ Domestic waste

☐ Recycling bin

☐ Hospital

☐ Health center

☐ Pharmacy

☐ Toilet

☐ Other ☐ Which? \_\_\_\_\_

6. At home do you usually prick your finger to measure your blood sugar (blood sugar level)?

☐ Yes

☐ No

**IF YOU ANSWERED NO TO QUESTIONS 2, 3 AND 6 STOP THE QUESTIONNAIRE. THANK YOU VERY MUCH FOR YOUR COOPERATION.**

7. Where do you usually deposit your lancets (to prick your finger) after use?

☐ Domestic waste

☐ Recycling bin

☐ Hospital

☐ Health center

☐ Pharmacy

☐ Toilet

☐ Other ☐ Which? \_\_\_\_\_

8. Were you informed about the proper place to waste the needles, devices with needles, or lancets (for pricking the finger)?

☐ Yes  
☐ No

**IF YOU ANSWERED NO TO QUESTION 8 GO TO QUESTION 11.**

9. Who informed you?

☐ Family/friend  
☐ Doctor  
☐ Nurse  
☐ Pharmacist  
☐ Television  
☐ Internet  
☐ Other? ☐ Which? \_\_\_\_\_

10. What was the indicated location?

☐ Domestic waste  
☐ Recycling bin  
☐ Hospital  
☐ Health center  
☐ Pharmacy  
☐ Toilet  
☐ Other ☐ Which? \_\_\_\_\_

11. Has anyone ever accidentally pricked themselves on one of your needles, devices with needles, or lancets (for pricking your finger) after you threw them away?

☐ Yes  
☐ No

THANK YOU VERY MUCH FOR YOUR COOPERATION.

## Appendix 2: Informed consent template

### INFORMED CONSENT FOR PARTICIPATION IN RESEARCH IN ACCORDANCE WITH THE DECLARATION OF HELSINKI<sup>1</sup> AND THE OVIEDO CONVENTION<sup>2</sup>

*Please read the following information carefully. If you feel that something is incorrect or unclear, do not hesitate to ask for more information. If you agree with the proposal that has been made to you, please sign this document.*

**Title of study:** What happens to our diabetics' needles and lancets?

**Background:** In 2015, the estimated prevalence of Diabetes Mellitus in the Portuguese population was 13.3%. Consequently, in the context of diabetes surveillance and therapy, the production of spiked waste or waste containing biological material is immense, but there is no legislation in Portugal to guide the management of such waste. For this reason, this project aims to evaluate the use and disposal of needles and lancets by diabetics.

**Study explanation:** The study consists of face-to-face questionnaires, at the level of 5 Family Health Units in the North Region (USF Joane, USF Famalicão I, USF Ara de Trajano, USF O Basto and USF Oceanos). These questionnaires were developed by the researchers in order to determine the use and disposal of needles and lancets by diabetics. The data obtained will be exported to Microsoft Office Excel 2019® and IBM SPSS Statistics 26.0® computer platforms, whose databases will be duly encrypted and the entity of the participating users protected. The answered questionnaires, the elaborated database and the respective written key will be destroyed at the end of this study.

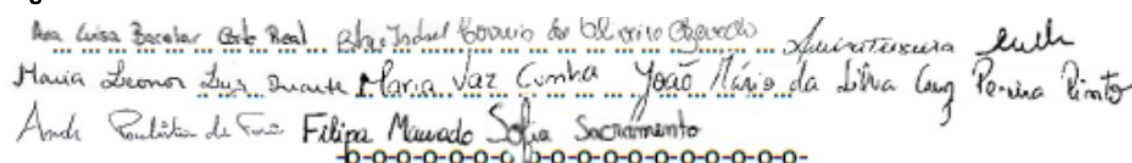
**Funding:** The entire study will be funded by the investigators. There will be no payment for travel or compensation. Participation in this study is voluntary. If you do not wish to participate, you must inform the investigator of your decision. This study was approved by the Ethics Committee for Health of ARS Norte.

**Confidentiality and anonymity:** The investigators guarantee the confidentiality and exclusive use of the data collected for this study. The researchers guarantee the anonymity of the data obtained. Contacts will be made in a private environment.

The researchers sincerely thank: Ana Luísa Corte Real, Luísa Teixeira, Maria Cunha, Ana Azevedo, Maria Leonor Duarte, Catarina Rebelo.

**Signature/s:**

Ana Luísa Corte Real, Luísa Teixeira, Maria Cunha, Ana Azevedo, Maria Leonor Duarte, Catarina Rebelo, Filipa Macedo, Sofia Sacramento



*I declare that I have read and understood this document and the verbal information given to me by the person/s signing above. I have been assured that I may, at any time, refuse to participate in this study without any consequences. Thus, I agree to participate in this study and allow the use of the data that I voluntarily provide, trusting that they will only be used for this research and the guarantees of confidentiality and anonymity given to me by the researcher.*

Name: ... ..

Signature: ... .. Date: ..... /.....

SE NÃO FOR O PRÓPRIO A ASSINAR POR IDADE OU INCAPACIDADE  
(se o menor tiver discernimento deve também assinar em cima, se consentir)

Nome: ... ..

BI/CD Nº: ..... Data ou Validade ..... /..... /.....

Grau de parentesco ou tipo de representação: .....

Assinatura ... ..

<sup>1-</sup> [http://portal.arsnorte.min-saude.pt/portal/page/portal/ARSNorte/Comiss%C3%A3o%20de%20C3%89tica/Ficheiros/Declaracao\\_Helsinquia\\_2008.pdf](http://portal.arsnorte.min-saude.pt/portal/page/portal/ARSNorte/Comiss%C3%A3o%20de%20C3%89tica/Ficheiros/Declaracao_Helsinquia_2008.pdf)

<sup>2-</sup> <http://dre.pt/pdf1sdip/2001/01/002A00/00140036.pdf>

### **Appendix 3: Opinion of the National Data Protection Commission**

Not Applicable

Reason: The researchers guarantee the anonymisation of the data obtained.

## Appendix 4: Opinion of the service managers

Exmo. Sr. Coordenador

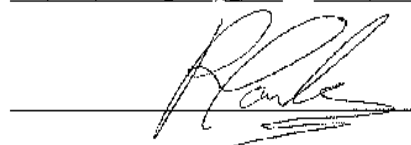
Da Unidade de Saúde Familiar Joane,

Vimos, por este meio, submeter à apreciação do Coordenador da USF Joane o protocolo do projeto de investigação intitulado **"QUAL O DESTINO DAS AGULHAS E LANCETAS DOS NOSSOS DIABÉTICOS?"**, a realizar nas Unidades de Saúde Familiares Ara de Trajano, Famalicão I, Joane, O Basto e Oeiras, dos Agrupamentos de Centros de Saúde do Alto Ave, Ave - Famalicão e Unidade Local de Saúde de Matosinhos, e cujos autores são: Ana Luísa Corte Real; Ana Luísa Fonseca Teixeira; Ana Correia de Azevedo; Catarina Calheno Rebelo; Leonor Luz Duarte; Maria Vaz Cunha; João Mário Pinto; Andreia Faria; Filipa Machado; Sofia Sacramento.

Para a realização do referido estudo, os autores propõem-se a avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

Assim, vimos por este meio solicitar a autorização do Exmo. Coordenador da USF Joane para a realização do presente estudo na Unidade Funcional acima referida.

VN Famalicão I de Maio de 2020



(Assinatura do Coordenador da USF Joane)

## TRANSLATION OF THE DOCUMENT

Dear Mr. Coordinator of the Family Health Unit Joane

We hereby submit for the appreciation of the Coordinator of the USF Joane the protocol of the research project entitled "WHERE DO OUR DIABETICS DISPOSE OF THEIR NEEDLES AND LANCETS?", to be carried out in the Family Health Units of Ara de Trajano, Famalicão I, Joane, O



Basto and Oceanos, of the Alto Ave, Ave-Famalicão Health Centre Groupings and Matosinhos Local Health Unit, and whose authors are: Ana Luísa Corte Real, Ana Luísa Fonseca Teixeira, Ana Correia de Azevedo, Catarina Calheno Rebelo, Leonor Luz Duarte, Maria Vaz Cunha, João Mário Pinto, Andreia Faria, Filipa Machado, and Sofia Sacramento.

For this study, the authors propose to evaluate the use and disposal of needles and lancets by diabetics.

Therefore, we hereby request the permission from the Coordinator of the USF Joane to conduct this study in the above-mentioned Functional Unit.

Vila Nova de Famalicão, May 5, 2020

(signature of the coordinator of the USF Joane)

Exmo Sr.(a) Coordenador(a)

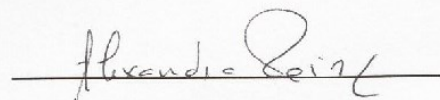
Da Unidade de Saúde Familiar Famalicão I

Vimos, por este meio, submeter à apreciação do Coordenador da USF Famalicão I o protocolo do projeto de investigação intitulado **"QUAL O DESTINO DAS AGULHAS E LANCETAS DOS NOSSOS DIABÉTICOS?"**, a realizar nas Unidades de Saúde Familiares Ara de Trajano, Famalicão I, Joane, O Basto e Oceanos, dos Agrupamentos de Centros de Saúde do Alto Ave, Ave - Famalicão e Unidade Local de Saúde de Matosinhos, e cujos autores são: Ana Luisa Corte Real; Ana Luísa Fonseca Teixeira; Ana Correia de Azevedo; Catarina Calheno Rebelo, Leonor Luz Duarte; Maria Vaz Cunha; João Mário Pinto, Andreia Faria, Filipa Machado, Sofia Sacramento.

Para a realização do referido estudo, os autores propõem-se a avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

Assim, vimos por este meio solicitar a autorização do Exmo. Coordenador da USF Famalicão I para a realização do presente estudo na Unidade Funcional acima referida.

Vila Nova de Famalicão, 5 de maio de 2020



(Assinatura do Coordenador(a) da USF)

#### TRANSLATION OF THE DOCUMENT

Dear Mr./Mrs. Coordinator of the Family Health Unit Famalicão I

We hereby submit for the appreciation of the Coordinator of the USF Famalicão I the protocol of the research project entitled **"WHERE DO OUR DIABETICS DISPOSE OF THEIR NEEDLES AND LANCETS?"**, to be carried out in the Family Health Units of Ara de Trajano, Famalicão I, Joane, O Basto and Oceanos, of the Alto Ave, Ave-Famalicão Health Centre Groupings and Matosinhos Local Health Unit, and whose authors are: Ana Luísa Corte Real, Ana Luísa Fonseca Teixeira, Ana Correia de Azevedo, Catarina Calheno Rebelo, Leonor Luz Duarte, Maria Vaz Cunha, João Mário Pinto, Andreia Faria, Filipa Machado, and Sofia Sacramento.

For this study, the authors propose to evaluate the use and disposal of needles and lancets by diabetics.

Therefore, we hereby request the permission from the Coordinator of the USF Famalicão I to conduct this study in the above-mentioned Functional Unit.

Vila Nova de Famalicão, May 5, 2020

(signature of the coordinator of the USF)

Exmo Sr.(a) Coordenador(a)

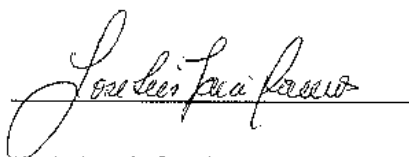
Da Unidade de Saúde Familiar O Basto,

Vimos, por este meio, submeter à apreciação do Coordenador da USF O Basto o protocolo do projeto de investigação intitulado **"QUAL O DESTINO DAS AGULHAS E LANCETAS DOS NOSSOS DIABÉTICOS?"**, a realizar nas Unidades de Saúde Familiares Ara de Trajano, Famalicão I, Joane, O Basto e Oeiras, dos Agrupamentos de Centros de Saúde do Alto Ave, Ave - Famalicão e Unidade Local de Saúde de Matosinhos, e cujos autores são: Ana Luísa Corte Real; Ana Luísa Fonseca Teixeira; Ana Correia de Azevedo; Catarina Calheno Rebelo, Leonor Luz Duarte; Maria Vaz Cunha; João Mário Pinto, Andreia Faria, Filipa Machado, Sofia Sacramento.

Para a realização do referido estudo, os autores propõem-se a avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

Assim, vimos por este meio solicitar a autorização do Exmo. Coordenador da USF O Basto para a realização do presente estudo na Unidade Funcional acima referida.

Cabeceiras de Basto, 05 de Maio de 2020



(Assinatura do Coordenador(a) da USF O Basto)

## TRANSLATION OF THE DOCUMENT

Dear Mr./Mrs. Coordinator of the Family Health Unit O Basto

We hereby submit for the appreciation of the Coordinator of the USF O Basto the protocol of the research project entitled "WHERE DO OUR DIABETICS DISPOSE OF THEIR NEEDLES AND LANCETS?", to be carried out in the Family Health Units of Ara de Trajano, Famalicão I, Joane, O Basto and Oceanos, of the Alto Ave, Ave-Famalicão Health Centre Groupings and Matosinhos Local Health Unit, and whose authors are: Ana Luísa Corte Real, Ana Luísa Fonseca Teixeira, Ana Correia de Azevedo, Catarina Calheno Rebelo, Leonor Luz Duarte, Maria Vaz Cunha, João Mário Pinto, Andreia Faria, Filipa Machado, and Sofia Sacramento.

For this study, the authors propose to evaluate the use and disposal of needles and lancets by diabetics.

Therefore, we hereby request the permission from the Coordinator of the USF O Basto to conduct this study in the above-mentioned Functional Unit.

Cabeceiras de Basto, May 5, 2020

(signature of the coordinator of the USF O Basto)

Exmo Sr.(a) Coordenador(a)

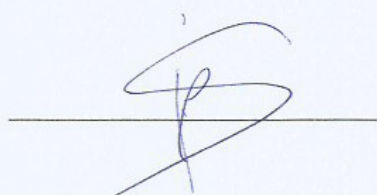
Da Unidade de Saúde Familiar Ara de Trajano,

Vimos, por este meio, submeter à apreciação do Coordenador da USF Ara de Trajano o protocolo do projeto de investigação intitulado **"QUAL O DESTINO DAS AGULHAS E LANCETAS DOS NOSSOS DIABÉTICOS?"**, a realizar nas Unidades de Saúde Familiares Ara de Trajano, Famalicão I, Joane, O Basto e Oceanos, dos Agrupamentos de Centros de Saúde do Alto Ave, Ave - Famalicão e Unidade Local de Saúde de Matosinhos, e cujos autores são: Ana Luísa Corte Real; Ana Luisa Fonseca Teixeira; Ana Correia de Azevedo; Catarina Calheno Rebelo, Leonor Luz Duarte; Maria Vaz Cunha; João Mário Pinto, Andreia Faria, Filipa Machado, Sofia Sacramento.

Para a realização do referido estudo, os autores propõem-se a avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

Assim, vimos por este meio solicitar a autorização do Exmo. Coordenador da USF Ara de Trajano para a realização do presente estudo na Unidade Funcional acima referida.

Taipas, 05 de maio de 2020

A handwritten signature in blue ink, consisting of a stylized 'P' and 'S' intertwined, written over a horizontal line.

(Assinatura do Coordenador(a) da USF Ara de Trajano)

## TRANSLATION OF THE DOCUMENT

Dear Mr./Mrs. Coordinator  
Of the Family Health Unit Ara de Trajano

We hereby submit for the appreciation of the Coordinator of the USF Ara de Trajano the protocol of the research project entitled "WHERE DO OUR DIABETICS DISPOSE OF THEIR NEEDLES AND LANCETS?", to be carried out in the Family Health Units of Ara de Trajano, Famalicão I, Joane, O Basto and Oceanos, of the Alto Ave, Ave-Famalicão Health Centre Groupings and Matosinhos Local Health Unit, and whose authors are: Ana Luísa Corte Real, Ana Luísa Fonseca Teixeira, Ana Correia de Azevedo, Catarina Calheno Rebelo, Leonor Luz Duarte, Maria Vaz Cunha, João Mário Pinto, Andreia Faria, Filipa Machado, and Sofia Sacramento.

For this study, the authors propose to evaluate the use and disposal of needles and lancets by diabetics.

Therefore, we hereby request the permission from the Coordinator of the USF Ara de Trajano to conduct this study in the above-mentioned Functional Unit.

Taipas, May 5, 2020  
(signature of the coordinator of the USF Ara de Trajano)

Exmo Sr. Coordenador

Da Unidade de Saúde Familiar Oceanos,

Vimos, por este meio, submeter à apreciação do Coordenador da USF Oceanos o protocolo do projeto de investigação intitulado **“QUAL O DESTINO DAS AGULHAS E LANCETAS DOS NOSSOS DIABÉTICOS?”**, a realizar nas Unidades de Saúde Familiares Ara de Trajano, Famalicão I, Joane, O Basto e Oceanos, dos Agrupamentos de Centros de Saúde do Alto Ave, Ave - Famalicão e Unidade Local de Saúde de Matosinhos, e cujos autores são: Ana Luísa Corte Real; Ana Luísa Fonseca Teixeira; Ana Correia de Azevedo; Catarina Calheno Rebelo, Leonor Luz Duarte; Maria Vaz Cunha; João Mário Pinto, Andreia Faria, Filipa Machado, Sofia Sacramento.

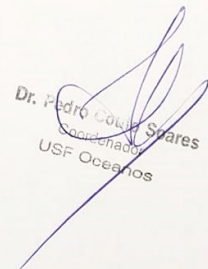
Para a realização do referido estudo, os autores propõem-se a avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

Assim, vimos por este meio solicitar a autorização do Exmo. Coordenador da USF Oceanos para a realização do presente estudo na Unidade Funcional acima referida.

Pedro, 6 de Março de 2020

*Nada a opor*

  
(Assinatura do Coordenador da USF Oceanos)

  
Dr. Pedro Cortes Soares  
Coordenador  
USF Oceanos



## TRANSLATION OF THE DOCUMENT

Dear Mr./Mrs. Coordinator  
Of the Family Health Unit Oceanos,

We hereby submit for the appreciation of the Coordinator of the USF Oceanos the protocol of the research project entitled "WHERE DO OUR DIABETICS DISPOSE OF THEIR NEEDLES AND LANCETS?", to be carried out in the Family Health Units of Ara de Trajano, Famalicão I, Joane, O Basto and Oceanos, of the Alto Ave, Ave-Famalicão Health Centre Groupings and Matosinhos Local Health Unit, and whose authors are: Ana Luísa Corte Real, Ana Luísa Fonseca Teixeira, Ana Correia de Azevedo, Catarina Calheno Rebelo, Leonor Luz Duarte, Maria Vaz Cunha, João Mário Pinto, Andreia Faria, Filipa Machado, and Sofia Sacramento.

For this study, the authors propose to evaluate the use and disposal of needles and lancets by diabetics.

Therefore, we hereby request the permission from the Coordinator of the USF Oceanos to conduct this study in the above-mentioned Functional Unit.

Matosinhos, May 6, 2020  
(signature of the coordinator of the USF Oceanos)



**SNS** SERVIÇO NACIONAL  
DE SAÚDE

Projeto / Estudo n.º 02 / 2020

Data de Receção: 08 / 05 / 2020

### PROJETO DE INVESTIGAÇÃO

#### Identificação do(s) investigador(es) do estudo

##### Nome Completo:

Ana Luísa Bacelar Corte Real<sup>1</sup>; Ana Isabel Correia de Oliveira Azevedo<sup>2</sup>; Ana Luísa Fonseca Teixeira<sup>3</sup>; Maria Leonor Luz Duarte<sup>4</sup>; Catarina Pereira Calheno Rebelo<sup>4</sup>; Maria Vaz Cunha<sup>5</sup>; João Mário Silva Cruz Pereira Pinto<sup>1</sup>; Andreia Paulista de Faria<sup>2</sup>; Sofia Sacramento<sup>5</sup>; Filipa Cristiana Fernandes Machado<sup>5</sup>.

Contato telefónico: 912941833 (Ana Luísa Corte Real)

E-Mail: [acortereal@arsnorte.min-saude.pt](mailto:acortereal@arsnorte.min-saude.pt)

Qualificação Académica: Mestrado Integrado em Medicina

Funções que desempenha: Interna (o) de Formação Específica em Medicina Geral e Familiar

Instituição: 1 - USF Joane, ACES Ave-Famalicão; 2 - USF Famalicão I, ACES Ave-Famalicão; 3 - USF O Basto, ACES Alto Ave; 4 - USF Oceanos, ACES Matosinhos; 5 - USF Ara de Trajano, ACES Alto Ave.

##### Designação do Estudo:

Qual o Destino das Agulhas e Lancetas dos Nossos Diabéticos?

##### Área científica em que se enquadra o estudo:

Diabetes mellitus

##### Vigência do Estudo (Data de princípio e de fim):

Data de princípio: mês de aprovação do projeto de investigação pelas entidades competentes

Data de fim: cerca de 8 meses após a data de princípio

##### Tipo de análise (quantitativa, qualitativa)

Quantitativa e qualitativa

Palavras – chave: Diabetes mellitus; corto-perfurantes; insulina; lancetas.

##### Co-Investigador(es) (quando aplicável)

Nome(s) Completo(s):

##### OUTROS PROFISSIONAIS ENVOLVIDOS (Exemplo: Orientador)

Nome(s) Completo(s): N/A

Instituição: N/A



### OUTRAS INFORMAÇÕES SOBRE ESTUDO

#### Objetivo Geral:

Avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

**Metodologia:** Estudo observacional transversal, realizado ao nível dos cuidados de saúde primários (CSP), com recurso a questionários, aplicados a uma amostra representativa de diabéticos, com idade superior a 18 anos, selecionados de forma aleatória, de cinco Unidades de Saúde Familiar da zona norte. Os indivíduos selecionados serão convidados a integrar o projeto presencialmente, aquando de consultas programadas nos CSP, ou telefonicamente, com agendamento de consulta para aplicação do questionário. Os dados obtidos serão estruturados informaticamente no Microsoft Office Excel 2019® e submetidos a estudo analítico no IBM SPSS 26.0®.

**População alvo:** Diabéticos, com idade superior a 18 anos, das USF Famalicão I, Joane, O Basto, Oceanos e Ara de Trajano.

**Amostra:** amostra representativa da população supracitada.

**Crítérios de inclusão:** idade igual ou superior a 18 anos; utentes com diagnóstico ativo de diabetes mellitus com os códigos ICPC-2 T89 e T90.

**Método de recolha dados (anexar instrumento recolha):** aplicação de questionário (em anexo)

**Descrição do que consiste a colaboração do ACeS:** Autorização para o desenvolvimento do estudo nas instalações das USF Joane e Famalicão I (utilização de infraestruturas) e apoio/cedência de recursos materiais (telefone, computador e material de escritório).

### Termo de Responsabilidade

Declaro assumir a liderança científica do projeto / estudo e as responsabilidades decorrentes da sua boa execução, bem como dar feedback do estudo em causa e suas conclusões ao ACeS Famalicão

Data: 07/05/2020

Assinatura: Ana Lúcia Barcelos Costa Real

Projeto / Estudo n.º \_\_\_\_\_ / \_\_\_\_\_


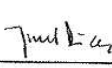
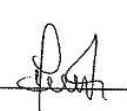
Data de Receção: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

### PARECER CONSELHO CLÍNICO E DE SAÚDE

Favorável ☒

Não Favorável ☐

O parecer favorável do ACeS não dispensa a submissão ao Conselho de Ética da ARSN

Assinaturas:   

### PARECER DO RESPONSÁVEL DO ACESSO À INFORMAÇÃO

Favorável ☒

Não Favorável ☐

Data:

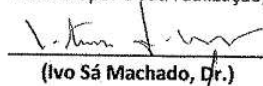
Assinaturas:



### O DIRETOR EXECUTIVO

ACeS Famalicão

Nada a opor à sua realização,

  
(Ivo Sá Machado, Dr.)

## TRANSLATION OF THE DOCUMENT

Project/Study nº 02/2020; Reception Date: 08/05/2020

## RESEARCH PROJECT

**Identification of the study investigators:** Ana Luísa Bacelar Corte Real<sup>1</sup>; Ana Isabel Correia de Oliveira Azevedo<sup>2</sup>; Ana Luísa Fonseca Teixeira<sup>3</sup>; Maria Leonor Luz Duarte<sup>4</sup>; Catarina Pereira Calheno Rebelo<sup>4</sup>; Maria Vaz Cunha<sup>5</sup>; João Mário Silva Cruz Pereira Pinto<sup>1</sup>; Andreia Paulista de Faria<sup>2</sup>; Sofia Sacramento<sup>5</sup>; Filipa Cristiana Fernandes Machado<sup>5</sup>.  
**Telephone Contact:** 912941833 (Ana Luísa Corte Real);  
**E.Mail:** acortereal@arsnorte.min-saude.pt  
**Academic Qualifications:** Integrated Master in Medicine  
**Functions performed:** Resident of Family Medicine; Institution: 1 – USF Joane, ACES Ave-Famalicão; 2 – USF Famalicão I, ACES Ave-Famalicão; 3 – USF O Basto, ACES Alto-Ave; 4 – USF Oceanos, ACES Matosinhos; 5- USF Ara de Trajano, ACES Alto-Ave.

**Study Title:** “Where do Our Diabetics Dispose of Their ‘Needles and Lancets?”  
**Scientific area in which the study is framed:** Diabetes mellitus  
**Date of beginning and end of study:** Beginning date: Month of approval of the research project by the authorities; End date: 8 months after initiation.  
**Type of analysis (quantitative, qualitative):** Quantitative and qualitative  
**Key-words:** Diabetes, Medical sharps, Disposal, Insulin, Lancets.  
**Co-investigators:** Not applicable  
**Other professionals involved:** Not applicable  
**OTHER INFORMATION ABOUT THE RESEARCH**  
**General Objective:** Evaluate the use of needles and lancets by diabetics  
**Methods:** This is a cross-sectional observational study, carried out at the primary health care level, using questionnaires applied to a representative sample of diabetics over 18 years of age, randomly selected from five family health units in the northern region. The selected individuals will be invited to join the project either in person, during scheduled appointments at the primary health care, or by telephone, with an appointment to apply the questionnaire. The data obtained will be structured in Microsoft Office Excel 2019 and analyzed using IBM SPSS 26.0. Target Population: Diabetics over the age of 18, from USF Famalicão I, Joane, O Basto, Oceanos and Ara de Trajano.  
**Sample:** Sample representative of the above-mentioned population.

**Inclusion Criteria:** Inclusion criteria: age 18 years or older; users diagnosed with diabetes mellitus with ICPC-2 codes T89 and T90.  
**Data collection method (attach collection instruments):** application of questionnaires (attached).  
**Description of what ACES collaboration consists of:** Authorization for the development of the study at the facilities of USF Joane and Famalicão I (use of infrastructure) and support / provision of material resources (telephone, computer and office supplies).  
**Term of responsibility:** I declare to assume the scientific leadership of the project/study and the responsibilities arising from its proper execution, as well as to provide feedback of the study in question and its conclusions to ACES Famalicão. – Signed by Ana Luísa Corte Real – researcher.  
**Opinion of the scientific and health council:** Favorable – signed by the competent authorities  
**Opinion of the access to information officer:** Favorable – signed by the competent authorities

Signed by the executive director of ACES Famalicão – Nothing to oppose

REPÚBLICA PORTUGUESA SNS ARS NORTE

Projeto / Estudo n.º / /  
Data de Receção: / /

**PROJECTO DE INVESTIGAÇÃO**  
Identificação do(s) Investigador(es) do Estudo: Diabetes Mellitus

**Nome Completo:**  
Ana Luísa Ferreira Costa Real, Ana Isabel Correia de Oliveira Azevedo, Ana Luísa Figueira Teixeira, Maria Leonor Loureiro Duarte, Catarina Moreira Calhano Helder, Maria Vaz Cunha, João Mário Silva Cruz, Ferreira Pinto, Andreia Paulista de Faria, Sofia Sacramento, Filipa Cristina Fernandes Machado.

**Contacto telefónico:**  
910410062 (Ana Luísa Teixeira)

**E-Mail:**  
allteixeira@arsnorte.mis-saude.pt (Ana Luísa Teixeira)

**Qualificação Académica:**  
Mestrado Integrado em Medicina

**Funções que desempenha:** Internato de Formação Específica em Medicina Geral e Familiar

**Instituição:** 1- USF Joane, ACES Ave Famalicão; 2- USF Famalicão; 3- USF O Busto, ACES Alto Ave; 4- USF Ourense, ACES Matosinhos; 5- USF Ara de Trájeiro, ACES Alto Ave.

**Designação do Estudo:**  
Qual o nível das Agulhas e Lancetas dos Doentes Diabéticos?

**Área científica em que se enquadra o estudo:**  
Diabetes mellitus

**Vigência do Estudo (Data de princípio e de fim):**  
Data de princípio: mês de aprovação do projeto de investigação pelas entidades competentes.  
Data de fim: cerca de 6 meses após a data do princípio.

**Tipo de análise (quantitativa, qualitativa):**  
Quantitativa e qualitativa

**Palavras-chave:** Diabetes mellitus, corte, percutâneos, Injeção, Lancetas.

**Co-Investigador(es) (quando aplicável):**  
Nome(s) Completo(s):

**OUTROS PROFISSIONAIS ENVOLVIDOS**  
(Exemplo: Orientador)  
Nome(s) Completo(s):  
Instituição:

**OUTRAS INFORMAÇÕES SOBRE ESTUDO**  
**Objetivo Geral:**  
Avaliar a utilização e descarte de agulhas e lancetas pelos diabéticos.

REPÚBLICA PORTUGUESA SNS ARS NORTE

**Metodologia:** Estudo observacional transversal, realizado a nível dos cuidados de saúde primários (CSP), com recurso a questionários, aplicados a uma amostra representativa de diabéticos, com idade superior a 18 anos, selecionados de forma aleatória, nos cinco Unidades de Saúde Familiar da zona norte. Os indivíduos selecionados serão convidados a integrar o projeto investigativo, segundo as consultas programadas nos CSP, ou telefonicamente, com agendamento de consulta para aplicação do questionário. Os dados obtidos serão inseridos no sistema informático do Microsoft Office Excel 2019 e armazenados no estudo analítico no RVS SPSS 26.0.

**População alvo:** Diabéticos, com idade superior a 18 anos, das USF Famalicão, Joane, O Busto, Ourense e Ara de Trájeiro.

**Crítérios de inclusão:** Idade igual ou superior a 18 anos, utente com diagnóstico ativo de diabetes mellitus com os códigos ICD-2 250 e 700.

**Método de recolha de dados (anexo Instrumento recolha):** Aplicação de questionário (em Anexo).

**Descrição do que consiste a colaboração do ACES:**  
Autorização para o desenvolvimento do estudo nas instalações das USF O Busto e Ara de Trájeiro (utilização de infra-estruturas) e disponibilização de recursos materiais (telefone, computador e material de escritório).

**Termo de Responsabilidade**  
Declaro assumir a responsabilidade científica do projeto / estudo e as responsabilidades decorrentes da sua boa execução, bem como a da fidelidade do estudo em todos os seus resultados ao ACES.

Data: 11/09/2020  
Assinatura: [Assinatura]

Projeto / Estudo n.º / /  
Data de Receção: / /

**PARER DO CONSELHO CLÍNICO E DE SAÚDE**  
Data: Favorável ☒ Não Favorável ☐

**Assinatura:**  
[Assinatura]  
PRESIDENTE DO CONSELHO CLÍNICO  
ACES DO ALTO AVE

**DIRETOR EXECUTIVO**  
Núlio e opor à sua execução.  
[Assinatura]  
Dr. José Manuel de Carvalho  
ACES DO ALTO AVE



## TRANSLATION OF THE DOCUMENT

Project/Study \_\_\_\_\_ n° \_\_\_\_\_  
 Reception Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## RESEARCH PROJECT

**Identification of the study investigators:** Ana Luísa Bacelar Corte Real<sup>1</sup>; Ana Isabel Correia de Oliveira Azevedo<sup>2</sup>; Ana Luísa Fonseca Teixeira<sup>3</sup>; Maria Leonor Luz Duarte<sup>4</sup>; Catarina Pereira Calheno Rebelo<sup>4</sup>; Maria Vaz Cunha<sup>5</sup>; João Mário Silva Cruz Pereira Pinto<sup>1</sup>; Andreia Paulista de Faria<sup>2</sup>; Sofia Sacramento<sup>5</sup>; Filipa Cristiana Fernandes Machado<sup>5</sup>.  
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**Academic Qualifications:** Integrated Master in Medicine  
**Functions performed:** Resident of Family Medicine; Institution: 1 – USF Joane, ACES Ave-Famalicão; 2 – USF Famalicão I, ACES Ave-Famalicão; 3 – USF O Basto, ACES Alto-Ave; 4 – USF Oceanos, ACES Matosinhos; 5- USF Ara de Trajano, ACES Alto-Ave.

**Study Title:** “Where do Our Diabetics Dispose of Their ‘ Needles and Lancets?”  
**Scientific area in which the study is framed:** Diabetes mellitus  
**Date of beginning and end of study:** Beginning date: Month of approval of the research project by the authorities; End date: 8 months after initiation.  
**Type of analysis (quantitative, qualitative):** Quantitative and qualitative  
**Key-words:** Diabetes, Medical sharps, Disposal, Insulin, Lancets.  
**Co-investigators:** Not applicable  
**Other professionals involved:** Not applicable

**OTHER INFORMATION ABOUT THE RESEARCH**  
**General Objective:** Evaluate the use of needles and lancets by diabetics  
**Methods:** This is a cross-sectional observational study, carried out at the primary health care level, using questionnaires applied to a representative sample of diabetics over 18 years of age, randomly selected from five family health units in the northern region. The selected individuals will be invited to join the project either in person, during scheduled appointments at the primary health care, or by telephone, with an appointment to apply the questionnaire. The data obtained will be structured in Microsoft Office Excel 2019 and analyzed using IBM SPSS 26.0.  
**Target Population:** Diabetics over the age of 18, from USF Famalicão I, Joane, O Basto, Oceanos and Ara de Trajano.  
**Inclusion Criteria:** Inclusion criteria: age 18 years or older; users diagnosed with diabetes mellitus with ICPC-2 codes T89 and T90.  
**Data collection method (attach collection instruments):** application of questionnaires (attached).  
**Description of what ACES collaboration consists of:** Authorization for the development of the study at the facilities of USF O Basto and Ara de Trajano (use of infrastructure) and support / provision of material resources (telephone, computer and office supplies).  
**Term of responsibility:** I declare to assume the scientific leadership of the project/study and the responsibilities arising from its proper execution, as well as to provide feedback of the study in question and its conclusions to ACES. – Signed by Ana Luísa Teixeira – researcher.  
**Opinion of the scientific and health council:** Favorable – signed by the competent authorities  
 Signed by the executive director of ACES Alto Ave – Nothing to oppose