

## RESEARCH PROTOCOL

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

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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

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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

## REFERENCES

1. Diabetes: Factos e Números - O Ano de 2015 - Relatório Anual do Observatório Nacional da Diabetes. 2016.
2. Glycemic Targets: Standards of Medical Care in Diabetes—2019. American Diabetes Association. *Diabetes Care*; 2019.
3. International Diabetes Federation. Guideline Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes. 2009.
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5. Pessoas com diabetes não têm como descartar agulhas em segurança. *Jornal Médico*-07/05/2019. Disponível em: <https://www.jornalmedico.pt/atualidade/37431-pessoas-com-diabetes-nao-tem-como-descartar-agulhas-em-seguranca.html>. Consultado em: 09/11/2019
6. Safe disposal of sharps used by people with diabetes- Position Statement (Updated: December 2018). Diabetes UK.
7. Best Way to Get Rid of Used Needles and Other Sharps. U.S. Food & Drug Administration. Disponível em: <https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/best-way-get-rid-used-needles-and-other-sharps>. Consultado em: 12/11/2019.



## 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

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#### 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.

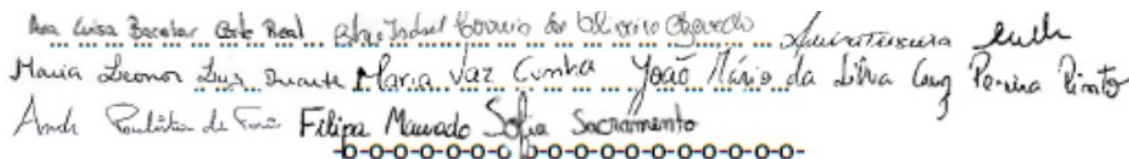
**Funding:** The entire study will be funded by the investigators. There will be no payment for travel or compensation. Participation in this study is voluntary. If you do not wish to participate, you must inform the investigator of your decision. This study was approved by the Ethics Committee for Health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

<p>SE NÃO FOR O PRÓPRIO A ASSINAR POR IDADE OU INCAPACIDADE (se o menor tiver discernimento deve <u>também</u> assinar em cima, se consentir)</p>	
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 á 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 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 Joane para a realização do presente estudo na Unidade Funcional acima referida.

VN Famalicão, 5 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)



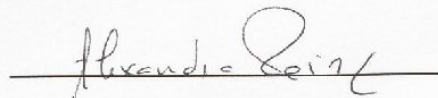
Exmo Sr.(a) Coordenador(a)  
Da Unidade de Saúde Familiar Famalicão I

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 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 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)

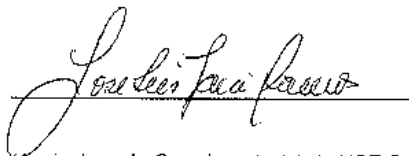
Exmo Sr.(a) Coordenador(a)  
Da Unidade de Saúde Familiar O Basto,

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)

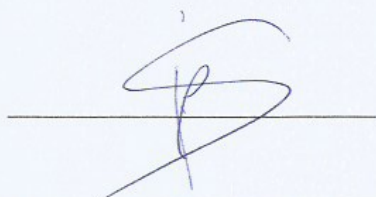
Da Unidade de Saúde Familiar Ara de Trajano,

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 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 Ara de Trajano para a realização do presente estudo na Unidade Funcional acima referida.

Taipas, 05 de maio de 2020



(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.

Porto, 6 de Maio de 2020

*Nada a opor*

\_\_\_\_\_  
(Assinatura do Coordenador da USF Oceanos)

*Dr. Pedro Sousa 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)





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>2</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

**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<sup>®</sup> e submetidos a estudo analítico no IBM SPSS 26.0<sup>®</sup>.

**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:  
 Presidente do Conselho Clínico e de Saúde: Frederico Sá Machado, Dr.  
 ACeS Famalicão

#### 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



ANEXO Nº 1  
 PROJECTO DE INVESTIGAÇÃO  
 Identificação do(s) Investigador(es) do estudo (nome do Conselho Diretivo)

Nome Completo: Ana Luísa Alves (Correia Real), Ana Isabel Correia de Oliveira Azevedo, Ana Luísa Figueira Teixeira, Maria Leonor (Luz Duarte), Catarina Henrieta Calhano Heitor, Maria Vaz Cunha, João Mário Silva Cruz, Ferreira Pinto, Andreia Paulista de Faria, Sofia Sacramento, Filipa Cristina Fernandes Machado.

Contacto telefónico: 910410302 (Ana Luísa Teixeira)

E-Mail: allteixeira@arsnorte.mtas.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 Famulção; 2- USF Famulção I, ACES Ave Famulção; 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 Desempenho das Agulhas e Lançetas 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 6 meses após a data de princípio


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

Palavras-chave: Diabetes mellitus, corte, percutantes, Injeção, Lançetas.

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 lançetas pelos diabéticos.



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, telefonados de forma aleatória, nos cinco Unidades de Saúde Familiar da zona norte. Os indivíduos selecionados serão convidados a integrar o projeto inicialmente, através de consultas programadas nos CSP, ou telefonicamente, com agendamento de consulta para aplicação do questionário. Os dados obtidos serão armazenados eletronicamente no Microsoft Office Excel 2019 e efetuados o estudo analítico no IBM SPSS 26.0.

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

Critérios de inclusão: Idade igual ou superior a 18 anos; tenham tido diagnóstico ativo de diabetes mellitus com os códigos ICD-2 250.0-250.9

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 Basto e Ara de Trajano (utilização de infra-estruturas) e apoio/vigência de recursos materiais (telefone, computador e material de escritório)

Termo de Responsabilidade

Declaro assumir a responsabilidade científica do projeto de estudo e as responsabilidades decorrentes da sua boa execução, bem como a dar feição ao estudo em caso de novas conclusões ao ACES.

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

Projecto / 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  
 Nela e opor à sua realização.  
*[Assinatura]*  
 Dr. José Manuel de Carvalho  
 DIRETOR EXECUTIVO  
 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>.  
**Telephone Contact:** 910403082 (Ana Luísa Teixeira)  
**E.Mail:** [alfteixeira@arsnorte.min-saude.pt](mailto:alfteixeira@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.  
**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