Evaluation of nurse's knowledge and perceptions regarding generic medicines - pilot study in Saragossa (Spain)

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ABSTRACT: *Several policies have been carried out in Spain in order to encourage the usage of generic medicines to reduce costs of the National Healthcare System. Nevertheless, the market share of generics in Spain is small when compared with other European countries. The aim of this study is to review the actual knowledge and perception of generic medicines in Spain to see if more training and information for nurses is necessary. A study using electronic self-administered questionnaires was conducted to survey the nurse's knowledge and perceptions of generic medicines in a pilot, conducted in Saragossa province (n=133). Nurses asked for more training and information about generic medicines in the questionnaire and results show it, although perception in general of generic medicines looks positive.*
This is the second survey of a much wider research on generic medicines perception and knowledge, done with patients, nurses, doctors and pharmacists.
KEY WORDS: *genericmedicine, perception, knowledge, nurse, generic substitution.*

I. INTRODUCTION

Spain is one of the countries reporting the biggest total consumption in medicines and other pharmaceutical products, with an expense representing a 1.77% of the Gross Domestic Product (GDP) in 2012. Since 2009 Spain has been able to reduce its pharmaceutical cost average per inhabitant, going from 273€ in that year to 212€ in 2011.[1] This situation is the result of the different policies the Spanish government has implemented in order to stop the increase of the pharmaceutical cost of the "Sistema Nacional de Salud", the National Healthcare System in Spain, including the preferred usage and substitution policies of generic medicines. However, although the increase of use of generic medicines has been promoted in the last years as an efficient and fast tool of saving for the public health administration, Spain is one of the countries with lower generic medicines penetration, with a market share of 17.4% in the first quarter of 2013.[2] This share is still small and far away from other market shares in other European countries such as Poland, UK or Germany and there are no expectations on a big increase of their market share neither on an increase on the usage of medicines in Spain.One of the top 5 European countries spending in health is Spain, with a projection of 24$Bn in 2020 (Actuals: 18.6$Bn in 2015)[4]

As a result, we find important to analyze the different factors that could influence the generic medicines consumption and especially the attitude of health professionals, as they are the main players when a change of health policy happens. We did a complete research in all health professional fields: nurses, pharmacists and medical doctors (MD).[3] There isn't any research taking into account the 3 professionals at the same time and in similar way. Health Authorities need to know and understand the knowledge and adherence to those policies by the players in the medicines chain, as their actions should be different relating to the results.

The goal of this paper is to evaluate the perception, opinion, knowledge and adherence to the health policy of generic medicines prescription and dispensing by the nurses, in contact with the final user of the generic medicines. Additionally, we would like to understand their perception of security, quality and efficacy of the generic medicines.

II. METHOD

In this research, we followed the building surveys process steps.[5]

The research was conducted in the level of the Saragossa province in Spain, as a pilot of a later research at national scale. Saragossa's special characteristics and medium size can be considered a representative city in the Spanish market, so it's a good place to conduct a pilot research prior to a national research.[6]

This research has been conducted in the steps defined below, mainly questionnaire development, validation by experts and survey conduction.

Questionnaire development

A. Topic specification and type of instrument

We developed structured questionnaires that were self-administrated by a web-survey system: Lime-survey (Lime-survey 1.91+Build 11379 license Universidad San Jorge).

The topic is the perception of generic medicines and its prescription, dispensing and usage.

B. Items and format generation

To generate the items of the survey, we made an exhaustive bibliographic research about surveys conducted in different countries about perception and/or knowledge at generic medicines. Once all the items were gathered, we aggregated them by theme.

The survey was divided in 3 parts:

1. Demographic data of the nurse about: age, gender, occupancy and medication dispensers. An introductory question is also included.
2. Generic medicines Knowledge
3. Perception and attitude against generic medicines

For each item in part 2 and 3 of the survey, we used an additive valuation scale (Likert type) or a closed answer of Yes, No, No Response (NR). Each item is presented as a positive closed statement followed by different answer options that indicate different agreement or disagreement levels. In the first type, to each answer a specific grade is given (from 0 to 4), being able then to calculate the total result by adding the grade of each item.

(*Figure 1. Translation of answers to qualitative ordinal variables code.*)

Label	Value
Strongly disagree	0
Disagree	1
Neither agree nor disagree	2
Agree	3
Strongly agree	4

Last question of part 3 has a multi-option answer, we defined the affirmative grade by the difference between the Yes and No answers between -100 and 100. An affirmative rank of -100 means that all the participants have answered No, a rank of 0 means 50% Yes and 50% No, a rank of 100 all the participants answered Yes.

Number of items in the survey:

We chose 7 items for the part of knowledge of EFG and 7+1 for the perception part. This last question (+1) is the only question with multi-option answer. This survey (with small modifications in the wording and definition of the demography to adapt to the surveyed group) was also used to conduct 2 other research, to MD and pharmacists.

Review and validation of the questionnaires by an expert panel

The review of the items in the survey was done with the Delphi methodology, but with the warranty, as the methodology indicate the confidentiality of the different expert opinions and without any opinion interchange between the different experts and trying to look for the agreement of the participants.[7, 8, 9] For each item a questionnaire was given with the questions below and closed answer Yes/No, except for one, where they had free text to rephrase the question.

(*Figure 2: Expert panel review questionnaire example*)

PART I: Knowledge EFG's

As an expert panel, 10 health professionals were chosen (MD, nurses and pharmacists), all of them working in Spain but not in Saragossa province and without any relation and conflict of interest with this research. We contacted them separately by email and received their answer in the same way. Two cycles were done, between April and July 2013. They were also not in contact between them.

In both cycles an introductory letter was sent with an explanation of the goal of the research and their opinion.

After the first cycle, where all the items were sent with the specific question above, all the answers were collected anonymously in an Excel data base for its analysis.

First results were:

- with 100% of positive answers about the order of the items
- some suggestions to rephrase some of the questions\include more options in the last question of the survey (multi-option question)

After small adjustments in the wording of the questions taking into account those proposals, a second cycle was conducted, with 100% consensus in the definitive survey.

Table 2. Questions in the survey

Theme	Detailed question
Knowledge Generic Medicines	I know the difference between a generic and a branded medicine
	I know the substitution process between branded and generic medicines
	I know the bioequivalence standards of generic medicines
	I need more information about safety and effectiveness of generic medicines
Perception and Attitude towards Generic Medicines	Socioeconomic factors and age of the patient have influence when prescribing/dispensing a medicine
	Credibility of the Pharmaceutical Company influences when dispensing/ prescribing a medicine
	Generic medicines have the same equivalence as branded medicines
	The quality of generic medicines is different to branded medicines
	The effectiveness of generic medicines is lower than branded medicines
	Generic medicines have more secondary effects than branded medicines
	Manufacturing standards are more relaxed with generic medicines than with branded
	Usage of generic medicines will contribute to reduce the public pharmaceutical expense in Spain
	I accept the substitution of branded with generic medicines
Aspects I consider when choosing a medicine to prescribe/dispense	Multioption selection

Survey conduction

A. Survey participants: exclusion and inclusion criteria
1. Inclusion: active nurses working or looking for a job in Saragossa province part of the Nurses Association in Saragossa
2. Exclusion: nurses not working in Saragossa province or retired nurses
A. Sampling procedure and sample size

Bibliography indicates that minimum 5 people per item the questionnaire has, should be interviewed, and it's not recommended less than 100 people interviewed in overall to achieve consistent results. That's why our goal in this pilot was to survey a minimum of 100 people interviewed.[8, 9] In this survey, 133 nurses answered the questionnaire.

It was checked the number of active nurses in Saragossa province when the study was conducted: 5.900 nurses end of 2012

A. Instrument

Anonymous questionnaires structured and self-administrated with a web survey.

A. Procedure of survey

A link of the web-survey was sent by email through the Professional Nurses Association in Saragossa. Through the link they were able to answer the survey in a website that kept anonymous all the answers. A support email contact was also given, but no support was required during the process by any of the participants.

A. Collection of data period

Results were collected between September and December 2013.

A. Research scope

The research, as stated before, is a pilot done in Saragossa province in Spain. After the analysis of the results out of this research, we will decide if it's needed another research in a country level.

A. Aggregation and data analysis

A database was created to collect and aggregate the received data.

Statistical treatment and data analysis:

We conducted a descriptive analysis of the studied sample for all the collected variables and we determined the association between the qualitative variables with the Chi-squared test. The results were expressed as the frequency of answers for each of them and by percentages. We considered statistical significant the differences with a value $p < 0.05$. The analysis was done with the system SPSS version 19.0 (SPSS-PC, Chicago, EE.UU.).

III. RESULTS

Demographic data

We received 133 surveys through Limesurvey system. From them, 84.47% were women and average of age was 34.85 years old, as vast majority were in the groups of 18-30 years old and 30-50 years old (60 and 56 nurses respectively). The respondent profile nurse is a woman of about 35 years old. From occupancy perspective 40.9% were nurse specialist and 15.91% primary care nurses. 15.15% were unemployed and 28.03% were the rest. (*Table 1 Demographic data*)

	Frequency	Percentage
Gender		
Male	18	13.53
Female	115	86.47
Age		
18-30 years old	60	45.45
31-50 years old	56	42.42
51-65 years old	16	12.12
More than 65 years old	0	0
No data	1	-
Employment		
Unemployed	20	15.15
Primary care	21	15.91
Specialist	54	40.9
Other	37	27.82
No data	1	-

Two thirds of the respondents answered that they do not dispense medicines. Of the 133 respondents, 2 didn't

respond to this question.

Knowledge of generic medicines
All respondents to this question replied that they know what a generic medicine is. They have answered 130 of 133 (3 answers in blank).

__Graph 1.__ Summary answers "Knowledge of Generic Medicines".

Difference between Generic and Branded medicines. Over 80% of nurses surveyed to know the difference between a generic and a branded medicine (71 agree and 35 people strongly agree). An average of 3.02 value out of 4 was the result on the knowledge of the differences between them.
When we go deeply in the knowledge, the results look a different.
Substitution process. Around 60% of the nurses know the substitution process of a branded medicine by a generic medicine. This makes a lower average value in general, only 2.57 for the substitution process. We expected this percentage to be higher, as they are very close the patients and have to answer many questions about the medicines the patients are prescribed.
**Bioequivalence standards.** An average of 1.94 value was the result of the knowledge of the bioequivalence standards. Strongly agree or Agree results were 39.84% and 40.65% were Disagree or Strongly disagree results . And 19.51% had a neutral answer Neither agree nor disagree.
Safety and effectiveness. We got a strong result on the need of more information on safety and effectiveness of generic medicines, as 2/3 of the interviewed nurses answered they needed: 64 and 18 nurses Agreed and Strongly Agreed respectively. Although the average value is only 2.56, 64 out of all the nurses answered "Agree" to the question, so we can see the high weight of the need.

Perception and attitude towards generic medicines.
After all questions related to the knowledge the nurses surveyed, we had as part of the questionnaire some items regarding their perception. The results look very different to what we would expect, as we had in some parts of the knowledge high results.

__Graph 2.__ Summary answers "Perception and Attitude towards Generic Medicines".
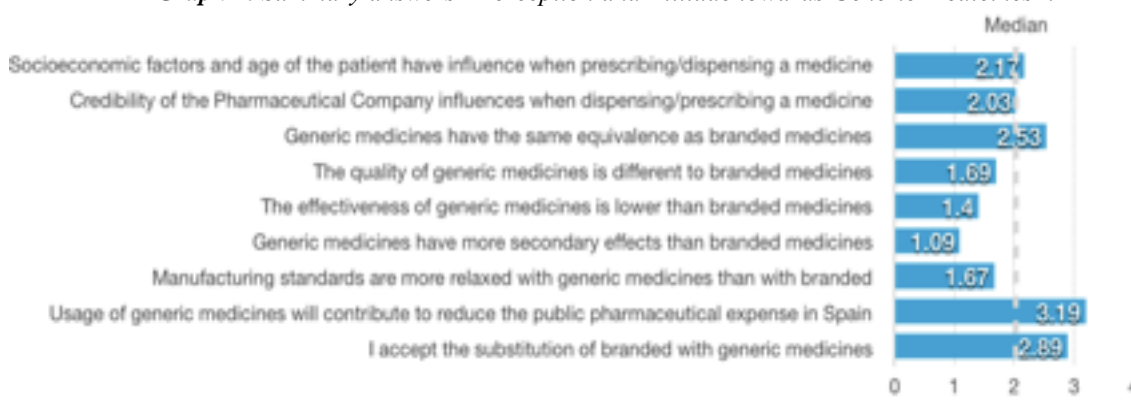
Socioeconomic factors and age influence. There is a high percentage of agreement or disagreement when

asking if the socioeconomic factors and age are influencing their decision when dispensing a medicine. The average value (2.17) is a little over half of the maximum score. Also 37 nurses answered Neither agree nor disagree, it's a question where we got very balanced results.

Credibility of thepharmaceutical company manufacturing the medicines. We have variety of answers, without going to the extremes. Average value is 2.03. If we represent the results in a graph, we will see we get a graph very similar to a Gauss curve. Graph 1: Credibility of the Pharma company when dispensing medicines.

Same equivalence generics and branded medicines. There is a high percentage of the nurses answering Agree versus the rest of the answers. The average of 2.53 is a bit far from 3, so it means there are no extremes in the answers to this question. the results of Agree and Strongly Agree represent 52.63% of the answers.

Quality of generics and branded is different. Not many nurses agree on the statement, being 25.56%, and only 3 answers were Strongly disagree. On the other hand, we do see many "middle answers" with Neither agree or disagree answer, more than expected. Disagree and Strongly disagree answers were 41.35%.

Effectiveness of generics is lower than branded. Nurses think that generic medicines aren't less effective than branded medicines. The average is 1.40. Strongly disagree and Disagree answers to the statement that the effectiveness of generics is lower than in branded medicines, is 51.12%.

Generics have more secondary effects than branded medicines. There is almost a total disagreement with the statement and surprisingly there is no Agree or Strongly agree answer to this statement. Nurses have a 63.15% disagreement to the statement (Disagree and Strongly disagree answers). Despite this good result, still 23.3% have no opinion or don't know the answer to it (Neither agree or disagree answers)

Manufacturing standards are more relaxed with generics than with branded medicines. There is not a really clear answer to this statement in comparison with the previous question. We can see a slight disagreement (32.33%), but there is a clear group that agree with the statement (13.53%) and a high percentage, of almost 40% of the answers, that have no opinion (Neither agree or disagree)

Usage of generic medicines will contribute to reduce the public pharmaceutical expense in Spain. Another clear result of agreement to the statement, were 90% of the answers are positive. The average demonstrates it, as it is 3.19.

Acceptance of the substitution of branded with generics. We can see here again a high agreement, with a 72% of the answers being positive about the statement. The average is 2.89, that shows this high agreement on the acceptance of the substitution.

Aspects to consider when choosing a medicine. The participants were asked about the aspects they considered important when choosing a medicine. There was not a clear factor of importance of any variable. We saw some variables that were important but not in a strong way for nurses. Big majority (affirmative rank between 10 and 50) pointed out the price, followed by the availability on capsules, tablets and suspension as dosage form of the medicines

(*Graph 3. Aspects to consider when choosing a generic medicine*).
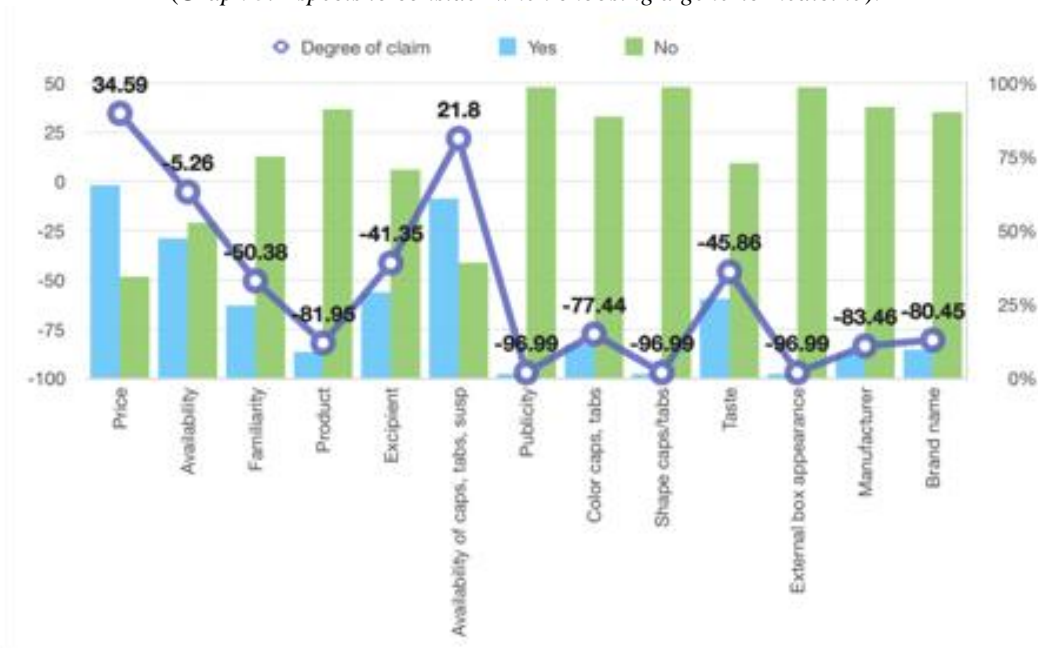
IV. DISCUSSION

Our goal was to research in the whole medicine chain with surveys to all the people that have a clear influence or major role, this is health professionals (MD, nurses and pharmacists) and patients. This second paper is focused on the nurses.[3] In other countries similar surveys were done to nurses and after the results there was estimated the necessity of implementing training and/or incentives that improve the adherence to generic medicines, with the reduction of the pharmaceutical expense in the country and better service level to the patients. Of course, the roles and responsibilities of nurses in other countries, may vary, as not always nurses are responsible of dispensing and prescribing medicines.

The results from this research show that in the majority of the participants, know what a generic medicine is and in general they have a good perception about it. The results are consistent with the data from similar researches. [10, 11, 12, 14]

Nevertheless, they ask for more training and information, something that shows the results in knowledge, when answering for example to the question of bioequivalence between branded and generic, where the answer was very spread, with 37 answers Disagree and 42 Agree. Same happens with the answer about the quality of the branded vs generics, with 37 Disagree and 31 Agree. Together with all of this, we can see in many questions, the high answer rate in Neither agree or disagree, that gives us the view of many of the respondents either don't want to answer because they don't have an opinion about the topic because they don't have enough information to respond either have no knowledge at all, therefore they cannot answer.

From their answers, we can see that they don't have a bad opinion on generic medicines versus branded, and we can see it specially in the last question, where they answer about the way they choose a medicine, where choosing a specific brand or a specific manufacturer, is not relevant (affirmative grade of -80.45 and -83.46 respectively).

We can conclude that this research highlights the need of a bigger effort in the country on generics information.[15-22, 25-28] A better knowledge would facilitate a more responsible usage of them and better recommendations to the patients from the nurses professional group. Education campaigns by the government, health authorities or health professional groups would be the best stakeholders. [13, 23, 24]

It's already demonstrated how the educational activities direct and individual about security and efficacy of generic medicines increases its acceptance and appreciation.[13, 23, 24] Health professionals (MD, pharmacists and nurses) are the ones in the best position to develop this educational work, so we need to give them the best tools and information to bring up the level of knowledge afterwards with the patients.This will create a much better communication to patients and society in general.
Biggest and wider researches can help to design those educational campaigns.

V. LIMITATIONS

Questions on this survey were just about general aspects about perception of generic medicines and acceptance of the substitution process, without going into the detail of the nurse to choose a generic medicine instead of a branded one.

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