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A close-up photograph of a person's hand wearing a bright blue nitrile glove. The hand is holding several small, dark brown glass vials with black caps. Each vial has a white label with black text. The labels include product names like 'TOCOPHEROL, D-ALPHA' and 'LUTEIN', along with lot numbers, quantities, and expiration dates. The background is a blurred white lab coat.

Medical, Ethical and Legal Perspectives

Accredited Social Health Activists (Ashas)

Highlights

Content in Foods Prepared in Restaurants

Objective Characteristics of Accommodation

Discovering Thoughts, Inventing Future



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Objective Characteristics of Accommodation in Present-Day Schoolchildren with Different Levels of Myopia

By O.V. Jukova, A.V. Zolotarev & Abida Mahdi

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Abstract- Purpose: We study the state of the accommodative function in present-day schoolchildren using the method of computer accomodography.

Patients and methods: 74 children (10–16 years old), 54 of them with different degrees of myopia and 20 children (control group) with emmetropia were tested on the computer accomodography devise Righton Speedy-K ver. MF-1. The strength of the accommodative response accorded to the presented accommodative stimulus was determined by calculating the accommodative coefficient response (CAO) and the contraction's nature of the ciliary body fibers by determining the microfluctuation coefficient (KMF).

Keywords: accommodation; computer accommodation; accommodative microfluctuations; myopia.

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Objective Characteristics of Accommodation in Present-Day Schoolchildren with Different Levels of Myopia

O.V. Jukova^α, A.V. Zolotarev^σ & Abida Mahdi^ρ

Abstract- Purpose: We study the state of the accommodative function in present-day schoolchildren using the method of computer accomodography.

Patients and methods: 74 children (10–16 years old), 54 of them with different degrees of myopia and 20 children (control group) with emmetropia were tested on the computer accomodography devise Righton Speedy-K ver. MF-1. The strength of the accommodative response accorded to the presented accommodative stimulus was determined by calculating the accommodative coefficient response (CAO) and the contraction's nature of the ciliary body fibers by determining the microfluctuation coefficient (KMF).

Results: It has been established that in groups of patients with emmetropia and low myopia, CAO and CMF exceed average normal values. Changes are especially pronounced in the group of children with low myopia. In groups of children with myopia moderate and high degree of CAO is significantly lower than in low myopia and emmetropia, while CMF also exceeds normal values.

Conclusion: In the pathogenesis of progressive myopia in contemporary schoolchildren, spastic component of accommodation, which is expressed in an increase in the accommodation response in relation to accommodation stimulus and a pathological increase in the frequency of accommodative microfluctuations.

Keywords: accommodation; computer accommodation; accommodative microfluctuations; myopia.

I. INTRODUCTION

Myopia is a condition in which the spherical equivalent refractive error of an eye is ≤ -0.50 D when ocular accommodation is relaxed [1]. It is the most common anomaly refractions in schoolchildren. In the lower grades, its frequency is 2.4%, in the senior classes - 38.6%. In high schools and

lyceums, this figure reaches 50.7%, which is associated with more intense visual loads [2]. Launcher mechanism and one of the most important pathogenetic factors in occurrence and development of progressive myopia are disturbances of accommodation. Majority researchers, describes the weakness of accommodation, which has place in myopic children [3, 4]. Spread in recent years of electronic devises has led contemporary children, not only during school hours, but also in their free time, an intense visual work, which, no doubt, has negatively affected their state of accommodation. Assessment of accommodative functions of children can be carried out both with the use of subjective as well as objective methods evaluate the qualitative and quantitative work indicators of the ciliary body. Subjective research methods, such as determining the margin of relative accommodation or the volume of absolute accommodation, allow you to determine pour quantitative change in dynamic refraction in the process of accommodation. Using objective methods research can be determined not only quantitative, but also qualitative indicators of the work of the ciliary muscle under accommodative load [5].

Purpose of the work is to study the state of accommodative functions in modern schoolchildren with the help of a computer accommodation.

II. PATIENTS AND METHODS

The study of the function of accommodation in schoolchildren was carried out day on the basis of a secondary school in the city of Samara, Russian Federation. Educational program in this educational institution does not provide for additional increased loads in the form of intensive forms of training. 54 schoolchildren (108 eyes): 28 girls and 26 boys grow 10–16 years old were examined. All of them were wearing glasses routinely. By the nature of refractive errors, children distributed as follows: 27 people (54 eyes) - with low myopia, 21 people (42 eyes) with moderate myopia, 6 people (12 eyes) - with high myopia. The comparison group included 20 children (40 eyes) with emmetropia. Visual acuity with correction in all patients forged was 0.9–1.0; astigmatic component was within 0.25–0.50 Diopters. All schoolchildren had smartphones or tablet computers that they used at

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breaks, as well as in free time. Total time spent using electronic gadgets in addition to the school load was at least 2 hours a day. The standard ophthalmic examination included visometry, subjective determination of refraction, and autorefractometry in a state of cycloplegia. Besides, all children made computer accommodography using automatic autorefractometer accommodograph with accommodation function device Righton Speedy-K ver. MF-1(Japan). The study is carried out monocularly.

In the automatic mode, traditional refractometry is initially carried out, and then the subject is positioned at different distances from the eye, from two meters to twenty centimeters. The accommodograph is given with a visual stimulus, which is called an accommodative stimulus. The accommodograph works in step-by-step mode. In response to the presented accommodative stimulus, the refraction of the examined eye is repeatedly measured, which is considered a research step. A change in refraction is recorded and depicted in the form of a diagram [6].

Developing the idea of the researchers, taking into account the lack of official programs for the mathematical analysis of the histogram obtained from the results of computer accommodation on the Speedy-K ver. MF-1 and the need for a comprehensive quantitative assessment of the work of the ciliary muscle, in order to objectively study the effectiveness of medication, hardware and other effects on the ciliary muscle, we set the task of developing our own method for calculating the corresponding mathematical indicators of the accommodogram [7].

The received accommodograms were evaluated visually and quantitatively. Quantification of accommodograms, obtained on a Righton Speedy-K ver. MF-1, was completed according to the Zharov-Egorova method [8]. Held calculation of the coefficient of accommodative response (CAO), characterizing the ratio of the force of accommodative to answer in relation to the value of the accommodative stimulus, as well as the microfluctuation coefficient (HFC), which characterizes the frequency of accommodative microfluctuations of ciliary muscle fibers during their abbreviations. CAO for each step of the accommodogram was calculated by the formula $CAO = AO/AC$, where AO is the value accommodative response in diopters, AC is the value of accommodation modulation stimulus in diopters. Average KAO for the whole accommodograms were calculated by the formula $CAO_{av} = \sum KAO/n$, where CAO_{av} is the average value of CAO for each level accommodation stimulus $\sum CAO_n$ is the sum of the CAO of all dimension columns; n is the number of dimension columns. CMF was calculated by the formula $CMF = HFC_{av} = \sum HFCn/n$, where HFCn is the frequency of microfluctuations of each measurement, n is the number of dimension columns. Statistical processing of the results was carried out

using Microsoft Excel 2010 with calculation Student's criterion.

III. RESULTS

The survey showed that the accommodative functions in modern schoolchildren with myopia are somewhat different from those traditionally described in the literature. According to literature, when conducting accommodation on the device Righton Speedy-K ver. MF-1 accommodative value the response in healthy emmetropes normally does not reach a value accommodative stimulus, but lags behind it on average by 20%, amounting to 0.7–0.8. CMF normally ranges from 50 up to 62 microfluctuations per minute [5]. Obtained averages values of CAO and CMF in the groups of examined schoolchildren presented in the table (Tab. 1).

The conducted studies showed that in the group of patients with emmetropia (control), the average value of CAO corresponded to the upper limit of the average norm according to the literature (0.7–0.8) and amounted to $0,823 \pm 0,140$. The CMF value exceeded the norm (50–62) and amounted to $63,811 \pm 1,260$ microfluctuations/min. On accommodograms, most children show a high accommodative response and a predominance of high-frequency accommodative microfluctuations (orange and red diagrams). At the same time, most children have a stable accommodative response and its uniform increase with an increase in the value of the accommodative stimulus (Fig. 1).

Unusual was the accommodative response in the group of children with low myopia. The accommodograms demonstrated the instability of the accommodative response and its uneven increase, which indicates a spastic state of the muscular component of the accommodative apparatus. In the majority of these patients, during one accommodogram, both a pronounced lag in the accommodative response and an excess of the accommodative response over the magnitude of the accommodative stimulus were noted. In general, the average CAO in this group was $0,943 \pm 0,270$. The accommodograms also showed the predominance of high-frequency accommodative microfluctuations ($CMF = 65,664 \pm 1,140$ microfluctuations/min) (Fig. 2).

In the group of children with moderate myopia, the accommodative response was weaker than in the group of children with low myopia and emmetropes. The value of the accommodative response in this group of patients was 60–70% of the value of the accommodative stimulus ($0,658 \pm 0,790$). The accommodative response was characterized by uneven and insufficient growth with increasing stimulus and instability. With an increase in the accommodative stimulus to 2.0 D and higher, "gaps" appeared on the accommodograms, indicating the absence of an accommodative response to the

presented stimulus. As for the frequency of accommodative microfluctuations, it also exceeded the average normal values and amounted to $63,781 \pm 0,540$ microfluctuations/min (Fig. 3).

In patients with high myopia, the nature of the accommodative response was the same as in the group of patients with moderate myopia: CAO was $0,592 \pm 0,320$; CMF = $65,529 \pm 0,740$ microfluctuations/min. Accommodograms in children with high myopia were also characterized by a reduced accommodative response and instability at a high frequency of accommodative microfluctuations (Fig. 4).

IV. DISCUSSION

When statistically processing the results, it was found that CAO did not differ in groups with low myopia and emmetropia, as well as in groups with moderate and high myopia. Statistically significant ($p \leq 0.05$) were the differences in CAO values between groups with emmetropia and low myopia, on the one hand, and moderate and high myopia, on the other. No statistically significant differences in the CMF index were found in all groups of the examined children. All noted an increase in the frequency of accommodative microfluctuations compared with normal values.

The study showed that, in general, the progression of myopia is accompanied by a weakening of the accommodative function, as evidenced by a decrease in the magnitude of the accommodative response in children with moderate and high myopia. However, in the pathogenesis of progressive myopia in modern schoolchildren, the spastic accommodative component is becoming increasingly important. Apparently, this is due to the high visual load caused not only by intense schoolwork, but also by the uncontrolled use of electronic devices (smartphones and tablets) by children.

V. CONCLUSION

In modern schoolchildren using electronic gadgets, the spastic component of accommodation is significantly expressed, which is manifested by a pathological increase in the frequency of accommodative microfluctuations and the appearance episodes of exceeding the magnitude of the accommodative response in relation to the accommodative stimulus, especially when low myopia.

REFERENCES RÉFÉRENCES REFERENCIAS

1. Flitcroft DI, He M, Jonas JB, Jong M, Naidoo K, Ohno-Matsui K, Rahi J, Resnikoff S, Vitale S, Yannuzzi L. IMI - Defining and Classifying Myopia: A Proposed Set of Standards for Clinical and Epidemiologic Studies. *Invest Ophthalmol Vis Sci*. 2019 Feb 28; 60(3): M20-M30. doi: 10.1167/iov.18-25957. PMID: 30817826; PMCID: PMC6735818.

2. Proskurina O.V., Markova E. Yu., Brzhesky V.V. and others. The prevalence of myopia in schoolchildren in some regions of Russia. *Ophthalmology*. 2018; 15(3): 348–53. doi: 10.18008/1816-5095-2018-3-348-353. [Проскурина О.В., Маркова Е.Ю., Бржеский В.В. и др. Распространенность миопии у школьников некоторых регионов России. *Офтальмология*. 2018; 15 (3): 348–53 (in English)].
3. Avetisov E.S. Myopia. Moscow: Medicine; 1986. [Аветисов Э.С. Близорукость. Москва: Медицина; 1986 (in English)].
4. Volkov V.V. On the probable mechanisms of myopization of the eye during school years. *Ophthalmological journal*. 1988; 3:129–32. [Волков В.В. О вероятных механизмах миопизации глаза в школьные годы. *Офтальмологический журнал*. 1988; 3: 129–32. (in English)].
5. Zhukova O.V., Egorova A.V. Computer accomodography. In the book: Katargina L.A., ed. Accommodation. Guide for doctors. Moscow: April; 2012: 63–7. [Жукова О.В., Егорова А.В. Компьютерная аккомодография. В кн.: Катаргина Л.А., ред. Аккомодация. Руководство для врачей. Москва: Апрель; 2012: 63–7. (in English)].
6. Zharov V.V., Nikishin R.A., Egorova A.V., Lyalin A.N., Konkova L.V. Clinical assessment of the state of accommodation using the method of computer accommodation. In: Eroshevsky Readings. Samara: Etching; 2007: 437–40. [Жаров В.В., Никишин Р.А., Егорова А.В., Лялин А.Н., Конкова Л.В. Клиническая оценка состояния аккомодации с помощью метода компьютерной аккомодографии. В кн.: Ерошевские чтения. Самара: Офорт; 2007: 437–40. (in English)].
7. Mahdi A. Features of accommodation function in contemporary schoolchildren with progressive myopia // *Aspirantskiy Vestnik Povolzhiya*. - 2020. - Vol. 20. - N. 5-6. - P. 58-62. doi: 10.17816/2072-2354.2020.20.3.58-62 [Махди А. Особенности аккомодационной функции у современных школьников с прогрессирующей миопией // *Аспирантский вестник Поволжья*. - 2020. - Т. 20. - №5-6. - С. 58-62. doi: 10.17816/2072-2354.2020.20.3.58-62 (in English)].
8. Zharov VV, Nikishin RA, Egorova AV. Komp'yuternaya akkomodografiya na pribore Speedy-K ver. Izhevsk: MF-1 (Yaponiya)/ Metodicheskie rekomendacii; 2007.

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Contribution of the authors to the work

O.V. Zhukova — conceptualization and design of the study, article editing; A.V. Zolotarev — final preparation of the article; M. Abida — conceptualization and design of the study, data collection and interpretation.

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Tab. 1: Coefficient of accommodative response (CAR) and coefficient of microfluctuations (CMF) values as determined by autorefractometer with an accomodography function Righton Speedy-K ver. MF-1

Refraction	CAR	CMF (mcf/min)
Low myopia	$0,943 \pm 0,270$	$65,664 \pm 1,140$
Moderate myopia	$0,658 \pm 0,790$	$63,781 \pm 0,540$
High myopia	$0,592 \pm 0,320$	$65,529 \pm 0,740$
Emmetropia	$0,823 \pm 0,140$	$63,811 \pm 1,260$

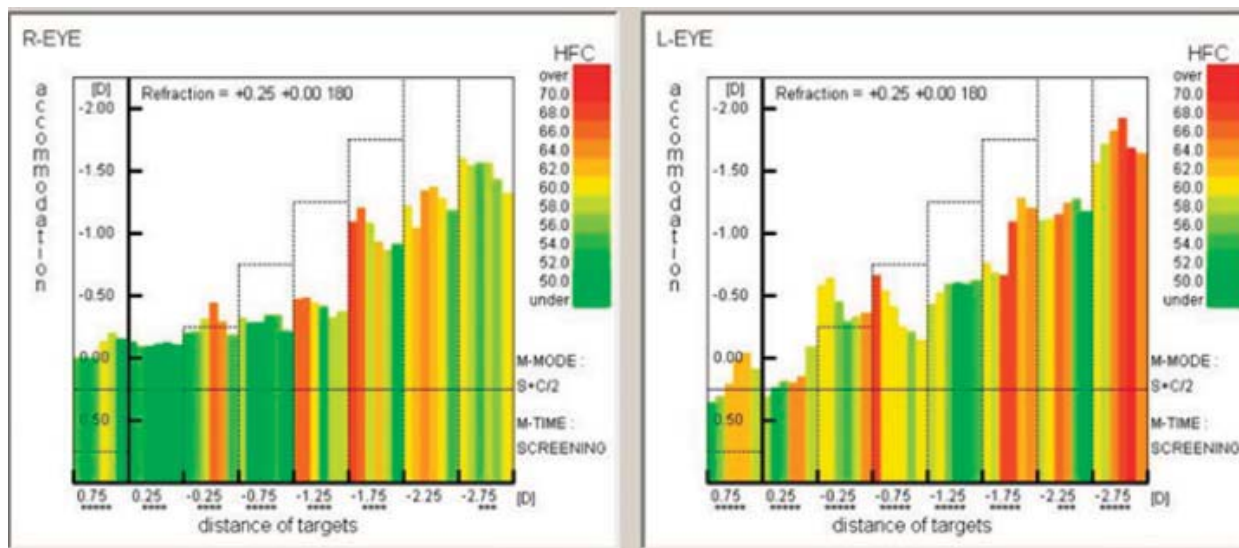


Fig. 1: Accomodogram of a child with emmetropia. Autorefractometer Righton Speedy-K ver. MF-1

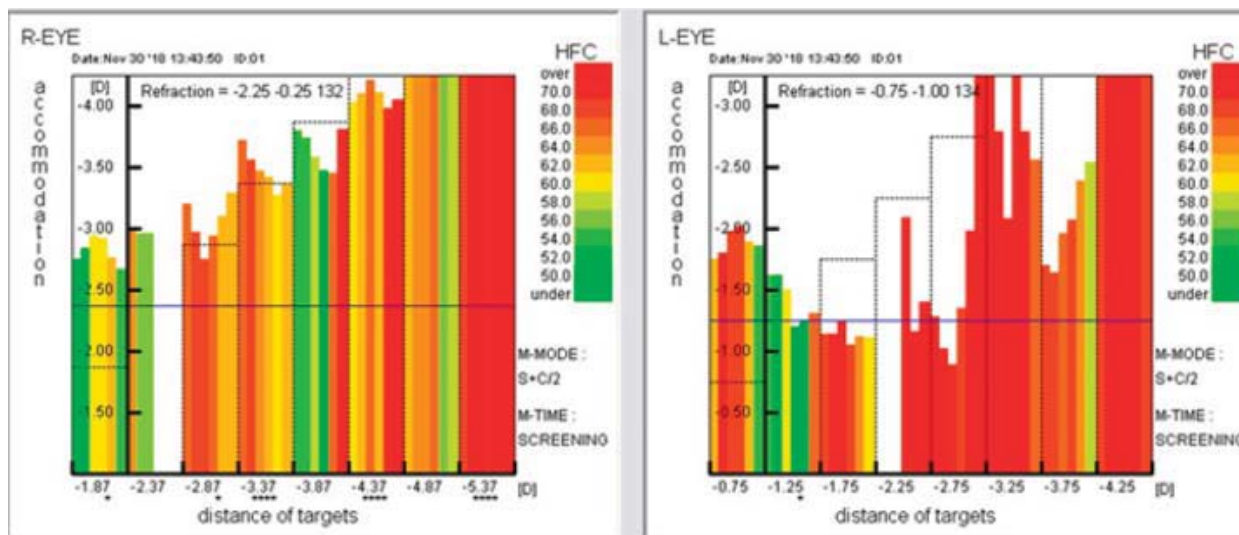


Fig. 2: Accomodogram of a child with low myopia. Autorefractometer Righton Speedy-K ver. MF-1

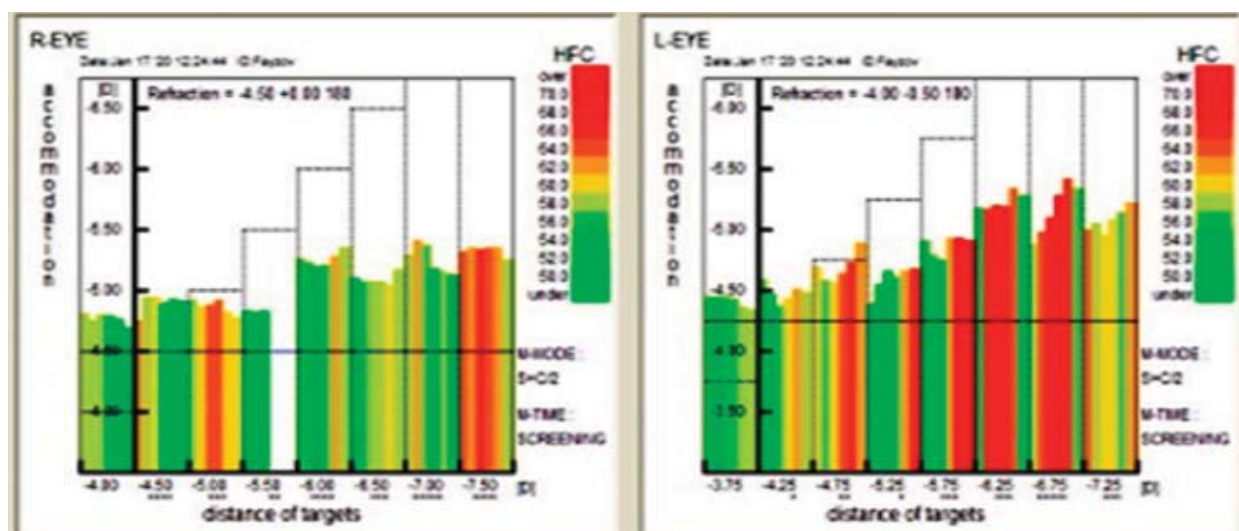


Fig. 3: Accommodogram of a child with moderate myopia. Autorefractometer Righton Speedy-K ver. MF-1

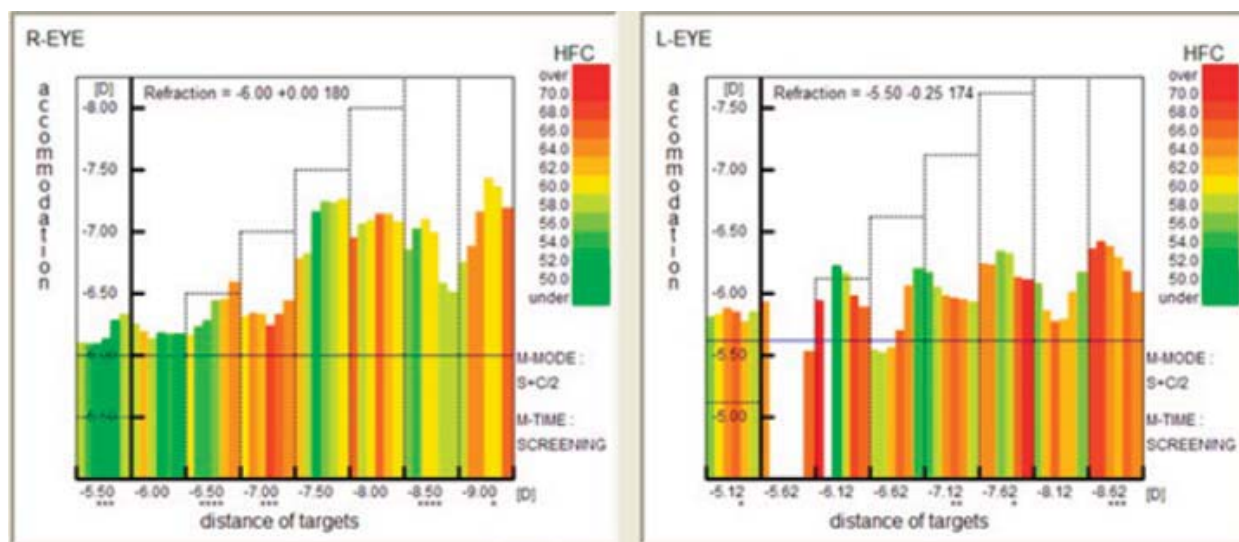


Fig. 4: Accommodogram of a child with high myopia. Autorefractometer Righton Speedy-K ver. MF-1



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Salt Profile and Content in Foods Prepared in Restaurants and Bakeries: Analysis of the 2 Main Urban Centers in Cape Verde

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SALT PROFILE AND CONTENT IN FOODS PREPARED IN RESTAURANTS AND BAKERIES ANALYSIS OF THE 2 MAIN URBAN CENTERS IN CAPE VERDE

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Salt Profile and Content in Foods Prepared in Restaurants and Bakeries: Analysis of the 2 Main Urban Centers in Cape Verde

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Abstract- The excessive intake of sodium from salt is associated with the risk of cardiovascular diseases. According to the Noncommunicable Diseases Survey (DNS, N/P), more than 35% of the Cape Verdean population is considered hypertensive. There are no data on the salt content of foods prepared by restaurants and bakeries in Cape Verde. Most restaurants and bakeries use iodized salt (97%) of national origin (81%), from the islands of Sal (45.6%) and Maio (20.9%). Approximately 53.3% of the bread samples had salt contents greater than 1.4 g/100 g. More than half (59.3%) of ready-to-eat meals collected from restaurants in Praia and 42.4% in Mindelo had a salt content equal or more than 5.0 g/meal. Restaurants and bakeries in the cities of Praia and Mindelo use salt in a nonstandardized manner. The results of this study may contribute to the redesign of salt intake reduction strategies in Cape Verde.

Keywords: salt (NaCl) profile, salt (NaCl) content, restaurants and bakeries.

1. INTRODUCTION

Noncommunicable diseases (NCDs) are responsible for the death of 41 million people annually, equivalent to 71% of all deaths worldwide, with cardiovascular diseases being the main cause (17.9 million) World Health Organization, Noncommunicable diseases, 2021). In turn, hypertension is the leading cause of cardiovascular disease and premature death worldwide (World Health Organization, Hypertension, 2021).

A medium-developed country, Cape Verde is located in the Atlantic Ocean, between the Equator and the Tropic of Cancer, between latitudes 14° 23' and 17° 12' north latitude and between 22° 40' and 25° 22' west longitude ("Portal informativo de Cabo Verde,"). The country imports the majority (>80%) of the food it consumes (ALMEIDA, 2022). In Cape Verde, due to changes in the demographic, epidemiological and nutritional profiles of the Cape Verdean population,

chronic NCDs are the leading cause of mortality in the country (MS, N/P). According to preliminary data from the 2019 Survey on Noncommunicable Diseases and Associated Risk Factors (IDNT II, acronym in Portuguese), 30.8% of the Cape Verdean population is hypertensive.

According to the World Health Organization (WHO), high blood pressure is responsible for at least 45% of deaths from heart disease and 51% of deaths from stroke (World Health Organization, Hypertension, 2021). The worldwide prevalence of high blood pressure (systolic and/or diastolic blood pressure $\geq 140/90$ mmHg) in adults (age ≥ 18 years) is estimated at 22% (Mills, Stefanescu, & He, 2020; World Health Organization, Hypertension, 2021). Data from the 2019 IDNT II indicate that cardiovascular diseases and cancer are leading causes of deaths in Cape Verde, highlighting poor eating habits among the most common risk factors (MS, N/P).

When poor eating habits are identified as one of the risk factors for circulatory system diseases and cancer, among other conditions, substances such as salt (Pure salt - sodium chloride, contains 39.34% sodium or 39.340 mg per 100g) and other additives such as preservatives used in canned foods, meat, fish, etc., are often mentioned. However, the identity and nature of these substances, as well as their effects on the body, are rarely explained (MOLOGNONI, 2019). In developed countries, up to three-quarters of the total salt intake comes from foods consumed outside the home and from processed foods, in contrast, the salt added to food, both at the table and during home preparation, generally represents a lower proportion of the total sodium intake (Coelho, 2021; Ruiz et al., 2020).

Sodium is an essential nutrient necessary for the normal functioning of cells. Its excessive intake is associated with adverse health conditions, particularly hypertension, which in turn is considered one of the main risk factors for some chronic diseases with high morbidity and mortality worldwide (National Academies of Sciences et al., 2019; World Health Organization, 2012; World Health Organization, 2020). According to Nascimento et al. (Nascimento, Gavron, Bowles, Chaves, & Bortolozzo, 2017), sodium (Na) intake comes

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mainly from table salt, salt-based foods and industrialized products. Complications are related to sodium intake in amounts above that recommended by the WHO of a maximum of 2 g/day (World Health Organization, 2020), considering all its forms of presentation.

Although the 2019 IDNT II (MS, N/P) indicates that close to one-third of the Cape Verdean population is hypertensive, there are no data on the salt profile and content of foods prepared by restaurants and bakeries in Cape Verde. Thus, the main objective of this study was to evaluate the profile and content of salt in foods prepared in restaurants and bakeries in the cities of Praia and Mindelo in Cape Verde.

II. MATERIALS AND METHODS

a) Study design and population

This was an observational, cross-sectional study with a qualitative-quantitative approach conducted in restaurants and bakeries in the cities of Praia and Mindelo. These cities have the largest populations in the country (Instituto Nacional de Estatística de Cabo Verde, 2020). All restaurants and bakeries in the 2 cities, based on georeferencing data provided by the Independent Health Regulatory Entity (ERIS, acronym in Portuguese), Municipal Councils and the General Directorate of Tourism, were selected for the study, and all representatives who agreed to participate did so voluntarily. In cases where the georeferenced establishment was already closed, the data were collected from the nearest unreferenced establishment. Written informed consent was provided by the representative of each establishment prior to data collection.

Inclusion criteria were being on the official list provided by the competent entity or the existence of the establishment being known to field agents even though it was not on the official list, and the person responsible voluntarily accepting to participate in the study, by signing the free and informed consent form.

As exclusion criteria, the establishment is not on the official list and its existence is not known to field agents, or the person in charge does not accept to participate in the study, by signing the free and informed consent form. The heading levels should not be more than 4 levels. The fond of heading and subheadings should be 12 point normal.

b) Participant characteristics

A total of 155 managers of restaurants and bakeries in the cities of Praia and Mindelo participated in the study, most of whom (61.4%) were female. Most subjects were aged 25-44 years (58.2%). The mean age of the respondents was 32.41 ± 8.41 years. Regarding education level, 48.1% completed secondary education, 28.5% completed primary education, 15.2% completed undergraduate education, 2.5% completed vocational

training, 1.9% had a master's degree, and 1.3% were illiterate.

c) Data collection

i. Questionnaires and food samples

A protocol cover sheet containing the identification data of the establishment and 2 adapted self-report questionnaires (Appendix I and II) (Viegas CACL, 2013) were applied to record observations on the origin, transport, storage and use of salt used in the establishments under study.

The data were collected by 11 investigators under the supervision of 2 supervisors; the investigators were distributed between the cities of Praia (6 investigators; 1 supervisor) and Mindelo (5 investigators; 1 supervisor). The investigators underwent 1 week of training on techniques for questionnaire application and techniques for collecting, packaging and transporting food samples, on the ethical issues of the research, and on the analysis and interpretation of salt iodization data based on the instructions of the Iodized Salt Field Test Kit.

The food samples were collected in dry sterile polyethylene bags to avoid any possible contamination and were transported in thermal bags containing cold packs in accordance with the best practices for food transport (Associação de restauração e similares de Portugal, 2008). In the laboratory, the samples were stored at -20 °C until analysis.

ii. Rapid salt iodization test

In each establishment, a small amount of salt (approximately one teaspoon) was collected on a white paper sheet, to which 1-2 drops of the test solution was added. Using a color table provided in the test kit, the result was recorded immediately under good lighting. For cases where no color was observed after 1 minute (suspicion of alkalinity in the salt sample), 5 drops of verification solution was added to a new salt sample, and 2 drops of the test solution was added to the sample (World Health Organization, 2007; Jooste PL & Strydom E, 2010).

16, 17). Last, using the color table, the result was recorded and transcribed to the questionnaire sheet.

d) Laboratory analysis

i. Sample preparation

Bread samples were ground in a blender immediately after their removal from the freezer, and the portion needed for salt content analysis was separated and set aside.

Samples of meals were slowly thawed, i.e., kept in a refrigerator at ~ 4 °C for a period of 24 hours. Then, the samples were homogenized in a blender, and the necessary portion was removed for analysis.

ii. Analysis of sodium chloride content

The sodium chloride content was evaluated through titration by the Mohr method. After sample preparation, approximately 5 g of Portuguese bread/ wheat bread and 10 g of meals were weighed in duplicate on an analytical inside 250-ml cups. Then, 100 ml of warm distilled water (50-55 °C) and 100 ml of boiling distilled water (~100 °C) were added to the cups containing bread and meal samples, respectively (Ward, R. E., & Carpenter, C. E., 2010).

The solution was vigorously homogenized (30 s) twice at an interval of 1 minute. After the solution had cooled to room temperature, the pH was adjusted to 6.5-10.0, and the solution was filtered through sterile gauze. Next, 15 ml of the filtered solution was transferred to a 250-ml Erlenmeyer flask, and 1.5 ml of 0.1 M potassium chromate indicator (K₂CrO₄) was added. The solution was then titrated with 0.1 M silver nitrate (AgNO₃) until the first appearance of a brownish red color; the process was continued for another 30 s, and the volume of titrant used was recorded.

iii. Calculations

The sodium chloride content in each replicate sample was calculated, and the mean, median, range and standard deviation were calculated.

e) Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS, v. 26). The data were described using absolute and relative frequencies, and the chi-square test was used to compare the salt content in food prepared by the establishments in Praia and Mindelo. All tests were two-sided, and P values less than 0.05 were considered to be statistically significant.

f) Ethics approval of research

This study was approved by the National Committee on Ethics in Health Research (deliberation no. 33/2019, 31 May). All participants signed an informed consent form, which was filed under confidentiality at the National Institute of Public Health of Cape Verde. Written informed consent for participation was obtained from managers of restaurants and bakeries and their privacy and confidentiality were maintained. All personal identifiers were excluded, and data was kept confidential and used for the proposed study only.

i. Guideline statement

Resolution No. 33/2019

1. It was submitted, under the terms of article 9 of Decree-Law No. 26/2007, of 30 July, for the purposes of the National Committee on Ethics in Health Research (CNEPS, acronym in Portuguese) opinion in order to authorize the realization of the Project entitled "Salt profile and content in foods prepared in restaurants and bakeries: Analysis of the 2 main urban centers in Cape Verde", presented

by the National Institute of Public Health, INSP, with Dr Júlio Monteiro Rodrigues as the main researcher, Executive Director of the aforementioned Institute, which has a partnership with the Institute of Hygiene and Tropical Medicine, Lisbon, Portugal.

2. The research project team is comprised not only of technicians responsible for the INSP, but also of the Coordinator of the National Nutrition Program, the National Directorate of Health and technicians from the Praia Health Precinct, among others.
3. This is an observational, cross-sectional study with quali-quantitative approaches.
4. The study will take place in the cities of Praia and Mindelo and will cover a representative sample of restaurants and bakeries, based on georeferencing, provided by the General Directorate of Tourism and/or the National Statistics Institute, INE.
5. Only duly registered restaurants and bakeries whose representatives accept to participate in the study will be considered.
6. As supporting documents, were presented, (i) the Letter addressed to CNEPS, (ii) the Research Project, (iii) the Schedule, (iv) the Indicative Budget, (v) the Information Sheets, (vi) the Terms of Free and Informed Consent, (vii) the Questionnaires to be applied and, (viii) the CV of the principal investigator?
7. CNEPS performed the document analysis of the research project during its 92nd Ordinary Meeting, held on April 25, 2019, and the project was pending additional information (see deliberation 28/2019).
8. On May 15, 2019, the research project with the corrections was submitted for reconsideration by the CNEPS.
9. CNEPS reassessed the research project during its 92nd Ordinary Meeting, held on May 30, 2019, having found that the aspects highlighted in the aforementioned determination were remedied, therefore, pursuant to article 11 of Decree-Law no. 26/2007, of 30 July, it decided to approve it.

III. RESULTS

a) Salt used in restaurants

A total of 125 restaurants were evaluated. Regarding the origin of the salt used during food preparation in the restaurants, 79% of restaurants used salt of national origin, 13.7% used salt of international origin, 4% used salt of both origins, and 3.2% used salt of an unknown origin.

Of the restaurants in which the salt used in food preparation was of national origin, 62.6% used salt from the island of Sal, and 25.3% used salt from the island of Maio; for 12.1%, the island of origin was unknown. Notably, the island of Santiago does not produce salt.

Of the restaurants in which the salt used in food preparation was of international origin, 95% used salt from Portugal, and 5% used salt from France.

Regarding the means used to transport salt, 61.1% of restaurants used a car, 18.2% used a car and boat, 7.1% used a car and plane, and 13.5% did not use any means of transport.

Most restaurants (58.4%) did not have a specific location for salt storage. The salt was stored in its original packaging (91.9%), protected from light (38.7%), exposed to heat in a nonventilated area (19.4%), stored in the presence of chemicals (9.7%), and exposed to moisture (6.5%).

Other forms of salt storage indicated by the respondents were in plastic buckets (30%), together with other nonperishable foods (25%), in flasks (15%), in stainless steel containers (10%), in plastic bowls (10%), inside a kitchen cabinet (5%) and in a bag inside a box (5%).

Among the restaurants that did not have a specific location for salt storage, in 79.6%, the salt was stored in the kitchen; in 12.2%, the salt was stored in the pantry; in 4.1%, the salt was stored on a kitchen shelf; and in 2%, the salt was stored on a shelf or near the stove.

Regarding the lighting where the salt was stored, the location was well lit in 30.6% and lit in 26.5% of restaurants, received natural light in 22.4%, low light in 12.2%, and no light in 4.1% of restaurants, and was exposed to light and heat in 2% of restaurants.

The salt storage location was ventilated in 44.7% of the restaurants, well ventilated in 23.4%, poorly ventilated in 12.8%, ventilated and exposed to heat in 6.4%, not ventilated in 4.3%, exposed to heat in 4.3% and exposed to natural ventilation in 2.1%.

In 29.2% of the restaurants, the salt was stored in its own packaging; in 37.5%, the salt was stored in plastic jars; in 12.5%, the salt was stored in a container with a lid; in 6.3%, the salt was stored in plastic bags; in 6.3%, the salt was stored in jars; in 4.2%, the salt was stored in a random container; and in 4.2%, the salt was stored in glass jars. In 82.1% of the restaurants, the salt was stored together with other products.

Most restaurants (83.3%) used a utensil for handling salt: spoon (69.8%), cup (4%), ladle (4%), stainless steel scoop (1.6%), spoon and jar (1.6%), milk pitcher (0.8%), jar (0.8%) and wooden spoon (0.8%).

b) Salt used in bakeries

A total of 30 bakeries were evaluated. Most of the salt used in the preparation of bread was of national origin, with 55.6% of bakeries using salt from the island of Sal and 37% using salt from the island of Maio; 7.4% reported not knowing the provenance.

The car was the most commonly used means for transporting salt (76.7%), followed by boat and car (20.0%) and plane and car (3.3%). Most bakeries purchased salt locally (76.7%) and stored it in a specific location (80%). Of these, 78.3% stored the salt in its original container, 47.8% stored the salt protected from light, 30.4% stored the salt in a location exposed to heat, 4.3% stored the salt in a nonventilated area, and 4.3% stored the salt in the presence of chemicals.

Of the 6 bakeries that did not have a specific location for salt storage, 50% stored it in the pantry, 33.3% stored it in the production area, and 16.7% stored it in a location with other products. In 66.7% of the bakeries, the salt was stored away from light; in 50%, the salt was stored in its own container; in 33.3%, the salt was exposed to heat; and in 16.7%, the salt was stored in an unventilated location.

A total of 96.4% of the bakeries used a utensil to handle the salt: cup (25.9%), ladle (25.9%), stainless steel scoop (14.8%), bowl (7.4%), shaker (7.4%), and either a spoon, scale plate, spatula, cake pan or jar (3.7% each).

c) Profile of the salt used in restaurants

Only 12% of the restaurant managers stated that they followed standard guidelines for the amount of salt to be used in food preparation.

Most (67.2%) restaurant managers believe that there are differences between different types of salt, whereas 30.4% think there are no differences and 2.4% do not know. Of those who reported the existence of differences between the types of salt, 59.5% referred to the quality, with emphasis on the presence of iodine (30%).

Table 1 shows the proportion of salt per meal used by restaurants in Praia and Mindelo. In both the soup and the main dish, most establishments used less than 1 g of salt.

Table 1: Amount of salt/meal used in restaurants

Salt	Restaurants			
	Soup		Main dish	
	n	%	n	%
< 1 g	75	59.5	65	51.6
1 to 2 g	25	19.8	40	31.7
2 to 4 g	7	5.6	14	11.1
4 to 6 g	1	0.8	2	1.6
> 6 g	-	-	5	4
Does not cook	17	13.5	-	-
Does not know	1	0.8	-	-
Total	126	100	126	100

Regarding the daily dose of salt recommended by the WHO, 48% of respondents were unaware of the existence of a WHO recommendation on the amount of salt that should be consumed daily per person; 18.4% were aware of such a recommendation. Only 37.3% of the respondents knew the relationship between salt and sodium.

d) Profile of the salt used in bakeries

Regarding the existence of a standard that regulates the amount of salt to be used in the preparation of bread, 83.3% of the bakeries reported that they followed a standard; for the remaining 16.7%, there was no compliance with any standard.

Iodized salt was the most used salt type (90%), followed by sea salt, fleur de sel and others, with 3.3% each.

Most respondents (69%) stated that there were differences between types of salt; the remaining 31% responded that no differences exist between different types. The most reported differences between the types of salt were quality (41.2%), followed by texture (17.6%). Among the respondents, 11.8% considered iodized salt the best, and differences were reported in terms of appearance, taste/aroma, presence of iodine, importance for health and salt content in the recipe (5.9% each).

The amount of salt per kg of dough was greater than 14 g/kg in 3 bakeries, and in 2 bakeries, the amount of salt was greater than 6 g per loaf (Table 2).

Table 2: Amount of salt per kg of dough and per loaf

Salt	kg of dough		Loaf	
	n	%	n	%
< 1 g	4	14.3	21	75
1 to 2 g	1	3.6	5	17.9
2 to 4 g	1	3.6	-	-
4 to 6 g	1	3.6	-	-
> 6 g	21	75	2	7.1

The majority of the bakery managers (96.7%) believe that salt has an impact on the health of all individuals. Only 3.3% considered that it has an impact only on the health of individuals with some disease.

Most respondents (66.7%) were unaware of the daily dose of salt recommended by the WHO (5 g/day); 6.7% were aware of such a recommendation.

Regarding the relationship between salt and sodium, 36.7% of the respondents answered that salt contains sodium; 53.3% did not know the relationship between the 2.

e) Laboratory results

A total of 155 food samples were collected and analyzed, 30 of which were bread (Portuguese/wheat bread) and 125 of which were meals ready for consumption. Of these, 75 were collected in the city of Praia (16 bread samples and 59 meal samples), and 80 were collected in the city of Mindelo (14 bread samples and 66 meal samples).

Of the bread samples analyzed, 53.3% (n = 16) had salt contents above the limit recommended by the

Portuguese standard (Decree Law no. 75/2009, of 12 August). This standard defines a maximum permitted salt content, i.e., 1.4 g per 100 g of baked bread (or 0.55 g of sodium per 100 g of bread). Of the samples with salt contents greater than 1.4 g/100 g, 43.75% (n = 7) were collected in the city of Praia, and 57.14% (n = 8) were collected in the city of Mindelo (Appendix I).

Approximately 59.3% (n=35) of the meal samples collected in the restaurants in Praia and 42.4% in Mindelo had a NaCl greater than 5.0 g/meal, with a median of 5.03 g (table 3). All of these samples had a common component (meat) that underwent some traditional preserving process (use of salt as a preservative).

In the present study, the amount of Na varied between 0.26 g and 6.89 g per meal (Appendix II), with a median of 2.01 g (table 3), indicating a high Na content based on the recommended daily intake of less than 2 g of Na established by WHO (World Health Organization, 2020).

Table 3: Statistical analysis of the salt content in the analyzed ready-to-eat food samples

Statistical analysis	Results (g/100g)			NaCl (g)/meal	Na (g)/meal
	NaCl	Na	Cl		
Mean	1,34	0,54	0,81	5,44	2,18
Median	1,30	0,52	0,78	5,03	2,01
Minimum	0,50	0,20	0,30	0,66	0,26

Maximum	2,70	1,08	1,62	17,22	6,89
Range	2,20	0,88	1,32	16,56	6,62
SD	0,50	0,20	0,30	2,83	1,13

Bakeries and restaurants in Mindelo used a mean of 1.50 ± 0.3 g of salt/100 g of bread and 1.4 ± 0.5 g of salt/100 g of meal respectively. In Praia, the

mean salt content in bread was 1.35 ± 0.25 g /100g, and that in meals was 1.3 ± 0.5 g/100 g respectively (Table 3 and table 4).

Table 4: Statistical analysis of the salt content in the analyzed bread samples

Statistical analysis	Results (g/100g)		
	NaCl	Na	Cl
Mean	1,46	0,58	0,88
Median	1,405	0,562	0,843
Minimum	1,1	0,44	0,66
Maximum	2,3	0,92	1,38
Range	1,2	0,48	0,72
SD	0,27	0,11	0,16

There were no significant differences between Praia and Mindelo regarding the salt content used in the bakeries ($\chi^2 = 71,778$; $p = 0.419$) and in the restaurants ($\chi^2 = 367,488$; $p = 0.641$).

Most of the salt samples collected (97%) contained iodine.

IV. DISCUSSION

Most restaurants did not have a specific location for storing salt. It was stored in its own packaging, protected from light, exposed to heat, stored in a nonventilated place, stored in the presence of chemicals, and exposed to moisture. Several studies have shown that storing iodized salt in a dry or cold place protected from sunlight preserves its composition (World Health Organization, 2007; Goris, J. M., et al., 2018; Mekonnen, T. C., et al., 2018; Abebe, Z., Gebeye, E., & Tariku, A. 2017).

In this study, most salt samples contained iodine (97%), a result that is in accordance with the WHO recommendations ($\geq 90\%$) established to eliminate iodine deficiency disorders (World Health Organization, 2007).

The high percentage (97%) of use of iodized salt by the restaurants and bakeries may be due to the efforts of the Cape Verdean government to stimulate improvements in the iodine status in recent years. This rate is consistent with that found in a study conducted in Nigeria (95%) and is higher than that found in studies in Ghana (75.6%) and Senegal (10%) on the salt iodine content in the household diet and associated factors (Anteneh, Z. A., Engidayehu, M., & Abeje, G. 2017; Obsie, G. F., Ketema, K., & Tekalegn, Y. 2020).

In this study, 50% of the analyzed bread samples revealed a salt content greater than the limit

recommended by the Portuguese standard, which is 1.4 g/100 g of bread or 0.55 g of sodium/100 g of bread (Assembleia da República, 2009). Bread is one of the most consumed foods in the world, accounting for an average of 30% of daily salt intake (2, 3). It contributes a significant percentage of salt to the diet of the Cape Verdean population.

Of the samples with salt contents greater than or equal to 1.4 g/100 g, 57.8% ($n = 11$) were collected in the city of Mindelo, and 42.2% ($n = 8$) were collected in the city of Praia (Assembleia da República, 2009). Similar results were found in a study on the evaluation of salt content in bread regularly consumed in the Eastern Mediterranean region (Assembleia da República, 2009; Al Jawaldeh, A., & Al-Khamaiseh, M. 2018).

The results of the present study indicate that the salt content in meals prepared in restaurants in Cape Verde is high ($\bar{x} = 5.44$ g/meal) based on the WHO recommendation (World Health Organization, Salt reduction, 2020).

A higher salt content was observed in meals that contained meat, french fries, chorizo or shellfish. This may be due to some traditional preservation processes (use of salt as a preservative) (Ludwig, L. M., et al., 2021). Conversely, the samples consisting essentially of salad had low salt contents (Nascimento RFd, et al., 2017).

In the present study, the amount of Na ranged from 780 mg to 4,330 mg/meal, with a median of 1,900 mg/meal, which exceeds not only the recommendation for a meal (18, 27, 28) but also the WHO daily recommendation, which establishes a maximum intake of 2,000 mg of Na/day (World Health Organization, Salt reduction, 2020).

The present findings draw attention to the greater sodium intake. Approximately 59,3% (n=35) of the meal samples collected in the restaurants in Praia and 42,4% in Mindelo had a NaCl greater than 5.0 g per meal, with a median of 5.03 g, suggesting a much higher daily NaCl intake than the maximum limit (<5 g/day) recommended by the WHO (World Health Organization, Hypertension, 2021; World Health Organization, Salt reduction, 2020). An intake of less than 5 g of salt per day in adults helps to reduce blood pressure and the risk of cardiovascular disease, stroke and heart attack (World Health Organization, Salt reduction, 2020).

The results should be interpreted considering that the data were collected only in the 2 main population centers. Thus, it is possible that there are other bakeries and restaurants that were not taken into account.

V. CONCLUSIONS

In general, food managers/handlers in restaurants and bakeries in the cities of Praia and Mindelo are unaware of the origin of the salt they use, the way in which it is transported and stored before reaching establishments. The lack of guidelines regarding the proper use of salt for each food preparation, thus contributing to its indiscriminate use.

Our study revealed unprecedented data on the profile and content of salt in the 2 main urban centers of Cape Verde (Praia and Mindelo). Thus contributing to the redesign of salt intake reduction strategies in these cities and in the country. It is imperative and urgent that national legislation regulates the unit weight of bread and the amount of salt that ready-to-eat food, including bread, should contain.

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Conflict of Interest

No funding was obtained for this study. The authors declare that they have no financial and/or personal conflicts of interest in the design and implementation of this study.

REFERENCES RÉFÉRENCES REFERENCIAS

- World Health Organization, Noncommunicable diseases, 2021. Available from: <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>.
- Portal informativo de Cabo Verde, Available from: <http://www.caboverde-info.com/Identidade/Geografia/Artigos/Coordenadas-geograficas>.
- ALMEIDA S, Todas as medidas do governo são no sentido de afastar o cenário da fome e mitigar a insegurança alimentar, Expresso das ilhas, 2022. Available from: <https://expressodasilhas.cv/pais/2022/06/18/todas-as-medidas-do-governo-sao-no-sentido-de-afastar-o-cenario-da-fome-e-mitigar-a-inseguranca-alimentar-gilberto-silva/80611>.
- Mills, K. T., Stefanescu, A., & He, J. (2020). The global epidemiology of hypertension. *Nature reviews. Nephrology*, 16(4), 223–237. <https://doi.org/10.1038/s41581-019-0244-2>.
- World Health Organization, Hypertension, 2021. Available from: <https://www.who.int/news-room/fact-sheets/detail/hypertension>.
- Molognoni, L., Daguer, H., Motta, G. E., Merlo, T. C., & Lindner, J. D. (2019). Interactions of preservatives in meat processing: Formation of carcinogenic compounds, analytical methods, and inhibitory agents. *Food research international (Ottawa, Ont.)*, 125, 108608. <https://doi.org/10.1016/j.foodres.2019.108608>. Available from: <https://pubmed.ncbi.nlm.nih.gov/31554117/>.
- Coelho PFdC. A prática social do consumo insustentável de alimentos para viagem no Brasil e Alemanha, 2021. Available from: <https://repositorio.ufc.br/handle/riufc/57926>.
- Ruiz, A., Lima, M. G., Medina, L., Pinto, R. L., Barros, M., & Filho, A. (2020). Can Meals Outside Homes Impact Sodium Intake?. *Current developments in nutrition*, 4(6), nzaa091. Available from: <https://doi.org/10.1093/cdn/nzaa091>.
- The National Academies Collection: Reports funded by National Institutes of Health. In: Oria M, Harrison M, Stallings VA, editors. *Dietary Reference Intakes for Sodium and Potassium*, Washington, 2019. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK538102/>.
- World Health Organization, Salt reduction, 2020. Available from: <https://www.who.int/news-room/fact-sheets/detail/salt-reduction>.
- World Health Organization, Guideline: sodium intake for adults and children, 2012. Available from: <https://www.who.int/publications/i/item/9789241504836>.
- Nascimento RFd, Gavron AB, Bowles S, Chaves ES, Bortolozzo EAFQ, (2017) Determination of the sodium and potassium levels in meals served in a university restaurant in the south of Brazil. *Braz. J. Food Technol.*, v. 20, e2016167. Available from: <http://dx.doi.org/10.1590/1981-6723.16716>.
- Instituto Nacional de Estatística de Cabo Verde, Anuário Estatístico – Cabo Verde 2018, 2020. Available from: <https://ine.cv/publicacoes/anuario-estatistico-cabo-verde-2018/>.
- Viegas CACL. O sal na alimentação dos jovens: avaliação e percepção do sal das refeições. 2013. Available from: <http://hdl.handle.net/10362/13224>.
- Associação de restauração e similares de Portugal, Código de boas práticas para o transporte de

- alimentos. 2008. Available from: https://ahresp.com/app/uploads/2018/10/Codigo-CBPH_AHRESP.pdf.
16. World Health Organization, (2007). Assessment of iodine deficiency disorders and monitoring their elimination: a guide for programme managers, 3rd ed. World Health Organization. Available from: <https://apps.who.int/iris/handle/10665/43781>.
 17. Jooste PL, Strydom E, (2010), Methods for determination of iodine in urine and salt. *Best practice & research Clinical endocrinology & metabolism*; 24(1): 77-88.
 18. Ward, R. E., & Carpenter, C. E. (2010). Traditional methods for mineral analysis. In *Food analysis* (p. 207), 4th ed. Springer, New York.
 19. Anteneh, Z. A., Engidayehu, M., & Abeje, G. (2017). Iodine content of dietary salt at household level and associated factors using Iodometric titration methods in Dera District, Northwest Ethiopia. *BMC nutrition*, 3, 83. Available from: <https://doi.org/10.1186/s40795-017-0203-x>
 20. Obsie, G. F., Ketema, K., & Tekalegn, Y. (2020). Availability of Adequately Iodized Dietary Salt and Associated Factors in a Town of Southeast Ethiopia: A Community-Based Cross-Sectional Survey. *Journal of nutrition and metabolism*, 2020, 1357192. Available from: <https://doi.org/10.1155/2020/1357192>.
 21. Goris, J. M., Temple, V. J., Zomerdijs, N., & Codling, K. (2018). Iodine status of children and knowledge, attitude, practice of iodised salt use in a remote community in Kerema district, Gulf province, Papua New Guinea. *PloS one*, 13(11), e0197647. Available from: <https://doi.org/10.1371/journal.pone.0197647>
 22. Mekonnen, T. C., Eshete, S., Wasihun, Y., Arefaynie, M., & Cherie, N. (2018). Availability of adequately iodized salt at household level in Dessie and Combolcha Towns, South Wollo, Ethiopia. *BMC public health*, 18(1), 1152. Available from: <https://doi.org/10.1186/s12889-018-6066-5>
 23. Abebe, Z., Gebeye, E., & Tariku, A. (2017). Poor dietary diversity, wealth status and use of un-iodized salt are associated with goiter among school children: a cross-sectional study in Ethiopia. *BMC public health*, 17(1), 44. Available from: <https://doi.org/10.1186/s12889-016-3914-z>
 24. Assembleia da República. Lei n.º 75/2009 de 12 de agosto Diário da República, 1.ª série, 2009 [5225 - 6]. Available from: <https://dre.pt/dre/detalhe/lei/75-2009-493513>.
 25. Al Jawaldeh, A., & Al-Khamaiseh, M. (2018). Assessment of salt concentration in bread commonly consumed in the Eastern Mediterranean Region. *Eastern Mediterranean health journal = La revue de sante de la Mediterranee orientale = al-Majallah al-sihhiyah li-sharq al-mutawassit*, 24(1), 18-24.
 26. Ludwig, L. M., Freitas, F. C. de, Chaves, M. A., Canan, C., & Corso, M. P. (2021). Estudo do processo de salga na produção de paleta suína salgada curada dessecada / Salting process study in obtaining a dried cured salted pork shoulder. *Brazilian Journal of Development*, 7(8), 85795-85806. Available from: <https://doi.org/10.34117/bjdv7n8-675>.
 27. National Research Council (US) Subcommittee on the Tenth Edition of the Recommended Dietary Allowances. (1989). *Recommended Dietary Allowances: 10th Edition*. National Academies Press (US).
 28. Feeding Guide for the Brazilian Population: Promoting the Health Food. (2008). – Brasília: Ministério da Saúde,. 210 p. Available from: https://bvsms.saude.gov.br/bvs/publicacoes/guia_alimentar_populacao_brasileira_2008.pdf.

Supplementary

Questionnaire applied to restaurants**A – SOCIODEMOGRAPHIC CHARACTERISTICS**

1. Gender: ☐ F ☐ M 2. Age: _____ 3. Education level: _____
4. Profession/role _____
5. In your establishment, is there a standard that dictates the ideal amount of salt to be used in food preparation?
☐ Yes ☐ No
6. Do you have any training in the field of Nutrition?
☐ Yes ☐ No
- 6.1. If yes, please describe: _____

B – FOOD PREPARATION IN RESTAURANTS

7. What type of salt do you use to prepare food?
☐ Coarse salt ☐ Refined salt ☐ Sea salt ☐ Fleur de sel ☐ Iodized salt
☐ Industrialized ☐ Nonindustrialized ☐ Other _____
8. Do you consider there to be a difference between these types of salt? ☐ Yes ☐ No

- 8.1. If yes, please describe: _____
9. What is the origin of the salt you use in your establishment?
☐ National ☐ International
 Island _____ Country _____
10. What was the means used to transport the salt to your establishment?
☐ Car ☐ Boat ☐ Airplane ☐ Other _____
11. Is there a specific location for salt storage?
☐ Yes ☐ No
- 11.1. If so, how is it stored?
☐ In its own packaging ☐ Protected from light ☐ Exposed to light ☐ Exposed to moisture
☐ Exposed to heat ☐ In the presence of chemical products ☐ In a nonventilated location
☐ Other _____
- 11.2. If not, specify the location and storage conditions:
 Location: _____
☐ In its own packaging ☐ Protected from light ☐ Exposed to light ☐ Exposed to moisture
☐ Exposed to heat ☐ In the presence of chemical products ☐ In a nonventilated location
☐ Other _____
12. Do you use any utensil to handle the salt?
☐ Yes ☐ No
- 12.1. If so, which ones?
☐ Spoon ☐ Cup ☐ Other _____
13. What is the amount of salt you use, per person, to make a soup?
☐ <1 g (less than 1/2 teaspoon) ☐ 1 to 2 g (1/2 to 1 teaspoon) ☐ 2 to 4 g (1 to 2 teaspoons)
☐ 4 to 6 g (2 to 3 teaspoons) ☐ >6 g (more than 1 tablespoon)
14. How much salt do you use, per person, to prepare a main dish?
☐ <1 g (less than 1/2 teaspoon) ☐ 1 to 2 g (1/2 to 1 teaspoon) ☐ 2 to 4 g (1 to 2 teaspoons)
☐ 4 to 6 g (2 to 3 teaspoons) ☐ >6 g (more than 1 tablespoon)
15. Do you consider that salt intake has an impact on health?
☐ Yes, for all individuals
☐ Yes, but only for individuals with some disease
☐ No
16. What is the daily dose of salt recommended by the World Health Organization?
☐ 12 g/day
☐ 10 g/day
☐ 5 g/day
☐ 3 g/day
☐ Other _____
17. The following describes the relationship between salt and sodium:
☐ They are the same
☐ Salt contains sodium
☐ Sodium contains salt
18. If you were asked to reduce the amount of salt used in cooking, what measures would you use to flavor the food, compensating for the lack of salt (you can choose more than one option)?
☐ Use of aromatic herbs
☐ Use of spices
☐ Use of concentrates (bouillon cubes)
☐ Other _____
19. Do you consider it important to reduce salt intake?
☐ Yes ☐ No ☐ Yes, but only for individuals with diseases
20. If you tried to reduce salt in the preparation of the meals you cook, what do you think would be the consumers' reaction (you can choose more than one option)?
☐ Eat in another establishment/location
☐ Complain to those responsible for the meals

- ☐ Complain in the complaints book
- ☐ Use a salt shaker, adding fine salt to the meals
- ☐ No reaction
- ☐ Another reaction _____

21. What are the diseases most associated with salt intake (you can choose more than one option)?

- ☐ High cholesterol
- ☐ Heart disease
- ☐ Hypertension
- ☐ Kidney disease
- ☐ Obesity
- ☐ Other _____

Many thanks for your participation!

Questionnaire applied to bakeries

A – SOCIODEMOGRAPHIC CHARACTERISTICS

1. Gender: ☐ F ☐ M 2. Age: _____ 3. Education level: _____

4. Profession/role _____

5. In your establishment, is there a standard that dictates the ideal amount of salt to be used in food preparation?

☐ Yes ☐ No

6. Do you have any training in the field of Nutrition?

☐ Yes ☐ No

6.1. If yes, please describe: _____

B – BREAD PREPARATION IN BAKERIES

7. What type of salt do you use to make bread?

☐ Coarse salt ☐ Refined salt ☐ Sea salt ☐ Fleur de sel ☐ Iodized salt

☐ Industrialized ☐ Nonindustrialized ☐ Other _____

8. Do you consider there to be a difference between these types of salt?

☐ Yes ☐ No

8.1. If yes, please describe: _____

9. What is the origin of the salt you use in your establishment?

☐ National ☐ International

Island _____ Country _____

10. What was the means used to transport the salt to your establishment?

☐ Car ☐ Boat ☐ Airplane ☐ Other _____

11. Is there a specific location for salt storage?

☐ Yes ☐ No

11.1. If so, how is it stored?

☐ In its own packaging ☐ Protected from light ☐ Exposed to light ☐ Exposed to moisture

☐ Exposed to heat ☐ In the presence of chemical products ☐ In a nonventilated location

☐ Other _____

11.2. If not, specify the location and storage conditions:

Location: _____

☐ In its own packaging ☐ Protected from light ☐ Exposed to light ☐ Exposed to moisture

☐ Exposed to heat ☐ In the presence of chemical products ☐ In a nonventilated location

☐ Other _____

12. Do you use any utensil to handle the salt?

☐ Yes ☐ No

12.1. If so, which ones? ☐ Spoon ☐ Cup ☐ Other _____

13. What is the amount of salt you use, per kilo of dough?

☐ <1 g (less than 1/2 teaspoon) ☐ 1 to 2 g (1/2 to 1 teaspoon) ☐ 2 to 4 g (1 to 2 teaspoons)

☐ 4 to 6 g (2 to 3 teaspoons) ☐ >6 g (more than 1 tablespoon) ☐ Other _____

14. What is the amount of salt you use per loaf of bread?

☐ <1 g (less than 1/2 teaspoon) ☐ 1 to 2 g (1/2 to 1 teaspoon) ☐ 2 to 4 g (1 to 2 teaspoons)

☐ 4 to 6 g (2 to 3 teaspoons) ☐ >6 g (more than 1 tablespoon)

15. Do you consider that salt intake has an impact on health?

- ☐ Yes, for all individuals
☐ Yes, but only for individuals with some disease
☐ No

16. What is the daily dose of salt recommended by the World Health Organization?

- ☐ 12 g/day
☐ 10 g/day
☐ 5 g/day
☐ 3 g/day
☐ Other _____

17. The following describes the relationship between salt and sodium:

- ☐ They are the same
☐ Salt contains sodium
☐ Sodium contains salt

18. If you were asked to reduce the amount of salt used in bread-making, what measures would you use to flavor the bread, compensating for the lack of salt (you can choose more than one option)?

- ☐ Use of aromatic herbs
☐ Use of spices
☐ Use of concentrates (bouillon cubes)
☐ Other _____

19. Do you consider it important to reduce salt intake?

- ☐ Yes ☐ No ☐ Yes, but only for individuals with diseases

20. If you tried to reduce the salt in the preparation of the bread you produce, what do you think would be the consumers' reaction (you can choose more than one option)?

- ☐ Buy bread at another establishment/location
☐ Complain to those responsible for the establishment
☐ Complain in the complaints book
☐ Use of a salt shaker, adding fine salt to the bread
☐ No reaction
☐ Another reaction _____

21. What are the diseases most associated with salt intake (you can choose more than one option)?

- ☐ High cholesterol
☐ Heart disease
☐ Hypertension
☐ Kidney disease
☐ Obesity
☐ Other _____

Many thanks for your participation!

Amount of salt present in the analyzed bread samples

N	Provenance	Results (g/100g)		
		NaCl	Na	Cl
1	Praia	1,2	0,48	0,72
2	Praia	1,3	0,52	0,78
3	Praia	1,3	0,52	0,78
4	Praia	1,2	0,48	0,72
5	Praia	1,2	0,48	0,72
6	Praia	1,2	0,48	0,72
7	Praia	1,3	0,52	0,78

8	Praia	1,1	0,44	0,66
9	Praia	1,43	0,572	0,858
10	Praia	1,81	0,724	1,086
11	Praia	1,41	0,564	0,846
12	Praia	1,5	0,6	0,9
13	Praia	2,03	0,812	1,218
14	Praia	1,46	0,584	0,876
15	Praia	1,7	0,68	1,02
16	Praia	1,4	0,56	0,84
Mean		1,40	0,56	0,85
SD		0,25	0,10	0,15
17	Mindelo	1,6	0,64	0,96
18	Mindelo	1,2	0,48	0,72
19	Mindelo	1,53	0,612	0,918
20	Mindelo	1,4	0,56	0,84
21	Mindelo	1,5	0,6	0,9
22	Mindelo	2,3	0,92	1,38
23	Mindelo	1,2	0,48	0,72
24	Mindelo	1,4	0,56	0,84
25	Mindelo	1,6	0,64	0,96
26	Mindelo	1,4	0,56	0,84
27	Mindelo	1,9	0,76	1,14
28	Mindelo	1,2	0,48	0,72
29	Mindelo	1,6	0,64	0,96
30	Mindelo	1,5	0,6	0,9
Mean		1,52	0,61	0,91
SD		0,29	0,12	0,18

Amount of salt present in the analyzed ready-to-eat food samples

N	Provenance	Results (g/100g)			NaCl (g)/meal	Na (g)/meal
		NaCl	Na	Cl		
1	Praia	1,10	0,44	0,66	2,07	0,83
2	Praia	1,60	0,64	0,96	4,11	1,64
3	Praia	0,70	0,28	0,42	1,90	0,76
4	Praia	1,10	0,44	0,66	3,30	1,32
5	Praia	1,14	0,46	0,68	3,45	1,38
6	Praia	2,30	0,92	1,38	7,06	2,82
7	Praia	1,30	0,52	0,78	4,28	1,71
8	Praia	1,44	0,58	0,86	4,81	1,92
9	Praia	1,20	0,48	0,72	4,08	1,63
10	Praia	1,30	0,52	0,78	4,71	1,88
11	Praia	1,60	0,64	0,96	5,84	2,34
12	Praia	1,10	0,44	0,66	4,08	1,63
13	Praia	2,00	0,80	1,20	7,54	3,02
14	Praia	1,40	0,56	0,84	5,60	2,24

15	Praia	1,80	0,72	1,08	7,22	2,89
16	Praia	1,90	0,76	1,14	7,81	3,12
17	Praia	1,30	0,52	0,78	5,62	2,25
18	Praia	1,20	0,48	0,72	5,20	2,08
19	Praia	1,30	0,52	0,78	5,64	2,26
20	Praia	1,30	0,52	0,78	5,69	2,28
21	Praia	0,66	0,26	0,40	2,90	1,16
22	Praia	1,30	0,52	0,78	5,79	2,31
23	Praia	0,90	0,36	0,54	4,11	1,65
24	Praia	1,20	0,48	0,72	5,58	2,23
25	Praia	1,00	0,40	0,60	4,75	1,90
26	Praia	1,20	0,48	0,72	5,76	2,30
27	Praia	0,80	0,32	0,48	4,07	1,63
28	Praia	1,20	0,48	0,72	6,13	2,45
29	Praia	0,90	0,36	0,54	4,66	1,86
30	Praia	0,90	0,36	0,54	4,73	1,89
31	Praia	1,10	0,44	0,66	6,18	2,47
32	Praia	0,60	0,24	0,36	3,49	1,39
33	Praia	1,00	0,40	0,60	5,90	2,36
34	Praia	0,80	0,32	0,48	4,76	1,90
35	Praia	1,30	0,52	0,78	7,75	3,10
36	Praia	0,50	0,20	0,30	2,99	1,19
37	Praia	1,10	0,44	0,66	6,60	2,64
38	Praia	2,40	0,96	1,44	14,50	5,80
39	Praia	2,40	0,96	1,44	14,76	5,90
40	Praia	1,80	0,72	1,08	11,12	4,45
41	Praia	0,80	0,32	0,48	4,95	1,98
42	Praia	1,10	0,44	0,66	6,82	2,73
43	Praia	0,80	0,32	0,48	5,44	2,18
44	Praia	0,90	0,36	0,54	6,26	2,51
45	Praia	0,70	0,28	0,42	5,03	2,01
46	Praia	0,80	0,32	0,48	5,94	2,38
47	Praia	0,90	0,36	0,54	7,02	2,81
48	Praia	0,90	0,36	0,54	7,34	2,93
49	Praia	0,90	0,36	0,54	7,39	2,96
50	Praia	2,00	0,80	1,20	17,22	6,89
51	Praia	0,90	0,36	0,54	2,28	0,91
52	Praia	1,30	0,52	0,78	5,20	2,08
53	Praia	2,70	1,08	1,62	10,83	4,33



54	Praia	0,90	0,36	0,54	3,60	1,44
55	Praia	2,60	1,04	1,56	10,40	4,16
56	Praia	1,50	0,60	0,90	2,82	1,13
57	Praia	1,40	0,56	0,84	3,57	1,43
58	Praia	1,00	0,40	0,60	6,00	2,40
59	Praia	1,40	0,56	0,84	5,60	2,24
Mean		1,26508	0,5061	0,75898	5,93644	2,37424
SD		0,49818	0,19936	0,29882	2,91939	1,16795
60	Mindelo	1,50	0,60	0,90	6,00	2,40
61	Mindelo	1,10	0,44	0,66	4,40	1,76
62	Mindelo	1,00	0,40	0,60	4,00	1,60
63	Mindelo	0,90	0,36	0,54	2,70	1,08
64	Mindelo	1,60	0,64	0,96	4,80	1,92
65	Mindelo	1,40	0,56	0,84	5,60	2,24
66	Mindelo	1,20	0,48	0,72	4,80	1,92
67	Mindelo	2,10	0,84	1,26	8,40	3,36
68	Mindelo	1,20	0,48	0,72	4,80	1,92
69	Mindelo	1,50	0,60	0,90	6,00	2,40
70	Mindelo	1,70	0,68	1,02	6,80	2,72
71	Mindelo	0,90	0,36	0,54	3,60	1,44
72	Mindelo	2,10	0,84	1,26	8,40	3,36
73	Mindelo	1,20	0,48	0,72	4,80	1,92
74	Mindelo	1,40	0,56	0,84	5,60	2,24
75	Mindelo	2,30	0,92	1,38	9,20	3,68
76	Mindelo	1,40	0,56	0,84	4,20	1,68
77	Mindelo	0,70	0,28	0,42	2,80	1,12
78	Mindelo	0,60	0,24	0,36	0,66	0,26
79	Mindelo	1,20	0,48	0,72	1,66	0,66
80	Mindelo	2,00	0,80	1,20	2,92	1,17
81	Mindelo	1,50	0,60	0,90	2,24	0,89
82	Mindelo	1,10	0,44	0,66	1,76	0,70
83	Mindelo	1,80	0,72	1,08	3,10	1,24
84	Mindelo	0,70	0,28	0,42	1,24	0,50
85	Mindelo	1,40	0,56	0,84	2,56	1,02
86	Mindelo	1,50	0,60	0,90	2,76	1,10
87	Mindelo	0,60	0,24	0,36	1,12	0,45
88	Mindelo	0,90	0,36	0,54	1,69	0,68
89	Mindelo	0,70	0,28	0,42	1,39	0,55
90	Mindelo	0,80	0,32	0,48	1,60	0,64

91	Mindelo	0,80	0,32	0,48	1,68	0,67
92	Mindelo	1,90	0,76	1,14	4,20	1,68
93	Mindelo	2,00	0,80	1,20	4,54	1,82
94	Mindelo	0,80	0,32	0,48	1,91	0,76
95	Mindelo	1,70	0,68	1,02	4,17	1,67
96	Mindelo	2,30	0,92	1,38	5,68	2,27
97	Mindelo	1,30	0,52	0,78	3,38	1,35
98	Mindelo	1,20	0,48	0,72	3,24	1,30
99	Mindelo	1,70	0,68	1,02	4,81	1,92
100	Mindelo	2,20	0,88	1,32	6,38	2,55
101	Mindelo	2,00	0,80	1,20	6,00	2,40
102	Mindelo	2,10	0,84	1,26	6,45	2,58
103	Mindelo	0,60	0,24	0,36	1,86	0,74
104	Mindelo	2,00	0,80	1,20	6,38	2,55
105	Mindelo	1,30	0,52	0,78	4,55	1,82
106	Mindelo	2,30	0,92	1,38	8,14	3,26
107	Mindelo	1,30	0,52	0,78	4,65	1,86
108	Mindelo	1,60	0,64	0,96	5,76	2,30
109	Mindelo	1,70	0,68	1,02	6,24	2,50
110	Mindelo	1,70	0,68	1,02	6,29	2,52
111	Mindelo	2,40	0,96	1,44	9,60	3,84
112	Mindelo	1,80	0,72	1,08	7,25	2,90
113	Mindelo	0,60	0,24	0,36	2,46	0,98
114	Mindelo	1,70	0,68	1,02	7,31	2,92
115	Mindelo	1,60	0,64	0,96	7,20	2,88
116	Mindelo	0,90	0,36	0,54	4,14	1,66
117	Mindelo	0,90	0,36	0,54	4,31	1,72
118	Mindelo	1,50	0,60	0,90	7,79	3,11
119	Mindelo	0,90	0,36	0,54	4,73	1,89
120	Mindelo	1,00	0,40	0,60	5,70	2,28
121	Mindelo	1,40	0,56	0,84	8,15	3,26
122	Mindelo	1,50	0,60	0,90	9,33	3,73
123	Mindelo	1,90	0,76	1,14	12,96	5,18
124	Mindelo	1,50	0,60	0,90	10,41	4,16
125	Mindelo	1,30	0,52	0,78	11,01	4,40
Mean		1,41515	0,56606	0,84909	5,00394	2,00076
SD		0,49404	0,19762	0,29642	2,66494	1,06596

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Brunner Gland Adenoma with a KRAS G12D Point Mutation

By Nava, Victor E.

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We present a 64-year-old man evaluated for iron deficiency anemia harboring a 1.5 cm BGA found by duodenoscopy. Immunohistochemistry failed to reveal microsatellite instability, and next generation sequencing revealed a KRAS G12D point mutation.

GJMR-K Classification: DDC Code: 724 LCC Code: NA500



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I. INTRODUCTION

Brunner glands (BG), first described by the swiss anatomist Johann Conrad Brunner in 1688,¹ are located predominantly in the submucosa of the proximal duodenum and are composed of cells with columnar to cuboidal cytoplasm and basal nuclei, arranged in lobules separated by delicate fibrous septa. They secrete alkaline mucus (composed of mucin glycoproteins, bicarbonate and various additional factors including epidermal growth factor, trefoil peptides, bactericidal factors, proteinase inhibitors, and surface-active lipids) that protect the epithelium from digestive enzymes.² The exact classification of Brunner gland lesions (BGL) is evolving and hyperplasia (BGH), adenoma (BGA), hamartoma and brunneroma, have been used as descriptors. In general, lesions smaller than 0.5 cm are considered hyperplasia and not true neoplasias.³ Historically, BGL/BGH were first classified by Feyrter into three types: type 1 (diffuse nodular hyperplasia with sessile projections extending beyond the duodenal bulb), type 2 (nodular or sessile hyperplasia confined to the duodenal bulb), and type 3 (pedunculated or sessile adenoma forming a mass).⁴ However, a clear pathologic distinction based on clinical pathologic correlation has not been developed and the malignant potential of these benign lesions remains uncertain.⁵

BGL represent less than 1% of primary tumors in the small intestine, and approximately 10% of duodenal neoplasms. Rare reports have documented possible progression to carcinoma,⁶ and presenting symptoms vary widely according to the size of the lesions. They tend to be asymptomatic until growing

beyond 1.5 cm, while tumors larger than 2 cm may manifest with upper gastrointestinal bleeding and obstruction.³ The literature on genetic alterations in BGL is sparse and devoid of KRAS hits. We report the case of a 64-year-old male with a 1.5 cm polyp in the duodenum corresponding to a BGH type 3/BGA with a point mutation (G12D) in KRAS.

II. CASE REPORT

A 64-year-old male with history of heart failure with reduced ejection fraction, chronic renal failure stage 5, coronary artery disease, diabetes mellitus, hypertension, stroke, benign prostatic hyperplasia and tobacco use disorder, presented to the hospital for a nephrology follow up visit. Detection of combined iron deficiency and chronic disease anemia (decreased hemoglobin 6.6 g/dL, hematocrit 20.6 % and iron 34 ug/dL; with normal MCV 91.7 fL, and ferritin 69 ng/ml) prompted upper endoscopy and colonoscopy. The upper endoscopy showed a 1.5 cm, pink-tan polyp in the duodenum, which was resected. The histopathological examination revealed BGA/BGH type 3 without dysplasia or malignancy (Figure 1 & 2). Immunohistochemistry revealed intact expression of DNA mismatch repair proteins (MLH1, MSH2, MSH6 and PMS2) supporting lack of microsatellite instability. Due to the rarity of the lesion next generation sequencing (Oncomine Focus, ThermoFisher) was performed on extracted DNA revealing a KRAS G12D genetic alteration. In addition, the colonoscopy revealed three tubular adenomas (one 0.4 cm pedunculated polyp in the ascending colon and two sessile polyps ranging from 0.3 to 0.5 cm in the transverse colon). Of note, the patient died three months later due to respiratory failure from SARS-CoV-2 infection.

III. DISCUSSION

BGL present most commonly as an incidental endoscopic finding in asymptomatic patients during their fifth or sixth decade of life without a predilection towards gender or race.⁷ Although BG proliferations are traditionally considered benign they can be premalignant⁸ and develop dysplasia and even invasive carcinoma in ~2% and 0.3% of cases, respectively.⁹ However, the exact molecular pathogenesis is unknown. Brosens et al. reported a BG hamartoma in one patient with juvenile polyposis syndrome harboring a germline

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mutation in SMAD4/DPC4, a highly conserved transcription factor activated by TGF- β .¹⁰ Loss of the tumor suppressor LRIG1 (a transmembrane protein that interacts with EGFR family proteins) has been associated with increased proliferation of Brunner glands in mice and intestinal adenomatous polyps in humans.¹¹ In addition, Levi et al. described BGH smaller than 1 cm in 20% of 10 patients with Cowden syndrome (CS),¹² suggesting a pathogenic role for PTEN mutations, which are present in ~85% of patients affected by this syndrome.

Mutations in the Kirsten rat sarcoma viral oncogene homologue (KRAS) have not been previously reported in BGL to the best of our knowledge. This well-known proto-oncogene encodes a protein that acts as a molecular switch transducing extracellular signals from membrane receptors (like EGFR) to the cytosolic MAPK and PI3K/mTOR pathways, ultimately leading to activation of nuclear transcription controlling cell proliferation, differentiation, and survival.¹³ KRAS is mutated in approximately 25% of human tumors, representing one of the most commonly altered genes associated with cancer.¹⁴ Missense mutations in KRAS stabilize an active GTP-bound form of the protein promoting oncogenesis. The G12D point mutation we

identified in a BGA is a well-recognized and powerful cancer driver mutation with impaired GTPase catalytic activity.¹⁵ It is also the most prevalent alteration in human cancer, which is present in 4.2% of cases in the American Association of Cancer Research public database.¹⁶ Interestingly, KRAS G12D is embryonic lethal in mouse models, but is sufficient to initiate transformation of fibroblasts in cell culture and to induce preneoplastic epithelial hyperplasias in the lung and gastrointestinal tract.¹⁷ Because there is crosstalk between the MAPK, PTEN/PI3K and TGF- β /BMP pathways,¹⁸ it is possible that other altered genes (SMAD4, LRIG1 and PTEN) described in BGL may act in concert with KRAS to promote neoplasia. The classical adenoma-carcinoma sequence (with mutations in APC, KRAS, and p53) plays an important role in duodenal carcinogenesis when adenomatous change/dysplasia is present.¹⁹ However, the validity of this paradigm in BG neoplasia is unclear. Of note, BG adenocarcinoma arising from BGH has been associated with GNAS mutations arising in foveolar metaplasia.²⁰ The BGA presented here did not show dysplasia or metaplasia, and raises a potential role for KRAS in the regulation of BG proliferation, which deserves further studies.

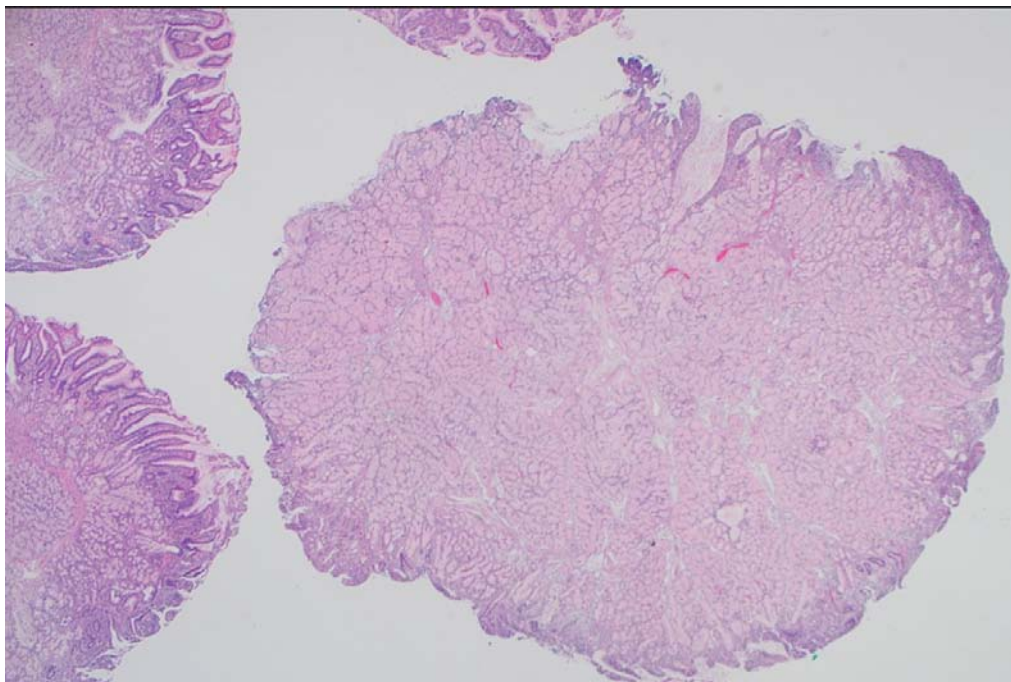


Figure 1: Photomicrograph of Brunner gland nodule (H & E x20)

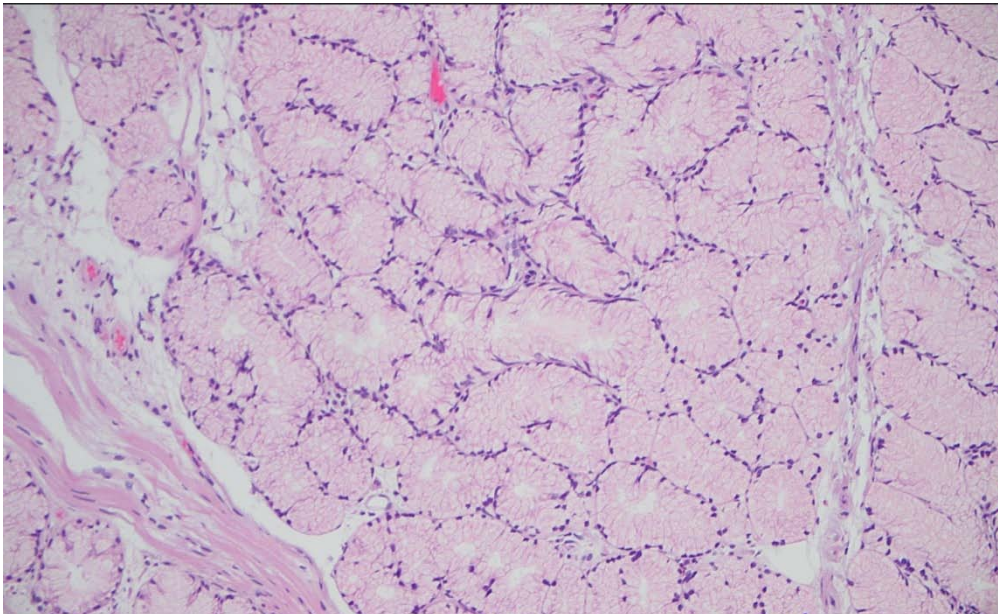


Figure 2: Photomicrograph of Brunner gland nodule (H & E x200)

REFERENCES RÉFÉRENCES REFERENCIAS

1. Rocco A. Large Brunner's gland adenoma: Case report and literature review. *World Journal of Gastroenterology*. 2006; 12(12): 1966. doi:10.3748/wjg.v12.i12.1966
2. Krause WJ. Brunner's glands: A structural, histochemical and pathological profile. *Progress in Histochemistry and Cytochemistry*. 2000; 35(4): 255-367. doi: 10.1016/s0079-6336(00)80006-6
3. Patel ND, Levy AD, Mehrotra AK, Sobin LH. Brunner's gland hyperplasia and Hamartoma: Imaging features with Clinicopathologic Correlation. *American Journal of Roentgenology*. 2006; 187(3): 715-722. doi: 10.2214/ajr.05.0564
4. Lee WC, Yang HW, Lee YJ, et al. Brunner's gland hyperplasia: Treatment of severe diffuse nodular hyperplasia mimicking a malignancy on pancreaticoduodenal area. *Journal of Korean Medical Science*. 2008; 23(3): 540. doi: 10.3346/jkms.2008.23.3.540
5. Zhu M, Li H, Wu Y, et al. Brunner's gland hamartoma of the duodenum: A literature review. *Advances in Therapy*. 2021. doi: 10.1007/s12325-021-01750-6
6. Koizumi M, Sata N, Yoshizawa K, et al. Carcinoma arising from Brunner's gland in the duodenum after 17 years of observation – A case report and literature review. *Case Reports in Gastroenterology*. 2007; 1(1): 103-109. doi: 10.1159/000108944
7. de Nes LCF, Ouwehand F, Peters SHA, Boom MJ. A large Brunner's gland hamartoma causing gastrointestinal bleeding and obstruction. *Digestive Surgery*. 2007; 24(6): 450-452. doi: 10.1159/000111075
8. Brookes MJ. Malignant potential in a Brunner's gland hamartoma. *Postgraduate Medical Journal*. 2003; 79(933): 416-417. doi: 10.1136/pmj.79.933.416
9. Sakurai T, Sakashita H, Honjo G, et al. Gastric foveolar metaplasia with dysplastic changes in Brunner gland hyperplasia. *The American Journal of Surgical Pathology*. 2005; 29(11): 1442-1448. doi: 10.1097/01.pas.0000180449.15827.88
10. Brosens LAA, et al. Juvenile polyposis syndrome. *World Journal of Gastroenterology*. 2011; 17(44): 4839. doi: 10.3748/wjg.v17.i44.4839
11. Wang Y, Shi C, Lu Y, Poulin EJ, et al. Loss of LRIG1 leads to expansion of Brunner glands followed by duodenal adenomas with gastric metaplasia. *The American Journal of Pathology*. 2015; 185(4): 1123-1134. doi: 10.1016/j.ajpath.2014.12.014
12. Levi Z, Baris HN, Kedar I, et al. Upper and lower gastrointestinal findings in PTEN mutation-positive Cowden syndrome patients participating in an active surveillance program. *Clinical and Translational Gastroenterology*. 2011; 2(11). doi: 10.1038/ctg.2011.4
13. Martinelli E, Morgillo F, Troiani T, Ciardiello F. Cancer resistance to therapies against the EGFR-ras-raf pathway: The role of mek. *Cancer Treatment Reviews*. 2017; 53: 61-69. doi: 10.1016/j.ctrv.2016.12.001
14. Burge RA, Hobbs GA. Not all RAS mutations are equal: A detailed review of the functional diversity of Ras Hot Spot Mutations. *Advances in Cancer Research*. 2022; 29-61. doi: 10.1016/bs.acr.2021.07.004
15. Vatansever S, Erman B, Gümüş ZH. Oncogenic G12D mutation alters local conformations and dynamics of K-Ras. *Scientific Reports*. 2019; 9(1). doi:10.1038/s41598-019-48029-z

16. AACR Project Genie: Powering Precision Medicine through an international consortium. *Cancer Discovery*. 2017; 7(8): 818-831. doi: 10.1158/2159-8290.cd-17-0151
17. Tuveson DA, Shaw AT, Willis NA, et al. Endogenous oncogenic K-RASG12D stimulates proliferation and widespread neoplastic and developmental defects. *Cancer Cell*. 2004; 5(4): 375-387. doi: 10.1016/s1535-6108(04)00085-6
18. Carracedo A, Pandolfi PP. The PTEN–PI3K pathway: Of feedbacks and cross-talks. *Oncogene*. 2008; 27(41): 5527-5541. doi: 10.1038/onc.2008.247
19. Guo X, Wang X-F. Signaling cross-talk between TGF- β /BMP and other pathways. *Cell Research*. 2008; 19(1): 71-88. doi: 10.1038/cr.2008.302
20. Matsuo Y, Yamamoto H, Sato Y, et al. Gnas-mutated carcinoma arising from gastric foveolar metaplasia in the duodenum after 9 years of observation. *Clinical Journal of Gastroenterology*. 2018; 11(5): 391-395. doi: 10.1007/s12328-018-0856-2





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Risk Factors Associated with the Prevalence of the Zika Virus

By Cinthia Botacio de Tejada

Summary- Zika is a viral infection caused primarily by the bite of the *Aedes aegypti* mosquito. It is asymptomatic and may present: fever, headache, myalgia, arthralgia, asthenia and maculopapular rash. Neurological or autoimmune complications.

Objective: To analyze the behavior of the Zika virus and its association with risk factors in the population of Herrera.

Methodology: Retrospective cross-sectional prevalence study, using the digitalized mandatory notification form of the Surveillance System and the report on the presence of breeding sites from the MINSA vector department. A database was developed in the Excel program and inferential analysis in epiinfo.

Keywords: risk factors, zika virus, prevalence, zika confirmatory test.

GJMR-K Classification: DDC Code: 614.57 LCC Code: RC114.5



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Risk Factors Associated with the Prevalence of the Zika Virus

Factores De Riesgo Asociados En La Prevalencia Del Virus Zika

Cinthia Botacio de Tejada

Summary- Zika is a viral infection caused primarily by the bite of the *Aedes aegypti* mosquito. It is asymptomatic and may present: fever, headache, myalgia, arthralgia, asthenia and maculopapular rash. Neurological or autoimmune complications.

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Methodology: Retrospective cross-sectional prevalence study, using the digitalized mandatory notification form of the Surveillance System and the report on the presence of breeding sites from the MINSA vector department. A database was developed in the Excel program and inferential analysis in epiinfo.

Results: The prevalence rate of the Zika virus for 2016 is 8.5 and for 2017 it is 6.03 per 10,000 inhabitants. Of 342 suspected cases, 161 (47%) were determined to have positive tests. Statistical significance was demonstrated in the place of residence generalized to the population in the corregimiento of San Juan Bautista (X^2 : 4.18, p : 0.0205), it is a risk factor (OR: 1.76, I.C: 1.02-3.05), the corregimiento of Llano Bonito as a protective factor (X^2 : 5.42, p : 0.01) (O.R: 0.49, I.C: 0.027-0.90), not having breeding sites as a protective factor (X^2 : 4.88, p : 0.0136) (O.R: 0.48, I.C: 0.25- 0.93), the IV epidemiological trimester as a risk factor (X^2 : 27.01, p :0.000, OR:3.24, I.C:2.07-5.08) and the I and II trimesters as a protective factor against the virus (I trimester I.C: 0.28-0.27 and II trimester CI: 0.17-0.81). All results can be generalized to the study population.

Conclusion: The environmental characteristics are related to Zika viral infection, with the variable location, season of the year and male sex also being relevant.

Keywords: risk factors, zika virus, prevalence, zika confirmatory test.

I. INTRODUCTION

Zika virus is an emerging viral infection of the flaviviridae family, transmitted mainly by the *Aedes aegypti* mosquito. It was first identified in 1947 in the Zika forests deriving from there its name, this incidence was given by the investigations of yellow fever in Rhesus monkeys. Then the virus spread in various populations throughout the continent, especially in countries where climatic conditions were appropriate for the spread and proliferation of mosquitoes. That is why the Zika virus has spread from various epidemiological outbreaks in the world, research of the virus requires

knowing more about the factors associated with prevalence and complications in populations. As an emerging disease in the scientific community, which is prevalent in the study population, it is necessary to know about the risk factors associated with this virus. This study aims to analyze the behavior of the Zika virus and the association with risk factors in the population of Herrera from January 2016 to December 2017; using the Epidemiological Surveillance System (SISVIG) with the use of mandatory notification forms and national database for Zika in Herrera, as well as the report of the presence of hatcheries according to sector by vector personnel of the Ministry of Health. This article details the methodology and presents the main results found, among which we can mention that the highest concentration of cases was in the districts of San Juan Bautista with 11.1% (38), Monagrillo with 9.6% (33) and Llano Bonito 5% (18). The risk factors that had statistical significance were: the presence of breeding sites in the months of October, November and December, ages from 20 to 39 years and male sex, in addition there is no relationship between the characteristics of people and the infection of the Zika virus. With the contributions of this study, it is expected to contribute to the construction of new forms of approach that lead to health strategies, in the field of public health, that promote alternatives favorable to health by the authorities.

II. METHODOLOGY

Study design: The type of study is a retrospective cross-sectional prevalence study because the aim is to determine the prevalence and the various factors associated with the acquisition of Zika virus in Herrera.

Prevalence describes the proportion of the population suffering from the disease, which we want to study, at a given time, that is, it is like a still photo. (Ibanez, 2012). So it is also cross-sectional.

Population and sample: According to the 2010 National Population Census, the Province of Herrera has approximately 109,955 inhabitants, of which 55,508 were men and 54,447 women. (INEC, 2018).

In the Institute of Statistics and Census, the estimated population for the Province of Herrera for the year 2016 was 114,254 and for 2017 it was 114,353 inhabitants, respectively.

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For this prevalence study, all suspected symptomatic cases with Zika virus captured in the Epidemiological Surveillance System (SISVIG) in the period January 2016-December 2017 were taken, corresponding to 342 suspected cases. This database is continuously fed by medical and nursing staff (37), both from the Ministry of Health and the Social Security Fund that work in the province of Herrera, Republic of Panama.

Due to the fact that all the information was captured in the epidemiological surveillance system and the report of the vector control personnel in home visits; we worked with 100% of the same, that is, no sample was used, which allows us to know the real prevalence of the Zika virus in the population studied.

Inclusion and exclusion criteria: The inclusion criterion that was taken into account in the case definition was that it had all the complete information in the Epidemiological Surveillance System through the mandatory notification form and Zika virus databases. No cases were excluded because all forms were completed according to the registry of notifiable disease forms.

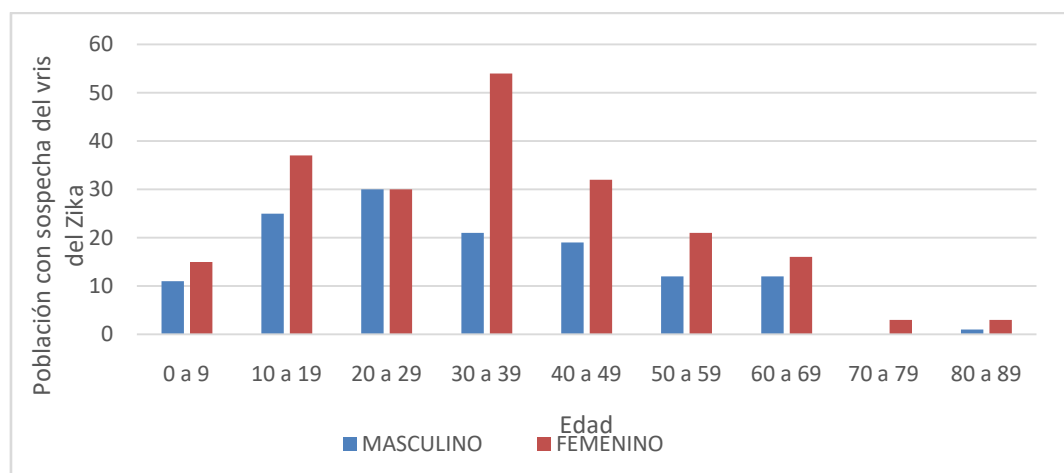
Ethical considerations: The development of the study did not require direct intervention; the participants were not subjected to any risk of complications or toxic or adverse effect. However, it was governed by the Declaration of Helsinki of the World Medical Association, the Code of Dentistry and Good Clinical Practices. Each of the participants was registered in the SISVIG system, so it was necessary to comply with the authorized signatures of the authorities of the Ministry of Health. The information received was used confidentially. Subjects were identified with numbers from 01 to 342 for confirmed cases of Zika virus disease. The results obtained were evaluated and are kept confidential for research purposes.

Procedures for data collection: Secondary sources were used in this study. The database of the Epidemiological Surveillance System, SISVIG, was used, as well as the mandatory notification disease forms and the reports provided by the vector staff of the Ministry of Health. An instrument was developed and used to determine the risk factors associated with the prevalence of Zika virus in the Herrera Health Region. In it, epidemiological variables of person and place were found, such as: age, sex, origin, presence of breeding sites detected in sectors visited and reported by the vector staff of the Ministry of Health. In addition, they handled the data on the condition of care or clinical management of the patient, such as: suspected and confirmed diagnoses of the virus, date of onset of symptoms grouped by epidemiological quarter according to years, confirmation or ruling out of cases, presence of the Zika virus.

Procedures for the presentation and analysis of results: the Epiinfo program was used, where a database was generated that dynamically allowed the crossing of variables and the calculation of descriptive and inferential statistics to determine the prevalence of the Zika virus. Analytical tables of both qualitative and quantitative variables and measures of central tendency and statistical significance with the chi square test (χ^2), set at 95% certainty and degree of freedom (χ^2 : 3.84) with a percentage of 5% error (p : 0.05); in order to prove or reject the null hypothesis of the investigation. As well as determining the strength of association of risk factors measured through the OR risk test, attributable risks and attributable risks of the exposed population. To know if the results can be generalized to the population, the confidence limits test will be used.

III. RESULTS

The incidence of Zika virus in the Herrera health region is unknown. When the outbreak was declared with 39 cases at the end of December.



Graph 1: Population With Zika Virus Infection According To Age In The Herrera Health Region.

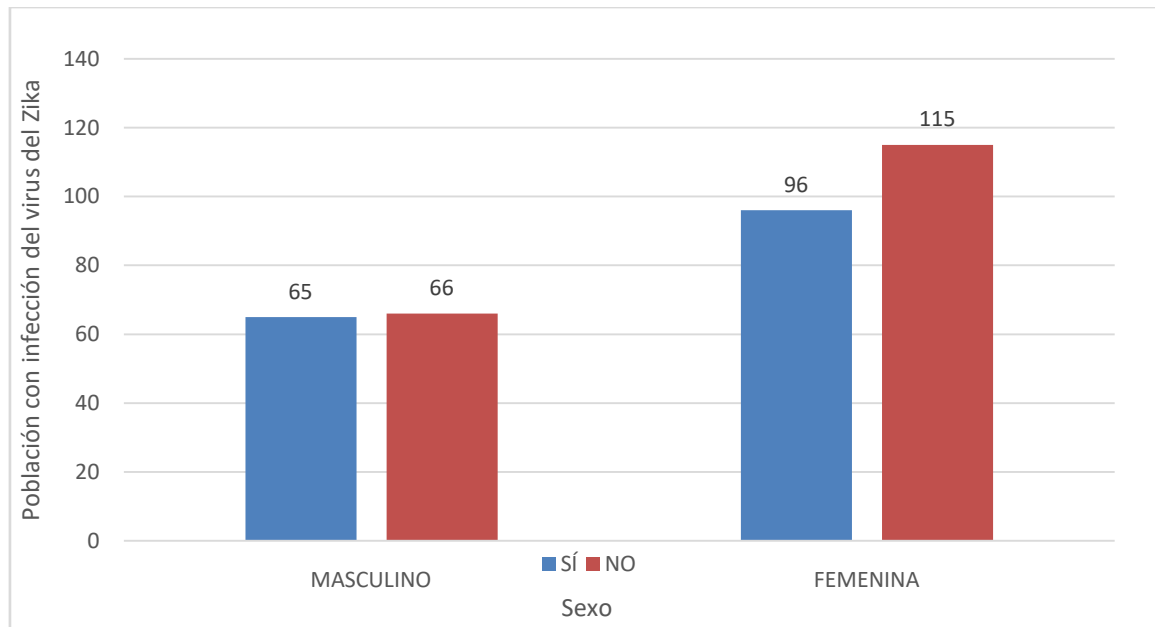
Source: Database of the Epidemiological Surveillance System of the Health Region of Herrera 2016 and 2017.

The population with suspected Zika virus is mostly between the ages of 30 to 39 years with 21.9% (75), of which 15.8% (54) are female. In second place are young people between 10 and 19 years old 18.1% (62), where there is also a greater increase in women 10.8% (37); followed by the ages of 20 to 29 years with 17.5% (60) with no difference between the sexes.

Regarding gender, it was found that the majority of people with suspected Zika virus are female, 61.7%

(211). In the ages, it was observed that in the majority, more than 50% of the cases occurred between the economically productive and reproductive ages of 10 to 49 years.

Men and women become fertile in adolescence, after puberty from the age of 14; Reproductive potential declines as women age, and fertility typically ends five to ten years before menopause. (Birmingham, 2013).



Graph 2: Population With Zika Virus Infection According To Sex In The Herrera Health Region, 2016 And 2017.

Source: Database of the Epidemiological Surveillance System of the Health Region of Herrera 2016 and 2017.
RA. DE EXPUESTOS: 49.6%.

When relating Zika virus infection according to sex, it was shown that males represent 38.3% (131) and females 61.7% (211). The positive tests determined the male sex in 19.0% (65), in negative tests 19.3% (66), the female sex positive tests 28.1% (96) and negative tests 33.6% (115). The statistical association in both sexes and Zika virus infection was shown to be non-existent (χ^2 : 0.55, p 0.2290). When measuring the relationship of variables, Zika virus infection applied to sex, it was shown that male sex is a risk factor for becoming infected with Zika virus (OR: 1.18), and female sex as a protective factor (OR: 0.85).). The confidence interval does not allow to generalize to the study population, since the sample is small; it is necessary to expand the sample to measure the variable according to female sex. (I.C: 0.55-1.31) and male (I.C: 0.76-1.83).

In publications of the magazine Vida Actual for 2019 they refer that According to Dutch experts, mosquitoes locate their victims by the carbon dioxide they emit. That is, people who exhale more carbon dioxide in their breath, such as pregnant women or large people, will surely suffer more from their bites. Some studies suggest that they prefer women because their

skin is thinner, which makes it easier to bite. In addition, the "sweet blood" attracts. (Michelin, 2019).

There is a relationship with saccharides in the blood, but it is because this compound feeds the bacteria on the skin (the bacteria that give sweat its bad smell). Dutch studies found that mosquitoes avoid people with a high number of bacteria on their skin and also those with very few. They prefer those that have a more balanced ecosystem. (Michelin, 2019).

However, the research shows that the risk factor for Zika virus infection is being male, which could be related to current behavioral changes in men, in relation to personal hygiene, wearing shorts, waxing of their villi, and probably even the fragrance or body scents they wear, could attract mosquitoes.

Table N°1: Population With Zika Virus Infection, According To Usual Residence, Herrera Health Region, 2016 And 2027. Población Con Infección Del Virus Del Zika, Según Residencia Habitual, Región De Salud De Herrera 2016 Y 2027.

RESIDENCIA HABITUAL	TOTAL		INFECCIÓN DEL VIRUS ZIKA							
			SÍ		NO					
	Nº	%	Nº	%	Nº	%	X²	p	OR	IC
TOTAL	342	100.0	161	47.1	181	52.9				
Chitré	59	17.3	32	9.4	27	7.9	1.47	0.1131	1.42	0.81-2.49
La Arena	56	16.4	29	8.5	27	7.9	0.60	0.2200	1.25	0.71-2.22
Monagrillo	69	20.2	33	9.6	36	10.5	0.02	0.4444	1.04	0.61-1.76
Llano Bonito	55	16.1	18	5.3	37	10.8	5.42	0.0100	0.49	0.27-0.90
San Juan Bautista	65	19.0	38	11.1	27	7.9	4.18	0.0205	1.76	1.02-3.05
Parita	25	7.3	8	2.3	17	5.0	2.46	0.0584	0.50	0.21-1.20
Santa María	1	0.3	0	0.0	1	0.3	0.89	0.1725	0.00	0-0
Pesé	11	3.2	3	0.9	8	2.3	1.79	0.0963	0.41	0.11-1.58
Los Pozos	1	0.3	0	0.0	1	0.3	0.89	0.1725	0.00	0-0

Fuente: Base de datos del sistema de vigilancia Epidemiológica de la Región de Salud de Herrera 2016 y 2017.



Factor de riesgo



Factor protector

Ra. De Expuestos: 58.5%.

In relation to the detection of the Zika virus, it was determined that 47.1% (161) of the confirmatory tests came out positive, of which the majority are found in the corregimiento of San Juan Bautista at 11.1% (38), followed by the Corregimiento of Monagrillo with 9.6% (32) and Chitré with 9.4% (32). Regarding the number of samples, the Corregimiento de Monagrillo was obtained with 20.0% (69), followed by the Corregimiento de San Juan Bautista 19% (65). These results are due to the density of the population in urban areas and close to the head of the District of Chitré. When measuring the relationship of variables, Zika virus infection and habitual residence, statistical significance was demonstrated in the Corregimiento San Juan Bautista with (X²: 4.18, p: 0.0205), that is, there is a statistical association between both variables; In addition, this corregimiento is a risk factor for the population to acquire the Zika virus (OR: 1.76), being able to generalize the results (CI: 1.02-3.05). The district of Llano Bonito also showed a

statistical association between Zika virus infection and residence (X²: 54.1, p: 0.0099). This corregimiento becomes a protective factor against becoming infected with the Zika virus (OR: 0.48), a result that can be generalized to the population of this corregimiento (CI: 0.026 - 0.90). The AR result in exposed patients showed that with a Zika virus prevention program, the prevalence of cases in this population in the province of Herrera can be reduced by 32.7%. In the different investigations reviewed on the Zika virus, it is evident that one of the greatest risks of becoming infected with the Zika virus is staying in endemic areas of the vector. This refers to the potential risk of disease transmission, which lies in the fact that the virus-transmitting mosquitoes live in the region and its population density. (BBC, 2016). Transmission occurs in urban and wild cycles, depending on the mosquito vectors involved. Thus, Aedes aegypti is related to urban transmission. (Castro, 2016).

Table N°2: Statistical Summary of Risk Factors For Zika Viral Infection.

FACTOR DE RIESGO	X ²	p	OR	IC
Procedencia en San Juan Bautista	4.18	0.0205	1.76	1.02-3.05
Con criaderos de mosquitos	4.88	0.0136	2.08	1.08-4.11
IV trimestre epidemiológico con población afectada	27.01	0.0000	3.24	2.07-5.08
II trimestre con presencia de criaderos	5.23	0.0111	4.49	1.12 - 17.97
III trimestre con presencia de criaderos	6.91	0.0043	8.25	1.31- 52.01

Fuente: Base de datos del Sistema de Vigilancia Epidemiológica de la Región de Salud de Herrera 2016 y 2017.

The II and III epidemiological trimester is a risk factor for the presence of mosquito breeding sites. 55% of the cases yielded positive results. Of the confirmed cases with positive Zika tests, 55.3% were tested in the fourth quarter, of which 4.7% have the presence of breeding sites. In the rest of the quarters the presence of breeding sites was the same. Regarding the association, it found that the I, II, III quarters have statistical significance, that is, there is an association between these quarters and the presence of breeding sites in the cases of positive tests (X^2 greater than 3.84 in each of them). The risk estimate showed that the I and III trimesters are risk factors for having breeding sites (OR: 0.49, OR: 8.25 respectively), both results can be generalized to the total population as indicated by the CI (1.012-17.97, 1.31 to 52.01). Although it is advisable to expand the sample due to the disperse of the intervals. These results explain that it may be due to the fact that they coincide with the country's rainy season.

The I trimester constitutes a protective factor (OR: 0.26) for not having breeding sites and the results

can be generalized in CI 0.08 - 0.79; a result that coincides with the dry season where the presence of breeding sites decreases. When measuring the relationship of the variables, it was shown ($X^2 = 6.33$, $p = 0.0059$) that the cases confirmed by Zika virus in the I trimester is a protective factor (OR= 0.26) and the III trimester, as risk factor (OR= 8.25). It is considered good, but not very precise to apply it to the population (CI=1.31- 52.01). The female of the 'Aedes Aegypti' is capable of laying 700 eggs and biting and infecting several people (WHO, 2015).

Humidity, temperature, the sex of the mosquito and the time of year are factors that allow the life of mosquitoes; males usually live for short times, about a week, while females survive up to a month. (WHO, 2016). The eggs can withstand very dry conditions (desiccation) and remain viable for several months without water. (WHO, 2019). That is why staying with mosquito breeding sites is a risk factor for Zika virus infection.

Table N°3: Statistical Summary of Risk Factors for Zika Viral Infection.

FACTOR DE PROTECTOR	X^2	p	OR	IC
Procedencia en Llano Bonito	5.42	0.01	0.49	0.27-0.90
Sin criaderos	4.88	0.0136	0.48	0.25-0.93
I trimestre epidemiológico en población en estudio	14.14	0.0001	0.44	0.28- 0.67
II trimestre epidemiológico en población en estudio	6.43	0.0056	0.37	0.17-0.81
I trimestre epidemiológico con criaderos	6.33	0.0059	0.26	0.08-0.79

Fuente: Base de datos del Sistema de Vigilancia Epidemiológica de la Región de Salud de Herrera 2016 y 2017.

The I trimester and the II trimester were protective factors for not having the Zika virus (I trimester OR: 0.44, II trimester OR: 0.37), respectively. Both quarters can be generalized to the Health Region of Herrera by the results of the confidence intervals of the sample, (I quarter CI: 0.28 -0.67 and II quarter CI: 0.17-0.81). There are times of the year when the different species of mosquitoes may be more abundant than others, but not all mosquitoes are affected or favored by the same climatic-environmental conditions.

For each species there are certain environmental characteristics that are more or less favorable. "If we refer to Aedes Aegypti, vector of dengue, fiebre amarilla, Zika and Chikungunya, Chikungunya, among other viruses, we say that the time of highest temperatures and rainfall is the most favorable for reproduction. And that the low temperatures of winter (below 13°C) affect adult females and males and they die. But the eggs resist these low temperatures and even lower, spending the embryo all winter inside the egg" (Álvarez, 2017.)

In the Herrera Region in 2016 and 2017, 342 suspected cases of Zika virus were detected, in which 161 cases distributed throughout the Chitré district were

confirmed. Of these, they occurred with the highest concentration in the districts of San Juan Bautista with 11.1% (38), Monagrillo with 9.6% (33) and Llano Bonito with 5% (18). Therefore, it is important to increase epidemiological surveillance measures for the Zika virus at all levels of care, both in public and private facilities, for timely detection of the virus; as well as the follow-up and complications that it produces.

The risk factors were: the presence of breeding sites in the months of October, November and December, it is frequent in the ages of 20 to 39 years and the male sex, in addition there is no relationship between the characteristics of people and the infection of the virus of Zika. Therefore, the Zika virus test should be mandatory for the timely detection of all pregnant women, blood donors, organ donors, all couples in the process of contracting marriage, and all men and women of childbearing age who request it.

REFERENCIAS BIBLIOGRÁFICAS

1. Álvarez Escobar, María del Carmen, Torres Álvarez, Arnella, Torres Álvarez, Arling, Semper,
2. Abel Iván, & Romeo Almanza, Daniel. (2018). Dengue, chikungunya, Virus de Zika. Determinantes

- sociales. *Revista Médica Electrónica*, 40(1), 120-128. Recuperado en 20 de abril de 2019, de http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S1684-18242018000100013&lng=es&tlng=es.
3. Birmingham. (2013). Edad y Fertilidad - ReproductiveFacts.org. 20 de Abril 2019, de AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE. Recuperado en: https://www.reproductivefacts.org/globalassets/.../edad_y_fertilidad-spanish.pdf.
 4. BBC Mundo. (2016). Qué es el virus zika, la enfermedad que se propagó por América Latina en 2016. 16 de junio 2016, de BBC NEW MUNDO. Recuperado en: https://www.bbc.com/mundo/noticias/2015/06/150611_salud_virus_zika_pregunta_s_respuestas_kv
 5. Castro, T. (2016). Virus Zika, una nueva epidemia en puerta.. *REVISTA BIOMÉDICA*, 27(1). doi:<https://doi.org/10.32776/revbiomed.v27i1.11>.
 6. Centers for Disease Control and Prevention. Zika Virus. (2016). Recuperado en: <http://www.cdc.gov/media/dpk/2016/dpk-zika-virus.html>.
 7. Dirección General de Epidemiología: Boletín Epidemiológico. Secretaría de Salud. (2016); 6(33): 35. [Acceso: 28 de septiembre del 2017]. Recuperado en: http://www.epidemiologia.salud.gob.mx/dgae/boletin/intd_boletin.html.
 8. Farreras Rozman (2016) Directrices para los laboratorios de los EE. UU que realicen pruebas de detección de la infección por el virus del Zika. CDC Foundation. Comprehensive Zika prevention campaign launches in Puerto Rico. Atlanta, GA: CDC Foundation; Recuperado en: <http://www.cdcfoundation.org/pr/2016/comprehensive-zika-prevention-campaign-launches-puerto-rico>.
 9. Ibáñez Martí, C. (2012). Que es la incidencia y la prevalencia de una enfermedad. 20 de abril 2019, de salud Pública y algo más. Recuperado en: https://www.madrimasd.org/blogs/salud_publica/2012/02/29/133136.
 10. Instituto Nacional de estadística y Censo. (2018). Características Generales 2010 y Educativas. 20 de abril 2019, de INEC. Recuperado en: https://www.inec.gob.pa/publicaciones/Default3.aspx?ID_PUBLICACION=356&ID_CATEGORIA=13&ID_SUBCATEGORIA=59
 11. OMS (2017). Informe sobre la situación virus de zika microcefalia síndrome de Guillain-barré 2 De febrero de 2017 (datos al 1 de febrero de 2017) Recuperado en: <http://apps.who.int/iris/bitstream/10665/254635/1/zikasitrep2feb17-spa.pdf>.
 12. OMS. (2015). Lucha contra el Dengue. 20 de abril 2019, de Organización Mundial de la Salud Sitio web: <https://www.who.int/denguecontrol/mosquito/es/>.
 13. OMS. (2016). Lucha contra el Dengue. 20 de abril 2019, de Organización Mundial de la Salud Sitio web: <https://www.who.int/denguecontrol/mosquito/es/>.
 14. OMS. (2019). Lucha contra el dengue. 20 DE ABRIL 2019, de Organización Mundial de la Salud Recuperado en: https://www.who.int/denguecontrol/control_strategies/es
 15. Zelmar Michelini, (2019). Mosquitos: ¿por qué te pican más?. 20 de abril 2019, de Montevideo, Uruguay. Copyright © EL PAIS S.A. Recuperado en: <https://www.elpais.com.uy/vida-actual/mosquitos>.



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Knowledge Evaluation of Accredited Social Health Activists (ASHAs) on Maternal and Child Health, in a Rural Area of Gomati District, Tripura

By Dr. Sampa Mitra

Abstract- Background: National Rural Health Mission (NRHM) provides a trained female community health worker i.e., Accredited Social Health Activist (ASHA), to every Indian village. An ASHA acts as a bridge between the rural people and the health service outlets.

Objective: The objective is to understand the knowledge levels of ASHAs regarding various aspects of maternal and child health.

Method: This cross-sectional study, conducted between April 2017 and July 2017, attempts to assess the knowledge levels of 232 ASHAs, working in Ompi CHC (Community Health Centre), Killa PHC (Primary Health Centre) and Atharabula PHC. These centres are located in Ompi RD (Rural Development) Block and Killa RD Block of Gomati District of Tripura. Knowledge level is assessed by performing binomial test at 5% level of significance.

Keywords: ASHA, Gomati District, knowledge level, maternal and child health, binomial test, cross-sectional study.

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Results: The test results show that a significant number of ASHAs (working in the aforesaid centres) have correct knowledge regarding various aspects of the subjects of antenatal care, postnatal care, breastfeeding, child health, immunization and family planning, except the following topics: (a) whether women should carry out heavy manual labour during pregnancy, (b) the minimum number of postnatal check-ups required, (c) the time interval after pregnancy, up to which abortion is legal, and (d) what an oral contraceptive pill (OCP) is.

Conclusions: Since all ASHAs should have correct knowledge about all aspects of all of the aforesaid subjects, there is no room for complacency, and immediate arrangements should be made for proper and adequate training of the ASHAs, especially with regard to the abovementioned topics.

Keywords: ASHA, Gomati District, knowledge level, maternal and child health, binomial test, cross-sectional study.

I. INTRODUCTION

One of the key features of the National Rural Health Mission (NRHM) is to provide a trained female community health worker i.e., Accredited Social Health Activist (ASHA) to every Indian village (1). An ASHA acts as a bridge between the rural people and the health service outlets, and plays a central role in achieving the national health and population policy goals. An ASHA is expected to provide antenatal, natal

and postnatal services to women, give primary medical care (using her kit), assist in the control of diseases with the help of proper information, education and surveillance, counsel people (especially women) on family planning, safe abortion, child immunization, Vitamin A supplementations, appropriate breastfeeding, birth spacing, sex discrimination, child marriage, girls' education, and care of the child (especially newborn), help in household surveys, collaborate with health functionaries working for the community disease control, create awareness on health and its determinants, support the people in utilizing the existing health services etc. (1).

The performance of ASHAs is, therefore, crucial for the success of NRHM.

The objective of this work is to assess the knowledge levels of the ASHAs, with regard to various aspects of maternal and child health, in a rural area of Gomati District, Tripura.

For understanding the knowledge levels of ASHAs, the binomial tests have been done at 5% level of significance.

Before undertaking this study, a brief literature survey has been conducted. However, no study dealing with knowledge evaluation of ASHAs of Gomati District of Tripura, on maternal and child health, has been found.

II. MATERIALS AND METHODS

It is a cross-sectional study, conducted between April 2017 and July 2017, on 232 ASHAs working in Ompi CHC (Community Health Centre), Killa PHC (Primary Health Centre) and Atharabula PHC. These centres (i.e., two PHCs and one CHC) are located in Ompi RD (Rural Development) Block and Killa RD Block; these two blocks have been selected by the simple random sampling method from the eight RD blocks of the Gomati District of Tripura.

All ASHAs working in the aforesaid centres, during the study period, who have given informed consent regarding participation in this study, have been included; only those ASHAs who are not willing to participate even after knowing the purpose of the study, have been excluded from the study. It may be noted here that, at the very beginning, the purpose and the objective of the study have been clearly discussed

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with the prospective participants, and they have been given the option to participate or quit at any time.

Data have been collected with the help of a pre-designed, pre-tested and semi-structured questionnaire. ASHAs have been visited on ASHA Varosa Divas of each centre, and interviewed face-to-face using the questionnaire. All the collected data have been tabulated, and utilized to perform binomial tests (2), and the results of the tests have been subsequently interpreted.

The formula (3,4) for calculating the p-value (p_1), pertaining to the binomial test, is given in equation-1:

$$p_1 = 2 (n! / ((n-X)! X!)) p^X q^{(n-X)} \dots \quad 1$$

where, n =total number of ASHAs participating in the study=232;

$X=n/2=116$;

p =proportion of ASHAs who have given correct answer, in response to a question;

q =proportion of ASHAs who have given incorrect answer, in response to the same question.

If $p_1 < 0.05$, for a question, then it can be inferred that a significant number of ASHAs have correct knowledge with regard to the topic associated with the question; otherwise, the number of ASHAs, having correct knowledge, is not significant.

The values of p_1 are calculated for all the questions associated with a particular subject, and subsequently averaged (using the formula for arithmetic mean) to get p_{1min} . If $p_{1min} < 0.05$, for a subject, then it can be inferred that a significant number of ASHAs have correct knowledge with regard to the particular subject; otherwise, the number of ASHAs, having correct knowledge, is not significant.

If $p < 0.5$ (and consequently, $q > 0.5$), then the value of p_1 may generate erroneous inference regarding significance. Hence, in these cases (where $p < 0.5$ and $q > 0.5$), p and q are both taken as 0.5 only for the sake of calculating p_1 .

Since the data have been collected for purely academic purpose, and the permission for data collection has been obtained from the CMOH (Chief Medical Officer of Health) of the Gomati District, and also the MOICs (Medical Officers in Charge) of the respective centres, there is no chance of any kind of exploitation involved in this study.

The necessary research and ethical clearances have been taken from the author's institution.

The method used in this work, is shown in fig.-1.

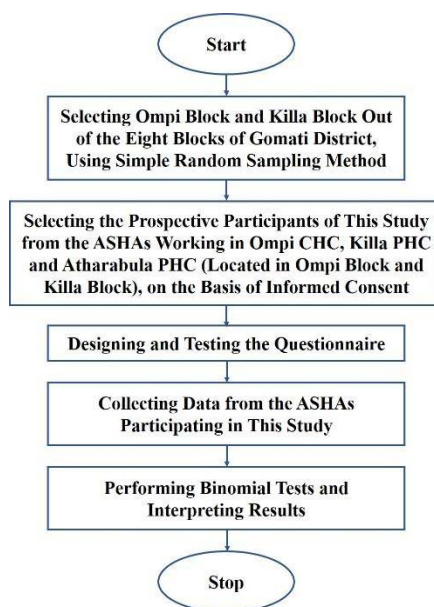


Fig.-1: Flowchart depicting the method

III. RESULTS

The knowledge levels of ASHAs with regard to antenatal care, postnatal care, breastfeeding, child health, immunization and family planning, are shown respectively in tables- 1-5.

Table-1: Knowledge of ASHAs regarding antenatal care (ANC) (n=232)

Serial Number	Question	Number of Correct Answers	Number of Incorrect Answers	p1
1.	What is the optimal time for registration of pregnant women?	222 (95.7%)	10 (4.3%)	0
2.	What is the minimum number of ANC check-ups required?	220 (94.8%)	12 (5.2%)	0
3.	Is early pregnancy diagnosis to be done by testing urine, stool or blood?	181 (78.0%)	51 (22.0%)	1.1549X10 ⁻²⁰
4.	What is the purpose of Nischay kit?	198 (85.3%)	34 (14.7%)	1.8090X10 ⁻³⁶
5.	How many times should the pregnant women (primi) be given tetanus toxoid (TT) injection?	210 (90.5%)	22 (9.5%)	0
6.	What is the implication if after blood test, haemoglobin concentration level is found to be less than 7.0 gm/dl?	168 (72.4%)	64 (27.6%)	5.4158X10 ⁻¹³
7.	Is there any necessity to give women more food during pregnancy?	219 (94.4%)	13 (5.6%)	0
8.	Should women carry out heavy manual labour during pregnancy?	102 (44.0%) 116 (50.0%) (for calculating p1)	130 (56.0%) 116 (50.0%) (for calculating p1)	0.1046
9.	What is the minimum period for which all pregnant women must take IFA (iron and folic acid) tablet (1 tablet daily) to prevent anaemia?	139 (59.9%)	93 (40.1%)	1.0111X10 ⁻³
10.	What are the side effects of IFA tablet?	151 (65.1%)	81 (34.9%)	1.5910X10 ⁻⁶
11.	What are the potential danger signs during pregnancy which prompt immediate referral?	196 (84.5%)	36 (15.5%)	2.8340X10 ⁻³⁴
12.	Is it the duty of an ASHA to escort the pregnant women to the hospital for institutional delivery?	229 (98.7%)	3 (1.3%)	0
13.	What should an ASHA do if, after home delivery, mother reports excessive vaginal bleeding or severe abdominal pain?	151 (65.1%)	81 (34.9%)	1.5910X10 ⁻⁶
14.	What is the meaning of birth-preparedness?	178 (76.7%)	54 (23.3%)	1.2826X10 ⁻¹⁸

For table-1, $p_{1\min}=0.008$. This implies that a significant number of ASHAs (78.9%) have correct knowledge with regard to antenatal care.

Table-2: Knowledge of ASHAs regarding postnatal care (PNC) (n=232)

Serial Number	Question	Number of Correct Answers	Number of Incorrect Answers	p1
1.	What is the meaning of postnatal period?	138 (59.5%)	94 (40.5%)	1.4699×10^{-3}
2.	What is the minimum number of postnatal check-ups required?	99 (42.7%) 116 (50.0%) (for calculating p1)	133 (57.3%) 116 (50.0%) (for calculating p1)	0.1046
3.	What are the common major complications which can happen during the postpartum period?	193 (83.2%)	39 (16.8%)	5.3545×10^{-31}
4.	What should be the minimum spacing between two live child births?	213 (91.8%)	19 (8.2%)	0
5.	Which women are more at the risk of developing complications during delivery?	158 (68.1%)	74 (31.9%)	8.7765×10^{-9}
6.	What is the time interval following delivery, after which the placenta usually comes out?	171 (73.7%)	61 (26.3%)	1.5836×10^{-14}

For table-2, $p_{1\min}=0.018$. This means that a significant number of ASHAs (69.8%) have correct knowledge regarding postnatal care.

Table-3: Knowledge of ASHAs regarding breastfeeding (n=232)

Serial Number	Question	Number of Correct Answers	Number of Incorrect Answers	p1
1.	Why is colostrum necessary for a newborn baby?	206 (88.8%)	26 (11.2%)	0
2.	When should a newborn be put to breast, after birth?	221 (95.3%)	11 (4.7%)	0
3.	At least how many times should a newborn be breastfed per day?	195 (84.1%)	37 (15.9%)	3.1401×10^{-33}
4.	What are the indications of inadequate breastfeeding to a baby?	170 (73.3%)	62 (26.7%)	4.8518×10^{-14}
5.	What should be the duration of exclusive breastfeeding, according to WHO (World Health Organization)?	210 (90.5%)	22 (9.5%)	0
6.	What is the age at which, complementary food is necessary for a baby?	225 (97.0%)	7 (3.0%)	0

For table-3, $p_{1\min}<0.001$. So, it can be said that a significant number of ASHAs (88.2%) have correct knowledge with regard to breastfeeding.

Table-4: Knowledge of ASHAs regarding child health (n=232)

Serial Number	Question	Number of Correct Answers	Number of Incorrect Answers	p1
1.	What is the minimum body weight of a normal baby at birth?	226 (97.4%)	6 (2.6%)	0
2.	When should a baby be considered to have low birthweight (LBW)?	128 (55.2%)	104 (44.8%)	0.0296
3.	What are the signs of a high risk baby?	148 (63.8%)	84 (36.2%)	1.0664X10 ⁻⁵
4.	What are the signs/symptoms due to which, an ASHA should advise the mother/family to take a baby to the hospital immediately?	182 (78.4%)	50 (21.6%)	2.4879X10 ⁻²¹
5.	What are the signs/symptoms which indicate severe dehydration of a baby in case of diarrhoeal disease?	183 (78.9%)	49 (21.1%)	3.4374X10 ⁻²²
6.	Should a baby be given bath immediately after birth?	203 (87.5%)	29 (12.5%)	0
7.	When can the body temperature of a newborn baby be considered as less than normal?	190 (81.9%)	42 (18.1%)	4.8999X10 ⁻²⁸
8.	How many times should an ASHA undertake home visit, in case of institutional delivery?	186 (80.2%)	46 (19.8%)	1.4319X10 ⁻²⁴
9.	How many times should an ASHA undertake home visit, in case of home delivery?	205 (88.4%)	27 (11.6%)	0

For table-4, $p_{1\min}=0.003$. Thus, it can be inferred that a significant number of ASHAs (79.1%) have correct knowledge regarding child health.

Table-5: Knowledge of ASHAs regarding immunization and family planning (n=232)

Serial Number	Question	Number of Correct Answers	Number of Incorrect Answers	p1
1.	What are the disease/diseases against which BCG (Bacillus Calmette-Guérin) vaccine provides protection?	225 (97.0%)	7 (3.0%)	0
2.	What are the disease/diseases against which DPT* vaccine provides protection?	192 (82.8%)	40 (17.2%)	4.6920X10 ⁻³⁰
3.	What is the minimum interval between two doses of Vitamin A?	182 (78.4%)	50 (21.6%)	2.4879X10 ⁻²¹
4.	Up to what time interval after pregnancy, is abortion legal?	108 (46.6%) 116 (50.0%) (for calculating p1)	124 (53.4%) 116 (50.0%) (for calculating p1)	0.1046
5.	What is a condom (nirodh)?	129 (55.6%)	103 (44.4%)	0.0242
6.	What is an oral contraceptive pill (OCP)?	92 (39.7%) 116 (50.0%) (for calculating p1)	140 (60.3%) 116 (50.0%) (for calculating p1)	0.1046
7.	What are the ways through which HIV (human immunodeficiency virus) can pass from one person to other persons?	151 (65.1%)	81 (34.9%)	1.5910X10 ⁻⁶

*DPT: diphtheria, pertussis and tetanus toxoid

For table-5, $p_{1\min}=0.033$. Hence, it may be concluded that a significant number of ASHAs (66.5%) have correct knowledge regarding immunization and family planning.

At the end of each table, the percentage for the significant number of ASHAs has been calculated by averaging the percentages corresponding to the number of correct answers, in the corresponding table.

The values of p_1 in tables- 1-5 show that a significant number of ASHAs have correct knowledge regarding the topic associated with each of the questions, except question number-8 of table-1, question number-2 of table-2, and question numbers- 4 and 6 of table-5.

IV. DISCUSSIONS

From tables- 1-5, the following inferences can be drawn:

- A significant number of ASHAs (working in the aforesaid centres) have correct knowledge with regard to various aspects of the subjects of antenatal care (78.9%), postnatal care (69.8%), breastfeeding (88.2%), child health (79.1%), immunization and family planning (66.5%).
- A significant number of ASHAs do not have correct knowledge on each of the following topics: (a) whether women should carry out heavy manual labour during pregnancy (56.0%), (b) the minimum number of postnatal check-ups required (57.3%), (c) the time interval after pregnancy, up to which abortion is legal (53.4%), and (d) what an oral contraceptive pill (OCP) is (60.3%).
- All ASHAs should have correct knowledge about all aspects of all of the aforesaid subjects (viz., antenatal care, postnatal care, breastfeeding, child health, immunization and family planning). But, the situation is quite far from the reality. Hence, there is no room for complacency, and immediate arrangements should be made for proper and adequate training of the ASHAs, particularly with regard to the four aforesaid topics, pertaining to each of which, a significant number of ASHAs do not have correct knowledge.

Now, a brief review of the outcomes of some of the other studies on ASHAs, may help in understanding the relevance of this work.

A study undertaken by Garg et al. shows that in some villages of rural Haryana, majority of ASHAs knew about assisting in immunization (100%), accompanying women for delivery (98%), and providing antenatal care (96.10%) and family planning (96.40%) services, as a part of their duty (5). In the current study also, it has been found that a significant number of ASHAs have thorough knowledge about antenatal care (78.9%), immunization and family planning (66.5%).

Fathima et al. conducted a survey on ASHAs of some parts of Karnataka, and found that a significant number of ASHAs (>80%) were involved in home visits, and counselling with regard to antenatal care, breastfeeding and immunization, but only a small proportion (<25%) of ASHAs gave advice on the use of contraceptives (6). These observations, except the one concerning contraceptives, are similar to those of the current study, where it has been found that a considerable number of ASHAs have good knowledge about antenatal care (78.9%), breastfeeding (88.2%), immunization and family planning (66.5%). However, in the present study, 55.6% of the ASHAs know what a condom (nirodh) is (though only 39.7% of them know what an oral contraceptive pill (OCP) is).

Guha et al. worked on the ASHAs of some villages of Maharashtra (Wardha), and observed that though majority of the ASHAs undertook home visits and assisted in antenatal care and postnatal care, only a few of them were aware of their roles in facilitating breastfeeding and the use of contraceptives (7). Regarding antenatal care and postnatal care, their findings are similar to those of the present study which indicates good knowledge among significant number of ASHAs about antenatal care (78.9%) and postnatal care (69.8%). But, unlike their observations about breastfeeding and contraceptives, the present study indicates that a considerable number of ASHAs are knowledgeable about breastfeeding (88.2%) and condom (nirodh) (55.6%). (However, according to the current study, only 39.7% of the ASHAs know what an oral contraceptive pill (OCP) is.)

Taksande et al. studied the ASHAs of selected villages of Maharashtra (Wardha), and found that 48% of them were aware of the antenatal care registration in clinic (8). This outcome is not quite in agreement with the finding of the current study that 78.9% of the ASHAs have good knowledge about antenatal care.

Panda et al. undertook a study on ASHAs working in some parts of Odisha, and found that 100% of the ASHAs helped in immunization, and 98% of them knew about family planning activities (9). Their observations are similar to that of the current study that majority of the ASHAs (66.5%) have correct knowledge about immunization and family planning.

Sugandha et al., after conducting a study on the ASHAs of Mysuru (Karnataka), noted that 51.5% of them had average knowledge about antenatal care, 86.1% had good knowledge regarding postnatal care, and 90.5% had thorough knowledge about contraception (10). With regard to postnatal care and contraception, there are similarities between their outcomes and those of the current study, since the present study indicates correct knowledge, among significant number of ASHAs, in the fields of postnatal care (69.8%), immunization and family planning (66.5%). However, in contrast to their observation

about antenatal care, the current study shows that a considerable number of ASHAs (78.9%) have good knowledge about antenatal care.

Chaurasiya et al., after analyzing relevant information regarding the services provided by the ASHAs, collected from their beneficiaries (i.e., mothers having child up to 2 years of age), in some villages of a district of western Uttar Pradesh, observed that ASHAs escorted 43.5% of the beneficiaries ≥ 4 times to the hospital/health centre for antenatal care visit, and performed ≥ 6 home visits for postnatal care for 57.2% of the beneficiaries (11). These observations indicate that majority of the ASHAs have good knowledge about postnatal care, but not antenatal care. However, in the present study, significant number of ASHAs have been found to have thorough knowledge regarding both antenatal care (78.9%) and postnatal care (69.8%).

Bhattacharya et al. worked on how the pregnant women utilized services of the ASHAs in some villages of the West Tripura District of Tripura, and found that the ASHAs helped 76.69% of the women to have adequate antenatal check-ups (12). This finding indicates that majority of the ASHAs have good knowledge about antenatal care, and hence, is similar to the outcome of the current study that 78.9% of the ASHAs have thorough knowledge about antenatal care.

V. CONCLUSIONS

The work has attempted to assess the knowledge levels of the ASHAs, with regard to various aspects of maternal and child health, in a rural area of Gomati District, Tripura. On the basis of the results of the binomial tests, it can be concluded that a significant number of ASHAs, associated with Ompi CHC, Killa PHC and Atharabula PHC, have correct knowledge regarding various aspects of the subjects of antenatal care, postnatal care, breastfeeding, child health, immunization and family planning, except certain topics viz., heavy manual labour by women during pregnancy, minimum number of postnatal check-ups, time-limit of abortion after pregnancy, and oral contraceptive pill (OCP). However, since all ASHAs need to become aware of all the relevant details with respect to the aforesaid subjects, there is an urgent need for proper and adequate training of the ASHAs, especially with regard to the four abovementioned topics.

A more comprehensive idea about the ASHAs of Tripura could have been had, if data were collected from other districts also. Besides, a more detailed questionnaire might have been helpful in judging the ASHAs' knowledge levels regarding various aspects of maternal and child health, to a greater degree. If possible, these tasks may be taken up in future.

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REFERENCES RÉFÉRENCES REFERENCIAS

1. National Health Mission. About Accredited Social Health Activist (ASHA) [Internet]. 2021. Available from: <https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=150&lid=226>
2. Newcastle University. Hypothesis Testing with the Binomial Distribution [Internet]. Newcastle University. 2022. Available from: <https://www.ncl.ac.uk/webtemplate/ask-assets/external/maths-resources/statistics/hypothesis-testing/hypothesis-testing-with-the-binomial-distribution.html>
3. Mitra S, Chakraborty B. A Study on the Socio-Demographic and the Clinical Profiles, Along with Some Management Indicators, of the MDR TB Patients at the Domjur Block, Howrah District, West Bengal, India. J Bacteriol Infect Dis [Internet]. 2020; S(2). Available from: <https://www.alliedacademies.org/articles/a-study-on-the-sociodemographic-and-the-clinical-profiles-along-with-some-management-indicators-of-the-mdr-tb-patients-a.pdf>
4. Van den Berg RG. Binomial Test - Simple Tutorial [Internet]. SPSS Tutorials. 2022. Available from: <https://www.spss-tutorials.com/binomial-test/>
5. Garg PK, Bhardwaj A, Singh A, Ahluwalia SK. An Evaluation of ASHA Worker's Awareness and Practice of Their Responsibilities in Rural Haryana. Natl J Community Med. 2013; 4(1): 76–80.
6. Fathima FN, Raju M, Varadharajan KS, Krishnamurthy A, Anathkumar SR, Mony PK. Assessment of 'Accredited Social Health Activists'-A National Community Health Volunteer Scheme in Karnataka State, India. J Heal Popul Nutr. 2015; 33(1): 137–45.
7. Guha I, Raut AV, Maliye CH, Mehendale AM, Garg BS. Qualitative Assessment of Accredited Social Health Activists (ASHA) Regarding Their Roles and Responsibilities and Factors Influencing Their Performance in Selected Villages of Wardha. Int J Adv Med Heal Res. 2018; 5(1): 21–6.
8. Taksande VD, Ashtankar PA, Bansod CR, Bawane AV, Burchunde PS, Dudhe DV, et al. To Assess the Job-Related Difficulties and Dissatisfaction of Asha

Workers in Selected Rural Area. J Evol Med Dent Sci. 2021; 10(2): 98–101.

9. Panda M, Nanda S, Giri RC. A Study on the Work Profile of ASHA Workers in a District of Odisha in Eastern India. Int J Community Med Public Heal. 2019; 6(2): 675–81.
10. Sugandha BK, Jagannath P. Knowledge of ASHA Workers About Maternal and Child Health Services in Mysuru. Public Heal Rev - Int J Public Heal Res. 2019; 6(4): 169–76.
11. Chaurasiya SK, Singh NP, Shukla SK, Bajpai PK, Mathew DJ. Assessment of the Services of ASHA Workers on Antenatal and Postnatal Care in a District of Western Uttar Pradesh, India. J Fam Med Prim Care. 2020; 9(7): 3502–7.
12. Bhattacharya H, Luwang N, Sarkar M, Chakraborty T, Baidya S. Utilization of ASHA Services by the Pregnant Women of Rural Tripura, India. Int J Res Med Sci. 2015; 3(9): 2223–7.





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The Questionnaire: Tools for Measuring and Evaluating Inpatient Satisfaction

By Moukhafi Sahar

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Abstract- Patient satisfaction is currently at the heart of recent economic studies in hospital management. It remains a goal and a challenge for all stakeholders. In fact, it is emerging as one of the ways to evaluate and improve the quality of care.

This article is inspired by the growing interest in assessing patient satisfaction as a key indicator of quality of care.

The objective of this article is therefore to define and identify the aspects of patient satisfaction measurement, in particular the questionnaire which represents an essential measurement tool in the field.

Keywords: *measurement of patient satisfaction, questionnaire, quality of care, hospital world.*

GJMR-K Classification: *DDC Code: 302.072 LCC Code: H62*



Strictly as per the compliance and regulations of:



The Questionnaire: Tools for Measuring and Evaluating Inpatient Satisfaction

Le Questionnaire: Outils De Mesure Et D'évaluation De La Satisfaction Des Patients Hospitalisés

Moukhafi Sahar

Résumé- Actuellement, la satisfaction des patients est au cœur des études économiques récentes en management hospitalier. elle demeure un objectif et un défi à la fois pour toutes les parties prenantes. En réalité, elle se profile comme l'une des voies permettant l'évaluation et l'amélioration de la qualité des soins.

Cet article s'inspire de cet engouement croissant envers l'évaluation de la satisfaction des patients autant qu'un indicateur primordial de la qualité des soins.

L'objectif de cet article est donc de définir et de cerner les aspects de mesure de la satisfaction du patient, en particulier le questionnaire qui représente un outil de mesure incontournable dans le domaine.

Mots-clés: mesure de la satisfaction du patient, questionnaire, qualité des soins, monde hospitalier.

Abstract- Patient satisfaction is currently at the heart of recent economic studies in hospital management. It remains a goal and a challenge for all stakeholders. In fact, it is emerging as one of the ways to evaluate and improve the quality of care.

This article is inspired by the growing interest in assessing patient satisfaction as a key indicator of quality of care.

The objective of this article is therefore to define and identify the aspects of patient satisfaction measurement, in particular the questionnaire which represents an essential measurement tool in the field.

Keywords: measurement of patient satisfaction, questionnaire, quality of care, hospital world.

INTRODUCTION

Nul ne semble contester aujourd'hui que la maîtrise de la qualité dans le secteur de santé publique constitue à la fois une exigence et une nécessité. La qualité des prestations hospitalières publiques doit généralement répondre aux besoins de la population et satisfaire ses exigences pour pouvoir créer les conditions nécessaires à une amélioration sûre et durable de toutes les activités socio- économiques du pays.

Il faut savoir que le développement des concepts de qualité dans le domaine des soins médicaux au cours de la dernière moitié du XX^{ème} siècle s'est accompagnée de changements importants dans la politique et l'éthique du secteur de santé. Avec le

temps, le principe du « bienfaisant » a été graduellement supplanté par les principes d'autonomie et de consumérisme des patients, et l'intérêt de la perspective du patient s'est développé. Une conséquence de ce paradigme est une augmentation des travaux liés aux points de vue des patients, à leurs désirs et à leurs attentes par rapport aux soins médicaux. L'appréciation du patient au travers de la satisfaction est une excellente occasion de le faire participer de façon active dans l'évaluation du processus de prise en charge des soins. Cette démarche est importante pour les politiciens, les managers, les cliniciens et les chercheurs. Respecter les préférences des patients est un des aspects qui permet d'améliorer la performance d'un système de soins. Les lois, les décrets et ordonnances ne conduisent pas automatiquement à une amélioration de la qualité de la prise en charge des patients. Ils visent avant tout à une recherche de la qualité – dans les actes et les gestes du personnel hospitalier ayant des contacts directs ou indirects avec les patients –, à établir un environnement le plus agréable possible et à organiser la prise en charge la plus cohérente possible.

En effet, L'amélioration de la qualité des soins passe par la modification des systèmes de soins. Pour cela, il est indispensable de chercher à répondre aux besoins des patients. Ainsi, parmi différentes approches de la qualité, l'évaluation de la satisfaction des patients, en tant qu'indicateur pertinent de la qualité des soins, s'est développée au cours des 25 dernières années. Plus récemment, le terme de satisfaction a été progressivement remplacé par celui d'évaluation de la qualité par le patient.

La mesure de la satisfaction des patients est considérée comme l'un des outils de l'évaluation de la qualité de soins. L'évaluation de la qualité des soins est une démarche frontière avec l'épidémiologie, discipline avec laquelle elle entretient des liens étroits. Tandis que l'épidémiologie est consacrée aux problèmes de santé de la population, l'évaluation de la qualité des soins privilégie:

- Un groupe de population particulier : les patients, c'est-à-dire les personnes ayant recours aux soins

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auprès d'un professionnel ou d'un établissement de santé.

- Un déterminant particulier de l'état de santé : les soins délivrés, en particulier les moyens utilisés, l'organisation mise en œuvre, et les pratiques des professionnels de santé.

Cette démarche permet en permanence de comparer la réalité des soins délivrés, avec des références. Sa mise au point fait appel aux méthodes épidémiologiques. Elle utilise un vocabulaire spécifique¹.

Ce qui nous pousse à se poser les questions suivantes:

Comment mesurer le niveau de satisfaction du patient ?

Comment rendre la satisfaction du patient qui porte un caractère subjectif quantitatif ?

Comment utiliser le questionnaire comme un outil de mesure performant ?

o Points de vue de la mesure de la satisfaction

Il y a trois aspects du point de vue de la mesure qu'il faut prendre en considération dans la mesure de la satisfaction du patient:

- a. A partir de quelle préoccupation est construit un instrument de mesure: des patients, des professionnels ou de l'administration ?
- b. Auprès de qui la mesure est-elle réalisée: les patients, les professionnels ou l'administration ?
- c. A qui sont destinés les résultats de la mesure: aux professionnels ou à l'administration ? Concernant les professionnels ; comprendre et répondre aux besoins des patients est la priorité de la médecine. Il faut savoir que connaître les attentes des patients génère une plus grande satisfaction au niveau des soins, ce qui engendre une plus grande adhésion au traitement. Analyser les buts et les attentes des patients permet de prendre les décisions cliniques dans lesquelles les préférences sont importantes, mais, à cause des attentes des patients qui peuvent parfois être déraisonnables, les praticiens doivent être préparés à éduquer leurs patients. Finalement, donner ne importance aux attentes des patients procure des chances pour les négociations cliniques et fait que le patient ait un rôle actif dans les relations médicales, qui peuvent elles-mêmes apporter de meilleurs résultats.

Concernant l'administration; améliorer la qualité des prestations tant des soins eux-mêmes que de l'environnement des soins est une nécessité. Et respecter les préférences des patients est une des dimensions qui permet de mesurer la performance d'un système de soins. Ceci dit, des attentes irréalistes ou erronées peuvent augmenter l'utilisation et le coût des

soins de santé alors qu'elles ne produisent qu'un petit bénéfice. Comprendre les attentes des patients peut aider les efforts éducatifs visant à réduire d'irraisonnables demandes (Kravitz, 1996)².

L'étude de la satisfaction n'est significative que si la position de celui qui observe, d'une part, et l'objectif poursuivi, d'autre part, sont connus³.

Il existe un autre point de vue dans la mesure de la satisfaction des patients, c'est celui des chercheurs qui ont pour but d'identifier les déterminants, les conséquences de la satisfaction ou les facteurs susceptibles de l'améliorer. Les attentes des patients peuvent servir de variables indépendantes dans l'étude de la satisfaction des patients, le comportement des praticiens, le choix des consommateurs pour le fournisseur de soins et la qualité des soins. Les attentes des patients peuvent servir également de variables dépendantes dans l'étude de la façon dont les patients développent leurs attentes, l'influence de la profession médicale et de l'industrie de soins sur leur développement et où l'éducation et les autres efforts de persuasion peuvent les mener.

Champs de l'épidémiologie

En 1968, l'OMS définit l'épidémiologie : « l'étude de la distribution des maladies et des invalidités dans les populations humaines, ainsi que des influences qui déterminent cette distribution ».

Il faut savoir que l'épidémiologie est opérationnelle: elle décrit, explique, évalue, pour agir.

Ainsi, elle fait partie de la démarche de santé publique, toujours selon l'OMS, « les études épidémiologiques ont trois objectifs:

- 1) Orienter le développement des services de santé en définissant l'ampleur et la distribution des phénomènes morbides dans la collectivité.
- 2) Dégager les facteurs étiologiques de façon à permettre d'enrayer ou de modifier la maladie.
- 3) Fournir une méthode de mesure de l'efficacité des services mis en œuvre pour lutter contre la maladie, et améliorer l'état de santé de la collectivité ».

Il existe donc trois types d'épidémiologie : descriptive, explicative et évaluative⁴.

Champs des études de la satisfaction

Comme nous l'avons déjà précisé dans la partie précédente « les points de vue de la mesure de la satisfaction », la mesure de la satisfaction peut s'intégrer dans deux grandes démarches pour les études de

¹ Czernichow P., Chaperon J., Le Contour X., « Épidémiologie - Connaissances et Pratiques », Masson, Paris, 2001.

² Kravitz, R. L. (1996). Patients' Expectations for Medical Care: An Expanded Formulation Based on Review of the Literature. Medical care Research and Review., 53, pp. 3-27.

³ Service d'Évaluation Hospitalière. (1996). La Satisfaction des Patients. Lors de Leur Prise en Charge dans les Établissements de Santé. Agence National pour le Développement de l'Évaluation Médicale p. 120.

⁴ Roumeau-Rouquette E., Blondel B., Kaminski M., Bréart G., « Épidémiologie - Méthodes et pratiques », Flammarion, Paris, 1993.

satisfaction : (1) la démarche d'évaluation professionnelle de la qualité des soins avec une approche descriptive, (2) la démarche de recherche : (la mesure de la satisfaction) est, elle-même, objet de recherche de type explicatif, ou critère de jugement dans une approche évaluative.

⇒ L'évaluation professionnelle de la qualité des soins

Elle a pour but de vérifier l'efficacité des soins délivrés aux patients par rapport à une pratique habituelle. Elle vérifie la qualité, l'efficacité réelle et l'efficacité dans un contexte d'application donné. Dans cette optique, l'objectif n'est pas de répondre aux questions de recherche, mais de savoir, par exemple, si les héparines de bas poids moléculaire sont prescrites chez les sujets à risque, et seulement chez eux, à la dose préconisée, avec la surveillance requise. Il s'agit alors, de comparer la pratique réalisée à des références externes définies au préalable et qui, théoriquement, s'obtiennent à partir des résultats de l'évaluation de recherche. Les différentes méthodes dans l'évaluation professionnelle sont : (1) approche purement qualitative, (2) approche descriptive, (3) approche analytique, (4) approche évaluative⁵.

La mesure de la satisfaction à objectif descriptif a pour but de décrire le niveau de satisfaction sans chercher à trouver des facteurs explicatifs. Cette description peut être une étape préalable à un programme d'amélioration de la qualité des soins, comme elle peut parfois en constituer le seul objectif. Elle se traduit par le recueil d'informations venant des patients (focus groupe, lettre de plaintes, questionnaires de sortie, enquêtes spécifiques par les questionnaires de satisfaction) ou d'informations pouvant avoir un impact sur l'attente ou l'appréciation par des patients (données sur l'hôpital, sur l'équipe soignante, sur le patient...). Bien que l'approche descriptive n'apporte que des informations dites « élémentaires », son importance est primordiale:

- Elle permet d'appréhender l'ampleur des phénomènes de santé (en appréciant leur prévalence) et de disposer d'une surveillance épidémiologique (ex: enquête périodique);
- Elle procure une aide à la décision dans les domaines de la planification et de la gestion des organisations ou des programmes de santé
- Elle peut être à l'origine d'hypothèses sur les causes de la situation

L'approche descriptive ne peut établir de lien de cause à effet, elle n'est pas prédictive.

⇒ Objectifs de recherche sur la satisfaction

Elle a comme objectif d'identifier les facteurs influençant la satisfaction, ou les attentes, les

prestations fournies, les écarts. Cette approche aide à mieux interpréter les résultats ou permet de faire une comparaison entre des unités des soins en prenant en considération ces facteurs. Les objectifs de cette approche sont de répondre aux questions suivantes

- o Quels sont les déterminants, les conséquences de la satisfaction ?
- o Quels sont les facteurs, les interventions susceptibles d'améliorer la satisfaction ?

Objectifs de la mesure

La mesure de la satisfaction des patients permet de sélectionner les dysfonctionnements. Les questionnaires et les enquêtes précisent l'origine des insatisfactions, cela aide les professionnels à choisir les mesures correctives nécessaires à mettre en place pour améliorer la qualité des soins et des services au sein de l'établissement. Ces mesures sont à "prioriser", et permettent de répondre de la manière la plus appropriée possible aux attentes des patients. Ces enquêtes servent aussi à détecter les aspects positifs, voire des points d'excellence, qui par la suite, doivent être mis en valeur auprès du personnel et être diffusés à l'extérieur.

L'utilisation des mesures de satisfaction peut s'appliquer dans des contextes différents:

- Un diagnostic des points forts et des points faibles: détection des dysfonctionnements et application des mesures correctives nécessaires, ainsi que reconnaissance et confirmation des points positifs.
- Un des indicateurs d'un programme d'assurance qualité: critère de jugement des démarches de la qualité, indicateur d'un système d'alerte dans les programmes d'assurance qualité.
- Un des indicateurs de mesure des résultats (outcomes) de la prise en charge des patients : critère de jugement d'essai thérapeutique, critère de jugement de la qualité de soins.

Le questionnaire comme outil de mesure

Dans une enquête de mesure de satisfaction, il est possible de choisir entre plusieurs méthodes de recueil de données, chacune d'elle inclut des avantages et des inconvénients. Il faut savoir que l'évaluation de la satisfaction des patients se base sur des enquêtes quantitatives (par ex. le questionnaire de sortie, le questionnaire dans les enquêtes spécifiques), mais aussi sur des enquêtes qualitatives approfondies, il est important d'intégrer les remontées du terrain et l'exploitation des réclamations clients. Ces méthodes d'évaluation de la satisfaction des patients se classent entre des techniques qualitatives et des techniques quantitatives, qui représentent deux approches complémentaires. L'approche quantitative permet de mesurer, et l'approche qualitative permet de fournir des éléments de compréhension et d'aller plus loin dans l'exploration grâce au caractère libre de la réponse.

⁵ Briançon S., Girard F., Empereur F., Guillemin F., « Evaluation des pratiques professionnelles », *Revue Épidémiologie et Santé Publique*. 48(6), 2000, pp. 541-550.

Plusieurs auteurs, parmi lesquels, Avis et Williams⁶⁷, préconisent d'assembler les techniques qualitative et quantitative de mesure de la satisfaction des patients, pour profiter de la complémentarité des informations qu'elles produisent

- L'approche qualitative: permet aux patients d'exprimer leurs expériences par leurs propres mots. Ils apportent des détails riches selon leur point de vue. Pourtant, elle n'est pas avantageuse si le but est d'obtenir des données généralisables ou de faire des comparaisons entre hôpitaux puisque les données obtenues ne sont pas favorables à l'analyse statistique.
- L'approche quantitative: il est évident que les études quantitatives, réalisées sur des échantillons représentatifs de la population cible, utilisent souvent des questionnaires fermés. Ces études permettent de calculer facilement des indices de satisfaction (% et/ou moyenne). Il est alors facile de comparer différentes populations entre elles ou une même population au cours du temps. Pourtant, pour ce type d'étude, il faut savoir que ce n'est pas évident de donner une interprétation juste des chiffres obtenus, en dehors de tout test statistique adapté, car de nombreux facteurs peuvent influencer les taux ou les scores de satisfaction, ce qui pose la question de la validation du questionnaire.

La pratique du questionnaire est la méthode la plus utilisée dans cette dernière approche. Dans l'analyse de la littérature, il est clair que c'est la méthode la plus répondue dans les enquêtes de satisfaction⁸⁹¹⁰. Cela vient probablement de son apparente simplicité d'utilisation. L'élaboration d'un système de mesure adapté constitue l'un des axes essentiels de la politique d'amélioration continue de la qualité des soins. Il s'agit, pour les établissements, d'inscrire cette démarche dans leur projet d'établissement., il existe plusieurs méthodes de recueil des données lors de mesure la satisfaction des patients. Le recueil des données par un questionnaire peut se faire pendant l'hospitalisation, la consultation ou à distance. On peut utiliser des questionnaires auto-administrés, remplis par les patients. On peut aussi opter pour les questionnaires remplis par un tiers au cours d'une interview en face-à-face (sur site ou à distance) ou téléphonique.

Chacune de ces méthodes inclut des avantages et des inconvénients.

Définition

Un questionnaire est un ensemble de questions (ou tems) dont chacune représente une donnée élémentaire. Un questionnaire peut être utilisé par contact direct avec des personnes interrogées, ou par les personnes elles-mêmes, mais également pour analyser secondairement les dossiers établis à l'occasion de soins des patients¹¹. Les questionnaires sont des outils de recueil des données standardisé qui ont comme objectif la reproductibilité et la validité des informations recueillies.

L'élaboration d'un questionnaire est une étape essentielle et complexe, qui nécessite l'expérience et le point de vue de différentes personnes. Les choix sont irréversibles et déterminent la qualité du résultat ultérieur. Ils sont liés aux objectifs et aux différentes perspectives impliquées. Un questionnaire universel n'existe pas et « *aucun système d'enquête n'est validé pour qu'il soit considéré [...] comme fiable, valide pour la mesure de la satisfaction* »¹². Pourtant, le temps d'élaboration d'un nouveau questionnaire est de 2 à 5 ans¹³¹⁴.

L'adoption d'un outil existant vise donc à économiser le temps et les dépenses. De plus, l'adoption (intégrale ou légèrement modifiée) de questionnaires déjà utilisés permet de s'assurer les mêmes propriétés que la version originale, à condition que la population étudiée soit peu différente¹⁵.

En France, il n'y a pas actuellement d'instrument standardisé unique reconnu, et de nombreuses équipes travaillent à élaboration d'instruments adéquats. On peut être amené à utiliser un outil étranger déjà validé. Et en raison de différences internationales tant culturelles que d'organisation sanitaire, les déterminants de la satisfaction varient d'un pays à l'autre, même pour des pays ayant des fonctionnements très proches¹⁶ la validation doit en conséquence être répétée pour son utilisation.

Un questionnaire de satisfaction comporte généralement 4 parties:

¹¹ Czernichow, P. C. (2001). Épidémiologie - Connaissances et Pratiques. Paris. Masson

¹² Hall, J. A. (1988). Meta-analysis of satisfaction with medical care: Description of research domain and analysis of overall satisfaction levels. *Social Science & Medicine*, 27(6), pp. 637- 644.

¹³ Carey, R. G. (1993). A patient survey system to measure quality improvement: Questionnaire Reliability and Validity. *Medical care*, 31(9), P: 834-845.

¹⁴ Fitzpatrick, R. (1991). Surveys of patient satisfaction: II. Designing a questionnaire and conducting a survey. *British Medical Journal*, 302, P: 1129-1132.

¹⁵ Pourin e. (1999). La mesure de la satisfaction des patients hospitalisés. 1^{re} partie : Aspects conceptuels et revue de travaux. *Journal d'Economie Médicale*, 17, P :101-105.

¹⁶ Gasquet, I. (1999). Satisfaction des patients et performance hospitalière. *La Presse Médicale.*, 28(29), P : 1610- 1613.

⁶ Williams, B. (1994). Patient satisfaction: A valid concept? *Social Science & Medicine*, 38(4), pp. 509-516.

⁷ Sitzia, J. «How valid and reliable are patient satisfaction data? An analysis of 195 studies. »*International Journal for Quality in Health Care*. 11(4): 319-328. 1999.

⁸ Sitzia, J. (1999). How valid and reliable are patient satisfaction data? An analysis of 195 studies. *International Journal for Quality in Health Care*. 11(4), P 319-328.

⁹ Service d'Évaluation Hospitalière, Op.cit.

¹⁰ Rubin, H. R. (1990). Can patients evaluate the quality of care? *Medical Care Review*, 47, pp 267-326.

1. Une partie portant sur les renseignements complémentaires de type sociodémographique et l'identification du patient.
2. Une partie portant sur des informations générales concernant l'expérience antérieure et l'organisation du séjour du patient.
3. Une partie correspondant à la satisfaction proprement dite.
4. Une partie comportant des variables indicatrices de validité « validity indicator variables » utilisées dans le processus d'amélioration des dimensions

Caractéristiques de l'instrument

Les outils de mesure de la satisfaction des patients se classent selon trois caractéristiques principales: la structure de soins concernée par le questionnaire, le niveau de spécificité du questionnaire et la typologie des items.

- La structure de soins

Il est primordial d'identifier et faire la différence entre les types de structure de soins : hospitalisation en court, moyen séjour ou long séjour, consultation, soins à domicile ou réseau de soins. De même pour les types de prises en charge: soins généraux, soins spécifiques tels que la pédiatrie, l'obstétrique, la cancérologie et la psychiatrie. Car chacune d'elles détient des caractéristiques différentes concernant le contexte de la structure, la relation entre le personnel soignant et le patient, et le mode d'offre de soins.

- Le niveau de spécificité du questionnaire: générique et spécifique

Un instrument spécifique s'utilise pour évaluer un événement particulier comme une hospitalisation ou consultation précise (la dernière, par exemple). Un instrument générique est destiné à mesurer la satisfaction des patients par rapport à l'offre de soins en général.

L'évaluation d'une structure de soins (un hôpital, par exemple) ou un type de prise en charge (comme la pédiatrie) se situe entre ces deux pôles, générique et spécifique, respectivement.

Un questionnaire spécifique comprend des items comme "est ce que le médecin vous a donné des explications assez claires sur votre problème de santé ?" (Par exemple, au cours de la dernière hospitalisation), tandis qu'un questionnaire générique a la formulation suivante « est-ce que votre médecin vous donne des explications suffisamment claires sur vos problèmes de santé ? ».

Il est clair que la satisfaction des patients est multidimensionnelle, donc le questionnaire de satisfaction inclut des questions spécifiques et centrées et non pas demander une appréciation globale de la satisfaction. Plus la question sera clairement spécifique et centrée, plus la comparaison de la satisfaction entre les différentes structures de soins sera facile. Hall et

Dornan¹⁷, affirment que des questionnaires avec un contenu plus spécifique ont tendance à produire plus de réponses favorables que ceux avec des questions formulées de façon générale qui produisent un point de vue légèrement plus négatif. D'autres auteurs déclarent que les questionnaires génériques génèrent des scores de satisfaction plus élevés que les questionnaires spécifiques.

Depuis quelques années, une tendance d'individualisation des réponses des patients est présente, en ajoutant la notion d " importance " pour chaque question dans le questionnaire. Le niveau d'importance est noté sur une échelle de 1 à 5 (pas du tout important ... très important).

La typologie des items et des réponses

Les items représentent les stimulus destinés à obtenir une réponse ¹⁸ et peuvent être des questions ou des affirmations. Dans la suite du texte, nous utiliserons indifféremment les mots item et question selon leur usage courant en français.

- Formulation des questions

Afin qu'une étude ait des résultats précis et utiles, les questions doivent représenter ce que les patients considèrent comme important pour eux. Les focus groups et les plaintes des patients sont un générateur riche de sujets pour des questions d'étude. Il est également essentiel, pour établir des questions avec des patients, de prendre en considération les éléments suivants:

- Le sujet des questions doit être assez spécifique pour être approprié, mais pas trop spécifique au point qu'il devient pénible d'y répondre.
- Aborder une seule idée par question.
- Éviter les sujets politiquement sensibles ou qui pourraient embarrasser des patients.
- Exprimer les questions en langage simple et direct.
- Considérer le but de la question en choisissant les mots et le format.

Formulation - Ouverte ou Fermée

Les questions ouvertes procurent au répondant une très grande liberté de réponse en choisissant librement ses mots et la longueur de la réponse ce qui permet au sujet de s'exprimer librement, de fournir des informations qualitatives. Elles offrent à l'étude la capacité d'analyser en profondeur une attitude ou d'une opinion ; les sujets sont illimités, mais elles sont plus difficiles à analyser et à récapituler que des questions fermées. Exemple d'une question ouverte : « Qu'est-ce que vous avez apprécié à l'hôpital ? ».

Les questions fermées se caractérisent par des réponses envisageables claires et précises. Exemple d'une question fermée: « Où êtes-vous allé en quittant

¹⁷ Hall, Op.cit. P 700-704

¹⁸ Nunally Je. « Psychométrie Theory. », McGraw-Hill, New York. Ed. Second, 1978. P 1-677.

l'hôpital ?». Les réponses « à la maison », « dans un autre hôpital », « dans un centre de rééducation », « dans une maison de retraite » sont logiques et augmentent l'efficacité de l'interrogation.

Les avantages des questions fermées: codification facile, interprétation des réponses simplifiée et tâche du répondant facile et rapide.

Il est préférable de compléter les questions fermées par quelques interlignes réservées aux « remarques ». Les patients peuvent alors approfondir ou ajouter des explications à leurs réponses.

➤ Formulation - Directe ou indirecte

Selon Fitzpatrick¹⁹ et une méta-analyse de 221 études réalisées en 1988 (Hall, 1988), on peut classer les questions de satisfaction selon leur formulation directe ou indirecte.²⁰

L'approche directe se caractérise par des questions abordées directement et liées niveaux de satisfaction « De quelle façon étiez-vous satisfait... ? ». Par exemple, « Êtes-vous satisfait de la qualité du traitement administré ? » ou une réponse positive pour « Est-ce que le traitement administré vous convient ? » qui sera interprété comme une réponse indiquant la satisfaction.

Alors que dans l'approche indirecte, la satisfaction se tire à partir des réponses. Les items indirects qui représentent une description de la prise en charge, par exemple: « avez-vous remarqué une amélioration dans votre état de santé après le traitement prescrit ? ». Le choix de la formulation des questions se fait à partir de l'objectif poursuivi: cherche-t-on plutôt à connaître l'avis des patients ou veut-on, par l'intermédiaire du patient, identifier des mauvaises pratiques ? A titre d'exemple, dans le cas de la prise en charge de la douleur, une question indirecte aide à vérifier si les modalités de prise en charge de la douleur sont conformes à ce qu'elles devraient être (normes, procédures, consensus). Il n'y a pas d'avantages établis d'une des deux approches. La distribution de ce caractère sur 200 études est de 43% en direct, de 37% en indirect et de 20% en combinant les deux²¹.

➤ Formulation- Observation (report) ou évaluation/ jugement (rating)

Les questions d'observation et d'expérience sont souvent formulées de la même manière, par exemple: « Vous a-t-on expliqué comment se déroule le travail quotidien au service ? ». Il s'agit d'une question factuelle, susceptible en principe, d'une vérification objective (c'est arrivé ou ça n'a pas eu lieu). Mais; ce qui compte dans ce cas est plutôt la question de savoir si les patients ont suffisamment vécu ce fait pour le percevoir en tant que tel et se le rappeler. Quelle que

soit la réponse donnée à ces questions, elle ne traduit pas directement si le patient est ou non satisfait de l'acte. Pour le savoir, il faut opter pour les questions d'évaluation/jugement, donc demander par exemple « Comment avez-vous trouvé les explications reçues sur la façon dont se déroule le travail quotidien au service ? ».

Pour pouvoir mieux comparer, les questions d'évaluation/jugement sont, dans la règle, posées sous une forme fermée, donc assorties d'une échelle de réponse allant d'une note positive à une note négative.

• Le format de réponses

Durant le développement du questionnaire de satisfaction, se pose le problème de la définition des échelles de réponse pour chaque item. Outre les échelles visuelles analogiques, qui sont assez peu appliquées dans le cadre d'études de la satisfaction, les réponses sont le plus souvent établies sur des échelles de réponse, s'apparentant à des questions à choix multiple, qui sont, soit binaires (oui/non), soit en plusieurs points. Ce choix est d'importance quant à ses répercussions sur les propriétés psychométriques des scores calculés

➤ « Oui/Non »

Il est considéré le format la plus simple, il est binaire, et malgré Les avantages de simplicité de ce format, selon plusieurs analystes, il reste accablé par le fait que la plupart des réponses de n'importe quel item touchant aux plupart des répondants demeurent des réponses favorables pour soins. Il ne permet pas de détecter des changements de satisfaction, et a des effets planchers et plafonds importants.

➤ Choix multiple

Actuellement, La quasi-totalité des questionnaires utilisent plus de deux réponses par question. Cela permet aux répondants d'exprimer précisément leur point de vue. D'autant plus que la fiabilité (reliability) des items augmente quand le nombre de réponses possibles augmentent. Par contre, la réduction du nombre de réponses dans l'échelle augmente la fiabilité dans le temps (il est plus probable qu'un même individu réponde de façon identique à la même question posée à deux reprises à un mois d'intervalle si l'échelle de réponse comporte 3 points que si elle en comporte 6), mais diminue d'autant son pouvoir de discrimination dans un continuum d'états d'altération de la qualité. Par exemple, une échelle de la satisfaction comportant 20 questions dont les réponses se font en 3 points permet de distinguer 60 (3x20) états différents, tandis que si les réponses se font en 5 points, elle permet d'en distinguer 100 (5x20).

Nunnally²² affirme que dans la pratique, le gain de précision et de fiabilité par l'augmentation des

¹⁹ Fitzpatrick. Op.cit. P 1129-1132.

²⁰ Hall. Op.cit. P 637- 644.

²¹ Hall. Op.cit. P 637- 644.

²² Nunnally. Op.cit. P 1-677.

réponses possibles est minime quand le nombre des réponses dépasse 7, et en général, 5 catégories de réponses sont utilisées. Un nombre de réponses impair permet au répondant de se positionner comme « neutre » ou « sans opinion » mais peut introduire une tendance à l'utilisation systématique de cette catégorie pour éviter d'avoir à se prononcer.

Les principales échelles sont:

- 1) Échelle nominale: qui liste une série de catégories d'une variable. Exemple: CSP

Exemple:

Absolument d'accord	Plutôt d'accord	D'accord	Plutôt en désaccord	Absolument en désaccord
1	2	3	4	5

- Échelle différentielle sémantique: instrument constitué de deux adjectifs contraires, disposés sur une échelle bipolaire à sept points; le sujet positionne sa réponse sur cette échelle qui décrit le mieux son opinion.

Passif | | | | | | | Actif

- Échelle à icônes



- Problèmes dans l'interprétation selon le format de réponse

Observation (report) vs Évaluation/Jugement (rating)

Il n'existe pas, de nos jours, de résultats clairs concernant l'influence du format de réponse sur l'évaluation de la satisfaction par les patients. Aucune étude à notre connaissance ne compare les formats de réponses (observation vs évaluation/jugement) en utilisant les mêmes questions. Les résultats de Mathiew, cité par Rubin, montrent qu'il y a plus de variation dans le type d'observation que celui d'évaluation²³. Le type d'observation est moins influencé par les caractéristiques des patients comme l'âge, le niveau d'étude, et le fait d'être fonctionnaire. Les évaluations/jugements, dans le cas de l'échelle de satisfaction en particulier (très satisfait - très insatisfait), sont aplatissement dans la distribution des scores (skewness) dans presque toutes les études.

Échelle « excellent/mauvais » vs « d'accord/pas d'accord »

L'échelle « excellent/mauvais » comporte des avantages dans la variabilité et validité des réponses en

- 2) Échelles ordinales

- Échelle de Likert: contient un nombre d'énoncés déclaratoires accompagnés d'une échelle graduée. Elle est une des échelles la plus souvent employée dans les enquêtes de satisfaction. Chacun d'entre eux a 5 réponses typiques, de « fortement/absolument d'accord » (strongly agree) à « fortement/absolument pas d'accord » (strongly disagree).

respectant de l'intention. Elle aide à comparer directement des aspects de soins, ce qui est impossible pour les autres échelles comme « d'accord/pas d'accord ». Ware et Hays dans une étude de satisfaction chez les consultants, affirment qu'il est préférable d'utiliser une échelle « excellent/mauvais » avec un item neutre qu'une échelle « très satisfaisant/pas du tout satisfaisant ». Ils montrent que l'échelle « excellent/mauvais » procure des résultats avec plus de variance, moins aplatissement de la distribution (skewness) et traduisent mieux les comportements des patients vis-à-vis des soins²⁴.

Élaboration d'un questionnaire

Pour élaborer un questionnaire, Il existe deux approches; soit l'élaboration d'un nouveau questionnaire qui débute par les deux étapes essentielles: le choix initial des items et la sélection ou la réduction des items; soit l'adoption d'un questionnaire qui commence par une revue de la littérature sur les questionnaires existants.

²⁴ Ware, J. E. and Rubin, H. R. «Methods for Measuring Patient Satisfaction with Specific Medical Encounters. » Medical care. 26(4). 1988. P : 393-402.

²³ Rubin. Op.cit. P 267-326

A. Choix initial des items

D'abord, il est utile de collecter tous les items candidats à l'outil définitif.

Après avoir défini la "population-cible", le développement d'un questionnaire débute par l'établissement d'une liste initiale d'items. Ceci s'effectue à travers la confrontation d'entretiens réalisés auprès d'un échantillon de patients que l'on désire étudier, à l'avis d'experts ou par analyse de la littérature, l'objectif est d'établir une liste des domaines et des items concernés. Il est également possible de retenir des domaines déjà mis en évidence dans la littérature.

Ces premiers entretiens avec les patients se réalisent généralement de façon libre ou semi-directive ; ils sont généralement enregistrés et retranscrits, et l'ensemble des données recueillies est analysé puis confronté à l'avis d'experts de la pathologie étudiée, afin de ne garder que les items qui semblent à priori pertinents. Ce premier questionnaire contient le plus souvent un grand nombre d'items (de 100 à 200 en général) et nécessite, afin d'être réellement exploitable, une réduction des items. Il peut même falloir mener une phase de pré pilotage avec des questions ouvertes, des entretiens exploratoires, dans lesquels un questionnaire complet et des dimensions du point de vue des patients ont été évaluées, avant de passer aux items du questionnaire fixés, fermés pour l'enquête pilote.

La réduction (sélection) des items

Cette phase de développement consiste à effectuer une pré-étude, qui se fait à travers l'administration du questionnaire à un second échantillon de patients. Ensuite, une analyse statistique se réalise, on en prenant en compte l'avis des experts, ou bien en combinant les deux méthodes afin de supprimer d'une part les items non discriminants, c'est-à-dire, ceux qui ne montrent pas de différence entre les deux populations, mais aussi ceux qui ne peuvent pas s'appliquer sur terrain, ou dont les réponses sont non exploitables. Pour prendre un exemple pratique, le développement du PJHQ (patient Judgements of Hospital Quality), un des questionnaires de satisfaction développé au milieu des années 90, a débuté par la réalisation d'un "pool" de 1000 items, à partir duquel un premier questionnaire s'est élaboré, ensuite, après réduction d'items, le questionnaire définitif comportant les 50 items les plus pertinents est proposé.

a) Les questionnaires d'origine anglo-saxonne

Depuis plus de 20 ans, la mesure de la satisfaction est le centre de préoccupation de nombreuses études à l'étranger, surtout dans les pays anglo-saxons. Plusieurs instruments sont créés et utilisés dans les enquêtes.

Nous citons ici des questionnaires souvent utilisés dans les enquêtes de satisfaction.

- Le questionnaire du patient de satisfaction (PSQ: Patient Satisfaction Questionnaire), comportant de 80 items, est initialement développé par Ware et ses collègues. Le PSQ-III est une version de 50-items avec les dimensions suivantes : la satisfaction globale, soins médicaux aussi bien que six aspects de soin : qualité technique, relation interpersonnelle, transmission, frais d'hospitalisation, temps passé avec le médecin, et accessibilité des soins. Ce questionnaire est utilisé entièrement ou partiellement dans plusieurs études. Van Campen conclut que ce questionnaire est bien adapté dans le domaine d'évaluation des services de soins à domicile. Le questionnaire prend 9-12 minutes pour se terminer.
- Le « Patients Judgements of Hospital Quality (PJHQ, 1990), se compose de 116 items dans lesquels 50 items de satisfaction proprement dit avec 7 dimensions : admission, nursing and daily care, hospital environment and ancillary staff, medical care, discharge, information et billing. Ce questionnaire est construit pour une population hospitalisée en 1987 en passant toutes les étapes nécessaires. Cette étude conduite dans 10 hôpitaux a contribué au développement de ces différents points:
 - Elle a identifié les aspects importants des soins, de l'opinion des patients.
 - Elle a testé les différentes méthodes d'administration des questionnaires.
 - Elle a décrit le plan d'analyse de validation de l'outil.

C'est un questionnaire spécifique pour les soins à l'hôpital. Il y a plusieurs études de satisfaction des patients hospitalisés qui choisissent d'utiliser ou d'adapter ce questionnaire ²⁵. Il faut environ 20 minutes pour le remplir.

- Les « Patient Judgement System » (PJS) (Nelson, 1989). Et « Patient Comment Card » (PCC) sont des versions développées à partir du PJHQ en réduisant le nombre d'items par Nelson et al.

Les questionnaires d'origine francophone

Actuellement, il n'existe pas de questionnaire de satisfaction validé en France, à l'exception d'un travail publié en 1999 par Labarere J et al dans Journal Clinical Performance Quality of Health Care « Out patient satisfaction: validation of a French-language questionnaire: data quality and identification of associated factors »²⁶.

La France est l'une des pays qui se sont intéressés aux outils de mesure de la satisfaction des

²⁵ van Campen, c., Sixma, H., Friele, R. D., Kerssens. (1995). Quality of Care and Patient Satisfaction: A Review of Measuring Instruments. Medical care Research and Review, 52, pp. 109-133

²⁶ Parasuraman A., B. L. (1991). Understanding customer expectations of service. Sloan Management Review., 39

patients, et cela depuis quelques années, l'adoption françaises du questionnaire PJHQ se réalise en 1997, et se publie dans Social Science et Médecine²⁷.

Dans ce cadre deux questionnaires se sont développés:

- Développé par l'équipe de Grenoble en 1998, et publié en 2001 dans International Journal for Quality in Health Care²⁸
- Conçu en 1998 par l'équipe AP-HP, il s'agit de l'EQS (échelle de qualité des soins). Cette échelle examine l'opinion des patients hospitalisés par rapport aux soins médicaux et infirmiers dans les services de médecine et chirurgie de court séjour. Elle contient deux dimensions: information médicale (13 items) et la relation avec les soignants - l'organisation du service (13 items) et 8 variables d'ajustement (caractéristiques des patients et modalités de séjour) qui permettent des comparaisons entre structures (établissements ou services cliniques). L'EQS génère 3 scores de 0 à 100 (niveau croissant de satisfaction): un score par dimension et un score global.

Il est certain qu'à l'heure actuelle, beaucoup de travaux en cours de préparation et étude par des équipes de recherche françaises sur d'autres populations: psychiatrie, enfant, monde carcéral.

Concept de la dimension dans un questionnaire

Il faut savoir que le questionnaire choisi aboutit à l'identification des dimensions explorant différents champs de la satisfaction et à un calcul des scores résultant de l'addition des réponses aux questions qui composent une dimension

Il existe deux manières de construire des dimensions: a priori et a posteriori.

Les étapes essentielles dans la construction de dimensions valides et fiables basées sur les items clé ou la partie « satisfaction proprement dite » dans un questionnaire de satisfaction sont:

1. Élaboration des dimensions a priori : items groupés en se basant sur la revue de la littérature et le cadre conceptuel qui en découle.
2. Réalisation d'une analyse factorielle exploratoire qui permet de tester les dimensions présumées et d'identifier éventuellement de nouvelles.
3. Construction des dimensions multi-items à partir des résultats de l'analyse factorielle exploratoire en prenant en compte les relations théoriques et le contenu des items.
4. Évaluation des propriétés psychométriques de ces dimensions par le calcul des statistiques descriptives pour chaque dimension, l'estimation de leur fiabilité et l'évaluation de leur validité.

a) Les dimensions a priori

Elles sont conçues à partir d'une réflexion logique, afin d'explorer les grands thèmes. Elles sont fixées par le concepteur du questionnaire. Il s'agit des dimensions empruntées de questionnaires préexistants, et utilisés pour apporter des données de référence à des buts comparatifs. Il est question de regrouper des items qui touchent a priori une même dimension, à travers une réalisation empirique, soit en s'appuyant sur les avis d'experts ou sur des données de la littérature. Ce regroupement doit ensuite être évalué par une étude statistique (cohérence interne et validité essentiellement).

Les dimensions a posteriori (post hoc)

Il est possible de les concevoir à travers l'analyse du questionnaire en recherchant les questions pour lesquelles il existe de fortes corrélations entre les réponses. Ces dimensions se construisent une fois que toutes les données sont collectées et cette méthode se fonde sur l'utilisation de l'analyse en composantes principales (analyse factorielle exploratoire).

Validation d'un instrument de mesure

La phase de validation se base sur une enquête pilote, et permet sélectionner les outils les plus appropriés de la satisfaction des patients.

Cette validation consiste à mettre en œuvre des enquêtes et des analyses statistiques spécifiques, afin de vérifier l'aptitude de l'instrument utilisé à mesurer effectivement ce qu'il est supposé mesurer et avec une manière optimale.

La validation sert également à identifier précisément les dimensions explorées par l'instrument.

La validation psychométrique représente une étape essentielle de l'utilisation d'un outil de mesure de la satisfaction. Elle a pour but la sélection des items, et la vérification de la validité de l'instrument définitif (validity) et sa fiabilité (reliability).

B. Validité

La validation est un processus qui a pour objectif de s'assurer que l'instrument de mesure est une représentation claire du concept de l'étude. Par exemple, si on désire mesurer la satisfaction concernant les informations liées aux soins, nous avons besoin de s'assurer que les items de l'outil mesure la satisfaction représentent des informations liées aux soins, non pas un autre concept.

Les différents points de validité sont présentés ci-dessous:

- 1) La validité d'apparence ou apparente (Face validity): La validité d'apparence est le jugement de l'utilisateur. Cette validité est liée à un jugement subjectif, prenant en compte les aspects visibles de l'échelle : longueur, libellé des items, modalités de réponse, etc..... Elle aide à rendre l'outil accessible et, la portée des patients, afin de garantir leur implication et leur réactivité, donc, la réalisation

²⁷ Nguyen Th, P. L. (.2002). Factors Determining Inpatient Satisfaction with Care. Social Science & Medicine, 54(4),P493-504.

²⁸ S. Briançon. Op.cit.

d'une enquête pilote est essentielle pour permettre de rassembler leurs remarques sur le contenu du questionnaire et sur la formalisation des items.

- 2) La validité de contenu (Content validity): ou validité externe, permet de juger si l'on répond correctement au problème posé, c'est à dire la capacité de l'instrument à mesurer effectivement ce qu'il est censé mesurer et varier avec ce qu'il mesure. Elle suppose que les items rassemblés explorent de façon complète l'ensemble des aspects d'une dimension donnée, sans redondance entre eux. Elle vérifie à quel point l'instrument est adéquat au domaine de l'étude, en fonction des concepts, de l'étendue du domaine pris en compte et des formulations employées. Ce type de validation exige la définition préalable des concepts et l'accord consensuel des experts.

- a. La validité de structure ou la validité du construit (Construct validity): L'étude de la structure de l'instrument, par diverses méthodes d'analyses multivariées, aide à vérifier la validité de structure ou du construit. Ces critères peuvent être utilisés, lorsqu'il n'existe pas de référence (gold standard). Elle constitue un des éléments qui aide à définir les dimensions de l'instrument. Elle est liée par la cohérence interne (validité de structure interne). Il s'agit de la capacité de l'instrument à mesurer de façon séparée les différentes dimensions. Sa vérification nécessite l'utilisation de l'analyse factorielle et à la cohérence interne.

L'analyse factorielle: à partir des résultats d'une enquête pilote sur un échantillon représentatif de la population cible, on peut, par exemple, rechercher la structure factorielle de l'instrument par une analyse en composantes principales. Les résultats aident à optimiser le nombre d'item de l'outil. Ainsi il est possible d'éliminer les items corrélés à plusieurs facteurs, à aucun facteur, ou encore des items qui appartiennent à une dimension expliquant une part faible de la variance totale. Toutefois, il n'est pas possible de calculer de score par sommation d'items que si ceux-ci appartiennent à une même dimension; il n'est donc pas théoriquement licite de calculer un score global dans le cas d'un instrument multidimensionnel.

Il faut savoir que La cohérence interne se base sur l'étude de la corrélation moyenne entre les items. La mesure utilisant le coefficient alpha de Cronbach est une approche populaire. Le coefficient de cohérence interne (alpha de Cronbach) est une estimation du fait que les items d'un questionnaire (ou d'une sous-échelle) mesurent un même concept. Il varie de 0 à 1. Plus le coefficient est élevé, plus la cohérence interne du questionnaire est satisfaisante; en pratique, une valeur d'au minimum de 0,8 est considérée comme un bon indicateur de cohérence interne. Mais ce coefficient a l'inconvénient d'être dépendant du nombre d'items.

- 3) La validité sur critère (criterion validity): Dans le cas où l'objet évalué par l'instrument est complètement et indiscutablement défini par une autre méthode de mesure. C'est la corrélation de la nouvelle échelle avec d'autres mesures, idéalement, un « gold standard » validé qui est bien accepté dans le champ.

Il est évident qu'en ce qui concerne les mesures de satisfaction des patients, il n'existe aucun standard universellement reconnu ou gold standard; c'est pourquoi ce type de validité ne peut être mesuré.

Fiabilité

La fiabilité représente le total des erreurs inhérentes dans les mesures. La variabilité est fondamentale dans ce concept. Par exemple, il est demandé à un patient d'évaluer la satisfaction en utilisant une échelle visuelle analogique de 100mm. Le résultat obtenu est 81. Il est redemandé alors au patient de répéter l'évaluation quatre fois, et trouvons que les résultats sont 79, 78, 76 et 81. Quel est donc le vrai niveau de satisfaction pour ce patient ? S'il est possible de faire l'hypothèse que la satisfaction du patient était stable au cours de la période, il est évident que la variation dans les scores est aléatoire. C'est l'erreur de mesure dans ce cas. Si l'expérience se répète avec 99 patients, nous constatons à la fois une variabilité entre sujets - certaines personnes seront plus satisfaites que d'autres - et cette erreur aléatoire.

La fiabilité est liée généralement à la reproductibilité (comprenant stabilité dans le temps et reproductibilité inter-observateurs), qui représente la capacité à avoir un résultat stable lorsque le questionnaire est administré à plusieurs reprises (ou par plusieurs observateurs) à une population stable.

Modalités de passation

A. Les modalités d'administration

- Entretien ou auto-administration

Les modalités de recueil des données se déterminent à partir du type de population et la taille d'échantillon, mais aussi, ces modalités varient entre l'entretien et le questionnaire auto-administré.

- Entretien (en individuel ou collectif)

Généralement, il est recommandé de donner aux malades le temps et la liberté de répondre. Il est aussi primordial de définir leurs expériences, même pour ceux présentant une capacité de communication ou d'autonomie (santé) réduite ou limitée. Le moyen le plus approprié pour interroger ces derniers est l'entretien personnel ou en groupe (avec ou sans l'aide d'un interprète, des parents ou proches).

Cette modalité se distingue par l'excellente qualité des données collectées, lorsque les enquêteurs sont entraînés: les données manquantes sont exceptionnelles, les refus de réponse sont généralement rares.

Cependant, la présence de l'enquêteur est susceptible d'influencer les réponses:

- 1) par l'effet Hawthorne, cette expression s'utilise pour exprimer le manque de fiabilité d'une expérience dans des situations données, car le simple fait qu'elle ait lieu influe sur les résultats obtenus. Cela s'explique par le fait que le personnel et les bénéficiaires du programme adaptent parfois un comportement très différent de leur comportement habituel s'ils savent qu'ils sont observés. C'est l'impact d'être inclus dans l'étude.
 - 2) la désirabilité sociale est, ce qui entraîne une sous-déclaration, des comportements illégaux, illicites ou socialement dévalorisés. C'est une tendance à agir de manière à se percevoir et à être perçu des autres de façon positive.
- Auto-administration

Les questionnaires auto-administrés sont transmis par voie postale ou en main propre sur site; remplis sur site ou à la maison; par la personne elle-même ou par un proche, avec aide ou sans aide.

Cette méthode aide à connaître directement le point de vue des patients. Il est vrai que le coût de cette modalité est moins élevé, mais le taux de réponse est généralement faible, de l'ordre de 10 à 50%, selon les auteurs (sans relance). Les répondants sont souvent différents de non répondants donc les résultats obtenus comportent un biais de sélection.

- Face-à-face, téléphone ou courrier

Nous exposons le tableau de Delbancon (1996), cité par Pourin (Pourin, 1999)²⁹ pour présenter les avantages et les inconvénients des différentes modalités de recueil des données.

- Le lieu de recueil des données : sur site ou à distance

Il est clair que l'endroit et le moment choisis de transmission et de remplissage du questionnaire sont susceptibles d'influer sur la manière dont les patients répondent. Les questionnaires peuvent être distribués ou remplis

- 1) sur site (l'hôpital, le lieu de consultation, la maternité). Dans ce cas, il est important de bien discuter des modalités comme le moment d'attribution du questionnaire - avant, pendant ou après la rencontre des soins; le moment de demande de remplissage du questionnaire - pendant ou après la rencontre des soins. Et la personne qui remet ou demande de remplir le questionnaire aux patients - le personnel d'accueil, le personnel soignant ou le personnel à l'extérieur de l'établissement.
- 2) à distance (au domicile, maison de retraite ...): le temps écoulé entre la sortie et le moment où l'on

administre le questionnaire est important, plusieurs auteurs recommandent un délai de 2 à 4 semaines^{30,31,32,33}. L'organisation et la logistique pour assurer les adresses ou les numéros de téléphone des patients. Et le mode de surveillance des non réponses si nécessaire (relance téléphonique, courrier...).

Le fait d'interroger des patients sur le lieu de soins engendre en général des scores de satisfaction plus élevés que les enquêtes réalisées à distance³⁴. Certains auteurs affirment que les réponses sont plus critiques, d'autres que les réponses peuvent être influencées positivement du fait que le patient est dans une situation de dépendance (relation d'iniquité).

Au niveau des questionnaires envoyés à domicile, peut se poser le problème de qui répond réellement.

Si les réponses sont faites avec l'aide des personnes plus jeunes, elles peuvent être plus critiques. Ceci peut généralement constituer un facteur qui peut expliquer la similitude des tendances des réponses faites entre des sujets jeunes et âgés, à savoir plus critiques et peu positives. Cette interprétation peut être cohérente avec celle de Thorslund et Wameryd. Leur travail porte sur l'existence d'une différence entre les patients très âgés qui avaient rempli les questionnaires avec aide et sans aide. Ils précisent ainsi que l'accès à l'aide pour remplir un questionnaire peut probablement influencer la perception de cette personne très âgée sur son propre état de santé de façon positive. Une autre interprétation possible, et peut-être plus naturelle, est que les patients très âgés ont une santé plus faible, avec un plus grand besoin de soins et donc un plus grand risque de voir ce besoin non satisfait. Le tableau suivant présente les avantages de 4 modalités (tableau 8).

³⁰ Ware J. Op.cit. P 539-540.

³¹ Cleary, P. D. (1991). Patients evaluate their hospital care: A national survey. Health Affairs, 10, P 254-267.

³² Carey, R. G. (1993). A patient survey system to measure quality improvement: Questionnaire Reliability and Validity. Medical care, 31(9), P834-845.

³³ Doering, E. R. (1983). Factors influencing inpatient satisfaction with care. Quality Review Bulletin., 9 (10), P 291-299.

³⁴ Rubin H. R. Op.cit. P267-326

²⁹ Pourine. Op.cit. P 117-132

Tableau 8: Les avantages et inconvénients des différentes modalités de recueil des données

Avantages	Inconvénients
Face-à-face	
Taux de réponse le plus élevé	Très coûteuse
L'enquêteur peut clarifier les questions et utiliser des instructions complexes	Limitée à un petit nombre de répondants et à une zone géographique
Autorise un entretien plus long avec un meilleur taux de réponse	Risque de biais lié à l'enquêteur
Processus interactif pour générer de nouvelles informations	Ne respecte pas l'anonymat
Permet d'aborder des sujets sensibles	
Permet de joindre des populations à bas niveau d'étude	
Téléphone	
Couvrir une grande zone géographique	Plus coûteux qu'une enquête postale
Taux de réponse meilleur par courrier	Les patients perçoivent moins bien l'anonymat qu'avec un questionnaire postal
L'enquêteur peut clarifier les réponses confuses et essayer de convaincre ceux qui refusent	Nécessite d'avoir des numéros de téléphone fiables
Possibilité d'utiliser les entretiens assistés par ordinateur	Taux d'abandon élevé pour les questionnaires au-dessus de 15-20 minutes de longueur
Permet de joindre des populations à bas niveau d'étude	Difficulté de joindre les patients qui travaillent la journée
Courrier	
Coût faible	Nécessite une organisation des envois et des relances
Peut être réalisée avec peu de personnels et de moyens	Difficulté à comprendre les questions compliquées
Peu couvrir une grande zone géographique et permet d'atteindre des personnes difficiles à joindre personnellement	De faible taux de réponse peuvent nécessiter des relances (par courrier ou par téléphone) impliquant une identification des questionnaires
Permet au répondant de prendre du temps pour réfléchir à la réponse	Les patients peuvent retourner des questionnaires incomplets
Les patients ont l'impression que la confidentialité est mieux conservée que par entretien	Prend davantage de temps que les méthodes par entretien
Permet d'élargir les critères d'inclusion de l'échantillon	Nécessite des sujets avec un niveau d'étude suffisant
Peut être utilisée de façon mixte avec une relance téléphonique	Nécessite des adresses exactes

Tableau 9: Les caractéristiques selon la modalité de recueil des données

Caractéristiques	Entretien		Auto-administré	
	Face-à-face	Téléphonique	Courrier	Sur site
Confidentialité et anonymat peuvent être assurés	-	±	++	±
Taux de réponse élevé	++	+	-	++
L'enquêteur/facilitateur peut clarifier	++	+	-	+
Souplesse de la discussion	++	+	-	-
Possibilité d'établir un rapport avec le patient	++	+	-	+
Sensibilité à concerner les patients	++	+	-	+
Approprié aux questions ouvertes multiples	++	+	-	-
Facilité d'analyse	-	±/+	++	++
Capacité à atteindre des populations à faible niveau d'instruction	++	+	-	-
Faible coût en personne et équipements	-	-	+	+
Les répondants ont le temps pour des réponses réfléchies	+	-	++	-
Le rappel des expériences est plus récent	+	-	+	++
Capacité à couvrir un grand nombre de patients.	-	±	++	+
Biais de l'enquêteur	++	±	-	±
Aucune formation spéciale des enquêteurs	-	-	+	±
Les patients peuvent répondre à leur convenance	-	±	++	±
L'échantillonnage aléatoire est faisable	+	+	+	+
Faisabilité de relance des non-répondants	?	+	+	±
Faisabilité d'évaluer la sortie et le suivi	+	+	+	-

(Source : NHS Trust-based Patient Surveys : inpatients - acute hospital. Listening to your patients02/ 2002)

Il faut savoir que les avantages cités dans ce tableau ne sont pas égaux. Prenons comme exemple, assurer la confidentialité aux patients, le taux de réponse élevé, et la facilité d'échantillonnage sont considérés comme des critères importants pour obtenir un feedback fiable et exigible des patients. L'enquête postale par questionnaire comporte aussi des avantages.

Le moment de recueil des données

- Le moment de réalisation de l'enquête

Afin d'entretenir une enquête de satisfaction des patients, il est préférable d'éviter le plus possible tout travail autour des périodes de vacances à cause du manque de disponibilité ou de l'absence des patients. Pendant l'hiver, l'étude peut suivre une épidémie de grippe.

La durée écoulée entre la sortie et le moment de réalisation de l'enquête

En ce qui concerne l'hospitalisation, seule une mesure après l'hospitalisation permet d'évaluer les conditions de sortie et la satisfaction par rapport au suivi. Cette mesure doit être réalisée juste après l'hospitalisation, et elle est considérée plus fiable lorsqu'elle est proche de la sortie que lorsqu'elle est effectuée plusieurs mois après. Et il est convenable d'éviter le cours de l'hospitalisation, notamment d'obtenir les réponses le jour de la sortie³⁵. Le moment idéal pour envoyer un questionnaire à un patient est de 2 à 4 semaines après sa sortie^{36,37,38,39}. Une durée plus longue (6 mois) est proposée dans le cas d'une intervention chirurgicale pour permettre au patient d'intégrer les résultats des soins⁴⁰.

Ce délai a pour objectif:

- 1) de procurer le temps nécessaire aux patients de se détacher de leurs expériences hospitalières, car s'il est trop proche de la sortie, on peut risquer le biais lié au traumatisme de l'hospitalisation et
- 2) de bien se rappeler ce qui leur est arrivé, car on peut risquer, avec un délai trop long, le biais de mémoire- De plus, une étude a montré que les patients sortis depuis plusieurs mois sont plus satisfaits que ceux qui ne sont sortis que depuis quelques semaines⁶. Il est conseillé de ne pas échantillonner les patients qui sont sortis de l'hôpital depuis plus de 3 mois, puisqu'il est peu probable que le détail des expériences des patients soit exactement retrouvé.

³⁵ Czernichow P. Op.cit.

³⁶ Ware J. Op.cit. P 539-540.

³⁷ Carey R. Op.cit. P 834-845.

³⁸ Doering E. Op.cit. P 291-299.

³⁹ Cleary P. Op.cit. P 254-267.

⁴⁰ IZane R. L., Maciejewski M., Finch M. "The relationship of patient satisfaction with care and clinical outcomes." Medical care. 35(7): 1997. P 714-730. 1997.

Le consentement, l'anonymat et la confidentialité

Le consentement et l'accord des patients ou de leur entourage est très important dans toute enquête, quelle que soit la méthode d'enquête employée. Charles et al, cité par Pourin, testent deux méthodes de recueil du consentement des patients au Canada. Une première technique est de faire recueillir ce consentement auprès du patient alors qu'il est encore hospitalisé, par un membre du service. L'autre technique se base à adresser à son domicile un courrier après sa sortie de l'hôpital. Dans les deux cas, les résultats de cette étude se traduisent avec un taux de réponse qui ne diffère pas significativement entre ces deux techniques. Pourtant, le recueil du consentement à l'hôpital présente plusieurs avantages : meilleure implication du personnel soignant, moindre coût, meilleure fiabilité de l'adresse et du téléphone.

Il est primordial de respecter le plus possible deux grands principes : l'anonymat ou la confidentialité des réponses et la neutralité de la personne qui collecte des données. Tous les deux aident principalement à privilégier la sincérité de l'expression du point de vue. Le principe de l'anonymat est complètement assuré si aucune méthode d'identification des répondants ne s'utilise, toutefois, il est nécessaire d'utiliser certaines techniques comme l'identification par des numéros de codage si l'étude demande le suivi des non-répondants. Même si elle empêche la possibilité de relance, la garantie de l'anonymat ou au moins de la confidentialité est importante dans ce type d'enquête où il existe une relation de dépendance, le patient étant susceptible de revenir dans l'hôpital et/ou les services de soins sur lequel il exprime son avis.

La déclaration de la confidentialité requière une explication simple sur comment l'information va être traitée et analysée. Plusieurs études tentent de garantir la neutralité de la personne qui collecte des données par l'implication d'instituts de recherche ou de groupes académiques, qui sont moins identifiés aux fournisseurs de la santé, lors de la collecte et de l'analyse des données, mais ceci peut ne pas être faisable. Il est donc préférable d'envisager l'hypothèse que le cadre dans lesquels les répondants expriment leurs points de vue influent sur les résultats, et que, par exemple, ils sont plus francs dans l'intimité de leur domicile. Pourtant, l'analyse systématique de l'effet du cadre n'a jamais pu mettre en évidence de telles faits.

Des travaux montrent que le taux de réponse est plus bas lorsque l'enquête est anonyme, cela s'explique par le fait que certaines personnes peuvent estimer que leurs opinions sont importantes seulement quand ils sont identifiés^{41,42}.

⁴¹ Asch D. A. Kathryn Jedrzejewski M. Christakis, N. A. "Response rates to mails surveys published in medical journals." Journal of Clinical Epidemiology. 50(10) .1997. P 1129-1136.

D'autres choisissent de ne répondre que s'ils sentent une certaine pression, la possibilité d'anonymat réduit cette pression. D'autres travaux affirment que la garantie de l'anonymat a peu d'influence sur le taux de réponse^{43,44}.

Pour résumer, il n'existe pas, à notre connaissance, de comparaison directe entre les différentes méthodes d'étude dans la littérature. Mais l'anonymat complet du questionnaire entraîne des problèmes méthodologiques qui ne permettent pas de valider les résultats comme la représentativité de l'échantillon.

Biais d'investigation

Les biais sont des erreurs systématiques et constantes plutôt qu'aléatoires. Cette partie traite des biais liés au recueil des données.

- Biais liés aux informations recueillies ou aux enquêtes

Les informations obtenues doivent être "exactes". Or l'oubli (données anciennes, personnes âgées), la peur (sujet ayant un impact social fort: drogue ...), la méfiance (perception négative de l'enquête), le degré d'implication, représentent autant d'éléments susceptibles d'aboutir à un recueil d'information erroné, "orienté" ou incomplet.

- Biais liés aux enquêteurs

Les enquêteurs doivent bien connaître leur questionnaire de façon à reformuler de manière identique l'enquête auprès de chaque personne (s'il s'agit d'entretien). Les enquêteurs doivent, dans la mesure du possible, garder une attitude "neutre". Les biais liés aux investigateurs peuvent concerner les différents types d'enquête. Toutefois les enquêtes rétrospectives sont plus facilement sujettes à ces biais.

o Effet d'acquiescement

La méconnaissance d'un effet de Halo ou d'effet d'acquiescement est une source de biais extrêmement courante dans les enquêtes de satisfaction par questionnaire. Le premier désigne l'orientation de la réponse à un item par celle fournie au précédent. Sa survenue est étroitement liée à l'ordre des questions. Il induit de n'interroger le sujet sur sa satisfaction globale qu'en fin de questionnaire: un patient se sentirait incohérent s'il émettait des critiques sur les aspects spécifiques de son expérience après avoir exprimé un jugement global positif. L'acquiescement (ou biais de positivité) reflète la tendance d'un sujet à utiliser

systématiquement la modalité de réponse positive. Il est plus fréquemment rencontré chez les sujets âgés, disposant d'un faible revenu, d'un bas de niveau d'études et révélant un score de santé perçue médiocre. L'acquiescement n'est toutefois pas indépendant du contenu de l'item⁴⁵. L'alternance d'item de signification favorable et défavorable maîtrise le biais d'acquiescement. D'autres caractéristiques du questionnaire influent sur les résultats de l'enquête. Ross effectue une comparaison entre sept instruments et affirme que les taux de satisfaction générés par chacun d'eux sont d'avantage corrélés s'ils comportent le même format de réponse.

Les auteurs classifient généralement les questions de satisfaction en deux catégories opposées: questions stricto-sensu ("Êtes-vous satisfait des informations du médecin sur votre traitement ?") et questions de fait ("Le médecin vous a-t-il informé des effets secondaires du traitement ?"). Ils affirment la discordance des réponses et reprochent aux premières de fournir une opinion sans qu'on connaisse les critères de jugement des répondants. Cela implique, en pratique, l'utilisation des deux types de formulation.

A quel point l'instrument est-il applicable ?

Afin d'assurer l'obtention des résultats utiles, l'instrument utilisé doit être pertinent, performant et aussi applicable, c'est-à-dire utilisable en pratique. Un instrument est applicable s'il a l'aptitude de répondre au minimum à 4 critères, d'après Rubin:

- Le coût de la mise en œuvre
- La facilité d'utilisation
- L'acceptabilité pour les patients et les administrateurs
- La facilité d'interprétation des résultats
- Les coûts de mise en œuvre

Ils dépendent de la méthode d'investigation. Dans le domaine concerné, il s'agit essentiellement de passation de questionnaires ou de grilles, le coût varie selon la durée d'investigation mais aussi selon la qualification de l'enquêteur. Il faut également prendre en considération le coût de leur formation et de la vérification des réponses. Il est nécessaire d'indiquer que dans un certain nombre de cas l'indicateur considéré est inclus dans un questionnaire plus large (grille) portant sur de multiples aspects. Dans certaines circonstances, l'indicateur est construit à partir d'une sélection d'items du questionnaire ; d'autres fois, on introduit dans un questionnaire des items d'un indicateur construit par ailleurs. Ce contexte peut influencer l'acceptabilité pour l'enquêteur.

⁴² Asch D. A. "Use of a coded postcard to maintain anonymity in a highly sensitive mail survey: cost, response rates, and bias. *Epidemiology*". 7(5)1996. P 550-551.

⁴³ Asch D. A. Kathryn Jedziewski M. Christakis, N. A. "Response rates to mails surveys published in medical journals." *Journal of Clinical Epidemiology*. 50(10).1997. P 1129-1136.

⁴⁴ Asch D. A. "Use of a coded postcard to maintain anonymity in a highly sensitive mail survey: cost, response rates, and bias. *Epidemiology*". 7(5) 1996. P 550-559.

⁴⁵ Cohen, G., Forbe, J., Garraway, M. "Can different patient satisfaction survey methods yield consistent results? Comparison of three surveys." *British Medical Journal*. 313(10).1996. P 841-844.

- Facilité d'utilisation

Plusieurs études optent pour le choix des auto-questionnaires, par courrier, par téléphone, ou en direct, et réussissent à atteindre l'objectif recherché, c'est vrai qu'un grand nombre de sociétés commerciales effectuent ces types études (surtout aux États-Unis). Mais la plupart d'entre elles ne communiquent pas d'informations concernant le coût de leurs méthodes, et ne fournissent pas de données sur la fiabilité et la validité, ceci dit leur présence sur le marché montre que ces études sont facilement.

- Acceptabilité

Il est important qu'elle soit ressentie par les enquêteurs et les patients.

- 1) Pour les enquêteurs: que ce soit question d'une grille ou d'un questionnaire, l'enquêteur doit approuver à l'instrument utilisé. Et connaître les principes de construction, de la philosophie sous-jacente aux objectifs visés, cela représente un préalable nécessaire à l'acceptabilité. Par exemple, il est primordial que l'enquêteur soit au courant en précision de la signification des items et des principes de cotation.
- 2) Pour les patients: les questions doivent être claires, univoques, sans ambiguïté et rédigées de façon à être comprises de la population touchée par l'enquête.

En résumé, pour assurer son accessibilité, l'instrument doit être:

- clair dans sa formulation qui doit être compréhensible pour les patients et pour l'enquêteur. Le choix d'instruments d'origine étrangère suscite une traduction associant des experts du pays d'origine et du pays d'utilisation;
- clair dans sa présentation;
- la longueur doit être convenable, en prenant en compte le contexte et de la fréquence d'application.

Il est important d'ajuster le besoin de précision et le risque de lasser le répondant; de tenir compte du mode d'administration: par téléphone: courte durée; à domicile: durée plus longue; il faut aussi prendre en considération le sujet traité: si le sujet l'intéresse vraiment, le répondant y accorde plus de temps, et enfin tenir compte du coût de l'étude et du temps d'analyse.

La dénomination de l'enquêteur (enquêteur professionnel, médecin, infirmière, ou assistante sociale, etc.) peut influencer les réponses des patients.

Il est clair qu'il faut prendre en compte le fait que les réponses sont orientées par la qualification de celui qui pose les questions. On rendra moins spontanément à un médecin des problèmes de l'environnement matériel. La crainte de perdre une prestation est aussi susceptible d'orienter les réponses.

Nous pouvons évaluer l'applicabilité d'un instrument en se basant sur le pourcentage de sujets

qui refusent de répondre à certaines questions (acceptabilité pour les patients), la durée de passation (non seulement des items de l'indicateur lui-même mais aussi de l'ensemble de l'instrument dans lequel il est inclus) et l'évaluation d'un coût moyen par sujet enquêté. Selon un récent travail qui tourne au tour de l'élaboration de procédures standardisées et efficaces d'administration des questionnaires, pour juger la qualité du questionnaire, il est possible de se baser sur les critères suivants:

1. Proportion de non-réponses
2. Qualité de remplissage (proportion des données manquantes)
3. Contenu discriminant des données (distribution des modalités d'opinion)
4. Temps de passation: le temps nécessaire pour compléter la grille ou le questionnaire est un facteur important d'acceptabilité et doit donc être connu. Il peut influencer sur la participation à l'enquête des personnes sollicitées.

- Interprétabilité

Il est clair que les études de mesure de la satisfaction des patients se qualifient d'utile par les administrateurs que si leurs résultats sont compris et amènent à souligner clairement les points d'amélioration. De nos jours, Personne n'a encore effectué de comparaisons entre les méthodes et les instruments d'étude concernant ce problème. Ce critère peut être en désaccord avec les autres critères qui assurent la fiabilité des mesures et leur validité ou valides. Par exemple, les échelles d'évaluation souvent utilisées peuvent être problématiques parce que l'interprétation par des patients du terme « mauvais » ou « excellent » peuvent s'avérer claire. Un administrateur peut demander à savoir avec quelle régularité.

Pourtant une échelle d'évaluation est capable de mieux aboutir à révéler les points de vue des patients sur la qualité des soins.

Il faut savoir, que dans la plupart du temps l'évaluation des soins de l'hôpital par les patients est mal interprétée. L'aplatissement de la distribution et l'insensibilité des estimations de la satisfaction peuvent avoir comme conséquence de considérer que 90 pour cent et 95 pour cent des patients « satisfaits » sont des résultats proches alors que de telles variations peuvent correspondre à une grande différence dans les conditions de soins réelles.

Pour garantir que l'étude reflète au mieux la réalité, l'interprétation des jugements des patients doit se baser des normes de population ou validées par d'autres. Ces normes déterminent ce que signifient les niveaux de réponse. Si les évaluations sont enregistrées seulement avec des proportions de patients « satisfaits » ou qui évaluent le soin comme « excellent », ils seront ininterprétables à moins que le seul but de l'étude ne soit de déterminer quel groupe parmi plusieurs mieux

les soins ou dans le cas d'une enquête permanente, ne soit de suivre des évolutions de chaque niveau.

Tester un questionnaire

Il est primordial d'effectuer un test au questionnaire choisi sur un échantillon des répondants avant une étude complète. Ceci aide à prédire plusieurs problèmes potentiels. Ce test permet d'examiner la clarté et l'acceptabilité des items du questionnaire. Aussi, si l'on procure aux répondants un espace ouvert pour des commentaires, les items supplémentaires ou les issues qui ne sont pas inclus dans la première version du questionnaire peuvent apparaître. De plus, la variabilité des réponses peut être vérifiée.

L'étude ne sera pas particulièrement informative si la version finale inclut trop d'items qui produisent des réponses uniformes.

BIBLIOGRAPHIE

1. Asch D. A. "Use of a coded postcard to maintain anonymity in a highly sensitive mail survey: cost, response rates, and bias. *Epidemiology*". 7(5) 1996. P 550-559.
2. Asch D. A. Kathryn Jedziewski M. Christakis, N. A. "Response rates to mails surveys published in medical journals." *Journal of Clinical Epidemiology*. 50(10) .1997. P 1129-1136. Asch D. A. "Use of a coded postcard to maintain anonymity in a highly sensitive mail survey: cost, response rates, and bias. *Epidemiology*". 7(5) 1996. P 550-551.
3. Asch D. A. Kathryn Jedziewski M. Christakis, N. A. "Response rates to mails surveys published in medical journals." *Journal of Clinical Epidemiology*. 50(10) .1997. P 1129-1136.
4. Briançon S., Girard F., Empereur F., Guillemin F., « Evaluation des pratiques professionnelles », *Revue Épidémiologie et Santé Publique*. 48(6), 2000, pp. 541-550.
5. Carey, R. G. (1993). A patient survey system to measure quality improvement: Questionnaire Reliability and Validity. *Medical care*, 31(9), P: 834-845.
6. Carey, R. G. (1993). A patient survey system to measure quality improvement: Questionnaire Reliability and Validity. *Medical care*, 31(9), pp. 34-45.
7. Cleary, P. D. (1991). Patients evaluate their hospital care: A national survey. *Health Affairs*, 10, pp. 254-267.
8. Cohen, G., Forbe, J., Garraway, M. "Can different patient satisfaction survey methods yield consistent results? Comparison of three surveys." *British Medical Journal*. 313(10). 1996. P 841-844.
9. Czernichow P., Chaperon J., Le Contour X., « Épidémiologie - Connaissances et Pratiques », Masson, Paris, 2001.
10. Czernichow, P. C. (2001). *Épidémiologie-Connaissances et Pratiques*. Paris. Masson
11. Doering, E. R. (1983). Factors influencing inpatient satisfaction with care. *Quality Review Bulletin*., 9 (10), pp. 291-299.
12. Encounters. » *Medical care*. 26(4). 1988. P: 393-402.
13. Fitzpatrick, R. (1991). Surveys of patient satisfaction: II. Designing a questionnaire and conducting a survey. *British Medical Journal*, 302, P: 1129-1132.
14. Gasquet, I. (1999). Satisfaction des patients et performance hospitalière. *La Presse Médicale*., 28(29), P : 1610- 1613.
15. Hall, J. A. (1988). Meta-analysis of satisfaction with medical care: Description of research domain and analysis of overall satisfaction levels. *Social Science & Medicine*, 27(6), pp. 637- 644.
16. Hall, J. A. (1988). Meta-analysis of satisfaction with medical care: Description of research domain and analysis of overall satisfaction levels. *Social Science & Medicine*, 27(6), pp. 637- 644.
17. IZane R. L., Maciejewski M., Finch M." The relationship of patient satisfaction with care and clinical outcomes. " *Medical care*. 35(7): 1997. P 714-730. 1997.
18. Kravitz, R. L. (1996). Patients' Expectations for Medical Care: An Expanded Formulation Based on Review of the Literature. . *Medical care Research and Review*., 53, pp. 3-27.
19. Kravitz, R. L. (1996). Patients' Expectations for Medical Care: An Expanded Formulation Based on Review of the Literature. *Medical care Research and Review*., 53, pp. 3-27.
20. Nelson, E. H. (1989). The patient judgement system: Reliability and validity. *Quality Review Bulletin*, 15, pp.: 185-191.
21. Nguyen Th, P. L. (.2002). Factors Determining Inpatient Satisfaction with Care. *Social Science & Medicine*, 54(4), pp. 493-504.
22. Nunally Je. « *Psychometrie Theory*. », McGraw-Hill, New York. Ed. Second, 1978. P 1-677.
23. Pourin e. (1999). La mesure de la satisfaction des patients hospitalisés. 1" partie : Aspects conceptuels et revue de travaux. *Journal d'Economie Médicale*, 17, P : 101-105.
24. Roumeau-Rouquette E., Blondel B., Kaminski M., Bréart G., « *Épidémiologie - Méthodes et pratiques* », Flammarion, Paris, 1993.
25. Rubin, H. R. (1990). Can patients evaluate the quality of care? *Medical Care Review*, 47, pp 267-326.
26. Service d'Évaluation Hospitalière, Op.cit.
27. Service d'Évaluation Hospitalière. (1996). *La Satisfaction des Patients. Lors de Leur Prise en Charge dans les Établissements de Santé*. Agence National pour le Développement de l'Évaluation Médicale p. 120.

27. Sitzia, J « How valid and reliable are patient satisfaction data? An analysis of 195 studies. » International Journal for Quality in Health Care. 11(4): 319-328. 1999.
28. Sitzia, J. (1999). How valid and reliable are patient satisfaction data? An analysis of 195 studies. International Journal for Quality in Health Care. 11(4), P 319-328.
29. van Campen, c., Sixma, H., Friele, R. D., Kerssens. (1995). Quality of Care and Patient Satisfaction: A Review of Measuring Instruments. Medical care Research and Review, 52, pp. 109-133.
30. Ware, J. E. and Rubin, H. R. « Methods for Measuring Patient Satisfaction with Specific Medical
31. Williams, B. (1994). Patient satisfaction: A valid concept? Social Science & Medicine, 38(4), pp. 509-516.





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Antenatal Genetic Diagnosis and the New Eugenics: European Vision from Medical, Ethical and Legal Perspectives

By Aitziber Emaldi-Ciri3n

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Abstract- The objective of this work will focus on the ethical and juridical study of reproductive technologies. We have to recognize the many advantages they bring, but it is also required to foresee and evaluate the consequences that these technologies have for human rights. Antenatal diagnostics are not allowed throughout Europe so the reasons are the different uses they can have: embryo selection, sex selection, genetic manipulation, etc. Preimplantation diagnosis involve ethical and legal approaches with solutions that are highly criticised by society due to the eugenic component that they entail. Result of this study reflect on the convenience of their practice and a proposal of the guidelines to respect human rights and guarantees.

Keywords: predictive test/ new technologies / eugenics / human rights/ ethics / preimplantation genetic diagnosis / ethics / embryo selection.

I. ANTENATAL TEST AND FUNDAMENTAL RIGHTS

We must place preimplantation genetic diagnosis in the context of assisted reproduction techniques and predictive medicine. This technique has been extended with this preimplantation genetic diagnosis as a solution for those couples in a situation of transmitting a congenital anomaly to their offspring. Due to this technological advance, new constitutional rights are requested.

1. Right to procreate

The fact that we have new reproductive technologies at our disposal raises the question of how far the right to procreation as such extends. Right to have children, which would derive from the right to privacy. If right to have children exists, we would have to analyze whether it is an absolute right that people have or whether, on the contrary, it could be limited to specific cases.

Assisted human reproduction makes it possible to exercise, more than ever before in history, the right of individuals to create a family. Sometimes, age, marital status or biology frustrate people aspirations to have offspring. Assisted Reproductive Technologies (ART) appear as a valuable instrument to satisfy this desire. Spanish Law 14/2014 on Assisted Human Reproduction

Techniques says that this right to procreate not only reaches couples but also fertile or infertile single women (art. 6), and people who have died - *post-mortem* fertilization - (art. 9).

Spain has ratified various treaties which proclaim the right to create a family. Right to procreate could be derived from the right to their privacy and right to the protection of their health¹. However, the fundamental problem with the exercise of this right is that it can compromise two different and sometimes conflicting interests:

- a) the right of individuals to procreate implies the use of assisted reproduction techniques.
- b) the right of the child born to have a father and a mother on an equal conditions with other children born in a naturally way.

Given this approach, the difficulty lies in whether or not to deduce the existence of this right to procreate from the constitutional precepts. Personally, I consider that there exists in the abstract a right to reproduce that couples - married or not have, which is based on the following rights:

- a) In freedom, as a value and in the right to free development of the personality² (arts. 1.1 and 10.1 Spanish Constitution), since all persons can freely decide on matters that affect them in their personal and intimate sphere. Right to create a family is based on freedom and the dignity. Right to reproduction is a right to physical self-determination. It is a fundamental right of Spanish Constitution- art.17.
- b) In the right to privacy (art. 18.1 Spanish Constitution), in the sense that there can be no state interference in such an intimate sphere as the family and procreation.

¹ GOMEZ SANCHEZ, Y. (1994), *El derecho a la reproducci3n humana*, Marcial Pons Ediciones Jur3dicas/Servicio de Publicaciones de la Facultad de Derecho de la Universidad Complutense de Madrid, Madrid, pp. 42 y ss.

² EMALDI CIRI3N, A. (2015) "El derecho al libre desarrollo de la personalidad y la libertad reproductiva", *Derecho y pobreza*, 3lvarez V3lez, Maria Isabel / Rey P3rez, Jos3 Luis (Directores), ISBN: 978-84-9098-570-0, Editorial Aranzadi — Thomson Reuters, Cizur Menor, Espa3a, (Parte IV, Cap3tulo 8).

- c) In the right to the protection of health (art. 41.3 Spanish Constitution), in the sense that the limitations to founding a family could suppose a psychological problem for people and, on the other hand, the necessary measures should be made available to all those people to solve their health problem. Non-procreation for these people would be a health problem that the State must to solve. It is also intended that the offspring should be healthy.

Consequently, this right to reproduction derives from the right to self-determination of individuals, without the possibility of specific State interferences in the exercise of this right, as these decisions belong to the sphere of private life. It can be concluded that there is a subjective right to procreate that can be limited by the interests of other people:

- a) the right to procreate of one of the partners may entail the deprivation of such a right concerning the other partner. On certain occasions, a woman exercising her right to reproduction may terminate her pregnancy following "
- b) Another limit to this right to procreation would arise when the woman wishes to procreate using assisted reproduction techniques and the husband opposes the insemination of his wife with the reproductive material of both of them- for example, using his cryopreserved sperm. In this case, the insemination would be unlawful. The lack of such consent does not prevent the husband from being the biological and legal father. The husband can sue his wife and sue the doctor who carried out the non-consensual insemination.
- c) Another limit to the right to reproduction that we will have to reflect on is when couples who, due to physiological circumstances, are unable to father their children let us think of a male couple but who could provide their reproductive material and resort to surrogate motherhood to have their right to procreate satisfied³

In conclusion, I consider that there is a subjective right to procreation recognized in the Spanish constitutional order, which is based on freedom as a value (art. 1.1), and on the dignity of the person (art. 10.1), we, also link it to the right to personal and family privacy (art. 18), right to the protection of health (art. 43.1) and respect for the right to found a family (European Convention). It is not an absolute right and will have the limits derived from the rights of others.

³ EMALDI-CIRIÓ A. (2018) "Surrogacy in Spain and the proposal of a legislative change for its regulation. Global phenomenon in Europe", *Revista de Derecho y Genoma Humano Genética, Biotecnología y Medicina Avanzada-Law and the Human Genome Review Genetics, Biotechnology and Advanced Medicine*, Ed. Dykinson, núm.49, pp. 75-99.

2. Right to health

The right to health is recognized in international Law as a human right, that is, a fundamental right, because its existence allows the exercise of other fundamental rights that are regulated, protected, and guaranteed by the public authorities. In this case, the guarantee of protection of the right is not only internal but also the rest of the Member States undertake to do so. There are several international treaties and agreements that promote health.

In Spain, the right to health is a constitutionally recognized right. Spanish Constitution refers to health in its Title I (On fundamental rights and duties), Chapter III (On the guiding principles of social and economic policy -articles 43 and 50). The right to the protection of health is a fundamental right.

New predictive tools are being made available to people, such as antenatal genetic diagnostics that allow to discard for reproduction those embryos that present some kind of anomaly, disease or predisposition even if this leads to a new and accepted eugenics called "neueugenics"⁴.

These diagnoses will do with all the information and a proper genetic counselling. The doctor will give all the information to people with reproductive problems. Genetic counseling is a requisite for preimplantation genetic diagnosis, - Biomedicine Convention of the Council of Europe signed in Spain in 1997 and Law 14/2007 on Biomedical Research -art. 55-.

On the other hand, we have to think about the possibility to force people to carry out this test. Some cases:

A. Health policy reasons

For health policy reasons, certain tests could be considered beneficial so compulsory submission will be justified. We refer to preimplantation genetic diagnosis that brings benefits and the results are relevant for decisions regarding reproduction. One problem arise if medical information will be given to the person but he/she prefers not to know.

B. Economic reasons

Another approach that could justify the compulsory of certain genetic diagnostic would be based on the high social and economic cost of the handicap people. This argument haven't got ethical value because financial costs are paid by the State and by the parents.

C. Descendant Health Protection

In this case, the question arises as to whether it is possible, in the interests of protecting the health of offspring, to compel parents at risk of transmitting

⁴ CARVALHO GONÇALVES ELER / MIRANDA RAMOS y PIRES DE OLIVEIRA, (2019), *Diagnóstico genético pré-implantação (DGP): Uma Eugenia mascarada?*, *Revista iberoamericana de bioética*, núm. 9, pp 60-75.

anomalies to their children to undergo genetic tests to confirm the probability or non-existence of the disease or abnormality in question. To sum up, whether it is possible to force people to know their congenital characteristics and to use this information in relation to their reproductive decisions.

D. Special cases imposed by Law

The cases in which genetic tests are compulsory because they are required by Law will be mentioned briefly, as they are outside the scope of the study of preimplantation genetic tests. The most critical cases in which genetic testing could be made compulsory are as follows:

a) Criminal investigation

Scientific and technical developments have introduced new techniques in a criminal investigation, which must be assessed and interpreted by the courts.

b) Investigation of paternity

According to the content of the Spanish Constitution -Art. 39.2- "Law shall make paternity investigation". If the subject refuses to undergo this kind of test, he/she cannot be obliged to do so, as there is no rule determining the consequences of such a refusal but this attitude will be interpreted by the judge, not as a "*ficta confessio*", but when combined with other evidence, it can lead to declare parentage" (Sentence Supreme Court 2017 -ROJ 2815/2017). Nowadays, with these genetic test it is possible to determine the paternity of a person with a 99% probability of success.

c) Public health risks

This approach does not apply during the process of preimplantation genetic diagnosis since diseases of gene origin do not represent a severe risk to public health.

It can be concluded that a person can not be submitted to any type of compulsory genetic test. Firstly, despite the benefits that both predictive and preventive medicine can bring, we must not forget that predictive knowledge can also lead us to consider psychological problems as well as stigmatization or social discrimination of people due to their belonging to a group or category. Secondly, this situation is against the right to privacy.

Finally, privacy would also be violated if the subject have been forced to undergo this type of test, since every subject has a "right not to know". Also, the right to dignity and the right to procreate will be affected, if the knowledge of specific genetic results limits the reproduction.

In defense of the safeguarding of the fundamental rights, no subject can be forced to undergo genetic testing except in two situations: a) concerning the analyses that must be carried out on gametes from donors to prevent them from transmitting specific pathologies when they are used in assisted reproduction techniques; b) the preimplantation

analyses whose purpose is to confirm that they comply with the due viability guarantees.

II. PREIMPLANTATION GENETIC DIAGNOSIS IN SPAIN

The regulation of preimplantation genetic diagnosis in our legal system is set out in Law 14/2006 on Assisted Human Reproduction Techniques of 2006⁵.

The Law in the Explanatory Memorandum, states that preimplantation genetic diagnosis is a complementary technique to assisted reproduction techniques and its purpose is to avoid the transmission of diseases to the offspring. Preimplantation diagnosis must be carried out when the National Commission for Assisted Reproduction gives the authorization.

According to article 12.1.a) this diagnosis reveals the possible presence in the pre-embryo of a monogenic disease. Concerning to the provisions of Article 12.1b) It will be used to detect alterations that may compromise the viability of the pre-embryo. Only the unaffected pre-embryos will be transferred to the woman.

The lawfulness of the diagnosis is conditional upon the authorisation of the competent authority with a prior favourable report from the National Commission on Assisted Human Reproduction, which will evaluate the clinical, therapeutic and social characteristics of each case.

The social and ethical debate is no longer centred on the risk of eugenics that may derive from the practice of preimplantation genetic diagnosis, but on the ethical implications that this embryo selection may entail, since it may be thought that the child born as a result of these processes is instrumentalised, since its conception is caused by the use of its person in favour of another person.

This regulation aims to identify the specific conditions under which it is lawful to carry out preimplantation genetic diagnosis⁶.

III. ASSISTED REPRODUCTIVE TECHNIQUES FRAMEWORK FOR PREIMPLANTATION GENETIC DIAGNOSIS

Predictive genetic diagnosis, and preimplantation genetic diagnosis, has evolved, and its use is increasing in the context of assisted reproduction techniques. It has different purposes⁷:

⁵ LOZANO ARANA. M. (2016), *Diagnóstico genético preimplantatorio. Implantación desarrollo y actualización de un programa de diagnóstico preimplantatorio en un Sistema Sanitario Público*, Tesis Doctoral, Universidad de Sevilla, España, 213pp (p.178).

⁶ FOX, D. (2017) "Reproductive negligence", *Columbia Law Review*, núm 17, pp. 149-241.

⁷ EMALDI CIRIÓN, A. (2020), "Derechos constitucionales y análisis jurídico en relación con el diagnóstico genético preimplantatorio en el contexto de la reproducción asistida", *Retos del Derecho ante un*

a) Improve human fertility

The fundamental purpose of Assisted Reproductive Techniques, is to combat human sterility⁸. Woman alone is also allowed to be the beneficiary of assisted reproduction techniques in a public sanitary system, and she may be fertile or, on the contrary, infertile.

b) To avoid the genetic or hereditary spread of illnesses to future generations

This specific purpose is related to preimplantation genetic diagnosis. During the genetic counseling process, people at risk of transmitting congenital anomalies to their offspring are warned to do sex selection for therapeutic reasons, fetal gene therapy, selection of non-pathological gametes, etc. Carrying out one of these options, people can prevent their offspring from suffering from any type of congenital disease or anomaly.

c) Human gametes or fertilized ova used in research

It is necessary to research and experiment with the reproductive material to improve assisted reproductive techniques. The use of the techniques makes possible to produce surplus embryos obtained *in vitro*. Law contemplates and regulates research and experimentation with human gametes and fertilized ova, provided that a series of requirements and controls are met (arts. 14, 15, 16).

Once preimplantation genetic diagnosis has been framed in the context of Assisted Reproductive Techniques, we have to analyze the pre-embryo generated *in vitro*, prior to being transferred to the woman. The aim is to avoid genetic disorders.

The advantage of this diagnosis is that people who carry it out will accept the discarding of embryos with a pathology⁹.

IV. RECOMMENDATIONS FOR CARRYING OUT A PREIMPLANTATION GENETIC DIAGNOSIS

The use of this practice is indicated for people who are in a clinical situation that recommends to discard those embryos that haven't got viability or those that have some predisposition or anomaly.

On the other hand, to use of preimplantation genetic diagnosis, it is also necessary to comply with another requirements that Spanish Law 14/2007 on assisted human reproduction techniques forces to

health professionals: a) the purpose of the predictive genetic analysis; b) the place where it is to be carried out; c) the destination of the biological sample at the end of the analysis; d) access to the results of the analyses when they are not going to be subjected to dissociation or anonymization procedures; e) to ask about the possibility of unexpected discoveries and their possible significance for the subject and for biological family; f) to ask about the implications that the information obtained may have for relatives and the advisability of their transmitting this information to them; g) to offer them genetic counseling, once the results of the analysis have been obtained and evaluated; h) to inform the subject about their rights over their personal data -access, rectification, opposition, and cancellation-. All this information affects the entire biological family.

V. SCIENTIFIC PROCEDURE OF PREIMPLANTATION GENETIC DIAGNOSIS

We shall analyse in detail the phases to proceed with this diagnosis¹⁰:

Firstly, the couple or the woman alone must consult a genetic counselor when there are possible reproductive problems. Professional will provide information about the preimplantation genetic analyses and the alternatives that the couple or a person-alone will have depending on the results of these analyses¹¹.

1. In vitro embryo fertilization phase

The use of assisted human reproduction techniques will be used, specifically, *in vitro* fertilization, to obtain embryos to be subjected to preimplantation genetic diagnosis and to rule them out if any type of anomaly, illness, or predisposition is detected in them.

2. Biopsy phase

A cell will extract from the embryo. Cells of the embryo will then continue to divide. Cell stage (6-8) will be the stage chosen for the embryo biopsy prior to be transferred¹².

3. Genetic analysis phase

The cell obtained will be processed to carry out chromosomal and molecular diagnostics to detect genetic alterations or chromosomal anomalies causing a disease or malformation of the pre-embryo. Two techniques are currently available:

¹⁰ HODGE C./ SANTOS, M.J. (2017), "Diagnostico Genético Preimplantatorio de embriones humanos: Técnica, ética y teología", Teología y vida, ISSN 0049-3449, pp. 275-300, (285 y ss).

¹¹ GENOFF GARZON / RUBIN / LOBEL / STELLING / PASTORE, (2018), "Review of patient decision-making factors and attitudes regarding preimplantation genetic diagnosis", *Clinical Genetics*, pp. 1-21.

¹² RODRÍGUEZ MARTÍNEZ, K. / REYES MARTÍNEZ, I. / FLORES SÁNCHEZ, RM. / MÉNDEZ VIDAL, J. (2017), "Factores clínico-terapéuticos y su relación con la calidad embrionaria en pacientes sometidas a fertilización *in vitro*", *Rev Cubana Endocrinología*, vol. 28, núm.1, Ciudad de la Habana., p. 15 y ss.

mundo global/ Ed. Tirant lo Blanch, ISBN 9788413558165, pp. 775-808 (p. 800).

⁸ Spanish Society of Gynaecology and Obstetrics (2018), "Estudios genéticos en la disfunción reproductiva. Diagnóstico genético preimplantatorio. Consejo preconcepcional", *Progresos de obstetricia y ginecología: revista oficial de la Sociedad Española de Ginecología y Obstetricia*, ISSN 0304-5013, Vol. 61, Nº. 4, pp. 403-409 (405)

⁹ SULLIAN-PIKE, C. / DOKRAS, A. (2018), "Preimplantation genetic screening and preimplantation genetic diagnosis", *Obstetric & Gynecology Clinics of North America*, 2018, núm. 45, pp. 113-125.

- a) Polymerase chain reaction (PCR), a procedure that allows the amplification of specific DNA sequences *in vitro*, is used to locate specific mutations causing monogenic diseases. Also allows specific detection of diseased embryos, with the advantage of not having to discard potentially diseased embryos simply because of their sex (e.g., in the case of sex-linked monogenic diseases).
- b) The Hybridisation procedure is used for chromosome analysis and involves the use of specific labeled DNA probes that hybridize to specific chromosomes or chromosome fragments. It is used for the diagnosis of X-linked diseases.

Subsequently, the embryo whose genetic analysis shows that it is not affected by an anomaly, disease or predisposition is transferred to the woman. Healthy embryos - or, in the case of X-linked diseases, the female embryos - are transferred to the mother, discarding the rest of the embryo.

Preimplantation genetic diagnosis arises two types of problems. On the one hand, whether the study of a single cell is representative of the totality of the embryo. Second, when the biological guarantees are met, the embryos will be transferred to the mother's uterus, and in a near future, possible anomalies can be detected doing a prenatal diagnostic tests.

VI. DIFFERENT USES OF PREIMPLANTATION GENETIC DIAGNOSIS: LEGAL AND ETHICAL ASPECTS

The uses for these predictive diagnostics are expanding, enabling: a) high-risk couples to avoid passing on a disease or genetic predisposition to their offspring; b) embryo selection; c) reducing the number of therapeutic abortions; d) sex selection when there are therapeutic reasons; e) embryo selection for third parties; f) use of discarded embryos for experimental and research purposes; and g) therapeutic techniques on the living preimplantation embryo. Although bioethical approach implies that they are pushing eugenics, these uses are recognized by Spanish Law and they are socially acceptable.

Opponents of this diagnosis have brought up several legal and ethical considerations in support of their objections, which are based on the UNESCO Universal Declaration on Bioethics and Human Rights. Considerations are behind the variety of applications that could result in healthy offspring (2005)¹³. This Declaration proclaims that the impact of life sciences on future generations, and particularly on genetic, must be taken into account. They also consider that there must

be rules governing the decisions to use genetic technology: embryo selection or gene therapy.

Second, some authors question the efficacy of the biopsy techniques on embryos undergoing preimplantation genetic diagnosis.¹⁴ As a result, they believe that it should have first been approved as an experimental technique before being implemented following the precautionary principle¹⁵.

Third, lawsuits against professionals may be filed if their careless conduct caused harm that required recompense¹⁶. Professional negligence¹⁷ provides an incorrect diagnosis, which could result in the implantation of embryos carrying a particular anomaly or, conversely, in the rejection of healthy embryos that would otherwise be used for procreation.

Fourthly, it is a practice that is significantly questioned ethically for several reasons, including the following¹⁸: A) It is possible to think that the methods used are unethical because the blastocyst is endangered during cell extraction, or because it is thought that the extracted cell, being totipotent, should be treated as another embryo once chosen, which is sacrificed for the excellent progress of procreation; B) it is possible to think that using preimplantation genetic diagnosis to rule out the implantation of some embryos is unethical because it prevents the implantation of other embryos. C) This practice will be condemned as tending toward eugenics because embryos will be destroyed.

I'll now examine in detail how ethically and legally acceptable preimplantation genetic diagnosis¹⁹.

1. Embryo selection for therapeutic purposes

One of the fundamental uses of this diagnosis is to choose healthy embryos for the woman to have an implant because no illnesses or predispositions are found²⁰. It is possible to find in the embryo:

¹⁴ BORINI, A., TAROZZI, N., LAGALLA C. (2016), "Preimplantation genetic diagnosis: Why are obstetric and neonatal risk increased? The need for more data" *Fertility and Sterility*, No. 106-6, pp. 1328-1329.

¹⁵ KAISER, M. (2010), "El principio de precaución y su importancia para la ciencia", *Ética de la BioTecnología. Una introducción*, Granada, Editorial Comares, pp. 135.

¹⁶ DIAS PEREIRA, AG. (2014), "Responsabilidade Civil: o Médico entre o Público e o Privado", *Boletim da Faculdade de Direito*, vol 89, Coimbra, Universidade de Coimbra, 2014, pp. 253-304.

¹⁷ MACIA MORILLO, Andrea, *Diagnóstico genético preimplantacional y responsabilidad médica por falsos negativos*, Ed. Reus, Madrid, 2018, pp. 165 y ss.

¹⁸ DE MIGUEL BERIAIN, I. (2021), *Un estudio de impacto ético y social de las nuevas tecnologías en la práctica de la biomedicina*, Tesis doctoral, Universidad del País Vasco - Euskal Herriko Unibertsitatea, España, pp.16 y ss.

¹⁹ EMALDI CIRIÓN A. (2017), "Aproximación a un estudio jurídico y ético de la medicina genética predictiva", *Revista Iberoamericana de Bioética*, Número 3, Ed. Universidad Pontificia Comillas, 2017.

²⁰ ENGUER GOSÁLBEZ, P./ RAMÓN FERNÁNDEZ, F. (2018), "Dilemas bioéticos y jurídicos de la reproducción asistida en la sociedad actual en España", *Revista Latinoamericana de Bioética*, ISSN-e 1657-4702, Vol. 18, N° 34-1, pp. 104-135 (p.111).

¹³ JIMÉNEZ GONZÁLEZ, J., (2016), "Marco legal Internacional y conflicto ético del diagnóstico genético preimplantacional y las nuevas técnicas de donación mitocondrial, *Ius et Scientia, Revista electrónica de derecho y ciencia*, vol, 2, núm. 2, p. 35.

A. Serious diseases

There are some illnesses that, due to their severity might affect a person's future development (X-linked Alport's Syndrome, Spinal Muscular Atrophy, Huntington's disease, Cystic fibrosis, Haemophilia A, Duchenne muscular dystrophy, and Haemophilia) B. As a result, these diagnoses that identify certain diseases are widely accepted by society and are permitted by law in many nations: Spanish, Greek, Belgian, French, British, Danish, Norwegian, Finnish, and Swedish.

Preimplantation genetic diagnosis is prohibited in some nations since they believe it violates the right to the protection of the embryo and puts people at risk of developing eugenic inclinations. Germany, Austria, Switzerland, and Italy prohibit Preimplantation Genetic Test ²¹.

B. Diseases and Predispositions with Multifactorial and Variable Phenotypic Expression

Preimplantation genetic diagnosis can be used to identify multifactorial disorders or predispositions that manifest in a variety of phenotypical ways. This dispute stems from the fact that a predisposition to a disease does not guarantee that it will manifest in the future; rather, it depends on a variety of environmental and nutritional circumstances, and a person may never get the disease as a result.

Based on this premise, the United Kingdom was the first nation to permit the use of these diagnostics to find predispositions in fetuses to prevent them from being passed on to the mother. Human Fertilization and Embryology Authority (HFEA) authorized the use of preimplantation genetic diagnosis to identify predisposition to several diseases, including familial adenomatous polyposis coli (FAPC) or Huntington's disease, Cystic Fibrosis, Duchenne muscular dystrophy, Beta-thalassemia, and Cystic Fibrosis.

The Biomedical Research Act of 2007 and the Assisted Reproduction Act of 2006 govern this diagnosis and the authorization to perform these analyses when they are used for: a) the detection of serious hereditary diseases that are not amenable to postnatal curative treatment, to carry out embryo selection of unaffected pre-embryos for transfer; b) the detection of alterations that may compromise the viability of the embryo.

As a result, a number of ethical issues are raised in light of this utility. To start, we must be mindful that we are rejecting a pre-embryo that could result in a healthy person. Second, if the couple from whom the

embryo with the disease decide the transfer we would be faced with a conflict of interest.

In this view, the question of who should take precedence—the parents who wishes to have children or the medical opinion that recommend not to transfer the embryo. In these situations, the transfer of these abnormal embryos would be illogical because the couple is using assisted reproductive technology to have healthy children.

Legally, it is advised against transferring embryos with biological traits. It is a serious offense to "transfer gametes or pre-embryos to the woman without the required biological guarantees."

C. Embryo selection for therapeutic purposes for a third party

Cellular transplantation of stem cells can treat several genetic illnesses (Falconi Anemia, Aplastic Anemia, Immunodeficiencies) and diseases (Leukemia, Thalassemia).

The best outcomes in this area occur when the ill person and the donor are histocompatible because this enables the latter to be cured, either through the transplantation of stem cells taken from the umbilical cord or through a subsequent organ or tissue donations²².

A couple with a child suffering from Myeloblastic Leukemia would request a preimplantation genetic diagnosis to identify a severe hereditary disease in conjunction with the determination of histocompatibility antigens. He would donate stem cells from the umbilical cord after birth or, if necessary, through a bone marrow transplant.

However, to resolve this clinical case, it is necessary to recognize the significance of the preceding actions since, following a preimplantation genetic diagnosis, any one of the following three scenarios could occur: a) There were healthy embryos - not carriers - that were not immunologically compatible with the sick child; b) there were some embryos that were carriers of the same disease that the first sick child already had; c) the analysis revealed the existence of healthy embryos that were immunologically compatible with the sick child to be treated with stem cells.

In this situation, it is possible that healthy embryos but not immunologically compatible will be eliminated for reproduction.

The current Law in Spain permit this procedure as long as the relevant health authority approves it. Additionally, a prior favorable report from the National Commission for Assisted Human Reproduction is required, which must evaluate the clinical, therapeutic, and social characteristics. It is legal to reject healthy embryos for implantation, even when they are

²¹ EMALDI CIRIÓ, A. (2017), "La diagnosi genetica preimpianto tra normativa e giurisprudenza", (n. 6/2017 della Collana "Mancipolo. Percorsi di diritto pubblico interno e comparato lungo i confini disciplinari", diretta da S. Prisco) R. FATTIBENE (a cura di), Editoriale Scientifica, Napoli, pp. I-332.

²² ARANGO RESTREPO, P., SÁNCHEZ ABAD, P. y PASTOR L. (2012), "Diagnóstico genético preimplantacional y el "bebe medicamento", Cuadernos de Bioética, 23, p. 301.

incompatible with the person to whom the therapy will be applied.

From an ethical point of view, this selection of embryos for therapeutic purposes for a third person would bring up the possible objectification of human beings and their instrumentalization²³ If people are treated with respect from the moment they are born, I believe that they would not be used as instruments. Another situation is when a baby is abandoned or given up for adoption after using the stem cells.

The creation histocompatible embryos with the sick sibling they are trying to cure may be the aspect that inspires the most ethical debate because it is to create twenty or more embryos before finding the best. The rest of surplus embryos will be cryopreserved and used for whatever the couple has decided: donation, research, reproduction, or destruction. We must, however, consider how many times the same couple could repeat this procedure. This is the reason why this diagnosis raises ethical questions.

2. Positive eugenics: the selection of embryos with an illness or defect

Some couples comprised of individuals suffering from specific pathologies, illnesses, request the selection of embryos with the same condition. This case involved a deaf couple who wanted embryo selection so they might have a kid with the same disabilities they had. The case occurred in the United Kingdom. They felt that an unaffected child might suffer more in a family of affected children, whom they would see as different.

Spanish Law prohibit harming to others. Choosing embryos with defects or illnesses could make parents liable for the harm done. It is possible for a kid to sue his or her parents in civil court.

From an ethical point of view, we reject this practice because people is looking personal interests instead of looking for the baby interest.

3. Sex selection of pre-embryos

Preimplantation genetic diagnosis permit to carry out a sex selection:

a) Sex selection for medical purposes: sex-related illnesses

Preimplantation diagnostics permit to select the embryo preventing the birth of children with a condition associated with the sex chromosome.

From a legal standpoint, this practice is regulated by the Assisted Human Reproduction Techniques Act of 2006 (art. 26) and the Convention on Biomedicine (art. 14), which prohibits the use of medically assisted reproductive techniques to do a sex

selection except if it is to avoid a serious hereditary sex-related disease.

An analysis of this article reveals that we have two possible interpretations

- A. No technique that allows for sex selection, including assisted reproduction methods, should be used.
- B. The Convention states "that the sex of the person to be born cannot be chosen".
- C. The goal of sex selection is "to prevent a significant hereditary sex-linked disease,". So sex selection for therapeutic purposes would not be forbidden under the following two circumstances:
 - 1) When sex choice is made to avoid the conception of a child who "may suffer" from a major sex-related hereditary condition.
 - 2) Sex selection will be permitted in cases where it is necessary to stop someone from being born "a carrier of a disease".

From an ethical standpoint, sex selection for therapeutic purposes may be acceptable due to this therapeutic goal.

Sex preference for non-pathological family factors

Preimplantation genetic diagnosis will use to select sex for non-therapeutic purposes. In this case, sex selection have not any pathology circumstance. This option can cause gender discrimination, economic discrimination, and population imbalance from an ethical perspective.

4. Pre-embryo in vitro therapy

A preimplantation genetic diagnosis may also be used to identify diseases or anomalies to treat the pre-embryo *in vitro*. If the treatment is possible will be necessary: a) Inform the parents about the processes, diagnostic tests, and hazards; b) confirm that the pathologies have a diagnosis and a cure; c) therapy does not alter non-pathological hereditary characteristics; d) therapy does not seek to select particular people or a particular race.

Although this is currently an exceptional case, it would be a case permitted by Law but would require the authorisation of the corresponding Health Authority, following a favourable report from the National Commission on Assisted Human Reproduction.

5. Research with in vitro embryos

To improve several assisted reproductive techniques will be necessary to research with in vitro pre-embryos. Pre-embryos that will be used in the study could originate from various sources, including:

- A. Embryos that are not deemed fit for reproduction based on the findings of preimplantation genetic diagnosis. According to Spanish Law, dead embryos and human embryos that have lost the ability to develop biologically will be donated for scientific research.

²³ GARCÍA MOYANO, L. / PELLICER GARCÍA, B. / BUIL TRICAS, B., JUÁREZ VELA, R., GUERRERO PORTILLO, S. / ANTÓN SOLANAS I., (2016), "Bioethical analysis of the generation of saviour sibling", *Rev. Bioética y Derecho*, núm.36, Barcelona, pp. 55-66.

- B. Surplus embryos: These are often viable and come from couples that use *in vitro* fertilization. It is permissible to produce more embryos and cryoconservate them for future situations.
- C. Gametic embryos: The Biomedicine Convention forbids the development of these embryos for the only purpose of study.
- D. Embryos produced by cloning procedures, which entail transferring a somatic cell nucleus from an individual to a human egg cell, to use them for research. There are many authors who consider that this procedure does not involve embryos as the nucleus is not of gametic origin –sperm and egg-.

Spain forbids the fertilization of human embryos for any reason other than human reproduction. It treats such a practice as a criminal offense because the Convention on Biomedicine forbids the creation of human embryos to research (art. 18.2). (Penal Code, art. 160.2).

VII. LIABILITY FOR FALSE DIAGNOSES

During the practice of preimplantation genetic diagnosis, due to medical negligence, an error occurs in the interpretation of the results.²⁴ Incorrect information given to the users of such a practice can be of two types:

- 1) False positives in the preimplantation genetic diagnosis

The information received is erroneous since the diagnosis establishes the existence of a disease in the pre-embryo analyzed that does not exist. Also, the diagnosis may deny the presence in the pre-embryo of specific histocompatibility characteristics that it does possess.

This error means that the embryos, which are healthy or which do have the histocompatibility characteristics are not implanted, and this is the basis on which a civil liability claim for medical negligence exist.

- 2) False negative preimplantation diagnosis

The information is erroneous because a preimplantation genetic diagnosis is not given. The diagnosis erroneously denies the existence of a disease. Another situation is that the diagnosis states the presence in the pre-embryo of certain histocompatibility characteristics that it does not possess.

In both cases, the decision on whether or not to implant the embryo is conditioned by the erroneous information that has been transmitted to the couple.

The damage for which compensation is claimed is that a child is born suffering from a disease or anomaly. In the other situation, a child who has born does not have the intended histocompatibility characteristics necessary to cure another person.

VIII. CONCLUSIONS

- 1) Concerning the transfer to the woman of embryos with anomalies when she requests it, this would be a contradiction. If the couple asks for assisted reproduction techniques, the objective is to have healthy children.
- 2) Preimplantation genetic diagnosis is a tool of preventive and predictive medicine. In some cases, it is used as a screening system between healthy and diseased embryos or between healthy embryos but selecting the one that does not have a predispose to a disease. This embryo selection promotes eugenics. We must reflect to what extent we can select pre-embryos with a predisposition. This selection should depend on the type of disease in question.
- 3) It would be interesting to develop research to carry out embryo therapies. Ethical problems such as the destruction of pre-embryos would be solved.
- 4) Sex selection for therapeutic reasons may be justified on therapeutic grounds. If sex selection is a technique that can be carried out easily, in a near future sex selection can be allowed. From an ethical point of view is open to criticism and limits should be placed.

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²⁴ BASTIDAS GOYES, L. / RUEDA BARRERA, A. (2020), “La aceptabilidad de las acciones de Wrongful Birth en el marco de la Teoría Discursiva del Derecho de Jürgen Habermas”, *Revista Estudios Socio-Jurídicos*, Vol. 22, Núm. 1, pp. 145-174 (150 y ss).

Mexicano de Derecho Comparado, Núm. 140, 2014;
ATIENZA, “Algunas consideraciones sobre la protección
de datos en el tratamiento de muestras biológicas ...”,
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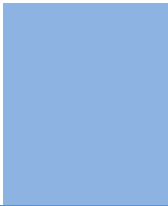
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Contributors to the research other than authors credited should be mentioned in Acknowledgments. The source of funding for the research can be included. Suppliers of resources may be mentioned along with their addresses.

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PREPARING YOUR MANUSCRIPT

Authors can submit papers and articles in an acceptable file format: MS Word (doc, docx), LaTeX (.tex, .zip or .rar including all of your files), Adobe PDF (.pdf), rich text format (.rtf), simple text document (.txt), Open Document Text (.odt), and Apple Pages (.pages). Our professional layout editors will format the entire paper according to our official guidelines. This is one of the highlights of publishing with Global Journals—authors should not be concerned about the formatting of their paper. Global Journals accepts articles and manuscripts in every major language, be it Spanish, Chinese, Japanese, Portuguese, Russian, French, German, Dutch, Italian, Greek, or any other national language, but the title, subtitle, and abstract should be in English. This will facilitate indexing and the pre-peer review process.

The following is the official style and template developed for publication of a research paper. Authors are not required to follow this style during the submission of the paper. It is just for reference purposes.



Manuscript Style Instruction (Optional)

- Microsoft Word Document Setting Instructions.
- Font type of all text should be Swis721 Lt BT.
- Page size: 8.27" x 11", left margin: 0.65, right margin: 0.65, bottom margin: 0.75.
- Paper title should be in one column of font size 24.
- Author name in font size of 11 in one column.
- Abstract: font size 9 with the word "Abstract" in bold italics.
- Main text: font size 10 with two justified columns.
- Two columns with equal column width of 3.38 and spacing of 0.2.
- First character must be three lines drop-capped.
- The paragraph before spacing of 1 pt and after of 0 pt.
- Line spacing of 1 pt.
- Large images must be in one column.
- The names of first main headings (Heading 1) must be in Roman font, capital letters, and font size of 10.
- The names of second main headings (Heading 2) must not include numbers and must be in italics with a font size of 10.

Structure and Format of Manuscript

The recommended size of an original research paper is under 15,000 words and review papers under 7,000 words. Research articles should be less than 10,000 words. Research papers are usually longer than review papers. Review papers are reports of significant research (typically less than 7,000 words, including tables, figures, and references)

A research paper must include:

- a) A title which should be relevant to the theme of the paper.
- b) A summary, known as an abstract (less than 150 words), containing the major results and conclusions.
- c) Up to 10 keywords that precisely identify the paper's subject, purpose, and focus.
- d) An introduction, giving fundamental background objectives.
- e) Resources and techniques with sufficient complete experimental details (wherever possible by reference) to permit repetition, sources of information must be given, and numerical methods must be specified by reference.
- f) Results which should be presented concisely by well-designed tables and figures.
- g) Suitable statistical data should also be given.
- h) All data must have been gathered with attention to numerical detail in the planning stage.

Design has been recognized to be essential to experiments for a considerable time, and the editor has decided that any paper that appears not to have adequate numerical treatments of the data will be returned unrefereed.

- i) Discussion should cover implications and consequences and not just recapitulate the results; conclusions should also be summarized.
- j) There should be brief acknowledgments.
- k) There ought to be references in the conventional format. Global Journals recommends APA format.

Authors should carefully consider the preparation of papers to ensure that they communicate effectively. Papers are much more likely to be accepted if they are carefully designed and laid out, contain few or no errors, are summarizing, and follow instructions. They will also be published with much fewer delays than those that require much technical and editorial correction.

The Editorial Board reserves the right to make literary corrections and suggestions to improve brevity.



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It is necessary that authors take care in submitting a manuscript that is written in simple language and adheres to published guidelines.

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The title page must carry an informative title that reflects the content, a running title (less than 45 characters together with spaces), names of the authors and co-authors, and the place(s) where the work was carried out.

Author details

The full postal address of any related author(s) must be specified.

Abstract

The abstract is the foundation of the research paper. It should be clear and concise and must contain the objective of the paper and inferences drawn. It is advised to not include big mathematical equations or complicated jargon.

Many researchers searching for information online will use search engines such as Google, Yahoo or others. By optimizing your paper for search engines, you will amplify the chance of someone finding it. In turn, this will make it more likely to be viewed and cited in further works. Global Journals has compiled these guidelines to facilitate you to maximize the web-friendliness of the most public part of your paper.

Keywords

A major lynchpin of research work for the writing of research papers is the keyword search, which one will employ to find both library and internet resources. Up to eleven keywords or very brief phrases have to be given to help data retrieval, mining, and indexing.

One must be persistent and creative in using keywords. An effective keyword search requires a strategy: planning of a list of possible keywords and phrases to try.

Choice of the main keywords is the first tool of writing a research paper. Research paper writing is an art. Keyword search should be as strategic as possible.

One should start brainstorming lists of potential keywords before even beginning searching. Think about the most important concepts related to research work. Ask, "What words would a source have to include to be truly valuable in a research paper?" Then consider synonyms for the important words.

It may take the discovery of only one important paper to steer in the right keyword direction because, in most databases, the keywords under which a research paper is abstracted are listed with the paper.

Numerical Methods

Numerical methods used should be transparent and, where appropriate, supported by references.

Abbreviations

Authors must list all the abbreviations used in the paper at the end of the paper or in a separate table before using them.

Formulas and equations

Authors are advised to submit any mathematical equation using either MathJax, KaTeX, or LaTeX, or in a very high-quality image.

Tables, Figures, and Figure Legends

Tables: Tables should be cautiously designed, uncrowned, and include only essential data. Each must have an Arabic number, e.g., Table 4, a self-explanatory caption, and be on a separate sheet. Authors must submit tables in an editable format and not as images. References to these tables (if any) must be mentioned accurately.



Figures

Figures are supposed to be submitted as separate files. Always include a citation in the text for each figure using Arabic numbers, e.g., Fig. 4. Artwork must be submitted online in vector electronic form or by emailing it.

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TIPS FOR WRITING A GOOD QUALITY MEDICAL RESEARCH PAPER

1. Choosing the topic: In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

2. Think like evaluators: If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

3. Ask your guides: If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

4. Use of computer is recommended: As you are doing research in the field of medical research then this point is quite obvious. Use right software: Always use good quality software packages. If you are not capable of judging good software, then you can lose the quality of your paper unknowingly. There are various programs available to help you which you can get through the internet.

5. Use the internet for help: An excellent start for your paper is using Google. It is a wondrous search engine, where you can have your doubts resolved. You may also read some answers for the frequent question of how to write your research paper or find a model research paper. You can download books from the internet. If you have all the required books, place importance on reading, selecting, and analyzing the specified information. Then sketch out your research paper. Use big pictures: You may use encyclopedias like Wikipedia to get pictures with the best resolution. At Global Journals, you should strictly follow here.



6. Bookmarks are useful: When you read any book or magazine, you generally use bookmarks, right? It is a good habit which helps to not lose your continuity. You should always use bookmarks while searching on the internet also, which will make your search easier.

7. Revise what you wrote: When you write anything, always read it, summarize it, and then finalize it.

8. Make every effort: Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

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11. Pick a good study spot: Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

12. Know what you know: Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

13. Use good grammar: Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

14. Arrangement of information: Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

15. Never start at the last minute: Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

16. Multitasking in research is not good: Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.

19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



20. Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

22. Report concluded results: Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

23. Upon conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium through which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

The introduction: This will be compiled from reference matter and reflect the design processes or outline of basis that directed you to make a study. As you carry out the process of study, the method and process section will be constructed like that. The results segment will show related statistics in nearly sequential order and direct reviewers to similar intellectual paths throughout the data that you gathered to carry out your study.

The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

Writing a research paper is not an easy job, no matter how trouble-free the actual research or concept. Practice, excellent preparation, and controlled record-keeping are the only means to make straightforward progression.

General style:

Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.



Mistakes to avoid:

- Insertion of a title at the foot of a page with subsequent text on the next page.
- Separating a table, chart, or figure—confine each to a single page.
- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

Introduction:

The introduction should "introduce" the manuscript. The reviewer should be presented with sufficient background information to be capable of comprehending and calculating the purpose of your study without having to refer to other works. The basis for the study should be offered. Give the most important references, but avoid making a comprehensive appraisal of the topic. Describe the problem visibly. If the problem is not acknowledged in a logical, reasonable way, the reviewer will give no attention to your results. Speak in common terms about techniques used to explain the problem, if needed, but do not present any particulars about the protocols here.



The following approach can create a valuable beginning:

- o Explain the value (significance) of the study.
- o Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- o Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
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Use past tense except for when referring to recognized facts. After all, the manuscript will be submitted after the entire job is done. Sort out your thoughts; manufacture one key point for every section. If you make the four points listed above, you will need at least four paragraphs. Present surrounding information only when it is necessary to support a situation. The reviewer does not desire to read everything you know about a topic. Shape the theory specifically—do not take a broad view.

As always, give awareness to spelling, simplicity, and correctness of sentences and phrases.

Procedures (methods and materials):

This part is supposed to be the easiest to carve if you have good skills. A soundly written procedures segment allows a capable scientist to replicate your results. Present precise information about your supplies. The suppliers and clarity of reagents can be helpful bits of information. Present methods in sequential order, but linked methodologies can be grouped as a segment. Be concise when relating the protocols. Attempt to give the least amount of information that would permit another capable scientist to replicate your outcome, but be cautious that vital information is integrated. The use of subheadings is suggested and ought to be synchronized with the results section.

When a technique is used that has been well-described in another section, mention the specific item describing the way, but draw the basic principle while stating the situation. The purpose is to show all particular resources and broad procedures so that another person may use some or all of the methods in one more study or referee the scientific value of your work. It is not to be a step-by-step report of the whole thing you did, nor is a methods section a set of orders.

Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- o Report the method and not the particulars of each process that engaged the same methodology.
- o Describe the method entirely.
- o To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- o Simplify—detail how procedures were completed, not how they were performed on a particular day.
- o If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

It is embarrassing to use vigorous voice when documenting methods without using first person, which would focus the reviewer's interest on the researcher rather than the job. As a result, when writing up the methods, most authors use third person passive voice.

Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- o Resources and methods are not a set of information.
- o Skip all descriptive information and surroundings—save it for the argument.
- o Leave out information that is immaterial to a third party.



Results:

The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

Content:

- o Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
- o In the manuscript, explain each of your consequences, and point the reader to remarks that are most appropriate.
- o Present a background, such as by describing the question that was addressed by creation of an exacting study.
- o Explain results of control experiments and give remarks that are not accessible in a prescribed figure or table, if appropriate.
- o Examine your data, then prepare the analyzed (transformed) data in the form of a figure (graph), table, or manuscript.

What to stay away from:

- o Do not discuss or infer your outcome, report surrounding information, or try to explain anything.
- o Do not include raw data or intermediate calculations in a research manuscript.
- o Do not present similar data more than once.
- o A manuscript should complement any figures or tables, not duplicate information.
- o Never confuse figures with tables—there is a difference.

Approach:

As always, use past tense when you submit your results, and put the whole thing in a reasonable order.

Put figures and tables, appropriately numbered, in order at the end of the report.

If you desire, you may place your figures and tables properly within the text of your results section.

Figures and tables:

If you put figures and tables at the end of some details, make certain that they are visibly distinguished from any attached appendix materials, such as raw facts. Whatever the position, each table must be titled, numbered one after the other, and include a heading. All figures and tables must be divided from the text.

Discussion:

The discussion is expected to be the trickiest segment to write. A lot of papers submitted to the journal are discarded based on problems with the discussion. There is no rule for how long an argument should be.

Position your understanding of the outcome visibly to lead the reviewer through your conclusions, and then finish the paper with a summing up of the implications of the study. The purpose here is to offer an understanding of your results and support all of your conclusions, using facts from your research and generally accepted information, if suitable. The implication of results should be fully described.

Infer your data in the conversation in suitable depth. This means that when you clarify an observable fact, you must explain mechanisms that may account for the observation. If your results vary from your prospect, make clear why that may have happened. If your results agree, then explain the theory that the proof supported. It is never suitable to just state that the data approved the prospect, and let it drop at that. Make a decision as to whether each premise is supported or discarded or if you cannot make a conclusion with assurance. Do not just dismiss a study or part of a study as "uncertain."



Research papers are not acknowledged if the work is imperfect. Draw what conclusions you can based upon the results that you have, and take care of the study as a finished work.

- o You may propose future guidelines, such as how an experiment might be personalized to accomplish a new idea.
- o Give details of all of your remarks as much as possible, focusing on mechanisms.
- o Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
- o One piece of research will not counter an overall question, so maintain the large picture in mind. Where do you go next? The best studies unlock new avenues of study. What questions remain?
- o Recommendations for detailed papers will offer supplementary suggestions.

Approach:

When you refer to information, differentiate data generated by your own studies from other available information. Present work done by specific persons (including you) in past tense.

Describe generally acknowledged facts and main beliefs in present tense.

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CRITERION FOR GRADING A RESEARCH PAPER (COMPILATION)
BY GLOBAL JOURNALS

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Topics	Grades		
	A-B	C-D	E-F
<i>Abstract</i>	Clear and concise with appropriate content, Correct format. 200 words or below	Unclear summary and no specific data, Incorrect form Above 200 words	No specific data with ambiguous information Above 250 words
<i>Introduction</i>	Containing all background details with clear goal and appropriate details, flow specification, no grammar and spelling mistake, well organized sentence and paragraph, reference cited	Unclear and confusing data, appropriate format, grammar and spelling errors with unorganized matter	Out of place depth and content, hazy format
<i>Methods and Procedures</i>	Clear and to the point with well arranged paragraph, precision and accuracy of facts and figures, well organized subheads	Difficult to comprehend with embarrassed text, too much explanation but completed	Incorrect and unorganized structure with hazy meaning
<i>Result</i>	Well organized, Clear and specific, Correct units with precision, correct data, well structuring of paragraph, no grammar and spelling mistake	Complete and embarrassed text, difficult to comprehend	Irregular format with wrong facts and figures
<i>Discussion</i>	Well organized, meaningful specification, sound conclusion, logical and concise explanation, highly structured paragraph reference cited	Wordy, unclear conclusion, spurious	Conclusion is not cited, unorganized, difficult to comprehend
<i>References</i>	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring



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