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Original Article

Pilot study to validate a standard operating procedure for providing health education to diabetic patients

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الملخص

أهداف البحث: إن عدم وجود إجراءات تشغيل معيارية لتوفير التثقيف الصحي لمرضى السكري يعني أن هذه الخدمة تقدم بطريقة غير متجانسة ومعزولة ومتقطعة ، مما يحد من جودتها.

طريقة البحث: تم تصميم إجراءات التشغيل القياسية من التحليل النظري للابحاث المتاحة ؛ تم استخدام تقنية العصف الذهني التشاركي لتحديد العمليات المدرجة في إجراءات التشغيل القياسية. تم إجراء البحث في عيادة الرعاية الصيدلانية الشاملة التابعة للمعهد المكسيكي للعلوم الصحية ، من أغسطس 2017 إلى مارس 2020. تم إجراء الاختبار التجريبي للإجراء على 15 مريضًا في العيادات الخارجية يعانون من مرض السكري من النوع الأول والثاني. تم إجراء التحقق من قبل لجنة من الخبراء باستخدام منهجية دلفي ، وتم تقدير الإجماع بين الخبراء من خلال تحديد معامل التوافق في كيندال. تم تحديد فعالية عيادة الممارسة لإجراءات التشغيل القياسية من خلال دراسة تجريبية على 15 مريضًا مصابًا بالسكري باستخدام مؤشرات العملية.

النتائج: تم تنظيم إجراءات التشغيل القياسية في تسعة أقسام مع نهج العملية الموضح في معايير ISO 9001: 2008. سمحت المعايير التي أصدرها الخبراء بشأن المحتوى والسجلات وأدوات استخراج البيانات بتحسين إجراءات التشغيل القياسية. أظهر الاختبار التجريبي الذي تم إجراؤه أن التثقيف الصحي ، باتباع إجراءات التشغيل القياسية ، يحسن التحكم في التمثيل الغذائي ، ومستوى المعرفة ، والالتزام العلاجي ، وسلوك أكثر من 80 ٪ من المرضى.

الاستنتاجات: كانت إجراءات التشغيل القياسية المصممة والمصادقة من قبل الخبراء فعالة في تثقيف مرضى السكري بسبب التأثير الكبير الذي تحقق مع التدخل ويتضمن مؤشرات لضمان جودة الخدمة الصحية المقدمة.

الكلمات المفتاحية: إجراءات التشغيل القياسية؛ التثقيف الصحي؛ السكري؛ التصميم؛ الرعاية الصيدلانية؛ الرعاية الأولية؛ الجودة في الخدمات الصحية؛ منهجية دلفي؛ التحقق من الصحة؛ المؤشرات

Abstract

Introduction: The lack of standard operating procedures (SOPs) to provide health education to patients with diabetes means that this service is provided in a heterogeneous, isolated and intermittent manner, thus limiting quality.

Objective: To validate a SOP to provide health education to diabetic patients using Delphi methodology and determining its efficacy in clinical practice by performing a pilot study.

Methods: The SOP was designed from a theoretical analysis of the available literature; a participatory brainstorming technique was used to define the processes included in the SOP. The research was carried out at the Comprehensive Pharmaceutical Care Polyclinic of a Mexican Institute of Health Sciences, from August 2017 to March 2020. The pilot test was carried out on 15 outpatients with diabetes type 1 and 2. The validation was carried out by a panel of experts using Delphi

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methodology, the consensus among the experts was estimated by determining Kendall's coefficient of concordance. The practice clinical efficacy of the SOP was determined by a pilot study in 15 diabetic patients using process indicators.

Results: The SOP was structured in nine sections with the process approach described in the ISO 9001:2008 standards. The criteria issued by the experts relating to content, records and data extraction tools allowed improvement of the SOP. The pilot test showed that health education, following the SOP, improved metabolic control, level of knowledge, therapeutic adherence and the attitudes of more than 80% of patients.

Conclusions: The SOP designed and validated by experts was effective in educating patients with diabetes due to the high impact achieved with the intervention and incorporates indicators to guarantee the quality of the health service provided.

Keywords: Delphi methodology; Diabetes; Health education; Indicators; Standard operating procedure; Validation

Introduction

The high rates of morbidity and mortality associated with diabetes mellitus throughout the world warn of the need to prevent this condition and avoid its complications. The International Diabetes Federation indicates that 463 million people live with diabetes in the world.[1] In Mexico in 2018, there were 8,600,000 people with diabetes mellitus and 104,354 Mexicans died from this disease.[2] These data are even more worrying if we consider that half of all diabetics do not follow their treatments and less than 30% change their habits or lifestyles,[3–6] so it is essential to design rigorously validated educational strategies.

Health education (HE) in the outpatient context is carried out mainly by doctors and to a lesser extent, by pharmacists.[7] Furthermore, it has been shown that quality and not time is the key to promoting the transfer of knowledge and skills for the lifestyle of individuals with diabetes.

In 2020, Sanaeinasab et al.[8] declared that a structured health education program has a greater impact on lifestyle modification and glycemic control of patients with type 2 diabetes than routine health care programs in Iran. Kelly and Rodgers[9] demonstrated the positive impact of HE in reducing glycosylated hemoglobin (HbA) values in patients with diabetics. In 2014, Spence et al.[10] obtained similar results and demonstrated improvements in adherence and cholesterol values by applying a clinical service program in an outpatient pharmacy. The quality of any health service requires that the proposed activities be carried out in a standardized, systematic and continuous manner[11] considering that the quality and performance of health systems contribute crucially to the well-being of patients.[12]

Currently, there are multiple methodologies for the education of patients with diabetes, although these are carried out in a heterogeneous and intermittent manner with variable results.[13–16] The most widely used educational methods consist of educational talks, while participatory techniques that promote learning and stimulate creativity are rarely used during the provision of HE.[17] To date, no procedure normalizes this activity, so it is necessary to carry out research to organize and standardize the educational service at the micro-level under a quality approach.[18]

In 2020, Abdulrhim et al.[19] evaluated the impact of pharmaceutical care on clinical, humanistic and economic outcomes related to diabetes in primary care settings, by carrying out a systematic review of publications on the subject and concluded that the incorporation of pharmacists into multidisciplinary diabetes care teams is beneficial.

Given the number of outpatients with diabetes (type I and II) who attend the Integral Pharmaceutical Care Polyclinic (PAFI) of the Institute of Health Sciences (ICSa) of the Autonomous University of the State of Hidalgo (UAEH), Mexico, it was necessary to design and validate a standard operating procedure (SOP) to provide health education to these patients from a holistic perspective so that this pharmaceutical service could take place in a standardized, systematic and continuous way. The impact of the implementation of this SOP on metabolic control, level of knowledge, therapeutic adherence and the attitude of the patients was evaluated to detect if it could be extended to regular practice at the first level of care.

Objective

To validate a standard operating procedure to provide health education to diabetic patients using Delphi methodology and determine its efficacy in clinical practice through a pilot study.

Materials and Methods

A methodological investigation was carried out on health systems and services aimed at the organization and development of a health education service for outpatients with diabetes, in the period from August 2017 to March 2020 at the PAFI of the ICSa of the UAEH, Mexico.

Standard operating procedure design

To design the SOP, we performed a theoretical analysis of the literature published from 2003 to 2019 related to the comprehensive management of diabetic patients by health professionals.[6,20–25] This search was performed in PubMed, MEDLINE, SpringerLink, DOAJ, Google Scholar and EMBASE databases.

The experience of experts using the participatory brainstorming technique was considered, as well as the requirements

of Good Pharmacy Practices, Good Pharmaceutical Care Practices,[26] and the process approach described in the ISO 9001: 2015[27] to define the main stages of the health education process and the work methodology for each step.

The registration and documentation forms for all activities were designed based on validated methods to provide health education and expert judgment in this area.[6,20–28]

Some indicators were proposed for the periodic evaluation of the process and to guarantee the continuous improvement of the service. All these elements allowed the design of an SOP for health education of patients with diabetes, which followed the structure established by the Quality Practices in Basic Biomedical Research.[29]

Validation of the SOP by experts

Once the SOP was designed, its content was validated by a panel of experts, following the Delphi methodology,[30] a necessary step to provide reliability to the procedure in the context of the first level of health care.

To constitute the panel of experts, the following inclusion criteria were considered: (1) graduates in pharmaceutical sciences or related professions, either with a doctorate or master's degree and experience in pharmaceutical care, pharmacotherapy follow-up, or the provision of medical care for diabetic patients; (2) experience in health care or teaching-related activities for 10 years or more; (3) A level of competence with a coefficient between 0.5 and 1 ($0.5 < K < 1$) and (4) consent to participate in the validation process.

The estimated sample included 15 specialists who met the aforementioned inclusion criteria and only seven were chosen, based on the evaluation of their coefficient of competence. To determine the number of experts in the panel, a precision level (i) of 0.05, an error rate (p) of 0.09, and a confidence level (K) of 6.656 were established.[31]

The competence of the experts was evaluated following the methodology developed by Hurtado et al.[32] and the Delphi method.[30,31] The proficiency coefficients of the experts were scored as high, medium or low using the following criteria: $0.8 \leq K \leq 1$ high proficiency coefficient; $0.5 \leq K \leq 0.8$ medium competition coefficient, and $K \leq 0.5$ low competition coefficient. Experts for which the coefficient of competence presented high and medium values were included.[33]

Evaluation of the content of the SOP was carried out using the Delphi method.[30,31]

The criteria used for the evaluation of the SOP corresponded to those proposed by Moriyama[34] and other authors[35,36] and were adapted for our specific research objectives. The criteria used for the evaluation of the global SOP were as follows:

- Reasonable and understandable: refers to the understanding of the different sections contained in the SOP
- Traceability: the SOP should reflect how to record and document all proposed activities.
- Simplicity: refers to the simplicity in which the operations proposed in the SOP can be carried out.
- Formal structure: the SOP must comply with the structure established by the World Health Organization.[29]
- Adequacy of the indicators: refers to the fact that the indicators reflect what is intended to be measured.[35]

Similarly, the criteria used for the evaluation of the SOP records were as follows:

- Reasonable and understandable: refers to the understanding of the information to be recorded.
- Formal structure: the forms must have an adequate structure to collect all the information that can be obtained from the process.
- Ease of registration: refers to the simplicity required to complete the registrations

In terms of the criteria used for the evaluation of the data extraction tools, we used the following criteria:

- Reasonable and understandable tool: the instrument that carries the record is understood and allows the information to be collected to be obtained.
- Sensitivity of the tool to variations in the phenomenon being measured: it refers to the fact that the items of the tools can discriminate between different degrees of response.
- Simplicity: refers to the simplicity of the tool to be applied.
- Tools with justifiable items: refers to the fact that the tool uses acceptable items for the dimensions or constructs to be measured.

The experts gave an evaluation from 1 to 5, using a Likert-type scale, using the following indicators:

- Very suitable (MA): 5
- Fairly adequate (BA): 4
- Suitable (A): 3
- Not very suitable (PA): 2
- Inadequate (I): 1

Once the first round had been carried out, the degree of coincidence for the evaluations made by the experts was calculated and all the opinions of the evaluators were analyzed to establish a second SOP, which was sent to the experts to be reevaluated in the second round. In both rounds, the non-parametric Kendall's Coefficient of Agreement (W) test was applied, which establishes the following values:

- $W = 1$: total agreement among the experts.
- $W = 0$: total disagreement.
- $0.5 < W < 1$: a balance of agreement between the experts.

Determination of the SOP efficacy in clinical practice

To determine the efficacy of the SOP in clinical practice, a pilot study was conducted on outpatients with diabetes who attended the PAFI for a period of 1 year (March 2019 to March 2020).

Fifteen patients were chosen to validate the standard operating procedure (SOP). These individuals were selected according to their arrival at the PAFI, based on previously established validity criteria that would guarantee the efficacy of the SOP in different populations.

Patients were selected to participate in the study based on the following inclusion and exclusion criteria:

- **Inclusion criteria:** All patients with a clinical diagnosis of type 1 or type 2 diabetes, diagnosed in the 12 months prior to the study, whose ages ranged between 18 and 65 years, treatment with hypoglycemic drugs started at least 3 months before starting this research, who knew how to read and write and who agreed to be included in the service.
- **Exclusion criteria:** Pregnant patients and patients with mobility problems.
- **Exit criteria:** Patients who moved to another location, died or stopped attending the Health Education service.

Once the sample was formed, three categories were established for stratification, based on the clinical characteristics of the patients.

In category A, all patients who had already suffered complications, such as blindness or chronic renal, cardiac or vascular disorders, were included.

Category B was made up of patients not included in category A who presented with one or more of the following characteristics:

1. Had been diagnosed in the 12 months prior to the study
2. Had received maximum doses of oral hypoglycemic agents
3. Started insulin treatment
4. Had poor metabolic control in the opinion of their physicians.

In category C, individuals classified in one of the two previous categories were excluded and those with a stable evolution of the disease were included.

The study was designed considering that the patients are under their own control because the changes that occur before and after the intervention were evaluated, thus contributing to complement the effect of the sample size.

The effectiveness of the SOPs in clinical practice was determined by measuring the impact of the actions of the health education service provided to diabetic patients using process indicators established in the SOPs and validated by experts. The process indicators used for this evaluation were as follows:

- Level of knowledge of the patients before and after the health intervention. (LKP)

$$LKP = (NPN1 + NPN2)/TPAS \times 100$$

Where:

NPN1: Number of patients with level 1 of knowledge

NPN2: Number of patients with level 2 of knowledge

TPAS: Total number of patients who accepted the service offered

- Degree of compliance of patients before and after the health intervention. (DCP)

$$DCP = NNCP/TPAS \times 100$$

Where:

NNCP: Number of non-compliant patients

TPAS: Total number of patients who accepted the service offered

- Metabolic control before and after the pharmaceutical intervention. (MC)

$$MC = NPMC/TPAS \times 100$$

Where:

NPMC: Number of patients with metabolic control

TPAS: Total number of patients who accepted the service offered

- Patients with a positive attitude and behavior before and after health interventions (PPAB)

$$PPAB = NPAB/TPAS \times 100$$

Where:

NPAB: Number of patients who showed a positive attitude and behavior

TPAS: Total number of patients who accepted the service offered

From the evaluated indicators, the impact of the intervention (II) was calculated as a measure of procedure effectiveness (PE). An adequate PE was considered when values equal to or greater than 80% were obtained in the II and an inappropriate PE when values less than 80% were obtained in the II.

The II was calculated using the following mathematical expression:

$$II = SE/TPAS \times 100$$

Where:

SE: Total number of patients who at the end of the educational intervention process showed a positive attitude and behavior, achieved metabolic control of their disease, and a level of knowledge and/or compliance higher than that obtained in the test carried out before the educational intervention.

TPAS: Total number of patients who accepted the service offered

Results

SOP design

The theoretical documentary analysis of the literature and the ideas of the experts obtained through the participatory brainstorming technique allowed the design of the SOP that was structured in 10 parts: objective, scope, departments involved, documentation of references, responsibilities, definitions, development (sequence of activities), register, indicators and annexes.

The objective, scope, departments involved, documentation of references and responsibilities were directed to the type of service to be provided, the type of patient and the professionals involved. The definitions included basic concepts related to the health education and comprehensive care of diabetic patients. Here, we describe the sequence of activities carried out during development.

Figure 1 shows a flow diagram that depicts the sequence of activities with a process approach as established by ISO-9001: 2015.[27] The diagram shows the interconnection

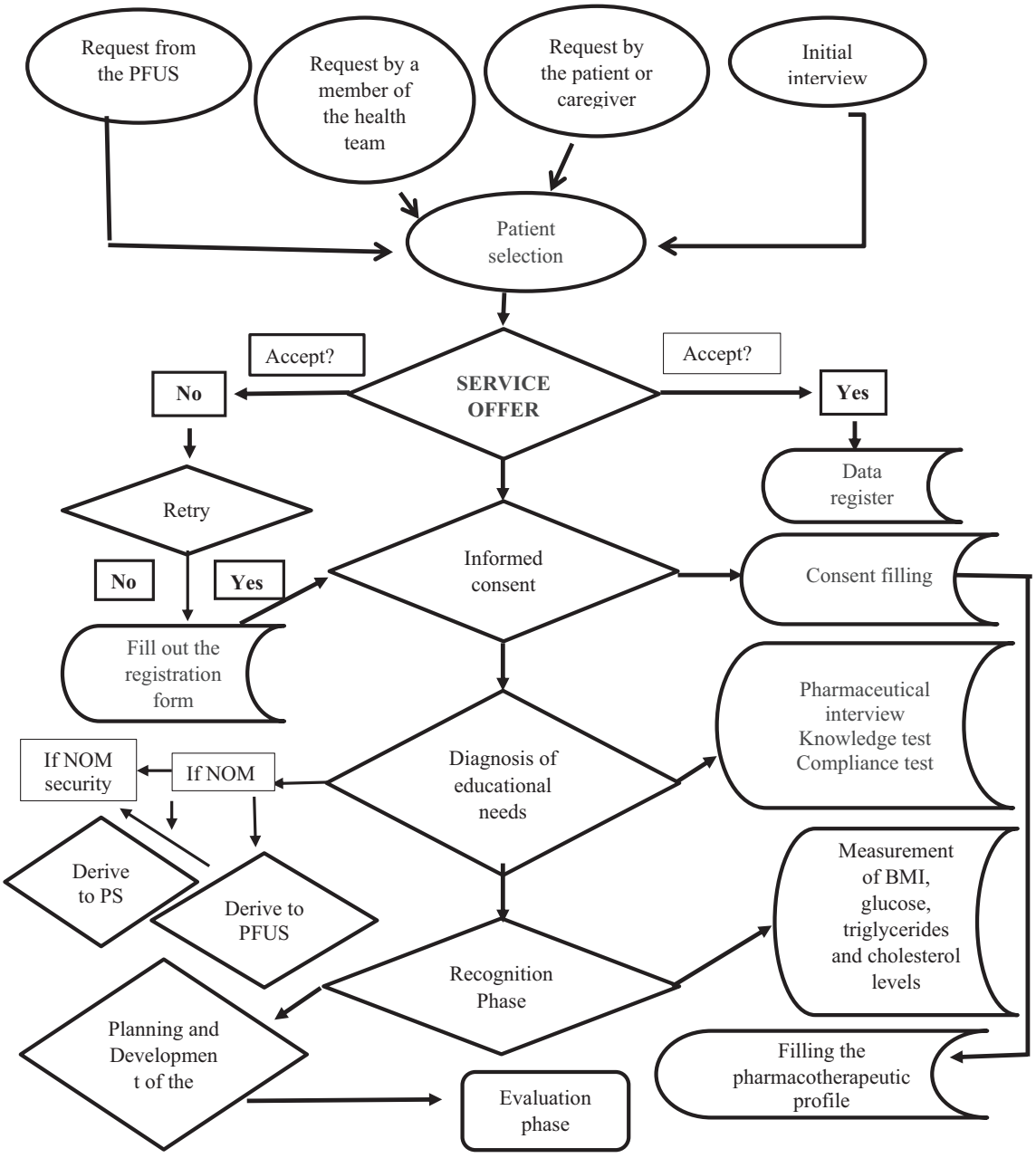

Figure 1: Flow diagram of the Health Education process**. Legend:** BMI: Body Mass Index; NOM: Negative Outcomes associated with Medication; PFUS: Pharmacotherapy follow-up; PS: Pharmacovigilance services.

between the pharmacotherapy follow-up (PFUS) and the pharmacovigilance services (PS) of the Clinic of Pharmaceutical Care, which reflects a comprehensive approach to providing the health education service to outpatient diabetic patients within the organization in a standardized way. The activities established in the SOP are described below.

Patient selection: admission to the HE service was considered in four ways: through the PFUS service, at the request of a member of the health team, at the request of the patients or the caregiver, and by the selection interview conducted by the pharmacist. Patients who accepted the service were registered and their written informed consent was requested.

Diagnosis of educational needs: This was carried out through a semi-structured interview, a validated knowledge test about the disease, the medications consumed, and the application of the Morinsky–Green test to determine therapeutic adherence. If during this phase the professional detects a Problem Related to Medication (PRM) and Negative Outcomes associated with Medication (NOM), the patient should be referred to the PFUS service. In the case of a patient having a NOM, they were classified to the PS.

Recognition phase: In this phase, the metabolic control of the patient is established by determining the body mass index (BMI) along with the levels of glucose, cholesterol and triglycerides in the patient's blood.

Planning and development of the educational program: At this stage, the educational program is designed, based on the diagnosis of educational needs, taking into account the metabolic control of the patient. The educational program was designed to be carried out for 1 year, based on the educational needs identified in the patient interview, in the knowledge test and the compliance test, as well as supported by the health promotion model of Pender et al.,[37] in theoretical models of health education[38] and taking into account the characteristics of the stages of health education: informative, focused on behavior change and participation.[39]

Evaluation phase: After a year of working with the patients, the results are evaluated, based on qualitative indicators (positive attitude and behavior, increased level of knowledge about the disease and its treatment, an increased degree of compliance with treatment) and metabolic control (levels of blood glucose, cholesterol, triglycerides, body mass index and blood pressure).

A novel aspect of this SOP is the proposal of indicators that measure the quality of the HE service and allow the identification of its strengths, but also its weaknesses (in which case corrective measures will need to be implemented).[40,41]

Validated indicators can be re-evaluated periodically and depending on their usefulness in the process; they can be maintained or modified according to the different educational needs of patients and the characteristics of the organization. This flexible strategy allows the continuous improvement of the quality of the service of HE of the PAFI of the ICSa of the UAEH.

The proposed indicators were designed under the Donabedian principles that consider three phases of the action sequences: (1) initial assessment of the patient; (2) design and implementation of a treatment plan for patient care and (3) evaluation of results in the patient.[41]

In addition, indicators were designed following a clinical and pharmacotherapeutic approach that considered metabolic control, adherence to treatment, attitude, and behavior to receive guidance on educational and health outcomes. In addition, humanistic parameters were considered considering the degree of patient satisfaction with the service and its impact on their care.[6,36,37,42]

Validation of the SOP by experts

To validate the SOP, seven experts participated who met the inclusion criteria and had a high or medium competence coefficient. Table 1 shows the results of the first and second rounds to evaluate the content, records and tools to extract data from the proposed SOP.

In the first round, a Kendall coefficient of 0.48 was obtained for the global evaluation of the SOP; thus, a balance was not achieved between the experts. However, for the evaluation of SOP records and the tools for data extraction, the coefficients obtained were 0.77 and 0.62, respectively; in both cases, there was a tendency towards agreement between the experts. Kendall's relatively low coefficient of agreement for the overall assessment of the SOP was a critical element that led to a second round. Table 2 shows the recommendations made by the experts during the first round of Delphi. These suggestions were considered for the improvement of the SOP so that in the second Delphi round a good agreement was achieved among experts.

In the first round, the suggestions on the content of the SOP were its formal structure and the adequacy of the indicators. Changes were suggested in the SOP records in their formal structure, as well as in the improvement of elements to make them reasonable, understandable, and simple. Regarding the tools for data extraction, the experts recommended changes to be sensitive to variations with justifiable elements, and in the suitability of the indicators, it was recommended to include two indicators and modify five; while in the second round, only the modification of two indicators was proposed.

Table 1: Behavior of the criteria evaluated by experts related to the content, records and data extraction tools used for the design of the SOP.

Global SOP evaluation criteria	**First round**	**Second round**
Reasonable and understandable	Highly adequate	Highly adequate
Traceability	Highly adequate	Highly adequate
Simplicity	Highly adequate	Highly adequate
Formal structure	Adequate	Highly adequate
Adequacy of the indicators	Adequate	Fairly adequate
Kendall's coefficient	0.48	0.73
SOP record evaluation criteria	**First round**	**Second round**
Reasonable and understandable	Quite adequate	Highly adequate
Formal structure	Adequate	Highly adequate
Ease of registration	Quite adequate	Highly adequate
Kendall's coefficient	0.77	0.84
Criteria for evaluating tools for extracting data	**First round**	**Second round**
Reasonable and understandable	Highly adequate	Highly adequate
Sensitivity to variations	Adequate	Highly adequate
Simplicity	Highly adequate	Highly adequate
Justifiable items	Adequate	Highly adequate
Kendall coefficient	0.62	0.91

Source: Expert validation. Delphi method.

Table 2: Expert recommendations for indicators in the first round Delphi.

Component	Indicators	Modifications suggested by experts
STRUCTURE	Furniture and equipment for the development of health education activities.	A mathematical formula was proposed to calculate this indicator
	PNO availability	A mathematical formula was proposed to calculate this indicator Include database availability as an indicator
PROCESS	Patients with negative attitude and behavior	To define the negative attitude and behavior in the indicator calculation method, taking into account the designed rubric.
PROCESS		To include patient satisfaction with the Health Education Service as an indicator.

Source: First Delphi Round of Expert Validation.

The specialists pointed out the need to ask closed questions instead of open ones and suggested using less technical language, avoiding questions referring to more than one aspect, as well as not using questions that could bother the patient or distort their answers. The ideas received from the first round allowed us to structure a more complex and refined proposal with clearer and more focused criteria. In the second round, all Kendall's coefficients were increased for the three evaluations ($W = 0.73$, $W = 0.84$, and $W = 0.91$), reaching a trend towards an agreement between experts

Determination of the SOP efficacy in clinical practice

The fifteen patients chosen for the SOP validation in clinical practice had a diagnosis of diabetes mellitus, aged between 41 and 60 years, with a mean age of 54 years. Of the selected patients, 9 patients were female (60%) while six patients were male (40%). Seven individuals had type 1 diabetes (46.7%) and eight type 2 diabetes (53.3%), with a disease evolution time of 6–10 years and a personal pathological history of arterial hypertension and hyperlipidemia. Of the patients affected with type 2 diabetes, 62.5% presented a stable evolution while 37.5% of the sample were under treatment with maximum doses of oral hypoglycemic agents or with insulin and had poor metabolic control.

Table 3: Behavior of the process indicators before and after the Pharmaceutical Intervention.

Indicators	Before PI (%)	After PI (%)
LKP	33.33	86.73
DPC	53.33	80.00
MC	46.71	80.00
PAB	26.72	86.71

LKP: Level of knowledge of patients.
DPC: Degree of patient compliance.
MC: Metabolic control before and after pharmaceutical intervention.
PAB: Patients with positive attitude and behavior.
PI: Pharmaceutical intervention.

Table 3 describes the behavior of the process indicators evaluated before and after the educational intervention. All of the evaluated indicators showed an increase at the end of the educational interventions, reaching a II of 80%, thus the PE was adequate.

Discussion

The design of this SOP offers a new approach to successfully carrying out the education of outpatients with diabetes. This document specifies the **objective** and aims to establish the sequence of threads and activities required within the requested-offered service of HE.

The **scope** of the SOP focused on all patients who meet the selection criteria established to offer HE, as **departments involved**, all areas were established, which directly or indirectly intervene in the development of the HE services since communication between health professionals is important in activities of this type, in which there must be a multidisciplinary collaboration to provide comprehensive and comprehensive health care, in which the patient's quality-of-life is guaranteed.[4]

In the **reference documentation** section, the most relevant bibliographies are described, so that the professional, in the event of any problem that arises during the process, can consult the references supporting the preparation of the SOP. In the **definitions** section, the relevant terms of the procedure are described, to which the professional can refer, in case of doubt.

The flowchart for the HE processes described in Figure 1 shows a holistic educational process that considers the organizational aspects of the health institution, as well as the individual and social needs of the patients. These factors are crucial to achieving substantial changes in their lifestyle and health.

Dalmau et al.[42] conducted a comparative study of the impact of health education in type 2 diabetic patients against individual education in improving knowledge, metabolic control, and risk factors for diabetes, but did not report significant differences between the two groups.

However, the methodology that supports this study by Dalmau et al. did not establish an interconnection between the services provided in the health institution such as pharmacotherapeutic follow-up and pharmacovigilance, which could enrich the educational program on the prevention and resolution of medication problems. Furthermore, these authors did not consider the organization of the health education process to carry out the activity in a systematic way.[42]

This study highlights the importance of managing documentation. For this reason, the data collection forms (records) needed to demonstrate the traceability of the process are described in our new SOP.[43,44] Our SOP design includes the proposal of indicators to measure the quality of HE services (Table 1). The literature reports that the quality of pharmaceutical care has been measured by a variety of indicators.[42–45] However, the lack of standardization of this activity and the poor quality of the studies makes it difficult to obtain validated measurement tools as guides for monitoring, evaluating, or improving the quality of these services.[4,46]

In the evaluation of the content of the SOP, seven experts with a high level of competence (Table 2), issued considerations in the first round, which led to the agreement between them and the restructuring of the SOP. Thus, in the second round, the SOP was clearer, more refined and complete, focusing on the objectives of health education and allowed total concordance values very close to 1.

The behavior of the process indicators evaluated before and after the educational intervention demonstrated the effectiveness of the SOP in practice. Following educational intervention, the patients changed their behavior, attitude, and adherence and achieved metabolic control of their disease.

Studies carried out by Roque et al., in 2015[46] aimed to evaluate the economic cost and profitability of a pharmaceutical care program for elderly diabetic and hypertensive patients in primary care. These authors showed that although the program added negligible expenses to the overall costs of medical care it also improved the measured clinical outcomes (blood pressure, fasting blood glucose, hemoglobin A1c, and cholesterol).

The literature refers to other studies[9,10,47] that have documented the positive effects of health education on the clinical results of patients with diabetes; but none of these studies used an SOP with a comprehensive approach to provide health education services in a standardized manner.

Limitations of the investigation

Hemoglobin A1c is not included in the patient's metabolic control, nor are the structure and outcome indicators evaluated; these could provide further criteria for the quality of the service provided.

Conclusions

The lack of a SOP to provide health education to patients with diabetes means that this service is provided in a heterogeneous, isolated and intermittent manner, thus limiting quality. The designed SOP constitutes the first procedure with efficacy in clinical practice because it is reasonable and understandable, due to its simplicity, traceability, its formal structure and the adequacy of the indicators described and according to the validation carried out by the experts. Furthermore, the SOP led to changes in the behavior, attitude, adherence and metabolic control of the patients with diabetes mellitus, who received the service, following the methodology proposed in the SOP.

The validated SOP has a holistic approach and allows individual work on the educational needs of patients with diabetes to face the enormous challenge of educating them systematically and continuously. In addition, the SOP incorporates a system of indicators that contribute to ensuring the quality of the health service provided and the effectiveness of the SOP. Given its simplicity and practicality, we believe that it could be incorporated into the practice related to the health education of patients with diabetes at the first level of health care.

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Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

The research was carried out in compliance with international standards for biomedical research and experimentation on human beings, established in the Declaration of Helsinki, for which the written informed consent given by the patients was taken into account at the time of the interview.

The objectives of the research and the benefits that the results would bring were explained to all patients and/or relatives or companions who attended Comprehensive Pharmaceutical Care Polyclinic. They were informed that the surveys and interviews carried out were anonymous and that the absolute discretion of the results was guaranteed, without any lack of attention to the patient due to her opinions.

This research was approved by the Research Directorate of the UAEH, Mexico (UAEH-DI-17-ICSA-FAR-CF-1). In addition, the research was reviewed and approved from a scientific, technical, and ethical point of view by the Academic Area of Pharmacy and by the Professional Development Program for Educators (PRODEP) (DSA/103.5/16/10282). Date: February 2018.

Authors contributions

IBBC conceived and designed the study, conducted research, analyzed and interpreted data. IRH provided research materials, collected and organized data, and wrote initial and final draft of article. ATL, MALL, and LBE provided research materials and proposed activities and aspects included in the SOP. MLO and MEGP designed and performed the validation analysis and provided logistic support. All authors have critically reviewed and approved

the final draft and are responsible for the content and similarity index of the manuscript.

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