

# Elaboration and Validation of an Educational Booklet for Liver Transplant Recipients

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## ABSTRACT

**Background:** Success after liver transplantation involves different particularities. As important as the surgical procedure is the need for health information for patients, fundamental educational strategies facilitate the understanding of the guidelines provided by the health team. **Objectives:** To describe the process of elaboration and validation of an educational booklet for a liver transplant recipient. **Materials and Methods:** Methodological research, for the elaboration and validation of an educational technology, developed in three stages: bibliographic survey, elaboration of the booklet and validation of the material. Validation took place between May and August 2021 with professionals from the care team and patients from a specialized outpatient clinic of a university hospital. To analyze the validity, the Content Validity Index (CVI) and the Research Electronic Data Capture (REDCap) program were adopted for data storage and analysis. Results: The CVI obtained with the 17 expert judges was 0.98, and with 20 patients, 0.99, which proves to be valid material. **Conclusion:** The booklet is valid and adequate for information to transplant patients, suggesting its implementation in the post-liver transplant routine as a guiding resource for care in order to make the process more effective.

**Keywords:** Validation Study; Educational Technology; Health; Liver Transplantation; Health Education.

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**Received:** 22-12-2022;

**Revised:** 03-01-2023;

**Accepted:** 11-02-2023.

## INTRODUCTION

Currently, Liver Transplantation (LTx) is considered one of the most complex surgical procedures; however, it represents an important advance in Medicine and is performed when there are no resources left to treat liver disease, allowing patients to improve their quality of life. However, those who undergo this procedure need adequate support from a multi-professional team, given the various adaptations they will undergo throughout this path.<sup>1</sup>

In this scenario, success in LTx involves different aspects such as the surgery itself and the patient's conditions, as well as those related to the needs for health information, care, effective information for graft survival, and readaptation to the patient's social environment, as fundamental educational strategies that ease the incorporation of all the information provided by the health team.<sup>2</sup> In general, all patients must understand the need to

adhere to their treatment and learn to perform the necessary care actions for a successful LTx.<sup>3</sup>

Educational materials such as booklets and notebooks can be considered as health promotion communication means,<sup>4</sup> since they deal with the structuring of diverse knowledge operationalized in health work, helping memorize content and directing health education activities.<sup>5</sup> Such technology favours empowerment of the patients, who gain independence, acting as protagonists of their own care and contributing to improving their living and health conditions.<sup>6</sup>

The use of printed educational technology with illustrations, layout, design, and accessible and objective writing, eases understanding of the content addressed and, when associated with other resources such as verbal ones, makes it possible to reinforce all the information and serve as a reference in case of doubts, assisting in decision-making and self-care.<sup>7-8</sup>

By analyzing the literature, it is verified that the use of educational material for information to transplanted patients is a topic with different approaches and under construction by the professionals involved in organ transplantation programs,<sup>7,9,10</sup> However, despite



DOI: 10.5530/jyp.2023.15.47

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the importance of this type of material, it is verified that this theme is little explored in terms of printed educational technology aimed at the target patients of this study, which justifies the motivation for proposing the elaboration and validation of a booklet with health and monitoring information for liver transplant patients. Given this scenario, the objective of this study is to describe the process to elaborate and validate a booklet with health and monitoring information for liver transplant recipients.

## MATERIALS AND METHODS

This is a methodological research study for the elaboration and validation of educational technology,<sup>11</sup> with the objective of clarifying doubts and assisting in post-liver transplant care.

The study took place between January 2020 and August 2021, at the Liver Transplant Service of the Walter Cantídio University Hospital belonging the Federal University of Ceará (*Hospital Universitário Walter Cantídio/Universidade Federal do Ceará, HUWC/UFC*) located in the city of Fortaleza, Ceará, Brazil. The service began its activities in 2002 and, since then, it has been working uninterruptedly to meet the needs of the health system, being a national reference center in transplants. The gateway for transplant patients is the outpatient service. Patients are referred from Basic Health Units and hospitals in Ceará and other states, where they will be monitored in the pre-and post-transplant phases. The service has a multi-professional team comprised of eleven physicians, a nutritionist, a psychologist, a physiotherapist, seven nurses, four nursing technicians, a social worker and a pharmacist.

The participants were health team members working at the outpatient service of the institution where the study was conducted, as well as liver transplant recipients.

### Elaboration

The research to prepare the booklet initially included a bibliographic survey in the technical-scientific literature to gather diverse information considered useful for post-transplant patients, such as medications to be administered; possible post-transplant complications; post-transplant patients' rights; and other possible doubts that the patients may have.

The literature review on the topics covered in the booklet was conducted in January 2020, contemplated by the analysis of publications, allowing for the categorization of the topics used in the booklet, delimitation of the content and structuring of the educational material. The following databases were consulted: LILACS (*Literatura Latino-Americana e do Caribe em Ciências da Saúde*), MEDLINE (Medical Literature Analysis and Retrieval System Online), Scopus and CINHALL, using the following health descriptors: "Liver Transplantat", "Health Education", "Medication Adherence" and "Immunosuppressive Agents", "Liver Disease"

and "Patient Rights". From this survey, we identified 15 studies of interest, cited in the booklet.

The booklet was prepared in order to ease the readers' understanding of the theme, with language suitable for the target audience, and was divided into two blocks. The first block contains general information about the post-transplantation period and is divided into four parts:

Part I - Talking about the rights of transplanted patients, with content about assistance (support for older adults and disabled people; sick pay; treatment outside the home), social security and disability retirement.

Part II - Monitoring the patients' health, with the following contents: first days after hospital discharge, consultation routines, prevention of infectious diseases, surgical wound care, other complications, general care;

Part III - Knowing your body: liver: characteristics and functions, complications of liver disease; and

Part IV - Medications in use addressing the following subject matters: immunosuppressants, gastric protector, prophylactics.

The second block contains charts for the multi-professional team and the patient to record information, related to the medications in use and how they are administered; monitoring of immunosuppression; adverse effects; pharmacotherapy follow-up and records of previous appointments.

Illustrations were obtained from the Canva® website to ease understanding of the content by the patients through the creation of charts of medications in use, pharmaceutical guidance, pharmacotherapy follow-up and consultation records, in addition to figures.

### Validation by expert judges

Validation consists in verifying that a given material meets the necessary prerequisites for which it is proposed. Understanding this procedure is fundamental for health professionals who intend to use reliable and appropriate materials for a specific population group.<sup>12-15</sup> This type of validity suggests whether the items contained in the educational material are adequate to measure the material prepared and if their mastery is sufficiently appropriate, necessarily based on a value judgment<sup>16</sup>. Carrying out this phase of the study is an indispensable procedure for researchers and professionals in the health area who need to use measures and materials that are duly grounded and suitable for the chosen population.<sup>12</sup>

The validation process took place with the professionals from the multi professional service team during May and June 2021, and involved 17 individuals, namely: four hepatologists, two surgeons, seven nurses, one pharmacist, one physiotherapist, one social worker and one psychologist, all working at the HUWC-UFC

Liver Transplant Outpatient Service. After acceptance, the Free and Informed Consent Form (FICF), the evaluation form and the booklet for transplanted patients were handed in. The evaluators were given two days to analyze the material and get back to the main researcher. When delivering the material in person, the evaluators were asked to add comments, if they deemed it necessary.

The form used to evaluate the booklet was adapted, comprising a questionnaire with 50 evaluative items. The first part contained diverse information about identification of the evaluators: training time, time working in the area, degree, and participation in projects involving Liver Transplants. The second part of the questionnaire contained questions related to the validation process itself, covering the following aspects: objectives, content, language, relevance, illustrations, layout, motivation and culture of the booklet for transplanted patients.<sup>17</sup>

The booklet validation analysis was performed by means of the Content Validity Index (CVI), which measures the agreement proportion on a given subject matter in an instrument.<sup>12</sup> The analysis of each item was performed using a Likert-type scale, with scores from 1 to 5, where: 1) I strongly disagree; 2) I disagree; 3) I neither disagree nor agree; 4) I agree; and 5) I totally agree. In the current study, the CVI was calculated based on the “4” and “5” answers, selected by the evaluators<sup>12</sup>.

Finally, for the full assessment of the booklet, all the separately calculated CVI values were added up, and then divided by the number of items in the instrument.<sup>11</sup>

The literature generally considers agreement indices between 78% and 100% as representative in studies with more than six participants, considering that rates greater than or equal to 0.78 (AI>0.78) indicate good validity<sup>16,18</sup>. Other authors recommend a minimum agreement index from 0.80 to 0.90 or more when it comes to new instruments.<sup>16,19</sup> In this study, a minimum agreement index of 0.80 was adopted.

### Validation by the target audience

After validation by the expert judges, the booklet was validated by post-liver transplant patients. This phase took place during August 2021. For this purpose, the following inclusion criteria were used: undergoing monitoring at the HUWC/UFC liver transplant outpatient service, belonging to the age group of 18 to 75 years old, and being able to answer the research questionnaires. Presenting any clinical complication during data collection was adopted as exclusion criterion.

For this stage of the study, post-liver transplant patients were sought at the HUWC-UFC Liver Transplant Outpatient Service. After acceptance, they signed the Free and Informed Consent Form (FICF) and were handed in the booklet assessment instrument and the booklet for transplanted patients itself.

During the period, 20 patients were available to participate and were given 60 minutes to analyze the material and return it to the researcher. When delivering the material, the patients were encouraged to add comments, if they deemed it necessary. This moment took place in a private room at the outpatient service.

The form used for the patients to evaluate the booklet was adapted to the literature according to the research objectives,<sup>17</sup> resulting in a questionnaire with 46 evaluative items. The first part contained questions related to identification of the patient interviewed, with questions regarding gender, age, schooling level, marital status, underlying disease and comorbidities. The second part of the questionnaire addressed aspects related to the validation process itself, such as objectives, organization, language, aesthetic aspect, illustrations and motivation.<sup>17</sup>

On the evaluation form, for each question, the patients could mark one of the following three items: 1-Yes, 2-No, and 3-Partly, in order to simplify the filling out process, although without interfering with data analysis.<sup>20</sup> To evaluate the booklet items, the CVI was obtained based on the “1” answers.

The study data were collected and managed using the *Research Electronic Data Capture* (REDCap1) data collection and management tool hosted at the Clinical Research Unit of the UFC University Hospital Complex.

For the numerical variables, the data were presented as mean and standard deviation. In the case of the categorical variables, the data were displayed as frequency and prevalence ratio in order to describe the characteristics of the sample under study.

The statistical analyses were performed using the JAMOVI statistical program and Microsoft Excel 2016.

This research was submitted to the Research Ethics Committee of the Federal University of Ceará and approved under opinion number 3,358,115.

## RESULTS

### Characterization of the expert judges

A total of 17 expert judges participated in the study. Most of them were female (64.0%). Their mean age was 44.8 years old (Standard Deviation = 9.01), varying from 30 to 65. Most of them had at least 20 years of professional training (58.8%), followed by 29.4% between 11 and 19 years, and 11.8% with up to ten. All had some graduate degrees in the area and 47% ( $n=8$ ) of them participated in research projects on the topic of liver transplants.

### Face and content validation by the expert judges

Regarding the face and content evaluation of the booklet for transplanted patients, according to objectives, content, language, relevance, illustrations, layout, motivation and culture, in Table 1 it can be seen that the lowest score obtained, in each of the subitems evaluated, corresponded to a Content Validity Index of

**Table 1: Content Validity Index, based on the experts' perception, by analyzed category of the booklet for liver transplant patients, CE, Brazil, 2021.**

Items	CVI	
	n	Score
Objectives	66	0.97
Content	146	0.95
Language	100	0.98
Relevance	101	0.99
Illustrations	83	0.98
Layout	119	1.00
Motivation	51	1.00
Culture	17	1.00
Global Index for the Booklet	683	0.98

n = Number of "4" (I agree) or "5" (I totally agree) answers for the respective questions; CVI = Content Validity Index.

**Table 2: Content Validity Index, based on the perception of the target audience, by analyzed category of the booklet for liver transplant patients, CE, Brazil, 2021.**

Items	CVI	
	n	Score
Objectives	79	0.99
Organization	160	1.00
Language	140	1.00
Aesthetic aspect	178	0.99
Motivation	119	0.99
Global Index for the Booklet	676	0.99

n = Number of "1" (Yes) answers; CVI = Content Validity Index.

0.95 and a maximum of one (1). The mean global CVI for the booklet was 0.98.

Some of the suggestions mentioned by the judges (Chart 1), include the following: improving information about retirement, treatment outside the home, vaccines and the best time to take them, surgery site care, water intake, physical activities, libido, pregnancy, update of the list of immunosuppressants, care in their administration, itching and diverse information about the COVID-19 pandemic. The suggestions were accepted based on support from the literature, in order to make the booklet more adequate. Some suggestions were not included due to the fact they were not supported by the scientific literature, for only presenting a personal point of view or for having no relation with the study that entailed inclusion in the booklet, such as stating that Vitamin B6 (pyridoxine) is administered due to its lack in the body, creating a banner, creating a flipcard and seeing the logistics of the booklet's hardcover.

## Characterization of the patients

Most of the 20 patients who were willing to participate in the booklet validation process, were male (65.0%) and aged at least 60 years old (55.0%), followed by 20% between 30 and 39 years old, 15% between 50 and 59 years old and 10% from 40 to 49 years old. In relation to schooling, most of the respondents had completed High School (37%) and incomplete Elementary School (26%).

## Face and content validation by the target audience

Regarding face and content evaluation of the booklet for transplanted patients (Table 2), most of the items obtained CVI = 1; the lowest score obtained was CVI = 0.99, ending with a global mean of 0.99 for the booklet.

The transplanted patients also made recommendations for changes or additions to the booklet, which can be seen in Chart 2. The suggestions regarding patients' rights, other complications such as the possibility of Herpes-Zoster infection, details on immunosuppressants, prophylactics and frequently asked questions were accepted based on the literature. The reasons for the suggestions that were not included were the following: not having sufficient scientific grounds, presenting incorrect information, or even not applying to the reality of the liver transplant process, only presenting a personal point of view.

## DISCUSSION

The study made it possible to validate the information booklet for transplanted patients among health professionals and patients from the HUWC/UFC transplant service, proving to be an educational resource with valid content and quality, as it reaches high agreement levels in the objectives, content, language, relevance, illustrations, layout, motivation and culture items.

Considering that the validity of educational materials must present a minimum agreement index of 0.80,<sup>12</sup> in this material, the global validity index for the booklet was 0.98 among the specialists, considered acceptable; therefore, it becomes a viable technology to assist the professionals in the area when carrying out their activities, with regard to informing the necessary care measures to be adopted by transplanted patients.

Also, in terms of the requirements to validate the booklet, despite its scientific content and relevance, other aspects need to be adapted to the target audience, such as language, motivation and aesthetic aspects, simplifying scientific language for the readers to understand it.<sup>21</sup> Thus, validation of the booklet was not limited to the expert judges; it also obtained a validity index greater than 0.80 among the patients.

Elaboration of the booklet emerged from the researchers' observation of the difficulties faced by transplanted recipients and their family members to manage the amount of information transmitted by the health professionals who assisted them and,



**Chart 1: Suggestions made by the expert judges based on the chapters of the booklet for transplanted patients, CE, Brazil, 2021.**

Booklet chapters	Suggestions made by the expert judges
Talking about the rights of transplanted patients	<p>Include “must be enrolled in the Single Registry to be eligible” in the first topic;</p> <p>Include that they must be enrolled in the General Social Security System in the first topic;</p> <p>Include the meaning of INSS;</p> <p>Inform that the social worker is the professional responsible for providing guidance regarding guarantee of rights;</p> <p>Inform that if the patient qualifies [for disability retirement] in the pre-transplant period, they can still receive the aid due to their severe liver disease. If the patient is still considered to have a severe liver disease even after the transplant, they can retire due to disability;</p> <p>Include where and how to look for TOH (Treatment Outside the Home);</p> <p>Enter the TOH initials in capital letters.</p>
Prevention of infectious diseases	<p>Include the new coronavirus vaccine;</p> <p>Change “ACWY” to “meningococcal (ACWY)”;</p> <p>Enter the appropriate period (pre- or post-transplant) to take each vaccine;</p>
Surgical wound care	<p>Change “neutral soap” to “neutral liquid soap”;</p> <p>Include the information that, if dry and healing well, the wound does not need to be covered, it only needs to be drained;</p>
Other complications	<p>Artery thrombosis does not necessarily mean rejection.</p>
General care	<p>Replace “cholesterol consumption” by something suitable;</p> <p>Include that the water to be drunk has to be mineral or filtered, and that the patient has to drink plenty of water;</p> <p>Include the recommended post-transplant time to be able to do physical exercise again;</p> <p>Include that the guidance to do physical exercise in a gym comes from the physician or physiotherapist;</p> <p>Inform that it is also necessary to wear a mask outside the house. If there is someone from outside, especially if they have flu and/or after taking a live virus vaccine, they must also wear a mask.</p> <p>Inform that it is observed that libido usually rises after the transplant, and that it drops before the surgical procedure. If the patient still has no libido after the transplant, they can consult a physician, and they should not abuse other medications in an attempt to compensate;</p> <p>Inform that it is recommended to stay 1 year without getting pregnant, and if the patient does become pregnant, notify the physician immediately to control the immunosuppressant.</p>
Liver: characteristics and functions	<p>Inform that bleeding is digestive.</p>
Immunosuppressants	<p>Include azathioprine and cyclosporine;</p> <p>Include some indication on “what if I take the medication and then I throw up?”</p>
Prophylactics	<p>Inform that sulfamethoxazole + trimethoprim is not to prevent inflammation in the intestine, but to prevent pneumocystosis.</p> <p>The PPD value is greater than or equal to 5, not only greater than.</p>
Frequently asked questions	<p>Withdraw rifampicin as immunosuppressant;</p> <p>It is not normal to react with significant dermatological itching. It can be a warning signal for bile duct stenosis, or for allergy to the medication.</p>

**Chart 2: Suggestions made by the target audience based on the chapters of the booklet for transplanted patients, CE, Brazil, 2021.**

Booklet chapters	Suggestions made by the target audience
Talking about the rights of transplanted patients	Develop more on the laws.
Other complications	Describe whether it is possible to have Herpes-Zoster in the post-transplant period, and whether there is a vaccine for it.
Immunosuppressants	Further explain the immunosuppressants indicated.
Prophylactics	Review part of the cytomegalovirus, how to add symptoms.
Frequently asked questions	Include what to do to solve itching, if felt.

consequently, the need for the service to offer an educational resource that would support the transplanted patients' follow-up process of after the surgical procedure.

The material developed was designed with the objective of showing the sequence of events that take place in the post-transplant period, minimally representing the patients' path from the perspective of guidelines regularly provided in the routine of the study *locus*, aiming to be used as educational support in health in liver transplant services.

The use of educational technologies to support the patients' therapeutic routine is a widely used resource among health professionals, such as in the case of patients who have suffered a stroke, women with breast cancer, patients with chronic kidney disease and women with stomas since, in addition to improving the patient's understanding and ability for self-management, they allow them to understand how their attitudes influence their health condition and contribute to guiding their caregivers' work.<sup>22-26</sup>

In the validated tool, for example, the patients must better understand their rights and their new healthcare routine, liver function and the reason why they use each type of medication.

With regard to their rights, it is known that transplanted patients face several difficulties during the post-surgical period, which can be medium- to long-term and which, among other issues, involve the relative financial conditions, essential to cope with the countless lifestyle changes that will need to be adopted. In this way, the first part of the booklet aims at showing which situations and financial benefits they are entitled to, a fundamental condition for improving their quality of life and social reintegration. For example, if the patients are older adults or disabled; in the case of not having the physical ability to engage in any paid activity on a temporary or permanent basis; if they have severe liver

disease; at the time of providing some public tender service; and if they need to move out of their city for treatment. This aspect becomes even more relevant because the study's local service is public, maintained by the Unified Health System (*Sistema Único de Saúde*, SUS) and serves patients with lower purchasing power and less access to supplementary services that could support them in this regard.

The booklet contents then move on to aspects related to the mediate post-transplant care measures, providing diverse information about food care, such as eating healthy nutrition products, using as little salt as possible when preparing meals, reducing the consumption of fats and sugars and increasing the intake of fibre-rich food options, in addition to not consuming drinks that contain alcohol; vaccination; surgical wound care, and measures to be adopted when there are warning signs such as fever, pain, heat, redness and swelling at the wound site during this post-surgery period.<sup>27-30</sup>

The following sections ("Knowing your body", "Medications in use" and "Patient's Diary") were planned with the objective of operationalizing the education activities in the patient care context and process in the outpatient service itself, where practical tools for recording and control of relevant information for the multi-professional follow-up adopted in the service were incorporated. However, before this, a brief theoretical introduction was considered necessary regarding the pathophysiology of liver disease and drug treatment, contents considered relevant and basic to all the professionals involved.

The proposal is to allow the recording of the information history about procedures performed at home, or not recorded in the medical chart, or even post-consultation information, with the 'Guidance table' in the 'Patient's Diary' section and all its content: identification of the patient, medications in use, pharmaceutical guidance and pharmacotherapy follow-up, which in turn includes monitoring of immunosuppression, adverse events and adherence to the treatment, followed by the "Record of consultations" and "Useful telephone numbers" topics.

Filling out of the tables by the professionals during the consultations allows the patient to access when outside the hospital environment, pertinent information previously described only in the medical chart.

In turn, the diaries allow asynchronous communication between patients and professionals, allowing minimizing memory bias and increasing the reliability of the diverse information regarding procedures performed at home by the patient during inter-consultation periods. These elements allow for stronger connections between consultations and home-based treatment follow-up.<sup>4</sup>

The fact that health technology still has space for interaction between the team and the patient renders this interaction more

comfortable and allows for a more reliable follow-up of the patient outside the outpatient setting;<sup>10</sup> as soon as a problem occurs (if it does), the patient can write in the space provided for this information that could be lost without the booklet, or even resort to information passed on verbally by the team and that is available outside the outpatient service.

In this way, the resource developed is a very important health technology, which, in addition to the indices obtained, was validated by a multi-professional team, fulfilling the purpose for which it was proposed.<sup>6</sup>

In addition, the post-transplant scenario is followed by an overload of information for the patient in a short period of time, in view of the countless lifestyle changes that will need to be adopted. Therefore, in addition to allowing the readers to choose the most appropriate time and place to read and consult the booklet whenever they deem it necessary, offering printed material containing the ideal post-transplant management has the potential to minimize various complications, as well as turning patients into protagonists of their own health care.<sup>7</sup>

## CONCLUSION

The need for liver transplanted patients to be aware of the post-transplant process is unquestionable. In view of what was presented in this study, the booklet that was prepared is valid in its content and suitable for informing transplanted patients, as it was prepared based on the situational diagnosis linked to diverse scientific evidence and analyzed by the target audience. Finally, it is suggested that the study about the booklet advances to clinical validation so that it can later be implemented in the post-liver transplant routine as a guiding resource for the care of this type of patient in order to render the process more effective.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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**Cite this article:** Bastos KX, Cavalcante LP, Passos ACB, Accioly GA, Cardoso MVLML, Arrais PSD. Elaboration and validation of an educational booklet for liver transplant recipients. *J Young Pharm.* 2023;15(2):352-9.