JOURNAL OF SURGERY AND RESEARCH

ISSN: 2640-1002

Research Article

Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method

Zineb Cherkaoui[1,2,3,4], Elodie Léost[5], Bastien Delattre[5], Grégoire Gessain[6,7], Véronique Christian[1], Stéphanie Mathis[1], Christiane Bruck[1], Elisa Martinis[1], Elena Bangoura[1], Sophie Blanès[1], Fabio Giannone[1,2,4], Fatema Alhammadi[1], Arne Kock[1], Constance Lugiez[5], Patrick Pessaux[1,2,4*], IHU-VBHC Working Group

Simple Summary: Hepatocellular carcinoma is the primary hepatic tumor that usually develops in a cirrhotic liver and is the third most common cause of cancer death per year. Looking for new models based on value to improve patient outcomes especially with severe prognosis, this article details the elaboration of a standardized outcome measurement set validated internationally by a Delphi method, to allow a value-based healthcare analysis of the care pathway for patients with hepatic cancers.

Abstract

Background: Global healthcare system is looking for new models based on value to improve patient outcomes. Therefore, it is necessary to identify standardized outcome measurements allowing monitor-ing and quality-of-care comparison. These outcomes include medical results (CROMs – Clinical Re-ported Outcome Measurements), symptoms and quality-of-life (PROMs – Patient Reported Outcome Measurements).

Objective: The aim was to create standardized metrics to be used for outcomes analysis of liver cancers.

Methods: A multidisciplinary working group (WG) was assembled. The systematic review conducted collected the most common outcomes in liver cancers' clinical studies. After 3 workshops, the WG reached a consensus on the definition of the main outcomes, identified existing questionnaires for PROMs collection, set the timeline for data collection. To validate the final set, an international external committee completed a Delphi process.

Results: After a systematic literature review, 377 clinical studies were reviewed, 1539 outcomes listed. The WG selected 141 outcomes (121 CROMs and 20 PROMs) to submit to the Delphi vote committee. In total 96 outcomes (86 CROMs and 10 PROMs) were retained. PROMs were added to monitor quali-ty-of-life, functioning, symptoms, through the EORTC QLQ-C30 and QLQ-HCC18 questionnaires.

Conclusions: A standardized set of outcome measures validated through an international health out-come comparisons and quality-of-care assessments was built for primary and secondary liver cancers.

Keywords: Value-based healthcare; Standard set; Hepatocellular carcinoma; Delphi method; CROMS; PROMS

Affiliation:

[1] Department of Visceral and Digestive Surgery, University Hospital of Strasbourg, France

[2] Inserm Unit UMR_S1110, Institute for Research on Viral and Hepatic Diseases, group "Relevance and Care Pathways", Strasbourg

[3] SSPC (Simplification of Surgical Patient Care), UR UPJV 7518, University of Picardie Jules Verne, Amiens, France

[4] IHU-Strasbourg, Institute of Image-Guided Surgery, Strasbourg, France

[5] Integrated Health Solutions (IHS), Medtronic France, Boulogne-Billancourt, 92100, France

[6] University of Paris, Faculty of Health, Paris, France

[7] Chair of Innovation & Value in Health, University of Paris, Paris, France

***Corresponding author:**

Patrick Pessaux, Department of Visceral and Digestive Surgery, University Hospital of Strasbourg, France.

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

Received: February 13, 2025
Accepted: February 21, 2025
Published: February 27, 2025

Introduction

With healthcare costs increasing globally, there is a marked transition towards value-based healthcare (VBHC) systems with the aim to improve health outcomes [1,2]. The main hurdle is to estab-lish uniform outcome metrics that allow effective monitoring and quality of care comparison, thus op-timizing medical practices and patient care pathways. A universally accepted definition of outcomes is necessary, encompassing both clinical results (CROMs – Clinical Reported Outcome Measurements) and patient-valued aspects such as symptoms and quality-of-life (PROMs – Patient Reported Outcome Measurements), which are crucial for serious conditions like liver cancers.

Hepatocellular carcinoma (HCC) is the most frequent type of liver tumors, primarily arising in cir-rhotic livers (75-80%), sometimes in non-cirrhotic chronic liver disease, and rarely in livers without any pre-existing condition. Globally, there are approximately 500,000 new liver cancer cases annually [3], making it the third leading cause of cancer-related death each year [4]. Among the various therapeutic decision-making frameworks, the Barcelona clinic liver cancer (BCLC) algorithm is the most widely used, considering tumor stage, liver function, and patient performance status to indicate a range of treatments from liver transplantation to supportive care, surgical resection, and other interventions [5]. Cholangiocarcinoma, another primary liver cancer, carries a poor prognosis [6].

Liver resection is a well-established treatment for colorectal liver metastases (CRLM), the leading cause of secondary liver cancers, with a 5-year survival rate of about 60% [7,8]. Over recent years, the management of CRLMs has evolved significantly due to the advances in perioperative medical care, the broadening of treatment indications, and the introduction of minimally invasive techniques [9], along-side the effective multimodal oncology treatments.

Despite the development of standardized questionnaires for assessing health outcomes via CROMs and PROMs in various cancers, such as breast [10], colon [11], lung [12], prostate [13,14], and pancreatic [15], there are no standardized outcome measurement sets for primary or secondary liver cancers.

Given our group's previous work in developing outcome sets for pancreatic carcinoma [15,16], we aimed to address this gap for liver cancer by creating the first standardized outcome measurement set, facilitating the monitoring of patient symptoms and quality-of-life, and aligning the best practices across care centers [17].

Methods

Our methodology followed the one used for pancreatic carcinoma outcomes set [15].

The role of the Working Group

A multidisciplinary Working Group (WG) was formed, comprising healthcare professionals, pa-tients, and other stakeholders. The WG started by analyzing existing care pathways for liver cancer pa-tients and gathering their inputs through interviews. They also conducted a systematic literature review to identify outcomes used in liver cancer clinical trials. After this review, duplicated outcomes were removed and the remaining ones were categorized into subjects of discussion. The WG then presented their selection to an international external validation committee (VC) for voting.

The role of the Validation Committee

The VC, comprising 102 members, including medical professionals (digestive surgeons, oncolo-gists, hepatologists, dieticians, nurses) and patients (Table 1), was tasked with a four-round Delphi pro-cess to refine and validate the final outcomes set (Figure 1). The patients involved were volunteers experiencing or having a liver cancer history. The tool used to conduct four rounds of surveys between De-cember 2018 and July 2019, focusing on CROMs and PROMs, was the Qualtrics platform. Participants were able to complete the surveys in either English or French, and phone assistance was available for those needing help. The final selection of the most appropriate patients related outcomes survey was choosen from eight questionnaires for the PROMs proposed earlier.

The WG determined the timeline to collect those outcomes confirming to various care episodes.

The PROMs

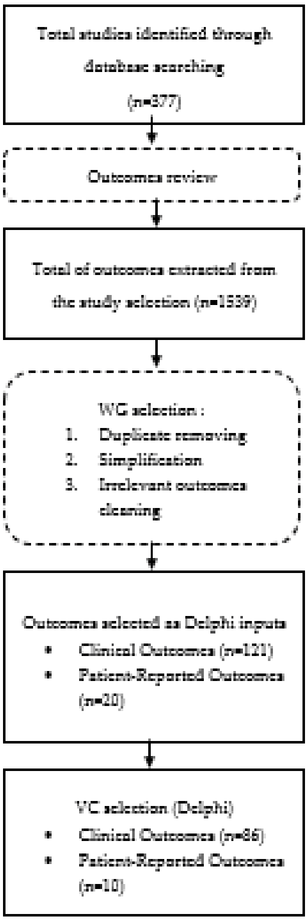
PROMs data was used to create a radar chart for each patient, depicting symptoms and quali-ty-of-life from the patient's perspective (Figure 2). This was achieved using the

Table 1: Composition of the Validation Committee.

Expertise	**n**	**%**
HBP Surgeons	49	48%
Dieticians	18	17.70%
Nurses	12	11.80%
Patients	11	10.80%
Medical Oncologists	8	7.80%
Hepatologists	3	2.90%
General practitioner	1	1.00%
Region	**n**	**%**
Europe	68	66.70%
North America	16	15.70%
South America	10	9.80%
Asia	8	7.80%

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

Cherkaoui Z, et al., J Surg Res 2025
DOI:10.26502/jsr.10020429



WG: Working Group; VC: Validation Committee

Figure 1: Systematic outcomes review flow chart.

EORTC QLQ-30 ques-tionnaire, with scores indicating better quality-of-life at lower values. The score of each question is represented: for the questions from 1 to 28, the answers are from 1 to 4 (the lower the score, the better the quality-of-life from the patient's perspective); for the questions 29 and 30, the score from 1 to 7 represent respectively the degree of overall health and quality-of-life.

Results

The WG defined the objectives of the project as encompassing all patients with primary or second-ary liver cancers, irrespective of the type or intent of treatment received, including those who had not received curative treatment. Patients undergoing treatment with experimental agents were excluded because these studies have their own outcome evaluations.

After the systematic literature review, a total of 377 clinical studies were selected and reviewed. 1539 outcomes were listed, including CROMs (1493 items) and PROMs (46 items).

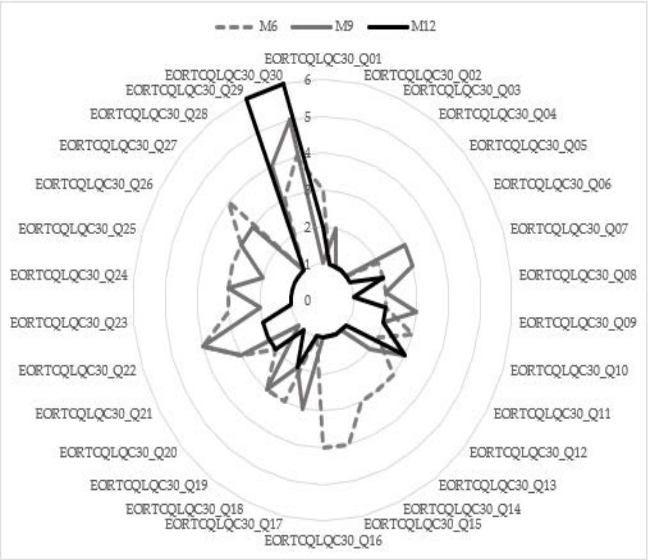


Figure 2: Radar chart representing the quality of life and symptoms of Patient 71 who had surgery for colon metastasis, assessed with EORTC QLQ-30 questionnaire at six-month, nine-month and one-year after surgery. The score of each question is represented: for the questions from 1 to 28, the answers are from 1 to 4 (the lower the score, the better the quality of life from the patient's perspective); for the questions 29 and 30, the score from 1 to 7 represent respectively the degree of overall health and quality of life.

These outcomes were put into 7 categories: Adverse Events monitoring, Cost, Efficacy endpoint in oncology, Progression Disease, Pharmacokinetics, Quality-of-Life, Toxicity/Safety/Tolerability. Redun-dancies and no relevant outcomes due to specific analysis (e.g., drugs, gene research) were removed. At the end, the WG selected 141 outcomes (121 CROMs; 20 PROMs) to submit to the international Delphi vote committee. In total, 96 outcomes (86 CROMs; 10 PROMs) were retained. One additional variable ("Diagnosis date") was suggested during the first round and retained during the second.

Outcomes classification

CROMs were divided into 2 parts: a baseline set (demographic factors, clinical characteristics, di-agnostic methodology, therapeutic strategy) (Table 2); a follow-up set: (treatment-related complications, survival and disease control indicators, evidence of relapse or disease progression (Table 3).

PROMs were grouped into health domains by the WG members using a method inspired by Mace-field et al. [18] and Van Rijssen et al. [19]. Quality-of-life (QOL) and functioning items were encom-passed in 3 categories: global health status, functional scales, symptom scales (Table 4).

CROMs: Clinical results

After the final validation process, 86 CROMs composed by demographic and baseline data, therapeutic strategy,

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

treatment effects, rehabilitation and follow-up data were selected (Tables 2 & 3).

- Demographic factors: sex, age weight, height, units of weight and height, family history of liver-related cancer.
- Baseline clinical factors prioritized for inclusion: the Eastern Cooperative On-cology Group (ECOG) score performance status [20], presence of comorbidities, the level of alco-hol consumption. The Charlson comorbidity index was selected for the comorbidity reporting [21]. The different methodologies used to verify the diagnosis were included, as the date of the tests. In case of hepatocarcinoma on cirrhotic liver, specific variables of cirrhosis as etiology (al-coholic, viral, non-alcoholic steato-hepatitis...), clinical severity (Child-Pugh/Meld Classification, portal hypertension...) were recorded. Clinical signs, pathology stage (TNM stage) were also collected.
- Therapeutic strategy was divided into two groups: general and specific therapeutic strategy data.
- Follow-up items were included to monitor the trends of medical outcomes com-prising treatment-related adverse events, with a collection of surgical complications and their severity according to the Clavien-Dindo classification [22]; common terminology criteria for ad-verse events in radiotherapy and chemotherapy (version 4.0) [23] (Table 3).

Some postoperative complications related to liver surgery (biliary fistula, hepatocellular failure, bleeding) were assessed separately and classified according to their severity [24,25]. Similarly, the implementation of nutritional support and the need for new admissions were selected from a set of proposed variables.

The following measures were included for survival and disease control: overall survival, cause-specific survival, recurrence-free survival, progression-free survival, need for readmission.

For patients who received neoadjuvant therapy or surgery, complete pathological response and margin status were included.

Onset of tumor recurrence, date of relapse (curative treatment) or disease progression (pallia-tive treatment) were also included in follow-up and considered as a new reference point.

PROMs: Functioning, symptoms, quality-of-life variables

The final PROMs set (Quality-of-Life, functioning, symptom measures) is listed in table 4.

A total of 10 PROMs were selected, with validated questionnaires, the EORTC QLQ-C30 [26] and EORTC QLQ-HCC18 [27], for outcomes collection. Patients have to answer the questionnaires themselves, supervised by a pathway coordinator if needed. For patients with liver metastasis and other liver malignant pathologies, only the EORTC QLQ-C30 questionnaire is required. Although, both questionnaires are needed to assess the quality-of-life and symptoms of patients with HCC. The choice of questionnaires is then adjusted according to the types of liver malignant diseases. Patients with liver metastasis or non-HCC primary lesions only answered the EORTC QLQ-C30 questionnaire; that pre-senting HCC answered EORTC QLQ-C30 as EORTC QLQ-HCC18.

The choice of using those questionnaires for outcomes collection was validated by the VC, after review of several common validated questionnaires and identification of those best covering the selected outcomes.

The use of PROMs improves the communication between clinicians and patients facilitating the discussion about some sensitive subjects.

The example chosen here concerns the Patient 71 who underwent hepatic resection for colon metastasis (Figure 2). He answered the EORTC-QLQ-C30 at six-month, nine-month, one-year after sur-gery reflecting his symptoms and the score evaluating his quality-of-life.

Planning of evaluation

The timing of the evaluation of the set of variables was determined by the WG to strike a balance between clinically relevant time periods ; pragmatic concerns faced by institutions and data collection practices.

The collection of CROMs and PROMs was recommended during the baseline, at 1 month (for sur-gical/loco-regional therapy), 3 months, 6 months, 9 months, one year after treatment, 18 months; annually up to 10 years, if possible.

First results of the French experience

Once the hepatic carcinoma standard set was validated, the Strasbourg’s team started collecting the patients’ outcomes after gathering their consents. From July 2019 to January 2021, 129 questionnaires were filled by 74 patients on the day of their surgical appointment with the 2 HBP surgeons implicated. The coordination nurse was present if needed to help patients understand the questionnaires. She noted that most of them felt well involved and found the PROMs collection as important as the clinical out-comes. The 74 patients answered at least one; 24 patients filled 2; 14 patients answered 3 questionnaires; 1 patient filled 4 of them. 65% were males; 51% presented with HCC, 40 % with colorectal metastasis, 5 patients with cholangiocarcinoma ; one patient had breast liver metastasis. 42% had liver surgery ; 10% still had a professional activity. The HBP surgeons found this approach complementary to the usual follow-up ; thanks to it, they could have each patient’s proper evolution chart (Figure 2).

Table 2: Clinical Reported Outcome Measurements (CROMs) Baseline set.

	Patient Population	Details	Data source	Timeline
1. DEMOGRAPHIC FACTORS				
Sex	All patients	Patient Sex	Administrative data	Baseline
Age		Date of Birth		
Weight$^{\mu}$		Unit of measurement (kg or lb)	Clinical abstraction	
Height		Unit of measurement (cm or ft)		
Personal History of HCC		Previous HCC & treatment (if applicable)		
2. CLINICAL CHARACTERISTICS				
Patient Characteristics				
Score Performance (ECOG)$^{\mu}$	All patients	Eastern Cooperative Oncology Group (ECOG) Performance Status	Clinical abstraction	Baseline
Comorbidities$^{\mu}$		Charlson Comorbidity Index		
Alcohol Consumption		Beverage-specific quantity and		
		frequency (units per day)		
Disease Characteristics				
Cardinal Symptoms	All patients	Onset date and nature of symptoms + date of first medical appointment & date of diagnosis	Clinical abstraction	Baseline
Tumor Location		Anatomical location of the tumor (AJCC Cancer Staging Manuel, 8th Edition, 2018)		
cTNM Stage		Preoperative staging of the disease		
Vascular invasion		If there is a tumor's vascular invasion		
Tumor diameter		The diameter of the tumor in centimeter (if applicable)		
Liver cirrhosis		If the patient presents a liver cirrhosis		
Encephalopathy	Patients with liver cirrhosis	If the patient presents an encephalopathy		
Portal hypertension		If the patient presents a portal hypertension		
Edema of the lower limbs		If the patient presents an edema of the lower limbs		
Ascites		If the patient presents an ascites		
HCV infection		If the patient has been infected by HCV & if cured		
HBV infection		If the patient has been infected by HBV & if cured		
3. DIAGNOSTIC METHODOLOGY				
CT-Scan	All patients	Test date (if applicable)	Administrative data	Baseline
MRI				
Biopsy		If biopsy performed, test date & histological diagnosis	Clinical abstraction	
4. THERAPEUTIC STRATEGY				
General				
Multidisciplinary Meeting	All patients	Meeting date (if applicable)	Clinical abstraction	Baseline
Intention of Treatment		Curative or palliative intent		&
Type of Treatment Selected		Modality of treatment chosen		Follow-up

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

Surgery				
ASA Score	Patients receiving surgery or interventional radiological procedure	Physical Status Classification System (American Society of Anesthesiologists)	Clinical abstraction	Follow-up
Date of Surgery	Patients receiving	Specify the date of the intervention	Surgical Report	
Type of Surgery	surgery	Specify procedure performed		
Approach		Minimally invasive or open surgery		
Quality of Resection		Specify specimen margin status (AJCC Cancer Staging Manuel, 7th Edition, 2010)	Pathological Report	
Standardized Pathological Report		Completeness of recommended parameters		
pTNM Stage		Postoperative staging of disease (AJCC Cancer Staging Manuel, 8th Edition, 2018)		
Hospitalization Length		Admission and discharge dates	Administrative data	
Waiting time for liver transplantation	Patients receiving liver transplantation	Waiting time in months	Administrative data	
Preoperative radiological procedure				
Type	Patients receiving surgery	Type and technical details (if applicable)	Clinical abstraction	Follow-up
Interventional radiology				
Type	Patients receiving interventional radiology	Treatment details and the date of the procedure	Clinical abstraction	Follow-up
Date of treatment				
Radiotherapy				
Type	Patients receiving neoadjuvant/ adjuvant/ palliative treatment	Start and finish date and treatment details (if applicable)	Clinical abstraction	Follow-up
Duration of treatment				
Chemotherapy				
Type	Patients receiving neoadjuvant/ adjuvant/ palliative treatment	Start and finish date and treatment details (if applicable)	Clinical abstraction	Follow-up
Duration of treatment				

[µ] baseline and follow-up.

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

Table 3: Clinical Reported Outcome Measurements (CROMs) Follow-Up set.

	Patient population	Details	Data source	Timeline
1. TREATMENT-RELATED COMPLICATIONS				
Surgery-Related Complications				
Post-Surgical Complications	Patients receiving surgery	Clavien-Dido classification of surgical complications	Clinical abstraction	Follow-up
Biliary Leakage		Biliary fistula management		
Hemorrhage	Patient receiving surgery and/or biopsy	Specify if the patient has experienced any hemorrhaging		
	Patients receiving surgery	Specify if the patient has experienced a surgical site infection		
Surgical Site infection				
Liver failure	Patients receiving surgery or interventional radiology	If there is evidence of liver failure		
Interventional Radiology-Related Complications				
Post-interventional complications	Patients receiving interventional radiology	If patient presented any complication	Clinical abstraction	Follow-up
Neoadjuvant / Palliative Treatment-Related Complications				
Tumor Response	All patients	No sign of residual cancer on diagnosis evaluation	Clinical abstraction	Follow-up
Undesirable Effects	Patients receiving systemic treatment	Common terminology criteria for adverse events		
Readmissions				
Need for Readmission	All patients	New admission at any time for any cause	Administrative data	Follow-up
Date of Readmission				
2. SURVIVAL AND DISEASE CONTROL				
Overall Survival	All patients	Date of death	Administrative data	Long-Term Follow-Up (Annual follow-up from the first year of treatment)
Cause-Specific Survival		Death attributed to liver cancer		
Recurrence-Free Survival	Patients with curative intent	Local, regional, or distal recurrence	Clinical abstraction	
Progression-Free Survival	Patients with advanced disease	Disease progression		
Need for Readmission	All patients	Evidence of margin involvement		
3. RELAPSE/PROGRESSION OF THE DISEASE				
Disease Relapse				
Relapse Date	Patients with curative intent	Onset date. Nature of event. Detection Method (clinical, imaging and/or pathological identification)	Clinical abstraction	Follow-up
Method of Detection				
Disease Progression				
Progression Date	Patients with advanced disease	Onset date. Nature of event. Detection Method (clinical, imaging and/or pathological identification)	Clinical abstraction	Follow-up
Method of Detection				

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

Table 4: Patient Reported Outcome Measurements (PROMs) set.

	Patient population	Details	Data source	Timeline
GLOBAL HEALTH STATUS / QOL				
Global health status/QoL	All patients	Tracked via EORTC QLQ-C30	Patient-reported source	Every follow-up control starting at baseline
FUNCTIONAL SCALES				
Physical functioning	All patients	Tracked via EORTC QLQ-C30	Patient-reported source	Every follow-up control starting at baseline
Role functioning				
Emotional functioning				
Cognitive functioning				
Social functioning				
SYMPTOM SCALES				
Nausea and vomiting	All patients	Tracked via EORTC QLQ-C30	Patient-reported source	Every follow-up control starting at baseline
Dyspnea				
Insomnia				
Appetite loss				
Constipation				
Diarrhea				
Financial difficulties				
Fatigue		Tracked via EORTC QLQ-C30 & HCC18		
Pain				
Body image		Tracked via EORTC QLQ-HCC18		
Jaundice				
Nutrition				
Fever				
Abdominal swelling				
Sex life				

QoL: Quality of Life.

This new evaluation combined to the usual medical check makes doctors tackle some points affecting the patient's quality-of-life that are not generally discussed. Furthermore, the medical care is thus global and not from the surgeon's but from the patient's point of view.

Discussion

The objective of this study is to develop a set of outcome variables to facilitate the collaboration among the various stakeholders in the healthcare systems.

These outcome indicators need to be collectively agreed upon by each one involved in the care pathway.

This requires a collaborative approach where all participants in the chain of value contribute to the development of these outcomes. According to the strategy of this study, a multidisciplinary and multi-professional team was formed, including patients, who uniquely experience the entire care path-way, and healthcare providers (HCPs) who maintain ongoing contact with patients. This team compo-sition emphasized patient experiences and expectations alongside medical expertise. However, one limitation was the absence of palliative care specialists, who could enhance discussions on patients' quality-of-life.

Comparing different centers can help improve care organization, and a set of outcome measures can help prioritize care under limited resources. For a specific disease, implementing a vali-dated set of outcomes requires digital data tracking of selected parameters. After data collection over time, stratified analyses should be conducted based on the disease stage and patient risk factors. Addi-tionally, HCPs can use the results from patient-reported outcome measures

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.

(PROMs) to refine treatment decisions [28]. In terms of rehabilitation, Enhanced Recovery after Surgery (ERAS) pathways, or other organizational innovations, systematic monitoring through Value-Based Healthcare (VBHC) question-naires provides real-life assessments of Clinical and Patient-Reported Outcome Measures (CROMs and PROMs).

These analyses enable comparisons, enhance care quality, and meet patient expectations. Once results are anonymously shared, each center can implement corrective actions if needed. This sets up a virtuous cycle for practices improvement through systematic results evaluation. Historically, quality assurance evaluations were not common practice. The aim is to prompt the conditions to create a virtuous circle to improve quality of care, notably to measure and compare means to better assess, understand and assert one's results and learn from others. This constraint-free audit approach is ongoing and successfully led to better treatment of an increasing number of patients [29,30].

This approach parallels quality assurance practices in services and industries. It benefits practitioners by enhancing their methods, patients by receiving relevant care, and the healthcare system by reducing inefficiencies, which incur costs [31]. Modifying the financial system to focus on quality over quantity is a powerful motivator for adopting these systematic quality assessments. This work is not about evaluating care costs but about defining indicators representing "medical service rendered" on both the clinical level with CROMs and in terms of patient feelings and expectations through PROMs. Sometimes, discrepancies exist between clinical data and patient perceptions. This value appeals to subjective human emotions. No individual value exists in isolation; value judgments are collective. A theoretical survival gains through chemotherapy, despite risks like peripheral neuropathy, will be valued differently based on individual circumstances, such as whether the patient is a professional violinist. This introduces a hierarchy of values, assessing what is prioritized. The question is how much we are collectively willing to invest in results that matter to patients or, for a given cost, what minimum patient-valued results are expected.

To facilitate the implementation of outcome indicators important to patients, several factors must be addressed. For key patient data like quality of life, patients can complete questionnaires themselves, supervised by a pathway coordinator if necessary [32]. Clinical outcomes are already documented in patient records and can be gathered through standardized data collection. Authors report successful validation and easy adoption of value-based digital health by healthcare professionals in their daily practice [33]. To support the success of a VBHC approach, the European University Hospital Alliance provides a diagram with eight elements across six phases [34].

It is crucial to emphasize that this approach is about valuing quality, not penalizing poor results. Criticisms suggesting patient selection for management based on low risk should be countered. Stratified analyses according to disease stage and patient risks should be conducted to compare similar out-comes. A transition period is necessary for teams to anonymously review their results, allowing for corrective actions.

Conclusions

A standardized set of patient-centered outcome measures for liver cancers has been developed to facilitate international health outcomes comparisons and quality-of-care evaluations. Implementing tools that measure both clinical treatment response parameters and patient-reported outcomes in clinical research and routine practice is a step towards ensuring effective care to every patient, regardless of their circumstances. The key elements for the success of this approach are education, clarity, transpar-ency, and continuous improvement. This necessary approach is essential to maintain the sustainability of healthcare systems. The process of collecting the validated outcomes set for hepatic carcinoma is cur-rently underway in our digestive department, with plans to expand to other centers.

Author contributions

Conceptualization, Z.C., E.L., B.D., C.L. and P.P.; methodology, Z.C., E.L., B.D., C.L. and P.P.; software, Z.C., E.L., B.D. and C.L.; validation, Z.C., E.L., B.D., G.G., V.C., S.M., C.B., E.M., E.B., S.B., F.G.C., A.K., C.L. and P.P.; formal analysis, Z.C., E.L., B.D. and C.L.; investigation, Z.C., E.L., B.D. and C.L.; resources, Z.C., E.L., B.D. and C.L.; data curation, Z.C., E.L., B.D. and C.L.; writing—original draft preparation, Z.C., E.L., B.D., C.L. and P.P.; writing—review and editing, Z.C., E.L., B.D., G.G., V.C., S.M., C.B., E.M., E.B., S.B., F.G.C., F.A., A.K., C.L. and P.P.; visualization, Z.C., E.L., B.D., C.L. and P.P.; supervision, Z.C., C.L. and P.P.; project administration, Z.C., E.L., B.D., C.L. and P.P.; funding acquisition, E.L., B.D., and C.L. All authors have read and agreed to the published version of the manuscript.

Funding

This work was supported by French state funds managed within the “Plan Investissements d’Avenir” and by the ANR (reference ANR-10-IAHU-02).

Research agreement between IHU & Medtronic : IHU pays a Medtronic translational team for data collection.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Conflicts of interest

The authors declare no conflict of interest.

Discloser

The abstract was presented at the 27th Annual Conference of the International Society for Quality of Life.

References

1. Porter ME. A strategy for health care reform-toward a value-based system. N Engl J Med 361 (2009): 109-112.
2. Van Staalduinen DJ, Van den Bekerom P, Groeneveld S, et al. The implementation of value-based healthcare: a scoping review. BMC Health Serv Res 22 (2022): 270.
3. El-Serag HB. Hepatocellular carcinoma. N Engl J Med 365 (2011): 1118-1127.
4. Ferlay J, Shin HR, Bray F, et al. Estimates of worldwide burden of cancer in 2008: GLOBOCAN 2008. Int J Cancer 127 (2010): 2893-2917.
5. Bruix J, Sherman M. American Association for the Study of Liver Diseases: Management of hepatocellular carcinoma: an update. Hepatology 53 (2011): 1020-1022.
6. El-Diwany R, Pawlik TM, Ejaz A. Intrahepatic Cholangiocarcinoma. Surg Oncol Clin N Am 28 (2019): 587-599.
7. Hallet J, Beyfuss K, Memeo R, et al. Short and long-term outcomes of laparoscopic compared to open liver resection for colorectal liver metastases. Hepatobiliary Surg Nutr 5 (2016): 300-310.
8. Waninger JJ, Ma VT, Chopra Z, et al. Evaluation of the Prognostic Role of Liver Metastases on Patient Outcomes: Systematic Review and Meta-analysis. Cancer J 29 (2023): 279-284.
9. Wakabayashi G, Cherqui D, Geller DA, et al. Recommendations for laparoscopic liver resection: a report from the second international consensus conference held in Morioka. Ann Surg 261 (2015): 619-629.
10. Ong WL, Schouwenburg MG, Van Bommel AC, et al. A standard set of value-based patient-centered outcomes for breast cancer: The International Consortium for Health Outcomes Measurement (ICHOM) Initiative. Jama Oncol 3 (2017): 677-685.
11. Zerillo JA, Schouwenburg MG, Van Bommel ACM, et al. A standard set of value-based patient-centered outcomes for colon cancer: The International Consortium for Health Outcomes Measurement (ICHOM) Initiative. JAMA Oncol 3 (2017): 686-694.
12. Mak KS, Van Bommel AC, Stowell C, et al. Defining a standard set of patient-centered outcomes for lung cancer. Eur Respir J 48 (2016): 852-860.
13. Martin NE, Massey L, Stowell C, et al. Defining a standard set of patient-centered outcomes for men with localized prostate cancer. Eur Urol 67 (2015): 460-467.
14. Morgans AK, Van Bommel AC, Stowell C, et al. Development of a standardized set of patient-centered outcomes for advanced prostate cancer: an international effort for a unified approach. Eur Urol 68 (2015): 891-898.
15. Cherkaoui Z, González C, Wakabayashi T, et al. A Standard Set of Value-Based Patient-Centered Outcomes for Pancreatic Carcinoma: An International Delphi Survey. Ann Surg Oncol 28 (2021): 1069-1078.
16. Pessaux P, Cherkaoui Z. ASO Author Reflections: A Standard Set of Value-Based Patient-Centered Outcomes for Pancreatic Carcinoma: An International Delphi Survey. Ann Surg Oncol. 2020 Dec;27(Suppl 3):773-774. doi: 10.1245/s10434-020-08701-5. Epub 2020 Jun 3. PMID: 32495283.
17. Memeo R, de Blasi V, Cherkaoui Z, Dehlawi A, De' Angelis N, Piardi T, Sommacale D, Marescaux J, Mutter D, Pessaux P. New Approaches in Locoregional Therapies for Hepatocellular Carcinoma. J Gastrointest Cancer 47 (2016): 239-246.
18. Macefield RC, Jacobs M, Korfage IJ, et al. Developing core outcomes sets: methods for identifying and including patient-reported outcomes (PROs). Trials 15 (2014): 49.
19. Van Rijssen LB, Gerritsen A, Henselmans I, et al. Core Set of Patient-reported Outcomes in Pancreatic Cancer (COPRAC): An International Delphi Study Among Patients and Health Care Providers. Ann Surg 270 (2019): 158-164.
20. Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol 5 (1982): 649-655.
21. Charlson M, Szatrowski TP, Peterson J. Validation of a combined comorbidity index. J Clin Epidemiol 47 (1994): 1245-1251.
22. Clavien PA, Barkun J, De Oliveira ML, et al. The Clavien-Dindo classification of surgical complications: five-year experience. Ann Surg 250 (2009): 187-196.
23. National Cancer Institute: Common Terminology Criteria for Adverse Events v.4.0 (CTCAE) (2019).
24. Koch M, Garden OJ, Padbury R, et al. Bile leakage after hepatobiliary and pancreatic surgery: a definition and grading of severity by the International Study Group of Liver Surgery. Surgery 149 (2011): 680-688.

25. Rahbari NN, Garden OJ, Padbury R, et al. Posthepatectomy liver failure: a definition and grading by the International Study Group of Liver Surgery (ISGLS). Surgery 149 (2011): 713-724.

26. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85 (1993): 365-376.

27. Blazeby JM, Currie E, Zee BC, et al. Development of a questionnaire module to supplement the EORTC QLQ-C30 to assess quality of life in patients with hepatocellular carcinoma, the EORTC QLQ-HCC18. Eur J Cancer 40 (2004): 2439-2444.

28. Stover AM, Haverman L, Van Oers HA, et al. ISOQOL PROMs/PREMs in Clinical Practice Implementation Science Work Group. Using an implementation science approach to implement and evaluate patient-reported outcome measures (PROM) initiatives in routine care settings. Qual Life Res 30 (2021): 3015-3033.

29. García-Lorenzo B, Gorostiza A, Alayo I, et al. European value-based healthcare benchmarking: moving from theory to practice. Eur J Public Health 34 (2024): 44-51.

30. Orlandi R, Scarci M, Cioffi U et al. Multi-level analysis and evaluation of organizational improvements in thoracic surgery according to a Value-Based HealthCare approach. J Thorac Dis 15 (2023): 1046-1056.

31. Pessaux P, Cherkaoui Z. Value-based healthcare: a novel approach to the evaluation of patient care. Hepatobiliary Surg Nutr 7 (2018): 125-126.

32. Cherkaoui Z, Merdinger-Rumpler C, Pessaux P, et al. Changing Practices for an Innovative Care Pathway, the Mediating Role of the Coordinator. Journal of Change Management 12 (2023): 121.

33. Nuno-solinis R, Urizar E, Merino M et al. Validation study of value-based digital health questionnaire. Int J Environ Res Public health 19 (2022): 7034.

34. Cossio-Gil Y, Omara M, Watson C et al. The roadmap for implementing Value-Basezd Healthcare in European University Hospitals-Consensus report and recommendations? Value Health 25 (2017): 1148-1156.

Citation: Zineb Cherkaoui, Elodie Léost, Bastien Delattre, Grégoire Gessain, Véronique Christian, Stéphanie Mathis, Christiane Bruck, Elisa Martinis, Elena Bangoura, Sophie Blanès, Fabio Giannone, Fatema Alhammadi, Arne Kock, Constance Lugiez, Patrick Pessaux, IHU-VBHC Working Group. Elaboration of a Standard Value-based Healthcare Metrics set for Hepatic Carcinoma and Validation by International Delphi Method. Journal of Surgery and Research. 8 (2025): 128-138.