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ORIGINAL ARTICLE – PANCREATIC TUMORS

A Standard Set of Value-Based Patient-Centered Outcomes for Pancreatic Carcinoma: An International Delphi Survey

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ABSTRACT

Background. Global health systems are shifting toward value-based health care to improve patient outcomes in the face of rising health care costs. The challenge is to identify standardized outcome measurements that allow optimal quality-of-care monitoring and comparison to optimize medical practices and patient pathways. A common outcomes definition is required, including medical results (Clinical Reported Outcomes Measurements [CROMs]) and quality-of-life components that matter most to patients (Patient-Reported Outcomes Measurements [PROMs]), which are particularly important for severe pathologies with short life expectancy such as pancreatic cancer. This study aimed to create standardized metrics that could be used for outcomes analysis of pancreatic cancer care.

Methods. A multidisciplinary working group (WG) was assembled. A systematic review was performed to collect the most used outcomes in clinical studies of pancreatic cancers. The study reviewed 570 studies published in the last 10 years. From these studies, 3370 outcomes, including CROMs, and PROMs, were listed and prioritized. The WG reached a consensus on key outcomes, proposed groupings for CROMs and PROMs, identified existing questionnaires that could be used for PROMs collection, and set the timeline for data collection. To refine and validate the final outcomes set, an international external committee completed a Delphi process (two rounds for both CROMS and PROMs).

Results. After the systematic literature review, the WG selected 102 outcomes (92 CROMs and 10 PROMs) for submission to the international Delphi vote committee. The committee retrained 89 outcomes (78 CROMs and 11 PROMs). For the PROMs, the WG and the international external committee chose a validated questionnaire, the Functional Assessment of Cancer Therapy-Hepatobiliary, which covers all of the 11 selected PROMs.

Conclusions. A standardized set of outcome measures that need to be validated through international health outcome comparisons and quality-of-care assessments was built. Pilot projects are underway to test and optimize the approach in real-life conditions.

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Pancreatic cancer is the second most common digestive cancer in the United States, with approximately 44,000 new cases each year. In Europe, pancreatic cancer accounts for 2.8% of cancers among men and 3.2% of cancers among women, making it the sixth most common cancer.[1] Based on GLOBOCAN 2012 estimates, pancreatic cancer is the cause of more than 331,000 deaths per year, representing the seventh leading cause of cancer-related deaths worldwide, with a 5-year survival rate lower than than 5%.[2]

Radical surgery is the only potential curative treatment for pancreatic cancer.[3] Despite the availability of newer and more effective chemotherapy regimens, the survival rate associated with this disease has remained consistently low, and the prognosis for most patients with pancreatic cancer remains grim. Therefore, providing outcomes that really matter is important for this patient population.

Global health systems are shifting to value-based health care (VBHC) to drive better health outcomes in the face of rising care costs.[4,5] The challenge is to identify standardized outcome metrics that allow optimal quality-of-care monitoring and comparison to optimize medical practices and patient pathways. A common outcomes definition is required that includes both medical results (Clinical Reported Outcomes Measurement [CROMs]) and quality-of-life (QoL) components that matter most to patients (Patient-Reported Outcomes Measurement [PROMs]). This is particularly important for severe pathologies with short life expectancy such as pancreatic cancer.[6]

Whereas several standardized data sets have been developed to measure both clinical and patient-oriented value-based health outcomes in the context of breast,[7] colon,[8] lung,[9] and prostate,[10,11] cancers, standardized outcome measurement sets for pancreatic cancer are not currently available.

This study aimed to develop a standardized outcome measurement set to be used in an outcomes analysis of pancreatic cancer pathways to monitor patient QoL and better meet patients' expectations, and to identify and align best practices between the different care centers.

MATERIALS AND METHODS

Working Group

A multidisciplinary working group (WG) of 20 people was assembled. The WG was composed of physicians (hepatobiliary pancreatic [HBP] surgeons, medical oncologists, gastroenterologists), paramedical personnel (nurses, dieticians, caregivers), patient, patient representative, administrative staff, and health care consultants. The WG was set up for preparation of a Delphi process to validate the outcomes metrics set.

Review of Clinical Trials and Outcomes Before Selection

A systematic literature review of outcomes used in pancreatic cancer clinical trials was performed by searching the *clinicaltrials.gov* database. Phase 2, 3, or 4 studies of the pancreatic cancer adult population published in the last 10 years were considered.

For the review, 570 clinical studies were selected and reviewed. The studies listed 3370 outcomes, including CROMs (3168 items) and PROMs (201 items). After a first review, 92 CROMs and 10 PROMs were selected by the WG (Fig. 1).

Outcomes Structuring

The CROMs were divided into two parts:

Part 1. A baseline set with four categories: demographic factors, clinical characteristics, diagnostic methodology, and therapeutic strategy (Table 1).

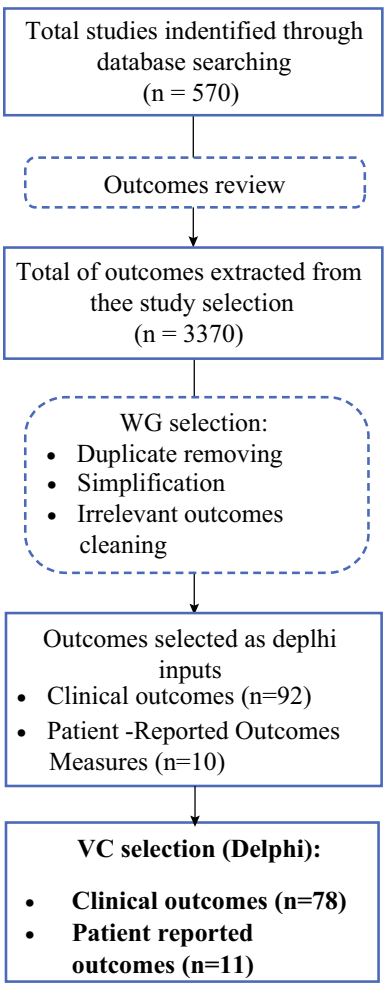

FIG. 1 Systematic outcomes review flow chart. *WG* working group, *VC* validation committee

TABLE 1 Clinical reported outcomes measurement (CROMs) baseline set

	Patient population	Details	Data source	Timeline
1. Demographic factors				
Sex	All patients	Patient sex	Administrative data	Baseline[a]
Age		Date of birth		
Weight[a]		Unit of measurement (kg or lb)	Clinical abstraction	
Height		Unit of measurement (cm or ft)		
Family history of cancer		First-degree parent with pancreas, breast/ovarian, colon, melanoma		
2. Clinical characteristics				
Patient characteristics				
Score performance (ECOG)[a]	All patients	ECOG performance status[14]	Clinical abstraction	Baseline[a]
Comorbidities[a]		Charlon comorbidity index[15]		
Alcohol consumption		Beverage-specific quantity and frequency (U/day)		
Tobacco use		Smoking exposure (pack-year)		
Disease characteristics				
Cardinal symptoms	All patients	Onset date and nature of symptoms	Clinical abstraction	Baseline[a]
Weight loss[a]		Amount and time of evolution		
Tumor location		Anatomic location of the tumor		
cTNM stage		Preoperative staging of the disease		
3. Diagnostic methods				
CT scan	All patients	Test date (if applicable)	Administrative data	Baseline
MRI				
Endoscopic ultrasound				
Biopsy				
4. Therapeutic strategy				
General				
Multidisciplinary meeting	All patients	Meeting date (if applicable)	Clinical abstraction	Baseline + follow-up
Intention of treatment		Curative or palliative intent		
Type of treatment selected		Method of treatment chosen		
Surgery				
ASA score	Patients receiving surgery	Physical status classification system	Clinical abstraction	Follow-up
Date of surgery		Specify the date of the intervention	Surgical report	
Type of surgery		Specify procedure performed		
Approach		Minimally invasive or open surgery		
Quality of resection		Specify specimen margin status	Pathological report	
Standardized pathologic report		Completeness of recommended parameters		
pTNM stage		Postoperative staging of disease		
Hospital length of stay		Admission and discharge dates	Administrative data	

TABLE 1 (continued)

	Patient population	Details	Data source	Timeline
Radiotherapy				
Type Dose (cGy) Duration of treatment	Patients receiving neoadjuvant/palliative treatment	Start and finish date and treatment details (if applicable)	Clinical abstraction	Follow-up
Chemotherapy				
Type Duration of treatment	Patients receiving neoadjuvant/palliative treatment	Start and finish date and treatment details (if applicable)	Clinical abstraction	Follow-up
Biliary drainage				
Type[μ] Date of treatment[a]	All patients	Placement date and technical details (if applicable)	Clinical abstraction	Baseline + follow-up

ECOG Eastern cooperative oncology group, *pTNM* pathologic tumor-node-metastasis, *MRI* magnetic resonance imaging, *ASA* American society of anesthesiology

[a]Baseline and follow-up assessment

Part 2. A follow-up set with three categories: treatment-related complications, survival and disease control indicators, and evidence of relapse or disease progression. The final list of outcomes is presented in Table 2.

The PROMs were grouped into health domains by the WG members using a method inspired by Macefield et al.[12] and Van Rijssen et al.[13] Quality-of-life and functioning items were encompassed in five categories: physical well-being, family and social well-being, emotional well-being, functional well-being, and current symptomatology (Table 3).

Validation Committee and Process

An international external validation committee (VC) was formed to complete a Delphi process to refine and validate the final set (Fig. 1). The VC comprised 93 individuals and included patients, HPB surgeons, radiologist, psychiatrist, oncologists, nurses, dieticians, and psychologist (Table 4). The Qualtrics platform was used to create and distribute questionnaires, and four rounds (2 for CROMs, 2 for PROMs) were carried out between 31 January and 15 June 2018.

Outcomes Validation

The questionnaires in the first two rounds focused on validation of the CROMs. The participants were required to answer the following question: "Please indicate if you would like to add or exclude the following variables in the final standard set." The participants could justify their choices during the first round. Only the variables reaching a threshold set at 85% of the addition rate were retained for the final standard set. Those under a threshold at 15% were not retained, and those between 15 and 85% had to be voted again in the second round. In the second round, the arguments from the first round were presented to the participants, and only the variables reaching 85% were retained. The questionnaires in the second two rounds focused on validation of the PROMs.

In the first round, the outcomes were listed, with examples (questions extracted from existing questionnaires). The VC was asked to select the most relevant outcomes. Only the variables reaching a threshold set at 85% of the addition rate were retained for the final standard set. Those under a threshold of 15% were not retained, and those between 15 and 85% had to be voted again in the second round. In the second round, only the variables reaching 85% were retained. The participants chose the most suitable existing questionnaire in relation to their PROMs selection.

Set Timeline

To finalize the deployment preparation, the WG decided to define a timeline for outcomes collection (patient record for the CROMs, questionnaires for the PROMs) to suit to the different care episodes.

RESULTS

The WG defined the scope of the project as including all patients with stages 1 to 4 invasive pancreatic cancer in accordance with the American Joint Committee of Cancer (AJCC) staging system regardless of type or intent of treatment received, including those who did not receive

TABLE 2 Clinical reported outcomes measurement (CROMs) follow-up set

	Patient population	Details	Data source	Timeline
1. Treatment-related complications				
Surgery-related complications				
Post-surgical complications	Patients receiving surgery	Clavien–Dindo classification of surgical complications[16]	Clinical abstraction	Follow-up
Pancreatic leakage		International study group for pancreatic surgery[18–20]		
Gastroparesis				
Hemorrhage				
Transfusion		Blood transfusion requirements		
Palliative/neoadjuvant treatment-related complications				
Tumor response	All patients	No sign of residual cancer on diagnosis evaluation	Clinical abstraction	Follow-up
Undesirable effects		CTCAE V4.03[17]		
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 pancreatic cancer		
Recurrence-free survival	Patients with curative intent	Local, regional, or distal recurrence	Clinical abstraction	
Progression-free survival	Patients with advanced disease	Disease progression		
Pathologic or clinical complete response	Patients receiving neoadjuvant treatment	No sign of residual invasive cancer of resected specimen or on diagnosis evaluation		
Need for readmission	All patients	Evidence of margin involvement		
3. Relapse/progression of the disease				
Disease relapse				
Relapse date Method of detection	Patients with curative intent	Onset date. Nature of event. Detection method (clinical, imaging and/or pathologic identification)	Clinical abstraction	Follow-up
Disease progression				
Progression date Method of detection	Patients with advanced disease	Onset date. Nature of event. Detection method (clinical, imaging and/or pathologic identification)	Clinical abstraction	Follow-up

CTCAE common terminology criteria for adverse events

therapy. Studies of the patients undergoing treatment with investigational agents were excluded because such studies have their own specific outcome assessments.

CROMs

Baseline items were included to allow for cross-treatment and cross-center comparison. The demographic factors included sex, date of birth, weight, height, units of weight and height, and family history of pancreas-related cancer.

The baseline clinical factors prioritized for inclusion were the Eastern Cooperative Oncology Group (ECOG) score performance status, presence of comorbidities, and level of alcohol and/or tobacco consumption.[14] The Charlson Comorbidity Index was selected for comorbidity

TABLE 3 Patient-reported outcomes measurement (PROMs) set

	Patient population	Details	Data source	Timeline
1. Physical well-being				
Energy	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Nausea				
Physical autonomy				
Pain				
Treatment side effect				
Illness perception				
Prostration				
2. Family/social well-being				
Relatives support	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Relatives acceptance				
Communication with family and friends				
Satisfaction with sexual life				
3. Emotional well-being				
Sadness	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Coping capacities				
Hope				
Nervousness				
Fearness				
4. Functional well-being				
Fitness for work	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Work accomplishment				
Life enjoyment				
Illness acceptance				
Sleep quality				
QoL satisfaction				
5. Symptoms				
General				
Fatigue	All patients	Tracked via FACT-Hep[21]	Clinical abstraction/patient-reported sources	Every follow-up control starting at baseline
Fever				
Weight loss				
Insomnia				
Jaundice				
Itching				
Change of physical appearance				
Back pain				
Dry mouth				
Gastrointestinal				
Abdominal Distension/pain	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Dietary restrictions				
Nauseas and vomiting				
Ability to eat/appetite loss				
Bowel function				
Stool frequency	All patients	Tracked via FACT-Hep[21]	Patient-reported source	Every follow-up control starting at baseline
Diarrhea				
Constipation				
Fecal continence				

FACT-Hep functional assessment of cancer therapy-hepatobiliary, *QoL* quality of life

TABLE 4 Composition of the validation committee

	n	%
Expertise		
HBP surgeons	60	64.5
Patients	8	8.6
Nurses	8	8.6
Medical oncologists	8	8.6
Dieticians	5	5.3
Psychologist	1	1.1
General surgeon	1	1.1
Psychiatrist	1	1.1
Radiologist	1	1.1
Region		
Europe	46	49.5
North America	17	18.3
South America	16	17.2
Asia	14	15.0

HPB hepatobiliary pancreatic

reporting.[15] The different methods used to verify the diagnosis were included, as well as the date of the tests.

The following baseline diseases and tumor factors also were included: nature and date of onset of cardinal symptoms, amount of weight loss, duration of weight loss evolution, tumor location, and clinical tumor-node-metastasis (TNM) stage. The items related to the therapeutic strategy were grouped as general strategies (multidisciplinary care, intention of treatment, and type of treatment selected) and specific strategies (surgical treatment, radiotherapy treatment, chemotherapy treatment, and need for an approach to biliary drainage). Follow-up items were included to monitor the trends of medical outcomes.

The treatment-related event measures focused on short-term complications of treatment, including type and severity. An algorithmic evaluation to determine severity was developed based on the grading systems of the Clavien-Dindo classification for surgical complications[16]] and the Common Terminology Criteria for Adverse Events (CTCAE) for radiation therapy and chemotherapy (version 4.0).[17]

The causes of postsurgical complications related to pancreatic surgery (pancreatic fistula, gastroparesis, hemorrhage) were evaluated separately and classified according to their severity.[18–20] Similarly, the implementation of nutritional support and the need for new admissions were selected from the proposed variables. The following measures were included for survival and disease control: overall survival, cause-specific survival, recurrence-free survival, progression-free survival, and need for readmission.

For the patients who received neoadjuvant therapy or surgery, pathologic complete response and margin status were included because they could serve as intermediary outcomes, proxies of survival, and short-term indicators of surgical quality.

The occurrence, method of diagnosis, and date of relapse (for the patients treated with curative intent) or progression (for the patients treated with palliative indication) also were included in the follow-up variables. These events are reported because they were identified and are considered a new baseline point.

A total of 78 CROMs were selected, with response referentials and an administration timeline (Tables 1 and 2).

PROMs

The final PROMs set (QoL, functioning, and symptom measures) are listed in Table 3. It was recommended that the PROMs be collected at baseline (when the patient treatment was defined), then 1, 3, 6, 9, 12, and 18 months after treatment, and annually thereafter up to 10 years after treatment, where possible. A total of 11 PROMs were selected with a validated questionnaire, the Functional Assessment of Cancer Therapy-Hepatobiliary (FACT-Hep),[21] for outcomes collection.

DISCUSSION

To date, widely validated standardized outcome measures have been available for the follow-up evaluation of patients with pancreatic cancer. This study aimed to build an innovative metrics set to improve the quality and relevancy of care for patients, to facilitate comparison of results across treatments as well as between health care professionals and centers around the world, and to support the research on this disease. The outcomes measurement could allow a wider vision of the care pathway.

A standardized set of metrics is a decision support tool for care evaluation that allows a real dialogue between care providers and patients as well as a personalized treatment strategy. A comparison among centers can help to improve the care organization, and a set of outcomes measurement can contribute to the identification of care priorities essential under constrained resources.

Finally, continuous standardized outcomes assessment using real-time data together with integration of the patient's expectations (through the results of validated PROMs) could facilitate medical innovations because this approach would make it easier to appreciate the variations of the different indicators related to the introduction of technological or organizational innovations.

Outcomes reported by patients are becoming as important as the clinical results. A systematic review of the pancreatic cancer burden in Europe showed that pancreatic cancer results in a 98% loss of healthy life.[22] The severity of pancreatic cancer and the limited availability of effective treatment options[3] compel the medical community to prioritize patients' experiences and outcomes over objective medical results. Patient-centered outcomes reflect patients' life experience when dealing with their disease. The collection of PROMs has been shown to improve QoL and even overall survival in the context of other cancer types.[23] The report of the *Centre Fédéral d'Expertise des Soins de Santé* (Bruxelles-Belgium) implements the application of results and experiences reported by patients (PROMs and patient-reported experience measures [PREMs]) for clinical and management purposes. The report specifies the three following levels favored through its use: the relationship between patients and their health care provider to promote shared decision-making and patient-centered care (micro level), the health care facilities to contribute to improved quality of care (meso level), and public-policy to monitor and measure the performance of national health systems (macro level).[24]

Feasibility and Acceptability of Outcomes Measurement

A metrics set has to be accepted by all stakeholders in the care pathway. Doing this is a matter of co-building these indicators with all actors. The patient was subsequently considered to be an "actor" of his or her pathway in the same way as the other stakeholders, taking part in the care pathway. In our strategy, this multidisciplinary and multi-professional team, with the presence of patients, patient associations, and health care professionals in direct and long-term contact with patients, was respected within the WG and the international external committee. This presence highlighted patient experience and expectations beyond the medical expertise.

The metrics set has to be specific, measurable, achievable, and realistic (SMART) and must quantify the outcomes in terms of both CROMs and PROMs. Recently, the COPRAC study group established an international core set of PROMs selected by both patients and health care providers in the United States, Europe, and Asia.[13] This study included eight categories of PROMs (general QoL, general health, physical capacity, ability to work and perform usual activities, fear of recurrence, satisfaction with services and care organization, abdominal complaints, and relationship with partner or family). The limit of the COPRAC study was not to define each category content in detail.

Our set aims to measure outcomes in a valid and reliable manner. The VC considered that the most suitable questionnaire for assessing the selected PROMs was the FACT-Hep.[21] The FACT-Hep was developed in 1998 to measure health-related QoL for patients with hepatobiliary cancers.

The WG determined a timeline for the CROMs and PROMs collection, balanced between the clinically relevant times (i.e., the new treatment needs to be tightly monitored) and pragmatic concerns faced by institutions and practices regarding data collection (i.e., patient's scheduled follow-up visits).

In conclusion, a standardized set of patient-centered outcome measures that need to be monitored for international health outcome comparisons and quality-of-care assessments was built for pancreatic carcinoma. The implementation of instruments that integrate the measurement of clinical parameters of treatment response and patient-reported outcomes, both in clinical research protocols and in routine medical practice, is a step forward to ensure that each patient receives the necessary and effective care in each setting and situation.

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