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## Development and evaluation of an electronic bladder cancer database in Beirut, Lebanon

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### Abstract

**Background:** Bladder cancer very common in Lebanon. The use of electronic health records has recently been correlated with improved medical record reconstruction, however studies of the effectiveness of these records on bladder cancer data collection remain very scarce. This study evaluates and compares the efficiency of electronic health records to traditional data collection methods in a tertiary referral center.

**Methods:** This is a retrospective study of prospectively filled data after a redesign of the pre-existing databases on the systems already in use. The study analyzes 175 records, 88 of which used the new format and 87 of which used the traditional method. A quantitative and qualitative comparison of variables recorded on two different databases was performed to evaluate the effectiveness of bladder cancer-specific electronic health records.

**Results:** The new format proved significantly more efficient. Most of the variables added to the questionnaire were missing from the control records. Some variables were searched for more than others by the students, indicating weaknesses in the intern's questioning. The prevalence of family history of bladder cancer is higher in Lebanon compared to global figures. Alcohol and tobacco were the only reported addictions. Medical students need better awareness of certain topics and better practical training.

**Conclusion:** The use of electronic databases should be expanded to improve the collection of medical information within hospitals. These changes should not be limited to the intern's questionnaire but should also include specialty resident reports and long-term patient follow-ups.

**Keywords:** bladder cancer, Electronic Health Record, data collection, medical students.

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## **1. Introduction**

Bladder cancer (BC) is the tenth most frequent cancer worldwide with an annual incidence of approximately 550,000 cases (1). The incidence of this malignancy has been steadily increasing over the past decades, particularly in Western Europe and North America (2). Lebanon is one of the countries with the highest incidence rates for bladder cancer worldwide (3).

Given the high prevalence of bladder cancer in the Lebanese population and the lack of available standardized data, it would be beneficial to develop a new method medical data collection in order to gather all the necessary information for the optimal management of bladder cancer.

In the medical setting, efficient data collection allows health systems to undertake a holistic approach to the patients, tailor and perfect therapies, and increase communication between physicians and patients (4). Indeed, in any country, the health system must ensure the production, analysis, transmission, and use of accurate and reliable medical information.

Our study will first focus on the importance of improving the production and collection of information in the medical field. In practice, this could be accomplished by establishing Electronic Health Records (EHRs), which consist of a new computerized platform, allowing the collection of patient data such as their medical history, drug prescriptions, vital signs, lab results, imaging reports, and doctor's and nurse's notes (4).

Subsequently, a statistical analysis will be conducted to evaluate and compare the efficiency of the electronic health records to the data collection systems already established within the Hôtel-Dieu de France establishment.

## **2. Subjects and Methods**

The primary objective of this paper is to evaluate the role of a new computerized platform in bladder cancer data collection at the Hôtel-Dieu de France hospital center (HDF). This new platform is a redesigned version of the "intern observation" already present on the hospital's computer systems. A statistical analysis will be performed to compare the improved version's efficacy to that of the previous version.

### **2.1 Study population**

Cases of bladder cancer diagnosed from the implementation of this new platform will be studied in comparison with older cases from the computer systems already in use (DxCare) and/or the hospital's archives for those whose records are not computerized. The inclusion criteria will be any patient diagnosed with urothelial bladder cancer at the HDF from the implementation of the platform.

A control sample will also be studied for comparison. It will consist of patients diagnosed with

bladder cancer prior to the establishment of the platform. There will be no exclusion criteria for this demographic.

## **2.2 Creation of the database**

The creation of this revised database required ongoing modifications of pre-existent variables and datapoints, the addition of new variables, as well as an overall reshaping of the current data entry profile used at our institution.

Firstly, this process necessitated an exhaustive literature review to appropriately select the relevant variables in the field of bladder cancer. A comprehensive search of several databases from each database's inception was conducted. The databases included the Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid Cochrane Central Register of Controlled Trials, PubMed, Scopus, and Web of Science. The search strategy was designed and conducted by an experienced librarian with input from the study's principal investigator. Controlled vocabulary supplemented with keywords was searched for bladder cancer diagnosis and management.

The database was remodeled multiple times on a trial-and-error basis. The modification and addition of new variables was performed on a biweekly basis which was followed by a period of trial of 7 days. During this time span, the medical student had a printed version of the new variables, as a support during history taking and physical examination of the patient. The student asked the usual questions he/she was used to asking, and then completed with the remaining variables. When finished, the student filled in the form on the computerized platform in his/her office. At the end of each trial period, the first author and principal investigator of this work evaluated the percentage of response for each datapoint separately. If the added variable was filled in more than 50% of the reports, it was judged as valid and relevant, and it was maintained for the following version of the database. In the case of unfilled datapoints, the editors of the reports were contacted to debrief on the report and obtain feedback on potential adjustments. This first step of the process was completed in a period spanning a total of 8 weeks.

Following these changes, the revised database was further modified by requesting expert opinion from our institution's leaders in the field. Scheduled interviews were conducted by the first author of this manuscript with 7 different physicians specialized either in Urology or Oncology. A list containing all the variables was presented to the physicians and professional input based on personal experience was obtained.

Lastly, once the required clinical concepts were identified and clearly defined, pre-existing data models were sought on the openEHR Clinical Knowledge Manager (CKM) website to finalize our model. CKM being a public repository of clinical data models created and reviewed by clinicians and computer

experts from around the world.

### 2.3 Statistical analysis

All data were collected and coded for statistical analysis by presenting them as a percentage. This coding was done using the SPSS computer program. The correlations between the different items were studied using the Chi two test with a p-value considered significant when it was  $\leq 0.05$ .

Before data exploitation, an agreement of the ethics committee and the medical direction of the Hôtel Dieu de France was obtained. Anonymity and confidentiality of patient information were respected during data collection.

### 3. Results

In total, the statistical study included the records of 175 patients; 88 of which had a medical history completed by the medical intern after the creation of the new database in comparison with 87 control patients with a computerized record written as of January 2016. The variables were grouped into four categories: sociodemographic characteristics, comorbidities and past medical history, risk factors, and clinical presentation. For each variable, it will be indicated whether the statistical study was carried out on all the patients in the cohort or only on the new patient files. Some variables have been statistically tested, while others have not yet been added to the database.

#### 3.1. Socio-demographic characteristics

Of 175 patients, 138 were male (78.9%) and 37 were female (21.1%), with a male/female ratio of almost 4:1. The median age of bladder cancer patients was  $70.2 \pm 10.1$  years. Only 63 out of 175 patients were tested for body mass index (BMI) and their average BMI was  $27.9 \pm 3.6$  kg/m<sup>2</sup>. Most patients were Lebanese (94.5% or 69 patients). Regional distribution showed a slight predominance for the Mount Lebanon governorate (42.4%). Table 1 shows detailed results of the patients' risk socio-demographic characteristics.

Table (1) Socio-demographic characteristics

Variables	M±ET (Min-Max) or N (%)
Age, years (N=175, n=173)	70.2±10.1 (44-95)
Sex <sup>†</sup> , Male/Female (n=175)	138 (78.9) /37 (21.1)
BMI <sup>‡</sup> , kg/m <sup>2</sup> (N=175, n=63)	27.9±3.6 (20.2-36.7)
Nationality (N=88, n=73)	
Lebanese	69 (94.5)
Lebanese-French	2 (2.7)
Lebanese-Armenian	1 (1.4)
Lebanese-African	1 (1.4)
Governorate (N=175, n=66)	
Beirut	14 (21.3)
Mount Lebanon	28 (42.4)
South Lebanon	13 (19.7)
North Lebanon	4 (6.1)
Bekaa	7 (10.6)

Type of region (N=88, n=80)	
Urban	51 (63.7)
Rural	29 (36.3)

Variables not tested: race, socioeconomic level, education level, lifestyle. N= total cohort population; n= tested sample population; BMI = body mass index

### 3.2. Comorbidities and personal/family medical history

Most patients had associated medical conditions. Among the 168 respondents, 44 (26.2%) had diabetes, 108 (64.3%) had hypertension, and 72 (42.9%) had dyslipidemia. 89.9% of the patients had undergone surgery, while 15.2% of the 165 respondents reported drug allergies. In the new patient cohort (N=88 n=80), 15% had a first-degree and 5% had a second-degree family history of bladder cancer. Drug allergy details are shown in Table 2.

Table (2) Comorbidities and personal/familial history

Variables	N (%)
<b>Medical comorbidities</b>	
Comorbidities <sup>†</sup> (N=175, n=168)	142 (84.5)
Diabetes (N=175, n=168)	44 (26.2)
Hypertension (N=175, n=168)	108 (64.3)
Dyslipidemia (N=175, n=168)	72 (42.9)
<b>Personal medical history</b>	
Infectious-contagious diseases (N=88, n=58)	
Hepatitis	3 (5.2)
No	55 (94.8)
History of surgery (n=175)	151 (89.9)
Drug allergy (N=175, n=165)	
No	140 (84.8)
Yes	25 (15.2)
Causal drug	
Penicillin	8
Sulfonamides	3
Macrolides	2
Metronidazole	1
NSAIDs/Aspirin	4
Others	7
Non-drug allergy (N=175, n=163)	
No	153 (93.9)
Yes	10 (6.1)
Causal substance	
Food	5
Non-food	4
Allergy to iodine (N=175, n=163)	
No	163 (100)
Yes	-
<b>Family history</b>	
Family history (n=175)	29 (18.8)
History of bladder cancer (N=88, n=80)	
Yes	64 (80)
First degree	12 (15)
Second degree	4 (5)

N= total cohort population; n= tested sample population; NSAIDs= Non-steroidal anti-inflammatory drugs

### 3.3. Risk and protective factors for bladder cancer

By adding new variables in the category "risk factors for bladder cancer," the intern's history-

taking becomes more detailed and focused on BC. Among 88 patients, none reported bilharzia, 17% had one urinary tract infection per year, 3.8% took weight loss pills regularly and 8.8% consumed sweeteners daily (Table 3). Alcoholism was found in 11.4% of the 175 responders, while 79.9% had a history of smoking, and 44.1% and 22.8% were exposed to passive smoking at home and in the workplace, respectively. These variables may overlap and offer the possibility of a "Yes" answer to both questions for the same patient. However, no overlap is reported for patients in this cohort. Most smoked cigarettes (91.5%), and the average pack-years for smokers was  $62.1 \pm 34.6$  PY. Only 51.1% of patients reported hookah consumption, and 23.4% reported occupational exposure to a risk factor over an average duration of  $2.9 \pm 9.9$  years of work.

Table (3) Risk and protective factors for bladder cancer

Variables	M±ET (Min-Max) or N (%)
Bilharzia (N=88, n=88)	
No	88 (100)
Urinary tract infection per year (N=88, n=88)	
0	67 (76.1)
1	15 (17)
2	3 (3.4)
>3	3 (3.4)
Weight loss pill (N=88, n=79)	
Yes	3 (3.8)
No	76 (96.2)
Source of daily water (N=88, n=65)	
Tap water	6 (9.2)
Plastic containers	52 (80)
Well water	7 (10.8)
Consumption of fruits, portion/j (n=88)	2.1±1.3 (0-5)
Consumption of vegetables, portion/j (n=88)	2.6±1.4 (0-5)
Consumption of sweeteners (N=88, n=79)	
Yes	45 (56.9)
Rarely	23 (29.1)
Frequently	4 (5)
Always	7 (8.8)
Consumption of alcohol (N=175, n=175)	
Yes	20 (11.4)
No	155 (88.57)
Duration of consumption/years	D
Amount consumed/L/J	1.2±0.5 (0.5-2)
Description of consumption	
Occasional	7 (35)
Regular	13 (65)
Binge drinking	0 (0)
Others	0 (0)
Smoking (N=175, n=175)	
Actual status	
Active smoker	99 (56.5)
Former smoker	41 (23.4)
Nonsmoker	35 (20.1)
Passive smoking at home (N=88, n=59)	26 (44.1)
Passive smoking at work (N=88, n=57)	13 (22.8)
Type of tobacco (N=88, n=71)	
Cigarette	65 (91.5)
Cigar	6 (8.5)

Others	0 (0)
Number of Pack-Years (N=175, n=139)	62.1±34.6 (5-300)
Smoking cessation (years) (N=175, n=41)	14.1±11.4 (1-38)
Number of hookahs/week (N=88, n=45)	4±2.8 (1-7)
Duration of consumption (years) (n=5)	13±15.6 (1-40)
Use of other substances/other addictions (N=88, n=10)	0 (100)
Occupational exposure (N=88, n=64)	
Yes	15 (23.4)
Duration of exposure (years)	2.9±9.9 (0-50)
No	49 (76.6)
Ink	2
Dye	2
Paint	2
Colorant	
Rubber	1
Plasturgy	
Textile	1
Leather	1
Pesticide	1
Printing	2
Cosmetics	
Metallurgy	3

N= total cohort population; n= tested sample population; NSAIDs= Non-steroidal anti-inflammatory drugs

### 3.4. Clinical symptoms on admission and patients' management

The most common symptom was hematuria (84.5%; N=175 n=168). Physical examination responses were generally unsatisfactory, with the highest rate of responders reporting spontaneous abdominal pain (16.9%) and pain on palpation (18.4%). The rest of the clinical examination had a relatively low responder rate. A questionnaire on therapeutic management and follow-up was added: of the 88 patients, 4 received pelvic radiotherapy (5.6%; n=71) and 34 received intravesical installation (51.5%; n=66). This installation was either intravesical chemotherapy (5 patients or 14.7%) or intravesical BCG (29 patients or 85.3%). Only 19 patients had complications (N=88 n=23), such as infections, bleeding, acute urinary retention, or others. More details are shown in Table 4.

Table (4) Clinical symptoms on admission and patients' management

Variables	M±ET (Min-Max) or N (%)
Symptom	
Burning sensations (N=175, n=147)	
Yes	60 (40.8)
No	87 (59.2)
Urinary frequency (N=175, n=146)	
Yes	51 (34.9)
No	95 (65.1)
Anuria (N=175, n=70)	
Yes	2 (2.9)
No	68 (97.1)
Hematuria (N=175, n=168)	
Yes	142 (84.5)
No	26 (15.5)
Urinary retention (N=175, n=110)	
Yes	14 (12.7)

No	96 (87.3)
Other symptoms (N=175)	42 (24)
Spontaneous abdominal pain (N=175, n=142)	
Yes	24 (16.9)
No	118 (83.1)
Location of the spontaneous pain (n=24)	
Left lumbar pain	5 (16.7)
Right lumbar pain	1 (3.3)
Hypogastric pain	17 (56.7)
Umbilical pain	4 (13.3)
Left flank pain	3 (10)
Irradiation of the spontaneous pain (n=24)	
Yes	1 (50)
No	1(50)
Abdominal palpation (N=175, n=136)	
Abnormal	25 (18.4)
Normal	111 (81.6)
Location of pain on palpation (n=25)	
Left lumbar pain	5 (17.9)
Right lumbar pain	1 (3.6)
Hypogastric pain	17 (60.7)
Umbilical pain	3 (10.7)
Left flank pain	2 (7.1)
Irradiation of the pain (n=25)	
Yes	1 (20)
No	4 (80)
Abdominal guarding (N=175, n=95)	
Yes	2 (2.1)
No	93 (97.9)
Bladder globe (N=175, n=89)	
Yes	11 (12.4)
No	78 (87.6)
Right lumbar pain (N=175, n=85)	
Yes	1 (1.2)
No	84 (98.8)
Left lumbar pain (N=175, n=85)	
Yes	6 (7.1)
No	79 (92.9)
Digital rectal exam (N=175, n=64)	
Performed	6 (9.4)
No performed	58 (9.6)
Painful digital rectal exam (n=6)	
Yes	1 (16.6)
No	5 (83.3)
Benign prostatic hyperplasia (n=6)	
Yes	0 (0)
No	6 (100)
Vaginal examination (N=37, n=19)	
Not performed	19 (100)
Performed	0 (0)
Therapeutic management and follow-up	
Pelvic radiotherapy (N=88, n=71)	
Yes	4 (5.6)
No	67 (94.4)
Complication after surgical procedure (n=23)	
Acute urinary retention	4 (20)
Bleeding	5 (25)
Infection	9 (45)
Renal colic	1 (5)



Nothing	4 (20)
Intravesical instillation after surgical procedure (n=66)	
Chemotherapy	5 (7.6)
BCG	29 (43.9)
Nothing	32 (48.5)
Number of BCG sessions (n=29)	
2	1 (3.7)
3	3 (11.1)
6	23 (85.2)
Number of chemotherapy sessions (n=5)	
3	2 (40)
6	3 (60)

N= total cohort population; n= tested sample population; BCG = *Bacilli Calmette-Guerain*

### 3.5. Comparison of the rate of responders to the added variables between the old and the new database

The results of the direct comparison between the percentage of responders for the two databases, disregarding the nature of the response itself, are presented in Table 5. Most of the variables added to the new database were not present in the old records, except for five variables that were mentioned by the interns before the redesigned EHRs were implemented. However, the number of responders for these variables was considerably lower compared to that found in the new records. The statistical difference between the percentage of responses to these five questions was significant (p-value <0.001). Notably, the response rate for the question "consumption of hookah" was particularly low (51.1%).

On the other hand, the addition of bladder cancer-specific variables to the redesigned EHRs resulted in a significant increase in the number of responders for variables that were not tested in the old files. However, some variables were investigated more than others by the interns. For instance, the questions related to history of urinary tract infections, diet, and geographical distribution had a response rate of over 90%. Conversely, the response rate for other variables, such as addiction history, remained low (11.3%).

Table (5) Comparison of respondent rates for added variables between the old and new databases

Variables	Former N (%)		New N (%)		p-value
Bilharzia	2	(2.2)	88	(100)	<0.001
Pelvic radiotherapy	3	(3.4)	71	(80.6)	<0.001
Instillations since the surgical procedure	7	(8)	66	(75)	<0.001
Occupational exposure	5	(5.7)	64	(72.7)	<0.001
Consumption of hookahs	3	(3.4)	45	(51.1)	<0.001
Urinary tract infection per year	0	(0)	88	(100)	
Fruit consumption, servings/day	0	(0)	88	(100)	
Vegetable consumption, servings/day	0	(0)	88	(100)	
Demographic distribution	0	(0)	80	(90.9)	
History of bladder cancer	0	(0)	80	(90.9)	
Consumption of sweeteners	0	(0)	79	(89.7)	
Wight loss pull use	0	(0)	79	(89.7)	
Nationality	0	(0)	73	(82.9)	

Type of tobacco	0	(0)	71	(80.6)	
Source of water consumed	0	(0)	65	(73.8)	
Passive smoking at home	0	(0)	59	(67)	
Infectious-contagious diseases	0	(0)	58	(65.9)	
Passive smoking at work	0	(0)	57	(64.7)	
Other dependencies	0	(0)	10	(11.3)	

N= total cohort population

#### 4. Discussion

To the best of our knowledge, our study is the first to investigate the role of EHRs on bladder cancer in the Arab world. The objectives of the present study were to evaluate the usefulness of bladder cancer-specific electronic documentation compared to standard documentation methods used at a tertiary referral center in Beirut, Lebanon.

The results suggest that the use of this database leads to a more accurate reconstruction of medical history and risk factors compared to the standard health record. The creation of this database allowed the production of a structured medical report, offering the possibility of filling in the medical observation by entering options in predetermined fields.

The results obtained in our study showcase a sex ratio of 4:1 with a mean age of 70 years at diagnosis. These values are comparable to the worldwide figures which vary between 6:1 and 2:1 for the gender distribution and 65 to 70 years for the median age (5–7).

The low response rate found in the old format suggests that the modified data presentation significantly improves information collection. For the variables "bilharzia", "pelvic radiotherapy", "instillations" and "occupational exposure" the response rate, initially around 3 to 8%, reached values above 70%. This implies that the addition of epidemiologically useful data to the bladder cancer questionnaire improves the quality of the medical report (8). The excess of information and data to be filled in does not seem to be an obstacle to the compliance of the intern nor constitute an additional workload. For this reason, additional modifications should be made to the intern's questionnaires, but also to the operating room report written by the specialty residents (8).

Despite a marked improvement in data collection, some variables appear to be less sought after than others when interviewing the patient. This is evident in the question about hookah use. This variable was only noted for 45 (51.1%) patients in the cohort (N=88). The format of this question is like those added in the new EHR format. Therefore, this low response rate could reflect the Lebanese culture that does not generally differentiate between types of tobacco (9). Out of the 35 "nonsmoking" patients in the cohort, none reported hookah use. This could be explained by the fact that the interns tend not to develop the smoking interrogation by looking for possible hookah consumption after having identified the patient's

smoking status. For these reasons, the variables obtained are mainly quantitative (number of PY, date of cessation) and not qualitative (type of tobacco). Hookah smoking is a major risk factor for bladder cancer in Lebanon and worldwide (9). This frequent practice is more culturally accepted than cigarette smoking in Lebanon (10). Therefore, it should be systematically sought after and described during the interview independently of cigarette smoking history.

There are many issues associated with topics that are often considered "taboo" in Lebanon. For example: sexually transmitted and contagious diseases, cannabis use, opium use, or other addictions. These variables were associated with the lowest response rates in our study. Of the 58 patients (N=88 N=58) asked about their contagious risks, only 3 (or 5.1%) informed the intern.

Moreover, no patient in the entire cohort reported any other addiction apart from alcohol and tobacco. Indeed, the question was asked only 10 times for a total of 88 patients (i.e., 11.3%) without any positive response. Comparing these figures with those of the new variables added (Table 5), we notice that the addition of the question "other addictions" did not improve the percentage of responders in the new format.

According to United Nations statistics, 158.8 million people use cannabis, or more than 3.8% of the world's population. Lebanon is considered a cannabis producing country. Consumer rates appear to be higher than global figures (11). In addition, since April 2020, Lebanon has become the first Arab country to legalize the agriculture, production, and sale of cannabis for medicinal purposes (12). For these reasons, a higher responder rate should be expected considering that the relationship between cannabis and bladder cancer is proven (13). This leads us to improve the patient approach, aimed at creating a safe environment for sharing such information.

The addition of the variable "Family history of bladder cancer" to the redesigned questionnaire revealed a greater number of patients with a family history of bladder neoplasia than the global figures. In a sample of 80 patients, 12 (15%) had a first-degree history and 4 (5%) a second-degree history. Despite the lack of representation of this sample, these figures are still much higher than those found in the international literature (14). In a previous study of 690 patients in Italy, only 23 patients had a family history of bladder cancer. The RR was 1.99 with a 95% confidence interval [0.91-4.32] after further adjustment for smoking and number of siblings (15). This may imply a specific genetic predisposition and opens the door to further studies in the Lebanese population.

Regarding the history and physical examination of patients, the results of our institution are in line with those found in the literature (16). Indeed, this essential step in the evaluation of patients is becoming less and less practiced. Students tend to limit their interrogation to the signs and symptoms most

associated with each pathology (bladder cancer in this case) without going into sufficient depth in their clinical examination. Hematuria, being the most commonly presenting symptom, was the most sought after (N=175 n=168). Other less-telling symptoms were noted for only half of the patients. The physical examination itself was largely limited to abdominal palpation (N=175 n=136). Finally, the low rate of digital rectal examination (6 patients or 9.4%) among the patients in the cohort should be addressed. This examination has an orienting value for urological diagnoses. Better training would be required with adequate supervision of medical students.

To properly evaluate the usefulness of a new computerized system and its role in daily medical practice, formal usability tests of the software should be performed during its development and even after its implementation.

Evaluating its success has several dimensions that encompass system and information quality, as well as user satisfaction, individual impact, and organizational impact. In evaluating the effectiveness of our new bladder cancer information system, we focused on system and information quality only.

Limitations of this study include primarily the lack of completeness in the direct comparison between the two databases for the same patient.

An alternative study design could be a prospective evaluation of the two systems by comparing the clinical notes produced. This could be done on a broader scale by including specialty resident summary notes, operative reports, and quality of life assessments and postoperative patient follow-up. Bias would be minimized, but the study would result in a significant workload and potential delays in practical work. However, this work will allow us to compare user satisfaction as well as the time required to complete a structured report.

#### **4.1 Conclusion**

Re-engineering the computerized databases by adding specific variables has proven to be beneficial in improving the efficiency of the questionnaires. This approach should be considered for other pathologies, not only in the urology department, in order to improve the collection of information and make it more accessible to medical and non-medical staff. This work could elucidate new variables that can be used in the genesis of certain pathologies. Continuous evaluation of the variables studied is also necessary to identify weaknesses in a questionnaire and to modify them if necessary.

## **5. Declarations**

### **5.1 Conflict of Interest Statement**

The authors have no conflict of interests to declare.

### **5.2 Funding Disclosure**

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