Identification of Concepts of the International Classification of Functioning, Disability and Health in Measures of Quality of Life for Cervical Cancer

Identificação de Conceitos da Classificação Internacional de Funcionalidade, Incapacidade e Saúde em Medidas de Qualidade de Vida para o Câncer do Colo do Útero

Identificación de Conceptos de la Clasificación Internacional de Funcionamiento, Discapacidad y Salud en Medidas de Calidad de Vida para Cáncer del Cuello Uterino

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Abstract

Introduction: Cervical cancer is highly prevalent in low- and middle-income countries and has a negative impact on women's functioning. The interest in the measurement of therapeutic measures that are not restricted to the biomedical model has been assuming prominence in the field of Oncology. The International Classification of Functioning (ICF) appears on the world stage as a guiding tool for the construction of the biopsychosocial evaluation. **Objective:** To exemplify methodology for identifying the components of functioning in documents used in oncology care in cervical cancer. **Method:** Three-step study - Analysis of systematic reviews to identify the specific instruments for cervical cancer; extraction of evaluation measures; and linking the concepts contained in the outcome measures with the corresponding categories of ICF by two independent reviewers. **Results:** In the analysis of the Functional Assessment of Cancer Therapy-Cervix and the European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire Cervical Cancer Module, we identified 72 main contents, related to 35 categories of ICF. Of these, 23 referred to bodily functions, eight to activities and participation, tree to environmental factors and an to a body structure. **Conclusion:** The two instruments have a link with the ICF; however, they exploit insufficiently the contextual factors, which demonstrates the need for biopsychosocial guidance in health assessments for women with cervical cancer, to contemplate the components of functioning in the measurement of therapeutic outcomes equitably.
Key words: Uterine Cervical Neoplasms; Outcome Assessment (Health Care); International Classification of Functioning, Disability and Health.

Resumo

Introdução: O câncer do colo do útero apresenta elevada incidência em países de baixa e média rendas e provoca repercussões negativas sobre a funcionalidade das mulheres. O interesse na mensuração de medidas terapêuticas, que não se restrinjam às medidas do modelo biomédico, vem assumindo destaque no campo da oncologia. A Classificação Internacional de Funcionalidade (CIF) aparece no cenário mundial como ferramenta de orientação para construção da avaliação biopsicossocial. **Objetivo:** Exemplificar a metodologia para identificação dos componentes da funcionalidade em escalas específicas utilizadas no cuidado oncológico para mulheres com câncer do colo do útero. **Método:** Estudo realizado em três etapas: análise de revisões sistemáticas para identificação dos instrumentos específicos para avaliação de câncer do colo do útero; extração das medidas de avaliação; e ligação dos conceitos contidos nas medidas de desfecho com as categorias correspondentes da CIF por dois revisores independentes. **Resultados:** Na análise do *Functional Assessment of Cancer Therapy-Cervix* e da *European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire Cervical Cancer Module,* identificaram-se 72 conteúdos principais ligados a 35 categorias da CIF. Destas, 23 referiam-se às funções corporais, oito às atividades e participação, três aos fatores ambientais e uma à estrutura corporal. **Conclusão:** Os dois instrumentos possuem ligação com a CIF, no entanto, exploram de forma insuficiente os fatores contextuais, o que demonstra a necessidade de orientação biopsicossocial nas avaliações em saúde para mulheres com câncer do colo do útero de maneira a contemplar, de forma equânime, os componentes da funcionalidade na aferição dos desfechos terapêuticos.
Palavras-chave: Neoplasias do Colo do Útero; Avaliação de Resultados (Cuidados de Saúde); Classificação Internacional de Funcionalidade, Incapacidade e Saúde.

Resumen

Introducción: El cáncer de cuello de útero es altamente incidente en los países de baja y media renta y repercute negativamente en la funcionalidad de las mujeres. El interés en la medición de medidas terapéuticas que no se restrinjan a las medidas del modelo biomédico viene asumiendo destaque en el campo de la Oncología. La Clasificación Internacional de Funcionalidad (CIF) aparece en el escenario mundial como herramienta de orientación para la construcción de la evaluación biopsicosocial. **Objetivo:** Ejemplificar metodología para identificar los componentes de la funcionalidad en documentos utilizados en el cuidado oncológico en el cáncer del cuello del útero. **Método:** Estudio realizado en tres etapas: Análisis de revisiones sistemáticas para la identificación de los instrumentos específicos para el cáncer de cuello de útero; extracción de las medidas de evaluación; y conexión de los conceptos contenidos en las medidas de desenlace con las categorías correspondientes de la CIF por dos revisores independientes. **Resultados:** En el análisis del *Functional Assessment del Cáncer Terapia-Cervix* y de lo *European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire Cervical Cancer Module* se identificaron 72 contenidos principales, vinculados a 35 categorías de la CIF. De estas, 23 se referían a las funciones corporales, ocho a las actividades y participación, tres a los factores ambientales y una a la estructura corporal. **Conclusión:** Los dos instrumentos poseen conexión con la CIF, sin embargo, explotan de forma insuficiente los factores contextuales, lo que demuestra la necesidad de orientación biopsicosocial en las evaluaciones en salud para mujeres con cáncer del cuello del útero, para contemplar de forma ecuánime los componentes de la funcionalidad en la comparación de los resultados terapéuticos**.
Palabras clave: Neoplasias del Cuello Uterino; Evaluación de Resultado (Atención de Salud); Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud.

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INTRODUCTION

Although cervical cancer is a highly avoidable disease, it is still an important health public issue [1], it is the most common third type of cancer among women in the whole world [2]. Its incidence is considerably high in low and medium income countries[3,4] and regardless of dropping in the whole world, high rates still persist in areas of Africa, Latin America and South Asia[5-7]. The treatment and physiopathology of cervical cancer may have negative repercussions in the health-related quality of life[8], and psychological implications of the self-identity of the woman, which can be closely related to its trust, body image, social relations and perception as mother and spouse[9].

Currently, the mortality cannot be considered as a primary endpoint in oncology because the successes of the treatment made cancer a chronic disease. The existing epidemiological profile of the neoplasms justifies the importance of the insertion of the component of functioning in oncologic care[10]. However, the expansion of functional evaluation measures is being criticized because of the lack of uniformity of terms and mensuration instruments, which hampers the comparison of the results[11]. Since 2001, it is possible to identify and measure the concepts utilized in different measures of outcomes. The International Classification of Functioning, Disability and Health (ICF) provides a common language to describe and guide the functioning, disability and impairment. The classification in its multidimensional perspective does not relate only to information about the health physical and psychologic status, but also to life condition of the individual and its role in the society, which can be influenced by external factors as the physical environment, attitudes and behavior determined by the society and social policies. The classification is a tool to harmonize the information about health care within a universal setting [12].

The use of the biopsychosocial model can guide the elaboration of functioning profiles[13]. There is an ample scholar discussion about the benefits of use of the biopsychosocial model in detriment of the biomedical and social model[14]. The ICF was developed to serve as a tool capable of organizing a great variety of information about the health and health-related status, having a structure, which grants its use in areas as Education[15], Health[16] and Social Security[17], Statistics[18] and Epidemiology[19]. Within the clinical context, it can be used to evaluate the necessities, combining interventions for health specific conditions, evaluation of results and measures of rehabilitation[20]. The advantages of the biopsychosocial model address the unification of the language used by health caregivers[21], improved inter-professional collaboration[22], guidance about user-driven clinical reasoning[23] and strengthening of health information systems[24].

A core portion of the rehabilitation process is the planning and definition of functional therapeutic goals. Such procedures may, by itself, improve the autonomy, motivation and adherence to the treatment of the users, and this strategy is a powerful tool for rehabilitation. This process, nevertheless, is a challenge in the clinical routine of health care units[25]. The necessities of the users should be evaluated not only by the traditional survival indicators, they must be included in the models of biopsychosocial evaluation used in the information of oncologic care about activities, participation, environmental factors and personal aspects[26]. The objective of the present study is to identify the components of the functioning in documents used for oncologic care to patients with cervical cancer. That method allows to map the components of the functioning of the instruments of evaluation of therapeutic endpoints utilized in the routine health care units.

METHOD

The present study has three stages: identification of specific evaluation instruments for cervical cancer (selection of studies of systematic revision for identification); extraction of measures of evaluation of endpoints identified in the stage 1; link the concepts of the endpoints measures with the ICF corresponding categories.

Based in the findings of stage 1, the systematic revision of Tax et al.[27] concluded that there are two multidimensional and multicultural scales, of ample use for women with cervical cancer, the *Functional Assessment of Cancer Therapy-Cervix* (FACT-CX) and the module for evaluation of the quality of life of women with cervical cancer of the *European Organization for Research and Treatment of Cancer* (EORTC) Quality-of-Life Questionnaire Cervical Cancer Module (EORTC QLQ-CX24).

The FACT-CX consists of 42 questions, of which, 15 questions are specifically related to cervical cancer and 27 questions of FACT-G, a generic instrument to evaluate the quality of life in patients with chronic diseases, grouped in four domains of physical, social/family, emotional and functional well-being[28]. The FACT-CX is a questionnaire utilized in the whole world for the evaluation of the quality of life of women with cervical cancer and presents good psychometric properties in the Brazilian population, and able to distinguish women according to their perception of health[29]. The EORTC QLQ-CX24 consists of 24 questions that evaluate the quality of life of women in treatment for cervical cancer based in the functioning and some specific symptoms[30].

Based in the items of the questionnaires, two independent and experienced reviewers made the process of identification of ICF contents that followed the guidelines proposed by Cieza et al.[31]. It is a widely consolidated methodology and divulged in the literature. It was initially proposed in 2002 and had two updates[32,33]. The authors suggested eight rules to link the outcomes results with the ICF and five additional rules. The specific rules determine that all the significant contents of the instruments must be considered prior to linking with ICF categories and that the options of response, when containing relevant concepts, should also be included. If the concept of some item contains examples, these must also be connected. If the two reviewers disagree, a third reviewer was consulted to reach a consensus. An example of the process of linking is in Table 1. The agreement between the reviewers was verified through the coefficient of Kappa and the level of confidentiality was estimated by the scale of Rosner[34]. It was observed a good agreement between the process of categorization for FACT-CX (k=0.6884) and the EORTC-CX (k=0.6032).

The process of identification corresponds to stage 3 and initiated from the moment of definition of the main content for each item of the questionnaire. Next, the main content was associated to a category present in the ICF. Those who addressed personal factors were associated to categories of a list of personal factors proposed by Geyh et al.[35], since the ICF in its current version does not have specific categories for this component. After the identification of the contents and categories, it was calculated the percent of representativeness for each domain of the ICF, from the total number of categories identified and the number of categories for each domain.

RESULTS

From the questions of the questionnaires FACT-CX and EORTC-CX, it were identified 72 main contents. Because the main contents were considered at first, it was possible to make the identification of 35 different concepts found in the ICF, six personal factors and two uncovered concepts in ICF: one health condition (feeling ill) and one about quality of life. Of these categories, 23

address body functions, eight, activities and participation, three, environmental factors and one, the body structure (Table 2).

Figure 1 demonstrates a comparison between the questionnaires showing the proportion between the domains of ICF and personal factors. It is noticed that FACT-CX has the wider comprehensiveness of domains activity, participation and environmental factors.
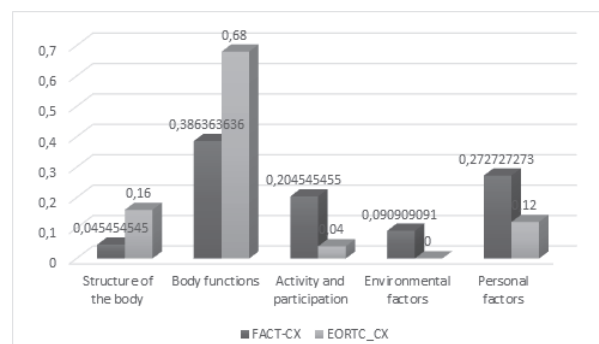

Figure 1. Comparison between the questionnaires showing the proportion between the coverage of ICF domains and personal matters

DISCUSSION

The present study exemplified a widely addressed methodology in literature about the mapping of instruments of endpoints with the bio-psychosocial model. The approach of the biomedical-guided model health care since the decade of 70 is being criticized because of its limitations [36]. In detriment to the biomedical model, it was proposed a social model that would muster also the social aspects of the health-disease process, presenting as major advantage the fact of understanding the process of getting ill in a quite comprehensive manner[37]. The proposal of ICF moves toward a more comprehensive approach than the biomedical and social model did. The psychosocial model incorporates information of activities, participation and contextual factors. If before the oncologic care were based in support and palliative measures, currently, the rehabilitation programs involve health-guided human

Table 1. Example of links between the contents of the Scale FACT-CX with ICF

Question of the questionnaire	Significative concept	Category	Description
I have a lack of energy	Energy	b130	Functions of energy and impulses
I have nausea	Nausea	b5350	Nausea sensation
Because of my physical condition, I have trouble meeting the needs of my family	Family needs	b730	Family relations
I have pain	Pain	b280	Pain sensation

Category	Title	FACT-CX	EORTC-CX
Body structure			
s63033	Vagina	Q29, 32	Q12, 13, 21, 22
Body Function			
b1263	Psychic stability	Q19, 20	
b1300	Level of energy	Q1	
b1302	Appetite	Q38	
b134	Sleeping functions	Q25	
b1522	Range of the emotion	Q34	
b1801	Body image	Q31, 36	
b265	Tactile function	Q10	
b280	Pain sensation	Q4	Q5, Q9
b4352	Functions of lymphatic vessels		Q8
b525	Functions of defecation	Q37	Q3
b5253	Fecal incontinence		Q2
b5322	Sensation of abdominal colic		Q1
b5350	Sensation of nausea	Q2	
b6200	Urination		Q7
b6201	Frequency of urination		Q4
b6202	Urinary incontinence	Q39	Q6
b630	Sensations associated to urinary functions	Q40, Q41	Q5
b640	Sexual functions		Q20, Q24
b6408	Sexual function, other specified	Q35	
b660	Functions of procreation	Q33	
b670	Sensations associated to sex and reproduction functions	Q28	Q11
b6700	Discomfort associated to sexual intercourse		Q18, Q23
b6702	Discomfort associated to menopause		Q14
Activities and participation			
d550	Eat	Q42	
d580	Paid work	Q22	
d7500	Informal relations with friends	Q8	
d760	Family relations	Q3	
d770	Intimate relations	Q13	
d7702	Sexual relations	Q14, Q30	Q19
d850	Paid work	Q21	
d920	Recreation and leisure	Q26	
Environmental Factors			
e310	Nuclear Family	Q9	
e320	Friends	Q10	
e410	Individual attitudes of the nuclear family	Q11, Q12	
Personal Factors			
i410	Emotions	Q15, 18, 22, 23	
i530	Personal attitudes	Q7, 16, 24	
i5402	Expectations	Q17	
i550	Personal values and norms		Q16, 17
i560	Personal evaluation	Q5, 27, 28	Q15
i570	Personal preferences	Q42	
Uncovered			
nc	Uncovered – health status	Q6	
nc	Uncovered – quality of life	Q27	

resources to prevent health damages, reclaim the integrity and enable means for the users to adapt themselves to their context in order to favor social participation. The expansion of interventions offered to the population with cancer throughout all the phases of the treatment and follow up should be monitored to verify the application of measures of therapeutic outcomes sensitive to the user's daily changes.

So far, it were encountered two papers related to oncology in the literature that utilized methodologies similar to the ones conducted in the present revision. In Brach et al.[38] work who addressed a systematic revision about the outcomes measures in patients with breast cancer, there was also a predominance of body functions related contents where the environmental factors were sub-represented. In Tschiesner et al.[39] article, while reviewing some studies with patients with head and neck cancer, it was observed a scarce uniformity of outcomes measures of therapeutic results. The results presented hereby are similar to the encountered in the two studies.

The analysis of the results obtained revealed that, despite both instruments revealed link to ICF, the levels are different. While EORTC-CX has 84% of its concepts linked to categories of functions or structures of the body, this percent is of 44% in FACT-CX, which indicates a predominant biomedical character in the approach of EORTC-CX. In relation to the activities and participation, FACT-CX is also advantageous over EORTC-CX, with 16% more categories of this component linked to concepts of the questionnaire, which reinforces the larger range of ICF comprehensiveness through this instrument, nearing more effectively to the bio-psychosocial model.

As for the uncovered domains by the therapeutic endpoint measures and that would be pertinent within the context of the impact of the cervix cancer treatment, some categories of the domains of activity and participation, as accomplishment of domestic tasks (d640), help others (d660) and family relations (d760) stand out . Plotti et al.[40], while assessing the subjective and family impacts within the context of cervix cancer, point out that the great cultural emphasis about sexuality, most of the times, forces women to assume the responsibility for poor sexual activity on behalf of the married couple. These beliefs negatively affect the women's health and are not an obstacle easy to overcome or change. The insertion of contextual factors (environmental and personal) may offer the capacity of steering the support networks to the women, contributing positively to the social participation.

This study still presents as less addressed endpoints of the instruments, those related to the social and environmental factors, where EORTC-CX does not have any content linked to environmental factors, while FACT-CX has only 9% of its items related to this component.

Environment is an important element in health care and is increasingly building in relevance[41], as well as personal factors [42]. It is perceived a necessity of bio-psychosocial guidance in the health assessments for women with cervix cancer to allow that the components of functioning are addressed in equanimity in the moment when therapeutic endpoints are verified.

CONCLUSION

Either FACT-CX or EORTC-CX have links with ICF at different levels. In despite of this, it was observed that contextual factors (environmental and personal) are explored insufficiently, which hampers the collection of important data for the assessment of women with cervix cancer. EORTC-CX, besides having the major part of its concepts linked to the domains of body functions and body structures, which reminds the biomedical model, does not address the environmental factors in any item, leaving an important void for the verification of the therapeutic endpoints in relation to the influence of these factors in the health-disease process. FACT-CX, on its turn, despite addressing yet insufficiently the environmental factors has a wider coverage of ICF and its domains, approaching more effectively the biopsychosocial model.

CONTRIBUTIONS

Luciana Castaneda, Juliana Cossich Trindade Alves, Thaissa Hamana de Macedo Dantas and Diego de Sousa Dantas participated of the design and planning of the study, analysis and interpretation of data and manuscript wording. All the authors approved the final version of the manuscript.

DECLARATION OF CONFLICT OF INTERESTS

There are no conflicts of interest to declare.

FUNDING SOURCES

None.

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