Self-reporting of Symptoms by the Patient with Cancer: the Time is Now

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Autoavaliação de Sintomas pelo Paciente com Câncer: a Hora é Agora

Autoevaluación de los Síntomas del Paciente con Cáncer: Ahora es el Momento

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INTRODUCTION

Globally, approximately 29 to 37 million new cases of cancer will be registered until 2040 according to the World Health Organization Report (WHO)[1].

The process of sickening by cancer demands timely optimized accurate decisions and unvariably with negative repercussions over the quality-of-life depending on socioeconomic and cultural factors which can favor or not faster and more effective responsiveness[2].

Education in health is able to empower the patient, it is an essential action for understanding, participation and decision taking since prevention, early detection, possible therapeutic intervention, finitude and or survival[3].

Sharing the sickening process with the patient means to offer information, stimulate proactive attitudes and possibly mitigate the unfavorable psychosocial consequences, a commitment the policies to control and fight chronic diseases should incorporate.

Operationally, it is advocated the application of the Chronic Care Model (CCM) to provide care to individuals with chronic non-communicable diseases (CNCD). CCM includes actions to the patient, family and the community within the scope of care. In the patient's perspective, the CCM encompasses: obtain information, education, motivation and trust to act as partners in their own care and feel supported to tell their experiences about sickening, necessities and preferences[4].

It is necessary to apply an articulated set of caring practices to facilitate the fulfillment of the patients' rights[5]. The present article has the objective to describe the self-report instrument Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE®) created by the USA Nacional Cancer Institute (NCI)[6] and analyze its impact on the care to the patient with cancer in antineoplastic treatment.

The design is analytical based on the authors' experience and data extracted from the literature on the proposal of utilizing the PRO-CTCAE®. The contents presented are found in selected articles published by the Virtual Health Library utilizing the descriptors: (patient reported outcome measures) AND (medical oncology) AND (antineoplastic agents) AND (patient-centered care) AND (db:("MEDLINE" OR "LILACS") AND la:("en" OR "es" OR "pt")) AND (*year_cluster*:[2017 TO 2022]).

DEVELOPMENT

CONSTRUCTION AND CREATION OF THE PRO-CTCAE®

The NCI belongs to the National Institute of Health (NIH), a USA-government held entity whose leadership plays an active role in shaping the research planning, training, and disclosing information about prevention, diagnosis and treatment of cancer worldwide.

In 1984, NCI created a descriptive terminology titled The Common Terminology Criteria for Adverse Events (CTCAE) listing all the possible adverse events associated with antineoplastic therapy. The CTCAE is an Adverse Event (AE) rating system to characterize the intensity of the reactions presented by the patient and harmonize its interpretation, allowing comparative analyzes, full account of the patient history, universal understanding by professionals and investigators among other applications[7,8]. The CTCAE is in permanent updating and the last version is 5.0 issued in 2018.

In 2014, the NCI created a patient-reported outcome measurement system to capture the frequency and intensity of patient reported AE called PRO-CTCAE®, a self-reported instrument the patient utilizes to evaluate and rate its symptoms[6]. Since its publication, several articles have been adopting shorter versions of PRO-CTCAE® with multiple diagnoses and different protocols of treatment.

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Seventy-eight (78) toxicities, also found on CTCAE were identified and for each one of them, a Likert-scale score from 0 to 4 is attributed to presence/absence, frequency, severity and interference in activities of the daily life. A default recall period of "the past seven days" was selected. The US Food and Drug Administration and the European Medicines Agency (EMA) approved the development and validation of PRO-CTCAE®[6,7].

PRO-CTCAE® is available in more than 15 languages including Portuguese (Brazil) with NCI-approved translations and validations issuing a certificate to ratify its equivalence[6-8].

The main objective of PRO-CTCAE® is to facilitate the accurate reporting of AE caused by sickening and antineoplastic treatments with the active participation of the patient, enabled to self-manage its own process and taking decisions, solve the problems, gather resources, create bonds with the professionals (partnership) and act with safety and proactivity[9].

VALIDITY AND RELIABILITY OF PRO-CTCAE®

A study with 975 patients evaluated the validity of the construct, reliability test-retest and PRO-CTCAE® responsiveness with positive results in all the analyzes[10].

A systematic review concluded that the professional's rating were lower than those gathered by the patient for some items in the comparison of the results between CTAE and PRO-CTCAE®. The study noticed a propensity of the professional to underestimate the intensity of the symptoms, indicating the importance of a complementary evaluation by the patient for shared decision-taking[7].

Other studies have also addressed the differences between the evaluation of the professional and the perception of the patient while utilizing the scale of symptoms or questionnaires about quality-of-life[11,12], showing how important the perspective of the patient is in decision-taking.

RELEVANT CONSIDERATIONS ABOUT THE UTILIZATION OF PRO-CTCAE® IN CARING PRACTICES AND IN CLINICAL TRIAL

PRO-CTCAE® is a long questionnaire and it is not indicated to be fully offered to the patient. Experienced professionals can pre-select the adverse events the patient can report from 78 toxicities, either based in the scientific literature or on the professionals own experience[8].

The process should be dynamic and based in effective communication. Any adverse event can be added any time or excluded if the patient deems it as irrelevant. The professional should be flexible and open to the patient's complaints and accept its faithful responses for further interventions, if the case[8,10].

The recall period for PRO-CTCAE® is the past seven days to evaluate each toxicity. A comparative study of the response in 7, 14, 21 and 28 days concluded that as longer the time, more odds of losing the information, possibly compromising the responses, making them less trustworthy[13]. On the other hand, responses in longer recall periods can best identify and characterize the chronic effects on the population of survivors. The PRO-CTCAE® can help the patient in oral medication to report additional information to help the team making him feel more present and closer, yet away from the health institution. Not to be neglected that cancer treatment is a prolonged process just like its adverse events, demanding attention for management of better quality-of-life and therapeutic adherence[8,10].

The format of the instrument is a key aspect to consider. Currently, tablets and apps appear to be the faster, more logical and technological choice as the system itself is able to send warns, reports among many functionalities that go beyond hard copies but though easy to use, require further tabulations and new impressions may surface if symptoms change (inclusion or exclusion)[14].

The institutions may have difficulties in absorbing the cost of tablets and simple training the patient needs but yet unpractical for older adults or with difficulties to access the Internet. The fast-pace progress of the digital technology and easy access to social media or bespoke apps can make the hurdles disappear, eventually[14].

In the perspective of scientific research, the utilization of PRO-CTCAE® in investigations of new drugs can help with data to design protocols and review the regulatory framework of the drug[10]. In these cases, the utilization of the full instrument can be invaluable because it will broaden the possibility of reporting any symptom, yet unexpected. For protocols already implemented, the clinician can choose which toxicities of PRO-CTCAE® should be included in the instrument, the initial time of application and periodicity[6,13,14] in advance or during the therapeutic applied.

PRO-CTCAE® AND PATIENT-CENTERED CARE

Patients and their families want to take decisions that rise from the sickening process, but many are the internal and external obstacles for their active participatioin as some studies have concluded[4,5,9]. As self-reporting is a learned process and the population with cancer may not be prepared to develop self-diagnosis, important and relevant are the tools to clarify the concepts and help them to rate and acquire the skills in the shortest period as possible[14].

In addition to this, the participation of the patient is essential for full care. The patient and its family should be able to comprehend the sickening process, be helped

in decision-taking in view of the extensive array of possible therapeutic planning, currently made available by the technological advances in oncology and invest in the preservation and or regaining the quality-of-life. Endorsing the passivity of the patient and its family is an outdated perspective and inclusive practices to strengthen the patient view and autonomy are in the foreseeable horizon[4,5,9].

Within the concept of patient-centered care, the effective communication favors the involvement of the patient and its family. Patients must feel themselves enabled to trust their perceptions and analyzes, cope with the diagnosis and incorporate behaviors and attitudes that make them active agents of decision-taking. PRO-CTCAE® can be an empowering tool for the patient while evaluating its own signs and symptoms[8,13]. The analysis of all the topics associated with the utilization of PRO-CTCAE® leads to the conclusion that it is a tool able to support the clinicians to manage the adverse events; it is not enough to learn how to utilize it, but to comprehend its core purpose when applying it. Be open to changes and utilize the creativity in providing care is a clear demand as new technologies are becoming common in the daily life, but always evidence-based to strengthen the actions.

The study limitations are related to its informative nature, shedding light on concepts and application and not analyzing the feasibility, acceptability or the effective results of the processes of implementation of PRO-CTCAE®.

CONCLUSION

PRO-CTCAE® is a tool that can improve the patient-professional communication, reveal symptoms so far unknown or neglected, empower the patient to decide about the planning and monitoring of its own treatment, mirroring the global strategies to control CNCD.

PRO-CTCAE® requires changes of behavior and attitudes for its practice, a challenge for patients and professionals because a new dynamic of communication is established, redefining the role of the professional as the main source of evaluation for the patient who must take over this function and embrace this responsibility.

CONTRIBUTIONS

Ana Maria Teixeira Pires and Edvane Birelo Lopes De Domenico contributed substantially for the study design, acquisition, analysis and interpretation of the data, wording and critical review. Ariel Galapo Kann and Fabio Rodrigues Kerbauy contributed to the wording and critical review. All the authors approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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