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Original Research

Multidisciplinary development of the Geriatric Core Dataset for clinical research in older patients with cancer: A French initiative with international survey

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Clinical trials;
Data set;

Abstract ***Background:*** To define a core set of geriatric data to be methodically collected in clinical cancer trials of older adults, enabling comparison across trials.
Patients and methods: Following a consensus approach, a panel of 14 geriatricians from oncology clinics identified seven domains of importance in geriatric assessment. Based on

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Delphi consensus;
Geriatric assessment;
Cancer;
Older patients

the international recommendations, geriatricians selected the mostly commonly used tools/items for geriatric assessment by domain (January–October 2015). The Geriatric Core Dataset (G-CODE) was progressively developed according to RAND appropriateness ratings and feedback during three successive Delphi rounds (July–September 2016). The face validity of the G-CODE was assessed with two large panels of health professionals (55 national and 42 international experts) involved both in clinical practice and cancer trials (March–September 2017).

Results and discussion: After the last Delphi round, the tools/items proposed for the G-CODE were the following: (1) social assessment: living alone or support requested to stay at home; (2) functional autonomy: Activities of Daily Living (ADL) questionnaire and short instrumental ADL questionnaire; (3) mobility: Timed Up and Go test; (4) nutrition: weight loss during the past 6 months and body mass index; (5) cognition: Mini-Cog test; (6) mood: mini-Geriatric Depression Scale and (7) comorbidity: updated Charlson Comorbidity Index. More than 70% of national experts (42 from 20 cities) and international experts (31 from 13 countries) participated. National and international surveys showed good acceptability of the G-CODE. Specific points discussed included age-year cut-off, threshold of each tool/item and information about social support, but no additional item was proposed.

Conclusion: We achieved formal consensus on a set of geriatric data to be collected in cancer trials of older patients. The dissemination and prospective use of the G-CODE is needed to assess its utility.

1. Introduction

Although cancer is prevalent in the older segment of the population, older adults with cancer remain underrepresented in cancer clinical trials that establish new standards of care [1]. As a result, we lack robust data on the benefit/risk balance for many treatment strategies in these patients.

Ageing is a heterogeneous process that stresses the clinical need to identify comorbid conditions and ageing-related physiologic changes, both well-known factors increasing the risk of treatment side-effects and poor outcomes [2].

Geriatric assessment (GA) is defined by geriatricians as a multidimensional interdisciplinary assessment of the general health status of the older patient, reviewing the medical, psychosocial, functional and environmental domains. For each domain, several tools are available, but consensus is lacking on which tool to use and the optimal cut-offs or threshold scores [3,4]. The literature supports the prognostic value of the GA and its utility in weighing the benefits and risks of cancer treatments in older adults [5–8]. However, GA has not been implemented in routine oncology practice or in cancer clinical trials.

In 2011, after a workshop on clinical trial methodology in older adults with cancer, the Elderly Task Force of the European Organization for Research and Treatment of Cancer (EORTC) recommended the use of a standardised minimum data set (minDS) for assessing the global health and functional status of older populations [9]. This minDS consisted of the G8 screening tool [10], the Instrumental Activities of Daily Living (IADL) questionnaire [11], the Charlson Comorbidity Index [12] and data on social situation. The approach and the scientific method used to define the minDS were not clearly explained, and the appropriation of the minDS for target users was not studied.

The DIalog for personALization of management in geriatric OncoloGy (DIALOG) intergroup was launched in 2014, bringing together the network of the Société Francophone d'OncoGériatrie (SoFOG, or French society of geriatric oncology) and the Unicancer cooperative group GERICO dedicated to clinical research in geriatric oncology. One of its first actions was to address the update of the EORTC initiative, with the goal to describe more accurately the population of older adults (≥70 years) with cancer and to standardise geriatric data collection in clinical trials in a brief and practical way. The proposed project, named Geriatric Core Dataset (G-CODE), implied the use of tools/items validated in older cancer and non-cancer populations that covered the main domains of the GA. In addition, the collection of data was to be feasible at baseline in the curative or palliative setting, regardless of the tumour type. For this purpose, DIALOG appointed a taskforce including geriatricians and oncologists to develop the G-CODE following an explicit consensus approach.

2. Method

2.1. Study design and general process

The process was divided into successive steps (Fig. 1) and with four groups of experts (Supplementary Data S1): (a) elaboration of the initial set of selected tools/